Anhang 4-G: Ergänzende Ergebnisdarstellung der Studie monarchE

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Anhang 4-G1.1: Behandlungsinformation

Anhang 4-G1.1.1: Disposition (Prämenopausale Patientinnen)

Summary of Subject Disposition
Cohort 1 Population - ITT - Premenopausal
I3Y-MC-JPCF
Data cutoff: 15JUL2025

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03:32 27OCT2025
PDPM

	LY2835219-150 mg+EDT*a (N=777) n (%)	EDT*a (N=728) n (%)	Total (N=1505) n (%)
Treated	777 (100.0)	728 (100.0)	1505 (100.0)
Off treatment*b	777 (100.0)	728 (100.0)	1505 (100.0)
Reason for discontinuation of treatment			
ADVERSE EVENT	40 (5.1)	5 (0.7)	45 (3.0)
COMPLETED	659 (84.8)	577 (79.3)	1236 (82.1)
DEATH	0 (0.0)	2 (0.3)	2 (0.1)
DISEASE RELAPSE	36 (4.6)	88 (12.1)	124 (8.2)
LOST TO FOLLOW-UP	3 (0.4)	3 (0.4)	6 (0.4)
NON-COMPLIANCE WITH STUDY DRUG	2 (0.3)	0 (0.0)	2 (0.1)
PHYSICIAN DECISION	5 (0.6)	1 (0.1)	6 (0.4)
PROTOCOL DEVIATION	0 (0.0)	4 (0.5)	4 (0.3)
WITHDRAWAL BY SUBJECT	32 (4.1)	48 (6.6)	80 (5.3)
Post-treatment-discontinuation follow-up*b			
No	38 (4.9)	43 (5.9)	81 (5.4)
Yes	739 (95.1)	685 (94.1)	1424 (94.6)
On post-treatment-discontinuation follow-up*b	594 (76.4)	514 (70.6)	1108 (73.6)
Off post-treatment-discontinuation follow-up*b	145 (18.7)	171 (23.5)	316 (21.0)
Reasons for end of post-discontinuation follow-up			
DEATH	65 (8.4)	88 (12.1)	153 (10.2)
LOST TO FOLLOW-UP	23 (3.0)	23 (3.2)	46 (3.1)
STUDY TERMINATED BY SPONSOR	16 (2.1)	15 (2.1)	31 (2.1)
WITHDRAWAL BY SUBJECT	41 (5.3)	45 (6.2)	86 (5.7)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin.
*b at the time of data cut-off on 15JUL2025
Abbreviations: N = number of subjects in the analysis population; n = number of subjects within category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_disp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_disp_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.1.2: Disposition (Postmenopausale Patientinnen)

Summary of Subject Disposition
Cohort 1 Population - ITT - Postmenopausal
I3Y-MC-JPCF
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
Treated	1284 (100.0)	1263 (100.0)	2547 (100.0)
Off treatment*b	1284 (100.0)	1263 (100.0)	2547 (100.0)
Reason for discontinuation of treatment			
ADVERSE EVENT	85 (6.6)	9 (0.7)	94 (3.7)
COMPLETED	1026 (79.9)	1047 (82.9)	2073 (81.4)
DEATH	12 (0.9)	8 (0.6)	20 (0.8)
DISEASE RELAPSE	77 (6.0)	118 (9.3)	195 (7.7)
LOST TO FOLLOW-UP	3 (0.2)	3 (0.2)	6 (0.2)
NON-COMPLIANCE WITH STUDY DRUG	2 (0.2)	0 (0.0)	2 (0.1)
PHYSICIAN DECISION	5 (0.4)	1 (0.1)	6 (0.2)
PROTOCOL DEVIATION	2 (0.2)	3 (0.2)	5 (0.2)
STUDY TERMINATED BY IRB / ERB	0 (0.0)	1 (0.1)	1 (0.0)
WITHDRAWAL BY SUBJECT	72 (5.6)	73 (5.8)	145 (5.7)
Post-treatment-discontinuation follow-up*b			
No	85 (6.6)	63 (5.0)	148 (5.8)
Yes	1199 (93.4)	1200 (95.0)	2399 (94.2)
On post-treatment-discontinuation follow-up*b	897 (69.9)	865 (68.5)	1762 (69.2)
Off post-treatment-discontinuation follow-up*b	302 (23.5)	335 (26.5)	637 (25.0)
Reasons for end of post-discontinuation follow-up			
DEATH	163 (12.7)	200 (15.8)	363 (14.3)
LOST TO FOLLOW-UP	41 (3.2)	29 (2.3)	70 (2.7)
STUDY TERMINATED BY SPONSOR	23 (1.8)	26 (2.1)	49 (1.9)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen.
*b at the time of data cut-off on 15JUL2025
Abbreviations: N = number of subjects in the analysis population; n = number of subjects within category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_disp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_disp_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Subject Disposition Page 2 of 2
Cohort 1 Population - ITT - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
WITHDRAWAL BY SUBJECT	75 (5.8)	80 (6.3)	155 (6.1)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen.
*b at the time of data cut-off on 15JUL2025
Abbreviations: N = number of subjects in the analysis population; n = number of subjects within category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_disp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_disp_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.1.3: Behandlungsdauer (Prämenopausale Patientinnen)

Summary of Drug Exposure for LY2835219 Page 1 of 3
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Number of Subjects	LY2835219-150 mg+EDT*a (N=776) n	(%)
Number of Subjects who received study drug-Endocrine (n)*b	774	(99.7)
Cycles received per subject *c		
Median	25.00	
Q1-Q3	24.00 - 25.00	
Min-Max	1.00 - 27.00	
Mean	21.09	
Std Dev.	7.50	
Subjects who received >=1 cycles	774	(99.7)
Subjects who received >=2 cycles	747	(96.3)
Subjects who received >=3 cycles	731	(94.2)
Subjects who received >=4 cycles	717	(92.4)
Subjects who received >=5 cycles	702	(90.5)
Subjects who received >=6 cycles	690	(88.9)
Subjects who received >=7 cycles	687	(88.5)
Subjects who received >=8 cycles	679	(87.5)
Subjects who received >=9 cycles	677	(87.2)
Subjects who received >=10 cycles	672	(86.6)
Subjects who received >=11 cycles	661	(85.2)
Subjects who received >=12 cycles	654	(84.3)
Subjects who received >=13 cycles	647	(83.4)
Subjects who received >=14 cycles	644	(83.0)
Subjects who received >=15 cycles	641	(82.6)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
*b Number of subjects who received at least one dose of study drug LY2835219 either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug LY2835219 either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_exp_ly2835219_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Drug Exposure for LY2835219 Page 2 of 3
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Number of Subjects	LY2835219-150 mg+EDT*a (N=776) n	(%)
Subjects who received >=16 cycles	636	(82.0)
Subjects who received >=17 cycles	634	(81.7)
Subjects who received >=18 cycles	629	(81.1)
Subjects who received >=19 cycles	625	(80.5)
Subjects who received >=20 cycles	621	(80.0)
Subjects who received >=21 cycles	618	(79.6)
Subjects who received >=22 cycles	616	(79.4)
Subjects who received >=23 cycles	614	(79.1)
Subjects who received >=24 cycles	595	(76.7)
Subjects who received >=25 cycles	404	(52.1)
Subjects who received >=26 cycles	6	(0.8)
Subjects who received >=27 cycles	1	(0.1)
Duration of Therapy (Week)		
Median	103.00	
Q1-Q3	100.43 - 103.29	
Min-Max	0.43 - 115.71	
Mean	87.91	
Std Dev.	31.86	
Cumulative Dose		
Median	165500.00	
Q1-Q3	103800.00 - 207050.0	
Min-Max	1650.00 - 237600.00	

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
*b Number of subjects who received at least one dose of study drug LY2835219 either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug LY2835219 either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_exp_ly2835219_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Drug Exposure for LY2835219 Page 3 of 3
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Number of Subjects	LY2835219-150 mg+EDT*a (N=776) n	(%)
Mean	147830.43	
Std Dev.	67142.59	

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
*b Number of subjects who received at least one dose of study drug LY2835219 either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug LY2835219 either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_exp_ly2835219_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Drug Exposure for Endocrine Page 1 of 3
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=776)		EDT*a (N=729)	
Number of Subjects	n	(%)	n	(%)
Number of Subjects who received study drug-Endocrine (n)*b	776	(100.0)	729	(100.0)
Cycles received per subject *c				
Median	25.00		25.00	
Q1-Q3	24.00 - 25.00		24.00 - 25.00	
Min-Max	1.00 - 28.00		1.00 - 27.00	
Mean	22.32		21.95	
Std Dev.	6.32		6.45	
Subjects who received >=1 cycles	776	(100.0)	729	(100.0)
Subjects who received >=2 cycles	757	(97.6)	707	(97.0)
Subjects who received >=3 cycles	745	(96.0)	695	(95.3)
Subjects who received >=4 cycles	735	(94.7)	691	(94.8)
Subjects who received >=5 cycles	726	(93.6)	686	(94.1)
Subjects who received >=6 cycles	720	(92.8)	680	(93.3)
Subjects who received >=7 cycles	718	(92.5)	674	(92.5)
Subjects who received >=8 cycles	713	(91.9)	672	(92.2)
Subjects who received >=9 cycles	711	(91.6)	667	(91.5)
Subjects who received >=10 cycles	710	(91.5)	663	(90.9)
Subjects who received >=11 cycles	705	(90.9)	660	(90.5)
Subjects who received >=12 cycles	701	(90.3)	657	(90.1)
Subjects who received >=13 cycles	696	(89.7)	650	(89.2)
Subjects who received >=14 cycles	694	(89.4)	645	(88.5)
Subjects who received >=15 cycles	692	(89.2)	641	(87.9)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
*b Number of subjects who received at least one dose of study drug Endocrine either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug Endocrine either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_exp_endocrine_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Drug Exposure for Endocrine
Cohort 1 Population - Safety - Premenopausal
I3Y-MC-JPCF
Data cutoff: 15JUL2025

Number of Subjects	LY2835219-150 mg+EDT*a (N=776) n	(%)	EDT*a (N=729) n	(%)
Subjects who received >=16 cycles	686	(88.4)	635	(87.1)
Subjects who received >=17 cycles	686	(88.4)	627	(86.0)
Subjects who received >=18 cycles	683	(88.0)	623	(85.5)
Subjects who received >=19 cycles	678	(87.4)	620	(85.0)
Subjects who received >=20 cycles	674	(86.9)	614	(84.2)
Subjects who received >=21 cycles	670	(86.3)	603	(82.7)
Subjects who received >=22 cycles	669	(86.2)	598	(82.0)
Subjects who received >=23 cycles	667	(86.0)	592	(81.2)
Subjects who received >=24 cycles	650	(83.8)	574	(78.7)
Subjects who received >=25 cycles	448	(57.7)	388	(53.2)
Subjects who received >=26 cycles	9	(1.2)	6	(0.8)
Subjects who received >=27 cycles	2	(0.3)	2	(0.3)
Subjects who received >=28 cycles	1	(0.1)	0	(0.0)
Duration of Therapy (Week)				
Median	103.00		103.00	
Q1-Q3	102.29 - 103.43		102.00 - 103.43	
Min-Max	0.14 - 118.14		0.14 - 115.14	
Mean	93.15		91.56	
Std Dev.	26.86		27.54	
Cumulative Dose				
Median	718.00		718.00	
Q1-Q3	699.00 - 722.00		693.00 - 722.00	

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
*b Number of subjects who received at least one dose of study drug Endocrine either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug Endocrine either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_exp_endocrine_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Drug Exposure for Endocrine — Page 3 of 3
Cohort 1 Population - Safety - Premenopausal — 03:32 27OCT2025
I3Y-MC-JPCF — PDPM
Data cutoff: 15JUL2025

Number of Subjects	LY2835219-150 mg+EDT*a (N=776) n	(%)	EDT*a (N=729) n	(%)
Min-Max	0.00 - 827.00		1.00 - 805.00	
Mean	645.08		636.07	
Std Dev.	189.25		192.64	

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
*b Number of subjects who received at least one dose of study drug Endocrine either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug Endocrine either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_exp_endocrine_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.1.4: Behandlungsdauer (Postmenopausale Patientinnen)

Summary of Drug Exposure for LY2835219 Page 1 of 3
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1283)	
Number of Subjects	n	(%)
Number of Subjects who received study drug-Endocrine (n)*b	1279	(99.7)
Cycles received per subject *c		
Median	24.00	
Q1-Q3	12.00 - 25.00	
Min-Max	1.00 - 27.00	
Mean	19.11	
Std Dev.	8.80	
Subjects who received >=1 cycles	1279	(99.7)
Subjects who received >=2 cycles	1203	(93.8)
Subjects who received >=3 cycles	1150	(89.6)
Subjects who received >=4 cycles	1123	(87.5)
Subjects who received >=5 cycles	1095	(85.3)
Subjects who received >=6 cycles	1073	(83.6)
Subjects who received >=7 cycles	1053	(82.1)
Subjects who received >=8 cycles	1035	(80.7)
Subjects who received >=9 cycles	1019	(79.4)
Subjects who received >=10 cycles	1002	(78.1)
Subjects who received >=11 cycles	985	(76.8)
Subjects who received >=12 cycles	969	(75.5)
Subjects who received >=13 cycles	954	(74.4)
Subjects who received >=14 cycles	947	(73.8)
Subjects who received >=15 cycles	938	(73.1)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
*b Number of subjects who received at least one dose of study drug LY2835219 either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug LY2835219 either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_exp_ly2835219_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Drug Exposure for LY2835219 Page 2 of 3
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1283)	
Number of Subjects	n	(%)
Subjects who received >=16 cycles	928	(72.3)
Subjects who received >=17 cycles	921	(71.8)
Subjects who received >=18 cycles	915	(71.3)
Subjects who received >=19 cycles	903	(70.4)
Subjects who received >=20 cycles	897	(69.9)
Subjects who received >=21 cycles	888	(69.2)
Subjects who received >=22 cycles	874	(68.1)
Subjects who received >=23 cycles	862	(67.2)
Subjects who received >=24 cycles	824	(64.2)
Subjects who received >=25 cycles	589	(45.9)
Subjects who received >=26 cycles	12	(0.9)
Subjects who received >=27 cycles	1	(0.1)
Duration of Therapy (Week)		
Median	102.71	
Q1-Q3	50.57 - 103.29	
Min-Max	0.14 - 113.43	
Mean	79.49	
Std Dev.	37.41	
Cumulative Dose		
Median	137900.00	
Q1-Q3	66950.00 - 193450.00	
Min-Max	0.00 - 247200.00	

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
*b Number of subjects who received at least one dose of study drug LY2835219 either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug LY2835219 either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_exp_ly2835219_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Drug Exposure for LY2835219 Page 3 of 3
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Number of Subjects	LY2835219-150 mg+EDT*a (N=1283) n	(%)
Mean	125106.84	
Std Dev.	71611.15	

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
*b Number of subjects who received at least one dose of study drug LY2835219 either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug LY2835219 either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_exp_ly2835219_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Drug Exposure for Endocrine Page 1 of 3
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1283)		EDT*a (N=1264)	
Number of Subjects	n	(%)	n	(%)
Number of Subjects who received study drug-Endocrine (n)*b	1283	(100.0)	1264	(100.0)
Cycles received per subject *c				
Median	25.00		25.00	
Q1-Q3	24.00 - 25.00		24.00 - 25.00	
Min-Max	1.00 - 27.00		1.00 - 29.00	
Mean	21.40		22.32	
Std Dev.	7.35		6.12	
Subjects who received >=1 cycles	1283	(100.0)	1264	(100.0)
Subjects who received >=2 cycles	1234	(96.2)	1233	(97.5)
Subjects who received >=3 cycles	1205	(93.9)	1224	(96.8)
Subjects who received >=4 cycles	1188	(92.6)	1214	(96.0)
Subjects who received >=5 cycles	1174	(91.5)	1202	(95.1)
Subjects who received >=6 cycles	1159	(90.3)	1192	(94.3)
Subjects who received >=7 cycles	1147	(89.4)	1183	(93.6)
Subjects who received >=8 cycles	1137	(88.6)	1174	(92.9)
Subjects who received >=9 cycles	1126	(87.8)	1171	(92.6)
Subjects who received >=10 cycles	1118	(87.1)	1160	(91.8)
Subjects who received >=11 cycles	1110	(86.5)	1151	(91.1)
Subjects who received >=12 cycles	1099	(85.7)	1146	(90.7)
Subjects who received >=13 cycles	1089	(84.9)	1137	(90.0)
Subjects who received >=14 cycles	1086	(84.6)	1129	(89.3)
Subjects who received >=15 cycles	1080	(84.2)	1125	(89.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
*b Number of subjects who received at least one dose of study drug Endocrine either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug Endocrine either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_exp_endocrine_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Drug Exposure for Endocrine
Cohort 1 Population - Safety - Postmenopausal
I3Y-MC-JPCF
Data cutoff: 15JUL2025

Number of Subjects	LY2835219-150 mg+EDT*a (N=1283) n	(%)	EDT*a (N=1264) n	(%)
Subjects who received >=16 cycles	1073	(83.6)	1118	(88.4)
Subjects who received >=17 cycles	1072	(83.6)	1106	(87.5)
Subjects who received >=18 cycles	1068	(83.2)	1100	(87.0)
Subjects who received >=19 cycles	1060	(82.6)	1089	(86.2)
Subjects who received >=20 cycles	1057	(82.4)	1078	(85.3)
Subjects who received >=21 cycles	1054	(82.2)	1076	(85.1)
Subjects who received >=22 cycles	1047	(81.6)	1070	(84.7)
Subjects who received >=23 cycles	1039	(81.0)	1066	(84.3)
Subjects who received >=24 cycles	1005	(78.3)	1039	(82.2)
Subjects who received >=25 cycles	734	(57.2)	735	(58.1)
Subjects who received >=26 cycles	15	(1.2)	27	(2.1)
Subjects who received >=27 cycles	2	(0.2)	5	(0.4)
Subjects who received >=28 cycles	0	(0.0)	3	(0.2)
Subjects who received >=29 cycles	0	(0.0)	1	(0.1)
Duration of Therapy (Week)				
Median	103.00		103.00	
Q1-Q3	102.00 - 103.57		102.29 - 103.43	
Min-Max	0.14 - 115.14		0.14 - 122.00	
Mean	89.21		93.08	
Std Dev.	31.25		26.12	
Cumulative Dose				
Median	718.00		720.00	

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
*b Number of subjects who received at least one dose of study drug Endocrine either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug Endocrine either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_exp_endocrine_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Drug Exposure for Endocrine Page 3 of 3
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1283)		EDT*a (N=1264)	
Number of Subjects	n	(%)	n	(%)
Q1-Q3	684.00 - 722.00		706.00 - 723.00	
Min-Max	0.00 - 805.00		1.00 - 836.00	
Mean	617.30		647.89	
Std Dev.	218.66		182.97	

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
*b Number of subjects who received at least one dose of study drug Endocrine either partial or complete
*c Subject is considered to have received a treatment cycle after receiving at least one dose of study drug Endocrine either partial or complete.
Cycle in this study was calculated by number of days of duration divided by 30.
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_exp.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_exp_endocrine_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.1.5: Begleitmedikation (Prämenopausale Patientinnen)

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 1 of 68
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776)		EDT*a (N=729)		Total (N=1505)	
	n	(%)	n	(%)	n	(%)
Subjects with >= 1 Medication	684	(88.1)	510	(70.0)	1194	(79.3)
LOPERAMIDE	434	(55.9)	6	(0.8)	440	(29.2)
PARACETAMOL	189	(24.4)	134	(18.4)	323	(21.5)
IBUPROFEN	89	(11.5)	81	(11.1)	170	(11.3)
AMOXICILLIN;CLAVULANIC ACID	68	(8.8)	42	(5.8)	110	(7.3)
AMOXICILLIN	56	(7.2)	29	(4.0)	85	(5.6)
LEVOFLOXACIN	43	(5.5)	35	(4.8)	78	(5.2)
LOXOPROFEN	36	(4.6)	33	(4.5)	69	(4.6)
DICLOFENAC	35	(4.5)	32	(4.4)	67	(4.5)
METAMIZOLE	30	(3.9)	36	(4.9)	66	(4.4)
METOCLOPRAMIDE	49	(6.3)	9	(1.2)	58	(3.9)
CIPROFLOXACIN	32	(4.1)	23	(3.2)	55	(3.7)
AZITHROMYCIN	34	(4.4)	19	(2.6)	53	(3.5)
BETAMETHASONE	30	(3.9)	23	(3.2)	53	(3.5)
DEXAMETHASONE	28	(3.6)	23	(3.2)	51	(3.4)
CEFALEXIN	31	(4.0)	18	(2.5)	49	(3.3)
OMEPRAZOLE	37	(4.8)	11	(1.5)	48	(3.2)
CLARITHROMYCIN	26	(3.4)	20	(2.7)	46	(3.1)
CARBOCISTEINE	22	(2.8)	23	(3.2)	45	(3.0)
TRAMADOL	20	(2.6)	23	(3.2)	43	(2.9)
LEVOCETIRIZINE	27	(3.5)	15	(2.1)	42	(2.8)
ONDANSETRON	28	(3.6)	14	(1.9)	42	(2.8)
PANTOPRAZOLE	32	(4.1)	10	(1.4)	42	(2.8)
BUTYLSCOPOLAMINE	35	(4.5)	6	(0.8)	41	(2.7)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,

/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
HERBAL PREPARATION	29 (3.7)	12 (1.6)	41 (2.7)
LORATADINE	20 (2.6)	19 (2.6)	39 (2.6)
AMBROXOL	24 (3.1)	13 (1.8)	37 (2.5)
KETOPROFEN	20 (2.6)	17 (2.3)	37 (2.5)
TRANEXAMIC ACID	23 (3.0)	14 (1.9)	37 (2.5)
FEXOFENADINE	26 (3.4)	10 (1.4)	36 (2.4)
NAPROXEN	13 (1.7)	23 (3.2)	36 (2.4)
ACETYLCYSTEINE	23 (3.0)	11 (1.5)	34 (2.3)
FOSFOMYCIN	22 (2.8)	12 (1.6)	34 (2.3)
METRONIDAZOLE	21 (2.7)	13 (1.8)	34 (2.3)
ZOLPIDEM	16 (2.1)	18 (2.5)	34 (2.3)
IRON	21 (2.7)	12 (1.6)	33 (2.2)
METHYLPREDNISOLONE	19 (2.4)	14 (1.9)	33 (2.2)
PREDNISOLONE	19 (2.4)	13 (1.8)	32 (2.1)
COLECALCIFEROL	10 (1.3)	21 (2.9)	31 (2.1)
DEXTROMETHORPHAN	20 (2.6)	11 (1.5)	31 (2.1)
CEFUROXIME	13 (1.7)	17 (2.3)	30 (2.0)
VENLAFAXINE	12 (1.5)	18 (2.5)	30 (2.0)
CELECOXIB	14 (1.8)	15 (2.1)	29 (1.9)
CETIRIZINE	19 (2.4)	10 (1.4)	29 (1.9)
HYDROCORTISONE	22 (2.8)	7 (1.0)	29 (1.9)
LEVOTHYROXINE	11 (1.4)	18 (2.5)	29 (1.9)
OSELTAMIVIR	20 (2.6)	9 (1.2)	29 (1.9)
DIOSMECTITE	27 (3.5)	1 (0.1)	28 (1.9)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 3 of 68
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CLINDAMYCIN	13 (1.7)	14 (1.9)	27 (1.8)
PREDNISONE	15 (1.9)	12 (1.6)	27 (1.8)
PREGABALIN	12 (1.5)	15 (2.1)	27 (1.8)
SULFAMETHOXAZOLE;TRIMETHOPRIM	16 (2.1)	11 (1.5)	27 (1.8)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	13 (1.7)	14 (1.9)	27 (1.8)
CAFFEINE;PARACETAMOL;PROMETHAZINE;SALICYLAMIDE	17 (2.2)	9 (1.2)	26 (1.7)
HEPARINOID	21 (2.7)	5 (0.7)	26 (1.7)
LIDOCAINE	13 (1.7)	13 (1.8)	26 (1.7)
MONTELUKAST	13 (1.7)	13 (1.8)	26 (1.7)
RANITIDINE	20 (2.6)	6 (0.8)	26 (1.7)
FLUCONAZOLE	11 (1.4)	14 (1.9)	25 (1.7)
TRIAMCINOLONE	15 (1.9)	10 (1.4)	25 (1.7)
URSODEOXYCHOLIC ACID	14 (1.8)	11 (1.5)	25 (1.7)
CALCIUM CARBONATE;COLECALCIFEROL	9 (1.2)	15 (2.1)	24 (1.6)
FAMOTIDINE	15 (1.9)	9 (1.2)	24 (1.6)
HYALURONIC ACID	14 (1.8)	10 (1.4)	24 (1.6)
MORPHINE	15 (1.9)	9 (1.2)	24 (1.6)
VITIS VINIFERA	11 (1.4)	13 (1.8)	24 (1.6)
ACICLOVIR	12 (1.5)	11 (1.5)	23 (1.5)
ALPRAZOLAM	11 (1.4)	12 (1.6)	23 (1.5)
CEFAZOLIN	11 (1.4)	12 (1.6)	23 (1.5)
CHLORPHENAMINE	15 (1.9)	8 (1.1)	23 (1.5)
CODEINE	14 (1.8)	9 (1.2)	23 (1.5)
KETOROLAC	16 (2.1)	7 (1.0)	23 (1.5)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 4 of 68
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CEFTRIAXONE	13 (1.7)	9 (1.2)	22 (1.5)
DOXYCYCLINE	14 (1.8)	8 (1.1)	22 (1.5)
ESOMEPRAZOLE	15 (1.9)	7 (1.0)	22 (1.5)
POTASSIUM	17 (2.2)	5 (0.7)	22 (1.5)
ACETYLSALICYLIC ACID	14 (1.8)	7 (1.0)	21 (1.4)
CEFCAPENE	8 (1.0)	13 (1.8)	21 (1.4)
CEFDITOREN	15 (1.9)	6 (0.8)	21 (1.4)
CEFIXIME	12 (1.5)	9 (1.2)	21 (1.4)
FENTANYL	10 (1.3)	11 (1.5)	21 (1.4)
GABAPENTIN	13 (1.7)	8 (1.1)	21 (1.4)
MOMETASONE	14 (1.8)	7 (1.0)	21 (1.4)
CLOBETASOL	10 (1.3)	10 (1.4)	20 (1.3)
LORAZEPAM	13 (1.7)	7 (1.0)	20 (1.3)
MAGNESIUM OXIDE	9 (1.2)	11 (1.5)	20 (1.3)
BEPOTASTINE	12 (1.5)	7 (1.0)	19 (1.3)
DIPHENHYDRAMINE	10 (1.3)	9 (1.2)	19 (1.3)
MELATONIN	6 (0.8)	13 (1.8)	19 (1.3)
OFLOXACIN	11 (1.4)	8 (1.1)	19 (1.3)
SODIUM CHLORIDE	15 (1.9)	4 (0.5)	19 (1.3)
CEFACLOR	12 (1.5)	6 (0.8)	18 (1.2)
ENOXAPARIN	9 (1.2)	9 (1.2)	18 (1.2)
GRANULOCYTE COLONY STIMULATING FACTOR	16 (2.1)	2 (0.3)	18 (1.2)
LEUCOGEN	16 (2.1)	2 (0.3)	18 (1.2)
MIRTAZAPINE	9 (1.2)	9 (1.2)	18 (1.2)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 5 of 68
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
PARACETAMOL;TRAMADOL	9 (1.2)	9 (1.2)	18 (1.2)
SALBUTAMOL	7 (0.9)	11 (1.5)	18 (1.2)
CEFDINIR	9 (1.2)	8 (1.1)	17 (1.1)
DESLORATADINE	13 (1.7)	4 (0.5)	17 (1.1)
FLUOROMETHOLONE	10 (1.3)	7 (1.0)	17 (1.1)
MOXIFLOXACIN	10 (1.3)	7 (1.0)	17 (1.1)
OLOPATADINE	10 (1.3)	7 (1.0)	17 (1.1)
PSEUDOEPHEDRINE	7 (0.9)	10 (1.4)	17 (1.1)
VALACICLOVIR	9 (1.2)	8 (1.1)	17 (1.1)
AMITRIPTYLINE	6 (0.8)	10 (1.4)	16 (1.1)
BILASTINE	9 (1.2)	7 (1.0)	16 (1.1)
CHLORPHENAMINE;DIHYDROCODEINE;METHYLEPHEDRINE	8 (1.0)	8 (1.1)	16 (1.1)
CODEINE;PARACETAMOL	11 (1.4)	5 (0.7)	16 (1.1)
DIAZEPAM	7 (0.9)	9 (1.2)	16 (1.1)
NITROFURANTOIN	11 (1.4)	5 (0.7)	16 (1.1)
OXYCODONE	8 (1.0)	8 (1.1)	16 (1.1)
PHENOXYMETHYLPENICILLIN	11 (1.4)	5 (0.7)	16 (1.1)
AMMONIUM CHLORIDE;CHLORPHENAMINE;DIHYDROCODEINE;METHYLEPHEDRINE	10 (1.3)	5 (0.7)	15 (1.0)
BETAMETHASONE;GENTAMICIN	8 (1.0)	7 (1.0)	15 (1.0)
DIMENHYDRINATE	7 (0.9)	8 (1.1)	15 (1.0)
ERDOSTEINE	8 (1.0)	7 (1.0)	15 (1.0)
ESCITALOPRAM	6 (0.8)	9 (1.2)	15 (1.0)
LANSOPRAZOLE	11 (1.4)	4 (0.5)	15 (1.0)
METFORMIN	3 (0.4)	12 (1.6)	15 (1.0)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ACECLOFENAC	9 (1.2)	5 (0.7)	14 (0.9)
AMLODIPINE	6 (0.8)	8 (1.1)	14 (0.9)
BIDENS BITERNATA;CAFFEINE;CHLORPHENAMINE;CHRYSANTHEMUM INDICUM;ILEX ASPRELLA;MELICOPE PTELEIFOLIA;MENTHA CANADENSIS;PARACETAMOL	11 (1.4)	3 (0.4)	14 (0.9)
CLOTRIMAZOLE	8 (1.0)	6 (0.8)	14 (0.9)
DEXKETOPROFEN	5 (0.6)	9 (1.2)	14 (0.9)
FLUCLOXACILLIN	6 (0.8)	8 (1.1)	14 (0.9)
FLUTICASONE	8 (1.0)	6 (0.8)	14 (0.9)
LEVODROPROPIZINE	5 (0.6)	9 (1.2)	14 (0.9)
MAGNESIUM	7 (0.9)	7 (1.0)	14 (0.9)
MUPIROCIN	10 (1.3)	4 (0.5)	14 (0.9)
PROPOFOL	6 (0.8)	8 (1.1)	14 (0.9)
ROXITHROMYCIN	8 (1.0)	6 (0.8)	14 (0.9)
ASCORBIC ACID	7 (0.9)	6 (0.8)	13 (0.9)
BENZYDAMINE	8 (1.0)	5 (0.7)	13 (0.9)
CALCIUM CARBONATE	6 (0.8)	7 (1.0)	13 (0.9)
DOMPERIDONE	11 (1.4)	2 (0.3)	13 (0.9)
EPINASTINE	10 (1.3)	3 (0.4)	13 (0.9)
ETORICOXIB	6 (0.8)	7 (1.0)	13 (0.9)
NIMESULIDE	5 (0.6)	8 (1.1)	13 (0.9)
PROMETHAZINE	10 (1.3)	3 (0.4)	13 (0.9)
SERTRALINE	7 (0.9)	6 (0.8)	13 (0.9)
BUDESONIDE	7 (0.9)	5 (0.7)	12 (0.8)
CLOSTRIDIUM BUTYRICUM	8 (1.0)	4 (0.5)	12 (0.8)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ENALAPRIL	5 (0.6)	7 (1.0)	12 (0.8)
GENTAMICIN	6 (0.8)	6 (0.8)	12 (0.8)
LACTULOSE	6 (0.8)	6 (0.8)	12 (0.8)
METOPROLOL	8 (1.0)	4 (0.5)	12 (0.8)
PROCHLORPERAZINE	10 (1.3)	2 (0.3)	12 (0.8)
ROSUVASTATIN	9 (1.2)	3 (0.4)	12 (0.8)
TIROPRAMIDE	10 (1.3)	2 (0.3)	12 (0.8)
VITAMIN D NOS	6 (0.8)	6 (0.8)	12 (0.8)
AZELASTINE	7 (0.9)	4 (0.5)	11 (0.7)
BICYCLOL	10 (1.3)	1 (0.1)	11 (0.7)
BROMHEXINE	8 (1.0)	3 (0.4)	11 (0.7)
CEFPODOXIME	7 (0.9)	4 (0.5)	11 (0.7)
CYCLOBENZAPRINE	3 (0.4)	8 (1.1)	11 (0.7)
DEQUALINIUM	6 (0.8)	5 (0.7)	11 (0.7)
DIOSMIN;HESPERIDIN	7 (0.9)	4 (0.5)	11 (0.7)
EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PUERARIA MONTANA VAR. LOBATA;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	6 (0.8)	5 (0.7)	11 (0.7)
FAVIPIRAVIR	3 (0.4)	8 (1.1)	11 (0.7)
FUROSEMIDE	6 (0.8)	5 (0.7)	11 (0.7)
GLUTATHIONE	10 (1.3)	1 (0.1)	11 (0.7)
GLYCYRRHIZIC ACID	11 (1.4)	0 (0.0)	11 (0.7)
HYDROXYZINE	5 (0.6)	6 (0.8)	11 (0.7)
MICONAZOLE	5 (0.6)	6 (0.8)	11 (0.7)
MOSAPRIDE	5 (0.6)	6 (0.8)	11 (0.7)

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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
POLYENE PHOSPHATIDYLCHOLINE	11 (1.4)	0 (0.0)	11 (0.7)
ROCURONIUM	6 (0.8)	5 (0.7)	11 (0.7)
SIMETICONE	10 (1.3)	1 (0.1)	11 (0.7)
BENZONATATE	5 (0.6)	5 (0.7)	10 (0.7)
CALCIUM;COLECALCIFEROL	6 (0.8)	4 (0.5)	10 (0.7)
CEFADROXIL	8 (1.0)	2 (0.3)	10 (0.7)
EPERISONE	2 (0.3)	8 (1.1)	10 (0.7)
GUALENIC ACID	8 (1.0)	2 (0.3)	10 (0.7)
HYDROMORPHONE	6 (0.8)	4 (0.5)	10 (0.7)
MELOXICAM	4 (0.5)	6 (0.8)	10 (0.7)
MIDAZOLAM	5 (0.6)	5 (0.7)	10 (0.7)
REBAMIPIDE	3 (0.4)	7 (1.0)	10 (0.7)
SANGUISORBA OFFICINALIS	9 (1.2)	1 (0.1)	10 (0.7)
STREPTODORNASE;STREPTOKINASE	7 (0.9)	3 (0.4)	10 (0.7)
TERBINAFINE	6 (0.8)	4 (0.5)	10 (0.7)
VITAMIN B12 NOS	7 (0.9)	3 (0.4)	10 (0.7)
ATORVASTATIN	3 (0.4)	6 (0.8)	9 (0.6)
BEZAFIBRATE	5 (0.6)	4 (0.5)	9 (0.6)
BIFIDOBACTERIUM NOS	8 (1.0)	1 (0.1)	9 (0.6)
BUDESONIDE;FORMOTEROL	5 (0.6)	4 (0.5)	9 (0.6)
CITALOPRAM	5 (0.6)	4 (0.5)	9 (0.6)
CLONAZEPAM	5 (0.6)	4 (0.5)	9 (0.6)
EBASTINE	6 (0.8)	3 (0.4)	9 (0.6)
FENOFIBRATE	6 (0.8)	3 (0.4)	9 (0.6)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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Indication: Adverse Event

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HYDROCODONE;PARACETAMOL	7 (0.9)	2 (0.3)	9 (0.6)
PHLOROGLUCINOL	7 (0.9)	2 (0.3)	9 (0.6)
RAMIPRIL	5 (0.6)	4 (0.5)	9 (0.6)
RUPATADINE	7 (0.9)	2 (0.3)	9 (0.6)
SILYBUM MARIANUM	5 (0.6)	4 (0.5)	9 (0.6)
SULFADIAZINE	2 (0.3)	7 (1.0)	9 (0.6)
TIPEPIDINE	6 (0.8)	3 (0.4)	9 (0.6)
ANTIBIOTICS	4 (0.5)	4 (0.5)	8 (0.5)
BETAHISTINE	3 (0.4)	5 (0.7)	8 (0.5)
BETAMETHASONE;DEXCHLORPHENIRAMINE	7 (0.9)	1 (0.1)	8 (0.5)
CALCIUM	4 (0.5)	4 (0.5)	8 (0.5)
CHLORPHENAMINE;DIHYDROCODEINE;GUAIFENESIN;METHYLEPHEDRINE	3 (0.4)	5 (0.7)	8 (0.5)
CYANOCOBALAMIN	4 (0.5)	4 (0.5)	8 (0.5)
DEXIBUPROFEN	5 (0.6)	3 (0.4)	8 (0.5)
GLUCOSAMINE	1 (0.1)	7 (1.0)	8 (0.5)
HYOSCINE	7 (0.9)	1 (0.1)	8 (0.5)
MEFENAMIC ACID	5 (0.6)	3 (0.4)	8 (0.5)
NYSTATIN	5 (0.6)	3 (0.4)	8 (0.5)
OXYBUTYNIN	4 (0.5)	4 (0.5)	8 (0.5)
PETHIDINE	6 (0.8)	2 (0.3)	8 (0.5)
PIPERACILLIN;TAZOBACTAM	6 (0.8)	2 (0.3)	8 (0.5)
PROPACETAMOL	8 (1.0)	0 (0.0)	8 (0.5)
PYRIDOXINE	5 (0.6)	3 (0.4)	8 (0.5)
RABEPRAZOLE	5 (0.6)	3 (0.4)	8 (0.5)

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RACECADOTRIL	8 (1.0)	0 (0.0)	8 (0.5)
RIVAROXABAN	7 (0.9)	1 (0.1)	8 (0.5)
SPIRONOLACTONE	4 (0.5)	4 (0.5)	8 (0.5)
TAMSULOSIN	7 (0.9)	1 (0.1)	8 (0.5)
ZALTOPROFEN	3 (0.4)	5 (0.7)	8 (0.5)
ZOLEDRONIC ACID	5 (0.6)	3 (0.4)	8 (0.5)
ARTEMISIA ARGYI	5 (0.6)	2 (0.3)	7 (0.5)
BECLOMETASONE	5 (0.6)	2 (0.3)	7 (0.5)
BISOPROLOL	6 (0.8)	1 (0.1)	7 (0.5)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	2 (0.3)	5 (0.7)	7 (0.5)
CEFPROZIL	4 (0.5)	3 (0.4)	7 (0.5)
CHLORAMPHENICOL	5 (0.6)	2 (0.3)	7 (0.5)
CHLORHEXIDINE	2 (0.3)	5 (0.7)	7 (0.5)
CHLORPHENAMINE;PARACETAMOL;PHENYLEPHRINE	4 (0.5)	3 (0.4)	7 (0.5)
CINNARIZINE	3 (0.4)	4 (0.5)	7 (0.5)
DEXPANTHENOL	4 (0.5)	3 (0.4)	7 (0.5)
ERYTHROMYCIN	7 (0.9)	0 (0.0)	7 (0.5)
FLURBIPROFEN	1 (0.1)	6 (0.8)	7 (0.5)
FLUTICASONE;VILANTEROL	3 (0.4)	4 (0.5)	7 (0.5)
FOLIC ACID	6 (0.8)	1 (0.1)	7 (0.5)
FUSIDIC ACID	4 (0.5)	3 (0.4)	7 (0.5)
GUAIAZULENE	3 (0.4)	4 (0.5)	7 (0.5)
HYDROCHLOROTHIAZIDE	1 (0.1)	6 (0.8)	7 (0.5)
LOSARTAN	3 (0.4)	4 (0.5)	7 (0.5)

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I3Y-MC-JPCF PDPM
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Indication: Adverse Event

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MEQUITAZINE	4 (0.5)	3 (0.4)	7 (0.5)
NEBIVOLOL	4 (0.5)	3 (0.4)	7 (0.5)
NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;PRUNUS SPP.	2 (0.3)	5 (0.7)	7 (0.5)
NORFLOXACIN	6 (0.8)	1 (0.1)	7 (0.5)
OXYCODONE;PARACETAMOL	5 (0.6)	2 (0.3)	7 (0.5)
PHOLCODINE	3 (0.4)	4 (0.5)	7 (0.5)
PIROXICAM	4 (0.5)	3 (0.4)	7 (0.5)
PIVMECILLINAM	6 (0.8)	1 (0.1)	7 (0.5)
PREDNICARBATE	4 (0.5)	3 (0.4)	7 (0.5)
TRIMEBUTINE	5 (0.6)	2 (0.3)	7 (0.5)
ZOPICLONE	5 (0.6)	2 (0.3)	7 (0.5)
ANILIDES	3 (0.4)	3 (0.4)	6 (0.4)
ATROPINE	1 (0.1)	5 (0.7)	6 (0.4)
BENZYLPENICILLIN	3 (0.4)	3 (0.4)	6 (0.4)
BETA-ALANINE	3 (0.4)	3 (0.4)	6 (0.4)
CAFFEINE;METAMIZOLE;ORPHENADRINE	3 (0.4)	3 (0.4)	6 (0.4)
CAPTOPRIL	2 (0.3)	4 (0.5)	6 (0.4)
COPTIS SPP.;HEDERA HELIX	2 (0.3)	4 (0.5)	6 (0.4)
DEXAMETHASONE;TOBRAMYCIN	4 (0.5)	2 (0.3)	6 (0.4)
DEXCHLORPHENIRAMINE	4 (0.5)	2 (0.3)	6 (0.4)
DIMEMORFAN	6 (0.8)	0 (0.0)	6 (0.4)
DIMETICONE	4 (0.5)	2 (0.3)	6 (0.4)
DOCUSATE	5 (0.6)	1 (0.1)	6 (0.4)
DULOXETINE	2 (0.3)	4 (0.5)	6 (0.4)

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Indication: Adverse Event

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EPRAZINONE	5 (0.6)	1 (0.1)	6 (0.4)
ESTRIOL	2 (0.3)	4 (0.5)	6 (0.4)
FAMCICLOVIR	2 (0.3)	4 (0.5)	6 (0.4)
GRANISETRON	5 (0.6)	1 (0.1)	6 (0.4)
HEPARIN	6 (0.8)	0 (0.0)	6 (0.4)
KETOCONAZOLE	4 (0.5)	2 (0.3)	6 (0.4)
LANINAMIVIR	2 (0.3)	4 (0.5)	6 (0.4)
MINOCYCLINE	4 (0.5)	2 (0.3)	6 (0.4)
NEOSTIGMINE	4 (0.5)	2 (0.3)	6 (0.4)
ORNIDAZOLE	3 (0.4)	3 (0.4)	6 (0.4)
ORPHENADRINE	3 (0.4)	3 (0.4)	6 (0.4)
ORPHENADRINE;PARACETAMOL	1 (0.1)	5 (0.7)	6 (0.4)
PELUBIPROFEN	4 (0.5)	2 (0.3)	6 (0.4)
PRANLUKAST	2 (0.3)	4 (0.5)	6 (0.4)
PROPRANOLOL	1 (0.1)	5 (0.7)	6 (0.4)
SACCHAROMYCES BOULARDII	6 (0.8)	0 (0.0)	6 (0.4)
TAPENTADOL	5 (0.6)	1 (0.1)	6 (0.4)
TRAZODONE	3 (0.4)	3 (0.4)	6 (0.4)
UREA	6 (0.8)	0 (0.0)	6 (0.4)
AFLOQUALONE	2 (0.3)	3 (0.4)	5 (0.3)
ALENDRONIC ACID	3 (0.4)	2 (0.3)	5 (0.3)
ANTIDIARRHEAL MICROORGANISMS	2 (0.3)	3 (0.4)	5 (0.3)
BACITRACIN;NEOMYCIN;POLYMYXIN B	2 (0.3)	3 (0.4)	5 (0.3)
BALOXAVIR MARBOXIL	3 (0.4)	2 (0.3)	5 (0.3)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
BATILOL	5 (0.6)	0 (0.0)	5 (0.3)
BISACODYL	2 (0.3)	3 (0.4)	5 (0.3)
BROMOPRIDE	5 (0.6)	0 (0.0)	5 (0.3)
CAFFEINE;CODEINE;PARACETAMOL	2 (0.3)	3 (0.4)	5 (0.3)
CALCIUM GLUCONATE	4 (0.5)	1 (0.1)	5 (0.3)
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL;PSEUDOEPHEDRINE	2 (0.3)	3 (0.4)	5 (0.3)
CIMETIDINE	4 (0.5)	1 (0.1)	5 (0.3)
CORYDALIS YANHUSUO;IPOMOEA NIL	4 (0.5)	1 (0.1)	5 (0.3)
CYANOCOBALAMIN;PYRIDOXINE;THIAMINE	2 (0.3)	3 (0.4)	5 (0.3)
DESONIDE	4 (0.5)	1 (0.1)	5 (0.3)
DICLOXACILLIN	3 (0.4)	2 (0.3)	5 (0.3)
DIHYDROCODEINE	4 (0.5)	1 (0.1)	5 (0.3)
DIMETINDENE	4 (0.5)	1 (0.1)	5 (0.3)
DIQUAFOSOL	2 (0.3)	3 (0.4)	5 (0.3)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	5 (0.6)	0 (0.0)	5 (0.3)
DOCUSATE;SENNOSIDE A+B	4 (0.5)	1 (0.1)	5 (0.3)
ECONAZOLE	2 (0.3)	3 (0.4)	5 (0.3)
ESTRADIOL	2 (0.3)	3 (0.4)	5 (0.3)
ETODOLAC	3 (0.4)	2 (0.3)	5 (0.3)
FILGRASTIM	5 (0.6)	0 (0.0)	5 (0.3)
FLUOCINONIDE	2 (0.3)	3 (0.4)	5 (0.3)
GARENOXACIN	3 (0.4)	2 (0.3)	5 (0.3)
GLYCEROL	4 (0.5)	1 (0.1)	5 (0.3)
HYPROMELLOSE	4 (0.5)	1 (0.1)	5 (0.3)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
IPRATROPIUM	2 (0.3)	3 (0.4)	5 (0.3)
L-CARBOCISTEINE	2 (0.3)	3 (0.4)	5 (0.3)
LIDOCAINE;TRIBENOSIDE	3 (0.4)	2 (0.3)	5 (0.3)
MACROGOL 3350;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	3 (0.4)	2 (0.3)	5 (0.3)
MAGNESIUM HYDROXIDE	1 (0.1)	4 (0.5)	5 (0.3)
MONTMORILLONITE	5 (0.6)	0 (0.0)	5 (0.3)
ORNITHINE	5 (0.6)	0 (0.0)	5 (0.3)
PLANTAGO OVATA	3 (0.4)	2 (0.3)	5 (0.3)
PSEUDOEPHEDRINE;TRIPROLIDINE	2 (0.3)	3 (0.4)	5 (0.3)
SENNOSIDE A+B	2 (0.3)	3 (0.4)	5 (0.3)
SEVOFLURANE	1 (0.1)	4 (0.5)	5 (0.3)
SODIUM PHOSPHATE	4 (0.5)	1 (0.1)	5 (0.3)
TOBRAMYCIN	2 (0.3)	3 (0.4)	5 (0.3)
TULOBUTEROL	3 (0.4)	2 (0.3)	5 (0.3)
VIDARABINE	2 (0.3)	3 (0.4)	5 (0.3)
ALBUMIN TANNATE	2 (0.3)	2 (0.3)	4 (0.3)
ALGINIC ACID	3 (0.4)	1 (0.1)	4 (0.3)
AMANTADINE;CAFFEINE;CHLORPHENAMINE;COW BEZOAR;PARACETAMOL	3 (0.4)	1 (0.1)	4 (0.3)
ARGININE;IBUPROFEN	4 (0.5)	0 (0.0)	4 (0.3)
ATROPINE;DIPHENOXYLATE	4 (0.5)	0 (0.0)	4 (0.3)
BENPROPERINE	1 (0.1)	3 (0.4)	4 (0.3)
BENZYDAMINE;CHLORHEXIDINE	1 (0.1)	3 (0.4)	4 (0.3)
BETAMETHASONE;FUSIDIC ACID	3 (0.4)	1 (0.1)	4 (0.3)
CAFFEINE;CARISOPRODOL;DICLOFENAC;PARACETAMOL	3 (0.4)	1 (0.1)	4 (0.3)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CALCIUM CHLORIDE;POTASSIUM;SODIUM LACTATE	4 (0.5)	0 (0.0)	4 (0.3)
CARBOMER	1 (0.1)	3 (0.4)	4 (0.3)
CARMELLOSE	3 (0.4)	1 (0.1)	4 (0.3)
CEFRADINE	3 (0.4)	1 (0.1)	4 (0.3)
CHLORZOXAZONE	1 (0.1)	3 (0.4)	4 (0.3)
CINCHOCAINE;POLICRESULEN	4 (0.5)	0 (0.0)	4 (0.3)
CINEOLE;DIPENTEN;PINENE	1 (0.1)	3 (0.4)	4 (0.3)
COLCHICINE	1 (0.1)	3 (0.4)	4 (0.3)
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	4 (0.5)	0 (0.0)	4 (0.3)
DALTEPARIN	3 (0.4)	1 (0.1)	4 (0.3)
DEXAMETHASONE;NEOMYCIN;POLYMYXIN B	2 (0.3)	2 (0.3)	4 (0.3)
DIFLUPREDNATE	3 (0.4)	1 (0.1)	4 (0.3)
DIMENHYDRINATE;PYRIDOXINE	3 (0.4)	1 (0.1)	4 (0.3)
DIPHENHYDRAMINE;HYDROCORTISONE;NEOMYCIN	2 (0.3)	2 (0.3)	4 (0.3)
DIPROPHYLLINE	2 (0.3)	2 (0.3)	4 (0.3)
ECONAZOLE;TRIAMCINOLONE	4 (0.5)	0 (0.0)	4 (0.3)
EPINEPHRINE;LIDOCAINE	2 (0.3)	2 (0.3)	4 (0.3)
ESCHERICHIA COLI;HYDROCORTISONE	3 (0.4)	1 (0.1)	4 (0.3)
FELBINAC	2 (0.3)	2 (0.3)	4 (0.3)
FENTICONAZOLE	2 (0.3)	2 (0.3)	4 (0.3)
FLUNARIZINE	2 (0.3)	2 (0.3)	4 (0.3)
FLUTICASONE;FORMOTEROL	2 (0.3)	2 (0.3)	4 (0.3)
FLUTICASONE;SALMETEROL	1 (0.1)	3 (0.4)	4 (0.3)
GENTIANA LUTEA;PRIMULA SPP.;RUMEX SPP.;SAMBUCUS NIGRA;VERBENA OFFICINALIS	2 (0.3)	2 (0.3)	4 (0.3)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
GLYCEROL;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (0.1)	3 (0.4)	4 (0.3)
GLYCOPYRRONIUM	3 (0.4)	1 (0.1)	4 (0.3)
GLYCYRRHIZA GLABRA	4 (0.5)	0 (0.0)	4 (0.3)
GLYCYRRHIZA SPP.;OPHIOPOGON JAPONICUS;ORYZA SATIVA;PANAX GINSENG;PINELLIA TERNATA;ZIZIPHUS JUJUBA	2 (0.3)	2 (0.3)	4 (0.3)
GUAIFENESIN	1 (0.1)	3 (0.4)	4 (0.3)
HERBAL POLLEN NOS;TOCOPHEROL	2 (0.3)	2 (0.3)	4 (0.3)
HYOSCINE;METAMIZOLE	4 (0.5)	0 (0.0)	4 (0.3)
INDOMETACIN	2 (0.3)	2 (0.3)	4 (0.3)
INSULIN NOS	1 (0.1)	3 (0.4)	4 (0.3)
IPRATROPIUM;SALBUTAMOL	4 (0.5)	0 (0.0)	4 (0.3)
IRON;JUGLANS REGIA;NEOLITSEA CASSIA;PANAX QUINQUEFOLIUS;SEA HORSE;ZIZIPHUS JUJUBA	4 (0.5)	0 (0.0)	4 (0.3)
KETOTIFEN	3 (0.4)	1 (0.1)	4 (0.3)
LACHESIS MUTA	2 (0.3)	2 (0.3)	4 (0.3)
LEVOCETIRIZINE;MONTELUKAST	2 (0.3)	2 (0.3)	4 (0.3)
LEVOCLOPERASTINE	4 (0.5)	0 (0.0)	4 (0.3)
LINCOMYCIN	3 (0.4)	1 (0.1)	4 (0.3)
LIVER THERAPY	2 (0.3)	2 (0.3)	4 (0.3)
LORNOXICAM	3 (0.4)	1 (0.1)	4 (0.3)
LYSOZYME	2 (0.3)	2 (0.3)	4 (0.3)
MECOBALAMIN	0 (0.0)	4 (0.5)	4 (0.3)
NADIFLOXACIN	2 (0.3)	2 (0.3)	4 (0.3)
NEFOPAM	2 (0.3)	2 (0.3)	4 (0.3)
NEOMYCIN	3 (0.4)	1 (0.1)	4 (0.3)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
OTHER EMOLLIENTS AND PROTECTIVES	4 (0.5)	0 (0.0)	4 (0.3)
OTHER GYNECOLOGICALS	1 (0.1)	3 (0.4)	4 (0.3)
OTHER OPHTHALMOLOGICALS	1 (0.1)	3 (0.4)	4 (0.3)
PARAFFIN, LIQUID	2 (0.3)	2 (0.3)	4 (0.3)
PENTOXIFYLLINE	0 (0.0)	4 (0.5)	4 (0.3)
PHENYLEPHRINE	2 (0.3)	2 (0.3)	4 (0.3)
PHLOROGLUCINOL;TRIMETHYLPHLOROGLUCINOL	2 (0.3)	2 (0.3)	4 (0.3)
POVIDONE-IODINE	1 (0.1)	3 (0.4)	4 (0.3)
REMIFENTANIL	0 (0.0)	4 (0.5)	4 (0.3)
RIFAXIMIN	4 (0.5)	0 (0.0)	4 (0.3)
SELENIUM	3 (0.4)	1 (0.1)	4 (0.3)
SEPIA OFFICINALIS	1 (0.1)	3 (0.4)	4 (0.3)
SOLIFENACIN	2 (0.3)	2 (0.3)	4 (0.3)
STREPTOKINASE	4 (0.5)	0 (0.0)	4 (0.3)
SUCRALFATE	3 (0.4)	1 (0.1)	4 (0.3)
SULFAMETHOXAZOLE	3 (0.4)	1 (0.1)	4 (0.3)
SUMATRIPTAN	1 (0.1)	3 (0.4)	4 (0.3)
TEPRENONE	2 (0.3)	2 (0.3)	4 (0.3)
THEOPHYLLINE	3 (0.4)	1 (0.1)	4 (0.3)
THIOCOLCHICOSIDE	0 (0.0)	4 (0.5)	4 (0.3)
TRIMETHOPRIM	4 (0.5)	0 (0.0)	4 (0.3)
VALPROIC ACID	3 (0.4)	1 (0.1)	4 (0.3)
VITAMIN B COMPLEX	3 (0.4)	1 (0.1)	4 (0.3)
VONOPRAZAN	3 (0.4)	1 (0.1)	4 (0.3)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
WATER PURIFIED	2 (0.3)	2 (0.3)	4 (0.3)
XYLOMETAZOLINE	2 (0.3)	2 (0.3)	4 (0.3)
ACETYLCARNITINE	2 (0.3)	1 (0.1)	3 (0.2)
ACETYLSALICYLIC ACID;HYDROTALCITE	2 (0.3)	1 (0.1)	3 (0.2)
ACHYRANTHES BIDENTATA;ACONITUM SPP.;ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;CORNUS OFFICINALIS;DIOSCOREA SPP.;NEOLITSEA CASSIA;PAEONIA X SUFFRUTICOSA;PLANTAGO ASIATICA;PORIA COCOS;	2 (0.3)	1 (0.1)	3 (0.2)
ACTAEA RACEMOSA	1 (0.1)	2 (0.3)	3 (0.2)
ACTAEA RACEMOSA;ARNICA MONTANA;GLYCERYL TRINITRATE;LACHESIS MUTA;SANGUINARIA CANADENSIS	2 (0.3)	1 (0.1)	3 (0.2)
ADEMETIONINE	1 (0.1)	2 (0.3)	3 (0.2)
ADENINE	3 (0.4)	0 (0.0)	3 (0.2)
ALGINIC ACID;POTASSIUM BICARBONATE	3 (0.4)	0 (0.0)	3 (0.2)
ALOE VERA	2 (0.3)	1 (0.1)	3 (0.2)
ALUMINIUM HYDROXIDE;CALCIUM CARBONATE;MAGNESIUM CARBONATE;OXETACAINE	1 (0.1)	2 (0.3)	3 (0.2)
AMPICILLIN	2 (0.3)	1 (0.1)	3 (0.2)
APIXABAN	2 (0.3)	1 (0.1)	3 (0.2)
ARNICA MONTANA	1 (0.1)	2 (0.3)	3 (0.2)
ATENOLOL	0 (0.0)	3 (0.4)	3 (0.2)
ATROPA BELLA-DONNA	1 (0.1)	2 (0.3)	3 (0.2)
BACLOFEN	3 (0.4)	0 (0.0)	3 (0.2)
BECLOMETASONE;FORMOTEROL	2 (0.3)	1 (0.1)	3 (0.2)
BENZOIC ACID;CEPHAELIS SPP.;GUAIFENESIN;IODINE;OXOMEMAZINE	3 (0.4)	0 (0.0)	3 (0.2)
BERBERINE	2 (0.3)	1 (0.1)	3 (0.2)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM INFANTIS	2 (0.3)	1 (0.1)	3 (0.2)

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Indication: Adverse Event

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BIFIDOBACTERIUM BIFIDUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	2 (0.3)	1 (0.1)	3 (0.2)
BIFONAZOLE	1 (0.1)	2 (0.3)	3 (0.2)
BIOTIN	1 (0.1)	2 (0.3)	3 (0.2)
BISACODYL;DOCUSATE	2 (0.3)	1 (0.1)	3 (0.2)
BISMUTH;RANITIDINE;SUCRALFATE	1 (0.1)	2 (0.3)	3 (0.2)
BROMELAINS	1 (0.1)	2 (0.3)	3 (0.2)
BUPIVACAINE	1 (0.1)	2 (0.3)	3 (0.2)
BUPRENORPHINE	0 (0.0)	3 (0.4)	3 (0.2)
CAFFEINE;CHLORPHENAMINE;COW BEZOAR;PARACETAMOL	2 (0.3)	1 (0.1)	3 (0.2)
CAFFEINE;CHLORPHENAMINE;PARACETAMOL;PHENYLEPHRINE	2 (0.3)	1 (0.1)	3 (0.2)
CAFFEINE;ISOMETHEPTENE;METAMIZOLE	2 (0.3)	1 (0.1)	3 (0.2)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE	1 (0.1)	2 (0.3)	3 (0.2)
CARISOPRODOL	1 (0.1)	2 (0.3)	3 (0.2)
CASSIA FISTULA;CORIANDRUM SATIVUM;SENNA ALEXANDRINA;TAMARINDUS INDICA	2 (0.3)	1 (0.1)	3 (0.2)
CICLOPIROX	0 (0.0)	3 (0.4)	3 (0.2)
CIPROFIBRATE	3 (0.4)	0 (0.0)	3 (0.2)
CIPROFLOXACIN;DEXAMETHASONE	2 (0.3)	1 (0.1)	3 (0.2)
CITRULLUS LANATUS;SODIUM SULFATE	2 (0.3)	1 (0.1)	3 (0.2)
CORDYCEPS SINENSIS	3 (0.4)	0 (0.0)	3 (0.2)
DEXLANSOPRAZOLE	3 (0.4)	0 (0.0)	3 (0.2)
DIETARY SUPPLEMENT	2 (0.3)	1 (0.1)	3 (0.2)
DIFENIDOL	3 (0.4)	0 (0.0)	3 (0.2)
DIFLUCORTOLONE;ISOCONAZOLE	0 (0.0)	3 (0.4)	3 (0.2)
DILTIAZEM	2 (0.3)	1 (0.1)	3 (0.2)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 20 of 68
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
DIOSMIN	2 (0.3)	1 (0.1)	3 (0.2)
DOMIPHEN	2 (0.3)	1 (0.1)	3 (0.2)
EPHEDRINE	0 (0.0)	3 (0.4)	3 (0.2)
EPINEPHRINE	2 (0.3)	1 (0.1)	3 (0.2)
ESOMEPRAZOLE;NAPROXEN	1 (0.1)	2 (0.3)	3 (0.2)
ETODOLAC;THIOCOLCHICOSIDE	0 (0.0)	3 (0.4)	3 (0.2)
EZETIMIBE	3 (0.4)	0 (0.0)	3 (0.2)
FENOTEROL	1 (0.1)	2 (0.3)	3 (0.2)
FLAVOXATE	1 (0.1)	2 (0.3)	3 (0.2)
FLUOCINOLONE ACETONIDE	3 (0.4)	0 (0.0)	3 (0.2)
FLUOXETINE	0 (0.0)	3 (0.4)	3 (0.2)
FORSYTHIA SUSPENSA;LONICERA JAPONICA;SCUTELLARIA BAICALENSIS	3 (0.4)	0 (0.0)	3 (0.2)
GINKGO BILOBA	0 (0.0)	3 (0.4)	3 (0.2)
GLUCOSE	1 (0.1)	2 (0.3)	3 (0.2)
GLYCYRRHIZA SPP.;PLATYCODON GRANDIFLORUS	3 (0.4)	0 (0.0)	3 (0.2)
HAMAMELIS VIRGINIANA	2 (0.3)	1 (0.1)	3 (0.2)
HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES	1 (0.1)	2 (0.3)	3 (0.2)
HYDROCODONE	2 (0.3)	1 (0.1)	3 (0.2)
IBANDRONIC ACID	3 (0.4)	0 (0.0)	3 (0.2)
IBUPROFEN;PARACETAMOL	2 (0.3)	1 (0.1)	3 (0.2)
IBUPROFEN;PHENYLEPHRINE	2 (0.3)	1 (0.1)	3 (0.2)
ITOPRIDE	2 (0.3)	1 (0.1)	3 (0.2)
ITRACONAZOLE	2 (0.3)	1 (0.1)	3 (0.2)
LENOGRASTIM	3 (0.4)	0 (0.0)	3 (0.2)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
LIDOCAINE;PRILOCAINE	3 (0.4)	0 (0.0)	3 (0.2)
LOTEPREDNOL	3 (0.4)	0 (0.0)	3 (0.2)
LOTEPREDNOL;TOBRAMYCIN	2 (0.3)	1 (0.1)	3 (0.2)
LULICONAZOLE	2 (0.3)	1 (0.1)	3 (0.2)
MACROGOL	1 (0.1)	2 (0.3)	3 (0.2)
MECILLINAM	3 (0.4)	0 (0.0)	3 (0.2)
MECLOZINE	1 (0.1)	2 (0.3)	3 (0.2)
METFORMIN;SITAGLIPTIN	1 (0.1)	2 (0.3)	3 (0.2)
MINOXIDIL	0 (0.0)	3 (0.4)	3 (0.2)
MISOPROSTOL	2 (0.3)	1 (0.1)	3 (0.2)
NALOXONE;OXYCODONE	0 (0.0)	3 (0.4)	3 (0.2)
NIFURATEL;NYSTATIN	1 (0.1)	2 (0.3)	3 (0.2)
OLMESARTAN	1 (0.1)	2 (0.3)	3 (0.2)
OMEGA-3-ACID ETHYL ESTER	2 (0.3)	1 (0.1)	3 (0.2)
OXETACAINE	3 (0.4)	0 (0.0)	3 (0.2)
PEMAFIBRATE	3 (0.4)	0 (0.0)	3 (0.2)
PHENAZOPYRIDINE	2 (0.3)	1 (0.1)	3 (0.2)
PIPRINHYDRINATE	2 (0.3)	1 (0.1)	3 (0.2)
POLAPREZINC	2 (0.3)	1 (0.1)	3 (0.2)
PRISTINAMYCIN	2 (0.3)	1 (0.1)	3 (0.2)
QUETIAPINE	3 (0.4)	0 (0.0)	3 (0.2)
RIBOFLAVIN	1 (0.1)	2 (0.3)	3 (0.2)
RIZATRIPTAN	2 (0.3)	1 (0.1)	3 (0.2)
SALICYLAMIDE	3 (0.4)	0 (0.0)	3 (0.2)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
SALVIA OFFICINALIS	1 (0.1)	2 (0.3)	3 (0.2)
SERTACONAZOLE	2 (0.3)	1 (0.1)	3 (0.2)
SUGAMMADEX	3 (0.4)	0 (0.0)	3 (0.2)
TACROLIMUS	3 (0.4)	0 (0.0)	3 (0.2)
TEGOPRAZAN	3 (0.4)	0 (0.0)	3 (0.2)
TEMAZEPAM	2 (0.3)	1 (0.1)	3 (0.2)
TENOXICAM	1 (0.1)	2 (0.3)	3 (0.2)
THEOBROMINE	1 (0.1)	2 (0.3)	3 (0.2)
THIAMAZOLE	0 (0.0)	3 (0.4)	3 (0.2)
TIARAMIDE	2 (0.3)	1 (0.1)	3 (0.2)
TIZANIDINE	2 (0.3)	1 (0.1)	3 (0.2)
VANCOMYCIN	3 (0.4)	0 (0.0)	3 (0.2)
WHITE SOFT PARAFFIN	1 (0.1)	2 (0.3)	3 (0.2)
ZINC	2 (0.3)	1 (0.1)	3 (0.2)
ACEMETACIN	0 (0.0)	2 (0.3)	2 (0.1)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	1 (0.1)	1 (0.1)	2 (0.1)
ACHILLEA MILLEFOLIUM;ACONITUM NAPELLUS;ARNICA MONTANA;ATROPA BELLA-DONNA;BELLIS PERENNIS;CALCIUM SULFIDE;CALENDULA OFFICINALIS;ECHINACEA ANGUSTIFOLIA;ECHINACEA PURPUREA;HAMAMELIS VIRGINIANA;	2 (0.3)	0 (0.0)	2 (0.1)
ACONITUM SPP.;ASARUM SPP.;EPHEDRA SPP.	1 (0.1)	1 (0.1)	2 (0.1)
ACORUS VERUS;ANEMARRHENA ASPHODELOIDES;CALCIUM SULFATE;CURCUMA SPP.;FORSYTHIA SUSPENSA;ISATIS TINCTORIA SUBSP. TINCTORIA;PHRAGMITES AUSTRALIS SUBSP. AUSTRALIS;POGOSTEMON CABLIN;REHMANNIA GLUTINOSA	1 (0.1)	1 (0.1)	2 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ACORUS VERUS;ANEMARRHENA ASPHODELOIDES;CALCIUM SULFATE;CURCUMA SPP.;FORSYTHIA SUSPENSA;ISATIS TINCTORIA;PHRAGMITES AUSTRALIS SUBSP. AUSTRALIS;POGOSTEMON CABLIN;REHMANNIA GLUTINOSA	1 (0.1)	1 (0.1)	2 (0.1)
ADENOSINE	1 (0.1)	1 (0.1)	2 (0.1)
ADIPHENINE;METAMIZOLE;PROMETHAZINE	1 (0.1)	1 (0.1)	2 (0.1)
ALGINIC ACID;CALCIUM CARBONATE;MAGNESIUM CARBONATE	1 (0.1)	1 (0.1)	2 (0.1)
ALIMEMAZINE	1 (0.1)	1 (0.1)	2 (0.1)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ATRACTYLODES SPP.;NEOLITSEA CASSIA;POLYPORUS UMBELLATUS;PORIA COCOS	0 (0.0)	2 (0.3)	2 (0.1)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;GELATIN;POLYPORUS UMBELLATUS;PORIA COCOS;TALC	1 (0.1)	1 (0.1)	2 (0.1)
ALLOPURINOL	2 (0.3)	0 (0.0)	2 (0.1)
ALTEPLASE	2 (0.3)	0 (0.0)	2 (0.1)
ALUMINIUM HYDROXIDE	2 (0.3)	0 (0.0)	2 (0.1)
ALUMINIUM HYDROXIDE-MAGNESIUM CARBONATE GEL;ALUMINIUM MAGNESIUM SILICATE;GLUCOSE;GLYCYRRHIZA GLABRA	2 (0.3)	0 (0.0)	2 (0.1)
ALUMINIUM HYDROXIDE;APRONAL;CAFFEINE;IBUPROFEN;PARACETAMOL	2 (0.3)	0 (0.0)	2 (0.1)
ALUMINIUM SILICATE	1 (0.1)	1 (0.1)	2 (0.1)
ALUMINIUM;MAGNESIUM HYDROXIDE;SIMETICONE	2 (0.3)	0 (0.0)	2 (0.1)
AMBROXOL;CARBOCISTEINE;CHLORPHENAMINE;DIHYDROCODEINE;PARACETAMOL;RIBOFLAVIN	2 (0.3)	0 (0.0)	2 (0.1)
AMINOPHYLLINE;CHLORPHENAMINE;METHOXYPHENAMINE;NOSCAPINE	0 (0.0)	2 (0.3)	2 (0.1)
AMMONIA;CAMPHOR;GLYCEROL;GLYCYRRHIZA GLABRA;GUAIFENESIN	0 (0.0)	2 (0.3)	2 (0.1)
AMMONIUM CHLORIDE;DIHYDROCODEINE;EPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
ANEMARRHENA ASPHODELOIDES;CALCIUM SULFATE;GLYCYRRHIZA SPP.;ORYZA SATIVA;PANAX GINSENG	0 (0.0)	2 (0.3)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ANGELICA ACUTILOBA;ATRACTYLODES SPP.;BUPLEURUM FALCATUM;GARDENIA JASMINOIDES;GLYCYRRHIZA SPP.;MENTHA CANADENSIS;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;ZINGIBER OFFICINALE	0 (0.0)	2 (0.3)	2 (0.1)
ANGELICA DAHURICA VAR. FORMOSANA;CITRUS RETICULATA;EPHEDRA SINICA;GLYCYRRHIZA URALENSIS;NEOLITSEA CASSIA;PERILLA FRUTESCENS VAR. CRISPA;PLATYCODON GRANDIFLORUS;PRUNUS ARMENIACA VAR. ARMENIACA;	2 (0.3)	0 (0.0)	2 (0.1)
ANGELICA DAHURICA;BUPLEURUM SPP.;CORYDALIS BUNGEANA;MENTHA CANADENSIS;NEPETA TENUIFOLIA;PERILLA FRUTESCENS;PHRAGMITES AUSTRALIS SUBSP. AUSTRALIS;PLATYCODON GRANDIFLORUS;PRUNUS SPP.;	2 (0.3)	0 (0.0)	2 (0.1)
ANGELICA SINENSIS;ASINI CORII COLLA;ASTRAGALUS MONGHOLICUS;EPIMEDIUM BREVICORNU;LESPEDEZA BUERGERI;SOPHORA FLAVESCENS;ZIZIPHUS JUJUBA	2 (0.3)	0 (0.0)	2 (0.1)
ANISODAMINE	1 (0.1)	1 (0.1)	2 (0.1)
ANTACIDS	2 (0.3)	0 (0.0)	2 (0.1)
ANTIHISTAMINES	1 (0.1)	1 (0.1)	2 (0.1)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	2 (0.3)	0 (0.0)	2 (0.1)
APRONAL;CAFFEINE;IBUPROFEN	0 (0.0)	2 (0.3)	2 (0.1)
APRONAL;CAFFEINE;IBUPROFEN;MAGNESIUM OXIDE	2 (0.3)	0 (0.0)	2 (0.1)
ARDISIA JAPONICA	1 (0.1)	1 (0.1)	2 (0.1)
ARIPIPRAZOLE	2 (0.3)	0 (0.0)	2 (0.1)
ASCORBIC ACID;BIOTIN;CALCIUM;CYANOCOBALAMIN;FIBRE NOS;FOLIC ACID;GLYCINE MAX;IRON;MAGNESIUM CARBONATE;MALTODEXTRIN;NICOTINAMIDE;PANTOTHENIC ACID;POTASSIUM CITRATE;PROTEINS NOS;PYRIDOXINE;RETINOL;	1 (0.1)	1 (0.1)	2 (0.1)
ASCORBIC ACID;HESPERIDIN;RUSCUS ACULEATUS	2 (0.3)	0 (0.0)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ASPARAGUS COCHINCHINENSIS;GLYCYRRHIZA URALENSIS;LONICERA CONFUSA;OPHIOPOGON JAPONICUS;SCROPHULARIA NINGPOENSIS	1 (0.1)	1 (0.1)	2 (0.1)
ASTRAGALUS MONGHOLICUS	2 (0.3)	0 (0.0)	2 (0.1)
ASTRAGALUS MONGHOLICUS;CIBOTIUM BAROMETZ;ECLIPTA PROSTRATA;LIGUSTRUM LUCIDUM;MORUS ALBA;PAEONIA LACTIFLORA;REYNOUTRIA MULTIFLORA	2 (0.3)	0 (0.0)	2 (0.1)
AZELASTINE;FLUTICASONE	1 (0.1)	1 (0.1)	2 (0.1)
AZULENE	1 (0.1)	1 (0.1)	2 (0.1)
BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS	2 (0.3)	0 (0.0)	2 (0.1)
BACITRACIN	2 (0.3)	0 (0.0)	2 (0.1)
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES;HYODEOXYCHOLIC ACID;ISATIS TINCTORIA SUBSP. TINCTORIA;LONICERA JAPONICA	2 (0.3)	0 (0.0)	2 (0.1)
BENZALKONIUM	2 (0.3)	0 (0.0)	2 (0.1)
BERAPROST	1 (0.1)	1 (0.1)	2 (0.1)
BISMUTH	2 (0.3)	0 (0.0)	2 (0.1)
BORIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
BROMAZEPAM	2 (0.3)	0 (0.0)	2 (0.1)
BROMHEXINE;CAFFEINE;CHLORPHENAMINE;DIHYDROCODEINE;IBUPROFEN;METHYLEPHEDRINE;TRANEXAMIC ACID	2 (0.3)	0 (0.0)	2 (0.1)
BROTIZOLAM	0 (0.0)	2 (0.3)	2 (0.1)
BUSPIRONE	1 (0.1)	1 (0.1)	2 (0.1)
BUTAMIRATE	1 (0.1)	1 (0.1)	2 (0.1)
BUTENAFINE	2 (0.3)	0 (0.0)	2 (0.1)
CAFFEINE;CHLORPHENAMINE;DIHYDROCODEINE;METHYLEPHEDRINE	2 (0.3)	0 (0.0)	2 (0.1)
CAFFEINE;CHLORPHENAMINE;PARACETAMOL;SALICYLAMIDE	0 (0.0)	2 (0.3)	2 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 26 of 68
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CALCIUM CARBONATE;MAGNESIUM CARBONATE	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	0 (0.0)	2 (0.3)	2 (0.1)
CALCIUM SULFATE;DRYOPTERIS CRASSIRHIZOMA;EPHEDRA SPP.;FORSYTHIA SUSPENSA;GLYCYRRHIZA GLABRA;HOUTTUYNIA CORDATA;ISATIS TINCTORIA;LONICERA JAPONICA;MENTHOL;POGOSTEMON CABLIN;PRUNUS SPP.;RHEUM SPP.;	2 (0.3)	0 (0.0)	2 (0.1)
CAMPHOR;MENTHOL;SALICYLIC ACID	2 (0.3)	0 (0.0)	2 (0.1)
CANDESARTAN	2 (0.3)	0 (0.0)	2 (0.1)
CANNABIDIOL	0 (0.0)	2 (0.3)	2 (0.1)
CARBAMAZEPINE	0 (0.0)	2 (0.3)	2 (0.1)
CARBIMAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
CARBOHYDRATES NOS;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	2 (0.3)	0 (0.0)	2 (0.1)
CARBOMER;GLYCEROL;PARAFFIN, LIQUID;POLYCARBOPHIL	1 (0.1)	1 (0.1)	2 (0.1)
CARVEDILOL	1 (0.1)	1 (0.1)	2 (0.1)
CELLULASE;ENZYMES NOS;PANCREATIC DIGESTIVE ENZYME TA;PROCTASE;SANACTASE	0 (0.0)	2 (0.3)	2 (0.1)
CETALKONIUM CHLORIDE;SALICYLIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
CETOMACROGOL	1 (0.1)	1 (0.1)	2 (0.1)
CHLOROPYRAMINE	1 (0.1)	1 (0.1)	2 (0.1)
CHLORPHENAMINE;IBUPROFEN;PSEUDOEPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
CHLORPHENAMINE;PARACETAMOL;PSEUDOEPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
CHLORZOXAZONE;PARACETAMOL	0 (0.0)	2 (0.3)	2 (0.1)
CHONDROITIN;GLUCOSAMINE	0 (0.0)	2 (0.3)	2 (0.1)
CHONDRUS CRISPUS;LIDOCAINE;TITANIUM DIOXIDE;ZINC	2 (0.3)	0 (0.0)	2 (0.1)
CHONDRUS CRISPUS;TITANIUM DIOXIDE;ZINC	2 (0.3)	0 (0.0)	2 (0.1)
CITRULLINE	2 (0.3)	0 (0.0)	2 (0.1)

*a According to appropriate comparator by G-BA:
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CITRUS MAXIMA;DELPHINIUM GRANDIFLORUM;GLYCYRRHIZA SPP.;PINELLIA TERNATA;PORIA COCOS;PRUNUS SPP.;SCHISANDRA CHINENSIS;VINCETOXICUM STAUNTONII	0 (0.0)	2 (0.3)	2 (0.1)
CLAVULANIC ACID	2 (0.3)	0 (0.0)	2 (0.1)
CLONIDINE	2 (0.3)	0 (0.0)	2 (0.1)
CLOPERASTINE	1 (0.1)	1 (0.1)	2 (0.1)
CLOXACILLIN	1 (0.1)	1 (0.1)	2 (0.1)
CODEINE;IBUPROFEN	1 (0.1)	1 (0.1)	2 (0.1)
CODEINE;IBUPROFEN;PARACETAMOL	1 (0.1)	1 (0.1)	2 (0.1)
CORTISONE	1 (0.1)	1 (0.1)	2 (0.1)
COW BEZOAR;METRONIDAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
CROTAMITON	2 (0.3)	0 (0.0)	2 (0.1)
CROTAMITON;HYDROCORTISONE	2 (0.3)	0 (0.0)	2 (0.1)
CYANOCOBALAMIN;DICLOFENAC;PYRIDOXINE;THIAMINE	1 (0.1)	1 (0.1)	2 (0.1)
CYCLIZINE	2 (0.3)	0 (0.0)	2 (0.1)
CYPROHEPTADINE	1 (0.1)	1 (0.1)	2 (0.1)
CYSTEINE	1 (0.1)	1 (0.1)	2 (0.1)
DEFLAZACORT	1 (0.1)	1 (0.1)	2 (0.1)
DENOSUMAB	1 (0.1)	1 (0.1)	2 (0.1)
DESFLURANE	1 (0.1)	1 (0.1)	2 (0.1)
DESOXIMETASONE	1 (0.1)	1 (0.1)	2 (0.1)
DESVENLAFAXINE	1 (0.1)	1 (0.1)	2 (0.1)
DEXTROMETHORPHAN;DOXYLAMINE;EPHEDRINE;ETHANOL;PARACETAMOL	0 (0.0)	2 (0.3)	2 (0.1)
DEXTROMETHORPHAN;GUAIFENESIN	1 (0.1)	1 (0.1)	2 (0.1)
DEXTROMETHORPHAN;LYSOZYME;POTASSIUM CRESOLSULFONATE	2 (0.3)	0 (0.0)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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DICYCLOVERINE	2 (0.3)	0 (0.0)	2 (0.1)
DIFLUCORTOLONE	1 (0.1)	1 (0.1)	2 (0.1)
DL- LACTIC ACID;HYALURONIC ACID;SODIUM LACTATE	1 (0.1)	1 (0.1)	2 (0.1)
DOBESILIC ACID	2 (0.3)	0 (0.0)	2 (0.1)
DROPERIDOL	0 (0.0)	2 (0.3)	2 (0.1)
DROTAVERINE	1 (0.1)	1 (0.1)	2 (0.1)
EBASTINE;PSEUDOEPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PRUNUS SPP.	0 (0.0)	2 (0.3)	2 (0.1)
ERIOBOTRYA JAPONICA;FRITILLARIA SPP.;MENTHOL;PLATYCODON GRANDIFLORUS	1 (0.1)	1 (0.1)	2 (0.1)
ESZOPICLONE	0 (0.0)	2 (0.3)	2 (0.1)
ETIZOLAM	1 (0.1)	1 (0.1)	2 (0.1)
ETOFENAMATE	2 (0.3)	0 (0.0)	2 (0.1)
FAROPENEM	2 (0.3)	0 (0.0)	2 (0.1)
FEXOFENADINE;PSEUDOEPHEDRINE	2 (0.3)	0 (0.0)	2 (0.1)
FISH OIL	1 (0.1)	1 (0.1)	2 (0.1)
FLUDROXYCORTIDE	2 (0.3)	0 (0.0)	2 (0.1)
FOLIC ACID;IRON	1 (0.1)	1 (0.1)	2 (0.1)
FORMOTEROL	0 (0.0)	2 (0.3)	2 (0.1)
FROVATRIPTAN	0 (0.0)	2 (0.3)	2 (0.1)
GARDENIA JASMINOIDES;ISATIS TINCTORIA SUBSP. TINCTORIA;PHELLODENDRON CHINENSE;SCAPHIUM AFFINE;SCUTELLARIA BAICALENSIS	1 (0.1)	1 (0.1)	2 (0.1)
GEMIFLOXACIN	1 (0.1)	1 (0.1)	2 (0.1)
GLIMEPIRIDE	1 (0.1)	1 (0.1)	2 (0.1)
GLYCINE;GLYCYRRHIZIC ACID;METHIONINE	2 (0.3)	0 (0.0)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA	2 (0.3)	0 (0.0)	2 (0.1)
GRAMICIDIN;NEOMYCIN;NYSTATIN;TRIAMCINOLONE	1 (0.1)	1 (0.1)	2 (0.1)
HERBAL EXPECTORANTS AND EMOLLIENTS	2 (0.3)	0 (0.0)	2 (0.1)
HYALURONIC ACID;TREHALOSE	2 (0.3)	0 (0.0)	2 (0.1)
HYDRALAZINE	0 (0.0)	2 (0.3)	2 (0.1)
HYDROCORTISONE;MICONAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
HYDROTALCITE	1 (0.1)	1 (0.1)	2 (0.1)
HYDROXYCHLOROQUINE	1 (0.1)	1 (0.1)	2 (0.1)
HYOSCYAMINE	1 (0.1)	1 (0.1)	2 (0.1)
IBUPROFEN;PSEUDOEPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
IMIDAFENACIN	1 (0.1)	1 (0.1)	2 (0.1)
INDAPAMIDE	1 (0.1)	1 (0.1)	2 (0.1)
INSULIN HUMAN	0 (0.0)	2 (0.3)	2 (0.1)
IRBESARTAN	2 (0.3)	0 (0.0)	2 (0.1)
IRON;JUGLANS REGIA;NEOLITSEA CASSIA;PANAX QUINQUEFOLIUS;ZIZIPHUS JUJUBA	1 (0.1)	1 (0.1)	2 (0.1)
ISATIS TINCTORIA SUBSP. TINCTORIA	1 (0.1)	1 (0.1)	2 (0.1)
ISOCONAZOLE	0 (0.0)	2 (0.3)	2 (0.1)
KALLIDINOGENASE	1 (0.1)	1 (0.1)	2 (0.1)
KETAMINE	2 (0.3)	0 (0.0)	2 (0.1)
LACTOBACILLUS ACIDOPHILUS	2 (0.3)	0 (0.0)	2 (0.1)
LACTOBACILLUS NOS	1 (0.1)	1 (0.1)	2 (0.1)
LAFUTIDINE	0 (0.0)	2 (0.3)	2 (0.1)
LASCUFLOXACIN	0 (0.0)	2 (0.3)	2 (0.1)
LEVOBUPIVACAINE	2 (0.3)	0 (0.0)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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LEVOSULPIRIDE	2 (0.3)	0 (0.0)	2 (0.1)
LIMAPROST	1 (0.1)	1 (0.1)	2 (0.1)
LORATADINE;PSEUDOEPHEDRINE	2 (0.3)	0 (0.0)	2 (0.1)
MACROGOL;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	1 (0.1)	1 (0.1)	2 (0.1)
MAGALDRATE	1 (0.1)	1 (0.1)	2 (0.1)
MAGNESIUM CHLORIDE	2 (0.3)	0 (0.0)	2 (0.1)
MAGNESIUM SULFATE	1 (0.1)	1 (0.1)	2 (0.1)
MEBHYDROLIN	1 (0.1)	1 (0.1)	2 (0.1)
MENTHOL	1 (0.1)	1 (0.1)	2 (0.1)
MEPIVACAINE	2 (0.3)	0 (0.0)	2 (0.1)
MEROPENEM	2 (0.3)	0 (0.0)	2 (0.1)
METHOTREXATE	2 (0.3)	0 (0.0)	2 (0.1)
METHYLPHENIDATE	1 (0.1)	1 (0.1)	2 (0.1)
MIRABEGRON	1 (0.1)	1 (0.1)	2 (0.1)
MIZOLASTINE	1 (0.1)	1 (0.1)	2 (0.1)
MONASCUS PURPUREUS	1 (0.1)	1 (0.1)	2 (0.1)
NABUMETONE	0 (0.0)	2 (0.3)	2 (0.1)
NEOMYCIN;NYSTATIN;POLYMYXIN B	0 (0.0)	2 (0.3)	2 (0.1)
NEPIDERMIN	2 (0.3)	0 (0.0)	2 (0.1)
NICERGOLINE	2 (0.3)	0 (0.0)	2 (0.1)
NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0 (0.0)	2 (0.3)	2 (0.1)
NIFEDIPINE	2 (0.3)	0 (0.0)	2 (0.1)
NITROUS OXIDE	1 (0.1)	1 (0.1)	2 (0.1)
NORTRIPTYLINE	0 (0.0)	2 (0.3)	2 (0.1)

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OLANZAPINE	2 (0.3)	0 (0.0)	2 (0.1)
OLEA EUROPAEA	2 (0.3)	0 (0.0)	2 (0.1)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	1 (0.1)	1 (0.1)	2 (0.1)
OPRELVEKIN	2 (0.3)	0 (0.0)	2 (0.1)
ORYZANOL	1 (0.1)	1 (0.1)	2 (0.1)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	2 (0.3)	0 (0.0)	2 (0.1)
OTHER ANALGESICS AND ANTIPYRETICS	1 (0.1)	1 (0.1)	2 (0.1)
OTHER COLD PREPARATIONS	1 (0.1)	1 (0.1)	2 (0.1)
OTHER DRUGS FOR CONSTIPATION	2 (0.3)	0 (0.0)	2 (0.1)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	2 (0.3)	0 (0.0)	2 (0.1)
OTHER UROLOGICALS	1 (0.1)	1 (0.1)	2 (0.1)
OXICONAZOLE	2 (0.3)	0 (0.0)	2 (0.1)
OXYMETAZOLINE	1 (0.1)	1 (0.1)	2 (0.1)
PANCREATIN	2 (0.3)	0 (0.0)	2 (0.1)
PANCREATIN;SIMETICONE;URSODEOXYCHOLIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
PAPAVER SOMNIFERUM;PARACETAMOL	2 (0.3)	0 (0.0)	2 (0.1)
PAPAVERINE	1 (0.1)	1 (0.1)	2 (0.1)
PARACETAMOL;PHENYLEPHRINE	2 (0.3)	0 (0.0)	2 (0.1)
PARACETAMOL;PSEUDOEPHEDRINE	2 (0.3)	0 (0.0)	2 (0.1)
PARAFFIN NOS	1 (0.1)	1 (0.1)	2 (0.1)
PARAFFIN NOS;WOOL FAT	1 (0.1)	1 (0.1)	2 (0.1)
PAROXETINE	2 (0.3)	0 (0.0)	2 (0.1)
PEGFILGRASTIM	1 (0.1)	1 (0.1)	2 (0.1)
PELARGONIUM SIDOIDES	2 (0.3)	0 (0.0)	2 (0.1)

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/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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PENICILLIN NOS	1 (0.1)	1 (0.1)	2 (0.1)
PENTOXYVERINE	2 (0.3)	0 (0.0)	2 (0.1)
PERINDOPRIL	0 (0.0)	2 (0.3)	2 (0.1)
PHENIRAMINE	1 (0.1)	1 (0.1)	2 (0.1)
PINAVERIUM	1 (0.1)	1 (0.1)	2 (0.1)
PINELLIA SPP.	2 (0.3)	0 (0.0)	2 (0.1)
PIPERACILLIN;SULBACTAM	1 (0.1)	1 (0.1)	2 (0.1)
PLATYCODON GRANDIFLORUS	2 (0.3)	0 (0.0)	2 (0.1)
POLYVINYL ALCOHOL;POVIDONE	2 (0.3)	0 (0.0)	2 (0.1)
POTASSIUM;SODIUM CHLORIDE	1 (0.1)	1 (0.1)	2 (0.1)
POVIDONE-IODINE;SUCROSE	1 (0.1)	1 (0.1)	2 (0.1)
PRAVASTATIN	1 (0.1)	1 (0.1)	2 (0.1)
RIFAMYCIN	1 (0.1)	1 (0.1)	2 (0.1)
RUTA GRAVEOLENS	0 (0.0)	2 (0.3)	2 (0.1)
SALICYLIC ACID	0 (0.0)	2 (0.3)	2 (0.1)
SANGUINARIA CANADENSIS	1 (0.1)	1 (0.1)	2 (0.1)
SENNA ALEXANDRINA	1 (0.1)	1 (0.1)	2 (0.1)
SENNA SPP.	0 (0.0)	2 (0.3)	2 (0.1)
SILICON DIOXIDE	1 (0.1)	1 (0.1)	2 (0.1)
SIMVASTATIN	1 (0.1)	1 (0.1)	2 (0.1)
SODIUM BICARBONATE	1 (0.1)	1 (0.1)	2 (0.1)
SODIUM PICOSULFATE	2 (0.3)	0 (0.0)	2 (0.1)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	2 (0.3)	0 (0.0)	2 (0.1)
SOLUTIONS FOR PARENTERAL NUTRITION	1 (0.1)	1 (0.1)	2 (0.1)

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Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
STRYCHNOS IGNATII	0 (0.0)	2 (0.3)	2 (0.1)
SULFUR	1 (0.1)	1 (0.1)	2 (0.1)
SULTAMICILLIN	1 (0.1)	1 (0.1)	2 (0.1)
SUVOREXANT	0 (0.0)	2 (0.3)	2 (0.1)
TARAXACUM SECT. TARAXACUM	2 (0.3)	0 (0.0)	2 (0.1)
TELMISARTAN	1 (0.1)	1 (0.1)	2 (0.1)
THIAMINE	1 (0.1)	1 (0.1)	2 (0.1)
TINZAPARIN	2 (0.3)	0 (0.0)	2 (0.1)
TOCOPHEROL	0 (0.0)	2 (0.3)	2 (0.1)
TOLPERISONE	1 (0.1)	1 (0.1)	2 (0.1)
TOSUFLOXACIN	1 (0.1)	1 (0.1)	2 (0.1)
TOXICODENDRON PUBESCENS	0 (0.0)	2 (0.3)	2 (0.1)
TRETOQUINOL	2 (0.3)	0 (0.0)	2 (0.1)
VACCINIUM MACROCARPON	2 (0.3)	0 (0.0)	2 (0.1)
VERATRUM VIRIDE	0 (0.0)	2 (0.3)	2 (0.1)
VITAMINS [UMBRELLA TERM]	1 (0.1)	1 (0.1)	2 (0.1)
VORTIOXETINE	1 (0.1)	1 (0.1)	2 (0.1)
WARFARIN	1 (0.1)	1 (0.1)	2 (0.1)
ZIPEPROL	1 (0.1)	1 (0.1)	2 (0.1)
(RS)-3 METHYL-2-OXOVALERIANIC ACID CALCIUM;(RS)-3-METHYL-2-OXOBUTYRIC ACID CALCIUM;CALCIUM (RS)-4-METHYL-2-OXOVALERIANAT;DESMENINOL;HISTIDINE;LYSINE;PHENYLPYRUVIC ACID;THREONINE;TRYPTOPHAN;TYROSINE	1 (0.1)	0 (0.0)	1 (0.1)
ACARBOSE	0 (0.0)	1 (0.1)	1 (0.1)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	0 (0.0)	1 (0.1)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ACETYLCYSTEINE;ALANINE;ARGININE;ASCORBIC ACID;ASPARTIC ACID;BIOTIN;CALCIUM CHLORIDE;CYANOCOBALAMIN;FOLIC ACID;GLUCOSE;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;MAGNESIUM SULFATE;	0 (0.0)	1 (0.1)	1 (0.1)
ACETYLCYSTEINE;ASCORBIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
ACETYLSALICYLIC ACID;ALUMINIUM GLYCINATE;MAGNESIUM CARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
ACETYLSALICYLIC ACID;ATORVASTATIN	0 (0.0)	1 (0.1)	1 (0.1)
ACETYLSALICYLIC ACID;CAFFEINE;CODEINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
ACETYLSALICYLIC ACID;CAFFEINE;DEXCHLORPHENIRAMINE;PHENYLEPHRINE	0 (0.0)	1 (0.1)	1 (0.1)
ACETYLSALICYLIC ACID;CHLORPHENAMINE;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.1)
ACHILLEA MILLEFOLIUM;AESCULUS HIPPOCASTANUM;ATROPA BELLA-DONNA;BENZOCAINE;CYTISUS SCOPARIUS;MATRICARIA CHAMOMILLA;POTENTILLA ERECTA	1 (0.1)	0 (0.0)	1 (0.1)
ACHYRANTHES BIDENTATA;CIBOTIUM BAROMETZ;ELEUTHEROCOCCUS NODIFLORUS;EUCOMMIA ULMOIDES;GLYCINE MAX;SAPOSHNIKOVIA DIVARICATA	0 (0.0)	1 (0.1)	1 (0.1)
ACITAZANOLAST	1 (0.1)	0 (0.0)	1 (0.1)
ACONITUM CARMICHAELII;ACONITUM KUSNEZOFFII;ANGELICA BISERRATA;ANGELICA SINENSIS;CONIOSELINUM SPP.;CYATHULA OFFICINALIS;EUCOMMIA ULMOIDES;GASTRODIA ELATA;NOTOPTERYGIUM SPP.;REHMANNIA GLUTINOSA;	0 (0.0)	1 (0.1)	1 (0.1)
ACONITUM SPP.;ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;CORNUS OFFICINALIS;DIOSCOREA SPP.;NEOLITSEA CASSIA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;REHMANNIA GLUTINOSA	1 (0.1)	0 (0.0)	1 (0.1)
ACRIVASTINE;PSEUDOEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.1)
ADENINE;BIFENDATE;CARNITINE;CYANOCOBALAMIN;LIVER;PYRIDOXINE;RIBOFLAVIN	0 (0.0)	1 (0.1)	1 (0.1)
ADENOPHORA SPP.;CITRUS MAXIMA;ERIOBOTRYA JAPONICA;FRITILLARIA SPP.;GLYCYRRHIZA SPP.;MENTHOL;PINELLIA TERNATA;PLATYCODON GRANDIFLORUS;POLYGALA SPP.;PORIA COCOS;PRUNUS SPP.;SCHISANDRA CHINENSIS;	1 (0.1)	0 (0.0)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
AESCULUS HIPPOCASTANUM;DAUCUS CAROTA;HIPPOPHAE RHAMNOIDES;SYZYGIUM AROMATICUM	1 (0.1)	0 (0.0)	1 (0.1)
AESCULUS HIPPOCASTANUM;HAMAMELIS VIRGINIANA;HYDRASTIS CANADENSIS;RUSCUS ACULEATUS;VIBURNUM OPULUS	1 (0.1)	0 (0.0)	1 (0.1)
AKEBIA QUINATA;CENTELLA ASIATICA;LYGODIUM JAPONICUM;ROSA LAEVIGATA;SMILAX CHINA	1 (0.1)	0 (0.0)	1 (0.1)
ALANINE;ARGININE;CYSTEINE;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN;VALINE	1 (0.1)	0 (0.0)	1 (0.1)
ALBENDAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
ALCLOMETASONE	0 (0.0)	1 (0.1)	1 (0.1)
ALDIOXA;ALUMINIUM MAGNESIUM SILICATE	1 (0.1)	0 (0.0)	1 (0.1)
ALENDRONIC ACID;COLECALCIFEROL	1 (0.1)	0 (0.0)	1 (0.1)
ALFENTANIL	1 (0.1)	0 (0.0)	1 (0.1)
ALGINIC ACID;ALUMINIUM HYDROXIDE;MAGNESIUM CARBONATE;SILICON DIOXIDE	0 (0.0)	1 (0.1)	1 (0.1)
ALGINIC ACID;ALUMINIUM HYDROXIDE;SODIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.1)
ALGINIC ACID;CALCIUM CARBONATE;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
ALGINIC ACID;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ANGELICA SINENSIS;ASARUM SPP.;ASTRAGALUS SPP.;CUSCUTA SPP.;DEER HORN;GASTRODIA ELATA;LYCIUM BARBARUM;PANAX GINSENG;REHMANNIA GLUTINOSA;SENNA SPP.	1 (0.1)	0 (0.0)	1 (0.1)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ATRACTYLODES LANCEA;BUPLEURUM FALCATUM;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PANAX GINSENG;PINELLIA TERNATA;POLYPORUS UMBELLATUS;PORIA COCOS;	0 (0.0)	1 (0.1)	1 (0.1)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ATRACTYLODES LANCEA;NEOLITSEA CASSIA;POLYPORUS UMBELLATUS;PORIA COCOS	1 (0.1)	0 (0.0)	1 (0.1)
ALIZAPRIDE	0 (0.0)	1 (0.1)	1 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ALL OTHER THERAPEUTIC PRODUCTS	0 (0.0)	1 (0.1)	1 (0.1)
ALLANTOIN;CETYLPYRIDINIUM;GLYCYRRHIZIC ACID;HINOKITIOL	1 (0.1)	0 (0.0)	1 (0.1)
ALLANTOIN;CHLORHEXIDINE;CHLORPHENAMINE;HYDROCORTISONE;LIDOCAINE;MENTHOL;TETRYZOLINE;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.1)
ALLANTOIN;ENOXOLONE;LIDOCAINE;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.1)
ALMAGATE	1 (0.1)	0 (0.0)	1 (0.1)
ALMASILATE;BIODIASTASE 2000;CALCIUM CARBONATE;GLYCYRRHIZA GLABRA;LIPASE;SCOPOLIA CARNIOLICA;SODIUM CARBONATE ANHYDROUS;TRIMEBUTINE	1 (0.1)	0 (0.0)	1 (0.1)
ALOGLIPTIN;PIOGLITAZONE	0 (0.0)	1 (0.1)	1 (0.1)
ALOIN;BEESWAX;GLYCEROL;LEVOMENOL;PALMITIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
ALPROSTADIL	0 (0.0)	1 (0.1)	1 (0.1)
ALUMINIUM COMPOUNDS	1 (0.1)	0 (0.0)	1 (0.1)
ALUMINIUM MAGNESIUM SILICATE;CINNAMOMUM SPP.;DIASTASE, TAKA;FOENICULUM VULGARE;GLYCYRRHIZA SPP.;HYDROTALCITE;LIPASE;MAGNESIUM HYDROXIDE;MALLOTUS JAPONICUS;MENTHOL;PHELLODENDRON SPP.;SCOPOLIA SPP.;	1 (0.1)	0 (0.0)	1 (0.1)
ALUMINIUM OXIDE	0 (0.0)	1 (0.1)	1 (0.1)
ALUMINIUM POTASSIUM SULFATE;TANNIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
ALVERINE	1 (0.1)	0 (0.0)	1 (0.1)
ALVERINE;SIMETICONE	0 (0.0)	1 (0.1)	1 (0.1)
AMBROXOL ACEFYLLINATE	1 (0.1)	0 (0.0)	1 (0.1)
AMCINONIDE	0 (0.0)	1 (0.1)	1 (0.1)
AMIDOTRIZOIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
AMINO ACIDS NOS;CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;VITAMINS NOS	0 (0.0)	1 (0.1)	1 (0.1)
AMINO ACIDS NOS;ELECTROLYTES NOS;GLUCOSE;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
AMINOCAPROIC ACID;CHLORPHENAMINE;NEOSTIGMINE;POTASSIUM ASPARTATE;TAURINE;TETRYZOLINE	1 (0.1)	0 (0.0)	1 (0.1)
AMINOPHENAZONE	1 (0.1)	0 (0.0)	1 (0.1)
AMINOPHENAZONE;BARBITAL	0 (0.0)	1 (0.1)	1 (0.1)
AMINOPHYLLINE	0 (0.0)	1 (0.1)	1 (0.1)
AMIODARONE	1 (0.1)	0 (0.0)	1 (0.1)
AMLEXANOX	1 (0.1)	0 (0.0)	1 (0.1)
AMLODIPINE;CHLORTALIDONE;TELMISARTAN	0 (0.0)	1 (0.1)	1 (0.1)
AMLODIPINE;INDAPAMIDE;PERINDOPRIL	1 (0.1)	0 (0.0)	1 (0.1)
AMLODIPINE;OLMESARTAN	1 (0.1)	0 (0.0)	1 (0.1)
AMLODIPINE;TELMISARTAN	0 (0.0)	1 (0.1)	1 (0.1)
AMLODIPINE;VALSARTAN	0 (0.0)	1 (0.1)	1 (0.1)
AMMONIUM CHLORIDE;ASTER TATARICUS;CITRUS RETICULATA;CITRUS X AURANTIUM;GLYCYRRHIZA SPP.;KITAGAWIA PRAERUPTORA;MENTHA CANADENSIS;NEPETA TENUIFOLIA;PAPAVER SOMNIFERUM;PLATYCODON GRANDIFLORUS;	0 (0.0)	1 (0.1)	1 (0.1)
AMMONIUM CHLORIDE;CHLORPHENAMINE;DEXTROMETHORPHAN;GUAIFENESIN	1 (0.1)	0 (0.0)	1 (0.1)
AMMONIUM CHLORIDE;DEXTROMETHORPHAN;SODIUM CITRATE	1 (0.1)	0 (0.0)	1 (0.1)
AMMONIUM CHLORIDE;DIPHENHYDRAMINE;SODIUM CITRATE	0 (0.0)	1 (0.1)	1 (0.1)
AMOBARBITAL;ATROPA BELLA-DONNA;DIMETICONE;ERGOTAMINE	1 (0.1)	0 (0.0)	1 (0.1)
AMOROLFINE	1 (0.1)	0 (0.0)	1 (0.1)
AMOXICILLIN;CLOXACILLIN	0 (0.0)	1 (0.1)	1 (0.1)
AMOXICILLIN;SULBACTAM	0 (0.0)	1 (0.1)	1 (0.1)
AMPHOTERICIN B;TETRACYCLINE	1 (0.1)	0 (0.0)	1 (0.1)
AMPICILLIN;CLOXACILLIN	1 (0.1)	0 (0.0)	1 (0.1)
AMYLMETACRESOL;DICHLOROBENZYL ALCOHOL	0 (0.0)	1 (0.1)	1 (0.1)

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AMYLMETACRESOL;DICHLOROBENZYL ALCOHOL;MENTHOL	1 (0.1)	0 (0.0)	1 (0.1)
ANALGESICS	0 (0.0)	1 (0.1)	1 (0.1)
ANDROGRAPHIS PANICULATA	1 (0.1)	0 (0.0)	1 (0.1)
ANDROGRAPHIS PANICULATA;ANGELICA SINENSIS;BERBERIS BEALEI;CODONOPSIS PILOSULA;FLEMINGIA PROSTRATA;ROSA LAEVIGATA;SPATHOLOBUS SUBERECTUS;ZANTHOXYLUM DISSITUM	0 (0.0)	1 (0.1)	1 (0.1)
ANDROGRAPHIS PANICULATA;FORSYTHIA SUSPENSA;ISATIS TINCTORIA SUBSP. TINCTORIA;LONICERA JAPONICA	1 (0.1)	0 (0.0)	1 (0.1)
ANDROGRAPHIS PANICULATA;HELICTERES ANGUSTIFOLIA	0 (0.0)	1 (0.1)	1 (0.1)
ANEMARRHENA ASPHODELOIDES;CONIOSELINUM OFFICINALE;GLYCYRRHIZA SPP.;PORIA COCOS;ZIZIPHUS JUJUBA	0 (0.0)	1 (0.1)	1 (0.1)
ANEMARRHENA ASPHODELOIDES;ISATIS TINCTORIA;LONICERA JAPONICA;LYSIMACHIA CHRISTINAE;RHEUM PALMATUM;SCUTELLARIA BAICALENSIS;STEMONA SESSILIFOLIA	1 (0.1)	0 (0.0)	1 (0.1)
ANESTHETICS, GENERAL	1 (0.1)	0 (0.0)	1 (0.1)
ANETHOLE;BORNEOL;CINEOLE;FENCHONE;PINENE	0 (0.0)	1 (0.1)	1 (0.1)
ANGELICA ACUTILOBA;ASTRAGALUS SPP.;ATRACTYLODES SPP.;CONIOSELINUM OFFICINALE;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PANAX GINSENG;PORIA COCOS;REHMANNIA GLUTINOSA	0 (0.0)	1 (0.1)	1 (0.1)
ANGELICA ACUTILOBA;ATRACTYLODES SPP.;COIX LACRYMA-JOBI VAR. MA-YUEN;EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA	0 (0.0)	1 (0.1)	1 (0.1)
ANGELICA ACUTILOBA;GARDENIA JASMINOIDES;GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA;PORIA COCOS;SCUTELLARIA BAICALENSIS	1 (0.1)	0 (0.0)	1 (0.1)
ANGELICA ARCHANGELICA;CARUM CARVI;CHELIDONIUM MAJUS;GLYCYRRHIZA GLABRA;IBERIS AMARA;MATRICARIA CHAMOMILLA;MELISSA OFFICINALIS;MENTHA X PIPERITA;SILYBUM MARIANUM	1 (0.1)	0 (0.0)	1 (0.1)

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ANGELICA DAHURICA;ASARUM SPP.;ASTRAGALUS MONGHOLICUS;BUPLEURUM SPP.;CLEMATIS SPP.;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';GARDENIA JASMINOIDES;MAGNOLIA SPP.;MENTHA CANADENSIS;PLATYCODON GRANDIFLORUS;	0 (0.0)	1 (0.1)	1 (0.1)
ANGELICA DAHURICA;BUPLEURUM CHINENSE;CORYDALIS BUNGEANA;MENTHA CANADENSIS;PERILLA FRUTESCENS VAR. CRISPA;PHRAGMITES AUSTRALIS SUBSP. AUSTRALIS;PLATYCODON GRANDIFLORUS;PRUNUS ARMENIACA VAR. ARMENIACA;	1 (0.1)	0 (0.0)	1 (0.1)
ANGELICA DAHURICA;CALCIUM SULFATE;CHRYSANTHEMUM X MORIFOLIUM;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';COPTIS CHINENSIS;FORSYTHIA SUSPENSA;GARDENIA JASMINOIDES;GLYCYRRHIZA SPP.;INULA JAPONICA;	0 (0.0)	1 (0.1)	1 (0.1)
ANGELICA DAHURICA;CHRYSANTHEMUM INDICUM;EPHEDRA SPP.;FORSYTHIA SUSPENSA;GLYCYRRHIZA SPP.;LIGUSTICUM SPP.;MAGNOLIA SPP.;MENTHA CANADENSIS;PORIA COCOS;REHMANNIA GLUTINOSA;SALVIA MILTIORRHIZA;	1 (0.1)	0 (0.0)	1 (0.1)
ANGELICA PUBESCENS;BORNEOL;BOSWELLIA SPP.;COPPER;EUPOLYPHAGA SINENSIS;PANAX NOTOGINSENG	0 (0.0)	1 (0.1)	1 (0.1)
ANGELICA SINENSIS;ASARUM SPP.;CONCHA MARGARITIFERA;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';CORYDALIS YANHUSUO;PAEONIA LACTIFLORA;PRUNELLA VULGARIS;REHMANNIA GLUTINOSA;SENNA SPP.;	1 (0.1)	0 (0.0)	1 (0.1)
ANGELICA SINENSIS;BORNEOL;CAMPHOR;CARTHAMUS TINCTORIUS;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';KAEMPFERIA GALANGA;MENTHOL;NEOLITSEA CASSIA;PIPER LONGUM;PIPER NIGRUM;RHEUM PALMATUM;SYZYGIUM AROMATICUM;	1 (0.1)	0 (0.0)	1 (0.1)
ANIMAL FECES NOS;BOMBYX MORI	1 (0.1)	0 (0.0)	1 (0.1)
ANTACIDS WITH ANTIFLATULENTS	1 (0.1)	0 (0.0)	1 (0.1)
ANTACIDS WITH ANTISPASMODICS	1 (0.1)	0 (0.0)	1 (0.1)
ANTACIDS, OTHER COMBINATIONS	0 (0.0)	1 (0.1)	1 (0.1)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (0.1)	0 (0.0)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ANTIFUNGALS FOR TOPICAL USE	1 (0.1)	0 (0.0)	1 (0.1)
ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS	0 (0.0)	1 (0.1)	1 (0.1)
ANTIPYRETICS, ANALGESICS AND ANTI-INFLAMMATORY AGENTS	1 (0.1)	0 (0.0)	1 (0.1)
APRONAL;CAFFEINE;PARACETAMOL;PROPYPHENAZONE	1 (0.1)	0 (0.0)	1 (0.1)
ARALIA CORDATA;ARCTIUM LAPPA;CALCIUM SULFATE;FORSYTHIA SPP.;GLYCYRRHIZA SPP.;NEPETA TENUIFOLIA;NOTOPTERYGIUM SPP.;PLATYCODON GRANDIFLORUS;SAPOSHNIKOVIA DIVARICATA	0 (0.0)	1 (0.1)	1 (0.1)
ARECA CATECHU;ATRACTYLODES LANCEA;CITRUS RETICULATA;CITRUS X AURANTIUM;CYPERUS ROTUNDUS;DOLOMIAEA COSTUS;GLYCYRRHIZA SPP.;MAGNOLIA OFFICINALIS;WURFBAINIA SPP.;ZINGIBER OFFICINALE	0 (0.0)	1 (0.1)	1 (0.1)
ARGININE GLUTAMATE	0 (0.0)	1 (0.1)	1 (0.1)
ARGININE;BETAINE	0 (0.0)	1 (0.1)	1 (0.1)
ARGININE;CYSTEINE;PYRIDOXINE;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
ARTEMISIA SPP.;BUPLEURUM SPP.;ISATIS TINCTORIA SUBSP. TINCTORIA;SCHISANDRA CHINENSIS;SWINE BILE;VIGNA RADIATA	1 (0.1)	0 (0.0)	1 (0.1)
ASARUM SPP.;EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PINELLIA TERNATA;SCHISANDRA CHINENSIS;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID (VITAMIN C), COMBINATIONS	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;BIOTIN;CALCIUM;CARBOHYDRATES	0 (0.0)	1 (0.1)	1 (0.1)
NOS;CHLORIDE;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FATS NOS;FOLIC ACID;IRON;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;PHOSPHORUS;POTASSIUM;			
ASCORBIC ACID;BIOTIN;CALCIUM;CARBOHYDRATES NOS;CHLORINE;CHOLINE;CHROMIUM;COPPER;FATS NOS;FOLIC ACID;FRUCTOOLIGOSACCHARIDES;IRON;LEVOCARNITINE;MAGNESIUM;MANGANESE;MOLYBDENUM;NICOTINIC ACID;	0 (0.0)	1 (0.1)	1 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1 /t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE;TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;CAFFEINE;CHLORPHENAMINE;DIHYDROCODEINE;IBUPROFEN;METHYLEPHEDRINE;THIAMINE	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;CODEINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;DIOSMIN;HESPERIDIN	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;DL-ALPHA TOCOPHEROL;FOLIC ACID;IRON;VITAMIN B12 NOS	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;FOLIC ACID;IRON;PROTEASE NOS	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;FOLIC ACID;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE;VITAMIN B12 NOS;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;PANTOTHENIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
ASPERGILLUS ORYZAE ENZYME;PANCREATIN	0 (0.0)	1 (0.1)	1 (0.1)
ASTER AGERATOIDES;FIRMIANA SIMPLEX;KITAGAWIA PRAERUPTORA;METAGENTIANA RHODANTHA;SCLEROMITRION DIFFUSUM;SCUTELLARIA BAICALENSIS;STEMONA SESSILIFOLIA	0 (0.0)	1 (0.1)	1 (0.1)
ASTER TATARICUS;CITRUS X AURANTIUM;EPHEDRA SPP.;FAGOPYRUM CYMOSUM;GLYCYRRHIZA SPP.;HOUTTUYNIA CORDATA;ILEX CHINENSIS;KITAGAWIA PRAERUPTORA	0 (0.0)	1 (0.1)	1 (0.1)
ASTRAGALUS MONGHOLICUS;ATRACTYLODES SPP.;BOSWELLIA SPP.;CARTHAMUS TINCTORIUS;CLEMATIS CHINENSIS;CODONOPSIS SPP.;COMMIPHORA MYRRHA;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';DOLOMITE;EUPOLYPHAGA SINENSIS;	1 (0.1)	0 (0.0)	1 (0.1)
ASTRAGALUS SPP.;ATRACTYLODES MACROCEPHALA;MORUS ALBA;PAEONIA LACTIFLORA;PLANTAGO SPP.;PORIA COCOS;REYNOUTRIA MULTIFLORA;RHEUM SPP.;SALVIA MILTIORRHIZA;SOPHORA FLAVESCENS	1 (0.1)	0 (0.0)	1 (0.1)
ATOMOXETINE	0 (0.0)	1 (0.1)	1 (0.1)
ATRACTYLODES MACROCEPHALA	1 (0.1)	0 (0.0)	1 (0.1)
ATROPA BELLA-DONNA;ERGOTAMINE;PHENOBARBITAL	1 (0.1)	0 (0.0)	1 (0.1)
ATROPA BELLA-DONNA;METAMIZOLE;PAPAVERINE	1 (0.1)	0 (0.0)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 42 of 68
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
AZELAIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
AZILSARTAN	1 (0.1)	0 (0.0)	1 (0.1)
BACILLUS COAGULANS;NICOTINAMIDE;PLANTAGO OVATA;SENNOSIDE A+B	0 (0.0)	1 (0.1)	1 (0.1)
BACILLUS COAGULANS;SIMETICONE	1 (0.1)	0 (0.0)	1 (0.1)
BACILLUS LICHENFORMIS	1 (0.1)	0 (0.0)	1 (0.1)
BACILLUS SUBTILIS;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	1 (0.1)	0 (0.0)	1 (0.1)
BACILLUS SUBTILIS;ENTEROCOCCUS FAECIUM	1 (0.1)	0 (0.0)	1 (0.1)
BACITRACIN;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
BAICALIN;BORNEOL;EPHEDRINE;LONICERA JAPONICA;MAGNOLIA SPP.	0 (0.0)	1 (0.1)	1 (0.1)
BAMBUSA SPP.;BUPLEURUM FALCATUM;CITRUS RETICULATA;CITRUS SPP.;COPTIS SPP.;CYPERUS ROTUNDUS;GLYCYRRHIZA SPP.;OPHIOPOGON JAPONICUS;PANAX GINSENG;PINELLIA TERNATA;PLATYCODON GRANDIFLORUS;PORIA COCOS;	1 (0.1)	0 (0.0)	1 (0.1)
BAMBUTEROL	1 (0.1)	0 (0.0)	1 (0.1)
BECLOMETASONE;CLOTRIMAZOLE;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
BEMIPARIN	0 (0.0)	1 (0.1)	1 (0.1)
BENAZEPRIL	1 (0.1)	0 (0.0)	1 (0.1)
BENDROFLUMETHIAZIDE;POTASSIUM	1 (0.1)	0 (0.0)	1 (0.1)
BENIDIPINE	0 (0.0)	1 (0.1)	1 (0.1)
BENZALKONIUM;BORIC ACID;POTASSIUM;SODIUM CHLORIDE;SODIUM PHOSPHATE	0 (0.0)	1 (0.1)	1 (0.1)
BENZETHONIUM;LIDOCAINE	0 (0.0)	1 (0.1)	1 (0.1)
BENZOCAINE	1 (0.1)	0 (0.0)	1 (0.1)
BENZOIC ACID;OXOMEMAZINE;SULFOGAIACOL	1 (0.1)	0 (0.0)	1 (0.1)
BERBERINE;BISMUTH;SCOPOLIA SPP.;URSODEOXYCHOLIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
BERBERINE;GERANIUM THUNBERGII	0 (0.0)	1 (0.1)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
BETAMETHASONE;CALCIPOTRIOL	1 (0.1)	0 (0.0)	1 (0.1)
BETAMETHASONE;CHLORPHENAMINE	0 (0.0)	1 (0.1)	1 (0.1)
BETAMETHASONE;CLIOQUINOL;GENTAMICIN;TOLNAFTATE	0 (0.0)	1 (0.1)	1 (0.1)
BETAMETHASONE;CLOTRIMAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
BETAMETHASONE;CLOTRIMAZOLE;GENTAMICIN	1 (0.1)	0 (0.0)	1 (0.1)
BETAMETHASONE;LIDOCAINE	0 (0.0)	1 (0.1)	1 (0.1)
BETAMETHASONE;LORATADINE	1 (0.1)	0 (0.0)	1 (0.1)
BETAMETHASONE;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
BETAMETHASONE;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
BIFENDATE	1 (0.1)	0 (0.0)	1 (0.1)
BIFIDOBACTERIUM BIFIDUM	1 (0.1)	0 (0.0)	1 (0.1)
BIFIDOBACTERIUM BIFIDUM;LACTIPLANTIBACILLUS PLANTARUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BREVIS;LACTOBACILLUS HELVETICUS;LACTOBACILLUS SALIVARIUS	0 (0.0)	1 (0.1)	1 (0.1)
BIFIDOBACTERIUM BIFIDUM;LACTOBACILLUS ACIDOPHILUS	0 (0.0)	1 (0.1)	1 (0.1)
BIFIDOBACTERIUM INFANTIS;BIFIDOBACTERIUM LONGUM	1 (0.1)	0 (0.0)	1 (0.1)
BIFIDOBACTERIUM LACTIS	0 (0.0)	1 (0.1)	1 (0.1)
BIFIDOBACTERIUM LONGUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	1 (0.1)	0 (0.0)	1 (0.1)
BIMATOPROST	0 (0.0)	1 (0.1)	1 (0.1)
BIODIASTASE 1000;CELLULASE;LIPASE;PANCREATIN;PANPROSIN;SIMETICONE;URSODEOXYCHOLIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
BIOTIN;BROMELAINS;LECITHIN;PAPAIN;SELENIUM	1 (0.1)	0 (0.0)	1 (0.1)
BIPERIDEN	1 (0.1)	0 (0.0)	1 (0.1)
BISACODYL;DOCUSATE;SENNOSIDE A+B	0 (0.0)	1 (0.1)	1 (0.1)
BISMUTH;CALCIUM CARBONATE;MAGNESIUM CARBONATE;SODIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.1)
BISMUTH;METRONIDAZOLE;TETRACYCLINE	0 (0.0)	1 (0.1)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
BISMUTH;MYROXYLON BALSAMUM;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
BLOOD AND RELATED PRODUCTS	1 (0.1)	0 (0.0)	1 (0.1)
BLOOD, CALF, DEPROT., LMW PORTION	1 (0.1)	0 (0.0)	1 (0.1)
BORIC ACID;EPHEDRINE;MAFENIDE;TAURINE;ZINC	0 (0.0)	1 (0.1)	1 (0.1)
BORON	1 (0.1)	0 (0.0)	1 (0.1)
BORON;CARTILAGE;HYALURONIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
BOVINE BASIC FIBROBLAST GROWTH FACTOR	1 (0.1)	0 (0.0)	1 (0.1)
BROMAZEPAM;PROPANTHELINE	1 (0.1)	0 (0.0)	1 (0.1)
BROMELAINS;DIMETICONE;PANCREATIN	0 (0.0)	1 (0.1)	1 (0.1)
BROMELAINS;TRYPSIN	1 (0.1)	0 (0.0)	1 (0.1)
BROMHEXINE;CAFFEINE;CARBINOXAMINE;DIHYDROCODEINE;LYSOZYME;METHYLEPHEDRINE;NOSCAPINE;PARACETAMOL;RIBOFLAVIN;SULBUTIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
BROMHEXINE;CAFFEINE;CARBINOXAMINE;DIHYDROCODEINE;METHYLEPHEDRINE;PARACETAMOL;RIBOFLAVIN;SULBUTIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
BROMHEXINE;CAFFEINE;DIHYDROCODEINE;DIPHENYLPYRALINE;L-CARBOCISTEINE;METHYLEPHEDRINE;NOSCAPINE;PARACETAMOL;RIBOFLAVIN	1 (0.1)	0 (0.0)	1 (0.1)
BROMHEXINE;CLEMASTINE;DIHYDROCODEINE;IBUPROFEN;METHYLEPHEDRINE;RIBOFLAVIN;THIAMINE;TRANEXAMIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
BROMHEXINE;GUAIFENESIN;MENTHOL;TERBUTALINE	1 (0.1)	0 (0.0)	1 (0.1)
BROMINE	1 (0.1)	0 (0.0)	1 (0.1)
BROMISOVAL;CAFFEINE;ETHENZAMIDE;IBUPROFEN	1 (0.1)	0 (0.0)	1 (0.1)
BROMISOVAL;CAFFEINE;ETHENZAMIDE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
BROMPHENIRAMINE;PHENYLEPHRINE	0 (0.0)	1 (0.1)	1 (0.1)
BUPIVACAINE;EPINEPHRINE	1 (0.1)	0 (0.0)	1 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
BUPROPION	0 (0.0)	1 (0.1)	1 (0.1)
BUTOCONAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
BUTYLSCOPOLAMINE;MEDAZEPAM	1 (0.1)	0 (0.0)	1 (0.1)
CABERGOLINE	0 (0.0)	1 (0.1)	1 (0.1)
CAFFEINE	1 (0.1)	0 (0.0)	1 (0.1)
CAFFEINE;CETIRIZINE;PARACETAMOL;PHENYLEPHRINE	0 (0.0)	1 (0.1)	1 (0.1)
CAFFEINE;CHLORPHENAMINE;CHRYSANTHEMUM INDICUM;CITRUS MEDICA;ILEX ASPRELLA;LONICERA JAPONICA;MELICOPE PTELEIFOLIA;PARACETAMOL;STROBILANTHES CUSIA	1 (0.1)	0 (0.0)	1 (0.1)
CAFFEINE;CHLORPHENAMINE;DIHYDROCODEINE;HESPERIDIN;ISOPROPAMIDE;METHYLEPHEDRINE;PARACETAMOL;TRANEXAMIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
CAFFEINE;CHLORPHENAMINE;PARACETAMOL;PHENYLEPHRINE;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
CAFFEINE;CHLORPHENAMINE;PARACETAMOL;PSEUDOEPHEDRINE	0 (0.0)	1 (0.1)	1 (0.1)
CAFFEINE;CHLORZOXAZONE;PARACETAMOL;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
CAFFEINE;CODEINE;DOXYLAMINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
CAFFEINE;CYCLOBENZAPRINE	0 (0.0)	1 (0.1)	1 (0.1)
CAFFEINE;DEXCHLORPHENIRAMINE;DIHYDROCODEINE;IBUPROFEN;L-CARBOCISTEINE;PSEUDOEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.1)
CAFFEINE;DIHYDROERGOTAMINE;METOCLOPRAMIDE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
CAFFEINE;EPHEDRINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
CAFFEINE;GLYCYRRHIZA SPP.;METHYLEPHEDRINE;NEOLITSEA CASSIA;PARACETAMOL;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.1)
CAFFEINE;PAPAVER SOMNIFERUM;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
CAFFEINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
CAFFEINE;PARACETAMOL;PROPYPHENAZONE	1 (0.1)	0 (0.0)	1 (0.1)
CALAMINE	1 (0.1)	0 (0.0)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 46 of 68
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CALAMINE;GLYCEROL;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
CALCIFEDIOL	1 (0.1)	0 (0.0)	1 (0.1)
CALCIPOTRIOL	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM CARBONATE;CALCIUM PHOSPHATE;CHLOROPHYLLIN COPPER COMPLEX;MAGNESIUM HYDROXIDE;SCOPOLIA JAPONICA	0 (0.0)	1 (0.1)	1 (0.1)
CALCIUM CARBONATE;CINNAMOMUM VERUM;COPTIS TRIFOLIA;DIASTASE, TAKA;FOENICULUM VULGARE;GLYCYRRHIZA GLABRA;MENTHOL;SIMALDRATE;SODIUM BICARBONATE;SYZYGIUM AROMATICUM;ZANTHOXYLUM AMERICANUM;	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM CARBONATE;MAGNESIUM CARBONATE;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM CARBONATE;MAGNESIUM HYDROXIDE	0 (0.0)	1 (0.1)	1 (0.1)
CALCIUM CARBONATE;VITAMIN D NOS	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM CHLORIDE;GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM CHLORIDE;MALTOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM GLUCONATE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	0 (0.0)	1 (0.1)	1 (0.1)
CALCIUM SULFATE;CHRYSANTHEMUM X MORIFOLIUM;EPHEDRA SPP.;GLYCYRRHIZA SPP.;KITAGAWIA PRAERUPTORA;LONICERA JAPONICA;MENTHA CANADENSIS;MORUS ALBA;PERILLA FRUTESCENS;PLATYCODON GRANDIFLORUS;PRUNUS SPP.;	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM SULFATE;EPHEDRA SPP.;GLYCYRRHIZA SPP.;PRUNUS SPP.	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM;COLECALCIFEROL;MAGNESIUM;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM;COLECALCIFEROL;MENAQUINONE	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM;VITAMIN D NOS	1 (0.1)	0 (0.0)	1 (0.1)
CALENDULA OFFICINALIS;HYPERICUM PERFORATUM;LAVANDULA ANGUSTIFOLIA;PINUS SIBIRICA;SYMPHYTUM OFFICINALE	1 (0.1)	0 (0.0)	1 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CAMOSTAT	1 (0.1)	0 (0.0)	1 (0.1)
CAMPHOR;CHLORPHENAMINE;HEXACHLOROPHENE;LIDOCAINE;MENTHOL;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
CAMPHOR;CHLORPHENAMINE;LIDOCAINE;MENTHOL;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
CAMPHOR;DIPHENHYDRAMINE;ENOXOLONE;MENTHOL;THYMOL	1 (0.1)	0 (0.0)	1 (0.1)
CAMPHOR;DIPHENHYDRAMINE;LIDOCAINE;TOCOPHEROL;UREA	1 (0.1)	0 (0.0)	1 (0.1)
CAMPHOR;MENTHA X PIPERITA;MENTHOL;NONIVAMIDE;SALICYLIC ACID;THYMOL	0 (0.0)	1 (0.1)	1 (0.1)
CAMPHOR;MENTHOL	1 (0.1)	0 (0.0)	1 (0.1)
CAMPHOR;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
CANNABIS SATIVA	1 (0.1)	0 (0.0)	1 (0.1)
CANRENOIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
CAPSAICIN	1 (0.1)	0 (0.0)	1 (0.1)
CARBINOXAMINE	1 (0.1)	0 (0.0)	1 (0.1)
CARMELLOSE;HYPROMELLOSE	0 (0.0)	1 (0.1)	1 (0.1)
CEFBUPERAZONE	1 (0.1)	0 (0.0)	1 (0.1)
CEFEPIME	1 (0.1)	0 (0.0)	1 (0.1)
CEFETAMET	0 (0.0)	1 (0.1)	1 (0.1)
CEFOPERAZONE;SULBACTAM	0 (0.0)	1 (0.1)	1 (0.1)
CEFOTAXIME	1 (0.1)	0 (0.0)	1 (0.1)
CEFOTIAM	0 (0.0)	1 (0.1)	1 (0.1)
CEFOXITIN	1 (0.1)	0 (0.0)	1 (0.1)
CEFROXADINE	1 (0.1)	0 (0.0)	1 (0.1)
CEFTAROLINE FOSAMIL	1 (0.1)	0 (0.0)	1 (0.1)
CEFTRIAXONE;SULBACTAM	1 (0.1)	0 (0.0)	1 (0.1)
CELLULASE;DIASTASE;PANCREATIN;PANCRELIPASE;PAPAIN;PEPSIN;URSODEOXYCHOLIC ACID	1 (0.1)	0 (0.0)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CELLULASE;DIMETICONE;OX BILE EXTRACT;PANCREATIN	0 (0.0)	1 (0.1)	1 (0.1)
CENTAURIUM ERYTHRAEA	0 (0.0)	1 (0.1)	1 (0.1)
CENTELLA ASIATICA;HYDROCORTISONE;NEOMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
CEPHAELIS SPP.;CINCHONA PUBESCENS;COCHINEAL;COPPER;DROSERA ROTUNDIFOLIA;HEDERA HELIX;HYOSCYAMUS NIGER	1 (0.1)	0 (0.0)	1 (0.1)
CEPHALOSPORIN NOS	1 (0.1)	0 (0.0)	1 (0.1)
CERAMIDE;COCOS NUCIFERA;GLYCEROL;N-CAPRIC ACID;OCTANOIC ACID;OLEA EUROPAEA;SQUALANE;VITELLARIA PARADOXA SUBSP. PARADOXA	0 (0.0)	1 (0.1)	1 (0.1)
CETRARIA ISLANDICA;MENTHA X PIPERITA	0 (0.0)	1 (0.1)	1 (0.1)
CETYLPYRIDINIUM	1 (0.1)	0 (0.0)	1 (0.1)
CETYLPYRIDINIUM;PHOLCODINE	0 (0.0)	1 (0.1)	1 (0.1)
CHARCOAL, ACTIVATED	1 (0.1)	0 (0.0)	1 (0.1)
CHLORDIAZEPOXIDE	1 (0.1)	0 (0.0)	1 (0.1)
CHLORDIAZEPOXIDE;DICYCLOVERINE;HYOSCINE	0 (0.0)	1 (0.1)	1 (0.1)
CHLORHEXIDINE;NEOMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
CHLORINATED SODA SOLUTION	0 (0.0)	1 (0.1)	1 (0.1)
CHLOROCARVACROL;ICHTHAMMOL;MENTHOL	1 (0.1)	0 (0.0)	1 (0.1)
CHLOROFORM;CODEINE;DRIMIA MARITIMA	0 (0.0)	1 (0.1)	1 (0.1)
CHLOROPHYLLIN COPPER COMPLEX	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;CROMOGLICIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;DICLOFENAC;MAGNESIUM TRISILICATE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;GLYCYRRHIZIC ACID;SULFAMETHOXAZOLE;TAURINE	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;GUAIFENESIN;METHYLEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;IBUPROFEN	0 (0.0)	1 (0.1)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CHLORPHENAMINE;LEVODROPROPIZINE	0 (0.0)	1 (0.1)	1 (0.1)
CHLORPHENAMINE;LYSOZYME;PYRIDOXINE;RETINOL;TETRYZOLINE;VITAMIN E NOS	0 (0.0)	1 (0.1)	1 (0.1)
CHLORPHENAMINE;MENISPERMUM DAURICUM;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;NAPHAZOLINE;VITAMIN B12 NOS	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;NEOSTIGMINE;PYRIDOXINE;TAURINE;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;OXOLAMINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
CHLORPHENAMINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
CHLORPHENAMINE;PHENYLEPHRINE	0 (0.0)	1 (0.1)	1 (0.1)
CHLORTALIDONE	0 (0.0)	1 (0.1)	1 (0.1)
CHOLINE ALFOSCERATE	0 (0.0)	1 (0.1)	1 (0.1)
CHONDROITIN	0 (0.0)	1 (0.1)	1 (0.1)
CHONDROITIN;HYALURONIC ACID;POLOXAMER 407	1 (0.1)	0 (0.0)	1 (0.1)
CHRYSANTHEMUM INDICUM;ILEX ASPRELLA;ISATIS TINCTORIA;LONICERA JAPONICA;MELICOPE PTELEIFOLIA;VITEX NEGUNDO	0 (0.0)	1 (0.1)	1 (0.1)
CHRYSANTHEMUM INDICUM;MORUS ALBA;PRUNELLA VULGARIS	1 (0.1)	0 (0.0)	1 (0.1)
CHRYSANTHEMUM X MORIFOLIUM;FORSYTHIA SUSPENSA;GLYCYRRHIZA URALENSIS;MENTHA CANADENSIS;MORUS ALBA;PHRAGMITES AUSTRALIS SUBSP. AUSTRALIS;PLATYCODON GRANDIFLORUS;PRUNUS ARMENIACA	1 (0.1)	0 (0.0)	1 (0.1)
CICADA SLOUGH;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';FORSYTHIA SUSPENSA;FRITILLARIA THUNBERGII;GLYCYRRHIZA SPP.;MENTHA CANADENSIS;MENTHOL;PLATYCODON GRANDIFLORUS;RHEUM SPP.;SENEGALIA CATECHU;	0 (0.0)	1 (0.1)	1 (0.1)
CILASTATIN;IMIPENEM	1 (0.1)	0 (0.0)	1 (0.1)
CINCHOCAINE;CLEMIZOLE;FLUOCORTOLONE	1 (0.1)	0 (0.0)	1 (0.1)
CINCHOCAINE;ESCULOSIDE;HYDROCORTISONE;NEOMYCIN	0 (0.0)	1 (0.1)	1 (0.1)

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/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 50 of 68
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CINCHOCAINE;FRAMYCETIN;HYDROCORTISONE	1 (0.1)	0 (0.0)	1 (0.1)
CINCHOCAINE;MENTHOL;PREDNISOLONE;RUSCOGENIN;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
CINCHOCAINE;PREDNISOLONE	1 (0.1)	0 (0.0)	1 (0.1)
CINNARIZINE;DIMENHYDRINATE	1 (0.1)	0 (0.0)	1 (0.1)
CIPROFLOXACIN;PHENAZOPYRIDINE	1 (0.1)	0 (0.0)	1 (0.1)
CIPROFLOXACIN;TINIDAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
CISATRACURIUM	0 (0.0)	1 (0.1)	1 (0.1)
CITRIC ACID;POTASSIUM CITRATE	0 (0.0)	1 (0.1)	1 (0.1)
CITRUS RETICULATA;CRATAEGUS PINNATIFIDA;DIOSCOREA POLYSTACHYA;HORDEUM VULGARE;PSEUDOSTELLARIA HETEROPHYLLA	1 (0.1)	0 (0.0)	1 (0.1)
CITRUS RETICULATA;CREOSOTE;GLYCYRRHIZA SPP.;PHELLODENDRON SPP.;UNCARIA GAMBIR	0 (0.0)	1 (0.1)	1 (0.1)
CITRUS SPP.;GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA;PLATYCODON GRANDIFLORUS;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	1 (0.1)	0 (0.0)	1 (0.1)
CLEBOPRIDE;SIMETICONE	1 (0.1)	0 (0.0)	1 (0.1)
CLEMASTINE	1 (0.1)	0 (0.0)	1 (0.1)
CLEMATIS SPP.;PRUNELLA VULGARIS;TRICHOSANTHES KIRILOWII	1 (0.1)	0 (0.0)	1 (0.1)
CLENBUTEROL	0 (0.0)	1 (0.1)	1 (0.1)
CLOBETASONE	1 (0.1)	0 (0.0)	1 (0.1)
CLOMIPRAMINE	1 (0.1)	0 (0.0)	1 (0.1)
CLOPIDOGREL	1 (0.1)	0 (0.0)	1 (0.1)
CODEINE;DOXYLAMINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
CODEINE;PARACETAMOL;PSEUDOEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.1)
CODEINE;PHENYLTOLOXAMINE	1 (0.1)	0 (0.0)	1 (0.1)
CODEINE;SULFOGAIACOL	0 (0.0)	1 (0.1)	1 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 51 of 68
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CODONOPSIS PILOSULA	1 (0.1)	0 (0.0)	1 (0.1)
COIX LACRYMA-JOBI VAR. MA-YUEN;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;PRUNUS SPP.	0 (0.0)	1 (0.1)	1 (0.1)
COLECALCIFEROL;MENAQUINONE-7	0 (0.0)	1 (0.1)	1 (0.1)
COLECALCIFEROL;RISEDRONIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
COLESTYRAMINE;DICLOFENAC	1 (0.1)	0 (0.0)	1 (0.1)
COLISTIN	1 (0.1)	0 (0.0)	1 (0.1)
COLLAGEN	0 (0.0)	1 (0.1)	1 (0.1)
COLLAGEN-HYDROXYAPATIT-COMPLEX	0 (0.0)	1 (0.1)	1 (0.1)
COPPER;CYANOCOBALAMIN;FOLIC ACID;IRON;PYRIDOXINE;SELENIUM;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
COPPER;SUCRALFATE;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
COPTIS CHINENSIS	1 (0.1)	0 (0.0)	1 (0.1)
COPTIS SPP.;GARDENIA JASMINOIDES;PHELLODENDRON SPP.;SCUTELLARIA BAICALENSIS	0 (0.0)	1 (0.1)	1 (0.1)
COPTIS SPP.;GLYCYRRHIZA SPP.;PANAX GINSENG;PINELLIA TERNATA;SCUTELLARIA BAICALENSIS;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	1 (0.1)	0 (0.0)	1 (0.1)
CORIANDRUM SATIVUM;FOENICULUM VULGARE;SENNA SPP.;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.1)
CORTICOSTEROIDS	0 (0.0)	1 (0.1)	1 (0.1)
CORTICOSTEROIDS FOR SYSTEMIC USE, COMBINATIONS	0 (0.0)	1 (0.1)	1 (0.1)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	1 (0.1)	0 (0.0)	1 (0.1)
CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTIBIOTICS	1 (0.1)	0 (0.0)	1 (0.1)
CORTICOSTEROIDS, WEAK, OTHER COMBINATIONS	1 (0.1)	0 (0.0)	1 (0.1)
CORYDALIS BUNGEANA;ISATIS TINCTORIA SUBSP. TINCTORIA;SCUTELLARIA BAICALENSIS;TARAXACUM SPP.	1 (0.1)	0 (0.0)	1 (0.1)
COUGH AND COLD PREPARATIONS	0 (0.0)	1 (0.1)	1 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
COUMARIN;TROXERUTIN	1 (0.1)	0 (0.0)	1 (0.1)
COVID-19 VACCINE	1 (0.1)	0 (0.0)	1 (0.1)
CRATAEGUS LAEVIGATA;GINKGO BILOBA;VISCUM ALBUM	1 (0.1)	0 (0.0)	1 (0.1)
CROMOGLICIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
CURCUMIN	0 (0.0)	1 (0.1)	1 (0.1)
CURCUMIN;LECITHIN;MANGIFERA INDICA;PIPER NIGRUM;PYRIDOXINE;RESVERATROL;RIBOFLAVIN	0 (0.0)	1 (0.1)	1 (0.1)
CYANOCOBALAMIN;DEXAMETHASONE;PARACETAMOL;PYRIDOXINE;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
CYANOCOBALAMIN;NICOTINAMIDE;PHOSPHOLIPIDS;PYRIDOXINE;RIBOFLAVIN;THIAMINE;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.1)
DANAPAROID	0 (0.0)	1 (0.1)	1 (0.1)
DAPAGLIFLOZIN	1 (0.1)	0 (0.0)	1 (0.1)
DAPTOMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
DEHYDROANDROGRAPHOLIDE	1 (0.1)	0 (0.0)	1 (0.1)
DEHYDROCHOLIC ACID;DIASTASE;MOLSIN;OX BILE EXTRACT;PANCREATIN;POLYPASE	0 (0.0)	1 (0.1)	1 (0.1)
DEMANNOSE;VACCINIUM MACROCARPON	1 (0.1)	0 (0.0)	1 (0.1)
DESLORATADINE;MONTELUKAST	1 (0.1)	0 (0.0)	1 (0.1)
DESLORATADINE;PSEUDOEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.1)
DESOXIMETASONE;NEOMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
DEXAMETHASONE;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
DEXAMETHASONE;NEOMYCIN;NYSTATIN;TYROTHRICIN	0 (0.0)	1 (0.1)	1 (0.1)
DEXAMETHASONE;OXYTETRACYCLINE	1 (0.1)	0 (0.0)	1 (0.1)
DEXPANTHENOL;XYLOMETAZOLINE	0 (0.0)	1 (0.1)	1 (0.1)
DEXTRAN	0 (0.0)	1 (0.1)	1 (0.1)
DEXTRAN SULFATE	1 (0.1)	0 (0.0)	1 (0.1)
DEXTROMETHORPHAN;EPHEDRINE;PROMETHAZINE	1 (0.1)	0 (0.0)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE	0 (0.0)	1 (0.1)	1 (0.1)
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.1)
DEXTROMETHORPHAN;PARACETAMOL;PROMETHAZINE	0 (0.0)	1 (0.1)	1 (0.1)
DEZOCINE	0 (0.0)	1 (0.1)	1 (0.1)
DICLOFENAC;PARACETAMOL;SERRAPEPTASE	1 (0.1)	0 (0.0)	1 (0.1)
DIFLUCORTOLONE;LIDOCAINE	1 (0.1)	0 (0.0)	1 (0.1)
DIISOPROPYLAMINE;GLUCONATE SODIUM	1 (0.1)	0 (0.0)	1 (0.1)
DIMETICONE;GUAIAZULENE	1 (0.1)	0 (0.0)	1 (0.1)
DIMETICONE;PROPYLENE GLYCOL	0 (0.0)	1 (0.1)	1 (0.1)
DIMETICONE;SILICON DIOXIDE	0 (0.0)	1 (0.1)	1 (0.1)
DIOXOPROMETHAZINE	1 (0.1)	0 (0.0)	1 (0.1)
DIPHENHYDRAMINE;LIDOCAINE	0 (0.0)	1 (0.1)	1 (0.1)
DIPHENHYDRAMINE;LIDOCAINE;NYSTATIN	0 (0.0)	1 (0.1)	1 (0.1)
DIPHENHYDRAMINE;MENTHOL	1 (0.1)	0 (0.0)	1 (0.1)
DIPHENHYDRAMINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
DIPHENOXYLATE	1 (0.1)	0 (0.0)	1 (0.1)
DIPHTHERIA VACCINE;TETANUS VACCINE	1 (0.1)	0 (0.0)	1 (0.1)
DIPROPHYLLINE;GUAIFENESIN	0 (0.0)	1 (0.1)	1 (0.1)
DIPYRIDAMOLE	1 (0.1)	0 (0.0)	1 (0.1)
DIURETICS	0 (0.0)	1 (0.1)	1 (0.1)
DL- LACTIC ACID;SODIUM LACTATE	0 (0.0)	1 (0.1)	1 (0.1)
DOCUSATE;SENNA ALEXANDRINA	0 (0.0)	1 (0.1)	1 (0.1)
DOCUSATE;SORBITOL	0 (0.0)	1 (0.1)	1 (0.1)
DOMPERIDONE;ESOMEPRAZOLE	0 (0.0)	1 (0.1)	1 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
DOMPERIDONE;PANTOPRAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
DOMPERIDONE;RABEPRAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
DOXEPIN	0 (0.0)	1 (0.1)	1 (0.1)
DOXYLAMINE;FOLIC ACID;PYRIDOXINE	1 (0.1)	0 (0.0)	1 (0.1)
DRUGS FOR CONSTIPATION	1 (0.1)	0 (0.0)	1 (0.1)
DYDROGESTERONE	0 (0.0)	1 (0.1)	1 (0.1)
EICOSAPENTAENOIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
ELECTROLYTES NOS;MACROGOL 3350	1 (0.1)	0 (0.0)	1 (0.1)
EMPAGLIFLOZIN	0 (0.0)	1 (0.1)	1 (0.1)
EMULSIFYING WAX;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (0.1)	0 (0.0)	1 (0.1)
ENSULIZOLE;OCTINOXATE;OCTISALATE;OXYBENZONE	1 (0.1)	0 (0.0)	1 (0.1)
ENTEROCOCCUS FAECALIS	1 (0.1)	0 (0.0)	1 (0.1)
EPHEDRA SPP.;GLYCYRRHIZA SPP.;PRUNUS SPP.;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.1)
ERGOCALCIFEROL	0 (0.0)	1 (0.1)	1 (0.1)
ERGOCALCIFEROL;PHYTOMENADIONE;RETINOL;TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.1)
ERGOTAMINE	1 (0.1)	0 (0.0)	1 (0.1)
ERIOBOTRYA JAPONICA;MENTHOL;MORUS ALBA;PAPAVER SOMNIFERUM;PLATYCODON GRANDIFLORUS;STEMONA SPP.;VINCETOXICUM SPP.	0 (0.0)	1 (0.1)	1 (0.1)
ESCHERICHIA COLI	0 (0.0)	1 (0.1)	1 (0.1)
ESCIN	1 (0.1)	0 (0.0)	1 (0.1)
ESCIN;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
ESKETAMINE	0 (0.0)	1 (0.1)	1 (0.1)
ESTRIOL;LACTOBACILLUS ACIDOPHILUS	1 (0.1)	0 (0.0)	1 (0.1)
ETAMSILATE	1 (0.1)	0 (0.0)	1 (0.1)

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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
EUCALYPTUS GLOBULUS	1 (0.1)	0 (0.0)	1 (0.1)
EXPECTORANTS	0 (0.0)	1 (0.1)	1 (0.1)
FAGOPYRUM CYMOSUM	1 (0.1)	0 (0.0)	1 (0.1)
FEBUXOSTAT	1 (0.1)	0 (0.0)	1 (0.1)
FELODIPINE	0 (0.0)	1 (0.1)	1 (0.1)
FENOVERINE	1 (0.1)	0 (0.0)	1 (0.1)
FERROUS PHOSPHATE;HERBAL NOS	1 (0.1)	0 (0.0)	1 (0.1)
FEXOFENADINE;MONTELUKAST	1 (0.1)	0 (0.0)	1 (0.1)
FISH OIL;XANTOFYL;ZEAXANTHIN	1 (0.1)	0 (0.0)	1 (0.1)
FLAVINE ADENINE DINUCLEOTIDE	0 (0.0)	1 (0.1)	1 (0.1)
FLOMOXEF	1 (0.1)	0 (0.0)	1 (0.1)
FLUFENAMIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
FLUMAZENIL	0 (0.0)	1 (0.1)	1 (0.1)
FLUNITRAZEPAM	1 (0.1)	0 (0.0)	1 (0.1)
FLUOCINOLONE ACETONIDE;LIDOCAINE;NEOMYCIN;POLYMYXIN B	0 (0.0)	1 (0.1)	1 (0.1)
FLUOCINOLONE ACETONIDE;NEOMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
FLUOCORTOLONE;LIDOCAINE	1 (0.1)	0 (0.0)	1 (0.1)
FLUOROMETHOLONE;TETRYZOLINE	1 (0.1)	0 (0.0)	1 (0.1)
FLUPENTIXOL;MELITRACEN	1 (0.1)	0 (0.0)	1 (0.1)
FLURBIPROFEN;THIOCOLCHICOSIDE	1 (0.1)	0 (0.0)	1 (0.1)
FLUTICASONE;UMECLIDINIUM;VILANTEROL	0 (0.0)	1 (0.1)	1 (0.1)
FOLIC ACID;MECOBALAMIN;PYRIDOXINE	0 (0.0)	1 (0.1)	1 (0.1)
FONDAPARINUX	1 (0.1)	0 (0.0)	1 (0.1)
FUCOIDAN	1 (0.1)	0 (0.0)	1 (0.1)

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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Indication: Adverse Event

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FUDOSTEINE	0 (0.0)	1 (0.1)	1 (0.1)
FUROSEMIDE;SPIRONOLACTONE	0 (0.0)	1 (0.1)	1 (0.1)
GADOTERIDOL	1 (0.1)	0 (0.0)	1 (0.1)
GALIUM APARINE;STILLINGIA SYLVATICA;TRIFOLIUM PRATENSE;ZANTHOXYLUM AMERICANUM	1 (0.1)	0 (0.0)	1 (0.1)
GARCINIA GUMMI-GUTTA	1 (0.1)	0 (0.0)	1 (0.1)
GATIFLOXACIN	1 (0.1)	0 (0.0)	1 (0.1)
GENISTEIN	0 (0.0)	1 (0.1)	1 (0.1)
GENTAMICIN;PREDNISOLONE	1 (0.1)	0 (0.0)	1 (0.1)
GINSENG NOS	1 (0.1)	0 (0.0)	1 (0.1)
GLIBENCLAMIDE	0 (0.0)	1 (0.1)	1 (0.1)
GLICLAZIDE	0 (0.0)	1 (0.1)	1 (0.1)
GLUCONATE SODIUM;MAGNESIUM CHLORIDE;POTASSIUM;POTASSIUM PHOSPHATE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM PHOSPHATE	0 (0.0)	1 (0.1)	1 (0.1)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.1)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM CITRATE	0 (0.0)	1 (0.1)	1 (0.1)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM CITRATE ACID	0 (0.0)	1 (0.1)	1 (0.1)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	0 (0.0)	1 (0.1)	1 (0.1)
GLYCINE	1 (0.1)	0 (0.0)	1 (0.1)
GLYCINE MAX	0 (0.0)	1 (0.1)	1 (0.1)
GLYCINE MAX;PERSEA AMERICANA	0 (0.0)	1 (0.1)	1 (0.1)
GLYCYRRHIZA GLABRA;PAPAVER SOMNIFERUM	0 (0.0)	1 (0.1)	1 (0.1)
GUAIFENESIN;THEOPHYLLINE	1 (0.1)	0 (0.0)	1 (0.1)
GUALENIC ACID;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
GUAREA GUIDONIA	1 (0.1)	0 (0.0)	1 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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HAEMOCOAGULASE	0 (0.0)	1 (0.1)	1 (0.1)
HALOMETASONE	1 (0.1)	0 (0.0)	1 (0.1)
HALOPERIDOL	1 (0.1)	0 (0.0)	1 (0.1)
HEDERA HELIX	0 (0.0)	1 (0.1)	1 (0.1)
HERBAL ANTIANEMIC PREPARATIONS	1 (0.1)	0 (0.0)	1 (0.1)
HERBAL ANTISPASMODIC AGENTS, OTHER	1 (0.1)	0 (0.0)	1 (0.1)
HERBAL CAPILLARY STABILIZING REMEDIES	1 (0.1)	0 (0.0)	1 (0.1)
HERBAL EXTRACT NOS	1 (0.1)	0 (0.0)	1 (0.1)
HERBAL EXTRACT NOS;HOMEOPATHICS NOS	1 (0.1)	0 (0.0)	1 (0.1)
HERBAL OIL NOS	0 (0.0)	1 (0.1)	1 (0.1)
HERBAL POLLEN NOS	1 (0.1)	0 (0.0)	1 (0.1)
HERBAL THROAT PREPARATIONS (TONSILLITIS)	1 (0.1)	0 (0.0)	1 (0.1)
HESPERIDIN	1 (0.1)	0 (0.0)	1 (0.1)
HETASTARCH	0 (0.0)	1 (0.1)	1 (0.1)
HISTIDINE	1 (0.1)	0 (0.0)	1 (0.1)
HOMEOPATHIC PREPARATION	0 (0.0)	1 (0.1)	1 (0.1)
HOMEOPATHICS NOS	1 (0.1)	0 (0.0)	1 (0.1)
HOMOCHLORCYCLIZINE	1 (0.1)	0 (0.0)	1 (0.1)
HOPANTENIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
HOUTTUYNIA CORDATA	1 (0.1)	0 (0.0)	1 (0.1)
HYALURONIC ACID;MALVA SYLVESTRIS;MATRICARIA CHAMOMILLA	1 (0.1)	0 (0.0)	1 (0.1)
HYDROCHLOROTHIAZIDE;IRBESARTAN	1 (0.1)	0 (0.0)	1 (0.1)
HYDROCORTISONE;OXYTETRACYCLINE	0 (0.0)	1 (0.1)	1 (0.1)
HYDROXOCOBALAMIN;LIDOCAINE;PYRIDOXINE;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
HYDROXOCOBALAMIN;PYRIDOXINE;THIAMINE	1 (0.1)	0 (0.0)	1 (0.1)
HYOSCINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
HYPNOTICS AND SEDATIVES IN COMBINATION, EXCL. BARBITURATES	1 (0.1)	0 (0.0)	1 (0.1)
IMMUNOGLOBULINS NOS	1 (0.1)	0 (0.0)	1 (0.1)
IMRECOXIB	1 (0.1)	0 (0.0)	1 (0.1)
INDOBUFEN	0 (0.0)	1 (0.1)	1 (0.1)
INDOCYANINE GREEN	0 (0.0)	1 (0.1)	1 (0.1)
INFLUENZA VACCINE	1 (0.1)	0 (0.0)	1 (0.1)
INOSITOL	1 (0.1)	0 (0.0)	1 (0.1)
INSULIN DEGLUDEC	1 (0.1)	0 (0.0)	1 (0.1)
INSULIN GLARGINE	0 (0.0)	1 (0.1)	1 (0.1)
INTERFERON ALFA-2B	1 (0.1)	0 (0.0)	1 (0.1)
INTERFERONS	0 (0.0)	1 (0.1)	1 (0.1)
IODINE	0 (0.0)	1 (0.1)	1 (0.1)
IODINE THERAPY	1 (0.1)	0 (0.0)	1 (0.1)
IOHEXOL	0 (0.0)	1 (0.1)	1 (0.1)
IOPAMIDOL	1 (0.1)	0 (0.0)	1 (0.1)
IRON IN OTHER COMBINATIONS	0 (0.0)	1 (0.1)	1 (0.1)
IRON;PROTEASE NOS	1 (0.1)	0 (0.0)	1 (0.1)
IRON;SUCROSE	0 (0.0)	1 (0.1)	1 (0.1)
ISATIS SPP.	0 (0.0)	1 (0.1)	1 (0.1)
ISATIS TINCTORIA;LOBELIA CHINENSIS;TARAXACUM SPP.;VIOLA PHILIPPICA VAR. PHILIPPICA	0 (0.0)	1 (0.1)	1 (0.1)
ISEPAMICIN	1 (0.1)	0 (0.0)	1 (0.1)
ISOSORBIDE	0 (0.0)	1 (0.1)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ISOTONIC SOLUTIONS	0 (0.0)	1 (0.1)	1 (0.1)
ISOTRETINOIN	0 (0.0)	1 (0.1)	1 (0.1)
IVABRADINE	1 (0.1)	0 (0.0)	1 (0.1)
IVERMECTIN	1 (0.1)	0 (0.0)	1 (0.1)
KETOCONAZOLE;PYRITHIONE	0 (0.0)	1 (0.1)	1 (0.1)
KITASAMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
LABETALOL	0 (0.0)	1 (0.1)	1 (0.1)
LACIDIPINE	0 (0.0)	1 (0.1)	1 (0.1)
LACTOBACILLUS REUTERI	0 (0.0)	1 (0.1)	1 (0.1)
LACTOBACILLUS REUTERI;LACTOBACILLUS RHAMNOSUS	0 (0.0)	1 (0.1)	1 (0.1)
LAMOTRIGINE	0 (0.0)	1 (0.1)	1 (0.1)
LAPPACONITINE	1 (0.1)	0 (0.0)	1 (0.1)
LAUROMACROGOL 400	0 (0.0)	1 (0.1)	1 (0.1)
LERCANIDIPINE	1 (0.1)	0 (0.0)	1 (0.1)
LEVOGLUTAMIDE	1 (0.1)	0 (0.0)	1 (0.1)
LEVOSALBUTAMOL	1 (0.1)	0 (0.0)	1 (0.1)
LIDOCAINE;METRONIDAZOLE;MICONAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
LIDOCAINE;NIFEDIPINE	1 (0.1)	0 (0.0)	1 (0.1)
LIDOCAINE;TINIDAZOLE;TIOCONAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
LIGUSTRUM LUCIDUM	1 (0.1)	0 (0.0)	1 (0.1)
LISINOPRIL	1 (0.1)	0 (0.0)	1 (0.1)
LITHIUM	1 (0.1)	0 (0.0)	1 (0.1)
LOMEFLOXACIN	1 (0.1)	0 (0.0)	1 (0.1)
LONICERA SPP.	0 (0.0)	1 (0.1)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Adverse Event

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LOPERAMIDE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
LOPINAVIR;RITONAVIR	1 (0.1)	0 (0.0)	1 (0.1)
LORATADINE;PARACETAMOL;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.1)
LYMECYCLINE	0 (0.0)	1 (0.1)	1 (0.1)
MACROGOL 3350	1 (0.1)	0 (0.0)	1 (0.1)
MACROGOL 4000	0 (0.0)	1 (0.1)	1 (0.1)
MAGNESIUM CARBONATE;MAGNESIUM OXIDE	0 (0.0)	1 (0.1)	1 (0.1)
MAGNESIUM CITRATE	1 (0.1)	0 (0.0)	1 (0.1)
MAGNESIUM HYDROXIDE;PARAFFIN, LIQUID	1 (0.1)	0 (0.0)	1 (0.1)
MAGNESIUM OXIDE;ZINC	0 (0.0)	1 (0.1)	1 (0.1)
MAGNESIUM;PYRIDOXINE	0 (0.0)	1 (0.1)	1 (0.1)
MAGNESIUM;VITAMIN B NOS	0 (0.0)	1 (0.1)	1 (0.1)
MAGNOLIA SPP.;PERILLA FRUTESCENS VAR. CRISPA;PINELLIA TERNATA;PORIA COCOS;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.1)
MANNITOL	0 (0.0)	1 (0.1)	1 (0.1)
MEBENDAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
MEBEVERINE	1 (0.1)	0 (0.0)	1 (0.1)
MEDROXYPROGESTERONE	0 (0.0)	1 (0.1)	1 (0.1)
MELILOTUS OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.1)
MENTHA X PIPERITA;ORIGANUM MAJORANA;SALVIA OFFICINALIS;SYZYGIUM AROMATICUM;THYMUS VULGARIS	1 (0.1)	0 (0.0)	1 (0.1)
MENTHOL;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
MEPENZOLATE	1 (0.1)	0 (0.0)	1 (0.1)
MEPHENOXALONE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)

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/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
MEPYRAMINE	1 (0.1)	0 (0.0)	1 (0.1)
MESALAZINE	0 (0.0)	1 (0.1)	1 (0.1)
METHENAMINE	1 (0.1)	0 (0.0)	1 (0.1)
METHENAMINE;METHYLTHIONINIUM	1 (0.1)	0 (0.0)	1 (0.1)
METHENAMINE;PAPAVERINE	0 (0.0)	1 (0.1)	1 (0.1)
METHENAMINE;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
METHOCARBAMOL	1 (0.1)	0 (0.0)	1 (0.1)
METHOCARBAMOL;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
METHYLETHYLPIRIDINOL	1 (0.1)	0 (0.0)	1 (0.1)
METHYLPARABEN	0 (0.0)	1 (0.1)	1 (0.1)
METHYLPREDNISOLONE;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
METHYLSCOPOLAMINE	1 (0.1)	0 (0.0)	1 (0.1)
METHYLURACIL	0 (0.0)	1 (0.1)	1 (0.1)
METOPIMAZINE	1 (0.1)	0 (0.0)	1 (0.1)
METOPROLOL;TELMISARTAN	0 (0.0)	1 (0.1)	1 (0.1)
METRONIDAZOLE;NYSTATIN	0 (0.0)	1 (0.1)	1 (0.1)
METRONIDAZOLE;SPIRAMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
METRONIDAZOLE;UREA	1 (0.1)	0 (0.0)	1 (0.1)
MINERAL OIL LIGHT;PETROLATUM;WOOL FAT	1 (0.1)	0 (0.0)	1 (0.1)
MORINIDAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
MORNIFLUMATE	0 (0.0)	1 (0.1)	1 (0.1)
MORUS SPP.	1 (0.1)	0 (0.0)	1 (0.1)
MULTIVITAMINS WITH MINERALS [UMBRELLA TERM]	1 (0.1)	0 (0.0)	1 (0.1)
MULTIVITAMINS, OTHER COMBINATIONS	1 (0.1)	0 (0.0)	1 (0.1)

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MULTIVITAMINS, PLAIN	1 (0.1)	0 (0.0)	1 (0.1)
MUSK	0 (0.0)	1 (0.1)	1 (0.1)
MYRTOL	1 (0.1)	0 (0.0)	1 (0.1)
NADROPARIN	0 (0.0)	1 (0.1)	1 (0.1)
NAPHAZOLINE	1 (0.1)	0 (0.0)	1 (0.1)
NAPHAZOLINE;PHENIRAMINE	1 (0.1)	0 (0.0)	1 (0.1)
NATAMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
NEMONOXACIN	1 (0.1)	0 (0.0)	1 (0.1)
NEOMYCIN;POLYMYXIN	1 (0.1)	0 (0.0)	1 (0.1)
NEPAFENAC	1 (0.1)	0 (0.0)	1 (0.1)
NICAMETATE	1 (0.1)	0 (0.0)	1 (0.1)
NICOTINAMIDE;PAPAVERINE	1 (0.1)	0 (0.0)	1 (0.1)
NIFLUMIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
NITROFURAL	0 (0.0)	1 (0.1)	1 (0.1)
NIZATIDINE	1 (0.1)	0 (0.0)	1 (0.1)
NOREPINEPHRINE	0 (0.0)	1 (0.1)	1 (0.1)
NOSCAPINE	1 (0.1)	0 (0.0)	1 (0.1)
OENOTHERA BIENNIS	0 (0.0)	1 (0.1)	1 (0.1)
OFLOXACIN;ORNIDAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
OLODATEROL;TIOTROPIUM	0 (0.0)	1 (0.1)	1 (0.1)
OPIPRAMOL	1 (0.1)	0 (0.0)	1 (0.1)
OPIUM ALKALOIDS AND DERIVATIVES	0 (0.0)	1 (0.1)	1 (0.1)
ORAL REHYDRATION SALT FORMULATIONS	1 (0.1)	0 (0.0)	1 (0.1)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	0 (0.0)	1 (0.1)	1 (0.1)

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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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OTHER ANTIDIARRHEALS	1 (0.1)	0 (0.0)	1 (0.1)
OTHER ANTIINFLAMMATORY/ANTIRHEUMATIC AGENTS IN COMBINATION WITH OTHER DRUGS	0 (0.0)	1 (0.1)	1 (0.1)
OTHER CAPILLARY STABILIZING AGENTS	0 (0.0)	1 (0.1)	1 (0.1)
OTHER DERMATOLOGICALS	1 (0.1)	0 (0.0)	1 (0.1)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	1 (0.1)	0 (0.0)	1 (0.1)
OTHER OTOLOGICALS	1 (0.1)	0 (0.0)	1 (0.1)
OTHER RESPIRATORY SYSTEM PRODUCTS	0 (0.0)	1 (0.1)	1 (0.1)
OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	1 (0.1)	0 (0.0)	1 (0.1)
OTILONIUM	0 (0.0)	1 (0.1)	1 (0.1)
OTILONIUM;SIMETICONE	0 (0.0)	1 (0.1)	1 (0.1)
OXACILLIN	1 (0.1)	0 (0.0)	1 (0.1)
OXAZOLAM	1 (0.1)	0 (0.0)	1 (0.1)
OXELADIN	0 (0.0)	1 (0.1)	1 (0.1)
OXIDIZED STARCH	1 (0.1)	0 (0.0)	1 (0.1)
OXOLAMINE	1 (0.1)	0 (0.0)	1 (0.1)
OXYBUPROCAINE	1 (0.1)	0 (0.0)	1 (0.1)
OXYGEN	1 (0.1)	0 (0.0)	1 (0.1)
OXYTOCIN	0 (0.0)	1 (0.1)	1 (0.1)
PALIPERIDONE	1 (0.1)	0 (0.0)	1 (0.1)
PALONOSETRON	0 (0.0)	1 (0.1)	1 (0.1)
PANCREATIN;SIMETICONE	1 (0.1)	0 (0.0)	1 (0.1)
PARAFFIN NOS;PARAFFIN, LIQUID;PETROLATUM;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.1)
PARECOXIB	0 (0.0)	1 (0.1)	1 (0.1)
PASSIFLORA INCARNATA	0 (0.0)	1 (0.1)	1 (0.1)

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PAULLINIA CUPANA	0 (0.0)	1 (0.1)	1 (0.1)
PAULLINIA CUPANA;SALIX ALBA;TANACETUM PARTHENIUM	1 (0.1)	0 (0.0)	1 (0.1)
PEMIROLAST	0 (0.0)	1 (0.1)	1 (0.1)
PENCICLOVIR	0 (0.0)	1 (0.1)	1 (0.1)
PENICILLIUM GLABRUM	1 (0.1)	0 (0.0)	1 (0.1)
PENTAZOCINE	0 (0.0)	1 (0.1)	1 (0.1)
PERIPLANETA AMERICANA	0 (0.0)	1 (0.1)	1 (0.1)
PERMETHRIN	1 (0.1)	0 (0.0)	1 (0.1)
PERPHENAZINE	1 (0.1)	0 (0.0)	1 (0.1)
PHENOL	0 (0.0)	1 (0.1)	1 (0.1)
PHENOXYETHANOL;TRITICUM AESTIVUM	1 (0.1)	0 (0.0)	1 (0.1)
PHENYLEPHRINE;PSEUDOEPHEDRINE	0 (0.0)	1 (0.1)	1 (0.1)
PIMECROLIMUS	1 (0.1)	0 (0.0)	1 (0.1)
PIPERACILLIN	1 (0.1)	0 (0.0)	1 (0.1)
PIRENOXINE	1 (0.1)	0 (0.0)	1 (0.1)
PIRITRAMIDE	0 (0.0)	1 (0.1)	1 (0.1)
PITAVASTATIN	0 (0.0)	1 (0.1)	1 (0.1)
PLANTAGO LANCEOLATA	0 (0.0)	1 (0.1)	1 (0.1)
PLANTAGO OVATA;SENNA SPP.	0 (0.0)	1 (0.1)	1 (0.1)
POTASSIUM ASPARTATE	1 (0.1)	0 (0.0)	1 (0.1)
POTASSIUM BICARBONATE;POTASSIUM CITRATE	1 (0.1)	0 (0.0)	1 (0.1)
POTASSIUM CRESOLSULFONATE	1 (0.1)	0 (0.0)	1 (0.1)
POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	0 (0.0)	1 (0.1)	1 (0.1)
PRALIDOXIME	1 (0.1)	0 (0.0)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
PRAMOCAINE	1 (0.1)	0 (0.0)	1 (0.1)
PRANOPROFEN	1 (0.1)	0 (0.0)	1 (0.1)
PRASTERONE	0 (0.0)	1 (0.1)	1 (0.1)
PRILOCAINE	0 (0.0)	1 (0.1)	1 (0.1)
PRIMULA SPP.;THYMUS VULGARIS	1 (0.1)	0 (0.0)	1 (0.1)
PRIMULA VERIS;SULFOGAIACOL;THYMUS VULGARIS	1 (0.1)	0 (0.0)	1 (0.1)
PROCATEROL	0 (0.0)	1 (0.1)	1 (0.1)
PROMESTRIENE	1 (0.1)	0 (0.0)	1 (0.1)
PROPIONIC ACID DERIVATIVES	1 (0.1)	0 (0.0)	1 (0.1)
PROPOLIS	0 (0.0)	1 (0.1)	1 (0.1)
PROTECTIVES AGAINST UV-RADIATION FOR TOPICAL USE	1 (0.1)	0 (0.0)	1 (0.1)
PRULIFLOXACIN	1 (0.1)	0 (0.0)	1 (0.1)
PYRIDOXAL	1 (0.1)	0 (0.0)	1 (0.1)
PYRIDOXINE;RIBOFLAVIN;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
PYRIDOXINE;THIAMINE;VITAMIN B12 NOS	1 (0.1)	0 (0.0)	1 (0.1)
RADIUM BROMIDE	0 (0.0)	1 (0.1)	1 (0.1)
RAMELTEON	0 (0.0)	1 (0.1)	1 (0.1)
RAMOSETRON	1 (0.1)	0 (0.0)	1 (0.1)
RECOMBINANT HUMAN THROMBOPOIETIN	1 (0.1)	0 (0.0)	1 (0.1)
RETINOL	1 (0.1)	0 (0.0)	1 (0.1)
RIBAVIRIN	1 (0.1)	0 (0.0)	1 (0.1)
RISEDRONIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
RISPERIDONE	0 (0.0)	1 (0.1)	1 (0.1)
ROXATIDINE	0 (0.0)	1 (0.1)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
RUBUS IDAEUS	1 (0.1)	0 (0.0)	1 (0.1)
RUSCOGENIN;TRIMEBUTINE	0 (0.0)	1 (0.1)	1 (0.1)
SALICYLIC ACID AND DERIVATIVES	1 (0.1)	0 (0.0)	1 (0.1)
SALVIA MILTIORRHIZA	1 (0.1)	0 (0.0)	1 (0.1)
SALVIA MILTIORRHIZA;SCHISANDRA CHINENSIS;ZIZIPHUS JUJUBA	1 (0.1)	0 (0.0)	1 (0.1)
SARRACENIA PURPUREA	0 (0.0)	1 (0.1)	1 (0.1)
SCHISANDRA CHINENSIS;SILYBUM MARIANUM	1 (0.1)	0 (0.0)	1 (0.1)
SCHISANDRA SPHENANTHERA	1 (0.1)	0 (0.0)	1 (0.1)
SCHOENOCAULON OFFICINALE	1 (0.1)	0 (0.0)	1 (0.1)
SCUTELLARIA BAICALENSIS	1 (0.1)	0 (0.0)	1 (0.1)
SEA WATER	1 (0.1)	0 (0.0)	1 (0.1)
SEMAGLUTIDE	1 (0.1)	0 (0.0)	1 (0.1)
SENEGA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.1)
SIGESBECKIA ORIENTALIS	1 (0.1)	0 (0.0)	1 (0.1)
SILIBININ	1 (0.1)	0 (0.0)	1 (0.1)
SILICON	0 (0.0)	1 (0.1)	1 (0.1)
SILVER NITRATE	0 (0.0)	1 (0.1)	1 (0.1)
SITAFLOXACIN	0 (0.0)	1 (0.1)	1 (0.1)
SITAGLIPTIN	0 (0.0)	1 (0.1)	1 (0.1)
SODIUM BICARBONATE;SODIUM PHOSPHATE	1 (0.1)	0 (0.0)	1 (0.1)
SODIUM CHLORIDE;TRANEXAMIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
SODIUM CITRATE ACID	1 (0.1)	0 (0.0)	1 (0.1)
SODIUM FLUORIDE	1 (0.1)	0 (0.0)	1 (0.1)
SOFT SOAP	0 (0.0)	1 (0.1)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
SPIRAMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
STARCH	1 (0.1)	0 (0.0)	1 (0.1)
STEMONA SPP.	1 (0.1)	0 (0.0)	1 (0.1)
STEROIDS	1 (0.1)	0 (0.0)	1 (0.1)
STREPTODORNASE	1 (0.1)	0 (0.0)	1 (0.1)
STRYCHNOS NUX-VOMICA	0 (0.0)	1 (0.1)	1 (0.1)
SUFENTANIL	0 (0.0)	1 (0.1)	1 (0.1)
SULBACTAM	1 (0.1)	0 (0.0)	1 (0.1)
SULFAMETHOXAZOLE;TETRYZOLINE	1 (0.1)	0 (0.0)	1 (0.1)
SULFAMETROLE;TRIMETHOPRIM	0 (0.0)	1 (0.1)	1 (0.1)
SULFUR;VINCETOXICUM HIRUNDINARIA	1 (0.1)	0 (0.0)	1 (0.1)
SULINDAC	0 (0.0)	1 (0.1)	1 (0.1)
SULODEXIDE	1 (0.1)	0 (0.0)	1 (0.1)
SULPIRIDE	0 (0.0)	1 (0.1)	1 (0.1)
SUXAMETHONIUM	1 (0.1)	0 (0.0)	1 (0.1)
TAZOBACTAM	1 (0.1)	0 (0.0)	1 (0.1)
TERBUTALINE	0 (0.0)	1 (0.1)	1 (0.1)
TERCONAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
TERPIN	0 (0.0)	1 (0.1)	1 (0.1)
TETANUS VACCINE	1 (0.1)	0 (0.0)	1 (0.1)
THROMBIN	0 (0.0)	1 (0.1)	1 (0.1)
THYMUS VULGARIS	0 (0.0)	1 (0.1)	1 (0.1)
TIAPROFENIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
TICAGRELOR	1 (0.1)	0 (0.0)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
TINIDAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
TIOCONAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
TIOTROPIUM	1 (0.1)	0 (0.0)	1 (0.1)
TIQUIZIUM	0 (0.0)	1 (0.1)	1 (0.1)
TIXOCORTOL	1 (0.1)	0 (0.0)	1 (0.1)
TOPIRAMATE	0 (0.0)	1 (0.1)	1 (0.1)
TORASEMIDE	1 (0.1)	0 (0.0)	1 (0.1)
TRADITIONAL CHINESE MEDICINE (TCM) DECOCTION	1 (0.1)	0 (0.0)	1 (0.1)
TRIAZOLAM	1 (0.1)	0 (0.0)	1 (0.1)
TRIPROLIDINE	0 (0.0)	1 (0.1)	1 (0.1)
TROMETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
TROXERUTIN	1 (0.1)	0 (0.0)	1 (0.1)
TROXIPIDE	1 (0.1)	0 (0.0)	1 (0.1)
UROGASTRONE	1 (0.1)	0 (0.0)	1 (0.1)
VALERIANA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.1)
VERATRUM SPP.	0 (0.0)	1 (0.1)	1 (0.1)
VILDAGLIPTIN	0 (0.0)	1 (0.1)	1 (0.1)
VINPOCETINE	1 (0.1)	0 (0.0)	1 (0.1)
VITAMIN B-COMPLEX, OTHER COMBINATIONS	0 (0.0)	1 (0.1)	1 (0.1)
VITAMIN B-COMPLEX, PLAIN	0 (0.0)	1 (0.1)	1 (0.1)
VITAMINS NOS	1 (0.1)	0 (0.0)	1 (0.1)
VITAMINS WITH MINERALS	0 (0.0)	1 (0.1)	1 (0.1)
VITAMINS, OTHER COMBINATIONS	0 (0.0)	1 (0.1)	1 (0.1)
ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.1)

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Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 1 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
Subjects with >= 1 Medication	361 (46.5)	326 (44.7)	687 (45.6)
LEVOTHYROXINE	46 (5.9)	33 (4.5)	79 (5.2)
PARACETAMOL	26 (3.4)	35 (4.8)	61 (4.1)
VENLAFAXINE	23 (3.0)	24 (3.3)	47 (3.1)
HEPARINOID	20 (2.6)	18 (2.5)	38 (2.5)
IBUPROFEN	21 (2.7)	14 (1.9)	35 (2.3)
GABAPENTIN	18 (2.3)	15 (2.1)	33 (2.2)
LOXOPROFEN	16 (2.1)	17 (2.3)	33 (2.2)
FEXOFENADINE	14 (1.8)	18 (2.5)	32 (2.1)
ALPRAZOLAM	13 (1.7)	14 (1.9)	27 (1.8)
ZOLPIDEM	16 (2.1)	11 (1.5)	27 (1.8)
BETAMETHASONE	16 (2.1)	10 (1.4)	26 (1.7)
METFORMIN	16 (2.1)	10 (1.4)	26 (1.7)
LORATADINE	15 (1.9)	10 (1.4)	25 (1.7)
LORAZEPAM	17 (2.2)	7 (1.0)	24 (1.6)
ESCITALOPRAM	12 (1.5)	11 (1.5)	23 (1.5)
BETAMETHASONE;GENTAMICIN	11 (1.4)	9 (1.2)	20 (1.3)
FLUTICASONE	13 (1.7)	7 (1.0)	20 (1.3)
LOSARTAN	11 (1.4)	9 (1.2)	20 (1.3)
OMEPRAZOLE	12 (1.5)	8 (1.1)	20 (1.3)
AMLODIPINE	6 (0.8)	12 (1.6)	18 (1.2)
BISOPROLOL	8 (1.0)	10 (1.4)	18 (1.2)
CITALOPRAM	7 (0.9)	11 (1.5)	18 (1.2)
FUROSEMIDE	10 (1.3)	8 (1.1)	18 (1.2)

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776)		EDT*a (N=729)		Total (N=1505)	
	n	(%)	n	(%)	n	(%)
MELATONIN	11	(1.4)	7	(1.0)	18	(1.2)
SERTRALINE	7	(0.9)	11	(1.5)	18	(1.2)
VITIS VINIFERA	12	(1.5)	6	(0.8)	18	(1.2)
MAGNESIUM OXIDE	9	(1.2)	8	(1.1)	17	(1.1)
SALBUTAMOL	12	(1.5)	4	(0.5)	16	(1.1)
PREGABALIN	9	(1.2)	6	(0.8)	15	(1.0)
HYDROCORTISONE	7	(0.9)	7	(1.0)	14	(0.9)
MOMETASONE	5	(0.6)	9	(1.2)	14	(0.9)
ZOPICLONE	7	(0.9)	7	(1.0)	14	(0.9)
AMITRIPTYLINE	7	(0.9)	6	(0.8)	13	(0.9)
CETIRIZINE	7	(0.9)	5	(0.7)	12	(0.8)
DULOXETINE	9	(1.2)	3	(0.4)	12	(0.8)
ESOMEPRAZOLE	7	(0.9)	5	(0.7)	12	(0.8)
PANTOPRAZOLE	7	(0.9)	5	(0.7)	12	(0.8)
PAROXETINE	8	(1.0)	4	(0.5)	12	(0.8)
COLECALCIFEROL	5	(0.6)	6	(0.8)	11	(0.7)
ATORVASTATIN	3	(0.4)	7	(1.0)	10	(0.7)
BUDESONIDE;FORMOTEROL	7	(0.9)	3	(0.4)	10	(0.7)
CANDESARTAN	5	(0.6)	5	(0.7)	10	(0.7)
CLONAZEPAM	7	(0.9)	3	(0.4)	10	(0.7)
RAMIPRIL	5	(0.6)	5	(0.7)	10	(0.7)
TRAZODONE	6	(0.8)	4	(0.5)	10	(0.7)
DIAZEPAM	4	(0.5)	5	(0.7)	9	(0.6)
FOLIC ACID	3	(0.4)	6	(0.8)	9	(0.6)

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
GUAIAZULENE	5 (0.6)	4 (0.5)	9 (0.6)
HYDROCHLOROTHIAZIDE	7 (0.9)	2 (0.3)	9 (0.6)
IRON	5 (0.6)	4 (0.5)	9 (0.6)
QUETIAPINE	5 (0.6)	4 (0.5)	9 (0.6)
TRAMADOL	4 (0.5)	5 (0.7)	9 (0.6)
ASCORBIC ACID;PANTOTHENIC ACID	6 (0.8)	2 (0.3)	8 (0.5)
CODEINE;PARACETAMOL	3 (0.4)	5 (0.7)	8 (0.5)
DIOSMIN;HESPERIDIN	4 (0.5)	4 (0.5)	8 (0.5)
ENALAPRIL	4 (0.5)	4 (0.5)	8 (0.5)
FLUOXETINE	5 (0.6)	3 (0.4)	8 (0.5)
HERBAL PREPARATION	3 (0.4)	5 (0.7)	8 (0.5)
MIRTAZAPINE	5 (0.6)	3 (0.4)	8 (0.5)
NAPROXEN	2 (0.3)	6 (0.8)	8 (0.5)
OLOPATADINE	7 (0.9)	1 (0.1)	8 (0.5)
ONDANSETRON	3 (0.4)	5 (0.7)	8 (0.5)
ROSUVASTATIN	6 (0.8)	2 (0.3)	8 (0.5)
BROMAZEPAM	5 (0.6)	2 (0.3)	7 (0.5)
CARVEDILOL	4 (0.5)	3 (0.4)	7 (0.5)
DICLOFENAC	2 (0.3)	5 (0.7)	7 (0.5)
EPINASTINE	4 (0.5)	3 (0.4)	7 (0.5)
HYALURONIC ACID	1 (0.1)	6 (0.8)	7 (0.5)
KETOPROFEN	5 (0.6)	2 (0.3)	7 (0.5)
LANSOPRAZOLE	3 (0.4)	4 (0.5)	7 (0.5)
LEVOCETIRIZINE	1 (0.1)	6 (0.8)	7 (0.5)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 4 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
METOPROLOL	6 (0.8)	1 (0.1)	7 (0.5)
MONTELUKAST	5 (0.6)	2 (0.3)	7 (0.5)
NEBIVOLOL	3 (0.4)	4 (0.5)	7 (0.5)
VITAMIN D NOS	2 (0.3)	5 (0.7)	7 (0.5)
AMOXICILLIN;CLAVULANIC ACID	4 (0.5)	2 (0.3)	6 (0.4)
BUPROPION	6 (0.8)	0 (0.0)	6 (0.4)
CALCIUM;COLECALCIFEROL	4 (0.5)	2 (0.3)	6 (0.4)
DIPHENHYDRAMINE	0 (0.0)	6 (0.8)	6 (0.4)
FLUTICASONE;SALMETEROL	2 (0.3)	4 (0.5)	6 (0.4)
INSULIN ASPART	5 (0.6)	1 (0.1)	6 (0.4)
INSULIN GLARGINE	4 (0.5)	2 (0.3)	6 (0.4)
LIDOCAINE	3 (0.4)	3 (0.4)	6 (0.4)
LISINOPRIL	4 (0.5)	2 (0.3)	6 (0.4)
MAGNESIUM	2 (0.3)	4 (0.5)	6 (0.4)
METAMIZOLE	3 (0.4)	3 (0.4)	6 (0.4)
OXYCODONE	1 (0.1)	5 (0.7)	6 (0.4)
SULFADIAZINE	1 (0.1)	5 (0.7)	6 (0.4)
SUMATRIPTAN	1 (0.1)	5 (0.7)	6 (0.4)
TRANEXAMIC ACID	4 (0.5)	2 (0.3)	6 (0.4)
VALSARTAN	3 (0.4)	3 (0.4)	6 (0.4)
AMLODIPINE;VALSARTAN	4 (0.5)	1 (0.1)	5 (0.3)
BEPOTASTINE	3 (0.4)	2 (0.3)	5 (0.3)
BROTIZOLAM	3 (0.4)	2 (0.3)	5 (0.3)
CALCIUM CARBONATE	1 (0.1)	4 (0.5)	5 (0.3)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 5 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CELECOXIB	3 (0.4)	2 (0.3)	5 (0.3)
ESTAZOLAM	2 (0.3)	3 (0.4)	5 (0.3)
GLUCOSAMINE	2 (0.3)	3 (0.4)	5 (0.3)
LAMOTRIGINE	4 (0.5)	1 (0.1)	5 (0.3)
METHYLPREDNISOLONE	3 (0.4)	2 (0.3)	5 (0.3)
NIFEDIPINE	1 (0.1)	4 (0.5)	5 (0.3)
OLANZAPINE	3 (0.4)	2 (0.3)	5 (0.3)
OLMESARTAN	1 (0.1)	4 (0.5)	5 (0.3)
PREDNISOLONE	3 (0.4)	2 (0.3)	5 (0.3)
PREDNISONE	3 (0.4)	2 (0.3)	5 (0.3)
RANITIDINE	3 (0.4)	2 (0.3)	5 (0.3)
SALMETEROL	4 (0.5)	1 (0.1)	5 (0.3)
SENNOSIDE A+B	3 (0.4)	2 (0.3)	5 (0.3)
SIMVASTATIN	4 (0.5)	1 (0.1)	5 (0.3)
TERBUTALINE	3 (0.4)	2 (0.3)	5 (0.3)
TOPIRAMATE	3 (0.4)	2 (0.3)	5 (0.3)
VALACICLOVIR	5 (0.6)	0 (0.0)	5 (0.3)
VALPROIC ACID	3 (0.4)	2 (0.3)	5 (0.3)
VITAMIN B COMPLEX	2 (0.3)	3 (0.4)	5 (0.3)
ACETYLSALICYLIC ACID	3 (0.4)	1 (0.1)	4 (0.3)
AMBROXOL	1 (0.1)	3 (0.4)	4 (0.3)
AMFETAMINE;DEXAMFETAMINE	2 (0.3)	2 (0.3)	4 (0.3)
APRONAL;CAFFEINE;IBUPROFEN	2 (0.3)	2 (0.3)	4 (0.3)
ARIPIPRAZOLE	3 (0.4)	1 (0.1)	4 (0.3)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 6 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ASCORBIC ACID	3 (0.4)	1 (0.1)	4 (0.3)
BECLOMETASONE;FORMOTEROL	3 (0.4)	1 (0.1)	4 (0.3)
BETAHISTINE	2 (0.3)	2 (0.3)	4 (0.3)
BETAMETHASONE;CALCIPOTRIOL	2 (0.3)	2 (0.3)	4 (0.3)
BUTYLSCOPOLAMINE	2 (0.3)	2 (0.3)	4 (0.3)
CEFALEXIN	2 (0.3)	2 (0.3)	4 (0.3)
CODEINE	3 (0.4)	1 (0.1)	4 (0.3)
GLIPIZIDE	1 (0.1)	3 (0.4)	4 (0.3)
INSULIN NOS	2 (0.3)	2 (0.3)	4 (0.3)
MECOBALAMIN	3 (0.4)	1 (0.1)	4 (0.3)
METHOTREXATE	2 (0.3)	2 (0.3)	4 (0.3)
PARACETAMOL;TRAMADOL	2 (0.3)	2 (0.3)	4 (0.3)
POTASSIUM	2 (0.3)	2 (0.3)	4 (0.3)
PROCHLORPERAZINE	3 (0.4)	1 (0.1)	4 (0.3)
RABEPRAZOLE	2 (0.3)	2 (0.3)	4 (0.3)
REBAMIPIDE	2 (0.3)	2 (0.3)	4 (0.3)
TELMISARTAN	0 (0.0)	4 (0.5)	4 (0.3)
TEMAZEPAM	1 (0.1)	3 (0.4)	4 (0.3)
TOCOPHEROL	0 (0.0)	4 (0.5)	4 (0.3)
ZINC	1 (0.1)	3 (0.4)	4 (0.3)
ATENOLOL	1 (0.1)	2 (0.3)	3 (0.2)
BILASTINE	1 (0.1)	2 (0.3)	3 (0.2)
CAFFEINE;METAMIZOLE;ORPHENADRINE	2 (0.3)	1 (0.1)	3 (0.2)
CALCIUM	1 (0.1)	2 (0.3)	3 (0.2)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 7 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CALCIUM CARBONATE;COLECALCIFEROL	3 (0.4)	0 (0.0)	3 (0.2)
CARBAMAZEPINE	2 (0.3)	1 (0.1)	3 (0.2)
CARBOCISTEINE	2 (0.3)	1 (0.1)	3 (0.2)
CEFUROXIME	2 (0.3)	1 (0.1)	3 (0.2)
CLOBETASOL	2 (0.3)	1 (0.1)	3 (0.2)
CLONIDINE	2 (0.3)	1 (0.1)	3 (0.2)
CYCLOBENZAPRINE	1 (0.1)	2 (0.3)	3 (0.2)
DESLORATADINE	3 (0.4)	0 (0.0)	3 (0.2)
DESOXIMETASONE	1 (0.1)	2 (0.3)	3 (0.2)
DESVENLAFAXINE	2 (0.3)	1 (0.1)	3 (0.2)
DIFLUPREDNATE	2 (0.3)	1 (0.1)	3 (0.2)
ETIZOLAM	2 (0.3)	1 (0.1)	3 (0.2)
FAMOTIDINE	0 (0.0)	3 (0.4)	3 (0.2)
FLUNITRAZEPAM	3 (0.4)	0 (0.0)	3 (0.2)
HERBAL POLLEN NOS;TOCOPHEROL	1 (0.1)	2 (0.3)	3 (0.2)
HYDROCHLOROTHIAZIDE;LISINOPRIL	2 (0.3)	1 (0.1)	3 (0.2)
HYDROXYCHLOROQUINE	2 (0.3)	1 (0.1)	3 (0.2)
INSULIN DETEMIR	2 (0.3)	1 (0.1)	3 (0.2)
LOPERAMIDE	1 (0.1)	2 (0.3)	3 (0.2)
MACROGOL 3350	1 (0.1)	2 (0.3)	3 (0.2)
MELOXICAM	2 (0.3)	1 (0.1)	3 (0.2)
OXYBUTYNIN	0 (0.0)	3 (0.4)	3 (0.2)
OXYCODONE;PARACETAMOL	1 (0.1)	2 (0.3)	3 (0.2)
PIROXICAM	3 (0.4)	0 (0.0)	3 (0.2)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 8 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
PROPRANOLOL	2 (0.3)	1 (0.1)	3 (0.2)
PYRIDOXINE	1 (0.1)	2 (0.3)	3 (0.2)
RILMAZAFONE	2 (0.3)	1 (0.1)	3 (0.2)
SEMAGLUTIDE	1 (0.1)	2 (0.3)	3 (0.2)
SPIRONOLACTONE	1 (0.1)	2 (0.3)	3 (0.2)
TACROLIMUS	3 (0.4)	0 (0.0)	3 (0.2)
THIAMAZOLE	0 (0.0)	3 (0.4)	3 (0.2)
TRIAMCINOLONE	1 (0.1)	2 (0.3)	3 (0.2)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	1 (0.1)	2 (0.3)	3 (0.2)
URSODEOXYCHOLIC ACID	1 (0.1)	2 (0.3)	3 (0.2)
WHITE SOFT PARAFFIN	2 (0.3)	1 (0.1)	3 (0.2)
ZALTOPROFEN	2 (0.3)	1 (0.1)	3 (0.2)
ACETYLCYSTEINE	1 (0.1)	1 (0.1)	2 (0.1)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	1 (0.1)	1 (0.1)	2 (0.1)
ACETYLSALICYLIC ACID;HYDROTALCITE	1 (0.1)	1 (0.1)	2 (0.1)
ACICLOVIR	0 (0.0)	2 (0.3)	2 (0.1)
ALENDRONIC ACID	2 (0.3)	0 (0.0)	2 (0.1)
ALUMINIUM ACETATE;HYDROCORTISONE;LIDOCAINE;ZINC	0 (0.0)	2 (0.3)	2 (0.1)
AMLODIPINE;OLMESARTAN	0 (0.0)	2 (0.3)	2 (0.1)
AMOXICILLIN	1 (0.1)	1 (0.1)	2 (0.1)
AZELASTINE	2 (0.3)	0 (0.0)	2 (0.1)
AZITHROMYCIN	1 (0.1)	1 (0.1)	2 (0.1)
BACTERIA NOS;HYDROCORTISONE	2 (0.3)	0 (0.0)	2 (0.1)
BENZALKONIUM	2 (0.3)	0 (0.0)	2 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 9 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
BENZYLPENICILLIN	2 (0.3)	0 (0.0)	2 (0.1)
BIFIDOBACTERIUM NOS	1 (0.1)	1 (0.1)	2 (0.1)
BIMATOPROST	1 (0.1)	1 (0.1)	2 (0.1)
BISACODYL;SENNOSIDE A+B	2 (0.3)	0 (0.0)	2 (0.1)
BRINZOLAMIDE	1 (0.1)	1 (0.1)	2 (0.1)
BROMOPRIDE	1 (0.1)	1 (0.1)	2 (0.1)
BUDESONIDE	1 (0.1)	1 (0.1)	2 (0.1)
CANNABIS SATIVA	2 (0.3)	0 (0.0)	2 (0.1)
CHLORPHENAMINE	1 (0.1)	1 (0.1)	2 (0.1)
CHLORTALIDONE	1 (0.1)	1 (0.1)	2 (0.1)
CHONDROITIN	0 (0.0)	2 (0.3)	2 (0.1)
CHONDROITIN;GLUCOSAMINE	0 (0.0)	2 (0.3)	2 (0.1)
CICLESONIDE	2 (0.3)	0 (0.0)	2 (0.1)
CINNARIZINE	1 (0.1)	1 (0.1)	2 (0.1)
CLINDAMYCIN	1 (0.1)	1 (0.1)	2 (0.1)
CYANOCOBALAMIN	2 (0.3)	0 (0.0)	2 (0.1)
DAPAGLIFLOZIN	1 (0.1)	1 (0.1)	2 (0.1)
DENOSUMAB	1 (0.1)	1 (0.1)	2 (0.1)
DESONIDE	1 (0.1)	1 (0.1)	2 (0.1)
DEXAMETHASONE	2 (0.3)	0 (0.0)	2 (0.1)
DEXKETOPROFEN	1 (0.1)	1 (0.1)	2 (0.1)
DEXLANSOPRAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
DIFLUCORTOLONE	1 (0.1)	1 (0.1)	2 (0.1)
DOCUSATE	2 (0.3)	0 (0.0)	2 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 10 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
DOXEPIN	0 (0.0)	2 (0.3)	2 (0.1)
DOXYCYCLINE	0 (0.0)	2 (0.3)	2 (0.1)
ERGOCALCIFEROL	0 (0.0)	2 (0.3)	2 (0.1)
ESCHERICHIA COLI;HYDROCORTISONE	2 (0.3)	0 (0.0)	2 (0.1)
ESZOPICLONE	1 (0.1)	1 (0.1)	2 (0.1)
FENOFIBRATE	2 (0.3)	0 (0.0)	2 (0.1)
FENOTEROL	1 (0.1)	1 (0.1)	2 (0.1)
FERUMOXYTOL	1 (0.1)	1 (0.1)	2 (0.1)
FLUCONAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
FLUOCINONIDE	0 (0.0)	2 (0.3)	2 (0.1)
FUSIDIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
GENTAMICIN	0 (0.0)	2 (0.3)	2 (0.1)
GINKGO BILOBA	1 (0.1)	1 (0.1)	2 (0.1)
GLYCYRRHIZIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
HYDROCHLOROTHIAZIDE;VALSARTAN	1 (0.1)	1 (0.1)	2 (0.1)
HYDROCODONE;PARACETAMOL	1 (0.1)	1 (0.1)	2 (0.1)
HYDROXYZINE	1 (0.1)	1 (0.1)	2 (0.1)
HYPROMELLOSE	1 (0.1)	1 (0.1)	2 (0.1)
INSULIN DEGLUDEC	0 (0.0)	2 (0.3)	2 (0.1)
INSULIN LISPRO	1 (0.1)	1 (0.1)	2 (0.1)
IODINE	2 (0.3)	0 (0.0)	2 (0.1)
IRBESARTAN	1 (0.1)	1 (0.1)	2 (0.1)
KETOROLAC	1 (0.1)	1 (0.1)	2 (0.1)
LACTULOSE	2 (0.3)	0 (0.0)	2 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 11 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
LEVOFLOXACIN	1 (0.1)	1 (0.1)	2 (0.1)
LIRAGLUTIDE	1 (0.1)	1 (0.1)	2 (0.1)
MAGNOLIA SPP.;PERILLA FRUTESCENS VAR. CRISPA;PINELLIA TERNATA;PORIA COCOS;ZINGIBER OFFICINALE	1 (0.1)	1 (0.1)	2 (0.1)
MESALAZINE	1 (0.1)	1 (0.1)	2 (0.1)
METFORMIN;VILDAGLIPTIN	1 (0.1)	1 (0.1)	2 (0.1)
MICONAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
MORPHINE	1 (0.1)	1 (0.1)	2 (0.1)
NITROFURANTOIN	2 (0.3)	0 (0.0)	2 (0.1)
OENOTHERA BIENNIS	1 (0.1)	1 (0.1)	2 (0.1)
OFLOXACIN	2 (0.3)	0 (0.0)	2 (0.1)
OLEA EUROPAEA	1 (0.1)	1 (0.1)	2 (0.1)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	1 (0.1)	1 (0.1)	2 (0.1)
OSMOTICALLY ACTING LAXATIVES	1 (0.1)	1 (0.1)	2 (0.1)
OTHER EMOLLIENTS AND PROTECTIVES	1 (0.1)	1 (0.1)	2 (0.1)
PERINDOPRIL	2 (0.3)	0 (0.0)	2 (0.1)
PHENYLEPHRINE	0 (0.0)	2 (0.3)	2 (0.1)
PIOGLITAZONE	1 (0.1)	1 (0.1)	2 (0.1)
POLAPREZINC	1 (0.1)	1 (0.1)	2 (0.1)
PRAMIPEXOLE	2 (0.3)	0 (0.0)	2 (0.1)
PROMETHAZINE	1 (0.1)	1 (0.1)	2 (0.1)
PSEUDOEPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
RAMELTEON	1 (0.1)	1 (0.1)	2 (0.1)
RISEDRONIC ACID	1 (0.1)	1 (0.1)	2 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
RUPATADINE	1 (0.1)	1 (0.1)	2 (0.1)
SENNA ALEXANDRINA	2 (0.3)	0 (0.0)	2 (0.1)
SENNA SPP.	2 (0.3)	0 (0.0)	2 (0.1)
SILYBUM MARIANUM	1 (0.1)	1 (0.1)	2 (0.1)
SITAGLIPTIN	1 (0.1)	1 (0.1)	2 (0.1)
SUVOREXANT	1 (0.1)	1 (0.1)	2 (0.1)
TETRACYCLINE	0 (0.0)	2 (0.3)	2 (0.1)
TIPEPIDINE	2 (0.3)	0 (0.0)	2 (0.1)
TORASEMIDE	2 (0.3)	0 (0.0)	2 (0.1)
UREA	0 (0.0)	2 (0.3)	2 (0.1)
VILDAGLIPTIN	2 (0.3)	0 (0.0)	2 (0.1)
ZONISAMIDE	1 (0.1)	1 (0.1)	2 (0.1)
2-AMINOETHYL DIHYDROGEN PHOSPHATE CALCIUM	1 (0.1)	0 (0.0)	1 (0.1)
ABATACEPT	1 (0.1)	0 (0.0)	1 (0.1)
ACECLOFENAC	0 (0.0)	1 (0.1)	1 (0.1)
ACETYLSALICYLIC ACID;ALUMINIUM GLYCINATE;MAGNESIUM CARBONATE	0 (0.0)	1 (0.1)	1 (0.1)
ACHYRANTHES BIDENTATA;ACONITUM SPP.;ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;CORNUS OFFICINALIS;DIOSCOREA SPP.;NEOLITSEA CASSIA;PAEONIA X SUFFRUTICOSA;PLANTAGO ASIATICA;PORIA COCOS;	0 (0.0)	1 (0.1)	1 (0.1)
ACONITUM SPP.	1 (0.1)	0 (0.0)	1 (0.1)
ACTAEA RACEMOSA;ARNICA MONTANA;GLYCERYL TRINITRATE;LACHESIS MUTA;SANGUINARIA CANADENSIS	1 (0.1)	0 (0.0)	1 (0.1)
ADENINE;BIFENDATE;CARNITINE;CYANOCOBALAMIN;LIVER;PYRIDOXINE;RIBOFLAVIN	0 (0.0)	1 (0.1)	1 (0.1)
ADENOSINE	0 (0.0)	1 (0.1)	1 (0.1)
AESCULUS HIPPOCASTANUM	1 (0.1)	0 (0.0)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	1 (0.1)	0 (0.0)	1 (0.1)
AKEBIA SPP.;ANGELICA ACUTILOBA;BIANCAEA SAPPAN;CARTHAMUS TINCTORIUS;CITRUS RETICULATA;CITRUS SPP.;GLYCYRRHIZA SPP.;MAGNOLIA SPP.;RHEUM SPP.;SODIUM SULFATE	1 (0.1)	0 (0.0)	1 (0.1)
ALBUMIN TANNATE	1 (0.1)	0 (0.0)	1 (0.1)
ALFACALCIDOL	0 (0.0)	1 (0.1)	1 (0.1)
ALGINIC ACID;CALCIUM CARBONATE;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
ALGINIC ACID;POTASSIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
ALGINIC ACID;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ATRACTYLODES SPP.;NEOLITSEA CASSIA;POLYPORUS UMBELLATUS;PORIA COCOS	1 (0.1)	0 (0.0)	1 (0.1)
ALLANTOIN;COAL TAR	1 (0.1)	0 (0.0)	1 (0.1)
ALMOTRIPTAN	1 (0.1)	0 (0.0)	1 (0.1)
ALUMINIUM HYDROXIDE;CALCIUM CARBONATE;MAGNESIUM CARBONATE;OXETACAINE	0 (0.0)	1 (0.1)	1 (0.1)
ALUMINIUM SILICATE	1 (0.1)	0 (0.0)	1 (0.1)
AMFETAMINE	1 (0.1)	0 (0.0)	1 (0.1)
AMINO ACIDS NOS;AMINOBENZOIC ACID;ASCORBIC ACID;BETAINE;BIOFLAVONOIDS NOS;BIOTIN;CHOLINE;DEOXYRIBONUCLEIC ACID;EQUISETUM ARVENSE;FOLIC ACID;INOSITOL;LECITHIN;MACROCYSTIS PYRIFERA;MINERALS NOS;	1 (0.1)	0 (0.0)	1 (0.1)
AMINOPHYLLINE;CHLORPHENAMINE;METHOXYPHENAMINE;NOSCAPINE	0 (0.0)	1 (0.1)	1 (0.1)
AMLODIPINE;ATENOLOL	0 (0.0)	1 (0.1)	1 (0.1)
AMLODIPINE;HYDROCHLOROTHIAZIDE;VALSARTAN	1 (0.1)	0 (0.0)	1 (0.1)
AMLODIPINE;LOSARTAN	1 (0.1)	0 (0.0)	1 (0.1)
AMLODIPINE;TELMISARTAN	0 (0.0)	1 (0.1)	1 (0.1)
AMMONIUM CHLORIDE;CHLORPHENAMINE;DEXTROMETHORPHAN;METHYLEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
AMOXICILLIN;CLARITHROMYCIN;LANSOPRAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
ANILIDES	1 (0.1)	0 (0.0)	1 (0.1)
APRONAL;CAFFEINE;IBUPROFEN;MAGNESIUM OXIDE	1 (0.1)	0 (0.0)	1 (0.1)
APRONAL;CAFFEINE;PARACETAMOL;PROPYPHENAZONE	0 (0.0)	1 (0.1)	1 (0.1)
ARCTIUM LAPPA;CICADA SLOUGH;EPHEDRA SPP.;ERIOBOTRYA JAPONICA;KITAGAWIA PRAERUPTORA;PERILLA FRUTESCENS;PHERETIMA SPP.;SCHISANDRA CHINENSIS	0 (0.0)	1 (0.1)	1 (0.1)
ARECA CATECHU;CITRUS SPP.;DOLOMIAEA COSTUS;GLYCYRRHIZA SPP.;MAGNOLIA SPP.;NEOLITSEA CASSIA;PERILLA FRUTESCENS VAR. CRISPA;PORIA COCOS;RHEUM SPP.;TETRADIUM RUTICARPUM;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;IRON	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
ATOMOXETINE	0 (0.0)	1 (0.1)	1 (0.1)
ATORVASTATIN;EZETIMIBE	0 (0.0)	1 (0.1)	1 (0.1)
ATORVASTATIN;METFORMIN	0 (0.0)	1 (0.1)	1 (0.1)
ATROPA BELLA-DONNA;CAFFEINE;CARBINOXAMINE;LYSOZYME;PSEUDOEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.1)
ATROPA BELLA-DONNA;CAFFEINE;GLYCYRRHIZIC ACID;MEQUITAZINE;METHYLEPHEDRINE;PSEUDOEPHEDRINE	0 (0.0)	1 (0.1)	1 (0.1)
AZELASTINE;FLUTICASONE	1 (0.1)	0 (0.0)	1 (0.1)
AZELNIDIPINE	1 (0.1)	0 (0.0)	1 (0.1)
AZILSARTAN	0 (0.0)	1 (0.1)	1 (0.1)
BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS	1 (0.1)	0 (0.0)	1 (0.1)
BACILLUS SUBTILIS;BACTERIA NOS;CALCIUM CARBONATE;CINNAMOMUM SPP.;DIMETICONE;FOENICULUM VULGARE;MAGNESIUM CARBONATE;SWERTIA SPP.;VITAMIN U	0 (0.0)	1 (0.1)	1 (0.1)
BACITRACIN;NEOMYCIN	0 (0.0)	1 (0.1)	1 (0.1)

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/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Medical History Event

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BASIC FIBROBLAST GROWTH FACTOR	0 (0.0)	1 (0.1)	1 (0.1)
BECLOMETASONE	1 (0.1)	0 (0.0)	1 (0.1)
BEESWAX;CETYL PALMITATE;LIGHT LIQUID PARAFFIN	1 (0.1)	0 (0.0)	1 (0.1)
BENPROPERINE	0 (0.0)	1 (0.1)	1 (0.1)
BENZOCAINE;DODECLONIUM;ENOXOLONE;ESCULOSIDE	0 (0.0)	1 (0.1)	1 (0.1)
BENZONATATE	1 (0.1)	0 (0.0)	1 (0.1)
BENZYDAMINE	0 (0.0)	1 (0.1)	1 (0.1)
BETAMETHASONE;DEXCHLORPHENIRAMINE	0 (0.0)	1 (0.1)	1 (0.1)
BETHANECHOL	1 (0.1)	0 (0.0)	1 (0.1)
BICYCLOL	0 (0.0)	1 (0.1)	1 (0.1)
BIMATOPROST;TIMOLOL	1 (0.1)	0 (0.0)	1 (0.1)
BIOFLAVONOIDS NOS	1 (0.1)	0 (0.0)	1 (0.1)
BISACODYL	1 (0.1)	0 (0.0)	1 (0.1)
BLUMEA BALSAMIFERA;BORNEOL;MENTHA CANADENSIS;MENTHOL	0 (0.0)	1 (0.1)	1 (0.1)
BORON	1 (0.1)	0 (0.0)	1 (0.1)
BRIMONIDINE	1 (0.1)	0 (0.0)	1 (0.1)
BRIVARACETAM	1 (0.1)	0 (0.0)	1 (0.1)
BROMELAINS;CHYMOTRYPSIN;PANCREATIN;PAPAIN;RUTOSIDE;TRYPSIN	1 (0.1)	0 (0.0)	1 (0.1)
BROMELAINS;CYSTEINE	0 (0.0)	1 (0.1)	1 (0.1)
BROMHEXINE	1 (0.1)	0 (0.0)	1 (0.1)
BUCLADESINE	0 (0.0)	1 (0.1)	1 (0.1)
BUPRENORPHINE	0 (0.0)	1 (0.1)	1 (0.1)
BUSPIRONE	1 (0.1)	0 (0.0)	1 (0.1)
BUTALBITAL;CAFFEINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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CAFFEINE;CODEINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
CALCIFEDIOL	1 (0.1)	0 (0.0)	1 (0.1)
CALCIPOTRIOL	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM CARBONATE;MAGNESIUM CARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM CHLORIDE;POTASSIUM;SODIUM LACTATE	0 (0.0)	1 (0.1)	1 (0.1)
CALCIUM SULFATE;EPHEDRA SPP.;GLYCYRRHIZA SPP.;MORUS ALBA;PRUNUS SPP.	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM;VITAMIN D NOS	0 (0.0)	1 (0.1)	1 (0.1)
CAMOSTAT	1 (0.1)	0 (0.0)	1 (0.1)
CAMPHOR;CHLORPHENAMINE;HEXACHLOROPHENE;LIDOCAINE;MENTHOL;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
CANNABINOL	1 (0.1)	0 (0.0)	1 (0.1)
CANRENOIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
CARBIDOPA;LEVODOPA	1 (0.1)	0 (0.0)	1 (0.1)
CARBIMAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
CARBOMER	0 (0.0)	1 (0.1)	1 (0.1)
CARMELLOSE	1 (0.1)	0 (0.0)	1 (0.1)
CEFACLOR	1 (0.1)	0 (0.0)	1 (0.1)
CEFADROXIL	1 (0.1)	0 (0.0)	1 (0.1)
CEFAZOLIN	0 (0.0)	1 (0.1)	1 (0.1)
CEFDINIR	1 (0.1)	0 (0.0)	1 (0.1)
CELIPROLOL	1 (0.1)	0 (0.0)	1 (0.1)
CENTELLA ASIATICA	1 (0.1)	0 (0.0)	1 (0.1)
CEPHARANTHINE	0 (0.0)	1 (0.1)	1 (0.1)
CETOMACROGOL	0 (0.0)	1 (0.1)	1 (0.1)
CHELIDONIUM MAJUS	1 (0.1)	0 (0.0)	1 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CHENODEOXYCHOLIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;NAPHAZOLINE	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;PARACETAMOL;PHENYLEPHRINE	0 (0.0)	1 (0.1)	1 (0.1)
CHLORPHENAMINE;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPROTHIXENE	0 (0.0)	1 (0.1)	1 (0.1)
CHLORZOXAZONE	1 (0.1)	0 (0.0)	1 (0.1)
CHONDROITIN;GLUCOSAMINE;METHYLSULFONYLMETHANE	0 (0.0)	1 (0.1)	1 (0.1)
CHRYSANTHEMUM INDICUM;CLONIDINE;CONCHA MARGARITIFERA;HYDROCHLOROTHIAZIDE;RUTOSIDE	0 (0.0)	1 (0.1)	1 (0.1)
CILAZAPRIL	0 (0.0)	1 (0.1)	1 (0.1)
CIMETIDINE	1 (0.1)	0 (0.0)	1 (0.1)
CINCHOCAINE;CLEMIZOLE;FLUOCORTOLONE	1 (0.1)	0 (0.0)	1 (0.1)
CINCHOCAINE;ESCULOSIDE;HYDROCORTISONE;NEOMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
CINEOLE;DIPENTEN;PINENE	0 (0.0)	1 (0.1)	1 (0.1)
CIPROFIBRATE	1 (0.1)	0 (0.0)	1 (0.1)
CITRUS MAXIMA;DELPHINIUM GRANDIFLORUM;GLYCYRRHIZA SPP.;PINELLIA TERNATA;PORIA COCOS;PRUNUS SPP.;SCHISANDRA CHINENSIS;VINCETOXICUM STAUNTONII	0 (0.0)	1 (0.1)	1 (0.1)
CLAVULANIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
CLOBAZAM	1 (0.1)	0 (0.0)	1 (0.1)
CLOPERASTINE	0 (0.0)	1 (0.1)	1 (0.1)
CLOTRIMAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
COLESTIPOL	0 (0.0)	1 (0.1)	1 (0.1)
COLESTYRAMINE	0 (0.0)	1 (0.1)	1 (0.1)
COLLAGEN;LIDOCAINE	0 (0.0)	1 (0.1)	1 (0.1)
CONTACT LAXATIVES	0 (0.0)	1 (0.1)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CORTICOSTEROIDS	0 (0.0)	1 (0.1)	1 (0.1)
CORTICOSTEROIDS, PLAIN	0 (0.0)	1 (0.1)	1 (0.1)
CROCUS SATIVUS	0 (0.0)	1 (0.1)	1 (0.1)
CROMOGLICIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
CROMOGLICIC ACID;REPROTEROL	0 (0.0)	1 (0.1)	1 (0.1)
CURCUMA LONGA;MAGNESIUM	0 (0.0)	1 (0.1)	1 (0.1)
CYANOCOBALAMIN;DICLOFENAC;PYRIDOXINE;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
CYANOCOBALAMIN;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
CYANOCOBALAMIN;PYRIDOXINE;THIAMINE	1 (0.1)	0 (0.0)	1 (0.1)
DELORAZEPAM	0 (0.0)	1 (0.1)	1 (0.1)
DEXAMETHASONE;TOBRAMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
DEXCHLORPHENIRAMINE	0 (0.0)	1 (0.1)	1 (0.1)
DEXIBUPROFEN	1 (0.1)	0 (0.0)	1 (0.1)
DEXPANTHENOL	1 (0.1)	0 (0.0)	1 (0.1)
DEXTROMETHORPHAN	1 (0.1)	0 (0.0)	1 (0.1)
DIACEREIN	1 (0.1)	0 (0.0)	1 (0.1)
DIFENIDOL	0 (0.0)	1 (0.1)	1 (0.1)
DIFLORASONE	0 (0.0)	1 (0.1)	1 (0.1)
DIFLUCORTOLONE;LIDOCAINE	0 (0.0)	1 (0.1)	1 (0.1)
DIMETICONE	1 (0.1)	0 (0.0)	1 (0.1)
DIOSMIN	0 (0.0)	1 (0.1)	1 (0.1)
DIPHENHYDRAMINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
DL- LACTIC ACID;HYDROCORTISONE;SODIUM PIDOLATE	1 (0.1)	0 (0.0)	1 (0.1)
DOBESILIC ACID	1 (0.1)	0 (0.0)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 19 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
DOCUSATE;SENNOSIDE A+B	0 (0.0)	1 (0.1)	1 (0.1)
DOMPERIDONE	0 (0.0)	1 (0.1)	1 (0.1)
DORZOLAMIDE;TIMOLOL	1 (0.1)	0 (0.0)	1 (0.1)
EBASTINE	1 (0.1)	0 (0.0)	1 (0.1)
ECONAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
EFINACONAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
ELBASVIR;GRAZOPREVIR	0 (0.0)	1 (0.1)	1 (0.1)
ELETRIPTAN	0 (0.0)	1 (0.1)	1 (0.1)
ENALAPRIL;HYDROCHLOROTHIAZIDE	0 (0.0)	1 (0.1)	1 (0.1)
EOSINE	1 (0.1)	0 (0.0)	1 (0.1)
EPERISONE	0 (0.0)	1 (0.1)	1 (0.1)
EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PUERARIA MONTANA VAR. LOBATA;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	0 (0.0)	1 (0.1)	1 (0.1)
ERGOTAMINE	0 (0.0)	1 (0.1)	1 (0.1)
ESTRADIOL	1 (0.1)	0 (0.0)	1 (0.1)
ESTRIOL	0 (0.0)	1 (0.1)	1 (0.1)
ETHOSUXIMIDE	1 (0.1)	0 (0.0)	1 (0.1)
ETOFENAMATE	1 (0.1)	0 (0.0)	1 (0.1)
ETORICOXIB	0 (0.0)	1 (0.1)	1 (0.1)
EXENATIDE	1 (0.1)	0 (0.0)	1 (0.1)
EZETIMIBE	0 (0.0)	1 (0.1)	1 (0.1)
FENTANYL	1 (0.1)	0 (0.0)	1 (0.1)
FERULA ASSA-FOETIDA;GENTIANA LUTEA;HUMULUS LUPULUS;VALERIANA OFFICINALIS	0 (0.0)	1 (0.1)	1 (0.1)
FESOTERODINE	1 (0.1)	0 (0.0)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
FEXOFENADINE;PSEUDOEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.1)
FLECAINIDE	1 (0.1)	0 (0.0)	1 (0.1)
FLUDROCORTISONE	1 (0.1)	0 (0.0)	1 (0.1)
FLUNARIZINE	1 (0.1)	0 (0.0)	1 (0.1)
FLUOCINOLONE ACETONIDE	1 (0.1)	0 (0.0)	1 (0.1)
FLUOROMETHOLONE	0 (0.0)	1 (0.1)	1 (0.1)
FLUOROMETHOLONE;TETRYZOLINE	1 (0.1)	0 (0.0)	1 (0.1)
FLURBIPROFEN	1 (0.1)	0 (0.0)	1 (0.1)
FLUTICASONE;VILANTEROL	1 (0.1)	0 (0.0)	1 (0.1)
FORMOTEROL	1 (0.1)	0 (0.0)	1 (0.1)
FOSFOMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
FROVATRIPTAN	1 (0.1)	0 (0.0)	1 (0.1)
FUDOSTEINE	0 (0.0)	1 (0.1)	1 (0.1)
GLATIRAMER	1 (0.1)	0 (0.0)	1 (0.1)
GLICLAZIDE	0 (0.0)	1 (0.1)	1 (0.1)
GLIMEPIRIDE	0 (0.0)	1 (0.1)	1 (0.1)
GLUCOCORTICOIDS	1 (0.1)	0 (0.0)	1 (0.1)
GLYCEROL	1 (0.1)	0 (0.0)	1 (0.1)
GLYCYRRHIZA SPP.;RHEUM SPP.	0 (0.0)	1 (0.1)	1 (0.1)
GRANULOCYTE COLONY STIMULATING FACTOR	0 (0.0)	1 (0.1)	1 (0.1)
GUAIFENESIN	0 (0.0)	1 (0.1)	1 (0.1)
HEPARINS OR HEPARINOIDS FOR TOPICAL USE	1 (0.1)	0 (0.0)	1 (0.1)
HIDROSMIN	1 (0.1)	0 (0.0)	1 (0.1)
HOMOCHLORCYCLIZINE	0 (0.0)	1 (0.1)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
HYDRALAZINE	1 (0.1)	0 (0.0)	1 (0.1)
HYDROCHLOROTHIAZIDE;IRBESARTAN	1 (0.1)	0 (0.0)	1 (0.1)
HYDROCHLOROTHIAZIDE;LOSARTAN	1 (0.1)	0 (0.0)	1 (0.1)
HYDROCHLOROTHIAZIDE;OLMESARTAN	0 (0.0)	1 (0.1)	1 (0.1)
HYDROCHLOROTHIAZIDE;TRIAMTERENE	1 (0.1)	0 (0.0)	1 (0.1)
HYDROCORTISONE;MICONAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
HYOSCYAMINE	0 (0.0)	1 (0.1)	1 (0.1)
HYOSCYAMINE;METHENAMINE;METHYLTHIONINIUM;PHENYL SALICYLATE;SODIUM PHOSPHATE	1 (0.1)	0 (0.0)	1 (0.1)
IMIDAFENACIN	1 (0.1)	0 (0.0)	1 (0.1)
INDAPAMIDE	0 (0.0)	1 (0.1)	1 (0.1)
INDAPAMIDE;PERINDOPRIL	1 (0.1)	0 (0.0)	1 (0.1)
IODINE;LEVOTHYROXINE	0 (0.0)	1 (0.1)	1 (0.1)
IRON IN OTHER COMBINATIONS	0 (0.0)	1 (0.1)	1 (0.1)
ITOPRIDE	1 (0.1)	0 (0.0)	1 (0.1)
IVABRADINE	1 (0.1)	0 (0.0)	1 (0.1)
IVERMECTIN	1 (0.1)	0 (0.0)	1 (0.1)
KETOCONAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
L-CARBOCISTEINE	0 (0.0)	1 (0.1)	1 (0.1)
LACOSAMIDE	1 (0.1)	0 (0.0)	1 (0.1)
LACTOBACILLUS NOS	0 (0.0)	1 (0.1)	1 (0.1)
LACTOBACILLUS REUTERI;LACTOBACILLUS RHAMNOSUS	0 (0.0)	1 (0.1)	1 (0.1)
LATANOPROST	0 (0.0)	1 (0.1)	1 (0.1)
LEFLUNOMIDE	1 (0.1)	0 (0.0)	1 (0.1)
LERCANIDIPINE	0 (0.0)	1 (0.1)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
LEVAMLODIPINE	0 (0.0)	1 (0.1)	1 (0.1)
LEVETIRACETAM	1 (0.1)	0 (0.0)	1 (0.1)
LEVOGLUTAMIDE	1 (0.1)	0 (0.0)	1 (0.1)
LEVOSALBUTAMOL	0 (0.0)	1 (0.1)	1 (0.1)
LISDEXAMFETAMINE	0 (0.0)	1 (0.1)	1 (0.1)
LIVER THERAPY	1 (0.1)	0 (0.0)	1 (0.1)
LORMETAZEPAM	1 (0.1)	0 (0.0)	1 (0.1)
LOXAPINE	1 (0.1)	0 (0.0)	1 (0.1)
MACROGOL 3350;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.1)
MACROGOL 4000	0 (0.0)	1 (0.1)	1 (0.1)
MACROGOL 400;PROPYLENE GLYCOL	1 (0.1)	0 (0.0)	1 (0.1)
MAGNESIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.1)
MAGNESIUM HYDROXIDE	1 (0.1)	0 (0.0)	1 (0.1)
MENTHOL	0 (0.0)	1 (0.1)	1 (0.1)
MEQUITAZINE	0 (0.0)	1 (0.1)	1 (0.1)
METAXALONE	0 (0.0)	1 (0.1)	1 (0.1)
METFORMIN;ROSUVASTATIN	0 (0.0)	1 (0.1)	1 (0.1)
METFORMIN;SITAGLIPTIN	0 (0.0)	1 (0.1)	1 (0.1)
METHADONE	0 (0.0)	1 (0.1)	1 (0.1)
METHOCARBAMOL	0 (0.0)	1 (0.1)	1 (0.1)
METHYLDOPA	0 (0.0)	1 (0.1)	1 (0.1)
METHYLPHENIDATE	1 (0.1)	0 (0.0)	1 (0.1)
METRONIDAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
MINOCYCLINE	0 (0.0)	1 (0.1)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
MIRABEGRON	0 (0.0)	1 (0.1)	1 (0.1)
MITIGLINIDE	1 (0.1)	0 (0.0)	1 (0.1)
MODAFINIL	0 (0.0)	1 (0.1)	1 (0.1)
MOSAPRIDE	0 (0.0)	1 (0.1)	1 (0.1)
MOXONIDINE	0 (0.0)	1 (0.1)	1 (0.1)
MUCOLYTICS	0 (0.0)	1 (0.1)	1 (0.1)
MUPIROCIN	1 (0.1)	0 (0.0)	1 (0.1)
NAFTAZONE	1 (0.1)	0 (0.0)	1 (0.1)
NALBUPHINE	0 (0.0)	1 (0.1)	1 (0.1)
NALOXONE	0 (0.0)	1 (0.1)	1 (0.1)
NALOXONE;OXYCODONE	0 (0.0)	1 (0.1)	1 (0.1)
NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;PRUNUS SPP.	1 (0.1)	0 (0.0)	1 (0.1)
NICARDIPINE	0 (0.0)	1 (0.1)	1 (0.1)
NORFLOXACIN	1 (0.1)	0 (0.0)	1 (0.1)
NORTRIPTYLINE	1 (0.1)	0 (0.0)	1 (0.1)
NYSTATIN;TRIAMCINOLONE	1 (0.1)	0 (0.0)	1 (0.1)
OMEGA-3-ACID ETHYL ESTER	0 (0.0)	1 (0.1)	1 (0.1)
OMEPRAZOLE;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
OTHER ANTIBACTERIALS	0 (0.0)	1 (0.1)	1 (0.1)
OTHER HYPNOTICS AND SEDATIVES	0 (0.0)	1 (0.1)	1 (0.1)
OTHER MINERAL PRODUCTS	1 (0.1)	0 (0.0)	1 (0.1)
OTHER NERVOUS SYSTEM DRUGS	0 (0.0)	1 (0.1)	1 (0.1)
OTHER OPHTHALMOLOGICALS	1 (0.1)	0 (0.0)	1 (0.1)
OXAZEPAM	0 (0.0)	1 (0.1)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
OXAZOLAM	0 (0.0)	1 (0.1)	1 (0.1)
OXCARBAZEPINE	0 (0.0)	1 (0.1)	1 (0.1)
OXICONAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
OXYTETRACYCLINE	0 (0.0)	1 (0.1)	1 (0.1)
PANAX GINSENG;TETRADIUM RUTICARPUM;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	0 (0.0)	1 (0.1)	1 (0.1)
PARAFFIN NOS	0 (0.0)	1 (0.1)	1 (0.1)
PEGYLATED GRANULOCYTE COLONY STIMULATING FACTOR	0 (0.0)	1 (0.1)	1 (0.1)
PELUBIPROFEN	1 (0.1)	0 (0.0)	1 (0.1)
PEMIROLAST	1 (0.1)	0 (0.0)	1 (0.1)
PENICILLIN NOS	1 (0.1)	0 (0.0)	1 (0.1)
PHENAZOPYRIDINE	0 (0.0)	1 (0.1)	1 (0.1)
PIPRINHYDRINATE	0 (0.0)	1 (0.1)	1 (0.1)
PIRENOXINE	1 (0.1)	0 (0.0)	1 (0.1)
PITAVASTATIN	0 (0.0)	1 (0.1)	1 (0.1)
PLANTAGO AFRA;SODIUM CHLORIDE;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
PLANTAGO OVATA	0 (0.0)	1 (0.1)	1 (0.1)
POTASSIUM BITARTRATE;SODIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.1)
PRANLUKAST	1 (0.1)	0 (0.0)	1 (0.1)
PRAVASTATIN	1 (0.1)	0 (0.0)	1 (0.1)
PREDNICARBATE	1 (0.1)	0 (0.0)	1 (0.1)
PRISTINAMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
PROPIOMAZINE	0 (0.0)	1 (0.1)	1 (0.1)
PROPIVERINE	0 (0.0)	1 (0.1)	1 (0.1)
PROPYLTHIOURACIL	1 (0.1)	0 (0.0)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 25 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
PSEUDOEPHEDRINE;TRIPROLIDINE	1 (0.1)	0 (0.0)	1 (0.1)
RADIUM BROMIDE	1 (0.1)	0 (0.0)	1 (0.1)
REPAGLINIDE	1 (0.1)	0 (0.0)	1 (0.1)
RIPASUDIL	1 (0.1)	0 (0.0)	1 (0.1)
RISPERIDONE	1 (0.1)	0 (0.0)	1 (0.1)
RITUXIMAB	1 (0.1)	0 (0.0)	1 (0.1)
RIZATRIPTAN	0 (0.0)	1 (0.1)	1 (0.1)
RUTA GRAVEOLENS	1 (0.1)	0 (0.0)	1 (0.1)
SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
SAXAGLIPTIN	1 (0.1)	0 (0.0)	1 (0.1)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	0 (0.0)	1 (0.1)	1 (0.1)
SILICON	1 (0.1)	0 (0.0)	1 (0.1)
SODIUM CITRATE;SODIUM LAURYL SULFOACETATE;SORBITOL	0 (0.0)	1 (0.1)	1 (0.1)
STERCULIA URENS	0 (0.0)	1 (0.1)	1 (0.1)
STEROIDS	0 (0.0)	1 (0.1)	1 (0.1)
SUBSTITUTED ALKYLAMINES	1 (0.1)	0 (0.0)	1 (0.1)
SUCRALFATE	1 (0.1)	0 (0.0)	1 (0.1)
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 (0.1)	0 (0.0)	1 (0.1)
SULFASALAZINE	1 (0.1)	0 (0.0)	1 (0.1)
SULGLICOTIDE	1 (0.1)	0 (0.0)	1 (0.1)
SULODEXIDE	1 (0.1)	0 (0.0)	1 (0.1)
TAFLUPROST	1 (0.1)	0 (0.0)	1 (0.1)
TAFLUPROST;TIMOLOL	1 (0.1)	0 (0.0)	1 (0.1)
TALNIFLUMATE	0 (0.0)	1 (0.1)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 26 of 26
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
TAPENTADOL	0 (0.0)	1 (0.1)	1 (0.1)
TAURINE	1 (0.1)	0 (0.0)	1 (0.1)
TENELIGLIPTIN	0 (0.0)	1 (0.1)	1 (0.1)
TERAZOSIN	0 (0.0)	1 (0.1)	1 (0.1)
TERBINAFINE	0 (0.0)	1 (0.1)	1 (0.1)
THIOCTIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
THYROID	1 (0.1)	0 (0.0)	1 (0.1)
TIANEPTINE	0 (0.0)	1 (0.1)	1 (0.1)
TINZAPARIN	0 (0.0)	1 (0.1)	1 (0.1)
TOXICODENDRON PUBESCENS	1 (0.1)	0 (0.0)	1 (0.1)
TRAVOPROST	1 (0.1)	0 (0.0)	1 (0.1)
TRIAZOLAM	0 (0.0)	1 (0.1)	1 (0.1)
TRIBENOSIDE	0 (0.0)	1 (0.1)	1 (0.1)
TRIMETAZIDINE	1 (0.1)	0 (0.0)	1 (0.1)
TROLAMINE	0 (0.0)	1 (0.1)	1 (0.1)
VALERIANA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.1)
VERAPAMIL	1 (0.1)	0 (0.0)	1 (0.1)
VITAMINS WITH MINERALS	1 (0.1)	0 (0.0)	1 (0.1)
VORTIOXETINE	1 (0.1)	0 (0.0)	1 (0.1)
WARFARIN	1 (0.1)	0 (0.0)	1 (0.1)
ZAFIRLUKAST	1 (0.1)	0 (0.0)	1 (0.1)
ZOLMITRIPTAN	0 (0.0)	1 (0.1)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 1 of 1
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Primary Study Condition

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
Subjects with >= 1 Medication	3 (0.4)	3 (0.4)	6 (0.4)
OXYCODONE	2 (0.3)	1 (0.1)	3 (0.2)
TRAMADOL	1 (0.1)	1 (0.1)	2 (0.1)
HYDROMORPHONE	0 (0.0)	1 (0.1)	1 (0.1)
MORPHINE	0 (0.0)	1 (0.1)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_primary_study_condition_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 1 of 1
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis of Bone Loss

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
Subjects with >= 1 Medication	33 (4.3)	25 (3.4)	58 (3.9)
ZOLEDRONIC ACID	25 (3.2)	19 (2.6)	44 (2.9)
DENOSUMAB	3 (0.4)	3 (0.4)	6 (0.4)
ALENDRONIC ACID	3 (0.4)	0 (0.0)	3 (0.2)
IBANDRONIC ACID	2 (0.3)	1 (0.1)	3 (0.2)
CLODRONIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
RISEDRONIC ACID	0 (0.0)	1 (0.1)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_of_bone_loss_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 1 of 1
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis of Bone Metastases

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
Subjects with >= 1 Medication	14 (1.8)	29 (4.0)	43 (2.9)
ZOLEDRONIC ACID	11 (1.4)	23 (3.2)	34 (2.3)
DENOSUMAB	1 (0.1)	6 (0.8)	7 (0.5)
IBANDRONIC ACID	2 (0.3)	1 (0.1)	3 (0.2)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_of_bone_metastases_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
Subjects with >= 1 Medication	506 (65.2)	388 (53.2)	894 (59.4)
COVID-19 VACCINE	62 (8.0)	51 (7.0)	113 (7.5)
COLECALCIFEROL	48 (6.2)	42 (5.8)	90 (6.0)
LOPERAMIDE	87 (11.2)	1 (0.1)	88 (5.8)
INFLUENZA VACCINE	41 (5.3)	32 (4.4)	73 (4.9)
CALCIUM CARBONATE;COLECALCIFEROL	34 (4.4)	35 (4.8)	69 (4.6)
PARACETAMOL	37 (4.8)	31 (4.3)	68 (4.5)
VITAMIN D NOS	37 (4.8)	23 (3.2)	60 (4.0)
CALCIUM;COLECALCIFEROL	25 (3.2)	24 (3.3)	49 (3.3)
REBAMIPIDE	27 (3.5)	21 (2.9)	48 (3.2)
OMEPRAZOLE	17 (2.2)	23 (3.2)	40 (2.7)
CALCIUM	26 (3.4)	13 (1.8)	39 (2.6)
ACETYLSALICYLIC ACID	19 (2.4)	17 (2.3)	36 (2.4)
PANTOPRAZOLE	22 (2.8)	12 (1.6)	34 (2.3)
IBUPROFEN	25 (3.2)	7 (1.0)	32 (2.1)
IRON	22 (2.8)	10 (1.4)	32 (2.1)
LIDOCAINE	19 (2.4)	11 (1.5)	30 (2.0)
VITAMINS NOS	15 (1.9)	15 (2.1)	30 (2.0)
ASCORBIC ACID	15 (1.9)	11 (1.5)	26 (1.7)
CEFAZOLIN	15 (1.9)	10 (1.4)	25 (1.7)
ENOXAPARIN	11 (1.4)	13 (1.8)	24 (1.6)
HEPARINOID	13 (1.7)	11 (1.5)	24 (1.6)
CEFALEXIN	17 (2.2)	6 (0.8)	23 (1.5)
FAMOTIDINE	15 (1.9)	8 (1.1)	23 (1.5)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 2 of 36
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
RANITIDINE	10 (1.3)	13 (1.8)	23 (1.5)
AMOXICILLIN;CLAVULANIC ACID	14 (1.8)	7 (1.0)	21 (1.4)
CALCIUM CARBONATE	5 (0.6)	16 (2.2)	21 (1.4)
MAGNESIUM	8 (1.0)	11 (1.5)	19 (1.3)
METOCLOPRAMIDE	12 (1.5)	7 (1.0)	19 (1.3)
ONDANSETRON	14 (1.8)	5 (0.7)	19 (1.3)
AMOXICILLIN	9 (1.2)	9 (1.2)	18 (1.2)
FISH OIL	9 (1.2)	9 (1.2)	18 (1.2)
HERBAL PREPARATION	14 (1.8)	4 (0.5)	18 (1.2)
MULTIVITAMINS, PLAIN	12 (1.5)	6 (0.8)	18 (1.2)
VITAMIN B COMPLEX	7 (0.9)	11 (1.5)	18 (1.2)
DEXAMETHASONE	9 (1.2)	8 (1.1)	17 (1.1)
CALCIUM;VITAMIN D NOS	10 (1.3)	6 (0.8)	16 (1.1)
MIDAZOLAM	7 (0.9)	9 (1.2)	16 (1.1)
TEPRENONE	8 (1.0)	8 (1.1)	16 (1.1)
MAGNESIUM OXIDE	5 (0.6)	9 (1.2)	14 (0.9)
PROPOFOL	7 (0.9)	7 (1.0)	14 (0.9)
TRAMADOL	8 (1.0)	6 (0.8)	14 (0.9)
VITAMIN B12 NOS	7 (0.9)	7 (1.0)	14 (0.9)
LANSOPRAZOLE	9 (1.2)	4 (0.5)	13 (0.9)
CHLORPHENAMINE	8 (1.0)	4 (0.5)	12 (0.8)
FENTANYL	7 (0.9)	5 (0.7)	12 (0.8)
HYALURONIC ACID	7 (0.9)	5 (0.7)	12 (0.8)
KETOPROFEN	4 (0.5)	8 (1.1)	12 (0.8)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 3 of 36
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
BIOTIN	7 (0.9)	4 (0.5)	11 (0.7)
LIDOCAINE;PRILOCAINE	4 (0.5)	7 (1.0)	11 (0.7)
LOXOPROFEN	5 (0.6)	6 (0.8)	11 (0.7)
PYRIDOXINE	4 (0.5)	7 (1.0)	11 (0.7)
SODIUM CHLORIDE	7 (0.9)	4 (0.5)	11 (0.7)
AMBROXOL	6 (0.8)	4 (0.5)	10 (0.7)
ATORVASTATIN	6 (0.8)	4 (0.5)	10 (0.7)
CEFUROXIME	7 (0.9)	3 (0.4)	10 (0.7)
CURCUMA LONGA	5 (0.6)	5 (0.7)	10 (0.7)
EPHEDRINE	6 (0.8)	4 (0.5)	10 (0.7)
ESOMEPRAZOLE	4 (0.5)	6 (0.8)	10 (0.7)
LACTULOSE	6 (0.8)	4 (0.5)	10 (0.7)
PROBIOTICS NOS	5 (0.6)	5 (0.7)	10 (0.7)
SELENIUM	7 (0.9)	3 (0.4)	10 (0.7)
ALPRAZOLAM	4 (0.5)	5 (0.7)	9 (0.6)
CALCIUM CARBONATE;VITAMIN D NOS	6 (0.8)	3 (0.4)	9 (0.6)
CIMETIDINE	6 (0.8)	3 (0.4)	9 (0.6)
EPINEPHRINE	6 (0.8)	3 (0.4)	9 (0.6)
LORATADINE	4 (0.5)	5 (0.7)	9 (0.6)
MOSAPRIDE	5 (0.6)	4 (0.5)	9 (0.6)
OXYCODONE	6 (0.8)	3 (0.4)	9 (0.6)
PANCREATIN	5 (0.6)	4 (0.5)	9 (0.6)
SACCHAROMYCES BOULARDII	8 (1.0)	1 (0.1)	9 (0.6)
UBIDECARENONE	2 (0.3)	7 (1.0)	9 (0.6)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CYANOCOBALAMIN	5 (0.6)	3 (0.4)	8 (0.5)
DICLOFENAC	2 (0.3)	6 (0.8)	8 (0.5)
FUROSEMIDE	3 (0.4)	5 (0.7)	8 (0.5)
LAFUTIDINE	5 (0.6)	3 (0.4)	8 (0.5)
METAMIZOLE	3 (0.4)	5 (0.7)	8 (0.5)
RAMOSETRON	4 (0.5)	4 (0.5)	8 (0.5)
ALMAGATE	5 (0.6)	2 (0.3)	7 (0.5)
ALPROSTADIL	5 (0.6)	2 (0.3)	7 (0.5)
BETAMETHASONE	2 (0.3)	5 (0.7)	7 (0.5)
BISMUTH;RANITIDINE;SUCRALFATE	5 (0.6)	2 (0.3)	7 (0.5)
CEFACLOR	4 (0.5)	3 (0.4)	7 (0.5)
CEFCAPENE	2 (0.3)	5 (0.7)	7 (0.5)
CELECOXIB	6 (0.8)	1 (0.1)	7 (0.5)
DIAZEPAM	5 (0.6)	2 (0.3)	7 (0.5)
FOLIC ACID	5 (0.6)	2 (0.3)	7 (0.5)
GLUCOSAMINE	2 (0.3)	5 (0.7)	7 (0.5)
GUALENIC ACID	3 (0.4)	4 (0.5)	7 (0.5)
LEVOTHYROXINE	3 (0.4)	4 (0.5)	7 (0.5)
POTASSIUM	4 (0.5)	3 (0.4)	7 (0.5)
RIVAROXABAN	6 (0.8)	1 (0.1)	7 (0.5)
ROCURONIUM	4 (0.5)	3 (0.4)	7 (0.5)
TRANEXAMIC ACID	4 (0.5)	3 (0.4)	7 (0.5)
ZINC	4 (0.5)	3 (0.4)	7 (0.5)
BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS	4 (0.5)	2 (0.3)	6 (0.4)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CALCITRIOL	5 (0.6)	1 (0.1)	6 (0.4)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	3 (0.4)	3 (0.4)	6 (0.4)
CEFADROXIL	5 (0.6)	1 (0.1)	6 (0.4)
CIPROFLOXACIN	3 (0.4)	3 (0.4)	6 (0.4)
CITRULLINE	6 (0.8)	0 (0.0)	6 (0.4)
CLINDAMYCIN	3 (0.4)	3 (0.4)	6 (0.4)
CLOSTRIDIUM BUTYRICUM	5 (0.6)	1 (0.1)	6 (0.4)
DEXKETOPROFEN	3 (0.4)	3 (0.4)	6 (0.4)
GLYCOPYRRONIUM	4 (0.5)	2 (0.3)	6 (0.4)
KETOROLAC	5 (0.6)	1 (0.1)	6 (0.4)
LACTOBACILLUS ACIDOPHILUS	6 (0.8)	0 (0.0)	6 (0.4)
LEUCOGEN	5 (0.6)	1 (0.1)	6 (0.4)
METHYLPREDNISOLONE	4 (0.5)	2 (0.3)	6 (0.4)
OTHER EMOLLIENTS AND PROTECTIVES	4 (0.5)	2 (0.3)	6 (0.4)
PETHIDINE	3 (0.4)	3 (0.4)	6 (0.4)
SULFADIAZINE	3 (0.4)	3 (0.4)	6 (0.4)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	5 (0.6)	1 (0.1)	6 (0.4)
URSODEOXYCHOLIC ACID	3 (0.4)	3 (0.4)	6 (0.4)
ZALTOPROFEN	4 (0.5)	2 (0.3)	6 (0.4)
ANTIDIARRHEAL MICROORGANISMS	4 (0.5)	1 (0.1)	5 (0.3)
ARTEMISIA ARGYI	2 (0.3)	3 (0.4)	5 (0.3)
BUTYLSCOPOLAMINE	3 (0.4)	2 (0.3)	5 (0.3)
CAFFEINE;PARACETAMOL;PROMETHAZINE;SALICYLAMIDE	4 (0.5)	1 (0.1)	5 (0.3)
CALCIFEDIOL	3 (0.4)	2 (0.3)	5 (0.3)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CEFIXIME	2 (0.3)	3 (0.4)	5 (0.3)
CETIRIZINE	3 (0.4)	2 (0.3)	5 (0.3)
EPINEPHRINE;LIDOCAINE	2 (0.3)	3 (0.4)	5 (0.3)
ERGOCALCIFEROL	5 (0.6)	0 (0.0)	5 (0.3)
FLOMOXEF	4 (0.5)	1 (0.1)	5 (0.3)
GLUCOSE	4 (0.5)	1 (0.1)	5 (0.3)
HYDROCORTISONE	5 (0.6)	0 (0.0)	5 (0.3)
LORAZEPAM	4 (0.5)	1 (0.1)	5 (0.3)
MAGNESIUM HYDROXIDE	4 (0.5)	1 (0.1)	5 (0.3)
OSELTAMIVIR	1 (0.1)	4 (0.5)	5 (0.3)
PAPAVERINE	2 (0.3)	3 (0.4)	5 (0.3)
PELUBIPROFEN	5 (0.6)	0 (0.0)	5 (0.3)
PLANTAGO OVATA	5 (0.6)	0 (0.0)	5 (0.3)
PNEUMOCOCCAL VACCINE	3 (0.4)	2 (0.3)	5 (0.3)
SENNOSIDE A+B	1 (0.1)	4 (0.5)	5 (0.3)
UREA	4 (0.5)	1 (0.1)	5 (0.3)
ACETYLCYSTEINE	2 (0.3)	2 (0.3)	4 (0.3)
AMITRIPTYLINE	3 (0.4)	1 (0.1)	4 (0.3)
ASCORBIC ACID;PANTOTHENIC ACID	4 (0.5)	0 (0.0)	4 (0.3)
BIOTIN;BROMELAINS;LECITHIN;PAPAIN;SELENIUM	2 (0.3)	2 (0.3)	4 (0.3)
BISOPROLOL	3 (0.4)	1 (0.1)	4 (0.3)
CALCIUM CHLORIDE;POTASSIUM;SODIUM LACTATE	0 (0.0)	4 (0.5)	4 (0.3)
CALCIUM;MAGNESIUM	2 (0.3)	2 (0.3)	4 (0.3)
CEFDINIR	4 (0.5)	0 (0.0)	4 (0.3)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Data cutoff: 15JUL2025

Indication: Prophylaxis

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CEFRADINE	3 (0.4)	1 (0.1)	4 (0.3)
CEFTRIAXONE	3 (0.4)	1 (0.1)	4 (0.3)
CHLORHEXIDINE	2 (0.3)	2 (0.3)	4 (0.3)
CISATRACURIUM	2 (0.3)	2 (0.3)	4 (0.3)
CYANOCOBALAMIN;PYRIDOXINE;THIAMINE	2 (0.3)	2 (0.3)	4 (0.3)
DIMENHYDRINATE	4 (0.5)	0 (0.0)	4 (0.3)
DIMETICONE	0 (0.0)	4 (0.5)	4 (0.3)
DIPHENHYDRAMINE	2 (0.3)	2 (0.3)	4 (0.3)
DOCUSATE	3 (0.4)	1 (0.1)	4 (0.3)
DOMPERIDONE	2 (0.3)	2 (0.3)	4 (0.3)
EUPATILIN	2 (0.3)	2 (0.3)	4 (0.3)
FLURBIPROFEN	1 (0.1)	3 (0.4)	4 (0.3)
GENTAMICIN	3 (0.4)	1 (0.1)	4 (0.3)
HEPARIN	1 (0.1)	3 (0.4)	4 (0.3)
HPV VACCINE	2 (0.3)	2 (0.3)	4 (0.3)
INDOCYANINE GREEN	3 (0.4)	1 (0.1)	4 (0.3)
LEVOFLOXACIN	2 (0.3)	2 (0.3)	4 (0.3)
LEVOGLUTAMIDE	3 (0.4)	1 (0.1)	4 (0.3)
MAGNESIUM;PYRIDOXINE	2 (0.3)	2 (0.3)	4 (0.3)
MELATONIN	2 (0.3)	2 (0.3)	4 (0.3)
MONTELUKAST	2 (0.3)	2 (0.3)	4 (0.3)
MORPHINE	3 (0.4)	1 (0.1)	4 (0.3)
NAPROXEN	1 (0.1)	3 (0.4)	4 (0.3)
NEOSTIGMINE	3 (0.4)	1 (0.1)	4 (0.3)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
PHENYLEPHRINE	3 (0.4)	1 (0.1)	4 (0.3)
PIROXICAM	1 (0.1)	3 (0.4)	4 (0.3)
POLYENE PHOSPHATIDYLCHOLINE	3 (0.4)	1 (0.1)	4 (0.3)
POVIDONE-IODINE	3 (0.4)	1 (0.1)	4 (0.3)
PREGABALIN	3 (0.4)	1 (0.1)	4 (0.3)
SANGUISORBA OFFICINALIS	4 (0.5)	0 (0.0)	4 (0.3)
SEVOFLURANE	1 (0.1)	3 (0.4)	4 (0.3)
SODIUM PICOSULFATE	3 (0.4)	1 (0.1)	4 (0.3)
SUGAMMADEX	3 (0.4)	1 (0.1)	4 (0.3)
TOCOPHEROL	3 (0.4)	1 (0.1)	4 (0.3)
TRIAMCINOLONE	2 (0.3)	2 (0.3)	4 (0.3)
VITIS VINIFERA	2 (0.3)	2 (0.3)	4 (0.3)
ADENOSINE	2 (0.3)	1 (0.1)	3 (0.2)
ALBUMIN HUMAN	2 (0.3)	1 (0.1)	3 (0.2)
ALFACALCIDOL	2 (0.3)	1 (0.1)	3 (0.2)
ALLIUM SATIVUM	1 (0.1)	2 (0.3)	3 (0.2)
ANESTHETICS, GENERAL	1 (0.1)	2 (0.3)	3 (0.2)
ASCORBIC ACID;ZINC	1 (0.1)	2 (0.3)	3 (0.2)
ATROPINE	2 (0.3)	1 (0.1)	3 (0.2)
BACILLUS SUBTILIS;ENTEROCOCCUS FAECIUM	2 (0.3)	1 (0.1)	3 (0.2)
BERAPROST	2 (0.3)	1 (0.1)	3 (0.2)
BIFIDOBACTERIUM NOS	1 (0.1)	2 (0.3)	3 (0.2)
BIMATOPROST	2 (0.3)	1 (0.1)	3 (0.2)
BISACODYL	2 (0.3)	1 (0.1)	3 (0.2)

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
BUPIVACAINE	1 (0.1)	2 (0.3)	3 (0.2)
CALCIUM CARBONATE;COLECALCIFEROL;SODIUM	3 (0.4)	0 (0.0)	3 (0.2)
CARBOCISTEINE	1 (0.1)	2 (0.3)	3 (0.2)
CARBOHYDRATES NOS;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	2 (0.3)	1 (0.1)	3 (0.2)
CEFDITOREN	2 (0.3)	1 (0.1)	3 (0.2)
CEFMETAZOLE	3 (0.4)	0 (0.0)	3 (0.2)
CORYDALIS YANHUSUO;IPOMOEA NIL	2 (0.3)	1 (0.1)	3 (0.2)
CURCUMIN	2 (0.3)	1 (0.1)	3 (0.2)
DALTEPARIN	3 (0.4)	0 (0.0)	3 (0.2)
DIOSMIN;HESPERIDIN	2 (0.3)	1 (0.1)	3 (0.2)
ESMOLOL	0 (0.0)	3 (0.4)	3 (0.2)
FENOFIBRATE	1 (0.1)	2 (0.3)	3 (0.2)
FLUCONAZOLE	1 (0.1)	2 (0.3)	3 (0.2)
FLUORESCEIN	2 (0.3)	1 (0.1)	3 (0.2)
FUSIDIC ACID	3 (0.4)	0 (0.0)	3 (0.2)
GABAPENTIN	2 (0.3)	1 (0.1)	3 (0.2)
GINKGO BILOBA	0 (0.0)	3 (0.4)	3 (0.2)
GRANISETRON	2 (0.3)	1 (0.1)	3 (0.2)
HYALURONIDASE	2 (0.3)	1 (0.1)	3 (0.2)
HYDROMORPHONE	2 (0.3)	1 (0.1)	3 (0.2)
IODINE	1 (0.1)	2 (0.3)	3 (0.2)
IRON;JUGLANS REGIA;NEOLITSEA CASSIA;PANAX QUINQUEFOLIUS;SEA HORSE;ZIZIPHUS JUJUBA	3 (0.4)	0 (0.0)	3 (0.2)
LEVOCETIRIZINE	1 (0.1)	2 (0.3)	3 (0.2)
LEVONORGESTREL	2 (0.3)	1 (0.1)	3 (0.2)

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Prophylaxis

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LIVER THERAPY	1 (0.1)	2 (0.3)	3 (0.2)
MACROGOL 3350	2 (0.3)	1 (0.1)	3 (0.2)
MAGNESIUM CITRATE	2 (0.3)	1 (0.1)	3 (0.2)
MECOBALAMIN	1 (0.1)	2 (0.3)	3 (0.2)
METFORMIN	2 (0.3)	1 (0.1)	3 (0.2)
METOPIMAZINE	0 (0.0)	3 (0.4)	3 (0.2)
METOPROLOL	3 (0.4)	0 (0.0)	3 (0.2)
METRONIDAZOLE	0 (0.0)	3 (0.4)	3 (0.2)
MIRTAZAPINE	1 (0.1)	2 (0.3)	3 (0.2)
MISOPROSTOL	0 (0.0)	3 (0.4)	3 (0.2)
MULTIVITAMINS WITH MINERALS [UMBRELLA TERM]	2 (0.3)	1 (0.1)	3 (0.2)
OFLOXACIN	3 (0.4)	0 (0.0)	3 (0.2)
OLANZAPINE	3 (0.4)	0 (0.0)	3 (0.2)
ORLISTAT	2 (0.3)	1 (0.1)	3 (0.2)
OXYTETRACYCLINE;POLYMYXIN B	2 (0.3)	1 (0.1)	3 (0.2)
PHLOROGLUCINOL	3 (0.4)	0 (0.0)	3 (0.2)
POLAPREZINC	3 (0.4)	0 (0.0)	3 (0.2)
POTASSIUM PHOSPHATE	3 (0.4)	0 (0.0)	3 (0.2)
PYRIDOXAL	1 (0.1)	2 (0.3)	3 (0.2)
RABEPRAZOLE	1 (0.1)	2 (0.3)	3 (0.2)
REMIFENTANIL	0 (0.0)	3 (0.4)	3 (0.2)
ROSUVASTATIN	2 (0.3)	1 (0.1)	3 (0.2)
SENNA ALEXANDRINA	1 (0.1)	2 (0.3)	3 (0.2)
SODIUM BICARBONATE	1 (0.1)	2 (0.3)	3 (0.2)

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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Indication: Prophylaxis

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SUFENTANIL	2 (0.3)	1 (0.1)	3 (0.2)
SULFAMETHOXAZOLE;TRIMETHOPRIM	2 (0.3)	1 (0.1)	3 (0.2)
TETRACYCLINE	1 (0.1)	2 (0.3)	3 (0.2)
THIOPENTAL	2 (0.3)	1 (0.1)	3 (0.2)
VARENICLINE	1 (0.1)	2 (0.3)	3 (0.2)
VITAMINS WITH MINERALS	2 (0.3)	1 (0.1)	3 (0.2)
ZOLPIDEM	2 (0.3)	1 (0.1)	3 (0.2)
ZOPICLONE	3 (0.4)	0 (0.0)	3 (0.2)
ACECLOFENAC	1 (0.1)	1 (0.1)	2 (0.1)
ACECLOFENAC;PARACETAMOL	1 (0.1)	1 (0.1)	2 (0.1)
ACHILLEA MILLEFOLIUM;ACONITUM SPP.;ARNICA SPP.;ATROPA BELLA-DONNA;BELLIS PERENNIS;CALENDULA SPP.;ECHINACEA ANGUSTIFOLIA;ECHINACEA PURPUREA;HAMAMELIS SPP.;HERBAL NOS;HYPERICUM SPP.;SULFURATED POTASH;	1 (0.1)	1 (0.1)	2 (0.1)
ADIPHENINE;METAMIZOLE;PROMETHAZINE	1 (0.1)	1 (0.1)	2 (0.1)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;GELATIN;POLYPORUS UMBELLATUS;PORIA COCOS;TALC	0 (0.0)	2 (0.3)	2 (0.1)
ALMASILATE;BIODIASTASE 2000;CALCIUM CARBONATE;GLYCYRRHIZA GLABRA;LIPASE;SCOPOLIA CARNIOLICA;SODIUM CARBONATE ANHYDROUS;TRIMEBUTINE	2 (0.3)	0 (0.0)	2 (0.1)
ALUMINIUM;MAGNESIUM HYDROXIDE;SIMETICONE	2 (0.3)	0 (0.0)	2 (0.1)
AMINO ACIDS NOS	0 (0.0)	2 (0.3)	2 (0.1)
AMINO ACIDS NOS;ELECTROLYTES NOS;GLUCOSE;THIAMINE	0 (0.0)	2 (0.3)	2 (0.1)
AMINOMETHYLBENZOIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
ANGELICA ACUTILOBA;ASTRAGALUS SPP.;ATRACTYLODES SPP.;CONIOSELINUM OFFICINALE;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PANAX GINSENG;PORIA COCOS;REHMANNIA GLUTINOSA	1 (0.1)	1 (0.1)	2 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 12 of 36
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ANGELICA ACUTILOBA;ATRACTYLODES LANCEA;BUPLEURUM FALCATUM;GARDENIA JASMINOIDES;GLYCYRRHIZA SPP.;MENTHA CANADENSIS;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;ZINGIBER OFFICINALE	0 (0.0)	2 (0.3)	2 (0.1)
ANTIBIOTICS	2 (0.3)	0 (0.0)	2 (0.1)
APIXABAN	2 (0.3)	0 (0.0)	2 (0.1)
ASCORBIC ACID;BENFOTIAMINE;BIOTIN;CHOLINE;CYANOCOBALAMIN;FOLIC ACID;INOSITOL;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;ZINC	1 (0.1)	1 (0.1)	2 (0.1)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	2 (0.3)	0 (0.0)	2 (0.1)
ASCORBIC ACID;CYSTEINE;PANTOTHENIC ACID;PYRIDOXINE;TRANEXAMIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
ASCORBIC ACID;MACROGOL 3350;POTASSIUM;SODIUM CHLORIDE;SODIUM SULFATE	1 (0.1)	1 (0.1)	2 (0.1)
ASCORBIC ACID;VITAMIN D NOS	0 (0.0)	2 (0.3)	2 (0.1)
AZITHROMYCIN	2 (0.3)	0 (0.0)	2 (0.1)
BACILLUS LICHENFORMIS	1 (0.1)	1 (0.1)	2 (0.1)
BENZYDAMINE	2 (0.3)	0 (0.0)	2 (0.1)
BETAMETHASONE;FUSIDIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
BEZAFIBRATE	1 (0.1)	1 (0.1)	2 (0.1)
BICYCLOL	1 (0.1)	1 (0.1)	2 (0.1)
BORON;CALCIUM;COLECALCIFEROL;COPPER;MANGANESE;ZINC	1 (0.1)	1 (0.1)	2 (0.1)
CALCITRIOL;CALCIUM CARBONATE;ZINC	2 (0.3)	0 (0.0)	2 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL;MAGNESIUM CARBONATE	0 (0.0)	2 (0.3)	2 (0.1)
CALCIUM GLUCONATE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM;ERGOCALCIFEROL	1 (0.1)	1 (0.1)	2 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 13 of 36
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CALCIUM;MAGNESIUM;VITAMIN D NOS	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM;VITAMIN D NOS;VITAMIN K NOS	2 (0.3)	0 (0.0)	2 (0.1)
CANNABIS SATIVA	1 (0.1)	1 (0.1)	2 (0.1)
CEPHARANTHINE	2 (0.3)	0 (0.0)	2 (0.1)
CINNARIZINE	0 (0.0)	2 (0.3)	2 (0.1)
CLARITHROMYCIN	1 (0.1)	1 (0.1)	2 (0.1)
COD-LIVER OIL	1 (0.1)	1 (0.1)	2 (0.1)
COLLAGEN	1 (0.1)	1 (0.1)	2 (0.1)
COPPER	1 (0.1)	1 (0.1)	2 (0.1)
COPTIS SPP.;GLYCYRRHIZA SPP.;PANAX GINSENG;PINELLIA TERNATA;SCUTELLARIA BAICALENSIS;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	2 (0.3)	0 (0.0)	2 (0.1)
CORDYCEPS SINENSIS	1 (0.1)	1 (0.1)	2 (0.1)
DESLORATADINE	1 (0.1)	1 (0.1)	2 (0.1)
DEXLANSOPRAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
DICLOXACILLIN	1 (0.1)	1 (0.1)	2 (0.1)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	2 (0.3)	0 (0.0)	2 (0.1)
DIQUAFOSOL	2 (0.3)	0 (0.0)	2 (0.1)
DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID	0 (0.0)	2 (0.3)	2 (0.1)
DOXYCYCLINE	1 (0.1)	1 (0.1)	2 (0.1)
DROPERIDOL	2 (0.3)	0 (0.0)	2 (0.1)
ENZYME PREPARATIONS	1 (0.1)	1 (0.1)	2 (0.1)
EPINASTINE	2 (0.3)	0 (0.0)	2 (0.1)
ETIZOLAM	0 (0.0)	2 (0.3)	2 (0.1)
ETORICOXIB	1 (0.1)	1 (0.1)	2 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
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Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
FEXOFENADINE	1 (0.1)	1 (0.1)	2 (0.1)
FLUOXETINE	1 (0.1)	1 (0.1)	2 (0.1)
FOSFOMYCIN	1 (0.1)	1 (0.1)	2 (0.1)
GLYCEROL	2 (0.3)	0 (0.0)	2 (0.1)
GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PRUNUS SPP.;RHEUM SPP.;SODIUM SULFATE	0 (0.0)	2 (0.3)	2 (0.1)
GLYCYRRHIZIC ACID	2 (0.3)	0 (0.0)	2 (0.1)
HAEMOCOAGULASE	1 (0.1)	1 (0.1)	2 (0.1)
HYDROXYZINE	1 (0.1)	1 (0.1)	2 (0.1)
INFLUENZA VACCINES	1 (0.1)	1 (0.1)	2 (0.1)
IOHEXOL	2 (0.3)	0 (0.0)	2 (0.1)
IOPROMIDE	0 (0.0)	2 (0.3)	2 (0.1)
IOVERSOL	1 (0.1)	1 (0.1)	2 (0.1)
LACTOBACILLUS RHAMNOSUS	1 (0.1)	1 (0.1)	2 (0.1)
LISINOPRIL	1 (0.1)	1 (0.1)	2 (0.1)
MACROGOL	0 (0.0)	2 (0.3)	2 (0.1)
MACROGOL;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	1 (0.1)	1 (0.1)	2 (0.1)
MAGNESIUM CHLORIDE	1 (0.1)	1 (0.1)	2 (0.1)
MAGNESIUM HYDROXIDE;PARAFFIN, LIQUID	2 (0.3)	0 (0.0)	2 (0.1)
MANNITOL	2 (0.3)	0 (0.0)	2 (0.1)
MENINGOCOCCAL VACCINE	1 (0.1)	1 (0.1)	2 (0.1)
METHYLERGOMETRINE	2 (0.3)	0 (0.0)	2 (0.1)
MOMETASONE	2 (0.3)	0 (0.0)	2 (0.1)
NADROPARIN	0 (0.0)	2 (0.3)	2 (0.1)
NEOMYCIN	2 (0.3)	0 (0.0)	2 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
NIFEDIPINE	1 (0.1)	1 (0.1)	2 (0.1)
OLOPATADINE	1 (0.1)	1 (0.1)	2 (0.1)
OMEGA-3 FATTY ACIDS	1 (0.1)	1 (0.1)	2 (0.1)
OXETACAINE	1 (0.1)	1 (0.1)	2 (0.1)
PENTAZOCINE	2 (0.3)	0 (0.0)	2 (0.1)
PENTOXIFYLLINE	1 (0.1)	1 (0.1)	2 (0.1)
PHENOXYMETHYLPENICILLIN	1 (0.1)	1 (0.1)	2 (0.1)
PHENYLEPHRINE;TROPICAMIDE	2 (0.3)	0 (0.0)	2 (0.1)
PHOSPHORIC ACID	2 (0.3)	0 (0.0)	2 (0.1)
PRAVASTATIN	2 (0.3)	0 (0.0)	2 (0.1)
PROCHLORPERAZINE	0 (0.0)	2 (0.3)	2 (0.1)
PRONASE	0 (0.0)	2 (0.3)	2 (0.1)
PYRIDOSTIGMINE	0 (0.0)	2 (0.3)	2 (0.1)
RETINOL	1 (0.1)	1 (0.1)	2 (0.1)
RHODIOLA ROSEA	2 (0.3)	0 (0.0)	2 (0.1)
SALICYLIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
SILYBUM MARIANUM	1 (0.1)	1 (0.1)	2 (0.1)
SIMETICONE	1 (0.1)	1 (0.1)	2 (0.1)
SODIUM PHOSPHATE	0 (0.0)	2 (0.3)	2 (0.1)
SUCRALFATE	2 (0.3)	0 (0.0)	2 (0.1)
TAPENTADOL	2 (0.3)	0 (0.0)	2 (0.1)
THEOBROMINE	1 (0.1)	1 (0.1)	2 (0.1)
THIOCTIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
TINZAPARIN	2 (0.3)	0 (0.0)	2 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
TONICS	0 (0.0)	2 (0.3)	2 (0.1)
TRAMETES VERSICOLOR	2 (0.3)	0 (0.0)	2 (0.1)
UBENIMEX	1 (0.1)	1 (0.1)	2 (0.1)
VARICELLA ZOSTER VACCINE	1 (0.1)	1 (0.1)	2 (0.1)
VITAMINS, OTHER COMBINATIONS	1 (0.1)	1 (0.1)	2 (0.1)
WITHANIA SOMNIFERA	1 (0.1)	1 (0.1)	2 (0.1)
ZANAMIVIR	2 (0.3)	0 (0.0)	2 (0.1)
(6S)-5-METHYLTETRAHYDROFOLATE;BETAINE;FOLINIC ACID;MECOBALAMIN;PYRIDOXAL;RIBOFLAVIN	1 (0.1)	0 (0.0)	1 (0.1)
ACETAZOLAMIDE	0 (0.0)	1 (0.1)	1 (0.1)
ACETYLCARNITINE	1 (0.1)	0 (0.0)	1 (0.1)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
ACETYLSALICYLIC ACID;CODEINE;PARACETAMOL;PHENOBARBITAL	1 (0.1)	0 (0.0)	1 (0.1)
ACHILLEA MILLEFOLIUM;ACONITUM NAPELLUS;ARNICA MONTANA;ATROPA BELLA-DONNA;BELLIS PERENNIS;CALCIUM SULFIDE;CALENDULA OFFICINALIS;ECHINACEA ANGUSTIFOLIA;ECHINACEA PURPUREA;HAMAMELIS VIRGINIANA;	1 (0.1)	0 (0.0)	1 (0.1)
ACHYRANTHES BIDENTATA;ACONITUM SPP.;ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;CORNUS OFFICINALIS;DIOSCOREA SPP.;NEOLITSEA CASSIA;PAEONIA X SUFFRUTICOSA;PLANTAGO ASIATICA;PORIA COCOS;	1 (0.1)	0 (0.0)	1 (0.1)
ADEMETIONINE	0 (0.0)	1 (0.1)	1 (0.1)
ADENINE;BIFENDATE;CARNITINE;CYANOCOBALAMIN;LIVER;PYRIDOXINE;RIBOFLAVIN	1 (0.1)	0 (0.0)	1 (0.1)
AGARICUS BLAZEI	1 (0.1)	0 (0.0)	1 (0.1)
AGARICUS CAMPESTRIS;ALLIUM SATIVUM;ARISTOLOCHIA INDICA;HYDRASTIS CANADENSIS;OKOUBAKA AUBREVILLEI;VINCETOXICUM HIRUNDINARIA	1 (0.1)	0 (0.0)	1 (0.1)
ALANINE	1 (0.1)	0 (0.0)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ALANINE;ARGININE;CYSTEINE;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN;VALINE	1 (0.1)	0 (0.0)	1 (0.1)
ALBENDAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
ALBUMIN TANNATE	1 (0.1)	0 (0.0)	1 (0.1)
ALFENTANIL	1 (0.1)	0 (0.0)	1 (0.1)
ALGINIC ACID;ALOE VERA;BENZETHONIUM;COLLAGEN;GLYCEROL;LIDOCAINE;TROLAMINE	1 (0.1)	0 (0.0)	1 (0.1)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ANGELICA SINENSIS;ASARUM SPP.;ASTRAGALUS SPP.;CUSCUTA SPP.;DEER HORN;GASTRODIA ELATA;LYCIUM BARBARUM;PANAX GINSENG;REHMANNIA GLUTINOSA;SENNA SPP.	1 (0.1)	0 (0.0)	1 (0.1)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;CORNUS OFFICINALIS;DIOSCOREA SPP.;PAEONIA X SUFFRUTICOSA;PORIA COCOS;REHMANNIA GLUTINOSA	0 (0.0)	1 (0.1)	1 (0.1)
ALISMA PLANTAGO-AQUATICA;ANGELICA SINENSIS;BUPLEURUM FALCATUM;GARDENIA JASMINOIDES;GENTIANA SCABRA;GLYCYRRHIZA URALENSIS;PLANTAGO MAJOR;REHMANNIA GLUTINOSA;SCUTELLARIA BAICALENSIS	0 (0.0)	1 (0.1)	1 (0.1)
ALLANTOIN;ENOXOLONE;LIDOCAINE;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.1)
ALLANTOIN;LIDOCAINE;PREDNISOLONE;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.1)
ALMASILATE;BIODIASTASE 2000;CALCIUM CARBONATE;GLYCYRRHIZA SPP.;LIPASE;SCOPOLIA SPP.;SODIUM BICARBONATE;TRIMEBUTINE	0 (0.0)	1 (0.1)	1 (0.1)
ALOE VERA;BENZALKONIUM;GLYCYRRHIZIC ACID;HYALURONIC ACID;POVIDONE	1 (0.1)	0 (0.0)	1 (0.1)
ALTEPLASE	0 (0.0)	1 (0.1)	1 (0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM CARBONATE	0 (0.0)	1 (0.1)	1 (0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;OXETACAINE	1 (0.1)	0 (0.0)	1 (0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	1 (0.1)	0 (0.0)	1 (0.1)
ALUMINIUM MAGNESIUM SILICATE	1 (0.1)	0 (0.0)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
AMIDES	0 (0.0)	1 (0.1)	1 (0.1)
AMIKACIN	0 (0.0)	1 (0.1)	1 (0.1)
AMMONIUM CHLORIDE;CHLORPHENAMINE;DIHYDROCODEINE;METHYLEPHEDRINE	0 (0.0)	1 (0.1)	1 (0.1)
AMPICILLIN	1 (0.1)	0 (0.0)	1 (0.1)
AMPICILLIN;SULBACTAM	0 (0.0)	1 (0.1)	1 (0.1)
AMYLASE;ASCORBIC ACID;CELLULASE;FOLIC ACID;LIPASE;PROTEASE NOS	1 (0.1)	0 (0.0)	1 (0.1)
ANDROGRAPHIS PANICULATA;ASCORBIC ACID;ECHINACEA PURPUREA;OLEA EUROPAEA;ZINC	0 (0.0)	1 (0.1)	1 (0.1)
ANEMARRHENA ASPHODELOIDES;CONIOSELINUM OFFICINALE;GLYCYRRHIZA SPP.;PORIA COCOS;ZIZIPHUS JUJUBA	0 (0.0)	1 (0.1)	1 (0.1)
ANGELICA ACUTILOBA;ASTRAGALUS SPP.;ATRACTYLODES LANCEA;BUPLEURUM FALCATUM;CIMICIFUGA SPP.;CITRUS X AURANTIUM;GLYCYRRHIZA SPP.;PANAX GINSENG;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	1 (0.1)	0 (0.0)	1 (0.1)
ANGELICA ACUTILOBA;ASTRAGALUS SPP.;ATRACTYLODES LANCEA;CITRUS RETICULATA;GLYCYRRHIZA SPP.;OPHIOPOGON JAPONICUS;PANAX GINSENG;PHELLODENDRON SPP.;SCHISANDRA CHINENSIS	0 (0.0)	1 (0.1)	1 (0.1)
ANGELICA SINENSIS;ASINI CORII COLLA;ASTRAGALUS MONGHOLICUS;EPIMEDIUM BREVICORNU;LESPEDEZA BUERGERI;SOPHORA FLAVESCENS;ZIZIPHUS JUJUBA	1 (0.1)	0 (0.0)	1 (0.1)
ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE	0 (0.0)	1 (0.1)	1 (0.1)
APIUM GRAVEOLENS	0 (0.0)	1 (0.1)	1 (0.1)
APREPITANT	1 (0.1)	0 (0.0)	1 (0.1)
APROTININ;CALCIUM CHLORIDE;FACTOR I (FIBRINOGEN);THROMBIN	1 (0.1)	0 (0.0)	1 (0.1)
ARGININE;CYSTEINE;PYRIDOXINE;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
ARGININE;IBUPROFEN	1 (0.1)	0 (0.0)	1 (0.1)
ARSENIC	1 (0.1)	0 (0.0)	1 (0.1)
ARTEMISIA SPP.	1 (0.1)	0 (0.0)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 19 of 36
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ARTICAINE;EPINEPHRINE	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;BETACAROTENE;BIOTIN;EQUISETUM ARVENSE;FOLIC ACID;IRON;MANGANESE;PANTOTHENIC ACID;SILICON DIOXIDE;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;BIOTIN;CALCIUM;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FOLIC ACID;IODINE;IRON;NICOTINIC ACID;PANTOTHENIC ACID;PHYTOMENADIONE;PYRIDOXINE;RETINOL;RIBOFLAVIN;SODIUM;THIAMINE;TOCOPHEROL;ZINC	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;BIOTIN;CAROTENOIDS NOS;CHROMIUM;COPPER;CYSTINE;FOLIC ACID;IODINE;IRON;MAGNESIUM;MANGANESE;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;SELENIUM;THIAMINE;VITAMIN B12 NOS;	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;BIOTIN;COLLAGEN;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;FURSULTIAMINE;IRON;NICOTINAMIDE;PYRIDOXINE;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;BIOTIN;DL-ALPHA TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;CHROMIUM;CREATINE;CYANOCOBALAMIN;FOLIC ACID;LEVOCARNITINE;LEVOGLUTAMIDE;MAGNESIUM;MAGNESIUM CITRATE;MAGNESIUM PHOSPHATE;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;POTASSIUM CITRATE;	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;CYANOCOBALAMIN;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;IRON	1 (0.1)	0 (0.0)	1 (0.1)
ASCORBIC ACID;IRON;VITAMIN B NOS	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;MACROGOL 4000;POTASSIUM;SODIUM CHLORIDE;SODIUM SULFATE	0 (0.0)	1 (0.1)	1 (0.1)
ASCORBIC ACID;VITAMIN B COMPLEX	1 (0.1)	0 (0.0)	1 (0.1)
ASENAPINE	1 (0.1)	0 (0.0)	1 (0.1)
ASTRAGALUS MONGHOLICUS	1 (0.1)	0 (0.0)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
ASTRAGALUS MONGHOLICUS;LIGUSTRUM LUCIDUM	0 (0.0)	1 (0.1)	1 (0.1)
ASTRAGALUS SPP.;GLYCYRRHIZA SPP.;LYCIUM SPP.;NELUMBO NUCIFERA;OPHIOPOGON JAPONICUS;PANAX GINSENG;PLANTAGO ASIATICA;PORIA COCOS;SCUTELLARIA BAICALENSIS	0 (0.0)	1 (0.1)	1 (0.1)
ATOVAQUONE;PROGUANIL	1 (0.1)	0 (0.0)	1 (0.1)
ATRACTYLODES MACROCEPHALA	1 (0.1)	0 (0.0)	1 (0.1)
ATRACURIUM	0 (0.0)	1 (0.1)	1 (0.1)
ATROPINE;DIPHENOXYLATE	1 (0.1)	0 (0.0)	1 (0.1)
AZADIRACHTA INDICA	0 (0.0)	1 (0.1)	1 (0.1)
BACILLUS COAGULANS;BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECIUM	1 (0.1)	0 (0.0)	1 (0.1)
BACITRACIN	0 (0.0)	1 (0.1)	1 (0.1)
BACITRACIN;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
BACOPA MONNIERI	0 (0.0)	1 (0.1)	1 (0.1)
BATROXOBIN	1 (0.1)	0 (0.0)	1 (0.1)
BEMIPARIN	0 (0.0)	1 (0.1)	1 (0.1)
BENDROFLUMETHIAZIDE	0 (0.0)	1 (0.1)	1 (0.1)
BENFOTIAMINE	1 (0.1)	0 (0.0)	1 (0.1)
BENFOTIAMINE;CAFFEINE;CLEMASTINE;DIHYDROCODEINE;LYSOZYME;METHYLEPHEDRINE;NOSCAPINE;PARACETAMOL;SULFOGAIACOL	1 (0.1)	0 (0.0)	1 (0.1)
BENIDIPINE	1 (0.1)	0 (0.0)	1 (0.1)
BENZETHONIUM	0 (0.0)	1 (0.1)	1 (0.1)
BENZETHONIUM;CHLORPHENAMINE;TETRYZOLINE	1 (0.1)	0 (0.0)	1 (0.1)
BERBERINE	1 (0.1)	0 (0.0)	1 (0.1)
BETAHISTINE	1 (0.1)	0 (0.0)	1 (0.1)
BIFIDOBACTERIUM ANIMALIS;COLECALCIFEROL	1 (0.1)	0 (0.0)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM INFANTIS	1 (0.1)	0 (0.0)	1 (0.1)
BIFIDOBACTERIUM BIFIDUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	1 (0.1)	0 (0.0)	1 (0.1)
BIFIDOBACTERIUM INFANTIS;BIFIDOBACTERIUM LACTIS;COLECALCIFEROL;FRUCTOOLIGOSACCHARIDES;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS;STREPTOCOCCUS THERMOPHILUS	0 (0.0)	1 (0.1)	1 (0.1)
BIFIDOBACTERIUM LACTIS;COLOSTRUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS	0 (0.0)	1 (0.1)	1 (0.1)
BIFIDOBACTERIUM LACTIS;LACTOBACILLUS ACIDOPHILUS	1 (0.1)	0 (0.0)	1 (0.1)
BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS;SACCHAROMYCES BOULARDII	1 (0.1)	0 (0.0)	1 (0.1)
BILASTINE	1 (0.1)	0 (0.0)	1 (0.1)
BIODIASTASE 2000;CALCIUM CARBONATE;GLYCYRRHIZIC ACID;LIPASE;SCOPOLIA CARNIOLICA;SIMALDRATE;SODIUM BICARBONATE;TRIMEBUTINE	0 (0.0)	1 (0.1)	1 (0.1)
BIOTIN;CYANOCOBALAMIN;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;SILICON DIOXIDE;THIAMINE;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
BIOTIN;CYSTINE;MAGNESIUM;METHIONINE;PANTOTHENIC ACID;PYRIDOXINE	1 (0.1)	0 (0.0)	1 (0.1)
BORAGO OFFICINALIS;FISH OIL;LINUM USITATISSIMUM	0 (0.0)	1 (0.1)	1 (0.1)
BORAGO OFFICINALIS;LINUM USITATISSIMUM;OMEGA-3 TRIGLYCERIDES	1 (0.1)	0 (0.0)	1 (0.1)
BORIC ACID;CALCIUM;COLECALCIFEROL;COPPER;MAGNESIUM OXIDE;MANGANESE;MENAQUINONE-7;SILICON DIOXIDE;ZINC	0 (0.0)	1 (0.1)	1 (0.1)
BORIC ACID;EPHEDRINE;MAFENIDE;TAURINE;ZINC	0 (0.0)	1 (0.1)	1 (0.1)
BOSWELLIA SERRATA	1 (0.1)	0 (0.0)	1 (0.1)
BROMAZEPAM	1 (0.1)	0 (0.0)	1 (0.1)
BROMELAINS;DIMETICONE;PANCREATIN	0 (0.0)	1 (0.1)	1 (0.1)
BROMHEXINE	1 (0.1)	0 (0.0)	1 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
BROMHEXINE;CAFFEINE;CARBINOXAMINE;DIHYDROCODEINE;METHYLEPHEDRINE;PARACETAMOL;RIBOFLAVIN;SULBUTIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
BROMOPRIDE	0 (0.0)	1 (0.1)	1 (0.1)
BROTIZOLAM	1 (0.1)	0 (0.0)	1 (0.1)
BUCINNAZINE	1 (0.1)	0 (0.0)	1 (0.1)
BUCLIZINE	1 (0.1)	0 (0.0)	1 (0.1)
BUDESONIDE;FORMOTEROL	0 (0.0)	1 (0.1)	1 (0.1)
BUPRENORPHINE	1 (0.1)	0 (0.0)	1 (0.1)
BUPROPION	0 (0.0)	1 (0.1)	1 (0.1)
BUTORPHANOL	1 (0.1)	0 (0.0)	1 (0.1)
BUTYLSCOPOLAMINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
CAFFEINE;CARISOPRODOL;DICLOFENAC;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL;COPPER;MAGNESIUM;MANGANESE;ZINC	0 (0.0)	1 (0.1)	1 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL;IRON;MAGNESIUM OXIDE;MANGANESE	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL;MAGNESIUM;ZINC	0 (0.0)	1 (0.1)	1 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL;PHYTOMENADIONE	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM CHLORIDE;GLUCONATE SODIUM;MAGNESIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	0 (0.0)	1 (0.1)	1 (0.1)
CALCIUM;CALCIUM CARBONATE	0 (0.0)	1 (0.1)	1 (0.1)
CALCIUM;COLECALCIFEROL;MAGNESIUM	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM;COLECALCIFEROL;MAGNESIUM CITRATE	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM;COLECALCIFEROL;MAGNESIUM OXIDE	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM;MAGNESIUM;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
CALCIUM;MENAQUINONE;VITAMIN D NOS	0 (0.0)	1 (0.1)	1 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 23 of 36
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CALCIUM;VITAMINS NOS	0 (0.0)	1 (0.1)	1 (0.1)
CALENDULA OFFICINALIS	0 (0.0)	1 (0.1)	1 (0.1)
CARBOMER	1 (0.1)	0 (0.0)	1 (0.1)
CARMELLOSE	1 (0.1)	0 (0.0)	1 (0.1)
CARMELLOSE;SILVER	1 (0.1)	0 (0.0)	1 (0.1)
CARTEOLOL;LATANOPROST	0 (0.0)	1 (0.1)	1 (0.1)
CARTHAMUS TINCTORIUS;CISTANCHE DESERTICOLA;CURCUMA LONGA;EPIMEDIUM SAGITTATUM;EUCOMMIA ULMOIDES;GLOYDIUS HALYS;LEONURUS JAPONICUS;LINDERA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PANAX GINSENG;	1 (0.1)	0 (0.0)	1 (0.1)
CARVEDILOL	0 (0.0)	1 (0.1)	1 (0.1)
CEFALOTIN	0 (0.0)	1 (0.1)	1 (0.1)
CEFMINOX	0 (0.0)	1 (0.1)	1 (0.1)
CEFOXITIN	0 (0.0)	1 (0.1)	1 (0.1)
CEFPODOXIME	1 (0.1)	0 (0.0)	1 (0.1)
CEFPROZIL	0 (0.0)	1 (0.1)	1 (0.1)
CERTOPARIN SODIUM	1 (0.1)	0 (0.0)	1 (0.1)
CHLORELLA SPP.	0 (0.0)	1 (0.1)	1 (0.1)
CHLOROQUINE	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPHENAMINE;NEOSTIGMINE;POTASSIUM ASPARTATE;PYRIDOXINE;RETINOL;TETRYZOLINE;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.1)
CHLORPROMAZINE	1 (0.1)	0 (0.0)	1 (0.1)
CHOLINE ALFOSCERATE	1 (0.1)	0 (0.0)	1 (0.1)
CHONDROITIN;GLUCOSAMINE	1 (0.1)	0 (0.0)	1 (0.1)
CHONDRUS CRISPUS;TITANIUM DIOXIDE;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
CHYMOTRYPSIN;TRYPSIN	1 (0.1)	0 (0.0)	1 (0.1)

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Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 24 of 36
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
CINITAPRIDE	1 (0.1)	0 (0.0)	1 (0.1)
CITRIC ACID;SODIUM BICARBONATE;SODIUM CITRATE;TARTARIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
CITRUS SPP.	1 (0.1)	0 (0.0)	1 (0.1)
CLONAZEPAM	1 (0.1)	0 (0.0)	1 (0.1)
CLONIXIN;CYCLOBENZAPRINE	1 (0.1)	0 (0.0)	1 (0.1)
COBAMAMIDE;HYDROXOCOBALAMIN;MECOBALAMIN	1 (0.1)	0 (0.0)	1 (0.1)
COCARBOXYLASE;HYDROXOCOBALAMIN;PYRIDOXINE	0 (0.0)	1 (0.1)	1 (0.1)
CODEINE	1 (0.1)	0 (0.0)	1 (0.1)
CODEINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
CODEINE;PSEUDOEPHEDRINE;TRIPROLIDINE	1 (0.1)	0 (0.0)	1 (0.1)
CODONOPSIS SPP.	1 (0.1)	0 (0.0)	1 (0.1)
COFFEA ARABICA;MAGNESIUM;PALLADIUM;PASSIFLORA INCARNATA;PHOSPHORIC ACID;STRYCHNOS IGNATII;TELLURIUM;ZALUZIANSKYA CAPENSIS	1 (0.1)	0 (0.0)	1 (0.1)
COIX LACRYMA-JOBI VAR. MA-YUEN;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;PRUNUS SPP.	0 (0.0)	1 (0.1)	1 (0.1)
COLCHICINE	1 (0.1)	0 (0.0)	1 (0.1)
COLECALCIFEROL-CHOLESTERIN	1 (0.1)	0 (0.0)	1 (0.1)
COLECALCIFEROL;MENADIONE	1 (0.1)	0 (0.0)	1 (0.1)
COLISTIN;ERYTHROMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
COLLAGEN;FISH OIL	1 (0.1)	0 (0.0)	1 (0.1)
CONIOSELINUM OFFICINALE;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;NUPHAR JAPONICA;QUERCUS SPP.;RHEUM SPP.;SYZYGIUM AROMATICUM	1 (0.1)	0 (0.0)	1 (0.1)
CONTACT LAXATIVES	0 (0.0)	1 (0.1)	1 (0.1)
COPPER;IRON;MAGNESIUM;MANGANESE;POTASSIUM ASPARTATE;ZINC	1 (0.1)	0 (0.0)	1 (0.1)

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Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
COPTIS SPP.;GARDENIA JASMINOIDES;PHELLODENDRON SPP.;SCUTELLARIA BAICALENSIS	0 (0.0)	1 (0.1)	1 (0.1)
CORDYCEPS SINENSIS;GANODERMA LUCIDUM;LENTINUS EDODES;TRAMETES VERSICOLOR;TREMELLA FUCIFORMIS	0 (0.0)	1 (0.1)	1 (0.1)
COUGH AND COLD PREPARATIONS	1 (0.1)	0 (0.0)	1 (0.1)
COW BEZOAR	1 (0.1)	0 (0.0)	1 (0.1)
CROTAMITON	1 (0.1)	0 (0.0)	1 (0.1)
CYANOCOBALAMIN;DEXPANTHENOL;NICOTINAMIDE;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.1)
CYANOCOBALAMIN;FOLIC ACID;IRON	1 (0.1)	0 (0.0)	1 (0.1)
CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE;ZINC	0 (0.0)	1 (0.1)	1 (0.1)
CYANOCOBALAMIN;FOLIC ACID;PYRIDOXINE	1 (0.1)	0 (0.0)	1 (0.1)
CYANOCOBALAMIN;INTRINSIC FACTOR;PYRIDOXINE;THIAMINE	1 (0.1)	0 (0.0)	1 (0.1)
CYCLIZINE	1 (0.1)	0 (0.0)	1 (0.1)
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
CYSTINE	0 (0.0)	1 (0.1)	1 (0.1)
DENDROBIUM SPP.	1 (0.1)	0 (0.0)	1 (0.1)
DEQUALINIUM	0 (0.0)	1 (0.1)	1 (0.1)
DEXAMETHASONE;TOBRAMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
DEXMEDETOMIDINE	1 (0.1)	0 (0.0)	1 (0.1)
DEXPANTHENOL;NICOTINAMIDE;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
DEXPANTHENOL;RETINOL	1 (0.1)	0 (0.0)	1 (0.1)
DEXTROMETHORPHAN;EPHEDRINE;PROMETHAZINE	1 (0.1)	0 (0.0)	1 (0.1)
DICLOFENAC;THIOCOLCHICOSIDE	0 (0.0)	1 (0.1)	1 (0.1)
DICYCLOVERINE	0 (0.0)	1 (0.1)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
DIETARY SUPPLEMENT	1 (0.1)	0 (0.0)	1 (0.1)
DIFLUPREDNATE	1 (0.1)	0 (0.0)	1 (0.1)
DIHYDROCODEINE	1 (0.1)	0 (0.0)	1 (0.1)
DIMEMORFAN	1 (0.1)	0 (0.0)	1 (0.1)
DIMENHYDRINATE;PYRIDOXINE	0 (0.0)	1 (0.1)	1 (0.1)
DIMETICONE;HEMICELLULASE;OX BILE;PANCREATIN	0 (0.0)	1 (0.1)	1 (0.1)
DIOSMECTITE	1 (0.1)	0 (0.0)	1 (0.1)
DIPHENHYDRAMINE;DIPROPHYLLINE	1 (0.1)	0 (0.0)	1 (0.1)
DIPHTHERIA VACCINE	0 (0.0)	1 (0.1)	1 (0.1)
DISULFIRAM	0 (0.0)	1 (0.1)	1 (0.1)
DOCOSAHEXAENOIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
DOCUSATE;SENNOSIDE A+B	1 (0.1)	0 (0.0)	1 (0.1)
DOMPERIDONE;PANTOPRAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
DOMPERIDONE;RANITIDINE	1 (0.1)	0 (0.0)	1 (0.1)
DROTAVERINE	0 (0.0)	1 (0.1)	1 (0.1)
ECONAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
EDOXABAN	1 (0.1)	0 (0.0)	1 (0.1)
ELDECALCITOL	0 (0.0)	1 (0.1)	1 (0.1)
ELECTROLYTES NOS	1 (0.1)	0 (0.0)	1 (0.1)
EMOLLIENTS AND PROTECTIVES	0 (0.0)	1 (0.1)	1 (0.1)
EMULSIFYING WAX;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (0.1)	0 (0.0)	1 (0.1)
ENALAPRIL	0 (0.0)	1 (0.1)	1 (0.1)
ENOXOLONE;HYALURONIC ACID;POVIDONE	1 (0.1)	0 (0.0)	1 (0.1)
ENTEROCOCCUS FAECALIS	0 (0.0)	1 (0.1)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PUERARIA MONTANA VAR. LOBATA;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	0 (0.0)	1 (0.1)	1 (0.1)
ESCHERICHIA COLI	1 (0.1)	0 (0.0)	1 (0.1)
ESCHERICHIA COLI;HYDROCORTISONE	0 (0.0)	1 (0.1)	1 (0.1)
ESCHSCHOLZIA CALIFORNICA;FRANGULA ALNUS;FRANGULA PURSHIANA;RHEUM SPP.;SENNA ALEXANDRINA	0 (0.0)	1 (0.1)	1 (0.1)
ESCITALOPRAM	1 (0.1)	0 (0.0)	1 (0.1)
ESSENTIAL OILS NOS	1 (0.1)	0 (0.0)	1 (0.1)
ESTAZOLAM	1 (0.1)	0 (0.0)	1 (0.1)
ESTRADIOL	1 (0.1)	0 (0.0)	1 (0.1)
ESTRIOL	1 (0.1)	0 (0.0)	1 (0.1)
ESTRIOL;LACTOBACILLUS ACIDOPHILUS	0 (0.0)	1 (0.1)	1 (0.1)
ETAMSILATE	1 (0.1)	0 (0.0)	1 (0.1)
EUTERPE OLERACEA	1 (0.1)	0 (0.0)	1 (0.1)
FACTOR I (FIBRINOGEN);THROMBIN	1 (0.1)	0 (0.0)	1 (0.1)
FAGOPYRUM CYMOSUM	1 (0.1)	0 (0.0)	1 (0.1)
FAROPENEM	1 (0.1)	0 (0.0)	1 (0.1)
FEBUXOSTAT	1 (0.1)	0 (0.0)	1 (0.1)
FILGRASTIM	1 (0.1)	0 (0.0)	1 (0.1)
FLUCLOXACILLIN	1 (0.1)	0 (0.0)	1 (0.1)
FLUOCINOLONE ACETONIDE	0 (0.0)	1 (0.1)	1 (0.1)
FLUOROMETHOLONE	1 (0.1)	0 (0.0)	1 (0.1)
FLUOROQUINOLONES	1 (0.1)	0 (0.0)	1 (0.1)
FLURAZEPAM	1 (0.1)	0 (0.0)	1 (0.1)
FLUTICASONE	0 (0.0)	1 (0.1)	1 (0.1)

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/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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FOLIC ACID;IRON	0 (0.0)	1 (0.1)	1 (0.1)
FORMOTEROL	0 (0.0)	1 (0.1)	1 (0.1)
FRAGARIA VESCA;VITIS VINIFERA	1 (0.1)	0 (0.0)	1 (0.1)
FRITILLARIA SPP.	1 (0.1)	0 (0.0)	1 (0.1)
FRUCTOSE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE;SODIUM PHOSPHATE	0 (0.0)	1 (0.1)	1 (0.1)
FRUCTOSE;GLYCEROL	1 (0.1)	0 (0.0)	1 (0.1)
FURSULTIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
FURSULTIAMINE;RIBOFLAVIN	0 (0.0)	1 (0.1)	1 (0.1)
GADOPENTETIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
GADOTERIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
GANODERMA SPP.	1 (0.1)	0 (0.0)	1 (0.1)
GARENOXACIN	0 (0.0)	1 (0.1)	1 (0.1)
GELATIN;SODIUM CHLORIDE;SODIUM HYDROXIDE;WATER FOR INJECTION	1 (0.1)	0 (0.0)	1 (0.1)
GELATINE HYDROLYSATE	1 (0.1)	0 (0.0)	1 (0.1)
GELSEMIUM SEMPERVIRENS	1 (0.1)	0 (0.0)	1 (0.1)
GENERAL NUTRIENTS	0 (0.0)	1 (0.1)	1 (0.1)
GINKGO BILOBA;KERATIN;RESVERATROL;SERENOA REPENS;VACCINIUM MYRTILLUS	1 (0.1)	0 (0.0)	1 (0.1)
GLIMEPIRIDE	0 (0.0)	1 (0.1)	1 (0.1)
GLUCONATE SODIUM;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.1)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.1)
GLUCOSE;POTASSIUM;SODIUM LACTATE	0 (0.0)	1 (0.1)	1 (0.1)
GLUCOSE;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.1)
GLUTAMIC ACID	0 (0.0)	1 (0.1)	1 (0.1)

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GLUTATHIONE	0 (0.0)	1 (0.1)	1 (0.1)
GLYCERYL TRINITRATE	1 (0.1)	0 (0.0)	1 (0.1)
GLYCINE;GLYCYRRHIZIC ACID;METHIONINE	0 (0.0)	1 (0.1)	1 (0.1)
GLYCYRRHIZA GLABRA	1 (0.1)	0 (0.0)	1 (0.1)
GLYCYRRHIZA GLABRA;PAPAVER SOMNIFERUM	0 (0.0)	1 (0.1)	1 (0.1)
GLYCYRRHIZA SPP.;OPHIOPOGON JAPONICUS;ORYZA SATIVA;PANAX GINSENG;PINELLIA TERNATA;ZIZIPHUS JUJUBA	0 (0.0)	1 (0.1)	1 (0.1)
GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA	1 (0.1)	0 (0.0)	1 (0.1)
GRIFOLA FRONDOSA	1 (0.1)	0 (0.0)	1 (0.1)
GUAIFENESIN	0 (0.0)	1 (0.1)	1 (0.1)
HARPAGOPHYTUM PROCUMBENS;HERBAL EXTRACT NOS;PERNA CANALICULUS EXTRACT	0 (0.0)	1 (0.1)	1 (0.1)
HEPATITIS A VACCINE	0 (0.0)	1 (0.1)	1 (0.1)
HEPATITIS B VACCINE	1 (0.1)	0 (0.0)	1 (0.1)
HERBAL POLLEN NOS;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.1)
HIBISCUS SPP.;PROPOLIS	0 (0.0)	1 (0.1)	1 (0.1)
HOMEOPATHIC PREPARATION	0 (0.0)	1 (0.1)	1 (0.1)
HUMULUS LUPULUS	1 (0.1)	0 (0.0)	1 (0.1)
HYALURONIC ACID;TREHALOSE	0 (0.0)	1 (0.1)	1 (0.1)
HYDROCHLOROTHIAZIDE	1 (0.1)	0 (0.0)	1 (0.1)
HYDROCODONE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.1)
HYDROCORTISONE;MICONAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
HYDROXOCOBALAMIN	1 (0.1)	0 (0.0)	1 (0.1)
HYDROXOCOBALAMIN;LIDOCAINE;PYRIDOXINE;THIAMINE	1 (0.1)	0 (0.0)	1 (0.1)
HYDROXYCHLOROQUINE	1 (0.1)	0 (0.0)	1 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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HYOSCINE	0 (0.0)	1 (0.1)	1 (0.1)
HYPNOTICS AND SEDATIVES	1 (0.1)	0 (0.0)	1 (0.1)
IMMUNOGLOBULIN HUMAN ANTI-TETANUS	1 (0.1)	0 (0.0)	1 (0.1)
INDOBUFEN	1 (0.1)	0 (0.0)	1 (0.1)
INDOLE-3-CARBINOL	1 (0.1)	0 (0.0)	1 (0.1)
INTRAUTERINE CONTRACEPTIVE DEVICE	0 (0.0)	1 (0.1)	1 (0.1)
IRON IN OTHER COMBINATIONS	1 (0.1)	0 (0.0)	1 (0.1)
IRON POLYSACCHARIDE COMPLEX	1 (0.1)	0 (0.0)	1 (0.1)
IRON;JUGLANS REGIA;NEOLITSEA CASSIA;PANAX QUINQUEFOLIUS;ZIZIPHUS JUJUBA	1 (0.1)	0 (0.0)	1 (0.1)
IRON;PROTEASE NOS	1 (0.1)	0 (0.0)	1 (0.1)
ISATIS TINCTORIA SUBSP. TINCTORIA	1 (0.1)	0 (0.0)	1 (0.1)
ISATIS TINCTORIA;ISATIS TINCTORIA SUBSP. TINCTORIA	1 (0.1)	0 (0.0)	1 (0.1)
ITOPRIDE	0 (0.0)	1 (0.1)	1 (0.1)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS	0 (0.0)	1 (0.1)	1 (0.1)
LACTOBACILLUS ACIDOPHILUS;PECTIN;PLANTAGO OVATA	1 (0.1)	0 (0.0)	1 (0.1)
LACTOBACILLUS NOS	1 (0.1)	0 (0.0)	1 (0.1)
LACTOBACILLUS REUTERI	1 (0.1)	0 (0.0)	1 (0.1)
LAPPACONITINE	1 (0.1)	0 (0.0)	1 (0.1)
LATANOPROST	1 (0.1)	0 (0.0)	1 (0.1)
LEECH	0 (0.0)	1 (0.1)	1 (0.1)
LEVAMISOLE	1 (0.1)	0 (0.0)	1 (0.1)
LEVETIRACETAM	0 (0.0)	1 (0.1)	1 (0.1)
LEVOBUPIVACAINE	1 (0.1)	0 (0.0)	1 (0.1)
LEVOCARNITINE	0 (0.0)	1 (0.1)	1 (0.1)

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Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
LEVOSULPIRIDE	1 (0.1)	0 (0.0)	1 (0.1)
LIDOCAINE;MENTHOL	0 (0.0)	1 (0.1)	1 (0.1)
LIGUSTRUM SPP.	1 (0.1)	0 (0.0)	1 (0.1)
LINUM USITATISSIMUM	1 (0.1)	0 (0.0)	1 (0.1)
LOMERIZINE	0 (0.0)	1 (0.1)	1 (0.1)
LOTEPREDNOL	0 (0.0)	1 (0.1)	1 (0.1)
LYSOZYME	0 (0.0)	1 (0.1)	1 (0.1)
MACROGOL 3350;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	1 (0.1)	0 (0.0)	1 (0.1)
MACROGOL 4000;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	0 (0.0)	1 (0.1)	1 (0.1)
MACROGOL 400;PROPYLENE GLYCOL	1 (0.1)	0 (0.0)	1 (0.1)
MAGNESIUM CHELATE	1 (0.1)	0 (0.0)	1 (0.1)
MAGNESIUM OXIDE;PYRIDOXINE	0 (0.0)	1 (0.1)	1 (0.1)
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	1 (0.1)	0 (0.0)	1 (0.1)
MELALEUCA SPP.	1 (0.1)	0 (0.0)	1 (0.1)
MEROPENEM	1 (0.1)	0 (0.0)	1 (0.1)
METHYLCELLULOSE	1 (0.1)	0 (0.0)	1 (0.1)
MONASCUS PURPUREUS	0 (0.0)	1 (0.1)	1 (0.1)
MONTMORILLONITE	1 (0.1)	0 (0.0)	1 (0.1)
MORUS SPP.	1 (0.1)	0 (0.0)	1 (0.1)
MOXIFLOXACIN	1 (0.1)	0 (0.0)	1 (0.1)
MULTIVITAMINS, COMBINATIONS	1 (0.1)	0 (0.0)	1 (0.1)
MUPIROCIN	0 (0.0)	1 (0.1)	1 (0.1)
NEBIVOLOL	1 (0.1)	0 (0.0)	1 (0.1)
NEOMYCIN;NYSTATIN;POLYMYXIN B	0 (0.0)	1 (0.1)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 32 of 36
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
NEPIDERMIN	1 (0.1)	0 (0.0)	1 (0.1)
NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0 (0.0)	1 (0.1)	1 (0.1)
NICOTINE	0 (0.0)	1 (0.1)	1 (0.1)
NIMESULIDE	0 (0.0)	1 (0.1)	1 (0.1)
NIMESULIDE;THIOCOLCHICOSIDE	0 (0.0)	1 (0.1)	1 (0.1)
NITROFURANTOIN	1 (0.1)	0 (0.0)	1 (0.1)
NUCLEOTIDES NOS;POLYPEPTIDE NOS	1 (0.1)	0 (0.0)	1 (0.1)
OCIMUM TENUIFLORUM	0 (0.0)	1 (0.1)	1 (0.1)
OENOTHERA BIENNIS	0 (0.0)	1 (0.1)	1 (0.1)
OENOTHERA BIENNIS;PYRIDOXINE	1 (0.1)	0 (0.0)	1 (0.1)
ORNITHINE	1 (0.1)	0 (0.0)	1 (0.1)
ORPHENADRINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	1 (0.1)	0 (0.0)	1 (0.1)
OTHER ANTIBIOTICS FOR TOPICAL USE	1 (0.1)	0 (0.0)	1 (0.1)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	1 (0.1)	0 (0.0)	1 (0.1)
OTHER ANTIVIRALS	0 (0.0)	1 (0.1)	1 (0.1)
OTHER DRUGS FOR BILE THERAPY	0 (0.0)	1 (0.1)	1 (0.1)
OTHER MINERAL PRODUCTS	1 (0.1)	0 (0.0)	1 (0.1)
OTHER NUTRIENTS	0 (0.0)	1 (0.1)	1 (0.1)
PALONOSETRON	1 (0.1)	0 (0.0)	1 (0.1)
PANAX GINSENG	1 (0.1)	0 (0.0)	1 (0.1)
PANCREATIN;SIMETICONE;URSODEOXYCHOLIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
PANTETHINE	1 (0.1)	0 (0.0)	1 (0.1)
PARACETAMOL;TRAMADOL	1 (0.1)	0 (0.0)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 33 of 36
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
PARECOXIB	0 (0.0)	1 (0.1)	1 (0.1)
PEGFILGRASTIM	1 (0.1)	0 (0.0)	1 (0.1)
PEGYLATED GRANULOCYTE COLONY STIMULATING FACTOR	0 (0.0)	1 (0.1)	1 (0.1)
PENEHYCLIDINE	1 (0.1)	0 (0.0)	1 (0.1)
PENICILLIN NOS	0 (0.0)	1 (0.1)	1 (0.1)
PEPTIDES NOS;THYMALFASIN	1 (0.1)	0 (0.0)	1 (0.1)
PHENOBARBITAL	1 (0.1)	0 (0.0)	1 (0.1)
PHENTERMINE	1 (0.1)	0 (0.0)	1 (0.1)
PHENTERMINE;TOPIRAMATE	1 (0.1)	0 (0.0)	1 (0.1)
PHOSPHORUS	1 (0.1)	0 (0.0)	1 (0.1)
PHYTOMENADIONE	0 (0.0)	1 (0.1)	1 (0.1)
PIPERACILLIN;TAZOBACTAM	1 (0.1)	0 (0.0)	1 (0.1)
PLANTAGO OVATA;SENNA SPP.	1 (0.1)	0 (0.0)	1 (0.1)
POLYCARBOPHIL	0 (0.0)	1 (0.1)	1 (0.1)
POLYSACCHARIDE-K	1 (0.1)	0 (0.0)	1 (0.1)
POSACONAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
POTASSIUM ASPARTATE	0 (0.0)	1 (0.1)	1 (0.1)
POTASSIUM BICARBONATE;SODIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.1)
POTASSIUM PERMANGANATE	1 (0.1)	0 (0.0)	1 (0.1)
PRAMOCAINE	1 (0.1)	0 (0.0)	1 (0.1)
PREBIOTICS NOS;PROBIOTICS NOS	1 (0.1)	0 (0.0)	1 (0.1)
PREDNISOLONE	1 (0.1)	0 (0.0)	1 (0.1)
PREPARATIONS WITH SALICYLIC ACID DERIVATIVES	0 (0.0)	1 (0.1)	1 (0.1)
PROMETHAZINE	1 (0.1)	0 (0.0)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
PROPACETAMOL	0 (0.0)	1 (0.1)	1 (0.1)
PSYLLIUM HYDROPHILIC MUCILLOID	1 (0.1)	0 (0.0)	1 (0.1)
PUNICA GRANATUM	1 (0.1)	0 (0.0)	1 (0.1)
PYRIDOXINE;VITAMIN B12 NOS	1 (0.1)	0 (0.0)	1 (0.1)
RABIES VACCINE	1 (0.1)	0 (0.0)	1 (0.1)
RAMIPRIL	1 (0.1)	0 (0.0)	1 (0.1)
REHMANNIA SPP.	0 (0.0)	1 (0.1)	1 (0.1)
RIBOFLAVIN	1 (0.1)	0 (0.0)	1 (0.1)
RIBOFLAVIN;THIAMINE;URSODEOXYCHOLIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
RILMAZAFONE	0 (0.0)	1 (0.1)	1 (0.1)
ROXATIDINE	1 (0.1)	0 (0.0)	1 (0.1)
RUPATADINE	1 (0.1)	0 (0.0)	1 (0.1)
SALBUTAMOL	0 (0.0)	1 (0.1)	1 (0.1)
SALMON OIL	1 (0.1)	0 (0.0)	1 (0.1)
SAMBUCUS NIGRA	1 (0.1)	0 (0.0)	1 (0.1)
SCORPION VENOM	1 (0.1)	0 (0.0)	1 (0.1)
SCUTELLARIA BAICALENSIS	1 (0.1)	0 (0.0)	1 (0.1)
SEA WATER	0 (0.0)	1 (0.1)	1 (0.1)
SEMAGLUTIDE	0 (0.0)	1 (0.1)	1 (0.1)
SERTRALINE	0 (0.0)	1 (0.1)	1 (0.1)
SILDENAFIL	0 (0.0)	1 (0.1)	1 (0.1)
SILICON DIOXIDE	1 (0.1)	0 (0.0)	1 (0.1)
SITAGLIPTIN	0 (0.0)	1 (0.1)	1 (0.1)
SODIUM LACTATE	0 (0.0)	1 (0.1)	1 (0.1)

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Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
SOFTENERS, EMOLLIENTS	0 (0.0)	1 (0.1)	1 (0.1)
SOTALOL	0 (0.0)	1 (0.1)	1 (0.1)
STAPHISAGRIA MACROSPERMA	0 (0.0)	1 (0.1)	1 (0.1)
STREPTOKINASE	1 (0.1)	0 (0.0)	1 (0.1)
SULGLICOTIDE	1 (0.1)	0 (0.0)	1 (0.1)
SUVOREXANT	0 (0.0)	1 (0.1)	1 (0.1)
SUXAMETHONIUM	0 (0.0)	1 (0.1)	1 (0.1)
SYNTHETIC ANTICHOLINERGIC AGENTS IN COMBINATION WITH PSYCHOLEPTICS	0 (0.0)	1 (0.1)	1 (0.1)
TECHNETIUM TC 99M MEDRONATE	1 (0.1)	0 (0.0)	1 (0.1)
TELMISARTAN	1 (0.1)	0 (0.0)	1 (0.1)
TEMAZEPAM	1 (0.1)	0 (0.0)	1 (0.1)
TENOFOVIR DISOPROXIL	1 (0.1)	0 (0.0)	1 (0.1)
TERPIN	0 (0.0)	1 (0.1)	1 (0.1)
TETANUS ANTITOXIN	0 (0.0)	1 (0.1)	1 (0.1)
TETANUS VACCINE	0 (0.0)	1 (0.1)	1 (0.1)
THYMALFASIN	0 (0.0)	1 (0.1)	1 (0.1)
THYMUS VULGARIS	0 (0.0)	1 (0.1)	1 (0.1)
TICK-BORNE ENCEPHALITIS VACCINE	1 (0.1)	0 (0.0)	1 (0.1)
TIROPRAMIDE	1 (0.1)	0 (0.0)	1 (0.1)
TOBRAMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
TRADITIONAL CHINESE MEDICINE (TCM) DECOCTION	1 (0.1)	0 (0.0)	1 (0.1)
TRADITIONAL MEDICINE	1 (0.1)	0 (0.0)	1 (0.1)
TRANILAST	0 (0.0)	1 (0.1)	1 (0.1)
TRIMEBUTINE	1 (0.1)	0 (0.0)	1 (0.1)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 36 of 36
Cohort 1 Population - Safety - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=776) n (%)	EDT*a (N=729) n (%)	Total (N=1505) n (%)
TRIMETAZIDINE	1 (0.1)	0 (0.0)	1 (0.1)
TROPISETRON	1 (0.1)	0 (0.0)	1 (0.1)
TROXIPIDE	1 (0.1)	0 (0.0)	1 (0.1)
TYPHOID VACCINE	1 (0.1)	0 (0.0)	1 (0.1)
TYROSINE	0 (0.0)	1 (0.1)	1 (0.1)
UBIDECARENONE;VITAMIN E NOS	1 (0.1)	0 (0.0)	1 (0.1)
UROGASTRONE	0 (0.0)	1 (0.1)	1 (0.1)
VACCINIUM MYRTILLUS	0 (0.0)	1 (0.1)	1 (0.1)
VALACICLOVIR	1 (0.1)	0 (0.0)	1 (0.1)
VALERIANA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.1)
VALPROIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
VANCOMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
VASOPRESSIN	0 (0.0)	1 (0.1)	1 (0.1)
VASOPROTECTIVES	1 (0.1)	0 (0.0)	1 (0.1)
VENLAFAXINE	0 (0.0)	1 (0.1)	1 (0.1)
VITAMIN D1	0 (0.0)	1 (0.1)	1 (0.1)
VITAMINS [UMBRELLA TERM]	0 (0.0)	1 (0.1)	1 (0.1)
WATER PURIFIED	1 (0.1)	0 (0.0)	1 (0.1)
YELLOW FEVER VACCINE	0 (0.0)	1 (0.1)	1 (0.1)
ZEAXANTHIN	0 (0.0)	1 (0.1)	1 (0.1)
ZOFENOPRIL	0 (0.0)	1 (0.1)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.1.6: Begleitmedikation (Postmenopausale Patientinnen)

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n	(%)	EDT*a (N=1264) n	(%)	Total (N=2547) n	(%)
Subjects with >= 1 Medication	1130	(88.1)	861	(68.1)	1991	(78.2)
LOPERAMIDE	760	(59.2)	26	(2.1)	786	(30.9)
PARACETAMOL	260	(20.3)	211	(16.7)	471	(18.5)
IBUPROFEN	110	(8.6)	114	(9.0)	224	(8.8)
AMOXICILLIN;CLAVULANIC ACID	101	(7.9)	79	(6.3)	180	(7.1)
DICLOFENAC	67	(5.2)	79	(6.3)	146	(5.7)
AMOXICILLIN	69	(5.4)	69	(5.5)	138	(5.4)
CIPROFLOXACIN	68	(5.3)	42	(3.3)	110	(4.3)
LEVOFLOXACIN	60	(4.7)	50	(4.0)	110	(4.3)
METAMIZOLE	49	(3.8)	56	(4.4)	105	(4.1)
AZITHROMYCIN	58	(4.5)	44	(3.5)	102	(4.0)
OMEPRAZOLE	71	(5.5)	31	(2.5)	102	(4.0)
PANTOPRAZOLE	63	(4.9)	30	(2.4)	93	(3.7)
TRAMADOL	47	(3.7)	40	(3.2)	87	(3.4)
METOCLOPRAMIDE	70	(5.5)	14	(1.1)	84	(3.3)
CEFALEXIN	40	(3.1)	43	(3.4)	83	(3.3)
METHYLPREDNISOLONE	49	(3.8)	32	(2.5)	81	(3.2)
ONDANSETRON	61	(4.8)	19	(1.5)	80	(3.1)
BETAMETHASONE	41	(3.2)	34	(2.7)	75	(2.9)
DEXAMETHASONE	49	(3.8)	26	(2.1)	75	(2.9)
LORATADINE	39	(3.0)	33	(2.6)	72	(2.8)
PREDNISONE	44	(3.4)	28	(2.2)	72	(2.8)
IRON	47	(3.7)	15	(1.2)	62	(2.4)
PREDNISOLONE	34	(2.7)	25	(2.0)	59	(2.3)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,

/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
SODIUM CHLORIDE	52 (4.1)	6 (0.5)	58 (2.3)
FEXOFENADINE	31 (2.4)	26 (2.1)	57 (2.2)
LOXOPROFEN	30 (2.3)	27 (2.1)	57 (2.2)
CEFUROXIME	37 (2.9)	19 (1.5)	56 (2.2)
CETIRIZINE	35 (2.7)	21 (1.7)	56 (2.2)
HYDROCORTISONE	36 (2.8)	19 (1.5)	55 (2.2)
POTASSIUM	43 (3.4)	12 (0.9)	55 (2.2)
NAPROXEN	18 (1.4)	36 (2.8)	54 (2.1)
GABAPENTIN	30 (2.3)	22 (1.7)	52 (2.0)
BUTYLSCOPOLAMINE	42 (3.3)	8 (0.6)	50 (2.0)
CODEINE;PARACETAMOL	25 (1.9)	24 (1.9)	49 (1.9)
NITROFURANTOIN	31 (2.4)	18 (1.4)	49 (1.9)
METRONIDAZOLE	28 (2.2)	20 (1.6)	48 (1.9)
CEFTRIAXONE	23 (1.8)	24 (1.9)	47 (1.8)
CLARITHROMYCIN	25 (1.9)	22 (1.7)	47 (1.8)
SULFAMETHOXAZOLE;TRIMETHOPRIM	31 (2.4)	16 (1.3)	47 (1.8)
DIPHENHYDRAMINE	23 (1.8)	23 (1.8)	46 (1.8)
ACICLOVIR	26 (2.0)	19 (1.5)	45 (1.8)
COLECALCIFEROL	22 (1.7)	23 (1.8)	45 (1.8)
KETOPROFEN	19 (1.5)	26 (2.1)	45 (1.8)
PREGABALIN	18 (1.4)	27 (2.1)	45 (1.8)
ACETYLCYSTEINE	24 (1.9)	20 (1.6)	44 (1.7)
CELECOXIB	20 (1.6)	24 (1.9)	44 (1.7)
FUROSEMIDE	27 (2.1)	17 (1.3)	44 (1.7)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ACETYLSALICYLIC ACID	26 (2.0)	17 (1.3)	43 (1.7)
ATORVASTATIN	22 (1.7)	21 (1.7)	43 (1.7)
CARBOCISTEINE	19 (1.5)	24 (1.9)	43 (1.7)
ENOXAPARIN	33 (2.6)	10 (0.8)	43 (1.7)
LEVOTHYROXINE	17 (1.3)	26 (2.1)	43 (1.7)
DEXTROMETHORPHAN	17 (1.3)	24 (1.9)	41 (1.6)
DOXYCYCLINE	24 (1.9)	16 (1.3)	40 (1.6)
LIDOCAINE	23 (1.8)	17 (1.3)	40 (1.6)
FENTANYL	23 (1.8)	16 (1.3)	39 (1.5)
TRIAMCINOLONE	23 (1.8)	16 (1.3)	39 (1.5)
VENLAFAXINE	16 (1.2)	22 (1.7)	38 (1.5)
AMBROXOL	22 (1.7)	15 (1.2)	37 (1.5)
CLINDAMYCIN	25 (1.9)	12 (0.9)	37 (1.5)
KETOROLAC	24 (1.9)	13 (1.0)	37 (1.5)
NYSTATIN	23 (1.8)	14 (1.1)	37 (1.5)
MOMETASONE	21 (1.6)	15 (1.2)	36 (1.4)
CODEINE	18 (1.4)	17 (1.3)	35 (1.4)
FOSFOMYCIN	20 (1.6)	15 (1.2)	35 (1.4)
HERBAL PREPARATION	21 (1.6)	13 (1.0)	34 (1.3)
HYALURONIC ACID	17 (1.3)	17 (1.3)	34 (1.3)
MORPHINE	20 (1.6)	14 (1.1)	34 (1.3)
OXYCODONE	13 (1.0)	21 (1.7)	34 (1.3)
DIOSMECTITE	32 (2.5)	1 (0.1)	33 (1.3)
BENZONATATE	19 (1.5)	12 (0.9)	31 (1.2)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ESOMEPRAZOLE	19 (1.5)	12 (0.9)	31 (1.2)
FLUCONAZOLE	22 (1.7)	9 (0.7)	31 (1.2)
PIPERACILLIN;TAZOBACTAM	20 (1.6)	11 (0.9)	31 (1.2)
TRANEXAMIC ACID	13 (1.0)	17 (1.3)	30 (1.2)
FAMOTIDINE	19 (1.5)	10 (0.8)	29 (1.1)
FOLIC ACID	24 (1.9)	5 (0.4)	29 (1.1)
HEPARINOID	17 (1.3)	12 (0.9)	29 (1.1)
MAGNESIUM	17 (1.3)	12 (0.9)	29 (1.1)
METFORMIN	15 (1.2)	14 (1.1)	29 (1.1)
SALBUTAMOL	18 (1.4)	11 (0.9)	29 (1.1)
ZOLPIDEM	17 (1.3)	12 (0.9)	29 (1.1)
LANSOPRAZOLE	20 (1.6)	8 (0.6)	28 (1.1)
ESCITALOPRAM	14 (1.1)	13 (1.0)	27 (1.1)
ALPRAZOLAM	13 (1.0)	13 (1.0)	26 (1.0)
CHLORPHENAMINE	13 (1.0)	13 (1.0)	26 (1.0)
MELOXICAM	14 (1.1)	12 (0.9)	26 (1.0)
MOXIFLOXACIN	20 (1.6)	6 (0.5)	26 (1.0)
TRIMETHOPRIM	16 (1.2)	10 (0.8)	26 (1.0)
VALACICLOVIR	17 (1.3)	9 (0.7)	26 (1.0)
DOCUSATE	14 (1.1)	11 (0.9)	25 (1.0)
DOMPERIDONE	21 (1.6)	4 (0.3)	25 (1.0)
FILGRASTIM	24 (1.9)	1 (0.1)	25 (1.0)
GUAIFENESIN	12 (0.9)	13 (1.0)	25 (1.0)
LORAZEPAM	12 (0.9)	13 (1.0)	25 (1.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PROMETHAZINE	18 (1.4)	7 (0.6)	25 (1.0)
ASCORBIC ACID	17 (1.3)	7 (0.6)	24 (0.9)
CALCIUM CARBONATE;COLECALCIFEROL	11 (0.9)	13 (1.0)	24 (0.9)
CEFCAPENE	11 (0.9)	13 (1.0)	24 (0.9)
CLOBETASOL	18 (1.4)	6 (0.5)	24 (0.9)
LEVOCETIRIZINE	16 (1.2)	8 (0.6)	24 (0.9)
MONTELUKAST	17 (1.3)	7 (0.6)	24 (0.9)
RANITIDINE	19 (1.5)	5 (0.4)	24 (0.9)
ALENDRONIC ACID	9 (0.7)	14 (1.1)	23 (0.9)
PARACETAMOL;TRAMADOL	10 (0.8)	13 (1.0)	23 (0.9)
VITAMIN D NOS	13 (1.0)	10 (0.8)	23 (0.9)
CYCLOBENZAPRINE	12 (0.9)	10 (0.8)	22 (0.9)
MAGNESIUM OXIDE	13 (1.0)	9 (0.7)	22 (0.9)
ROSUVASTATIN	12 (0.9)	10 (0.8)	22 (0.9)
SERTRALINE	6 (0.5)	16 (1.3)	22 (0.9)
AMITRIPTYLINE	8 (0.6)	13 (1.0)	21 (0.8)
BETAHISTINE	12 (0.9)	9 (0.7)	21 (0.8)
BETAMETHASONE;GENTAMICIN	12 (0.9)	9 (0.7)	21 (0.8)
BILASTINE	12 (0.9)	9 (0.7)	21 (0.8)
BISOPROLOL	12 (0.9)	9 (0.7)	21 (0.8)
CAFFEINE;PARACETAMOL;PROMETHAZINE;SALICYLAMIDE	8 (0.6)	13 (1.0)	21 (0.8)
DIOSMIN;HESPERIDIN	15 (1.2)	6 (0.5)	21 (0.8)
FLUTICASONE	10 (0.8)	11 (0.9)	21 (0.8)
HYDROXYZINE	16 (1.2)	5 (0.4)	21 (0.8)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
OXYCODONE;PARACETAMOL	10 (0.8)	11 (0.9)	21 (0.8)
SIMETICONE	14 (1.1)	7 (0.6)	21 (0.8)
VANCOMYCIN	11 (0.9)	10 (0.8)	21 (0.8)
VITAMIN B COMPLEX	13 (1.0)	8 (0.6)	21 (0.8)
ZOLEDRONIC ACID	10 (0.8)	11 (0.9)	21 (0.8)
AMLODIPINE	7 (0.5)	13 (1.0)	20 (0.8)
CYANOCOBALAMIN	15 (1.2)	5 (0.4)	20 (0.8)
GENTAMICIN	10 (0.8)	10 (0.8)	20 (0.8)
HEPARIN	13 (1.0)	7 (0.6)	20 (0.8)
HYDROCODONE;PARACETAMOL	12 (0.9)	8 (0.6)	20 (0.8)
IPRATROPIUM	16 (1.2)	4 (0.3)	20 (0.8)
MELATONIN	9 (0.7)	11 (0.9)	20 (0.8)
OSELTAMIVIR	13 (1.0)	7 (0.6)	20 (0.8)
CEFAZOLIN	8 (0.6)	11 (0.9)	19 (0.7)
CLOTRIMAZOLE	11 (0.9)	8 (0.6)	19 (0.7)
HYDROMORPHONE	9 (0.7)	10 (0.8)	19 (0.7)
LACTULOSE	11 (0.9)	8 (0.6)	19 (0.7)
URSODEOXYCHOLIC ACID	12 (0.9)	7 (0.6)	19 (0.7)
CALCIUM CARBONATE	13 (1.0)	5 (0.4)	18 (0.7)
CEFDINIR	7 (0.5)	11 (0.9)	18 (0.7)
DEXCHLORPHENIRAMINE	8 (0.6)	10 (0.8)	18 (0.7)
DEXKETOPROFEN	14 (1.1)	4 (0.3)	18 (0.7)
DULOXETINE	8 (0.6)	10 (0.8)	18 (0.7)
ETORICOXIB	9 (0.7)	9 (0.7)	18 (0.7)

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/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
FLUCLOXACILLIN	12 (0.9)	6 (0.5)	18 (0.7)
KETOCONAZOLE	6 (0.5)	12 (0.9)	18 (0.7)
MIDAZOLAM	12 (0.9)	6 (0.5)	18 (0.7)
NIMESULIDE	10 (0.8)	8 (0.6)	18 (0.7)
OLOPATADINE	9 (0.7)	9 (0.7)	18 (0.7)
ZINC	14 (1.1)	4 (0.3)	18 (0.7)
CORTISONE	5 (0.4)	12 (0.9)	17 (0.7)
DENOSUMAB	6 (0.5)	11 (0.9)	17 (0.7)
FUSIDIC ACID	12 (0.9)	5 (0.4)	17 (0.7)
LOSARTAN	6 (0.5)	11 (0.9)	17 (0.7)
RIVAROXABAN	14 (1.1)	3 (0.2)	17 (0.7)
ACECLOFENAC	10 (0.8)	6 (0.5)	16 (0.6)
CEFACLOR	9 (0.7)	7 (0.6)	16 (0.6)
DIAZEPAM	6 (0.5)	10 (0.8)	16 (0.6)
PIVMECILLINAM	8 (0.6)	8 (0.6)	16 (0.6)
PROCHLORPERAZINE	15 (1.2)	1 (0.1)	16 (0.6)
SENNOSIDE A+B	10 (0.8)	6 (0.5)	16 (0.6)
VITAMIN B12 NOS	14 (1.1)	2 (0.2)	16 (0.6)
AMMONIUM CHLORIDE;CHLORPHENAMINE;DIHYDROCODEINE;METHYLEPHEDRINE	11 (0.9)	4 (0.3)	15 (0.6)
APIXABAN	11 (0.9)	4 (0.3)	15 (0.6)
BISACODYL	6 (0.5)	9 (0.7)	15 (0.6)
BUDESONIDE	12 (0.9)	3 (0.2)	15 (0.6)
CALCIUM	7 (0.5)	8 (0.6)	15 (0.6)
DESLORATADINE	8 (0.6)	7 (0.6)	15 (0.6)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 8 of 81
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ENALAPRIL	5 (0.4)	10 (0.8)	15 (0.6)
FLUOXETINE	6 (0.5)	9 (0.7)	15 (0.6)
MICONAZOLE	5 (0.4)	10 (0.8)	15 (0.6)
MUPIROCIN	11 (0.9)	4 (0.3)	15 (0.6)
PHENAZOPYRIDINE	8 (0.6)	7 (0.6)	15 (0.6)
PROPOFOL	12 (0.9)	3 (0.2)	15 (0.6)
PSEUDOEPHEDRINE	7 (0.5)	8 (0.6)	15 (0.6)
SIMVASTATIN	8 (0.6)	7 (0.6)	15 (0.6)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	10 (0.8)	5 (0.4)	15 (0.6)
CAFFEINE;CARISOPRODOL;DICLOFENAC;PARACETAMOL	4 (0.3)	10 (0.8)	14 (0.5)
CITALOPRAM	11 (0.9)	3 (0.2)	14 (0.5)
FLUOROMETHOLONE	8 (0.6)	6 (0.5)	14 (0.5)
GUALENIC ACID	9 (0.7)	5 (0.4)	14 (0.5)
HYDROCHLOROTHIAZIDE	9 (0.7)	5 (0.4)	14 (0.5)
HYOSCINE	9 (0.7)	5 (0.4)	14 (0.5)
MECLOZINE	6 (0.5)	8 (0.6)	14 (0.5)
RACECADOTRIL	14 (1.1)	0 (0.0)	14 (0.5)
TRAZODONE	6 (0.5)	8 (0.6)	14 (0.5)
ATROPINE;DIPHENOXYLATE	13 (1.0)	0 (0.0)	13 (0.5)
BEZAFIBRATE	7 (0.5)	6 (0.5)	13 (0.5)
DROTAVERINE	10 (0.8)	3 (0.2)	13 (0.5)
FLURBIPROFEN	7 (0.5)	6 (0.5)	13 (0.5)
MEROPENEM	7 (0.5)	6 (0.5)	13 (0.5)
METOPROLOL	8 (0.6)	5 (0.4)	13 (0.5)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BENZYDAMINE	5 (0.4)	7 (0.6)	12 (0.5)
BEPOTASTINE	10 (0.8)	2 (0.2)	12 (0.5)
CAPTOPRIL	5 (0.4)	7 (0.6)	12 (0.5)
CEFDITOREN	7 (0.5)	5 (0.4)	12 (0.5)
CLONAZEPAM	7 (0.5)	5 (0.4)	12 (0.5)
DIMENHYDRINATE	10 (0.8)	2 (0.2)	12 (0.5)
EPINEPHRINE	7 (0.5)	5 (0.4)	12 (0.5)
GLUCOSE	10 (0.8)	2 (0.2)	12 (0.5)
GRANULOCYTE COLONY STIMULATING FACTOR	11 (0.9)	1 (0.1)	12 (0.5)
PLANTAGO OVATA	11 (0.9)	1 (0.1)	12 (0.5)
SILYBUM MARIANUM	6 (0.5)	6 (0.5)	12 (0.5)
SPIRONOLACTONE	8 (0.6)	4 (0.3)	12 (0.5)
SUCRALFATE	9 (0.7)	3 (0.2)	12 (0.5)
CALCIUM;COLECALCIFEROL	7 (0.5)	4 (0.3)	11 (0.4)
CEFIXIME	7 (0.5)	4 (0.3)	11 (0.4)
CHLORAMPHENICOL	5 (0.4)	6 (0.5)	11 (0.4)
CLAVULANIC ACID	4 (0.3)	7 (0.6)	11 (0.4)
CLOSTRIDIUM BUTYRICUM	10 (0.8)	1 (0.1)	11 (0.4)
IPRATROPIUM;SALBUTAMOL	6 (0.5)	5 (0.4)	11 (0.4)
LISINOPRIL	4 (0.3)	7 (0.6)	11 (0.4)
MACROGOL 3350	7 (0.5)	4 (0.3)	11 (0.4)
NORFLOXACIN	8 (0.6)	3 (0.2)	11 (0.4)
PHENYLEPHRINE	8 (0.6)	3 (0.2)	11 (0.4)
ROCURONIUM	8 (0.6)	3 (0.2)	11 (0.4)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
SANGUISORBA OFFICINALIS	10 (0.8)	1 (0.1)	11 (0.4)
TERBINAFINE	8 (0.6)	3 (0.2)	11 (0.4)
TOCOPHEROL	6 (0.5)	5 (0.4)	11 (0.4)
ALLOPURINOL	9 (0.7)	1 (0.1)	10 (0.4)
ANTIDIARRHEAL MICROORGANISMS	10 (0.8)	0 (0.0)	10 (0.4)
BECLOMETASONE	5 (0.4)	5 (0.4)	10 (0.4)
BISMUTH	8 (0.6)	2 (0.2)	10 (0.4)
BROMHEXINE	6 (0.5)	4 (0.3)	10 (0.4)
CEFPODOXIME	8 (0.6)	2 (0.2)	10 (0.4)
FOLIC ACID;IRON	8 (0.6)	2 (0.2)	10 (0.4)
HYOSCINE;METAMIZOLE	9 (0.7)	1 (0.1)	10 (0.4)
MACROGOL 3350;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	6 (0.5)	4 (0.3)	10 (0.4)
MIRTAZAPINE	3 (0.2)	7 (0.6)	10 (0.4)
OXYBUTYNIN	7 (0.5)	3 (0.2)	10 (0.4)
SODIUM BICARBONATE	8 (0.6)	2 (0.2)	10 (0.4)
TOBRAMYCIN	8 (0.6)	2 (0.2)	10 (0.4)
UREA	8 (0.6)	2 (0.2)	10 (0.4)
VITIS VINIFERA	6 (0.5)	4 (0.3)	10 (0.4)
ALIZAPRIDE	8 (0.6)	1 (0.1)	9 (0.4)
CAFFEINE;METAMIZOLE;ORPHENADRINE	4 (0.3)	5 (0.4)	9 (0.4)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	8 (0.6)	1 (0.1)	9 (0.4)
CALCIUM CHLORIDE;POTASSIUM;SODIUM LACTATE	7 (0.5)	2 (0.2)	9 (0.4)
CHLORHEXIDINE	8 (0.6)	1 (0.1)	9 (0.4)
CLEMASTINE	5 (0.4)	4 (0.3)	9 (0.4)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
DICLOXACILLIN	5 (0.4)	4 (0.3)	9 (0.4)
DIMETICONE	5 (0.4)	4 (0.3)	9 (0.4)
DIOSMIN	9 (0.7)	0 (0.0)	9 (0.4)
ERYTHROMYCIN	5 (0.4)	4 (0.3)	9 (0.4)
ESTRADIOL	4 (0.3)	5 (0.4)	9 (0.4)
ESTRIOL	6 (0.5)	3 (0.2)	9 (0.4)
FENOTEROL	6 (0.5)	3 (0.2)	9 (0.4)
MACROGOL	3 (0.2)	6 (0.5)	9 (0.4)
NOREPINEPHRINE	5 (0.4)	4 (0.3)	9 (0.4)
OFLOXACIN	3 (0.2)	6 (0.5)	9 (0.4)
OTHER EMOLLIENTS AND PROTECTIVES	7 (0.5)	2 (0.2)	9 (0.4)
PIROXICAM	6 (0.5)	3 (0.2)	9 (0.4)
PROPRANOLOL	4 (0.3)	5 (0.4)	9 (0.4)
PYRIDOXINE	7 (0.5)	2 (0.2)	9 (0.4)
SACCHAROMYCES BOULARDII	6 (0.5)	3 (0.2)	9 (0.4)
SULFADIAZINE	6 (0.5)	3 (0.2)	9 (0.4)
AMPICILLIN;SULBACTAM	6 (0.5)	2 (0.2)	8 (0.3)
BENZYLPENICILLIN	4 (0.3)	4 (0.3)	8 (0.3)
BIFIDOBACTERIUM NOS	7 (0.5)	1 (0.1)	8 (0.3)
BIOTIN	7 (0.5)	1 (0.1)	8 (0.3)
BUDESONIDE;FORMOTEROL	4 (0.3)	4 (0.3)	8 (0.3)
CARBOMER	6 (0.5)	2 (0.2)	8 (0.3)
CARVEDILOL	3 (0.2)	5 (0.4)	8 (0.3)
CHLORPHENAMINE;DIHYDROCODEINE;METHYLEPHEDRINE	6 (0.5)	2 (0.2)	8 (0.3)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CINNARIZINE	2 (0.2)	6 (0.5)	8 (0.3)
CURCUMA LONGA	3 (0.2)	5 (0.4)	8 (0.3)
CYANOCOBALAMIN;PYRIDOXINE;THIAMINE	5 (0.4)	3 (0.2)	8 (0.3)
DIFLUPREDNATE	7 (0.5)	1 (0.1)	8 (0.3)
DIMEMORFAN	4 (0.3)	4 (0.3)	8 (0.3)
ERDOSTEINE	6 (0.5)	2 (0.2)	8 (0.3)
FLUNARIZINE	3 (0.2)	5 (0.4)	8 (0.3)
GLUCOSAMINE	2 (0.2)	6 (0.5)	8 (0.3)
GRANISETRON	8 (0.6)	0 (0.0)	8 (0.3)
IBANDRONIC ACID	4 (0.3)	4 (0.3)	8 (0.3)
MACROGOL;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	5 (0.4)	3 (0.2)	8 (0.3)
MECOBALAMIN	5 (0.4)	3 (0.2)	8 (0.3)
MINOXIDIL	7 (0.5)	1 (0.1)	8 (0.3)
PHENOXYMETHYLPENICILLIN	5 (0.4)	3 (0.2)	8 (0.3)
RABEPRAZOLE	4 (0.3)	4 (0.3)	8 (0.3)
RAMIPRIL	4 (0.3)	4 (0.3)	8 (0.3)
REBAMIPIDE	7 (0.5)	1 (0.1)	8 (0.3)
THIOCTIC ACID	5 (0.4)	3 (0.2)	8 (0.3)
XYLOMETAZOLINE	5 (0.4)	3 (0.2)	8 (0.3)
AMIODARONE	4 (0.3)	3 (0.2)	7 (0.3)
CARBOMER;GLYCEROL;PARAFFIN, LIQUID;POLYCARBOPHIL	2 (0.2)	5 (0.4)	7 (0.3)
CHONDROITIN;GLUCOSAMINE	2 (0.2)	5 (0.4)	7 (0.3)
CLOPERASTINE	5 (0.4)	2 (0.2)	7 (0.3)
CLOPIDOGREL	4 (0.3)	3 (0.2)	7 (0.3)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
COUGH AND COLD PREPARATIONS	5 (0.4)	2 (0.2)	7 (0.3)
CROTAMITON	0 (0.0)	7 (0.6)	7 (0.3)
DEXLANSOPRAZOLE	4 (0.3)	3 (0.2)	7 (0.3)
DICYCLOVERINE	6 (0.5)	1 (0.1)	7 (0.3)
DIFENIDOL	4 (0.3)	3 (0.2)	7 (0.3)
EDOXABAN	4 (0.3)	3 (0.2)	7 (0.3)
ETOFENAMATE	3 (0.2)	4 (0.3)	7 (0.3)
FAVIPIRAVIR	6 (0.5)	1 (0.1)	7 (0.3)
GLYCEROL	4 (0.3)	3 (0.2)	7 (0.3)
HYPROMELLOSE	3 (0.2)	4 (0.3)	7 (0.3)
INSULIN GLARGINE	3 (0.2)	4 (0.3)	7 (0.3)
IVERMECTIN	5 (0.4)	2 (0.2)	7 (0.3)
MEQUITAZINE	3 (0.2)	4 (0.3)	7 (0.3)
METHOCARBAMOL	3 (0.2)	4 (0.3)	7 (0.3)
MIRABEGRON	4 (0.3)	3 (0.2)	7 (0.3)
MOSAPRIDE	4 (0.3)	3 (0.2)	7 (0.3)
MULTIVITAMINS, PLAIN	6 (0.5)	1 (0.1)	7 (0.3)
OTILONIUM	6 (0.5)	1 (0.1)	7 (0.3)
OXYGEN	4 (0.3)	3 (0.2)	7 (0.3)
PENICILLIN NOS	4 (0.3)	3 (0.2)	7 (0.3)
PERINDOPRIL	1 (0.1)	6 (0.5)	7 (0.3)
ROXITHROMYCIN	4 (0.3)	3 (0.2)	7 (0.3)
RUPATADINE	5 (0.4)	2 (0.2)	7 (0.3)
SODIUM PICOSULFATE	4 (0.3)	3 (0.2)	7 (0.3)

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/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
SULFAMETHOXAZOLE	4 (0.3)	3 (0.2)	7 (0.3)
TANNIC ACID	7 (0.5)	0 (0.0)	7 (0.3)
TINZAPARIN	7 (0.5)	0 (0.0)	7 (0.3)
TOCOPHERYL NICOTINATE	2 (0.2)	5 (0.4)	7 (0.3)
ADEMETIONINE	4 (0.3)	2 (0.2)	6 (0.2)
ALGINIC ACID;CALCIUM CARBONATE;SODIUM BICARBONATE	3 (0.2)	3 (0.2)	6 (0.2)
AMINOPHYLLINE;CHLORPHENAMINE;METHOXYPHENAMINE;NOSCAPINE	5 (0.4)	1 (0.1)	6 (0.2)
AZELASTINE	4 (0.3)	2 (0.2)	6 (0.2)
BACLOFEN	5 (0.4)	1 (0.1)	6 (0.2)
BALOXAVIR MARBOXIL	4 (0.3)	2 (0.2)	6 (0.2)
BROMAZEPAM	2 (0.2)	4 (0.3)	6 (0.2)
BUPIVACAINE	5 (0.4)	1 (0.1)	6 (0.2)
CANDESARTAN	2 (0.2)	4 (0.3)	6 (0.2)
CANNABIS SATIVA	1 (0.1)	5 (0.4)	6 (0.2)
CARMELLOSE	6 (0.5)	0 (0.0)	6 (0.2)
CEFADROXIL	5 (0.4)	1 (0.1)	6 (0.2)
CEFEPIME	5 (0.4)	1 (0.1)	6 (0.2)
CHLORPHENAMINE;PARACETAMOL;PHENYLEPHRINE	3 (0.2)	3 (0.2)	6 (0.2)
DESOXIMETASONE	5 (0.4)	1 (0.1)	6 (0.2)
DEXTROMETHORPHAN;DOXYLAMINE;EPHEDRINE;ETHANOL;PARACETAMOL	3 (0.2)	3 (0.2)	6 (0.2)
DIETARY SUPPLEMENT	2 (0.2)	4 (0.3)	6 (0.2)
DIHYDROCODEINE	5 (0.4)	1 (0.1)	6 (0.2)
DOCUSATE;SENNOSIDE A+B	3 (0.2)	3 (0.2)	6 (0.2)
EPINEPHRINE;LIDOCAINE	2 (0.2)	4 (0.3)	6 (0.2)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ERYTHROPOIETIN HUMAN	6 (0.5)	0 (0.0)	6 (0.2)
FELBINAC	3 (0.2)	3 (0.2)	6 (0.2)
FENOFIBRATE	4 (0.3)	2 (0.2)	6 (0.2)
GLUTATHIONE	2 (0.2)	4 (0.3)	6 (0.2)
GLYCERYL TRINITRATE	4 (0.3)	2 (0.2)	6 (0.2)
GRAMICIDIN;NEOMYCIN;NYSTATIN;TRIAMCINOLONE	3 (0.2)	3 (0.2)	6 (0.2)
GUAIAZULENE	4 (0.3)	2 (0.2)	6 (0.2)
INSULIN NOS	2 (0.2)	4 (0.3)	6 (0.2)
LACTOBACILLUS ACIDOPHILUS	4 (0.3)	2 (0.2)	6 (0.2)
MACROGOL 4000	3 (0.2)	3 (0.2)	6 (0.2)
MACROGOL 400;PROPYLENE GLYCOL	4 (0.3)	2 (0.2)	6 (0.2)
MEBEVERINE	3 (0.2)	3 (0.2)	6 (0.2)
PARACETAMOL;PHENYLEPHRINE	2 (0.2)	4 (0.3)	6 (0.2)
POVIDONE-IODINE	4 (0.3)	2 (0.2)	6 (0.2)
PREDNICARBATE	5 (0.4)	1 (0.1)	6 (0.2)
PSEUDOEPHEDRINE;TRIPROLIDINE	3 (0.2)	3 (0.2)	6 (0.2)
RED BLOOD CELLS	6 (0.5)	0 (0.0)	6 (0.2)
RISEDRONIC ACID	1 (0.1)	5 (0.4)	6 (0.2)
SUGAMMADEX	4 (0.3)	2 (0.2)	6 (0.2)
TAPENTADOL	3 (0.2)	3 (0.2)	6 (0.2)
THIAMINE	4 (0.3)	2 (0.2)	6 (0.2)
TIROPRAMIDE	4 (0.3)	2 (0.2)	6 (0.2)
ZOPICLONE	2 (0.2)	4 (0.3)	6 (0.2)
ACEMETACIN	3 (0.2)	2 (0.2)	5 (0.2)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ADENOSINE	1 (0.1)	4 (0.3)	5 (0.2)
ANTIBIOTICS	5 (0.4)	0 (0.0)	5 (0.2)
ARGININE GLUTAMATE	1 (0.1)	4 (0.3)	5 (0.2)
ARNICA MONTANA	3 (0.2)	2 (0.2)	5 (0.2)
BACITRACIN;NEOMYCIN	4 (0.3)	1 (0.1)	5 (0.2)
BENPROPERINE	1 (0.1)	4 (0.3)	5 (0.2)
BETAMETHASONE;FUSIDIC ACID	5 (0.4)	0 (0.0)	5 (0.2)
CAFFEINE;CODEINE;PARACETAMOL	4 (0.3)	1 (0.1)	5 (0.2)
CALCIUM;VITAMIN D NOS	1 (0.1)	4 (0.3)	5 (0.2)
CHONDROITIN	1 (0.1)	4 (0.3)	5 (0.2)
CODEINE;PROMETHAZINE	1 (0.1)	4 (0.3)	5 (0.2)
COLESTYRAMINE	5 (0.4)	0 (0.0)	5 (0.2)
CYANOCOBALAMIN;DICLOFENAC;PYRIDOXINE;THIAMINE	1 (0.1)	4 (0.3)	5 (0.2)
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	3 (0.2)	2 (0.2)	5 (0.2)
DESONIDE	4 (0.3)	1 (0.1)	5 (0.2)
DEXAMETHASONE;TOBRAMYCIN	4 (0.3)	1 (0.1)	5 (0.2)
DEXTROMETHORPHAN;GUAIFENESIN	2 (0.2)	3 (0.2)	5 (0.2)
DIMENHYDRINATE;PYRIDOXINE	4 (0.3)	1 (0.1)	5 (0.2)
ELDECALCITOL	3 (0.2)	2 (0.2)	5 (0.2)
EPHEDRINE	3 (0.2)	2 (0.2)	5 (0.2)
ESOMEPRAZOLE;NAPROXEN	2 (0.2)	3 (0.2)	5 (0.2)
ESTAZOLAM	1 (0.1)	4 (0.3)	5 (0.2)
FAMCICLOVIR	2 (0.2)	3 (0.2)	5 (0.2)
GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA	3 (0.2)	2 (0.2)	5 (0.2)

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Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
HYDROCODONE	2 (0.2)	3 (0.2)	5 (0.2)
HYDROXYCHLOROQUINE	2 (0.2)	3 (0.2)	5 (0.2)
IRON;JUGLANS REGIA;NEOLITSEA CASSIA;PANAX QUINQUEFOLIUS;SEA HORSE;ZIZIPHUS JUJUBA	5 (0.4)	0 (0.0)	5 (0.2)
LEUCOGEN	4 (0.3)	1 (0.1)	5 (0.2)
LEVODROPROPIZINE	4 (0.3)	1 (0.1)	5 (0.2)
LORNOXICAM	2 (0.2)	3 (0.2)	5 (0.2)
MAGNESIUM HYDROXIDE	2 (0.2)	3 (0.2)	5 (0.2)
MAGNESIUM SULFATE	5 (0.4)	0 (0.0)	5 (0.2)
MEFENAMIC ACID	0 (0.0)	5 (0.4)	5 (0.2)
MEGESTROL	4 (0.3)	1 (0.1)	5 (0.2)
MENTHOL	3 (0.2)	2 (0.2)	5 (0.2)
MEPHENOXALONE	3 (0.2)	2 (0.2)	5 (0.2)
METHYLURACIL	2 (0.2)	3 (0.2)	5 (0.2)
NALOXONE	4 (0.3)	1 (0.1)	5 (0.2)
NEBIVOLOL	1 (0.1)	4 (0.3)	5 (0.2)
NEOSTIGMINE	3 (0.2)	2 (0.2)	5 (0.2)
NEPAFENAC	4 (0.3)	1 (0.1)	5 (0.2)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	1 (0.1)	4 (0.3)	5 (0.2)
ORPHENADRINE	3 (0.2)	2 (0.2)	5 (0.2)
PARAFFIN, LIQUID	1 (0.1)	4 (0.3)	5 (0.2)
PRANLUKAST	1 (0.1)	4 (0.3)	5 (0.2)
PRANOPROFEN	3 (0.2)	2 (0.2)	5 (0.2)
PRAVASTATIN	0 (0.0)	5 (0.4)	5 (0.2)
PROBIOTICS NOS	5 (0.4)	0 (0.0)	5 (0.2)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PROPACETAMOL	5 (0.4)	0 (0.0)	5 (0.2)
RIFAMPICIN	4 (0.3)	1 (0.1)	5 (0.2)
SALICYLIC ACID	2 (0.2)	3 (0.2)	5 (0.2)
SODIUM PHOSPHATE	5 (0.4)	0 (0.0)	5 (0.2)
TETRACYCLINE	4 (0.3)	1 (0.1)	5 (0.2)
THEOBROMINE	5 (0.4)	0 (0.0)	5 (0.2)
TIZANIDINE	1 (0.1)	4 (0.3)	5 (0.2)
TULOBUTEROL	1 (0.1)	4 (0.3)	5 (0.2)
ZALTOPROFEN	4 (0.3)	1 (0.1)	5 (0.2)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	3 (0.2)	1 (0.1)	4 (0.2)
ALMAGATE	2 (0.2)	2 (0.2)	4 (0.2)
AMMONIUM CHLORIDE;CHLORPHENAMINE;DEXTROMETHORPHAN;GUAIFENESIN	3 (0.2)	1 (0.1)	4 (0.2)
ATENOLOL	4 (0.3)	0 (0.0)	4 (0.2)
ATROPINE	2 (0.2)	2 (0.2)	4 (0.2)
BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS	4 (0.3)	0 (0.0)	4 (0.2)
BENZYDAMINE;CHLORHEXIDINE	3 (0.2)	1 (0.1)	4 (0.2)
BICYCLOL	1 (0.1)	3 (0.2)	4 (0.2)
BIDENS BITERNATA;CAFFEINE;CHLORPHENAMINE;CHRYSANTHEMUM INDICUM;ILEX ASPRELLA;MELICOPE PTELEIFOLIA;MENTHA CANADENSIS;PARACETAMOL	2 (0.2)	2 (0.2)	4 (0.2)
BROMFENAC	2 (0.2)	2 (0.2)	4 (0.2)
BUPRENORPHINE	3 (0.2)	1 (0.1)	4 (0.2)
CAFFEINE;PARACETAMOL	3 (0.2)	1 (0.1)	4 (0.2)
CALCITRIOL	3 (0.2)	1 (0.1)	4 (0.2)
CARBAMAZEPINE	2 (0.2)	2 (0.2)	4 (0.2)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CEFOTIAM	3 (0.2)	1 (0.1)	4 (0.2)
CEFRADINE	2 (0.2)	2 (0.2)	4 (0.2)
CEFTERAM	2 (0.2)	2 (0.2)	4 (0.2)
CHARCOAL, ACTIVATED	3 (0.2)	1 (0.1)	4 (0.2)
CHLOROPYRAMINE	3 (0.2)	1 (0.1)	4 (0.2)
CHLORZOXAZONE	2 (0.2)	2 (0.2)	4 (0.2)
CODEINE;IBUPROFEN;PARACETAMOL	3 (0.2)	1 (0.1)	4 (0.2)
DALTEPARIN	3 (0.2)	1 (0.1)	4 (0.2)
DEQUALINIUM	2 (0.2)	2 (0.2)	4 (0.2)
DEXAMETHASONE;NEOMYCIN;POLYMYXIN B	4 (0.3)	0 (0.0)	4 (0.2)
DEXTRAN;HYPROMELLOSE	4 (0.3)	0 (0.0)	4 (0.2)
DEXTROMETHORPHAN;LYSOZYME;POTASSIUM CRESOLSULFONATE	1 (0.1)	3 (0.2)	4 (0.2)
DIQUAFOSOL	2 (0.2)	2 (0.2)	4 (0.2)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	3 (0.2)	1 (0.1)	4 (0.2)
EBASTINE	1 (0.1)	3 (0.2)	4 (0.2)
EPERISONE	2 (0.2)	2 (0.2)	4 (0.2)
EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PUERARIA MONTANA VAR. LOBATA;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	2 (0.2)	2 (0.2)	4 (0.2)
ERGOCALCIFEROL	2 (0.2)	2 (0.2)	4 (0.2)
ERTAPENEM	3 (0.2)	1 (0.1)	4 (0.2)
ETODOLAC	1 (0.1)	3 (0.2)	4 (0.2)
FLAVOXATE	2 (0.2)	2 (0.2)	4 (0.2)
FLUOCINOLONE ACETONIDE	0 (0.0)	4 (0.3)	4 (0.2)
FLUOCORTOLONE;LIDOCAINE	3 (0.2)	1 (0.1)	4 (0.2)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
FURAZIDIN	4 (0.3)	0 (0.0)	4 (0.2)
FUROSEMIDE;SPIRONOLACTONE	2 (0.2)	2 (0.2)	4 (0.2)
GATIFLOXACIN	3 (0.2)	1 (0.1)	4 (0.2)
GLUCOSE;SODIUM CHLORIDE	4 (0.3)	0 (0.0)	4 (0.2)
GLYCYRRHIZA GLABRA;PAPAVER SOMNIFERUM	3 (0.2)	1 (0.1)	4 (0.2)
HALOPERIDOL	3 (0.2)	1 (0.1)	4 (0.2)
HEDERA HELIX	3 (0.2)	1 (0.1)	4 (0.2)
HERBAL POLLEN NOS;TOCOPHEROL	1 (0.1)	3 (0.2)	4 (0.2)
HYDROCORTISONE;MICONAZOLE	4 (0.3)	0 (0.0)	4 (0.2)
IOHEXOL	4 (0.3)	0 (0.0)	4 (0.2)
ITRACONAZOLE	2 (0.2)	2 (0.2)	4 (0.2)
KETOTIFEN	3 (0.2)	1 (0.1)	4 (0.2)
LACTOBACILLUS NOS	3 (0.2)	1 (0.1)	4 (0.2)
LEVETIRACETAM	2 (0.2)	2 (0.2)	4 (0.2)
LEVOSULPIRIDE	1 (0.1)	3 (0.2)	4 (0.2)
LYSOZYME	1 (0.1)	3 (0.2)	4 (0.2)
MAGNESIUM CHLORIDE	1 (0.1)	3 (0.2)	4 (0.2)
MINOCYCLINE	2 (0.2)	2 (0.2)	4 (0.2)
MYRTOL	3 (0.2)	1 (0.1)	4 (0.2)
NALOXONE;TILIDINE	1 (0.1)	3 (0.2)	4 (0.2)
NIFUROXAZIDE	4 (0.3)	0 (0.0)	4 (0.2)
OPRELVEKIN	4 (0.3)	0 (0.0)	4 (0.2)
ORPHENADRINE;PARACETAMOL	0 (0.0)	4 (0.3)	4 (0.2)
OTHER GYNECOLOGICALS	2 (0.2)	2 (0.2)	4 (0.2)

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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PARACETAMOL;PSEUDOEPHEDRINE	3 (0.2)	1 (0.1)	4 (0.2)
PARAFFIN NOS	1 (0.1)	3 (0.2)	4 (0.2)
PENTOXIFYLLINE	2 (0.2)	2 (0.2)	4 (0.2)
PERMETHRIN	3 (0.2)	1 (0.1)	4 (0.2)
PETHIDINE	3 (0.2)	1 (0.1)	4 (0.2)
PHENYLEPHRINE;TROPICAMIDE	4 (0.3)	0 (0.0)	4 (0.2)
PHLOROGLUCINOL	2 (0.2)	2 (0.2)	4 (0.2)
PHOLCODINE	3 (0.2)	1 (0.1)	4 (0.2)
PHOSPHOLIPIDS	2 (0.2)	2 (0.2)	4 (0.2)
PIRACETAM	3 (0.2)	1 (0.1)	4 (0.2)
PIRENOXINE	3 (0.2)	1 (0.1)	4 (0.2)
POTASSIUM;SODIUM CHLORIDE	4 (0.3)	0 (0.0)	4 (0.2)
PREPARATIONS WITH SALICYLIC ACID DERIVATIVES	1 (0.1)	3 (0.2)	4 (0.2)
REMIFENTANIL	2 (0.2)	2 (0.2)	4 (0.2)
ROPIVACAINE	1 (0.1)	3 (0.2)	4 (0.2)
SACUBITRIL;VALSARTAN	2 (0.2)	2 (0.2)	4 (0.2)
TACROLIMUS	3 (0.2)	1 (0.1)	4 (0.2)
TELMISARTAN	2 (0.2)	2 (0.2)	4 (0.2)
TENOXICAM	1 (0.1)	3 (0.2)	4 (0.2)
THIAMAZOLE	1 (0.1)	3 (0.2)	4 (0.2)
TIPEPIDINE	3 (0.2)	1 (0.1)	4 (0.2)
TOSUFLOXACIN	2 (0.2)	2 (0.2)	4 (0.2)
TRIMETAZIDINE	2 (0.2)	2 (0.2)	4 (0.2)
VALERIANA OFFICINALIS	1 (0.1)	3 (0.2)	4 (0.2)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
VALSARTAN	3 (0.2)	1 (0.1)	4 (0.2)
VIDARABINE	2 (0.2)	2 (0.2)	4 (0.2)
WHITE SOFT PARAFFIN	4 (0.3)	0 (0.0)	4 (0.2)
ACETYLLEUCINE	2 (0.2)	1 (0.1)	3 (0.1)
ACONITUM SPP.;ASARUM SPP.;EPHEDRA SPP.	1 (0.1)	2 (0.2)	3 (0.1)
ACTAEA RACEMOSA;ARNICA MONTANA;GLYCERYL TRINITRATE;LACHESIS MUTA;SANGUINARIA CANADENSIS	2 (0.2)	1 (0.1)	3 (0.1)
ADIPHENINE;METAMIZOLE;PROMETHAZINE	1 (0.1)	2 (0.2)	3 (0.1)
ALGINIC ACID	3 (0.2)	0 (0.0)	3 (0.1)
ALPROSTADIL	3 (0.2)	0 (0.0)	3 (0.1)
ALTEPLASE	0 (0.0)	3 (0.2)	3 (0.1)
AMBROXOL;CHLORPHENAMINE;DIHYDROCODEINE;IBUPROFEN;L-CARBOCISTEINE;METHYLEPHEDRINE;RIBOFLAVIN	1 (0.1)	2 (0.2)	3 (0.1)
AMFETAMINE;DEXAMFETAMINE	1 (0.1)	2 (0.2)	3 (0.1)
AMINOPHYLLINE	1 (0.1)	2 (0.2)	3 (0.1)
AMPICILLIN	0 (0.0)	3 (0.2)	3 (0.1)
ANESTHETICS, GENERAL	2 (0.2)	1 (0.1)	3 (0.1)
ANGELICA ARCHANGELICA;CARUM CARVI;CHELIDONIUM MAJUS;GLYCYRRHIZA GLABRA;IBERIS AMARA;MATRICARIA CHAMOMILLA;MELISSA OFFICINALIS;MENTHA X PIPERITA;SILYBUM MARIANUM	2 (0.2)	1 (0.1)	3 (0.1)
ASCORBIC ACID;COLECALCIFEROL;CURCUMA LONGA;ZINGIBER OFFICINALE	2 (0.2)	1 (0.1)	3 (0.1)
ASCORBIC ACID;NITROFURANTOIN	2 (0.2)	1 (0.1)	3 (0.1)
ASCORBIC ACID;PARACETAMOL;PHENYLEPHRINE	2 (0.2)	1 (0.1)	3 (0.1)
ASCORBIC ACID;PARACETAMOL;PHENYLEPHRINE;SODIUM CITRATE	0 (0.0)	3 (0.2)	3 (0.1)
BEMIPARIN	3 (0.2)	0 (0.0)	3 (0.1)
BETAMETHASONE;DEXCHLORPHENIRAMINE	0 (0.0)	3 (0.2)	3 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BETAMETHASONE;KETOCONAZOLE;NEOMYCIN	2 (0.2)	1 (0.1)	3 (0.1)
BIMATOPROST	1 (0.1)	2 (0.2)	3 (0.1)
BRIMONIDINE	2 (0.2)	1 (0.1)	3 (0.1)
BROMISOVAL;DIHYDROCODEINE;DIPHENHYDRAMINE;DIPROPHYLLINE;METHYLEPHEDRINE;PARACETAMOL	1 (0.1)	2 (0.2)	3 (0.1)
BUTYLSCOPOLAMINE;PARACETAMOL	3 (0.2)	0 (0.0)	3 (0.1)
CAFFEINE;CHLORPHENAMINE;DIHYDROCODEINE;METHYLEPHEDRINE	2 (0.2)	1 (0.1)	3 (0.1)
CAFFEINE;PARACETAMOL;PROPYPHENAZONE	2 (0.2)	1 (0.1)	3 (0.1)
CALAMINE	2 (0.2)	1 (0.1)	3 (0.1)
CALCIFEDIOL	2 (0.2)	1 (0.1)	3 (0.1)
CALCIUM CARBONATE;MAGNESIUM CARBONATE	1 (0.1)	2 (0.2)	3 (0.1)
CALCIUM CHLORIDE	1 (0.1)	2 (0.2)	3 (0.1)
CALCIUM GLUCONATE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	1 (0.1)	2 (0.2)	3 (0.1)
CEFOXITIN	3 (0.2)	0 (0.0)	3 (0.1)
CEFPROZIL	1 (0.1)	2 (0.2)	3 (0.1)
CETIRIZINE;PSEUDOEPHEDRINE	2 (0.2)	1 (0.1)	3 (0.1)
CHLORPHENAMINE;PARACETAMOL;PSEUDOEPHEDRINE	3 (0.2)	0 (0.0)	3 (0.1)
CHLORZOXAZONE;PARACETAMOL	1 (0.1)	2 (0.2)	3 (0.1)
CIMETIDINE	0 (0.0)	3 (0.2)	3 (0.1)
CINCHOCAINE;DIPHENHYDRAMINE;ZINC	2 (0.2)	1 (0.1)	3 (0.1)
CINCHOCAINE;POLICRESULEN	3 (0.2)	0 (0.0)	3 (0.1)
CIPROFIBRATE	1 (0.1)	2 (0.2)	3 (0.1)
CLEMATIS SPP.;PRUNELLA VULGARIS;TRICHOSANTHES KIRILOWII	1 (0.1)	2 (0.2)	3 (0.1)
CLOBETASONE	2 (0.2)	1 (0.1)	3 (0.1)

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Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CLOTRIMAZOLE;HYDROCORTISONE	1 (0.1)	2 (0.2)	3 (0.1)
CODEINE;DIPHENHYDRAMINE;EPHEDRINE;GUAREA GUIDONIA	1 (0.1)	2 (0.2)	3 (0.1)
COLCHICINE	1 (0.1)	2 (0.2)	3 (0.1)
COLLAGEN	2 (0.2)	1 (0.1)	3 (0.1)
COPTIS SPP.;HEDERA HELIX	3 (0.2)	0 (0.0)	3 (0.1)
CYANOCOBALAMIN;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	2 (0.2)	3 (0.1)
CYCLIZINE	3 (0.2)	0 (0.0)	3 (0.1)
CYPROHEPTADINE	1 (0.1)	2 (0.2)	3 (0.1)
DAPTOMYCIN	2 (0.2)	1 (0.1)	3 (0.1)
DESLORATADINE;PSEUDOEPHEDRINE	2 (0.2)	1 (0.1)	3 (0.1)
DESVENLAFAXINE	1 (0.1)	2 (0.2)	3 (0.1)
DEXPANTHENOL	2 (0.2)	1 (0.1)	3 (0.1)
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRINE	1 (0.1)	2 (0.2)	3 (0.1)
DEXTROMETHORPHAN;PARACETAMOL;PSEUDOEPHEDRINE	3 (0.2)	0 (0.0)	3 (0.1)
DICLOFENAC;PARACETAMOL;SERRAPEPTASE	3 (0.2)	0 (0.0)	3 (0.1)
DIFLUCORTOLONE;ISOCONAZOLE	1 (0.1)	2 (0.2)	3 (0.1)
DILTIAZEM	3 (0.2)	0 (0.0)	3 (0.1)
DROPERIDOL	2 (0.2)	1 (0.1)	3 (0.1)
DROPROPIZINE	2 (0.2)	1 (0.1)	3 (0.1)
EBASTINE;PSEUDOEPHEDRINE	2 (0.2)	1 (0.1)	3 (0.1)
EMOLLIENTS AND PROTECTIVES	1 (0.1)	2 (0.2)	3 (0.1)
ERYTHROPOIETIN	3 (0.2)	0 (0.0)	3 (0.1)
ESCHERICHIA COLI	2 (0.2)	1 (0.1)	3 (0.1)
ESFLURBIPROFEN;MENTHA SPP.	0 (0.0)	3 (0.2)	3 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
EZETIMIBE	1 (0.1)	2 (0.2)	3 (0.1)
FISH OIL	1 (0.1)	2 (0.2)	3 (0.1)
FLECAINIDE	2 (0.2)	1 (0.1)	3 (0.1)
FLUOCINONIDE	2 (0.2)	1 (0.1)	3 (0.1)
FLUOROURACIL	1 (0.1)	2 (0.2)	3 (0.1)
FLUTICASONE;VILANTEROL	2 (0.2)	1 (0.1)	3 (0.1)
FOLIC ACID;NICOTINAMIDE;VITAMIN B12 NOS	3 (0.2)	0 (0.0)	3 (0.1)
FUSIDIC ACID;HYDROCORTISONE	2 (0.2)	1 (0.1)	3 (0.1)
GLICLAZIDE	2 (0.2)	1 (0.1)	3 (0.1)
GLYCOPYRRONIUM	2 (0.2)	1 (0.1)	3 (0.1)
GLYCYRRHIZA SPP.;OPHIOPOGON JAPONICUS;ORYZA SATIVA;PANAX GINSENG;PINELLIA TERNATA;ZIZIPHUS JUJUBA	0 (0.0)	3 (0.2)	3 (0.1)
GLYCYRRHIZA SPP.;PLATYCODON GRANDIFLORUS	1 (0.1)	2 (0.2)	3 (0.1)
GLYCYRRHIZIC ACID	2 (0.2)	1 (0.1)	3 (0.1)
INDOMETACIN	0 (0.0)	3 (0.2)	3 (0.1)
INSULIN HUMAN	2 (0.2)	1 (0.1)	3 (0.1)
INSULIN LISPRO	2 (0.2)	1 (0.1)	3 (0.1)
L-CARBOCISTEINE	1 (0.1)	2 (0.2)	3 (0.1)
LANINAMIVIR	0 (0.0)	3 (0.2)	3 (0.1)
LERCANIDIPINE	0 (0.0)	3 (0.2)	3 (0.1)
LEVOCETIRIZINE;MONTELUKAST	1 (0.1)	2 (0.2)	3 (0.1)
LEVOMEPROMAZINE	1 (0.1)	2 (0.2)	3 (0.1)
LEVOSALBUTAMOL	1 (0.1)	2 (0.2)	3 (0.1)
LULICONAZOLE	1 (0.1)	2 (0.2)	3 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
MAGNESIUM;POTASSIUM ASPARTATE	0 (0.0)	3 (0.2)	3 (0.1)
MANNITOL	1 (0.1)	2 (0.2)	3 (0.1)
MESALAZINE	2 (0.2)	1 (0.1)	3 (0.1)
MIANSERIN	1 (0.1)	2 (0.2)	3 (0.1)
MINERALS NOS;VITAMINS NOS	3 (0.2)	0 (0.0)	3 (0.1)
MONASCUS PURPUREUS	2 (0.2)	1 (0.1)	3 (0.1)
MONTMORILLONITE	2 (0.2)	1 (0.1)	3 (0.1)
NADIFLOXACIN	3 (0.2)	0 (0.0)	3 (0.1)
NADROPARIN	1 (0.1)	2 (0.2)	3 (0.1)
NAFTAZONE	2 (0.2)	1 (0.1)	3 (0.1)
NEFOPAM	2 (0.2)	1 (0.1)	3 (0.1)
NITROFURAL	2 (0.2)	1 (0.1)	3 (0.1)
NOSCAPINE	1 (0.1)	2 (0.2)	3 (0.1)
OLEA EUROPAEA	2 (0.2)	1 (0.1)	3 (0.1)
ONONIS SPINOSA;ORTHOSIPHON ARISTATUS;SOLIDAGO VIRGAUREA	2 (0.2)	1 (0.1)	3 (0.1)
ORNITHINE	2 (0.2)	1 (0.1)	3 (0.1)
OXAZEPAM	2 (0.2)	1 (0.1)	3 (0.1)
OXOLAMINE	1 (0.1)	2 (0.2)	3 (0.1)
PAPAVERINE	0 (0.0)	3 (0.2)	3 (0.1)
PELUBIPROFEN	1 (0.1)	2 (0.2)	3 (0.1)
PHENIRAMINE	1 (0.1)	2 (0.2)	3 (0.1)
PLATYCODON GRANDIFLORUS	1 (0.1)	2 (0.2)	3 (0.1)
POLYENE PHOSPHATIDYLCHOLINE	2 (0.2)	1 (0.1)	3 (0.1)
PRISTINAMYCIN	3 (0.2)	0 (0.0)	3 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PROCATEROL	1 (0.1)	2 (0.2)	3 (0.1)
QUETIAPINE	1 (0.1)	2 (0.2)	3 (0.1)
RIFAXIMIN	3 (0.2)	0 (0.0)	3 (0.1)
RISPERIDONE	2 (0.2)	1 (0.1)	3 (0.1)
SEA WATER	1 (0.1)	2 (0.2)	3 (0.1)
SERRAPEPTASE	0 (0.0)	3 (0.2)	3 (0.1)
SEVOFLURANE	1 (0.1)	2 (0.2)	3 (0.1)
SITAGLIPTIN	1 (0.1)	2 (0.2)	3 (0.1)
SODIUM FLUORIDE	1 (0.1)	2 (0.2)	3 (0.1)
SOLIFENACIN	0 (0.0)	3 (0.2)	3 (0.1)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	2 (0.2)	1 (0.1)	3 (0.1)
SULPIRIDE	1 (0.1)	2 (0.2)	3 (0.1)
SUVOREXANT	1 (0.1)	2 (0.2)	3 (0.1)
TAMSULOSIN	2 (0.2)	1 (0.1)	3 (0.1)
TEICOPLANIN	1 (0.1)	2 (0.2)	3 (0.1)
TIMOLOL	1 (0.1)	2 (0.2)	3 (0.1)
TIMONACIC	2 (0.2)	1 (0.1)	3 (0.1)
VASOPRESSIN	2 (0.2)	1 (0.1)	3 (0.1)
WARFARIN	2 (0.2)	1 (0.1)	3 (0.1)
ACETAZOLAMIDE	1 (0.1)	1 (0.1)	2 (0.1)
ACETYLSALICYLIC ACID;CHLORPHENAMINE;PHENYLEPHRINE	2 (0.2)	0 (0.0)	2 (0.1)
ACETYLSALICYLIC ACID;HYDROTALCITE	1 (0.1)	1 (0.1)	2 (0.1)
ACONITUM NAPELLUS;BENZOIC ACID;CODEINE;PRUNUS LAUROCERASUS	1 (0.1)	1 (0.1)	2 (0.1)
ACRIVASTINE;PSEUDOEPHEDRINE	0 (0.0)	2 (0.2)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ACTEIN	2 (0.2)	0 (0.0)	2 (0.1)
ALBUMIN HUMAN	2 (0.2)	0 (0.0)	2 (0.1)
ALBUMIN TANNATE;ETHACRIDINE	2 (0.2)	0 (0.0)	2 (0.1)
ALLANTOIN;CHLORHEXIDINE;CINCHOCAINE;TOCOPHEROL;ZINC	0 (0.0)	2 (0.2)	2 (0.1)
ALTHAEA OFFICINALIS	2 (0.2)	0 (0.0)	2 (0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM CARBONATE	2 (0.2)	0 (0.0)	2 (0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE	2 (0.2)	0 (0.0)	2 (0.1)
ALVERINE;SIMETICONE	2 (0.2)	0 (0.0)	2 (0.1)
AMANTADINE	1 (0.1)	1 (0.1)	2 (0.1)
AMIKACIN	1 (0.1)	1 (0.1)	2 (0.1)
AMINOPHENAZONE;CAFFEINE;CHLORPHENAMINE;PARACETAMOL	1 (0.1)	1 (0.1)	2 (0.1)
AMMONIA;CAMPHOR;GLYCEROL;GLYCYRRHIZA GLABRA;GUAIFENESIN	2 (0.2)	0 (0.0)	2 (0.1)
AMMONIUM CHLORIDE;ASTER TATARICUS;CITRUS RETICULATA;CITRUS X AURANTIUM;GLYCYRRHIZA SPP.;KITAGAWIA PRAERUPTORA;MENTHA CANADENSIS;NEPETA TENUIFOLIA;PAPAVER SOMNIFERUM;PLATYCODON GRANDIFLORUS;	1 (0.1)	1 (0.1)	2 (0.1)
AMOROLFINE	1 (0.1)	1 (0.1)	2 (0.1)
AMPHOTERICIN B	1 (0.1)	1 (0.1)	2 (0.1)
AMPHOTERICIN B;TETRACYCLINE	2 (0.2)	0 (0.0)	2 (0.1)
ANALGESICS	0 (0.0)	2 (0.2)	2 (0.1)
ANEMARRHENA ASPHODELOIDES;CULLEN CORYLIFOLIUM;DIPSACUS ASPER;EPIMEDIUM SPP.;REHMANNIA GLUTINOSA;SALVIA MILTIORRHIZA	1 (0.1)	1 (0.1)	2 (0.1)
ANILIDES	1 (0.1)	1 (0.1)	2 (0.1)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	2 (0.2)	0 (0.0)	2 (0.1)
ARCTOSTAPHYLOS UVA-URSI	1 (0.1)	1 (0.1)	2 (0.1)

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/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ARDISIA JAPONICA;BORNEOL;MENTHOL	1 (0.1)	1 (0.1)	2 (0.1)
ARNICA MONTANA;MENTHOL;SALICYLIC ACID	0 (0.0)	2 (0.2)	2 (0.1)
ASCORBIC ACID;BIOTIN;CALCIUM;CARBOHYDRATES	2 (0.2)	0 (0.0)	2 (0.1)
NOS;CHLORIDE;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FATS NOS;FOLIC ACID;IRON;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;PHOSPHORUS;POTASSIUM;			
ASCORBIC ACID;BIOTIN;CALCIUM;CYANOCOBALAMIN;FIBRE NOS;FOLIC ACID;GLYCINE MAX;IRON;MAGNESIUM CARBONATE;MALTODEXTRIN;NICOTINAMIDE;PANTOTHENIC ACID;POTASSIUM CITRATE;PROTEINS NOS;PYRIDOXINE;RETINOL;	2 (0.2)	0 (0.0)	2 (0.1)
ASCORBIC ACID;COLLAGEN	1 (0.1)	1 (0.1)	2 (0.1)
ASCORBIC ACID;IBUPROFEN;PSEUDOEPHEDRINE	2 (0.2)	0 (0.0)	2 (0.1)
ASCORBIC ACID;RUTOSIDE	1 (0.1)	1 (0.1)	2 (0.1)
ASCORBIC ACID;ZINC	1 (0.1)	1 (0.1)	2 (0.1)
ASPARTIC ACID;PYRIDOXINE	1 (0.1)	1 (0.1)	2 (0.1)
ATROPA BELLA-DONNA;ERGOTAMINE;PHENOBARBITAL	1 (0.1)	1 (0.1)	2 (0.1)
BACITRACIN	2 (0.2)	0 (0.0)	2 (0.1)
BACITRACIN;NEOMYCIN;POLYMYXIN B	1 (0.1)	1 (0.1)	2 (0.1)
BECLOMETASONE;FORMOTEROL	1 (0.1)	1 (0.1)	2 (0.1)
BENZOCAINE;MENTHOL	0 (0.0)	2 (0.2)	2 (0.1)
BENZOIC ACID;CEPHAELIS SPP.;GUAIFENESIN;IODINE;OXOMEMAZINE	2 (0.2)	0 (0.0)	2 (0.1)
BENZYL ALCOHOL;BENZYL BENZOATE;BENZYL CINNAMATE;WOOL FAT;ZINC	1 (0.1)	1 (0.1)	2 (0.1)
BETAMETHASONE;KETOCONAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
BIFIDOBACTERIUM LACTIS	1 (0.1)	1 (0.1)	2 (0.1)
BIOTIN;BROMELAINS;LECITHIN;PAPAIN;SELENIUM	1 (0.1)	1 (0.1)	2 (0.1)
BISMUTH;RANITIDINE;SUCRALFATE	1 (0.1)	1 (0.1)	2 (0.1)

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Indication: Adverse Event

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BLOOD PLASMA	1 (0.1)	1 (0.1)	2 (0.1)
BLOOD, CALF, DEPROT., LMW PORTION	2 (0.2)	0 (0.0)	2 (0.1)
BOVINE BASIC FIBROBLAST GROWTH FACTOR	2 (0.2)	0 (0.0)	2 (0.1)
BRIVUDINE	1 (0.1)	1 (0.1)	2 (0.1)
BROMELAINS;CYSTEINE	1 (0.1)	1 (0.1)	2 (0.1)
BROMOPRIDE	1 (0.1)	1 (0.1)	2 (0.1)
BROMPHENIRAMINE;PHENYLEPHRINE	0 (0.0)	2 (0.2)	2 (0.1)
BUCLIZINE	2 (0.2)	0 (0.0)	2 (0.1)
BUPROPION	1 (0.1)	1 (0.1)	2 (0.1)
BUTALBITAL;CAFFEINE;PARACETAMOL	1 (0.1)	1 (0.1)	2 (0.1)
BUTAMIRATE	2 (0.2)	0 (0.0)	2 (0.1)
BUTENAFINE	2 (0.2)	0 (0.0)	2 (0.1)
BUTYLSCOPOLAMINE;METAMIZOLE	1 (0.1)	1 (0.1)	2 (0.1)
CAFFEINE;CHLORPHENAMINE;COW BEZOAR;PARACETAMOL	1 (0.1)	1 (0.1)	2 (0.1)
CAFFEINE;CHLORPHENAMINE;DIHYDROCODEINE;HESPERIDIN;ISOPROPAMIDE;METHYLEPHEDRINE;PARACETAMOL;TRANEXAMIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
CAFFEINE;CHLORPHENAMINE;METAMIZOLE	0 (0.0)	2 (0.2)	2 (0.1)
CAFFEINE;CHLORPHENAMINE;PARACETAMOL;PHENYLEPHRINE	1 (0.1)	1 (0.1)	2 (0.1)
CAFFEINE;DEXCHLORPHENIRAMINE;DIHYDROCODEINE;IBUPROFEN;L-CARBOCISTEINE;PSEUDOEPHEDRINE	2 (0.2)	0 (0.0)	2 (0.1)
CALCIUM ACETATE;MAGNESIUM;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL;MAGNESIUM CARBONATE	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM CARBONATE;VITAMIN D NOS	0 (0.0)	2 (0.2)	2 (0.1)
CALCIUM CHLORIDE;GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM GLUCONATE	1 (0.1)	1 (0.1)	2 (0.1)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CAPSAICIN;NIMESULIDE	0 (0.0)	2 (0.2)	2 (0.1)
CARBAZOCHROME	1 (0.1)	1 (0.1)	2 (0.1)
CARBIMAZOLE	0 (0.0)	2 (0.2)	2 (0.1)
CARBINOXAMINE;PSEUDOEPHEDRINE	0 (0.0)	2 (0.2)	2 (0.1)
CARBOHYDRATES NOS;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	2 (0.2)	0 (0.0)	2 (0.1)
CARISOPRODOL;PARACETAMOL	2 (0.2)	0 (0.0)	2 (0.1)
CARTHAMUS TINCTORIUS;SALVIA MILTIORRHIZA	2 (0.2)	0 (0.0)	2 (0.1)
CEFAZEDONE	2 (0.2)	0 (0.0)	2 (0.1)
CEFMETAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
CEFTAZIDIME	1 (0.1)	1 (0.1)	2 (0.1)
CEFTIBUTEN	1 (0.1)	1 (0.1)	2 (0.1)
CENTAURIUM ERYTHRAEA;LEVISTICUM OFFICINALE;ROSA CANINA;SALVIA ROSMARINUS	1 (0.1)	1 (0.1)	2 (0.1)
CETALKONIUM CHLORIDE;SALICYLIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL	2 (0.2)	0 (0.0)	2 (0.1)
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL;PSEUDOEPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
CHLORPHENAMINE;DIHYDROCODEINE;GUAIFENESIN;METHYLEPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
CHLORPHENAMINE;OXOLAMINE;PARACETAMOL	2 (0.2)	0 (0.0)	2 (0.1)
CHLORTALIDONE	2 (0.2)	0 (0.0)	2 (0.1)
CHYMOTRYPSIN;TRYPSIN	0 (0.0)	2 (0.2)	2 (0.1)
CINCHOCAINE;HYDROCORTISONE	2 (0.2)	0 (0.0)	2 (0.1)
CLONIDINE	2 (0.2)	0 (0.0)	2 (0.1)
CLOXACILLIN	2 (0.2)	0 (0.0)	2 (0.1)
COCOS NUCIFERA	2 (0.2)	0 (0.0)	2 (0.1)
CODEINE;IBUPROFEN	1 (0.1)	1 (0.1)	2 (0.1)

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Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
COIX LACRYMA-JOBI VAR. MA-YUEN	2 (0.2)	0 (0.0)	2 (0.1)
COLESTIPOL	2 (0.2)	0 (0.0)	2 (0.1)
COLISTIN	0 (0.0)	2 (0.2)	2 (0.1)
COLONY STIMULATING FACTORS	2 (0.2)	0 (0.0)	2 (0.1)
CORYDALIS YANHUSUO;IPOMOEA NIL	1 (0.1)	1 (0.1)	2 (0.1)
CROMOGLICIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
CURCUMIN	0 (0.0)	2 (0.2)	2 (0.1)
CYANOCOBALAMIN;LIDOCAINE;PYRIDOXINE;THIAMINE	2 (0.2)	0 (0.0)	2 (0.1)
CYSTEINE	1 (0.1)	1 (0.1)	2 (0.1)
DEFLAZACORT	2 (0.2)	0 (0.0)	2 (0.1)
DESFLURANE	2 (0.2)	0 (0.0)	2 (0.1)
DEXAMETHASONE;NEOMYCIN	1 (0.1)	1 (0.1)	2 (0.1)
DEXIBUPROFEN	1 (0.1)	1 (0.1)	2 (0.1)
DEXKETOPROFEN;THIOCOLCHICOSIDE	1 (0.1)	1 (0.1)	2 (0.1)
DEXMEDETOMIDINE	1 (0.1)	1 (0.1)	2 (0.1)
DEXTROMETHORPHAN;EPHEDRINE;PROMETHAZINE	1 (0.1)	1 (0.1)	2 (0.1)
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
DICLOFENAC;THIOCOLCHICOSIDE	2 (0.2)	0 (0.0)	2 (0.1)
DIMETICONE;MAGALDRATE	2 (0.2)	0 (0.0)	2 (0.1)
DIPHENHYDRAMINE;DIPROPHYLLINE	1 (0.1)	1 (0.1)	2 (0.1)
DOBESILIC ACID	2 (0.2)	0 (0.0)	2 (0.1)
DOCUSATE;SENNA ALEXANDRINA	2 (0.2)	0 (0.0)	2 (0.1)
DOMPERIDONE;PANTOPRAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
DONEPEZIL	1 (0.1)	1 (0.1)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
DORZOLAMIDE;TIMOLOL	1 (0.1)	1 (0.1)	2 (0.1)
DOXEPIN	0 (0.0)	2 (0.2)	2 (0.1)
ELCATONIN	2 (0.2)	0 (0.0)	2 (0.1)
ELECTROLYTES NOS	1 (0.1)	1 (0.1)	2 (0.1)
ENTEROCOCCUS FAECALIS	2 (0.2)	0 (0.0)	2 (0.1)
EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PRUNUS SPP.	1 (0.1)	1 (0.1)	2 (0.1)
EPINASTINE	1 (0.1)	1 (0.1)	2 (0.1)
EPRAZINONE	1 (0.1)	1 (0.1)	2 (0.1)
ERIOBOTRYA JAPONICA;MENTHOL;MORUS ALBA;PAPAVER SOMNIFERUM;PLATYCODON GRANDIFLORUS;STEMONA SPP.;VINCETOXICUM SPP.	0 (0.0)	2 (0.2)	2 (0.1)
ESCIN;SALICYLIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
ESMOLOL	1 (0.1)	1 (0.1)	2 (0.1)
ETAMSILATE	2 (0.2)	0 (0.0)	2 (0.1)
ETIZOLAM	1 (0.1)	1 (0.1)	2 (0.1)
ETODOLAC;THIOCOLCHICOSIDE	1 (0.1)	1 (0.1)	2 (0.1)
EZETIMIBE;SIMVASTATIN	0 (0.0)	2 (0.2)	2 (0.1)
FEBUXOSTAT	2 (0.2)	0 (0.0)	2 (0.1)
FENBUFEN;METRONIDAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
FENOTEROL;IPRATROPIUM	2 (0.2)	0 (0.0)	2 (0.1)
FENTICONAZOLE	0 (0.0)	2 (0.2)	2 (0.1)
FESOTERODINE	0 (0.0)	2 (0.2)	2 (0.1)
FISH OIL;GLYCINE MAX;OLEA EUROPAEA;TRIGLYCERIDES	2 (0.2)	0 (0.0)	2 (0.1)
FLOMOXEF	1 (0.1)	1 (0.1)	2 (0.1)
FLUDROXYCORTIDE	1 (0.1)	1 (0.1)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
FLUMETASONE;SALICYLIC ACID	2 (0.2)	0 (0.0)	2 (0.1)
FLUTICASONE;SALMETEROL	0 (0.0)	2 (0.2)	2 (0.1)
FONDAPARINUX	0 (0.0)	2 (0.2)	2 (0.1)
FOSSILIA OSSIS MASTODI;GYPSOPHILA VACCARIA;LAMINARIA SPP.;OYSTER SHELL;PRUNUS MUME;SARGASSUM PALLIDUM	2 (0.2)	0 (0.0)	2 (0.1)
GARENOXACIN	1 (0.1)	1 (0.1)	2 (0.1)
GELSEMIUM SEMPERVIRENS	1 (0.1)	1 (0.1)	2 (0.1)
GENTIANA LUTEA;PRIMULA SPP.;RUMEX SPP.;SAMBUCUS NIGRA;VERBENA OFFICINALIS	0 (0.0)	2 (0.2)	2 (0.1)
GINKGO BILOBA	2 (0.2)	0 (0.0)	2 (0.1)
GLIPIZIDE	1 (0.1)	1 (0.1)	2 (0.1)
GLUCOSE;SODIUM CHLORIDE;SODIUM LACTATE	2 (0.2)	0 (0.0)	2 (0.1)
GRAMICIDIN	2 (0.2)	0 (0.0)	2 (0.1)
GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE	0 (0.0)	2 (0.2)	2 (0.1)
GUAIFENESIN;PHENYLEPHRINE	0 (0.0)	2 (0.2)	2 (0.1)
GUALENIC ACID;SODIUM BICARBONATE	1 (0.1)	1 (0.1)	2 (0.1)
HAEMOCOAGULASE	1 (0.1)	1 (0.1)	2 (0.1)
HALOMETASONE	1 (0.1)	1 (0.1)	2 (0.1)
HAMAMELIS VIRGINIANA	2 (0.2)	0 (0.0)	2 (0.1)
HERBAL EXPECTORANTS AND EMOLLIENTS	1 (0.1)	1 (0.1)	2 (0.1)
HYALURONIC ACID;TREHALOSE	2 (0.2)	0 (0.0)	2 (0.1)
HYDRALAZINE	2 (0.2)	0 (0.0)	2 (0.1)
HYDROCHLOROTHIAZIDE;TRIAMTERENE	2 (0.2)	0 (0.0)	2 (0.1)
HYDROQUINONE	0 (0.0)	2 (0.2)	2 (0.1)
HYDROTALCITE	1 (0.1)	1 (0.1)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
HYDROXOCOBALAMIN	2 (0.2)	0 (0.0)	2 (0.1)
I.V. SOLUTIONS	1 (0.1)	1 (0.1)	2 (0.1)
IBUPROFEN;PARACETAMOL	1 (0.1)	1 (0.1)	2 (0.1)
IBUPROFEN;PSEUDOEPHEDRINE	0 (0.0)	2 (0.2)	2 (0.1)
INSULIN ASPART	2 (0.2)	0 (0.0)	2 (0.1)
INSULIN DEGLUDEC	2 (0.2)	0 (0.0)	2 (0.1)
IRON POLYSACCHARIDE COMPLEX	1 (0.1)	1 (0.1)	2 (0.1)
ISOCONAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
ISONIAZID	2 (0.2)	0 (0.0)	2 (0.1)
ITOPRIDE	0 (0.0)	2 (0.2)	2 (0.1)
IVABRADINE	1 (0.1)	1 (0.1)	2 (0.1)
KAGOCEL	1 (0.1)	1 (0.1)	2 (0.1)
KETAMINE	0 (0.0)	2 (0.2)	2 (0.1)
LACTIPLANTIBACILLUS PLANTARUM	1 (0.1)	1 (0.1)	2 (0.1)
LAMOTRIGINE	2 (0.2)	0 (0.0)	2 (0.1)
LATANOPROST	1 (0.1)	1 (0.1)	2 (0.1)
LEVOCLOPERASTINE	1 (0.1)	1 (0.1)	2 (0.1)
LIDOCAINE;METHYLPREDNISOLONE	1 (0.1)	1 (0.1)	2 (0.1)
LIDOCAINE;NYSTATIN;WATER	2 (0.2)	0 (0.0)	2 (0.1)
LIDOCAINE;TRIBENOSIDE	2 (0.2)	0 (0.0)	2 (0.1)
LIGHT LIQUID PARAFFIN;WHITE SOFT PARAFFIN	2 (0.2)	0 (0.0)	2 (0.1)
LINAGLIPTIN	2 (0.2)	0 (0.0)	2 (0.1)
LORATADINE;PSEUDOEPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
LOTEPREDNOL	2 (0.2)	0 (0.0)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
MAGALDRATE	2 (0.2)	0 (0.0)	2 (0.1)
MAGIC MOUTHWASH	0 (0.0)	2 (0.2)	2 (0.1)
MAGNESIUM;PYRIDOXINE	1 (0.1)	1 (0.1)	2 (0.1)
MECILLINAM	2 (0.2)	0 (0.0)	2 (0.1)
MEPIVACAINE	1 (0.1)	1 (0.1)	2 (0.1)
METHOTREXATE	1 (0.1)	1 (0.1)	2 (0.1)
METOPIMAZINE	1 (0.1)	1 (0.1)	2 (0.1)
MIKANIA GLOMERATA	1 (0.1)	1 (0.1)	2 (0.1)
MULTIVITAMINS WITH MINERALS [UMBRELLA TERM]	2 (0.2)	0 (0.0)	2 (0.1)
NABUMETONE	1 (0.1)	1 (0.1)	2 (0.1)
NALOXONE;OXYCODONE	1 (0.1)	1 (0.1)	2 (0.1)
NAPHAZOLINE	1 (0.1)	1 (0.1)	2 (0.1)
NAPROXEN;PARACETAMOL	2 (0.2)	0 (0.0)	2 (0.1)
NEOMYCIN	1 (0.1)	1 (0.1)	2 (0.1)
NICARDIPINE	1 (0.1)	1 (0.1)	2 (0.1)
NICERGOLINE	1 (0.1)	1 (0.1)	2 (0.1)
NIFEDIPINE	0 (0.0)	2 (0.2)	2 (0.1)
NORTRIPTYLINE	1 (0.1)	1 (0.1)	2 (0.1)
NUTRIENTS NOS	1 (0.1)	1 (0.1)	2 (0.1)
OLMESARTAN	0 (0.0)	2 (0.2)	2 (0.1)
ORNIDAZOLE	2 (0.2)	0 (0.0)	2 (0.1)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	2 (0.2)	0 (0.0)	2 (0.1)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	2 (0.2)	0 (0.0)	2 (0.1)
OTHER ANALGESICS AND ANTIPYRETICS	1 (0.1)	1 (0.1)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	1 (0.1)	1 (0.1)	2 (0.1)
OTHER CICATRIZANTS	2 (0.2)	0 (0.0)	2 (0.1)
OTHER DERMATOLOGICALS	0 (0.0)	2 (0.2)	2 (0.1)
OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	0 (0.0)	2 (0.2)	2 (0.1)
OXETACAINE	0 (0.0)	2 (0.2)	2 (0.1)
OXYTETRACYCLINE;POLYMYXIN B	2 (0.2)	0 (0.0)	2 (0.1)
PANAX NOTOGINSENG	0 (0.0)	2 (0.2)	2 (0.1)
PANCREATIN	1 (0.1)	1 (0.1)	2 (0.1)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (0.1)	1 (0.1)	2 (0.1)
PARECOXIB	0 (0.0)	2 (0.2)	2 (0.1)
PAROXETINE	0 (0.0)	2 (0.2)	2 (0.1)
PETROLATUM	2 (0.2)	0 (0.0)	2 (0.1)
PIMECROLIMUS	2 (0.2)	0 (0.0)	2 (0.1)
PINAVERIUM	0 (0.0)	2 (0.2)	2 (0.1)
PIPEMIDIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
PIPERACILLIN	2 (0.2)	0 (0.0)	2 (0.1)
PITAVASTATIN	1 (0.1)	1 (0.1)	2 (0.1)
POLYMETHYLSILOXANE	1 (0.1)	1 (0.1)	2 (0.1)
POTASSIUM CRESOLSULFONATE	2 (0.2)	0 (0.0)	2 (0.1)
PRALIDOXIME	1 (0.1)	1 (0.1)	2 (0.1)
PRAMIPEXOLE	1 (0.1)	1 (0.1)	2 (0.1)
PROPAFENONE	0 (0.0)	2 (0.2)	2 (0.1)
PROTEIN	2 (0.2)	0 (0.0)	2 (0.1)
PROXYMETACAINE	2 (0.2)	0 (0.0)	2 (0.1)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
QUININE	0 (0.0)	2 (0.2)	2 (0.1)
RANOLAZINE	1 (0.1)	1 (0.1)	2 (0.1)
RETINOL	1 (0.1)	1 (0.1)	2 (0.1)
RIBAVIRIN	1 (0.1)	1 (0.1)	2 (0.1)
SECNIDAZOLE	2 (0.2)	0 (0.0)	2 (0.1)
SELENIUM	2 (0.2)	0 (0.0)	2 (0.1)
SENNA ALEXANDRINA	2 (0.2)	0 (0.0)	2 (0.1)
SILIBININ	1 (0.1)	1 (0.1)	2 (0.1)
SILODOSIN	1 (0.1)	1 (0.1)	2 (0.1)
SITAFLOXACIN	2 (0.2)	0 (0.0)	2 (0.1)
SODIUM BICARBONATE;SODIUM PHOSPHATE	2 (0.2)	0 (0.0)	2 (0.1)
SOTALOL	1 (0.1)	1 (0.1)	2 (0.1)
STEROIDS	2 (0.2)	0 (0.0)	2 (0.1)
STREPTODORNASE;STREPTOKINASE	1 (0.1)	1 (0.1)	2 (0.1)
SUFENTANIL	1 (0.1)	1 (0.1)	2 (0.1)
SULTAMICILLIN	2 (0.2)	0 (0.0)	2 (0.1)
TENELIGLIPTIN	1 (0.1)	1 (0.1)	2 (0.1)
TEPRENONE	1 (0.1)	1 (0.1)	2 (0.1)
TERBUTALINE	0 (0.0)	2 (0.2)	2 (0.1)
THEOPHYLLINE	1 (0.1)	1 (0.1)	2 (0.1)
THIETHYLPERAZINE	2 (0.2)	0 (0.0)	2 (0.1)
THIOCOLCHICOSIDE	2 (0.2)	0 (0.0)	2 (0.1)
TILORONE	0 (0.0)	2 (0.2)	2 (0.1)
TINIDAZOLE	1 (0.1)	1 (0.1)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
TORASEMIDE	2 (0.2)	0 (0.0)	2 (0.1)
TOXICODENDRON PUBESCENS	0 (0.0)	2 (0.2)	2 (0.1)
TRIMEBUTINE	2 (0.2)	0 (0.0)	2 (0.1)
TROXERUTIN	1 (0.1)	1 (0.1)	2 (0.1)
VALPROIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
VECURONIUM	0 (0.0)	2 (0.2)	2 (0.1)
VILDAGLIPTIN	2 (0.2)	0 (0.0)	2 (0.1)
VINPOCETINE	2 (0.2)	0 (0.0)	2 (0.1)
VITAMIN B-COMPLEX, PLAIN	2 (0.2)	0 (0.0)	2 (0.1)
VITAMIN K NOS	1 (0.1)	1 (0.1)	2 (0.1)
VONOPRAZAN	1 (0.1)	1 (0.1)	2 (0.1)
VORICONAZOLE	2 (0.2)	0 (0.0)	2 (0.1)
WOOL FAT	2 (0.2)	0 (0.0)	2 (0.1)
(RS)-3 METHYL-2-OXOVALERIANIC ACID CALCIUM;(RS)-3-METHYL-2-OXOBUTYRIC ACID CALCIUM;CALCIUM (RS)-4-METHYL-2-OXOVALERIANAT;DESMENINOL;HISTIDINE;LYSINE;PHENYLPYRUVIC ACID;THREONINE;TRYPTOPHAN;TYROSINE	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLCARNITINE	0 (0.0)	1 (0.1)	1 (0.0)
ACETYLCYSTEINE;AMBROXOL	0 (0.0)	1 (0.1)	1 (0.0)
ACETYLCYSTEINE;AMBROXOL ACEFYLLINATE	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLSALICYLIC ACID;ALUMINIUM GLYCINATE;MAGNESIUM CARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLSALICYLIC ACID;CAFFEINE	0 (0.0)	1 (0.1)	1 (0.0)
ACETYLSALICYLIC ACID;CAFFEINE;DEXCHLORPHENIRAMINE;PHENYLEPHRINE	0 (0.0)	1 (0.1)	1 (0.0)
ACETYLSALICYLIC ACID;CAFFEINE;ORPHENADRINE;PHENACETIN	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLSALICYLIC ACID;CODEINE;MAGNESIUM OXIDE	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ACETYLSALICYLIC ACID;MAGNESIUM HYDROXIDE	0 (0.0)	1 (0.1)	1 (0.0)
ACETYLSALICYLIC ACID;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
ACETYLSALICYLIC ACID;PSEUDOEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.0)
ACHILLEA MILLEFOLIUM;ALTHAEA OFFICINALIS;EQUISETUM SPP.;JUGLANS REGIA;MATRICARIA CHAMOMILLA;QUERCUS SPP.;TARAXACUM SPP.	1 (0.1)	0 (0.0)	1 (0.0)
ACHYRANTHES BIDENTATA;ACONITUM SPP.;ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;CORNUS OFFICINALIS;DIOSCOREA SPP.;NEOLITSEA CASSIA;PAEONIA X SUFFRUTICOSA;PLANTAGO ASIATICA;PORIA COCOS;	1 (0.1)	0 (0.0)	1 (0.0)
ACHYRANTHES BIDENTATA;ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ATRACTYLODES MACROCEPHALA;CHRYSANTHEMUM X MORIFOLIUM;CITRUS RETICULATA;ECLIPTA PROSTRATA;GLYCYRRHIZA SPP.;LIGUSTRUM LUCIDUM;	1 (0.1)	0 (0.0)	1 (0.0)
ACHYRANTHES BIDENTATA;ANGELICA SINENSIS;ASTRAGALUS SPP.;BOSWELLIA SACRA;CARTHAMUS TINCTORIUS;COMMIPHORA MYRRHA;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';LEECH;MESOBUTHUS MARTENSII;MORUS ALBA;	0 (0.0)	1 (0.1)	1 (0.0)
ACHYRANTHES BIDENTATA;ASTRAGALUS SPP.;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';PHERETIMA SPP.	1 (0.1)	0 (0.0)	1 (0.0)
ACHYRANTHES BIDENTATA;CORNUS OFFICINALIS;DIOSCOREA OPPOSITIFOLIA;EUCOMMIA ULMOIDES;FOENICULUM VULGARE;GYNOCHTHODES OFFICINALIS;LYCIUM BARBARUM;POLYGALA SPP.;PORIA COCOS;REHMANNIA GLUTINOSA;	1 (0.1)	0 (0.0)	1 (0.0)
ACONITUM KUSNEZOFFII;ACONITUM SPP.;HERBAL NOS	1 (0.1)	0 (0.0)	1 (0.0)
ACONITUM KUSNEZOFFII;ANGELICA SINENSIS;ANIMAL FECES NOS;BOSWELLIA SPP.;COMMIPHORA MYRRHA;HERBAL NOS;LIQUIDAMBAR FORMOSANA;MOMORDICA COCHINCHINENSIS;MUSK;PHERETIMA SPP.	1 (0.1)	0 (0.0)	1 (0.0)
ACONITUM NAPELLUS	0 (0.0)	1 (0.1)	1 (0.0)
ACONITUM SPP.	0 (0.0)	1 (0.1)	1 (0.0)

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/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ACONITUM SPP.;ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;CORNUS OFFICINALIS;DIOSCOREA SPP.;NEOLITSEA CASSIA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;REHMANNIA GLUTINOSA	0 (0.0)	1 (0.1)	1 (0.0)
ACONITUM SPP.;ATRACTYLODES SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PORIA COCOS;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	1 (0.1)	0 (0.0)	1 (0.0)
ACTAEA RACEMOSA	0 (0.0)	1 (0.1)	1 (0.0)
ACTINOQUINOL;HYALURONIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
ADAPALENE	1 (0.1)	0 (0.0)	1 (0.0)
ADENINE;CARNITINE;CYANOCOBALAMIN;LIVER;PYRIDOXINE;RIBOFLAVIN	1 (0.1)	0 (0.0)	1 (0.0)
AESCULUS HIPPOCASTANUM;HAMAMELIS VIRGINIANA;HYDRASTIS CANADENSIS;RUSCUS ACULEATUS;VIBURNUM OPULUS	0 (0.0)	1 (0.1)	1 (0.0)
AFLOQUALONE	1 (0.1)	0 (0.0)	1 (0.0)
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	1 (0.1)	0 (0.0)	1 (0.0)
AKEBIA QUINATA;CENTELLA ASIATICA;LYGODIUM JAPONICUM;ROSA LAEVIGATA;SMILAX CHINA	1 (0.1)	0 (0.0)	1 (0.0)
AKEBIA SPP.;ANGELICA ACUTILOBA;BIANCAEA SAPPAN;CARTHAMUS TINCTORIUS;CITRUS RETICULATA;CITRUS SPP.;GLYCYRRHIZA SPP.;MAGNOLIA SPP.;RHEUM SPP.;SODIUM SULFATE	1 (0.1)	0 (0.0)	1 (0.0)
ALANINE;ARGININE;CYSTEINE;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN;VALINE	0 (0.0)	1 (0.1)	1 (0.0)
ALBUMIN TANNATE;BISMUTH;KAOLIN;SCOPOLIA CARNIOLICA	1 (0.1)	0 (0.0)	1 (0.0)
ALDIOXA;SIMALDRATE	1 (0.1)	0 (0.0)	1 (0.0)
ALFENTANIL	1 (0.1)	0 (0.0)	1 (0.0)
ALGINIC ACID;ALUMINIUM HYDROXIDE	1 (0.1)	0 (0.0)	1 (0.0)
ALGINIC ACID;ALUMINIUM HYDROXIDE;MAGNESIUM TRISILICATE;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
ALGINIC ACID;ALUMINIUM HYDROXIDE;SODIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.0)
ALGINIC ACID;GLUCOSE;GLUCOSE OXIDASE;GUAIACOL;LACTOPEROXIDASE;MACROGOL	1 (0.1)	0 (0.0)	1 (0.0)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ALGINIC ACID;POTASSIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
ALGINIC ACID;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
ALIMEMAZINE	1 (0.1)	0 (0.0)	1 (0.0)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ATRACTYLODES SPP.;NEOLITSEA CASSIA;POLYPORUS UMBELLATUS;PORIA COCOS	0 (0.0)	1 (0.1)	1 (0.0)
ALL OTHER NON-THERAPEUTIC PRODUCTS	0 (0.0)	1 (0.1)	1 (0.0)
ALLANTOIN	1 (0.1)	0 (0.0)	1 (0.0)
ALLANTOIN;ALOE VERA;CITRUS X AURANTIUM;MAGNESIUM SULFATE;SILVER;TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.0)
ALLANTOIN;DEXPANTHENOL;HEPARIN	1 (0.1)	0 (0.0)	1 (0.0)
ALLANTOIN;GLYCEROL;MATRICARIA CHAMOMILLA	1 (0.1)	0 (0.0)	1 (0.0)
ALLANTOIN;HEXACHLOROPHENE;SQUALANE	0 (0.0)	1 (0.1)	1 (0.0)
ALLANTOIN;POVIDONE-IODINE	1 (0.1)	0 (0.0)	1 (0.0)
ALOE VERA;CALENDULA OFFICINALIS;CENTELLA ASIATICA;HYALURONIC ACID;MELALEUCA ALTERNIFOLIA	1 (0.1)	0 (0.0)	1 (0.0)
ALOE VERA;CONVOLVULUS SCAMMONIA;EUPHORBIA HUMIFUSA;TERMINALIA BELLIRICA;TERMINALIA CHEBULA	0 (0.0)	1 (0.1)	1 (0.0)
ALOGLIPTIN	0 (0.0)	1 (0.1)	1 (0.0)
ALOGLIPTIN;METFORMIN	1 (0.1)	0 (0.0)	1 (0.0)
ALTHAEA OFFICINALIS;CICHORIUM SPP.;FOENICULUM VULGARE;GLYCYRRHIZA GLABRA;PIMPINELLA ANISUM;RHEUM SPP.;RIBES NIGRUM	1 (0.1)	0 (0.0)	1 (0.0)
ALUMINIUM ACETATE;HYDROCORTISONE;LIDOCAINE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ALUMINIUM HYDROXIDE	0 (0.0)	1 (0.1)	1 (0.0)
ALUMINIUM HYDROXIDE;CAFFEINE;IBUPROFEN;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
ALUMINIUM HYDROXIDE;CALCIUM CARBONATE;LIPASE;MAGNESIUM CARBONATE;SODIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.0)
ALUMINIUM HYDROXIDE;CALCIUM CARBONATE;MAGNESIUM CARBONATE	0 (0.0)	1 (0.1)	1 (0.0)

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	0 (0.0)	1 (0.1)	1 (0.0)
ALUMINIUM MAGNESIUM SILICATE	0 (0.0)	1 (0.1)	1 (0.0)
ALUMINIUM POTASSIUM SULFATE;CAMPHOR;MENTHOL;PHENOL;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
ALUMINIUM SILICATE	0 (0.0)	1 (0.1)	1 (0.0)
ALUMINIUM SILICATE;AMOMUM SPP.;ANGELICA SINENSIS;ASTRAGALUS SPP.;ATRACTYLODES MACROCEPHALA;CODONOPSIS SPP.;CORYDALIS YANHUSUO;CULLEN CORYLIFOLIUM;DOLOMIAEA COSTUS;GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA;	0 (0.0)	1 (0.1)	1 (0.0)
ALUMINIUM SULFATE;CALCIUM ACETATE	0 (0.0)	1 (0.1)	1 (0.0)
AMANTADINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
AMBROXOL;CARBOCISTEINE;CHLORPHENAMINE;DIHYDROCODEINE;PARACETAMOL;RIBOFLAVIN	1 (0.1)	0 (0.0)	1 (0.0)
AMBROXOL;DEXTROMETHORPHAN	1 (0.1)	0 (0.0)	1 (0.0)
AMCINONIDE	1 (0.1)	0 (0.0)	1 (0.0)
AMENAMEVIR	0 (0.0)	1 (0.1)	1 (0.0)
AMIDES	0 (0.0)	1 (0.1)	1 (0.0)
AMINO ACIDS [UMBRELLA TERM]	0 (0.0)	1 (0.1)	1 (0.0)
AMINOALKYL ETHERS	1 (0.1)	0 (0.0)	1 (0.0)
AMINOBENZOIC ACID;CYSTEINE;KERATIN;PANTOTHENIC ACID;THIAMINE;YEAST	1 (0.1)	0 (0.0)	1 (0.0)
AMINOPHENAZONE;CAFFEINE;PHENACETIN;PHENOBARBITAL	1 (0.1)	0 (0.0)	1 (0.0)
AMLODIPINE;ATENOLOL	0 (0.0)	1 (0.1)	1 (0.0)
AMLODIPINE;BISOPROLOL	1 (0.1)	0 (0.0)	1 (0.0)
AMLODIPINE;CANDESARTAN	0 (0.0)	1 (0.1)	1 (0.0)
AMLODIPINE;LOSARTAN	1 (0.1)	0 (0.0)	1 (0.0)
AMLODIPINE;OLMESARTAN	0 (0.0)	1 (0.1)	1 (0.0)
AMLODIPINE;VALSARTAN	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
AMMONIUM BICARBONATE;SENEGA OFFICINALIS	0 (0.0)	1 (0.1)	1 (0.0)
AMMONIUM CHLORIDE;CHLORPHENAMINE;DEXTROMETHORPHAN;METHYLEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.0)
AMMONIUM CHLORIDE;DIPHENHYDRAMINE	0 (0.0)	1 (0.1)	1 (0.0)
AMOXICILLIN;CLARITHROMYCIN;LANSOPRAZOLE	0 (0.0)	1 (0.1)	1 (0.0)
AMPICILLIN;CLOXACILLIN	1 (0.1)	0 (0.0)	1 (0.0)
AMPICILLIN;PHENAZOPYRIDINE	1 (0.1)	0 (0.0)	1 (0.0)
AMYLASE	1 (0.1)	0 (0.0)	1 (0.0)
AMYLMETACRESOL;DICHLOROBENZYL ALCOHOL	1 (0.1)	0 (0.0)	1 (0.0)
AMYLOCAINE;BENZALKONIUM;BENZOCAINE;ESCULOSIDE;HYDROCORTISONE	0 (0.0)	1 (0.1)	1 (0.0)
ANEMARRHENA ASPHODELOIDES;GARDENIA JASMINOIDES;KITAGAWIA PRAERUPTORA;PHELLODENDRON AMURENSE;PLATYCODON GRANDIFLORUS;RHEUM PALMATUM;SCUTELLARIA BAICALENSIS;SOPHORA FLAVESCENS;TRICHOSANTHES KIRILOWII	1 (0.1)	0 (0.0)	1 (0.0)
ANETHOLE TRITHIONE	0 (0.0)	1 (0.1)	1 (0.0)
ANGELICA ACUTILOBA;ANGELICA DAHURICA;BUPLEURUM FALCATUM;CITRUS SPP.;CONIOSELINUM OFFICINALE;COPTIS SPP.;FORSYTHIA SPP.;GARDENIA JASMINOIDES;GLYCYRRHIZA SPP.;MENTHA CANADENSIS;NEPETA TENUIFOLIA;	1 (0.1)	0 (0.0)	1 (0.0)
ANGELICA ACUTILOBA;ATRACTYLODES SPP.;BUPLEURUM FALCATUM;GARDENIA JASMINOIDES;GLYCYRRHIZA SPP.;MENTHA CANADENSIS;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.0)
ANGELICA ACUTILOBA;ATRACTYLODES SPP.;COIX LACRYMA-JOBI VAR. MA-YUEN;EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA	0 (0.0)	1 (0.1)	1 (0.0)
ANGELICA ACUTILOBA;GARDENIA JASMINOIDES;GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA;PORIA COCOS;SCUTELLARIA BAICALENSIS	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ANGELICA ARCHANGELICA;ARGENTINA ANSERINA;ARTEMISIA ABSINTHIUM;CENTAUREA BENEDICTA;GLYCYRRHIZA GLABRA;HYPERICUM PERFORATUM;MATRICARIA CHAMOMILLA	0 (0.0)	1 (0.1)	1 (0.0)
ANGELICA DAHURICA VAR. FORMOSANA;CITRUS RETICULATA;EPHEDRA SINICA;GLYCYRRHIZA URALENSIS;NEOLITSEA CASSIA;PERILLA FRUTESCENS VAR. CRISPA;PLATYCODON GRANDIFLORUS;PRUNUS ARMENIACA VAR. ARMENIACA;	0 (0.0)	1 (0.1)	1 (0.0)
ANGELICA DAHURICA;ARECA CATECHU;ATRACTYLODES SPP.;CITRUS RETICULATA;GLYCYRRHIZA URALENSIS;MAGNOLIA OFFICINALIS;PERILLA FRUTESCENS;PINELLIA TERNATA;POGOSTEMON CABLIN;PORIA COCOS	1 (0.1)	0 (0.0)	1 (0.0)
ANGELICA DAHURICA;ATRACTYLODES LANCEA;CHRYSANTHEMUM SPP.;CITRUS MAXIMA;COIX LACRYMA-JOBI VAR. MA-YUEN;DOLOMIAEA COSTUS;HERBAL NOS;MAGNOLIA OFFICINALIS;MENTHA CANADENSIS;ORYZA SATIVA;POGOSTEMON SPP.;	1 (0.1)	0 (0.0)	1 (0.0)
ANGELICA PUBESCENS;BORNEOL;BOSWELLIA SPP.;COPPER;EUPOLYPHAGA SINENSIS;PANAX NOTOGINSENG	1 (0.1)	0 (0.0)	1 (0.0)
ANGELICA SINENSIS;ANGELICA SPP.;BORNEOL;CALCIUM SULFATE;CHRYSANTHEMUM X MORIFOLIUM;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';COPTIS SPP.;COW BEZOAR;FORSYTHIA SUSPENSA;GARDENIA JASMINOIDES;	1 (0.1)	0 (0.0)	1 (0.0)
ANGELICA SINENSIS;ASARUM HETEROTROPOIDES;CONCHA MARGARITIFERA;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';CORYDALIS YANHUSUO;PAEONIA LACTIFLORA;PRUNELLA VULGARIS;REHMANNIA GLUTINOSA;SENNA OBTUSIFOLIA;	1 (0.1)	0 (0.0)	1 (0.0)
ANGELICA SINENSIS;ASINI CORII COLLA;ASTRAGALUS MONGHOLICUS;EPIMEDIUM BREVICORNU;LESPEDEZA BUERGERI;SOPHORA FLAVESCENS;ZIZIPHUS JUJUBA	0 (0.0)	1 (0.1)	1 (0.0)
ANGELICA SINENSIS;BUPLEURUM SPP.;CITRUS RETICULATA;CITRUS X AURANTIUM;COPTIS SPP.;CORYDALIS YANHUSUO;CURCUMA SPP.;CYPERUS ROTUNDUS;DOLOMIAEA COSTUS;GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA;	1 (0.1)	0 (0.0)	1 (0.0)
ANIMAL UNSPECIFIED;BORNEOL;COW BEZOAR;FUNGI NOS;INDIGO;PEARL	1 (0.1)	0 (0.0)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ANISODAMINE	1 (0.1)	0 (0.0)	1 (0.0)
ANTACIDS	1 (0.1)	0 (0.0)	1 (0.0)
ANTACIDS, OTHER COMBINATIONS	1 (0.1)	0 (0.0)	1 (0.0)
ANTAZOLINE;TETRYZOLINE	1 (0.1)	0 (0.0)	1 (0.0)
ANTIBACTERIALS FOR SYSTEMIC USE	1 (0.1)	0 (0.0)	1 (0.0)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	0 (0.0)	1 (0.1)	1 (0.0)
ANTIFUNGALS FOR TOPICAL USE	1 (0.1)	0 (0.0)	1 (0.0)
ANTIHISTAMINES	0 (0.0)	1 (0.1)	1 (0.0)
ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS	1 (0.1)	0 (0.0)	1 (0.0)
ANTISEPTICS	1 (0.1)	0 (0.0)	1 (0.0)
ARCTIUM LAPPA;ASCORBIC ACID;CHLORPHENAMINE;FORSYTHIA SUSPENSA;GLYCINE MAX;GLYCYRRHIZA URALENSIS;LONICERA JAPONICA;LOPHATHERUM GRACILE;MENTHA CANADENSIS;NEPETA TENUIFOLIA;PARACETAMOL;	1 (0.1)	0 (0.0)	1 (0.0)
ARCTIUM LAPPA;CICADA SLOUGH;EPHEDRA SPP.;ERIOBOTRYA JAPONICA;KITAGAWIA PRAERUPTORA;PERILLA FRUTESCENS;PHERETIMA SPP.;SCHISANDRA CHINENSIS	0 (0.0)	1 (0.1)	1 (0.0)
ARCTIUM LAPPA;FORSYTHIA SUSPENSA;GLYCINE MAX;GLYCYRRHIZA SPP.;LONICERA JAPONICA;LOPHATHERUM GRACILE;MENTHA CANADENSIS;NEPETA TENUIFOLIA;PHRAGMITES AUSTRALIS SUBSP. AUSTRALIS;PLATYCODON GRANDIFLORUS	1 (0.1)	0 (0.0)	1 (0.0)
ARDISIA JAPONICA	0 (0.0)	1 (0.1)	1 (0.0)
ARECA CATECHU;CITRUS RETICULATA;CURCUMA SPP.;DOLOMIAEA COSTUS;GLEDITSIA SINENSIS;IPOMOEA SPP.;MAGNOLIA OFFICINALIS;SPARGANIUM STOLONIFERUM	1 (0.1)	0 (0.0)	1 (0.0)
ARGININE;ASCORBIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
ARGININE;CYSTINE;PYRIDOXINE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ARGININE;IBUPROFEN	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 47 of 81
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ARSENIC TRIIODIDE;MERCURIC IODIDE RED;POTASSIUM DICHROMATE;SULFURATED POTASH	1 (0.1)	0 (0.0)	1 (0.0)
ARTEMISIA ANNUA;BUPLEURUM CHINENSE;ISATIS TINCTORIA;LANXANGIA TSAO-KO;LONICERA JAPONICA;PARIS CHINENSIS;RHEUM PALMATUM;SCUTELLARIA BAICALENSIS;TARAXACUM MONGOLICUM	1 (0.1)	0 (0.0)	1 (0.0)
ARTEMISIA ANNUA;CALCIUM SULFATE;CHLORPHENAMINE;ILEX PUBESCENS;ISATIS TINCTORIA;METAMIZOLE;NOTOPTERYGIUM SPP.;PUERARIA MONTANA VAR. LOBATA;VERBENA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.0)
ARTEMISIA ARGYI	0 (0.0)	1 (0.1)	1 (0.0)
ARTEMISIA SPP.;BAICALIN;GANODERMA SPP.;GARDENIA JASMINOIDES;ISATIS TINCTORIA SUBSP. TINCTORIA	0 (0.0)	1 (0.1)	1 (0.0)
ARTEMISIA SPP.;BUPLEURUM SPP.;ISATIS TINCTORIA SUBSP. TINCTORIA;SCHISANDRA CHINENSIS;SWINE BILE;VIGNA RADIATA	1 (0.1)	0 (0.0)	1 (0.0)
ARTICAINE	1 (0.1)	0 (0.0)	1 (0.0)
ASARUM SPP.;CAFFEINE;CHLORPHENAMINE;GLYCYRRHIZA SPP.;MAGNOLIA SPP.;PSEUDOEPHEDRINE;ZINGIBER OFFICINALE	0 (0.0)	1 (0.1)	1 (0.0)
ASARUM SPP.;EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PINELLIA TERNATA;SCHISANDRA CHINENSIS;ZINGIBER OFFICINALE	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;IRON;MAGNESIUM;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE;TOCOPHEROL;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;BIFIDOBACTERIUM BIFIDUM;FRUCTOOLIGOSACCHARIDES;GLUCOSAMINE;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LEVOGLUTAMIDE;ORYZANOL	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;BIOTIN;CALCIUM;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FOLIC ACID;IRON;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANAX GINSENG;PYRIDOXINE;RETINOL;RIBOFLAVIN;SELENIUM;THIAMINE;TOCOPHEROL;ZINC	1 (0.1)	0 (0.0)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ASCORBIC ACID;BIOTIN;CHROMIUM;COPPER;FOLIC ACID;IODINE;IRON;MANGANESE;MOLYBDENUM;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RETINOL;RIBOFLAVIN;SELENIUM;VITAMIN B1 NOS;VITAMIN B12 NOS;VITAMIN D NOS;	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;CHLORPHENAMINE;METAMIZOLE	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;CHONDROITIN;GLUCOSAMINE;METHYLSULFONYLMETHANE	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;COLECALCIFEROL;COLLAGEN;GELATINE HYDROLYSATE	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;COLECALCIFEROL;MAGNESIUM OXIDE;MAGNESIUM PHOSPHATE;MANGANESE;PYRIDOXINE	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;COLECALCIFEROL;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;COPPER;FISH OIL;GLUTATHIONE;SELENIUM;TAGETES ERECTA;TOCOPHEROL;VITIS VINIFERA;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;CYANOCOBALAMIN;DOCUSATE;FOLIC ACID;IRON;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;CYANOCOBALAMIN;FOLIC ACID;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;DEXPANTHENOL;ERGOCALCIFEROL;NICOTINAMIDE;PYRIDOXINE;RETINOL;RIBOFLAVIN;THIAMINE;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;FOLIC ACID;IRON;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;IRON	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;IRON;VITAMIN B12 NOS	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;PANTOTHENIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;PARACETAMOL;PHENIRAMINE;PHENYLEPHRINE	0 (0.0)	1 (0.1)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ASCORBIC ACID;POLIGLUSAM	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;TOCOPHEROL;XANTOFYL;ZEAXANTHIN;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ASTAXANTHIN;BERBERINE;FOLIC ACID;MONASCUS PURPUREUS;POLICOSANOL;UBIDECARENONE	1 (0.1)	0 (0.0)	1 (0.0)
ASTER TATARICUS	0 (0.0)	1 (0.1)	1 (0.0)
ASTER TATARICUS;ERIOBOTRYA JAPONICA;KITAGAWIA PRAERUPTORA;PLATYCODON GRANDIFLORUS;PRUNUS ARMENIACA;PYRUS BRETSCHNEIDERI;TUSSILAGO FARFARA	1 (0.1)	0 (0.0)	1 (0.0)
ATORVASTATIN;EZETIMIBE	1 (0.1)	0 (0.0)	1 (0.0)
ATRACURIUM	0 (0.0)	1 (0.1)	1 (0.0)
ATROPA	0 (0.0)	1 (0.1)	1 (0.0)
BELLA-DONNA;BENFOTIAMINE;BROMHEXINE;CAFFEINE;CLEMASTINE;DIHYDROCODEINE;IBUPROFEN;METHYLEPHEDRINE;RIBOFLAVIN			
ATROPA	0 (0.0)	1 (0.1)	1 (0.0)
BELLA-DONNA;BENFOTIAMINE;BROMHEXINE;CAFFEINE;CLEMASTINE;DIHYDROCODEINE;METHYLEPHEDRINE;NOSCAPINE;PARACETAMOL			
ATROPA	0 (0.0)	1 (0.1)	1 (0.0)
BELLA-DONNA;BENFOTIAMINE;BROMHEXINE;CAFFEINE;CLEMASTINE;DIHYDROCODEINE;METHYLEPHEDRINE;PARACETAMOL;TRANEXAMIC ACID			
AVENA SATIVA	0 (0.0)	1 (0.1)	1 (0.0)
AZELASTINE;FLUTICASONE	1 (0.1)	0 (0.0)	1 (0.0)
BACILLUS CLAUSII	1 (0.1)	0 (0.0)	1 (0.0)
BACILLUS COAGULANS;DEXPANTHENOL;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0 (0.0)	1 (0.1)	1 (0.0)
BACILLUS LICHENFORMIS	0 (0.0)	1 (0.1)	1 (0.0)
BACITRACIN;LIDOCAINE;NEOMYCIN;POLYMYXIN B	0 (0.0)	1 (0.1)	1 (0.0)
BACITRACIN;POLYMYXIN B	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BACOPA MONNIERI	0 (0.0)	1 (0.1)	1 (0.0)
BACOPA MONNIERI;CITICOLINE;GINKGO BILOBA;PHOSPHATIDYL SERINE;SALVIA OFFICINALIS;THIOCTIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
BACTERIA NOS;HYDROCORTISONE	1 (0.1)	0 (0.0)	1 (0.0)
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES;HYODEOXYCHOLIC ACID;ISATIS TINCTORIA SUBSP. TINCTORIA;LONICERA JAPONICA	1 (0.1)	0 (0.0)	1 (0.0)
BALLOTA NIGRA;CRATAEGUS LAEVIGATA;PASSIFLORA INCARNATA	1 (0.1)	0 (0.0)	1 (0.0)
BATILOL	1 (0.1)	0 (0.0)	1 (0.0)
BECLOMETASONE;FORMOTEROL;GLYCOPYRRONIUM	1 (0.1)	0 (0.0)	1 (0.0)
BENFOTIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
BENFOTIAMINE;CAFFEINE;CLEMASTINE;DIHYDROCODEINE;LYSOZYME;METHYLEPHEDRINE;NOSCAPINE;PARACETAMOL;SULFOGAIACOL	1 (0.1)	0 (0.0)	1 (0.0)
BENFOTIAMINE;CYANOCOBALAMIN;PYRIDOXINE	1 (0.1)	0 (0.0)	1 (0.0)
BENSERAZIDE;LEVODOPA	1 (0.1)	0 (0.0)	1 (0.0)
BENZALKONIUM;HEXETIDINE	1 (0.1)	0 (0.0)	1 (0.0)
BENZALKONIUM;IDOXURIDINE;LIDOCAINE	0 (0.0)	1 (0.1)	1 (0.0)
BENZALKONIUM;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
BENZALKONIUM;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.0)
BENZBROMARONE	1 (0.1)	0 (0.0)	1 (0.0)
BENZETHONIUM	1 (0.1)	0 (0.0)	1 (0.0)
BENZETHONIUM;CHLORHEXIDINE	0 (0.0)	1 (0.1)	1 (0.0)
BENZOCAINE;CETYLPYRIDINIUM	1 (0.1)	0 (0.0)	1 (0.0)
BENZOCAINE;CHLOROTHYMOL;SODIUM MORRHUATE	1 (0.1)	0 (0.0)	1 (0.0)
BENZOCAINE;CHLORPHENAMINE	0 (0.0)	1 (0.1)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BENZOCAINE;RESORCINOL	1 (0.1)	0 (0.0)	1 (0.1)
BENZOYL PEROXIDE	0 (0.0)	1 (0.1)	1 (0.1)
BENZOYL PEROXIDE;ERYTHROMYCIN	1 (0.1)	0 (0.0)	1 (0.1)
BENZYDAMINE;DICHLOROBENZYL ALCOHOL;LIDOCAINE	0 (0.0)	1 (0.1)	1 (0.1)
BENZYL BENZOATE	1 (0.1)	0 (0.0)	1 (0.1)
BENZYLHYDROCHLOROTHIAZIDE	0 (0.0)	1 (0.1)	1 (0.1)
BERAPROST	1 (0.1)	0 (0.0)	1 (0.1)
BERBERINE	1 (0.1)	0 (0.0)	1 (0.1)
BETA GLUCAN	0 (0.0)	1 (0.1)	1 (0.1)
BETAINE;CHOLINE;METHIONINE	0 (0.0)	1 (0.1)	1 (0.1)
BETAINE;POTASSIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.1)
BETAINE;POTASSIUM;POTASSIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.1)
BETAMETHASONE;CHLORAMPHENICOL	1 (0.1)	0 (0.0)	1 (0.1)
BETAMETHASONE;CLIOQUINOL	1 (0.1)	0 (0.0)	1 (0.1)
BETAMETHASONE;CLOTRIMAZOLE	1 (0.1)	0 (0.0)	1 (0.1)
BETAMETHASONE;LORATADINE	0 (0.0)	1 (0.1)	1 (0.1)
BETAMETHASONE;NEOMYCIN	0 (0.0)	1 (0.1)	1 (0.1)
BETAMETHASONE;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.1)
BETHANECHOL	0 (0.0)	1 (0.1)	1 (0.1)
BIFENDATE	0 (0.0)	1 (0.1)	1 (0.1)
BIFIDOBACTERIUM BIFIDUM	1 (0.1)	0 (0.0)	1 (0.1)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM INFANTIS	1 (0.1)	0 (0.0)	1 (0.1)

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Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM INFANTIS;FRUCTOOLIGOSACCHARIDES;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS CASEI;LACTOBACILLUS RHAMNOSUS;STREPTOCOCCUS THERMOPHILUS	1 (0.1)	0 (0.0)	1 (0.0)
BIFIDOBACTERIUM LACTIS;LACTOBACILLUS ACIDOPHILUS	1 (0.1)	0 (0.0)	1 (0.0)
BIFIDOBACTERIUM LONGUM;CYANOCOBALAMIN;FRUCTOOLIGOSACCHARIDES;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
BIMATOPROST;TIMOLOL	1 (0.1)	0 (0.0)	1 (0.0)
BIODIASTASE	0 (0.0)	1 (0.1)	1 (0.0)
BIOFLAVONOIDS NOS	1 (0.1)	0 (0.0)	1 (0.0)
BIOFLAVONOIDS NOS;DIOSMIN;HESPERIDIN	0 (0.0)	1 (0.1)	1 (0.0)
BIOFLAVONOIDS [UMBRELLA TERM]	1 (0.1)	0 (0.0)	1 (0.0)
BIOTIN;CYSTINE;PANICUM MILIACEUM;PANTOTHENIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
BISACODYL;DOCUSATE	0 (0.0)	1 (0.1)	1 (0.0)
BISMUTH;BUFEXAMAC;LIDOCAINE;TITANIUM DIOXIDE	0 (0.0)	1 (0.1)	1 (0.0)
BISMUTH;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
BISOPROLOL;HYDROCHLOROTHIAZIDE	0 (0.0)	1 (0.1)	1 (0.0)
BORIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
BORNEOL;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG'	1 (0.1)	0 (0.0)	1 (0.0)
BORNEOL;COW BEZOAR;LIQUIDAMBAR ORIENTALIS;MUSK;NEOLITSEA CASSIA;PANAX GINSENG;TOAD VENOM	1 (0.1)	0 (0.0)	1 (0.0)
BORNEOL;PANAX NOTOGINSENG;SALVIA MILTIORRHIZA	1 (0.1)	0 (0.0)	1 (0.0)
BOTULINUM TOXIN TYPE A	1 (0.1)	0 (0.0)	1 (0.0)
BRIMONIDINE;BRINZOLAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
BRIMONIDINE;TIMOLOL	1 (0.1)	0 (0.0)	1 (0.0)
BRINZOLAMIDE	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BRINZOLAMIDE;TIMOLOL	0 (0.0)	1 (0.1)	1 (0.0)
BROMELAINS	1 (0.1)	0 (0.0)	1 (0.0)
BROMELAINS;DIOSMIN;VITEXIN	1 (0.1)	0 (0.0)	1 (0.0)
BROMELAINS;PAPAIN;SELENIUM;VICIA LENS	0 (0.0)	1 (0.1)	1 (0.0)
BROMELAINS;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.0)
BROMHEXINE;CLEMASTINE;DIHYDROCODEINE;IBUPROFEN;METHYLEPHEDRINE;RIBOFLAVIN;THIAMINE;TRANEXAMIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
BROMHEXINE;DEXTROMETHORPHAN	0 (0.0)	1 (0.1)	1 (0.0)
BROMHEXINE;DOXYLAMINE;ORCIPRENALINE	0 (0.0)	1 (0.1)	1 (0.0)
BROMHEXINE;GUAIFENESIN;MENTHOL;TERBUTALINE	0 (0.0)	1 (0.1)	1 (0.0)
BROMINE;CINCHOCAINE;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
BROTIZOLAM	0 (0.0)	1 (0.1)	1 (0.0)
BRYONIA SPP.	0 (0.0)	1 (0.1)	1 (0.0)
BUMETANIDE	1 (0.1)	0 (0.0)	1 (0.0)
BUPIVACAINE;EPINEPHRINE	0 (0.0)	1 (0.1)	1 (0.0)
BUPLEURUM CHINENSE;CODONOPSIS PILOSULA;GLYCYRRHIZA URALENSIS;PINELLIA TERNATA;SCUTELLARIA BAICALENSIS;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	0 (0.0)	1 (0.1)	1 (0.0)
BUPLEURUM SPP.	0 (0.0)	1 (0.1)	1 (0.0)
BUSPIRONE	1 (0.1)	0 (0.0)	1 (0.0)
BUTAMIRATE;GUAIFENESIN	1 (0.1)	0 (0.0)	1 (0.0)
BUTORPHANOL	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;CETIRIZINE;PARACETAMOL;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;CHLORPHENAMINE;CODEINE;LYSOZYME;METHYLEPHEDRINE;SENEGA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;CHLORPHENAMINE;CODEINE;METHYLEPHEDRINE;SENEGA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CAFFEINE;CHLORPHENAMINE;DEXTROMETHORPHAN;GLYCYRRHIZA GLABRA;METHYLEPHEDRINE;PARACETAMOL;PROPYPHENAZONE;PRUNUS JAMASAKURA	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;CHLORPHENAMINE;DIHYDROCODEINE;GLYCYRRHIZA GLABRA;METHYLEPHEDRINE;PARACETAMOL;PROPYPHENAZONE	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;CHLORPHENAMINE;DIHYDROCODEINE;GUAIFENESIN	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;CHLORPHENAMINE;PARACETAMOL;PHENYLPROPANOLAMINE	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;DIHYDROERGOTAMINE;METAMIZOLE	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;DIHYDROERGOTAMINE;METOCLOPRAMIDE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;EPHEDRINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;PAPAVER SOMNIFERUM;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
CALAMINE;CAMPHOR;DIPHENHYDRAMINE;GLYCEROL;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
CALAMINE;GLYCEROL;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
CALCIPOTRIOL	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CARBONATE;CALCIUM PHOSPHATE;KAOLIN;MAGNESIUM CARBONATE;MAGNESIUM HYDROXIDE;MAGNESIUM OXIDE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CARBONATE;FAMOTIDINE;MAGNESIUM HYDROXIDE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CARBONATE;MAGNESIUM	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CARBONATE;MAGNESIUM CARBONATE;MAGNESIUM TRISILICATE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CARBONATE;MAGNESIUM HYDROXIDE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CHLORIDE;GLUCOSE;MAGNESIUM SULFATE;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CHLORIDE;GLUCOSE;POTASSIUM;SODIUM ACETATE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CHLORIDE;GLUCOSE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CHLORIDE;GLUCOSE;POTASSIUM;SODIUM LACTATE	0 (0.0)	1 (0.1)	1 (0.0)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CHLORIDE;MALTOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CHLORIDE;POTASSIUM;SODIUM ACETATE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM GLYCEROPHOSPHATE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM POLYSTYRENE SULFONATE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM SULFATE;EPHEDRA SPP.;GLYCYRRHIZA SPP.;MORUS ALBA;PRUNUS SPP.	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM;COLECALCIFEROL;MAGNESIUM;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM;MAGNESIUM	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM;MAGNESIUM;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
CAMELLIA SINENSIS;MAGNESIUM CARBONATE;UBIDECARENONE	1 (0.1)	0 (0.0)	1 (0.0)
CAMPHOR	1 (0.1)	0 (0.0)	1 (0.0)
CAMPHOR;CHLORPHENAMINE;HEXACHLOROPHENE;LIDOCAINE;MENTHOL;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
CAMPHOR;CRATAEGUS LAEVIGATA;ETHYL ETHER;GOLD CHLORIDE;SELENICEREUS GRANDIFLORUS;STROPHANTHUS HISPIDUS;VALERIANA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.0)
CAMPHOR;DIPHENHYDRAMINE;MENTHOL;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
CAMPHOR;EUCALYPTUS GLOBULUS;MENTHOL;PINUS PINASTER;THYMOL	0 (0.0)	1 (0.1)	1 (0.0)
CAMPHOR;PINUS PINASTER;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
CANNABIS SATIVA;CITRUS RETICULATA;DOLOMIAEA COSTUS;PAEONIA LACTIFLORA;PRUNUS SPP.;RHEUM SPP.	1 (0.1)	0 (0.0)	1 (0.0)
CANRENOIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
CAPSAICIN	1 (0.1)	0 (0.0)	1 (0.0)
CAPSICUM SPP.	0 (0.0)	1 (0.1)	1 (0.0)
CAPSICUM SPP.;DRIMIA MARITIMA	0 (0.0)	1 (0.1)	1 (0.0)

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Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CARBACHOL	1 (0.1)	0 (0.0)	1 (0.0)
CARBIDOPA;LEVODOPA	0 (0.0)	1 (0.1)	1 (0.0)
CARBINOXAMINE	0 (0.0)	1 (0.1)	1 (0.0)
CARBOHYDRATES NOS;FATS NOS;FIBRE NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1 (0.1)	0 (0.0)	1 (0.0)
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEIN;VITAMINS NOS	1 (0.1)	0 (0.0)	1 (0.0)
CARBOHYDRATES NOS;LIPIDS NOS;MINERALS NOS;PROTEINS NOS	1 (0.1)	0 (0.0)	1 (0.0)
CARBOMER;HYALURONIC ACID;TREHALOSE	1 (0.1)	0 (0.0)	1 (0.0)
CARICA PAPAYA	0 (0.0)	1 (0.1)	1 (0.0)
CARISOPRODOL	0 (0.0)	1 (0.1)	1 (0.0)
CARISOPRODOL;CYANOCOBALAMIN;METAMIZOLE;PYRIDOXINE;THIAMINE	0 (0.0)	1 (0.1)	1 (0.0)
CARMELLOSE;GLYCEROL	1 (0.1)	0 (0.0)	1 (0.0)
CARUM CARVI;FOENICULUM VULGARE;MATRICARIA CHAMOMILLA;MENTHA X PIPERITA	0 (0.0)	1 (0.1)	1 (0.0)
CARUM CARVI;MENTHA X PIPERITA	0 (0.0)	1 (0.1)	1 (0.0)
CASANTHRANOL;DOCUSATE	0 (0.0)	1 (0.1)	1 (0.0)
CASSIA FISTULA;CORIANDRUM SATIVUM;GLYCYRRHIZA GLABRA;SENNA SPP.;TAMARINDUS INDICA	1 (0.1)	0 (0.0)	1 (0.0)
CEFAZOLIN;LIDOCAINE	0 (0.0)	1 (0.1)	1 (0.0)
CEFMINOX	0 (0.0)	1 (0.1)	1 (0.0)
CEFODIZIME	1 (0.1)	0 (0.0)	1 (0.0)
CEFOPERAZONE;SULBACTAM	1 (0.1)	0 (0.0)	1 (0.0)
CEFOTETAN	0 (0.0)	1 (0.1)	1 (0.0)
CEFPIROME	1 (0.1)	0 (0.0)	1 (0.0)
CEFROXADINE	1 (0.1)	0 (0.0)	1 (0.0)
CEFTIZOXIME	0 (0.0)	1 (0.1)	1 (0.0)
CELLULASE;ENZYMES NOS;PANCREATIC DIGESTIVE ENZYME TA;PROCTASE;SANACTASE	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CENTELLA ASIATICA	1 (0.1)	0 (0.0)	1 (0.0)
CEPHARANTHINE	1 (0.1)	0 (0.0)	1 (0.0)
CERAMIDE;DEXPANTHENOL;GLYCEROL;LINUM USITATISSIMUM;OLEA EUROPAEA;VITELLARIA PARADOXA SUBSP. PARADOXA	1 (0.1)	0 (0.0)	1 (0.0)
CEROUS NITRATE;SULFADIAZINE	1 (0.1)	0 (0.0)	1 (0.0)
CERTOPARIN SODIUM	0 (0.0)	1 (0.1)	1 (0.0)
CETRIMIDE;CHLORHEXIDINE	0 (0.0)	1 (0.1)	1 (0.0)
CETYLPYRIDINIUM;CHLORHEXIDINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORAMPHENICOL;METHYLURACIL	0 (0.0)	1 (0.1)	1 (0.0)
CHLORHEXIDINE;CHLOROBUTANOL	0 (0.0)	1 (0.1)	1 (0.0)
CHLORHEXIDINE;CHLOROCRESOL;HEXAMIDINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORHEXIDINE;DEXAMETHASONE;NYSTATIN	1 (0.1)	0 (0.0)	1 (0.0)
CHLORHEXIDINE;METRONIDAZOLE	0 (0.0)	1 (0.1)	1 (0.0)
CHLORMEZANONE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
CHLOROTHIAZIDE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORPHENAMINE;CHONDROITIN;NEOSTIGMINE;PANTHENOL;TAURINE;TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.0)
CHLORPHENAMINE;CODEINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORPHENAMINE;CODEINE;GUAIFENESIN;PAPAVERINE	0 (0.0)	1 (0.1)	1 (0.0)
CHLORPHENAMINE;DEXTROMETHORPHAN	1 (0.1)	0 (0.0)	1 (0.0)
CHLORPHENAMINE;DEXTROMETHORPHAN;GUAIFENESIN;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL;PHENYLPROPANOLAMINE	0 (0.0)	1 (0.1)	1 (0.0)
CHLORPHENAMINE;HYDROCODONE	0 (0.0)	1 (0.1)	1 (0.0)
CHLORPHENAMINE;IBUPROFEN	1 (0.1)	0 (0.0)	1 (0.0)
CHLORPHENAMINE;METAMIZOLE	0 (0.0)	1 (0.1)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CHLORPHENAMINE;NAPHAZOLINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORPHENAMINE;NEOSTIGMINE;PYRIDOXINE;TAURINE;TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.0)
CHLORPHENAMINE;OXOLAMINE;PARACETAMOL;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORPHENAMINE;PHENYLPROPANOLAMINE	0 (0.0)	1 (0.1)	1 (0.0)
CHLORPHENOXAMINE	0 (0.0)	1 (0.1)	1 (0.0)
CHLORPROMAZINE	1 (0.1)	0 (0.0)	1 (0.0)
CHONDROITIN;HYALURONIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
CHONDRUS CRISPUS;LIDOCAINE;TITANIUM DIOXIDE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
CHONDRUS CRISPUS;TITANIUM DIOXIDE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
CHRYSANTHEMUM INDICUM;CONIOSELINUM ANTHRISCOIDES 'CHUANXIONG';EUCOMMIA ULMOIDES;GASTRODIA ELATA	1 (0.1)	0 (0.0)	1 (0.0)
CICLESONIDE	1 (0.1)	0 (0.0)	1 (0.0)
CICLONIUM;CODEINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
CICLOPIROX	0 (0.0)	1 (0.1)	1 (0.0)
CILOSTAZOL	1 (0.1)	0 (0.0)	1 (0.0)
CINCHOCAINE	0 (0.0)	1 (0.1)	1 (0.0)
CINCHOCAINE;FLUOCORTOLONE	1 (0.1)	0 (0.0)	1 (0.0)
CINEOLE;DIPENTEN;PINENE	0 (0.0)	1 (0.1)	1 (0.0)
CINEPAZIDE	1 (0.1)	0 (0.0)	1 (0.0)
CINITAPRIDE;SIMETICONE	1 (0.1)	0 (0.0)	1 (0.0)
CINNARIZINE;DIMENHYDRINATE	1 (0.1)	0 (0.0)	1 (0.0)
CIPROFLOXACIN;HYDROCORTISONE	0 (0.0)	1 (0.1)	1 (0.0)
CISTANCHE SPP.;DRYNARIA ROOSII;EPIMEDIUM SPP.;PYROLA SPP.;RAPHANUS RAPHANISTRUM SUBSP. SATIVUS;REHMANNIA GLUTINOSA;SPATHOLOBUS SUBERECTUS	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CITRIC ACID;DIMETICONE;METOCLOPRAMIDE;POTASSIUM CITRATE;SODIUM BICARBONATE;TARTARIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
CITRIC ACID;GLUCOSE;POTASSIUM CITRATE;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
CITRIC ACID;POTASSIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
CITRIC ACID;SODIUM BICARBONATE;SODIUM CARBONATE ANHYDROUS	0 (0.0)	1 (0.1)	1 (0.0)
CITRIC ACID;SODIUM BICARBONATE;TARTARIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
CITRULLINE	1 (0.1)	0 (0.0)	1 (0.0)
CITRULLUS LANATUS;SODIUM SULFATE	1 (0.1)	0 (0.0)	1 (0.0)
CITRUS MAXIMA;DELPHINIUM GRANDIFLORUM;GLYCYRRHIZA SPP.;PINELLIA TERNATA;PORIA COCOS;PRUNUS SPP.;SCHISANDRA CHINENSIS;VINCETOXICUM STAUNTONII	1 (0.1)	0 (0.0)	1 (0.0)
CITRUS MEDICA	1 (0.1)	0 (0.0)	1 (0.0)
CLENBUTEROL	1 (0.1)	0 (0.0)	1 (0.0)
CLOBAZAM	0 (0.0)	1 (0.1)	1 (0.0)
CLOBETASONE;NYSTATIN;OXYTETRACYCLINE	0 (0.0)	1 (0.1)	1 (0.0)
CLODRONIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
CLOMIPRAMINE	0 (0.0)	1 (0.1)	1 (0.0)
CLONIXIN;CYCLOBENZAPRINE	1 (0.1)	0 (0.0)	1 (0.0)
CLOTRIMAZOLE;UREA	1 (0.1)	0 (0.0)	1 (0.0)
COBAMAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
COD-LIVER OIL	0 (0.0)	1 (0.1)	1 (0.0)
CODEINE;GUAIFENESIN	1 (0.1)	0 (0.0)	1 (0.0)
CODEINE;PARACETAMOL;PSEUDOEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.0)
CODEINE;PARACETAMOL;PSEUDOEPHEDRINE;TRIPROLIDINE	0 (0.0)	1 (0.1)	1 (0.0)
CODEINE;PSEUDOEPHEDRINE;TRIPROLIDINE	0 (0.0)	1 (0.1)	1 (0.0)
CODEINE;SULFOGAIACOL	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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I3Y-MC-JPCF PDPM
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	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
COLESEVELAM	1 (0.1)	0 (0.0)	1 (0.0)
COLLINSONIA CANADENSIS;PERSICARIA PUNCTATA;SENNA ALEXANDRINA;SODIUM PICOSULFATE	1 (0.1)	0 (0.0)	1 (0.0)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS	1 (0.1)	0 (0.0)	1 (0.0)
COPPER	1 (0.1)	0 (0.0)	1 (0.0)
COPTIS CHINENSIS;RHEUM PALMATUM;SCUTELLARIA BAICALENSIS	1 (0.1)	0 (0.0)	1 (0.0)
COPTIS SPP.;GLYCYRRHIZA SPP.;PANAX GINSENG;PINELLIA TERNATA;SCUTELLARIA BAICALENSIS;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	1 (0.1)	0 (0.0)	1 (0.0)
CORDYCEPS SINENSIS	1 (0.1)	0 (0.0)	1 (0.0)
CORTICOSTEROIDS	0 (0.0)	1 (0.1)	1 (0.0)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION	1 (0.1)	0 (0.0)	1 (0.0)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)	0 (0.0)	1 (0.0)
CORTICOSTEROIDS, PLAIN	0 (0.0)	1 (0.1)	1 (0.0)
CORTICOSTEROIDS, WEAK (GROUP I)	0 (0.0)	1 (0.1)	1 (0.0)
CORYDALIS BUNGEANA;ISATIS TINCTORIA SUBSP. TINCTORIA;SCUTELLARIA BAICALENSIS;TARAXACUM SPP.	0 (0.0)	1 (0.1)	1 (0.0)
COUMARIN;TROXERUTIN	1 (0.1)	0 (0.0)	1 (0.0)
COVID-19 VACCINE	1 (0.1)	0 (0.0)	1 (0.0)
COW BEZOAR;METRONIDAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
CROTAMITON;HYDROCORTISONE	1 (0.1)	0 (0.0)	1 (0.0)
CUCUMIS MELO;DEER BONE	0 (0.0)	1 (0.1)	1 (0.0)
CURCUMA ZEDOARIA;LAMINARIA JAPONICA	0 (0.0)	1 (0.1)	1 (0.0)
CYANOCOBALAMIN;FOLIC ACID;IRON;PYRIDOXINE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
CYANOCOBALAMIN;LEVOMEFOLIC ACID;MAGNESIUM;PYRIDOXINE;TAURINE	0 (0.0)	1 (0.1)	1 (0.0)
CYNARA CARDUNCULUS	0 (0.0)	1 (0.1)	1 (0.0)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CYSTINE;METHIONINE;OENOTHERA BIENNIS;SOYA ISOFLAVONES;VITAMINS NOS;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
CYSTINE;RETINOL;SACCHAROMYCES CEREVISIAE;SULFUR	1 (0.1)	0 (0.0)	1 (0.0)
CYTIDINE;DISODIUM URIDINE MONOPHOSPHATE;URIDINE;URIDINE TRIPHOSPHATE	0 (0.0)	1 (0.1)	1 (0.0)
CYTIDINE;HYDROXOCOBALAMIN;URIDINE TRIPHOSPHATE	0 (0.0)	1 (0.1)	1 (0.0)
DABIGATRAN	1 (0.1)	0 (0.0)	1 (0.0)
DALBAVANCIN	1 (0.1)	0 (0.0)	1 (0.0)
DAPAGLIFLOZIN	0 (0.0)	1 (0.1)	1 (0.0)
DARBEPOETIN ALFA	1 (0.1)	0 (0.0)	1 (0.0)
DEMANNOSE	1 (0.1)	0 (0.0)	1 (0.0)
DEMANNOSE;VACCINIUM MACROCARPON	0 (0.0)	1 (0.1)	1 (0.0)
DEXAMETHASONE;FRAMYCETIN;GRAMICIDIN	0 (0.0)	1 (0.1)	1 (0.0)
DEXAMETHASONE;NEOMYCIN;TRAMAZOLINE	1 (0.1)	0 (0.0)	1 (0.0)
DEXCHLORPHENIRAMINE;GUAIFENESIN;PSEUDOEPHEDRINE	0 (0.0)	1 (0.1)	1 (0.0)
DEXKETOPROFEN;TRAMADOL	0 (0.0)	1 (0.1)	1 (0.0)
DEXPANTHENOL;HYALURONIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
DEXPANTHENOL;HYPROLOSE	1 (0.1)	0 (0.0)	1 (0.0)
DEXPANTHENOL;RETINOL	1 (0.1)	0 (0.0)	1 (0.0)
DEXTRIN	1 (0.1)	0 (0.0)	1 (0.0)
DEXTROMETHORPHAN;DOXYLAMINE;EPHEDRINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
DEXTROMETHORPHAN;DOXYLAMINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.0)
DEXTROMETHORPHAN;MELISSA OFFICINALIS;TILIA SPP.	0 (0.0)	1 (0.1)	1 (0.0)
DEXTROMETHORPHAN;PSEUDOEPHEDRINE;TRIPROLIDINE	0 (0.0)	1 (0.1)	1 (0.0)
DEZOCINE	1 (0.1)	0 (0.0)	1 (0.0)

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Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
DIACEREIN	0 (0.0)	1 (0.1)	1 (0.0)
DIBEKACIN	0 (0.0)	1 (0.1)	1 (0.0)
DICLOFENAC;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
DICLOFENAC;SERRAPEPTASE	0 (0.0)	1 (0.1)	1 (0.0)
DICYCLOVERINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
DIFLUCORTOLONE	1 (0.1)	0 (0.0)	1 (0.0)
DIFLUCORTOLONE;LIDOCAINE	1 (0.1)	0 (0.0)	1 (0.0)
DIGOXIN	1 (0.1)	0 (0.0)	1 (0.0)
DIHYDROERGOCRISTINE;ESCULOSIDE;RUTOSIDE	1 (0.1)	0 (0.0)	1 (0.0)
DIHYDROERGOTOXINE	0 (0.0)	1 (0.1)	1 (0.0)
DIMETHICONOL;DIMETICONE;GLYCEROL;GLYCERYL MONOSTEARATE;NICOTINAMIDE;PARAFFIN, LIQUID;VITELLARIA PARADOXA SUBSP. PARADOXA	0 (0.0)	1 (0.1)	1 (0.0)
DIMETINDENE	1 (0.1)	0 (0.0)	1 (0.0)
DIPHENHYDRAMINE;IBUPROFEN	1 (0.1)	0 (0.0)	1 (0.0)
DIPHENHYDRAMINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
DIPHENHYDRAMINE;PARACETAMOL;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.0)
DIPROPHYLLINE	0 (0.0)	1 (0.1)	1 (0.0)
DOBUTAMINE	0 (0.0)	1 (0.1)	1 (0.0)
DOCOSANOL	1 (0.1)	0 (0.0)	1 (0.0)
DOXOFYLLINE	1 (0.1)	0 (0.0)	1 (0.0)
DOXYLAMINE	0 (0.0)	1 (0.1)	1 (0.0)
DOXYLAMINE;FOLIC ACID;PYRIDOXINE	0 (0.0)	1 (0.1)	1 (0.0)
DRIMIA MARITIMA;GUAREA GUIDONIA;SENEGA OFFICINALIS	0 (0.0)	1 (0.1)	1 (0.0)
DRIMIA MARITIMA;MORPHINE	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
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Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
DRUGS FOR ACID RELATED DISORDERS	1 (0.1)	0 (0.0)	1 (0.0)
DRUGS FOR CONSTIPATION	1 (0.1)	0 (0.0)	1 (0.0)
DULAGLUTIDE	1 (0.1)	0 (0.0)	1 (0.0)
ECHINACEA SPP.	0 (0.0)	1 (0.1)	1 (0.0)
ECONAZOLE	0 (0.0)	1 (0.1)	1 (0.0)
ECTOINE;HYALURONIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
EDETIC ACID;GLYCEROL	0 (0.0)	1 (0.1)	1 (0.0)
EFINACONAZOLE	0 (0.0)	1 (0.1)	1 (0.0)
EFLORNITHINE	0 (0.0)	1 (0.1)	1 (0.0)
EMEDASTINE	1 (0.1)	0 (0.0)	1 (0.0)
EMPAGLIFLOZIN	1 (0.1)	0 (0.0)	1 (0.0)
EMU OIL	0 (0.0)	1 (0.1)	1 (0.0)
EMULSIFYING WAX;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	0 (0.0)	1 (0.1)	1 (0.0)
ENTEROCOCCUS FAECIUM	1 (0.1)	0 (0.0)	1 (0.0)
ENZYME PREPARATIONS	1 (0.1)	0 (0.0)	1 (0.0)
ENZYMES NOS;PANCREATIN	1 (0.1)	0 (0.0)	1 (0.0)
EPHEDRINE;GLAUCINE	0 (0.0)	1 (0.1)	1 (0.0)
EPLERENONE	1 (0.1)	0 (0.0)	1 (0.0)
ERGOTAMINE	0 (0.0)	1 (0.1)	1 (0.0)
ESCHERICHIA COLI;HYDROCORTISONE	1 (0.1)	0 (0.0)	1 (0.0)
ESCHSCHOLZIA CALIFORNICA;FRANGULA ALNUS;FRANGULA PURSHIANA;RHEUM SPP.;SENNA ALEXANDRINA	1 (0.1)	0 (0.0)	1 (0.0)
ESCIN	1 (0.1)	0 (0.0)	1 (0.0)
ESCIN;THIAMINE	0 (0.0)	1 (0.1)	1 (0.0)
ESTRIOL;LACTOBACILLUS ACIDOPHILUS	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ETHAMBUTOL	1 (0.1)	0 (0.0)	1 (0.0)
ETHANOL	0 (0.0)	1 (0.1)	1 (0.0)
ETOMIDATE	0 (0.0)	1 (0.1)	1 (0.0)
EUCALYPTUS GLOBULUS;MENTHOL;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
EXPECTORANTS	0 (0.0)	1 (0.1)	1 (0.0)
EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS	1 (0.1)	0 (0.0)	1 (0.0)
FAROPENEM	1 (0.1)	0 (0.0)	1 (0.0)
FELODIPINE	1 (0.1)	0 (0.0)	1 (0.0)
FENOFIBRIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
FENSPIRIDE	0 (0.0)	1 (0.1)	1 (0.0)
FENYRAMIDOL	1 (0.1)	0 (0.0)	1 (0.0)
FERRIC HYDROXIDE	1 (0.1)	0 (0.0)	1 (0.0)
FERUMOXYTOL	1 (0.1)	0 (0.0)	1 (0.0)
FICUS CARICA;FOENICULUM VULGARE;LINUM USITATISSIMUM;PLANTAGO SPP.;PRUNUS DOMESTICA;RHEUM SPP.;TAMARINDUS INDICA	0 (0.0)	1 (0.1)	1 (0.0)
FIDAXOMICIN	1 (0.1)	0 (0.0)	1 (0.0)
FLUMETASONE	1 (0.1)	0 (0.0)	1 (0.0)
FLUNISOLIDE	1 (0.1)	0 (0.0)	1 (0.0)
FLUOCINOLONE ACETONIDE;LIDOCAINE;NEOMYCIN;POLYMYXIN B	0 (0.0)	1 (0.1)	1 (0.0)
FLUOCINOLONE ACETONIDE;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
FLUORINE;XYLITOL	1 (0.1)	0 (0.0)	1 (0.0)
FLUOROQUINOLONES	1 (0.1)	0 (0.0)	1 (0.0)
FLUPREDNIDENE	1 (0.1)	0 (0.0)	1 (0.0)
FOENICULUM VULGARE;GLYCYRRHIZA SPP.;SENNA SPP.;SULFUR	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
FOLIC ACID;FURSULTIAMINE;MECOBALAMIN;PYRIDOXINE;TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.0)
FOLIC ACID;MECOBALAMIN	1 (0.1)	0 (0.0)	1 (0.0)
FOLINIC ACID;IRON	0 (0.0)	1 (0.1)	1 (0.0)
FORMOTEROL	1 (0.1)	0 (0.0)	1 (0.0)
FORSYTHIA SUSPENSA;HOUTTUYNIA CORDATA;ISATIS TINCTORIA;LONICERA JAPONICA;SCUTELLARIA BAICALENSIS	0 (0.0)	1 (0.1)	1 (0.0)
FORSYTHIA SUSPENSA;LONICERA JAPONICA;SCUTELLARIA BAICALENSIS	1 (0.1)	0 (0.0)	1 (0.0)
FRAMYCETIN	0 (0.0)	1 (0.1)	1 (0.0)
FRAMYCETIN;NAPHAZOLINE;PREDNISOLONE	1 (0.1)	0 (0.0)	1 (0.0)
FRITILLARIA SPP.;GINKGO BILOBA;GLYCYRRHIZA URALENSIS;LILIUM LANCIFOLIUM;PINELLIA TERNATA;PLATYCODON GRANDIFLORUS;PRUNUS AMYGDALUS;SCUTELLARIA BAICALENSIS;TUSSILAGO FARFARA;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.0)
FRUCTOOLIGOSACCHARIDES;PROBIOTICS NOS	1 (0.1)	0 (0.0)	1 (0.0)
FRUCTOSE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE;SODIUM PHOSPHATE	1 (0.1)	0 (0.0)	1 (0.0)
FRUCTOSE;GLUCOSE;SODIUM CITRATE	1 (0.1)	0 (0.0)	1 (0.0)
FRUCTOSE;GLYCEROL;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
FURAZOLIDONE	1 (0.1)	0 (0.0)	1 (0.0)
FURSULTIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
GADOBENIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
GADOTERIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
GELATINE HYDROLYSATE	0 (0.0)	1 (0.1)	1 (0.0)
GELSEMIUM SEMPERVIRENS;GRINDELIA HIRSUTULA;MELALEUCA VIRIDIFLORA	0 (0.0)	1 (0.1)	1 (0.0)
GEMIFLOXACIN	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
GENERAL NUTRIENTS	1 (0.1)	0 (0.0)	1 (0.0)
GIDAZEPAM	0 (0.0)	1 (0.1)	1 (0.0)
GLIMEPIRIDE;METFORMIN	1 (0.1)	0 (0.0)	1 (0.0)
GLUCOCORTICOIDS	0 (0.0)	1 (0.1)	1 (0.0)
GLUCONATE SODIUM;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.0)
GLUCOSAMINE;METHYLSULFONYLMETHANE	0 (0.0)	1 (0.1)	1 (0.0)
GLUCOSE OXIDASE;LACTOFERRIN;LACTOPEROXIDASE;LYSOZYME	1 (0.1)	0 (0.0)	1 (0.0)
GLUCOSE OXIDASE;LACTOFERRIN;LACTOPEROXIDASE;LYSOZYME;SODIUM FLUOROPHOSPHATE	1 (0.1)	0 (0.0)	1 (0.0)
GLUCOSE OXIDASE;LACTOPEROXIDASE	0 (0.0)	1 (0.1)	1 (0.0)
GLUCOSE;HISTIDINE;LYSINE;METHIONINE;PYRIDOXINE;RIBOFLAVIN;TAURINE;THIAMINE	0 (0.0)	1 (0.1)	1 (0.0)
GLUCOSE;POTASSIUM;SODIUM	1 (0.1)	0 (0.0)	1 (0.0)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.0)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM L-LACTATE	1 (0.1)	0 (0.0)	1 (0.0)
GLUCOSE;SODIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.0)
GLYCEROL;PROPYLENE GLYCOL	0 (0.0)	1 (0.1)	1 (0.0)
GLYCINE MAX;OLEA EUROPAEA	1 (0.1)	0 (0.0)	1 (0.0)
GLYCYRRHIZA GLABRA	0 (0.0)	1 (0.1)	1 (0.0)
GLYCYRRHIZA GLABRA;PAPAVER SOMNIFERUM;PIMPINELLA ANISUM	0 (0.0)	1 (0.1)	1 (0.0)
GLYCYRRHIZA GLABRA;PLATYCODON GRANDIFLORUS;PRUNUS ARMENIACA;SENEGA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.0)
GUAIACOL	1 (0.1)	0 (0.0)	1 (0.0)
GUAIFENESIN;MENTHOL	0 (0.0)	1 (0.1)	1 (0.0)
GUAIFENESIN;TERBUTALINE	1 (0.1)	0 (0.0)	1 (0.0)
GUALENIC ACID;LEVOGLUTAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
HAMAMELIS VIRGINIANA;ZINC	1 (0.1)	0 (0.0)	1 (0.0)

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
HARPAGOPHYTUM PROCUMBENS	0 (0.0)	1 (0.1)	1 (0.0)
HELICIDINE	0 (0.0)	1 (0.1)	1 (0.0)
HEPARIN;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
HEPARINOID;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
HERBAL ANTIEMETICS, OTHER	1 (0.1)	0 (0.0)	1 (0.0)
HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES	1 (0.1)	0 (0.0)	1 (0.0)
HERBAL ANTISPASMODIC AGENTS CONTAINING BISABOLOL DERIVATIVES AND/OR FLAVANOIDS	1 (0.1)	0 (0.0)	1 (0.0)
HERBAL POLLEN NOS	1 (0.1)	0 (0.0)	1 (0.0)
HESPERIDIN	1 (0.1)	0 (0.0)	1 (0.0)
HETASTARCH;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
HISTAMINE	1 (0.1)	0 (0.0)	1 (0.0)
HOMATROPINE;SIMETICONE	0 (0.0)	1 (0.1)	1 (0.0)
HOMEOPATHICS NOS	1 (0.1)	0 (0.0)	1 (0.0)
HYALURONIC ACID;MALVA SYLVESTRIS;MATRICARIA CHAMOMILLA	1 (0.1)	0 (0.0)	1 (0.0)
HYALURONIDASE	1 (0.1)	0 (0.0)	1 (0.0)
HYDROCHLOROTHIAZIDE;LISINOPRIL	1 (0.1)	0 (0.0)	1 (0.0)
HYDROCHLOROTHIAZIDE;LOSARTAN	0 (0.0)	1 (0.1)	1 (0.0)
HYDROCHLOROTHIAZIDE;OLMESARTAN	0 (0.0)	1 (0.1)	1 (0.0)
HYDROCHLOROTHIAZIDE;SPIRONOLACTONE	1 (0.1)	0 (0.0)	1 (0.0)
HYDROCHLOROTHIAZIDE;TELMISARTAN	0 (0.0)	1 (0.1)	1 (0.0)
HYDROCODONE;METHYLHOMATROPINE	1 (0.1)	0 (0.0)	1 (0.0)
HYDROCORTISONE;HYDROXYTETRACAINE	0 (0.0)	1 (0.1)	1 (0.0)
HYDROCORTISONE;LAUROMACROGOL 400	1 (0.1)	0 (0.0)	1 (0.0)
HYDROCORTISONE;NEOMYCIN;POLYMYXIN B	0 (0.0)	1 (0.1)	1 (0.0)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
HYDROCORTISONE;OXYTETRACYCLINE	0 (0.0)	1 (0.1)	1 (0.0)
HYPERIMMUNE PLASMA COVID-19	1 (0.1)	0 (0.0)	1 (0.0)
HYPROMELLOSE;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
ICHTHAMMOL;TITANIUM DIOXIDE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ILAPRAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
IMIDAZOLE AND TRIAZOLE DERIVATIVES	0 (0.0)	1 (0.1)	1 (0.0)
IMIDAZOLYL ETHANAMIDE PENTANDIOIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
IMIPENEM	1 (0.1)	0 (0.0)	1 (0.0)
IMIPRAMINE	1 (0.1)	0 (0.0)	1 (0.0)
IMMUNOGLOBULIN HUMAN NORMAL	1 (0.1)	0 (0.0)	1 (0.0)
INDAPAMIDE	0 (0.0)	1 (0.1)	1 (0.0)
INDAPAMIDE;PERINDOPRIL	0 (0.0)	1 (0.1)	1 (0.0)
INDOCYANINE GREEN	1 (0.1)	0 (0.0)	1 (0.0)
INDOMETACIN;MENTHOL;TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.0)
INFLUENZA VACCINE	1 (0.1)	0 (0.0)	1 (0.0)
IODINE	1 (0.1)	0 (0.0)	1 (0.0)
IODINE;POLYVINYL ALCOHOL	0 (0.0)	1 (0.1)	1 (0.0)
IOPAMIDOL	1 (0.1)	0 (0.0)	1 (0.0)
IPRAGLIFLOZIN	1 (0.1)	0 (0.0)	1 (0.0)
IRON;JUGLANS REGIA;NEOLITSEA CASSIA;PANAX QUINQUEFOLIUS;ZIZIPHUS JUJUBA	1 (0.1)	0 (0.0)	1 (0.0)
IRSOGLADINE	0 (0.0)	1 (0.1)	1 (0.0)
ISATIS SPP.	0 (0.0)	1 (0.1)	1 (0.0)
ISATIS TINCTORIA SUBSP. TINCTORIA	0 (0.0)	1 (0.1)	1 (0.0)
ISATIS TINCTORIA SUBSP. TINCTORIA;TARAXACUM SPP.	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ISEPAMICIN	0 (0.0)	1 (0.1)	1 (0.0)
ISOFLURANE	0 (0.0)	1 (0.1)	1 (0.0)
ISOSORBIDE DINITRATE	0 (0.0)	1 (0.1)	1 (0.0)
ITRACONAZOLE;SECNIDAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
JOSAMYCIN	0 (0.0)	1 (0.1)	1 (0.0)
KAOLIN;RHEUM PALMATUM;SENNA ALEXANDRINA;SULFUR	0 (0.0)	1 (0.1)	1 (0.0)
KERATIN	1 (0.1)	0 (0.0)	1 (0.0)
LABETALOL	1 (0.1)	0 (0.0)	1 (0.0)
LACTIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
LACTIC ACID;PARAFFIN, LIQUID;PROPYLENE GLYCOL;UREA	0 (0.0)	1 (0.1)	1 (0.0)
LACTITOL	1 (0.1)	0 (0.0)	1 (0.0)
LACTOBACILLUS GASSERI	0 (0.0)	1 (0.1)	1 (0.0)
LACTOBACILLUS HELVETICUS;LACTOBACILLUS RHAMNOSUS	0 (0.0)	1 (0.1)	1 (0.0)
LACTOBACILLUS RHAMNOSUS	1 (0.1)	0 (0.0)	1 (0.0)
LAFUTIDINE	1 (0.1)	0 (0.0)	1 (0.0)
LAUROMACROGOL 400;SODIUM OLEATE	1 (0.1)	0 (0.0)	1 (0.0)
LAUROMACROGOL 400;UREA	1 (0.1)	0 (0.0)	1 (0.0)
LEAD ACETATE	0 (0.0)	1 (0.1)	1 (0.0)
LEFLUNOMIDE	1 (0.1)	0 (0.0)	1 (0.0)
LENOGRASTIM	1 (0.1)	0 (0.0)	1 (0.0)
LEVOGLUTAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
LEVOTHYROXINE;LIOTHYRONINE	0 (0.0)	1 (0.1)	1 (0.0)
LIDOCAINE;NAPROXEN	1 (0.1)	0 (0.0)	1 (0.0)
LIDOCAINE;NIFEDIPINE	1 (0.1)	0 (0.0)	1 (0.0)

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Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
LIDOCAINE;TRIAMCINOLONE	1 (0.1)	0 (0.0)	1 (0.0)
LIGUSTRAZINE;SALVIA MILTIORRHIZA	1 (0.1)	0 (0.0)	1 (0.0)
LINACLOTIDE	0 (0.0)	1 (0.1)	1 (0.0)
LINEZOLID	0 (0.0)	1 (0.1)	1 (0.0)
LIPID MODIFYING AGENTS, PLAIN	0 (0.0)	1 (0.1)	1 (0.0)
LIRAGLUTIDE	1 (0.1)	0 (0.0)	1 (0.0)
LONICERA JAPONICA;SCUTELLARIA BAICALENSIS	1 (0.1)	0 (0.0)	1 (0.0)
LOPINAVIR;RITONAVIR	1 (0.1)	0 (0.0)	1 (0.0)
LORMETAZEPAM	0 (0.0)	1 (0.1)	1 (0.0)
LOSARTAN;RAMIPRIL	1 (0.1)	0 (0.0)	1 (0.0)
LOTEPREDNOL;TOBRAMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
LUBIPROSTONE	1 (0.1)	0 (0.0)	1 (0.0)
MACROGOL 400	1 (0.1)	0 (0.0)	1 (0.0)
MACROGOL 4000;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
MACROGOL;PROPYLENE GLYCOL	0 (0.0)	1 (0.1)	1 (0.0)
MAGNESIUM BROMIDE;MAGNESIUM FLUORIDE;MAGNESIUM HYDROXIDE	1 (0.1)	0 (0.0)	1 (0.0)
MAGNESIUM CARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
MAGNESIUM CARBONATE;MAGNESIUM OXIDE	1 (0.1)	0 (0.0)	1 (0.0)
MAGNESIUM HYDROXIDE;PARAFFIN, LIQUID	0 (0.0)	1 (0.1)	1 (0.0)
MAGNESIUM HYDROXIDE;PARAFFIN, LIQUID;SODIUM PICOSULFATE	1 (0.1)	0 (0.0)	1 (0.0)
MAGNESIUM OXIDE;PYRIDOXINE	0 (0.0)	1 (0.1)	1 (0.0)
MAGNESIUM SILICATE	1 (0.1)	0 (0.0)	1 (0.0)
MAGNESIUM;MAGNESIUM CITRATE	1 (0.1)	0 (0.0)	1 (0.0)
MAGNESIUM;PASSIFLORA INCARNATA;VALERIANA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
MAGNOLIA SPP.;PERILLA FRUTESCENS VAR. CRISPA;PINELLIA TERNATA;PORIA COCOS;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.0)
MANGANESE;SEA WATER	0 (0.0)	1 (0.1)	1 (0.0)
MEBHYDROLIN	0 (0.0)	1 (0.1)	1 (0.0)
MECLOZINE;PYRIDOXINE	1 (0.1)	0 (0.0)	1 (0.0)
MEGLUMINE ADENOSINE CYCLOPHOSPHATE	0 (0.0)	1 (0.1)	1 (0.0)
MELDONIUM	0 (0.0)	1 (0.1)	1 (0.0)
MENTHA X PIPERITA	0 (0.0)	1 (0.1)	1 (0.0)
MEPENZOLATE	1 (0.1)	0 (0.0)	1 (0.0)
METAMIZOLE;PAPAVERINE	0 (0.0)	1 (0.1)	1 (0.0)
METFORMIN;VILDAGLIPTIN	0 (0.0)	1 (0.1)	1 (0.0)
METHENAMINE	1 (0.1)	0 (0.0)	1 (0.0)
METHENAMINE;METHYLTHIONINIUM	0 (0.0)	1 (0.1)	1 (0.0)
METHIONINE	0 (0.0)	1 (0.1)	1 (0.0)
METHOCARBAMOL;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
METHOXYPHENAMINE	1 (0.1)	0 (0.0)	1 (0.0)
METHYLEPHEDRINE	0 (0.0)	1 (0.1)	1 (0.0)
METHYLETHYLPIRIDINOL	1 (0.1)	0 (0.0)	1 (0.0)
METHYLPREDNISOLONE;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
METOCLOPRAMIDE;PANCREATIN	1 (0.1)	0 (0.0)	1 (0.0)
MICONAZOLE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
MIDODRINE	1 (0.1)	0 (0.0)	1 (0.0)
MIMOSA ZIMAPANENSIS	0 (0.0)	1 (0.1)	1 (0.0)
MINERAL WAX;PARAFFIN, LIQUID;PETROLATUM;WOOL ALCOHOLS	1 (0.1)	0 (0.0)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
MIROGABALIN	0 (0.0)	1 (0.1)	1 (0.0)
MISOPROSTOL	1 (0.1)	0 (0.0)	1 (0.0)
MITIGLINIDE	1 (0.1)	0 (0.0)	1 (0.0)
MYRTECAINE;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
NAFTIFINE	1 (0.1)	0 (0.0)	1 (0.0)
NAFTOPIDIL	1 (0.1)	0 (0.0)	1 (0.0)
NALBUPHINE	1 (0.1)	0 (0.0)	1 (0.0)
NAPHAZOLINE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
NASAL PREPARATIONS	0 (0.0)	1 (0.1)	1 (0.0)
NEDOCROMIL	1 (0.1)	0 (0.0)	1 (0.0)
NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;PRUNUS SPP.	0 (0.0)	1 (0.1)	1 (0.0)
NEOLITSEA CASSIA;PIPER LONGUM;SYZYGIUM AROMATICUM	0 (0.0)	1 (0.1)	1 (0.0)
NEOMYCIN;NYSTATIN;POLYMYXIN B	1 (0.1)	0 (0.0)	1 (0.0)
NEOMYCIN;NYSTATIN;PREDNISOLONE;TINIDAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
NEPIDERMIN	0 (0.0)	1 (0.1)	1 (0.0)
NICAMETATE	0 (0.0)	1 (0.1)	1 (0.0)
NICORANDIL	1 (0.1)	0 (0.0)	1 (0.0)
NICOTINAMIDE;PANTOTHENIC ACID;RETINOL	1 (0.1)	0 (0.0)	1 (0.0)
NIFURATEL	1 (0.1)	0 (0.0)	1 (0.0)
NIFURATEL;NYSTATIN	1 (0.1)	0 (0.0)	1 (0.0)
NIMESULIDE;THIOCOLCHICOSIDE	1 (0.1)	0 (0.0)	1 (0.0)
NITRIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
NITROGEN, LIQUID	1 (0.1)	0 (0.0)	1 (0.0)
NITROIMIDAZOLE DERIVATIVES	1 (0.1)	0 (0.0)	1 (0.0)

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/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
NITROXOLINE	1 (0.1)	0 (0.0)	1 (0.0)
NIZATIDINE	1 (0.1)	0 (0.0)	1 (0.0)
OCTREOTIDE	1 (0.1)	0 (0.0)	1 (0.0)
OFLOXACIN;ORNIDAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
OLODATEROL;TIOTROPIUM	1 (0.1)	0 (0.0)	1 (0.0)
OMALIZUMAB	0 (0.0)	1 (0.1)	1 (0.0)
OMEGA-3-ACID ETHYL ESTER	1 (0.1)	0 (0.0)	1 (0.0)
OPHIOPOGON JAPONICUS;PANAX GINSENG;SCHISANDRA CHINENSIS	1 (0.1)	0 (0.0)	1 (0.0)
OPIPRAMOL	1 (0.1)	0 (0.0)	1 (0.0)
OPIUM DERIVATIVES AND EXPECTORANTS	0 (0.0)	1 (0.1)	1 (0.0)
ORLISTAT	0 (0.0)	1 (0.1)	1 (0.0)
ORNIDAZOLE;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.0)
ORYZANOL	1 (0.1)	0 (0.0)	1 (0.0)
OTHER ANTIDIARRHEALS	0 (0.0)	1 (0.1)	1 (0.0)
OTHER ANTIEMETICS	1 (0.1)	0 (0.0)	1 (0.0)
OTHER ANTISEPTICS AND DISINFECTANTS	0 (0.0)	1 (0.1)	1 (0.0)
OTHER CENTRALLY ACTING AGENTS	1 (0.1)	0 (0.0)	1 (0.0)
OTHER COUGH SUPPRESSANTS AND EXPECTORANTS	0 (0.0)	1 (0.1)	1 (0.0)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	1 (0.1)	0 (0.0)	1 (0.0)
OTHER HYPNOTICS AND SEDATIVES	0 (0.0)	1 (0.1)	1 (0.0)
OTHER INTESTINAL ADSORBENTS	1 (0.1)	0 (0.0)	1 (0.0)
OTHER NASAL PREPARATIONS	1 (0.1)	0 (0.0)	1 (0.0)
OTHER OPHTHALMOLOGICALS	1 (0.1)	0 (0.0)	1 (0.0)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
OTHER THERAPEUTIC PRODUCTS	1 (0.1)	0 (0.0)	1 (0.0)
OXACILLIN	1 (0.1)	0 (0.0)	1 (0.0)
OXIGLUTATIONE	0 (0.0)	1 (0.1)	1 (0.0)
OXOMEMAZINE	1 (0.1)	0 (0.0)	1 (0.0)
OXYBUPROCAINE	1 (0.1)	0 (0.0)	1 (0.0)
OXYMETAZOLINE	0 (0.0)	1 (0.1)	1 (0.0)
OZENOXACIN	0 (0.0)	1 (0.1)	1 (0.0)
PAMIDRONIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
PANAX GINSENG	1 (0.1)	0 (0.0)	1 (0.0)
PANCREATIN;SIMETICONE	0 (0.0)	1 (0.1)	1 (0.0)
PANCREATIN;SIMETICONE;URSODEOXYCHOLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
PANCRELIPASE	0 (0.0)	1 (0.1)	1 (0.0)
PANTETHINE	1 (0.1)	0 (0.0)	1 (0.0)
PAPAVER SOMNIFERUM	1 (0.1)	0 (0.0)	1 (0.0)
PAPAVER SOMNIFERUM;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
PARACETAMOL;THIOCOLCHICOSIDE	0 (0.0)	1 (0.1)	1 (0.0)
PARAFFIN NOS;PARAFFIN, LIQUID;PETROLATUM;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.0)
PAZUFLOXACIN	1 (0.1)	0 (0.0)	1 (0.0)
PENTAZOCINE	1 (0.1)	0 (0.0)	1 (0.0)
PENTOXYVERINE	0 (0.0)	1 (0.1)	1 (0.0)
PERAMIVIR	1 (0.1)	0 (0.0)	1 (0.0)
PETROLATUM, HYDROPHILIC	1 (0.1)	0 (0.0)	1 (0.0)
PETROLATUM;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
PHENOXYETHANOL;TRITICUM AESTIVUM	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PHENPROBAMATE	0 (0.0)	1 (0.1)	1 (0.0)
PHENYTOIN	0 (0.0)	1 (0.1)	1 (0.0)
PHLOROGLUCINOL;TRIMETHYLPHLOROGLUCINOL	1 (0.1)	0 (0.0)	1 (0.0)
PHYLLANTHUS EMBLICA	1 (0.1)	0 (0.0)	1 (0.0)
PIPOXOLAN	1 (0.1)	0 (0.0)	1 (0.0)
PLATYPHYLLINE	1 (0.1)	0 (0.0)	1 (0.0)
PODOPHYLLOTOXIN	0 (0.0)	1 (0.1)	1 (0.0)
POLAPREZINC	1 (0.1)	0 (0.0)	1 (0.0)
POLICRESULEN	1 (0.1)	0 (0.0)	1 (0.0)
POLYCARBOPHIL	1 (0.1)	0 (0.0)	1 (0.0)
POLYMYXIN B;TRIMETHOPRIM	0 (0.0)	1 (0.1)	1 (0.0)
POLYVINYL ALCOHOL;POVIDONE	1 (0.1)	0 (0.0)	1 (0.0)
POTASSIUM ASPARTATE	1 (0.1)	0 (0.0)	1 (0.0)
POTASSIUM;POTASSIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
POTASSIUM;POTASSIUM BICARBONATE;POTASSIUM CARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
POVIDONE-IODINE;SUCROSE	1 (0.1)	0 (0.0)	1 (0.0)
PRASTERONE	0 (0.0)	1 (0.1)	1 (0.0)
PREDNISOLONE;TETRYZOLINE	0 (0.0)	1 (0.1)	1 (0.0)
PRENOXDIAZIN	0 (0.0)	1 (0.1)	1 (0.0)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	1 (0.1)	0 (0.0)	1 (0.0)
PRIDINOL	0 (0.0)	1 (0.1)	1 (0.0)
PROMESTRIENE	1 (0.1)	0 (0.0)	1 (0.0)
PROPIONIC ACID DERIVATIVES	1 (0.1)	0 (0.0)	1 (0.0)
PROPYLPARABEN	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PROTAMINE	0 (0.0)	1 (0.1)	1 (0.0)
PRULIFLOXACIN	0 (0.0)	1 (0.1)	1 (0.0)
PRUNUS AMYGDALUS	1 (0.1)	0 (0.0)	1 (0.0)
PSEUDOEPHEDRINE, COMBINATIONS	0 (0.0)	1 (0.1)	1 (0.0)
PSYCHOLEPTICS	0 (0.0)	1 (0.1)	1 (0.0)
PYRAZINAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
PYRIDOSTIGMINE	1 (0.1)	0 (0.0)	1 (0.0)
PYRIDOXINE;SELENIUM;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
RABBIT VACCINIA EXTRACT	1 (0.1)	0 (0.0)	1 (0.0)
RACEPINEFRINE	1 (0.1)	0 (0.0)	1 (0.0)
RADIUM BROMIDE	0 (0.0)	1 (0.1)	1 (0.0)
RALOXIFENE	0 (0.0)	1 (0.1)	1 (0.0)
RAMOSETRON	0 (0.0)	1 (0.1)	1 (0.0)
REMDESIVIR	1 (0.1)	0 (0.0)	1 (0.0)
REPAGLINIDE	0 (0.0)	1 (0.1)	1 (0.0)
RESVERATROL	0 (0.0)	1 (0.1)	1 (0.0)
RHEUM SPP.;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
RHODODENDRON DAURICUM	1 (0.1)	0 (0.0)	1 (0.0)
RIBOFLAVIN	0 (0.0)	1 (0.1)	1 (0.0)
RIFAMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
RILMAZAFONE	0 (0.0)	1 (0.1)	1 (0.0)
RIMANTADINE	1 (0.1)	0 (0.0)	1 (0.0)
RIZATRIPTAN	0 (0.0)	1 (0.1)	1 (0.0)
ROCIVERINE	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ROPINIROLE	0 (0.0)	1 (0.1)	1 (0.0)
ROTIGOTINE	0 (0.0)	1 (0.1)	1 (0.0)
ROXATIDINE	1 (0.1)	0 (0.0)	1 (0.0)
RUBUS IDAEUS;SAMBUCUS NIGRA	1 (0.1)	0 (0.0)	1 (0.0)
RUBUS URSINUS	0 (0.0)	1 (0.1)	1 (0.0)
RUTA GRAVEOLENS	0 (0.0)	1 (0.1)	1 (0.0)
SALVIA OFFICINALIS	0 (0.0)	1 (0.1)	1 (0.0)
SENNA SPP.	1 (0.1)	0 (0.0)	1 (0.0)
SERTACONAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
SHARK CARTILAGE	0 (0.0)	1 (0.1)	1 (0.0)
SIDEROXYLON SPINOSUM	0 (0.0)	1 (0.1)	1 (0.0)
SILICON	0 (0.0)	1 (0.1)	1 (0.0)
SILICON DIOXIDE	1 (0.1)	0 (0.0)	1 (0.0)
SODIUM BICARBONATE;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.0)
SODIUM LAURYL SULFOACETATE	1 (0.1)	0 (0.0)	1 (0.0)
SODIUM POLYSTYRENE SULFONATE	1 (0.1)	0 (0.0)	1 (0.0)
SOFT PARAFFIN AND FAT PRODUCTS	1 (0.1)	0 (0.0)	1 (0.0)
SOFT SOAP	1 (0.1)	0 (0.0)	1 (0.0)
SOLIDAGO VIRGAUREA	0 (0.0)	1 (0.1)	1 (0.0)
SOLUTIONS FOR PARENTERAL NUTRITION	1 (0.1)	0 (0.0)	1 (0.0)
SOPHORA FLAVESCENS	1 (0.1)	0 (0.0)	1 (0.0)
STREPTODORNASE	1 (0.1)	0 (0.0)	1 (0.0)
STRYCHNOS IGNATII	0 (0.0)	1 (0.1)	1 (0.0)
SULFACETAMIDE;SULFUR	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
SULFADIAZINE;TRIMETHOPRIM	0 (0.0)	1 (0.1)	1 (0.0)
SULFAMETHIZOLE	0 (0.0)	1 (0.1)	1 (0.0)
SULGLICOTIDE	0 (0.0)	1 (0.1)	1 (0.0)
SULINDAC	0 (0.0)	1 (0.1)	1 (0.0)
SUMATRIPTAN	1 (0.1)	0 (0.0)	1 (0.0)
SUPLATAST TOSILATE	0 (0.0)	1 (0.1)	1 (0.0)
SUXAMETHONIUM	1 (0.1)	0 (0.0)	1 (0.0)
SYMPHYTUM OFFICINALE	0 (0.0)	1 (0.1)	1 (0.0)
SYZYGIUM AROMATICUM	1 (0.1)	0 (0.0)	1 (0.0)
TAFLUPROST	1 (0.1)	0 (0.0)	1 (0.0)
TALC;TANNIC ACID;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
TALTIRELIN	1 (0.1)	0 (0.0)	1 (0.0)
TARAXACUM MONGOLICUM	1 (0.1)	0 (0.0)	1 (0.0)
TAURINE	1 (0.1)	0 (0.0)	1 (0.0)
TERIPARATIDE	1 (0.1)	0 (0.0)	1 (0.0)
TETANUS ANTITOXIN	0 (0.0)	1 (0.1)	1 (0.0)
TETANUS VACCINE	1 (0.1)	0 (0.0)	1 (0.0)
TETRYZOLINE	1 (0.1)	0 (0.0)	1 (0.0)
THIOTRIAZOLINE	0 (0.0)	1 (0.1)	1 (0.0)
THROAT PREPARATIONS	1 (0.1)	0 (0.0)	1 (0.0)
THROMBIN	1 (0.1)	0 (0.0)	1 (0.0)
THYMOL	1 (0.1)	0 (0.0)	1 (0.0)
THYMOPENTIN	1 (0.1)	0 (0.0)	1 (0.0)
THYMUS SPP.	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
THYMUS VULGARIS	0 (0.0)	1 (0.1)	1 (0.0)
TIAGABINE	1 (0.1)	0 (0.0)	1 (0.0)
TIARAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
TICAGRELOR	1 (0.1)	0 (0.0)	1 (0.0)
TICLOPIDINE	1 (0.1)	0 (0.0)	1 (0.0)
TIOPRONIN	1 (0.1)	0 (0.0)	1 (0.0)
TIOTROPIUM	0 (0.0)	1 (0.1)	1 (0.0)
TOCILIZUMAB	0 (0.0)	1 (0.1)	1 (0.0)
TOFACITINIB	1 (0.1)	0 (0.0)	1 (0.0)
TOLPERISONE	1 (0.1)	0 (0.0)	1 (0.0)
TOLTERODINE	0 (0.0)	1 (0.1)	1 (0.0)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	0 (0.0)	1 (0.1)	1 (0.0)
TRADITIONAL CHINESE MEDICINE (TCM) DECOCTION	0 (0.0)	1 (0.1)	1 (0.0)
TRAVOPROST	1 (0.1)	0 (0.0)	1 (0.0)
TRIAZOLAM	0 (0.0)	1 (0.1)	1 (0.0)
TRIFLUOPERAZINE	0 (0.0)	1 (0.1)	1 (0.0)
TRIFLURIDINE	0 (0.0)	1 (0.1)	1 (0.0)
TRIMECAINE	0 (0.0)	1 (0.1)	1 (0.0)
TRIMETHOBENZAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
TROPICAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
TROPISETRON	1 (0.1)	0 (0.0)	1 (0.0)
TROXIPIDE	1 (0.1)	0 (0.0)	1 (0.0)
UBIDECARENONE	1 (0.1)	0 (0.0)	1 (0.0)
UFENAMATE	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
UMECLIDINIUM;VILANTEROL	1 (0.1)	0 (0.0)	1 (0.0)
UMIFENOVIR	1 (0.1)	0 (0.0)	1 (0.0)
URAPIDIL	1 (0.1)	0 (0.0)	1 (0.0)
UROKINASE	0 (0.0)	1 (0.1)	1 (0.0)
VACCINIUM MACROCARPON	1 (0.1)	0 (0.0)	1 (0.0)
VARENICLINE	0 (0.0)	1 (0.1)	1 (0.0)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)	0 (0.0)	1 (0.0)
VERAPAMIL	1 (0.1)	0 (0.0)	1 (0.0)
VIBEGRON	0 (0.0)	1 (0.1)	1 (0.0)
VILANTEROL	0 (0.0)	1 (0.1)	1 (0.0)
VISCOELASTIC SUBSTANCES	0 (0.0)	1 (0.1)	1 (0.0)
VITAMIN B NOS	0 (0.0)	1 (0.1)	1 (0.0)
VITAMIN E NOS	1 (0.1)	0 (0.0)	1 (0.0)
VITAMIN U	1 (0.1)	0 (0.0)	1 (0.0)
VITAMINS NOS	1 (0.1)	0 (0.0)	1 (0.0)
VITAMINS WITH MINERALS	0 (0.0)	1 (0.1)	1 (0.0)
VITAMINS [UMBRELLA TERM]	0 (0.0)	1 (0.1)	1 (0.0)
VITAMINS, OTHER COMBINATIONS	1 (0.1)	0 (0.0)	1 (0.0)
WATER FOR INJECTION	0 (0.0)	1 (0.1)	1 (0.0)
WATER PURIFIED	0 (0.0)	1 (0.1)	1 (0.0)
WITHANIA SOMNIFERA	1 (0.1)	0 (0.0)	1 (0.0)
YEAST	1 (0.1)	0 (0.0)	1 (0.0)
YELLOW PHENOLPHTHALEIN	1 (0.1)	0 (0.0)	1 (0.0)
ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_adverse_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Adverse Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ZIPEPROL	0 (0.0)	1 (0.1)	1 (0.0)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
Subjects with >= 1 Medication	865 (67.4)	861 (68.1)	1726 (67.8)
LEVOTHYROXINE	157 (12.2)	138 (10.9)	295 (11.6)
METFORMIN	121 (9.4)	106 (8.4)	227 (8.9)
AMLODIPINE	78 (6.1)	90 (7.1)	168 (6.6)
PARACETAMOL	80 (6.2)	60 (4.7)	140 (5.5)
ATORVASTATIN	79 (6.2)	60 (4.7)	139 (5.5)
LOSARTAN	66 (5.1)	54 (4.3)	120 (4.7)
OMEPRAZOLE	64 (5.0)	51 (4.0)	115 (4.5)
METOPROLOL	52 (4.1)	52 (4.1)	104 (4.1)
GABAPENTIN	53 (4.1)	48 (3.8)	101 (4.0)
BISOPROLOL	51 (4.0)	46 (3.6)	97 (3.8)
SIMVASTATIN	43 (3.4)	49 (3.9)	92 (3.6)
IBUPROFEN	37 (2.9)	50 (4.0)	87 (3.4)
HYDROCHLOROTHIAZIDE	37 (2.9)	45 (3.6)	82 (3.2)
ROSUVASTATIN	37 (2.9)	45 (3.6)	82 (3.2)
ACETYLSALICYLIC ACID	42 (3.3)	38 (3.0)	80 (3.1)
ALPRAZOLAM	39 (3.0)	33 (2.6)	72 (2.8)
ENALAPRIL	35 (2.7)	37 (2.9)	72 (2.8)
PREGABALIN	31 (2.4)	33 (2.6)	64 (2.5)
ZOLPIDEM	27 (2.1)	37 (2.9)	64 (2.5)
PANTOPRAZOLE	32 (2.5)	29 (2.3)	61 (2.4)
LORAZEPAM	28 (2.2)	32 (2.5)	60 (2.4)
SALBUTAMOL	30 (2.3)	30 (2.4)	60 (2.4)
COLECALCIFEROL	26 (2.0)	31 (2.5)	57 (2.2)

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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ESCITALOPRAM	28 (2.2)	29 (2.3)	57 (2.2)
HEPARINOID	27 (2.1)	30 (2.4)	57 (2.2)
LISINOPRIL	30 (2.3)	27 (2.1)	57 (2.2)
TRAMADOL	30 (2.3)	23 (1.8)	53 (2.1)
DULOXETINE	26 (2.0)	25 (2.0)	51 (2.0)
LORATADINE	18 (1.4)	32 (2.5)	50 (2.0)
SERTRALINE	24 (1.9)	25 (2.0)	49 (1.9)
ATENOLOL	28 (2.2)	20 (1.6)	48 (1.9)
VENLAFAXINE	25 (1.9)	23 (1.8)	48 (1.9)
FUROSEMIDE	25 (1.9)	22 (1.7)	47 (1.8)
VALSARTAN	24 (1.9)	19 (1.5)	43 (1.7)
GLICLAZIDE	21 (1.6)	21 (1.7)	42 (1.6)
RAMIPRIL	18 (1.4)	24 (1.9)	42 (1.6)
TRAZODONE	29 (2.3)	12 (0.9)	41 (1.6)
BETAMETHASONE	24 (1.9)	13 (1.0)	37 (1.5)
CANDESARTAN	12 (0.9)	24 (1.9)	36 (1.4)
CITALOPRAM	19 (1.5)	16 (1.3)	35 (1.4)
MELATONIN	22 (1.7)	13 (1.0)	35 (1.4)
CETIRIZINE	9 (0.7)	25 (2.0)	34 (1.3)
FLUTICASONE	16 (1.2)	18 (1.4)	34 (1.3)
NEBIVOLOL	13 (1.0)	21 (1.7)	34 (1.3)
METAMIZOLE	16 (1.2)	17 (1.3)	33 (1.3)
DIPHENHYDRAMINE	21 (1.6)	11 (0.9)	32 (1.3)
PERINDOPRIL	16 (1.2)	16 (1.3)	32 (1.3)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
GLIMEPIRIDE	12 (0.9)	19 (1.5)	31 (1.2)
INDAPAMIDE	17 (1.3)	14 (1.1)	31 (1.2)
CALCIUM CARBONATE	17 (1.3)	13 (1.0)	30 (1.2)
CLONAZEPAM	12 (0.9)	18 (1.4)	30 (1.2)
AMITRIPTYLINE	12 (0.9)	17 (1.3)	29 (1.1)
DICLOFENAC	12 (0.9)	17 (1.3)	29 (1.1)
FLUOXETINE	9 (0.7)	20 (1.6)	29 (1.1)
PRAVASTATIN	13 (1.0)	16 (1.3)	29 (1.1)
DENOSUMAB	12 (0.9)	16 (1.3)	28 (1.1)
ONDANSETRON	11 (0.9)	16 (1.3)	27 (1.1)
CARVEDILOL	12 (0.9)	14 (1.1)	26 (1.0)
BUDESONIDE;FORMOTEROL	13 (1.0)	12 (0.9)	25 (1.0)
MONTELUKAST	14 (1.1)	11 (0.9)	25 (1.0)
INSULIN GLARGINE	8 (0.6)	16 (1.3)	24 (0.9)
MAGNESIUM OXIDE	12 (0.9)	12 (0.9)	24 (0.9)
MELOXICAM	9 (0.7)	15 (1.2)	24 (0.9)
MOMETASONE	10 (0.8)	14 (1.1)	24 (0.9)
NAPROXEN	8 (0.6)	16 (1.3)	24 (0.9)
ALENDRONIC ACID	13 (1.0)	10 (0.8)	23 (0.9)
NIFEDIPINE	13 (1.0)	10 (0.8)	23 (0.9)
TELMISARTAN	12 (0.9)	11 (0.9)	23 (0.9)
VITAMIN D NOS	12 (0.9)	11 (0.9)	23 (0.9)
ESOMEPRAZOLE	10 (0.8)	12 (0.9)	22 (0.9)
IRON	15 (1.2)	7 (0.6)	22 (0.9)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
LOXOPROFEN	9 (0.7)	13 (1.0)	22 (0.9)
PROPRANOLOL	13 (1.0)	9 (0.7)	22 (0.9)
FEXOFENADINE	15 (1.2)	6 (0.5)	21 (0.8)
INSULIN NOS	10 (0.8)	11 (0.9)	21 (0.8)
RANITIDINE	9 (0.7)	12 (0.9)	21 (0.8)
CALCIUM CARBONATE;COLECALCIFEROL	9 (0.7)	11 (0.9)	20 (0.8)
CELECOXIB	8 (0.6)	12 (0.9)	20 (0.8)
FLUTICASONE;SALMETEROL	8 (0.6)	12 (0.9)	20 (0.8)
HYDROCODONE;PARACETAMOL	10 (0.8)	10 (0.8)	20 (0.8)
HYDROCORTISONE	7 (0.5)	13 (1.0)	20 (0.8)
MIRTAZAPINE	10 (0.8)	10 (0.8)	20 (0.8)
PAROXETINE	9 (0.7)	11 (0.9)	20 (0.8)
SPIRONOLACTONE	11 (0.9)	9 (0.7)	20 (0.8)
SULFADIAZINE	10 (0.8)	10 (0.8)	20 (0.8)
BUPROPION	11 (0.9)	8 (0.6)	19 (0.7)
HYALURONIC ACID	8 (0.6)	11 (0.9)	19 (0.7)
LANSOPRAZOLE	6 (0.5)	13 (1.0)	19 (0.7)
SITAGLIPTIN	8 (0.6)	11 (0.9)	19 (0.7)
ZOLEDRONIC ACID	7 (0.5)	12 (0.9)	19 (0.7)
ALLOPURINOL	7 (0.5)	11 (0.9)	18 (0.7)
CALCIUM	3 (0.2)	15 (1.2)	18 (0.7)
CALCIUM;COLECALCIFEROL	8 (0.6)	10 (0.8)	18 (0.7)
HYDROCHLOROTHIAZIDE;LOSARTAN	11 (0.9)	7 (0.6)	18 (0.7)
IRBESARTAN	8 (0.6)	10 (0.8)	18 (0.7)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PREDNISOLONE	9 (0.7)	9 (0.7)	18 (0.7)
PROCHLORPERAZINE	7 (0.5)	11 (0.9)	18 (0.7)
CYCLOBENZAPRINE	7 (0.5)	10 (0.8)	17 (0.7)
TRIAMCINOLONE	8 (0.6)	9 (0.7)	17 (0.7)
DIAZEPAM	9 (0.7)	7 (0.6)	16 (0.6)
FAMOTIDINE	7 (0.5)	9 (0.7)	16 (0.6)
LERCANIDIPINE	8 (0.6)	8 (0.6)	16 (0.6)
OLMESARTAN	10 (0.8)	6 (0.5)	16 (0.6)
ZOPICLONE	6 (0.5)	10 (0.8)	16 (0.6)
CAPTOPRIL	8 (0.6)	7 (0.6)	15 (0.6)
CODEINE;PARACETAMOL	2 (0.2)	13 (1.0)	15 (0.6)
EZETIMIBE	10 (0.8)	5 (0.4)	15 (0.6)
GLIBENCLAMIDE	6 (0.5)	9 (0.7)	15 (0.6)
KETOPROFEN	7 (0.5)	8 (0.6)	15 (0.6)
SUMATRIPTAN	8 (0.6)	7 (0.6)	15 (0.6)
BETAHISTINE	6 (0.5)	8 (0.6)	14 (0.5)
EMPAGLIFLOZIN	6 (0.5)	8 (0.6)	14 (0.5)
HYDROCHLOROTHIAZIDE;VALSARTAN	10 (0.8)	4 (0.3)	14 (0.5)
IBANDRONIC ACID	6 (0.5)	8 (0.6)	14 (0.5)
INDAPAMIDE;PERINDOPRIL	7 (0.5)	7 (0.6)	14 (0.5)
LIDOCAINE	8 (0.6)	6 (0.5)	14 (0.5)
OXYBUTYNIN	8 (0.6)	6 (0.5)	14 (0.5)
TEMAZEPAM	6 (0.5)	8 (0.6)	14 (0.5)
BROMAZEPAM	7 (0.5)	6 (0.5)	13 (0.5)

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/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
FENOFIBRATE	10 (0.8)	3 (0.2)	13 (0.5)
GLUCOSAMINE	4 (0.3)	9 (0.7)	13 (0.5)
LATANOPROST	6 (0.5)	7 (0.6)	13 (0.5)
MACROGOL 3350	3 (0.2)	10 (0.8)	13 (0.5)
MECOBALAMIN	8 (0.6)	5 (0.4)	13 (0.5)
OLANZAPINE	5 (0.4)	8 (0.6)	13 (0.5)
RIVAROXABAN	8 (0.6)	5 (0.4)	13 (0.5)
SOLIFENACIN	4 (0.3)	9 (0.7)	13 (0.5)
TIOTROPIUM	8 (0.6)	5 (0.4)	13 (0.5)
TRIMETAZIDINE	5 (0.4)	8 (0.6)	13 (0.5)
VITAMIN B COMPLEX	8 (0.6)	5 (0.4)	13 (0.5)
BETAMETHASONE;GENTAMICIN	6 (0.5)	6 (0.5)	12 (0.5)
CLOPIDOGREL	7 (0.5)	5 (0.4)	12 (0.5)
CODEINE	6 (0.5)	6 (0.5)	12 (0.5)
CYANOCOBALAMIN	7 (0.5)	5 (0.4)	12 (0.5)
DOCUSATE	3 (0.2)	9 (0.7)	12 (0.5)
MAGNESIUM	6 (0.5)	6 (0.5)	12 (0.5)
OXYCODONE;PARACETAMOL	6 (0.5)	6 (0.5)	12 (0.5)
PIOGLITAZONE	7 (0.5)	5 (0.4)	12 (0.5)
QUETIAPINE	5 (0.4)	7 (0.6)	12 (0.5)
THIOCTIC ACID	6 (0.5)	6 (0.5)	12 (0.5)
AMLODIPINE;PERINDOPRIL	3 (0.2)	8 (0.6)	11 (0.4)
BROTIZOLAM	4 (0.3)	7 (0.6)	11 (0.4)
DESLORATADINE	6 (0.5)	5 (0.4)	11 (0.4)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
DILTIAZEM	8 (0.6)	3 (0.2)	11 (0.4)
HYDROCHLOROTHIAZIDE;LISINOPRIL	6 (0.5)	5 (0.4)	11 (0.4)
METFORMIN;SITAGLIPTIN	5 (0.4)	6 (0.5)	11 (0.4)
OXYCODONE	6 (0.5)	5 (0.4)	11 (0.4)
RISEDRONIC ACID	3 (0.2)	8 (0.6)	11 (0.4)
TORASEMIDE	6 (0.5)	5 (0.4)	11 (0.4)
APIXABAN	6 (0.5)	4 (0.3)	10 (0.4)
BECLOMETASONE;FORMOTEROL	5 (0.4)	5 (0.4)	10 (0.4)
BUDESONIDE	4 (0.3)	6 (0.5)	10 (0.4)
CALCIUM;VITAMIN D NOS	6 (0.5)	4 (0.3)	10 (0.4)
DAPAGLIFLOZIN	6 (0.5)	4 (0.3)	10 (0.4)
ESTRADIOL	7 (0.5)	3 (0.2)	10 (0.4)
ETORICOXIB	6 (0.5)	4 (0.3)	10 (0.4)
HERBAL PREPARATION	2 (0.2)	8 (0.6)	10 (0.4)
HYDROCHLOROTHIAZIDE;TELMISARTAN	4 (0.3)	6 (0.5)	10 (0.4)
INSULIN ASPART	5 (0.4)	5 (0.4)	10 (0.4)
LINAGLIPTIN	3 (0.2)	7 (0.6)	10 (0.4)
LOPERAMIDE	6 (0.5)	4 (0.3)	10 (0.4)
OLOPATADINE	4 (0.3)	6 (0.5)	10 (0.4)
PARACETAMOL;TRAMADOL	6 (0.5)	4 (0.3)	10 (0.4)
PREDNISONE	3 (0.2)	7 (0.6)	10 (0.4)
VILDAGLIPTIN	4 (0.3)	6 (0.5)	10 (0.4)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ACHYRANTHES BIDENTATA;ACONITUM SPP.;ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;CORNUS OFFICINALIS;DIOSCOREA SPP.;NEOLITSEA CASSIA;PAEONIA X SUFFRUTICOSA;PLANTAGO ASIATICA;PORIA COCOS;	5 (0.4)	4 (0.3)	9 (0.4)
AMLODIPINE;VALSARTAN	5 (0.4)	4 (0.3)	9 (0.4)
HYDROCODONE	1 (0.1)	8 (0.6)	9 (0.4)
HYDROXYZINE	4 (0.3)	5 (0.4)	9 (0.4)
LEVOCETIRIZINE	4 (0.3)	5 (0.4)	9 (0.4)
METFORMIN;VILDAGLIPTIN	4 (0.3)	5 (0.4)	9 (0.4)
METOCLOPRAMIDE	5 (0.4)	4 (0.3)	9 (0.4)
OXAZEPAM	3 (0.2)	6 (0.5)	9 (0.4)
POTASSIUM	3 (0.2)	6 (0.5)	9 (0.4)
PYRIDOXINE	3 (0.2)	6 (0.5)	9 (0.4)
SENNOSIDE A+B	4 (0.3)	5 (0.4)	9 (0.4)
VITIS VINIFERA	4 (0.3)	5 (0.4)	9 (0.4)
AMLODIPINE;INDAPAMIDE;PERINDOPRIL	5 (0.4)	3 (0.2)	8 (0.3)
CANDESARTAN;HYDROCHLOROTHIAZIDE	2 (0.2)	6 (0.5)	8 (0.3)
CANNABIS SATIVA	2 (0.2)	6 (0.5)	8 (0.3)
CHLORTALIDONE	5 (0.4)	3 (0.2)	8 (0.3)
DOXAZOSIN	3 (0.2)	5 (0.4)	8 (0.3)
ETIZOLAM	3 (0.2)	5 (0.4)	8 (0.3)
FLUTICASONE;VILANTEROL	6 (0.5)	2 (0.2)	8 (0.3)
HYDROCHLOROTHIAZIDE;OLMESARTAN	3 (0.2)	5 (0.4)	8 (0.3)
LAMOTRIGINE	8 (0.6)	0 (0.0)	8 (0.3)
SODIUM CHLORIDE	3 (0.2)	5 (0.4)	8 (0.3)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
AMILORIDE;HYDROCHLOROTHIAZIDE	4 (0.3)	3 (0.2)	7 (0.3)
AMOXICILLIN	2 (0.2)	5 (0.4)	7 (0.3)
BECLOMETASONE	4 (0.3)	3 (0.2)	7 (0.3)
BETAXOLOL	4 (0.3)	3 (0.2)	7 (0.3)
BUSPIRONE	5 (0.4)	2 (0.2)	7 (0.3)
CHONDROITIN;GLUCOSAMINE	3 (0.2)	4 (0.3)	7 (0.3)
DEXAMETHASONE	4 (0.3)	3 (0.2)	7 (0.3)
DIOSMIN;HESPERIDIN	2 (0.2)	5 (0.4)	7 (0.3)
FENTANYL	5 (0.4)	2 (0.2)	7 (0.3)
FOLIC ACID	3 (0.2)	4 (0.3)	7 (0.3)
HYDRALAZINE	6 (0.5)	1 (0.1)	7 (0.3)
HYDROCHLOROTHIAZIDE;TRIAMTERENE	4 (0.3)	3 (0.2)	7 (0.3)
INSULIN LISPRO	4 (0.3)	3 (0.2)	7 (0.3)
IPRATROPIUM	5 (0.4)	2 (0.2)	7 (0.3)
REPAGLINIDE	4 (0.3)	3 (0.2)	7 (0.3)
VALPROIC ACID	3 (0.2)	4 (0.3)	7 (0.3)
VITAMIN B12 NOS	4 (0.3)	3 (0.2)	7 (0.3)
WARFARIN	2 (0.2)	5 (0.4)	7 (0.3)
ACETYLCYSTEINE	3 (0.2)	3 (0.2)	6 (0.2)
ACETYLSALICYLIC ACID;MAGNESIUM HYDROXIDE	5 (0.4)	1 (0.1)	6 (0.2)
AMIODARONE	4 (0.3)	2 (0.2)	6 (0.2)
BENDROFLUMETHIAZIDE	3 (0.2)	3 (0.2)	6 (0.2)
BENIDIPINE	3 (0.2)	3 (0.2)	6 (0.2)
BIOTIN	2 (0.2)	4 (0.3)	6 (0.2)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CARBAMAZEPINE	4 (0.3)	2 (0.2)	6 (0.2)
CHONDROITIN	4 (0.3)	2 (0.2)	6 (0.2)
CLONIDINE	2 (0.2)	4 (0.3)	6 (0.2)
CYANOCOBALAMIN;PYRIDOXINE;RIBOFLAVIN;THIAMINE	6 (0.5)	0 (0.0)	6 (0.2)
DABIGATRAN	4 (0.3)	2 (0.2)	6 (0.2)
DIPHENHYDRAMINE;PARACETAMOL	3 (0.2)	3 (0.2)	6 (0.2)
DULAGLUTIDE	3 (0.2)	3 (0.2)	6 (0.2)
EPINASTINE	1 (0.1)	5 (0.4)	6 (0.2)
ESTAZOLAM	3 (0.2)	3 (0.2)	6 (0.2)
ESZOPICLONE	0 (0.0)	6 (0.5)	6 (0.2)
GLIPIZIDE	5 (0.4)	1 (0.1)	6 (0.2)
GUAIAZULENE	2 (0.2)	4 (0.3)	6 (0.2)
HYDROCHLOROTHIAZIDE;IRBESARTAN	4 (0.3)	2 (0.2)	6 (0.2)
IODINE	1 (0.1)	5 (0.4)	6 (0.2)
NORTRIPTYLINE	4 (0.3)	2 (0.2)	6 (0.2)
NYSTATIN	3 (0.2)	3 (0.2)	6 (0.2)
PROMETHAZINE	3 (0.2)	3 (0.2)	6 (0.2)
QUINAPRIL	5 (0.4)	1 (0.1)	6 (0.2)
RISPERIDONE	3 (0.2)	3 (0.2)	6 (0.2)
ROPINIROLE	2 (0.2)	4 (0.3)	6 (0.2)
SENNA ALEXANDRINA	4 (0.3)	2 (0.2)	6 (0.2)
TOLTERODINE	6 (0.5)	0 (0.0)	6 (0.2)
VERAPAMIL	1 (0.1)	5 (0.4)	6 (0.2)
AMLODIPINE;OLMESARTAN	5 (0.4)	0 (0.0)	5 (0.2)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
AZELASTINE	2 (0.2)	3 (0.2)	5 (0.2)
BEZAFIBRATE	2 (0.2)	3 (0.2)	5 (0.2)
BISACODYL	3 (0.2)	2 (0.2)	5 (0.2)
BISOPROLOL;HYDROCHLOROTHIAZIDE	4 (0.3)	1 (0.1)	5 (0.2)
CEFALEXIN	3 (0.2)	2 (0.2)	5 (0.2)
CLOBETASOL	2 (0.2)	3 (0.2)	5 (0.2)
CURCUMA LONGA	2 (0.2)	3 (0.2)	5 (0.2)
DEXTROMETHORPHAN	3 (0.2)	2 (0.2)	5 (0.2)
DIFLUPREDNATE	2 (0.2)	3 (0.2)	5 (0.2)
DIOSMIN	2 (0.2)	3 (0.2)	5 (0.2)
ELDECALCITOL	5 (0.4)	0 (0.0)	5 (0.2)
FORMOTEROL	2 (0.2)	3 (0.2)	5 (0.2)
GLYCERYL TRINITRATE	2 (0.2)	3 (0.2)	5 (0.2)
HYDROXYCHLOROQUINE	4 (0.3)	1 (0.1)	5 (0.2)
INSULIN HUMAN	3 (0.2)	2 (0.2)	5 (0.2)
ISOSORBIDE MONONITRATE	2 (0.2)	3 (0.2)	5 (0.2)
LACTULOSE	3 (0.2)	2 (0.2)	5 (0.2)
LEVOFLOXACIN	3 (0.2)	2 (0.2)	5 (0.2)
LIRAGLUTIDE	1 (0.1)	4 (0.3)	5 (0.2)
LOVASTATIN	1 (0.1)	4 (0.3)	5 (0.2)
METHYLPREDNISOLONE	2 (0.2)	3 (0.2)	5 (0.2)
METRONIDAZOLE	2 (0.2)	3 (0.2)	5 (0.2)
MIRABEGRON	3 (0.2)	2 (0.2)	5 (0.2)
MORPHINE	3 (0.2)	2 (0.2)	5 (0.2)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
OTHER EMOLLIENTS AND PROTECTIVES	3 (0.2)	2 (0.2)	5 (0.2)
OTHER OPHTHALMOLOGICALS	2 (0.2)	3 (0.2)	5 (0.2)
PITAVASTATIN	2 (0.2)	3 (0.2)	5 (0.2)
RILMENIDINE	3 (0.2)	2 (0.2)	5 (0.2)
TENELIGLIPTIN	5 (0.4)	0 (0.0)	5 (0.2)
THIAMAZOLE	3 (0.2)	2 (0.2)	5 (0.2)
TIZANIDINE	2 (0.2)	3 (0.2)	5 (0.2)
TOCOPHEROL	1 (0.1)	4 (0.3)	5 (0.2)
TOPIRAMATE	2 (0.2)	3 (0.2)	5 (0.2)
TRIAZOLAM	0 (0.0)	5 (0.4)	5 (0.2)
URSODEOXYCHOLIC ACID	1 (0.1)	4 (0.3)	5 (0.2)
VALACICLOVIR	3 (0.2)	2 (0.2)	5 (0.2)
VONOPRAZAN	3 (0.2)	2 (0.2)	5 (0.2)
ACECLOFENAC	2 (0.2)	2 (0.2)	4 (0.2)
ACENOCOUMAROL	3 (0.2)	1 (0.1)	4 (0.2)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (0.2)	2 (0.2)	4 (0.2)
ALFACALCIDOL	1 (0.1)	3 (0.2)	4 (0.2)
AMLODIPINE;TELMISARTAN	3 (0.2)	1 (0.1)	4 (0.2)
AMOXICILLIN;CLAVULANIC ACID	1 (0.1)	3 (0.2)	4 (0.2)
APREMILAST	2 (0.2)	2 (0.2)	4 (0.2)
ATORVASTATIN;EZETIMIBE	2 (0.2)	2 (0.2)	4 (0.2)
BACLOFEN	2 (0.2)	2 (0.2)	4 (0.2)
BENAZEPRIL	3 (0.2)	1 (0.1)	4 (0.2)
BENDROFLUMETHIAZIDE;POTASSIUM	3 (0.2)	1 (0.1)	4 (0.2)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BIMATOPROST	1 (0.1)	3 (0.2)	4 (0.2)
CAFFEINE;METAMIZOLE;ORPHENADRINE	3 (0.2)	1 (0.1)	4 (0.2)
CICLOPIROX	4 (0.3)	0 (0.0)	4 (0.2)
CLOSTRIDIUM BUTYRICUM	2 (0.2)	2 (0.2)	4 (0.2)
CORTISONE	2 (0.2)	2 (0.2)	4 (0.2)
CYANOCOBALAMIN;PYRIDOXINE;THIAMINE	1 (0.1)	3 (0.2)	4 (0.2)
DAPAGLIFLOZIN;METFORMIN	1 (0.1)	3 (0.2)	4 (0.2)
DEXCHLORPHENIRAMINE	2 (0.2)	2 (0.2)	4 (0.2)
DIFENIDOL	3 (0.2)	1 (0.1)	4 (0.2)
DIGOXIN	1 (0.1)	3 (0.2)	4 (0.2)
DOXYCYCLINE	1 (0.1)	3 (0.2)	4 (0.2)
ERYTHROMYCIN	3 (0.2)	1 (0.1)	4 (0.2)
EZETIMIBE;ROSUVASTATIN	1 (0.1)	3 (0.2)	4 (0.2)
FISH OIL	1 (0.1)	3 (0.2)	4 (0.2)
FLUNARIZINE	3 (0.2)	1 (0.1)	4 (0.2)
FLUOCINONIDE	2 (0.2)	2 (0.2)	4 (0.2)
FLUOROMETHOLONE	2 (0.2)	2 (0.2)	4 (0.2)
GENTAMICIN	3 (0.2)	1 (0.1)	4 (0.2)
HYDROCHLOROTHIAZIDE;RAMIPRIL	3 (0.2)	1 (0.1)	4 (0.2)
HYPROMELLOSE	3 (0.2)	1 (0.1)	4 (0.2)
IVABRADINE	2 (0.2)	2 (0.2)	4 (0.2)
KETOROLAC	3 (0.2)	1 (0.1)	4 (0.2)
LATANOPROST;TIMOLOL	2 (0.2)	2 (0.2)	4 (0.2)
LIOTHYRONINE	3 (0.2)	1 (0.1)	4 (0.2)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
LITHIUM	3 (0.2)	1 (0.1)	4 (0.2)
LORMETAZEPAM	2 (0.2)	2 (0.2)	4 (0.2)
METHOTREXATE	0 (0.0)	4 (0.3)	4 (0.2)
MIANSERIN	1 (0.1)	3 (0.2)	4 (0.2)
MONASCUS PURPUREUS	4 (0.3)	0 (0.0)	4 (0.2)
OLEA EUROPAEA	3 (0.2)	1 (0.1)	4 (0.2)
PLANTAGO OVATA	2 (0.2)	2 (0.2)	4 (0.2)
RABEPRAZOLE	2 (0.2)	2 (0.2)	4 (0.2)
SOTALOL	0 (0.0)	4 (0.3)	4 (0.2)
SUCRALFATE	3 (0.2)	1 (0.1)	4 (0.2)
SULFASALAZINE	0 (0.0)	4 (0.3)	4 (0.2)
TIMOLOL	1 (0.1)	3 (0.2)	4 (0.2)
TRANEXAMIC ACID	2 (0.2)	2 (0.2)	4 (0.2)
TRAVOPROST	2 (0.2)	2 (0.2)	4 (0.2)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	3 (0.2)	1 (0.1)	4 (0.2)
ACARBOSE	3 (0.2)	0 (0.0)	3 (0.1)
ACTAEA RACEMOSA	3 (0.2)	0 (0.0)	3 (0.1)
ALGINIC ACID	2 (0.2)	1 (0.1)	3 (0.1)
ALOE VERA	1 (0.1)	2 (0.2)	3 (0.1)
AMFETAMINE;DEXAMFETAMINE	2 (0.2)	1 (0.1)	3 (0.1)
AMLODIPINE;BENAZEPRIL	1 (0.1)	2 (0.2)	3 (0.1)
AZILSARTAN	0 (0.0)	3 (0.2)	3 (0.1)
AZITHROMYCIN	2 (0.2)	1 (0.1)	3 (0.1)
BEPOTASTINE	2 (0.2)	1 (0.1)	3 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BIMATOPROST;TIMOLOL	2 (0.2)	1 (0.1)	3 (0.1)
BORIC ACID;POTASSIUM;SODIUM CARBONATE ANHYDROUS;SODIUM CHLORIDE;SODIUM PHOSPHATE	0 (0.0)	3 (0.2)	3 (0.1)
CALCIUM CARBONATE;VITAMIN D NOS	1 (0.1)	2 (0.2)	3 (0.1)
CARBIMAZOLE	2 (0.2)	1 (0.1)	3 (0.1)
CARBOCISTEINE	0 (0.0)	3 (0.2)	3 (0.1)
CICLESONIDE	1 (0.1)	2 (0.2)	3 (0.1)
CILAZAPRIL;HYDROCHLOROTHIAZIDE	1 (0.1)	2 (0.2)	3 (0.1)
CLINDAMYCIN	1 (0.1)	2 (0.2)	3 (0.1)
CLOMIPRAMINE	2 (0.2)	1 (0.1)	3 (0.1)
CYAMEMAZINE	0 (0.0)	3 (0.2)	3 (0.1)
DEXLANSOPRAZOLE	3 (0.2)	0 (0.0)	3 (0.1)
DICYCLOVERINE	1 (0.1)	2 (0.2)	3 (0.1)
DIETARY SUPPLEMENT	1 (0.1)	2 (0.2)	3 (0.1)
DIFLUCORTOLONE	0 (0.0)	3 (0.2)	3 (0.1)
DIMETICONE	3 (0.2)	0 (0.0)	3 (0.1)
DIPHENHYDRAMINE;IBUPROFEN	3 (0.2)	0 (0.0)	3 (0.1)
DIQUAFOSOL	1 (0.1)	2 (0.2)	3 (0.1)
DOMPERIDONE	2 (0.2)	1 (0.1)	3 (0.1)
DORZOLAMIDE;TIMOLOL	2 (0.2)	1 (0.1)	3 (0.1)
DOXYLAMINE	1 (0.1)	2 (0.2)	3 (0.1)
ELETRIPTAN	1 (0.1)	2 (0.2)	3 (0.1)
EPERISONE	1 (0.1)	2 (0.2)	3 (0.1)
ERGOCALCIFEROL	2 (0.2)	1 (0.1)	3 (0.1)
EXENATIDE	1 (0.1)	2 (0.2)	3 (0.1)

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
EZETIMIBE;SIMVASTATIN	2 (0.2)	1 (0.1)	3 (0.1)
FELBINAC	1 (0.1)	2 (0.2)	3 (0.1)
FELODIPINE	2 (0.2)	1 (0.1)	3 (0.1)
FENOFIBRATE;PRAVASTATIN	1 (0.1)	2 (0.2)	3 (0.1)
FIMASARTAN	0 (0.0)	3 (0.2)	3 (0.1)
FLECAINIDE	2 (0.2)	1 (0.1)	3 (0.1)
FUSIDIC ACID	3 (0.2)	0 (0.0)	3 (0.1)
GLIMEPIRIDE;METFORMIN	2 (0.2)	1 (0.1)	3 (0.1)
GLYCEROL	2 (0.2)	1 (0.1)	3 (0.1)
GLYCOPYRRONIUM	2 (0.2)	1 (0.1)	3 (0.1)
GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA	2 (0.2)	1 (0.1)	3 (0.1)
HEPARIN	2 (0.2)	1 (0.1)	3 (0.1)
IMIPRAMINE	3 (0.2)	0 (0.0)	3 (0.1)
INDOMETACIN	0 (0.0)	3 (0.2)	3 (0.1)
INSULIN DEGLUDEC	1 (0.1)	2 (0.2)	3 (0.1)
INSULIN DETEMIR	1 (0.1)	2 (0.2)	3 (0.1)
INSULIN PORCINE	2 (0.2)	1 (0.1)	3 (0.1)
IPRAGLIFLOZIN	2 (0.2)	1 (0.1)	3 (0.1)
LEVAMLODIPINE	1 (0.1)	2 (0.2)	3 (0.1)
LEVETIRACETAM	1 (0.1)	2 (0.2)	3 (0.1)
LIDOCAINE;PRILOCAINE	2 (0.2)	1 (0.1)	3 (0.1)
LINAGLIPTIN;METFORMIN	2 (0.2)	1 (0.1)	3 (0.1)
LYSINE	1 (0.1)	2 (0.2)	3 (0.1)
MACROGOL	1 (0.1)	2 (0.2)	3 (0.1)

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
MACROGOL 3350;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	2 (0.2)	1 (0.1)	3 (0.1)
METHOCARBAMOL	1 (0.1)	2 (0.2)	3 (0.1)
MIDAZOLAM	1 (0.1)	2 (0.2)	3 (0.1)
MULTIVITAMINS, PLAIN	1 (0.1)	2 (0.2)	3 (0.1)
MUPIROCIN	2 (0.2)	1 (0.1)	3 (0.1)
NITRENDIPINE	1 (0.1)	2 (0.2)	3 (0.1)
NITROFURANTOIN	2 (0.2)	1 (0.1)	3 (0.1)
OPIPRAMOL	2 (0.2)	1 (0.1)	3 (0.1)
OXCARBAZEPINE	1 (0.1)	2 (0.2)	3 (0.1)
PANCREATIN	1 (0.1)	2 (0.2)	3 (0.1)
PARAFFIN NOS	2 (0.2)	1 (0.1)	3 (0.1)
PENTOXIFYLLINE	2 (0.2)	1 (0.1)	3 (0.1)
PIROXICAM	1 (0.1)	2 (0.2)	3 (0.1)
PRAZEPAM	2 (0.2)	1 (0.1)	3 (0.1)
PROBIOTICS NOS	0 (0.0)	3 (0.2)	3 (0.1)
PROPAFENONE	2 (0.2)	1 (0.1)	3 (0.1)
RABBIT VACCINIA EXTRACT	2 (0.2)	1 (0.1)	3 (0.1)
RAMELTEON	2 (0.2)	1 (0.1)	3 (0.1)
SODIUM PICOSULFATE	2 (0.2)	1 (0.1)	3 (0.1)
SUVOREXANT	0 (0.0)	3 (0.2)	3 (0.1)
TAPENTADOL	2 (0.2)	1 (0.1)	3 (0.1)
THIAMINE	1 (0.1)	2 (0.2)	3 (0.1)
VOGLIBOSE	1 (0.1)	2 (0.2)	3 (0.1)
VORTIOXETINE	1 (0.1)	2 (0.2)	3 (0.1)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ZOLMITRIPTAN	0 (0.0)	3 (0.2)	3 (0.1)
ACETYLSALICYLIC ACID;CAFFEINE	1 (0.1)	1 (0.1)	2 (0.1)
ACTAEA RACEMOSA;ARNICA MONTANA;GLYCERYL TRINITRATE;LACHESIS MUTA;SANGUINARIA CANADENSIS	1 (0.1)	1 (0.1)	2 (0.1)
ADENOSINE	1 (0.1)	1 (0.1)	2 (0.1)
AGOMELATINE	1 (0.1)	1 (0.1)	2 (0.1)
ALGINIC ACID;CALCIUM CARBONATE;SODIUM BICARBONATE	2 (0.2)	0 (0.0)	2 (0.1)
ALLANTOIN;ALOE VERA;COLLAGEN;HYALURONIC ACID;LIDOCAINE	1 (0.1)	1 (0.1)	2 (0.1)
ALOGLIPTIN	1 (0.1)	1 (0.1)	2 (0.1)
AMBROXOL	1 (0.1)	1 (0.1)	2 (0.1)
AMLODIPINE;ATORVASTATIN	0 (0.0)	2 (0.2)	2 (0.1)
AMLODIPINE;HYDROCHLOROTHIAZIDE;VALSARTAN	1 (0.1)	1 (0.1)	2 (0.1)
AMLODIPINE;LOSARTAN	1 (0.1)	1 (0.1)	2 (0.1)
ANGELICA ACUTILOBA;ATRACTYLODES LANCEA;BUPLEURUM FALCATUM;CONIOSELINUM OFFICINALE;GLYCYRRHIZA SPP.;PORIA COCOS;UNCARIA SPP.	1 (0.1)	1 (0.1)	2 (0.1)
ANTACIDS	2 (0.2)	0 (0.0)	2 (0.1)
ARIPIPRAZOLE	2 (0.2)	0 (0.0)	2 (0.1)
ASCORBIC ACID	2 (0.2)	0 (0.0)	2 (0.1)
ASCORBIC ACID;COD-LIVER OIL;DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;MAGNESIUM SULFATE;MUCIN;PYRIDOXAL;RETINOL;RIBES NIGRUM;TOCOPHEROL	0 (0.0)	2 (0.2)	2 (0.1)
ASCORBIC ACID;COPPER;VITAMIN E NOS;XANTOFYL;ZEAXANTHIN;ZINC	0 (0.0)	2 (0.2)	2 (0.1)
AZULENE	1 (0.1)	1 (0.1)	2 (0.1)
BENFOTIAMINE;PYRIDOXINE	1 (0.1)	1 (0.1)	2 (0.1)
BETAMETHASONE;CALCIPOTRIOL	0 (0.0)	2 (0.2)	2 (0.1)
BISACODYL;DOCUSATE	1 (0.1)	1 (0.1)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BRIMONIDINE	1 (0.1)	1 (0.1)	2 (0.1)
BRIMONIDINE;BRINZOLAMIDE	2 (0.2)	0 (0.0)	2 (0.1)
BRIMONIDINE;TIMOLOL	1 (0.1)	1 (0.1)	2 (0.1)
BRINZOLAMIDE	0 (0.0)	2 (0.2)	2 (0.1)
BUMETANIDE	1 (0.1)	1 (0.1)	2 (0.1)
BUPRENORPHINE	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL;SODIUM	0 (0.0)	2 (0.2)	2 (0.1)
CALCIUM;ERGOCALCIFEROL	2 (0.2)	0 (0.0)	2 (0.1)
CALENDULA OFFICINALIS	2 (0.2)	0 (0.0)	2 (0.1)
CANAGLIFLOZIN	1 (0.1)	1 (0.1)	2 (0.1)
CARBIDOPA;LEVODOPA	0 (0.0)	2 (0.2)	2 (0.1)
CARBOMER	0 (0.0)	2 (0.2)	2 (0.1)
CARMELLOSE	0 (0.0)	2 (0.2)	2 (0.1)
CEFCAPENE	1 (0.1)	1 (0.1)	2 (0.1)
CEFUROXIME	0 (0.0)	2 (0.2)	2 (0.1)
CHLORPHENAMINE	1 (0.1)	1 (0.1)	2 (0.1)
CICLOSPORIN	2 (0.2)	0 (0.0)	2 (0.1)
CILNIDIPINE	1 (0.1)	1 (0.1)	2 (0.1)
CIMETIDINE	2 (0.2)	0 (0.0)	2 (0.1)
CINITAPRIDE	0 (0.0)	2 (0.2)	2 (0.1)
CINNARIZINE	1 (0.1)	1 (0.1)	2 (0.1)
CITRIC ACID;SODIUM BICARBONATE;SODIUM CITRATE;TARTARIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
CLOBETASONE	0 (0.0)	2 (0.2)	2 (0.1)
CLOTIAZEPAM	2 (0.2)	0 (0.0)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
COLCHICINE	1 (0.1)	1 (0.1)	2 (0.1)
CORTICOSTEROIDS, PLAIN	2 (0.2)	0 (0.0)	2 (0.1)
CYANOCOBALAMIN;DICLOFENAC;PYRIDOXINE;THIAMINE	0 (0.0)	2 (0.2)	2 (0.1)
DESVENLAFAXINE	0 (0.0)	2 (0.2)	2 (0.1)
DEXAMFETAMINE	0 (0.0)	2 (0.2)	2 (0.1)
DEXKETOPROFEN	1 (0.1)	1 (0.1)	2 (0.1)
DEXTRAN;HYPROMELLOSE	1 (0.1)	1 (0.1)	2 (0.1)
DEXTROMETHORPHAN;DOXYLAMINE;EPHEDRINE;ETHANOL;PARACETAMOL	2 (0.2)	0 (0.0)	2 (0.1)
DEXTROMETHORPHAN;GUAIFENESIN	0 (0.0)	2 (0.2)	2 (0.1)
DIACEREIN	1 (0.1)	1 (0.1)	2 (0.1)
DIOSMECTITE	1 (0.1)	1 (0.1)	2 (0.1)
DOBESILIC ACID	0 (0.0)	2 (0.2)	2 (0.1)
DOCUSATE;SENNOSIDE A+B	2 (0.2)	0 (0.0)	2 (0.1)
DORZOLAMIDE	0 (0.0)	2 (0.2)	2 (0.1)
DRUGS FOR ACID RELATED DISORDERS	2 (0.2)	0 (0.0)	2 (0.1)
EMOLLIENTS AND PROTECTIVES	1 (0.1)	1 (0.1)	2 (0.1)
EMPAGLIFLOZIN;LINAGLIPTIN	0 (0.0)	2 (0.2)	2 (0.1)
ENALAPRIL;HYDROCHLOROTHIAZIDE	1 (0.1)	1 (0.1)	2 (0.1)
ENOXAPARIN	2 (0.2)	0 (0.0)	2 (0.1)
EPINEPHRINE	1 (0.1)	1 (0.1)	2 (0.1)
EPLERENONE	1 (0.1)	1 (0.1)	2 (0.1)
ETANERCEPT	1 (0.1)	1 (0.1)	2 (0.1)
ETODOLAC	2 (0.2)	0 (0.0)	2 (0.1)
FEBUXOSTAT	1 (0.1)	1 (0.1)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
FELODIPINE;METOPROLOL	1 (0.1)	1 (0.1)	2 (0.1)
FESOTERODINE	2 (0.2)	0 (0.0)	2 (0.1)
FLUCONAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
FLURBIPROFEN	2 (0.2)	0 (0.0)	2 (0.1)
FOLIC ACID;IRON	1 (0.1)	1 (0.1)	2 (0.1)
GEMFIBROZIL	2 (0.2)	0 (0.0)	2 (0.1)
HALOPERIDOL	0 (0.0)	2 (0.2)	2 (0.1)
HERBAL POLLEN NOS;TOCOPHEROL	1 (0.1)	1 (0.1)	2 (0.1)
HYDROCHLOROTHIAZIDE;QUINAPRIL	2 (0.2)	0 (0.0)	2 (0.1)
HYDROCHLOROTHIAZIDE;SPIRONOLACTONE	0 (0.0)	2 (0.2)	2 (0.1)
HYOSCINE	1 (0.1)	1 (0.1)	2 (0.1)
IMIDAPRIL	0 (0.0)	2 (0.2)	2 (0.1)
INSULIN BOVINE	2 (0.2)	0 (0.0)	2 (0.1)
INSULIN GLULISINE	1 (0.1)	1 (0.1)	2 (0.1)
IODINE;LEVOTHYROXINE	1 (0.1)	1 (0.1)	2 (0.1)
ISOSORBIDE DINITRATE	1 (0.1)	1 (0.1)	2 (0.1)
KETOCONAZOLE	0 (0.0)	2 (0.2)	2 (0.1)
KETOTIFEN	2 (0.2)	0 (0.0)	2 (0.1)
LACIDIPINE	1 (0.1)	1 (0.1)	2 (0.1)
LEVOGLUTAMIDE	1 (0.1)	1 (0.1)	2 (0.1)
LEVOTHYROXINE;LIOTHYRONINE	2 (0.2)	0 (0.0)	2 (0.1)
LIFITEGRAST	2 (0.2)	0 (0.0)	2 (0.1)
LINUM USITATISSIMUM	1 (0.1)	1 (0.1)	2 (0.1)
MACROGOL 400;PROPYLENE GLYCOL	2 (0.2)	0 (0.0)	2 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
MAGNESIUM HYDROXIDE	2 (0.2)	0 (0.0)	2 (0.1)
MAGNESIUM;POTASSIUM ASPARTATE	2 (0.2)	0 (0.0)	2 (0.1)
MANIDIPINE	0 (0.0)	2 (0.2)	2 (0.1)
MECLOZINE	2 (0.2)	0 (0.0)	2 (0.1)
MEPIVACAINE	1 (0.1)	1 (0.1)	2 (0.1)
METHYLPHENIDATE	2 (0.2)	0 (0.0)	2 (0.1)
MILNACIPRAN	2 (0.2)	0 (0.0)	2 (0.1)
MINERALS NOS;VITAMINS NOS	0 (0.0)	2 (0.2)	2 (0.1)
MOSAPRIDE	1 (0.1)	1 (0.1)	2 (0.1)
MOXONIDINE	2 (0.2)	0 (0.0)	2 (0.1)
NARATRIPTAN	2 (0.2)	0 (0.0)	2 (0.1)
NATEGLINIDE	2 (0.2)	0 (0.0)	2 (0.1)
NEFOPAM	1 (0.1)	1 (0.1)	2 (0.1)
NIMESULIDE	0 (0.0)	2 (0.2)	2 (0.1)
OFLOXACIN	2 (0.2)	0 (0.0)	2 (0.1)
ORPHENADRINE	0 (0.0)	2 (0.2)	2 (0.1)
PINAVERIUM	1 (0.1)	1 (0.1)	2 (0.1)
PIRACETAM	1 (0.1)	1 (0.1)	2 (0.1)
PIRENOXINE	1 (0.1)	1 (0.1)	2 (0.1)
POLYCARBOPHIL	1 (0.1)	1 (0.1)	2 (0.1)
POLYENE PHOSPHATIDYLCHOLINE	0 (0.0)	2 (0.2)	2 (0.1)
PRAMIPEXOLE	0 (0.0)	2 (0.2)	2 (0.1)
PRANLUKAST	1 (0.1)	1 (0.1)	2 (0.1)
PRANOPROFEN	1 (0.1)	1 (0.1)	2 (0.1)

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/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PROBUCOL	1 (0.1)	1 (0.1)	2 (0.1)
PROPOFOL	1 (0.1)	1 (0.1)	2 (0.1)
PROPYLTHIOURACIL	1 (0.1)	1 (0.1)	2 (0.1)
PSEUDOEPHEDRINE	0 (0.0)	2 (0.2)	2 (0.1)
PSEUDOEPHEDRINE;TRIPROLIDINE	0 (0.0)	2 (0.2)	2 (0.1)
PYRIDOXINE;THIAMINE;VITAMIN B12 NOS	2 (0.2)	0 (0.0)	2 (0.1)
PYRIDOXINE;THIOCTIC ACID;VITAMIN B1 NOS;VITAMIN B12 NOS	2 (0.2)	0 (0.0)	2 (0.1)
RANOLAZINE	0 (0.0)	2 (0.2)	2 (0.1)
REBAMIPIDE	2 (0.2)	0 (0.0)	2 (0.1)
RETINOL	2 (0.2)	0 (0.0)	2 (0.1)
RIZATRIPTAN	2 (0.2)	0 (0.0)	2 (0.1)
ROCURONIUM	1 (0.1)	1 (0.1)	2 (0.1)
SARPOGRELATE	1 (0.1)	1 (0.1)	2 (0.1)
SAXAGLIPTIN	1 (0.1)	1 (0.1)	2 (0.1)
SENNA SPP.	2 (0.2)	0 (0.0)	2 (0.1)
SIMETICONE	1 (0.1)	1 (0.1)	2 (0.1)
SODIUM BICARBONATE	1 (0.1)	1 (0.1)	2 (0.1)
SULODEXIDE	1 (0.1)	1 (0.1)	2 (0.1)
SULPIRIDE	1 (0.1)	1 (0.1)	2 (0.1)
TACROLIMUS	1 (0.1)	1 (0.1)	2 (0.1)
TERBINAFINE	1 (0.1)	1 (0.1)	2 (0.1)
THEOBROMINE	2 (0.2)	0 (0.0)	2 (0.1)
THYROID	1 (0.1)	1 (0.1)	2 (0.1)
TRANILAST	0 (0.0)	2 (0.2)	2 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
TYROSINE	0 (0.0)	2 (0.2)	2 (0.1)
UBIDECARENONE	1 (0.1)	1 (0.1)	2 (0.1)
UMECLIDINIUM;VILANTEROL	2 (0.2)	0 (0.0)	2 (0.1)
ABACAVIR	0 (0.0)	1 (0.1)	1 (0.0)
ABRUS PRECATORIUS;ACONITUM NAPELLUS;ATROPA BELLA-DONNA;CALENDULA OFFICINALIS;CHELIDONIUM MAJUS;VIBURNUM OPULUS	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLSALICYLIC ACID;ATORVASTATIN;CLOPIDOGREL	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLSALICYLIC ACID;BUTALBITAL;CAFFEINE	0 (0.0)	1 (0.1)	1 (0.0)
ACETYLSALICYLIC ACID;BUTALBITAL;CAFFEINE;CODEINE	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLSALICYLIC ACID;CODEINE	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLSALICYLIC ACID;OXYCODONE	0 (0.0)	1 (0.1)	1 (0.0)
ACHILLEA MILLEFOLIUM;ACONITUM NAPELLUS;ARNICA MONTANA;ATROPA BELLA-DONNA;BELLIS PERENNIS;CALCIUM SULFIDE;CALENDULA OFFICINALIS;ECHINACEA ANGUSTIFOLIA;ECHINACEA PURPUREA;HAMAMELIS VIRGINIANA;	1 (0.1)	0 (0.0)	1 (0.0)
ACICLOVIR	1 (0.1)	0 (0.0)	1 (0.0)
ACLIDINIUM	1 (0.1)	0 (0.0)	1 (0.0)
ACONITUM NAPELLUS;ATROPINE;MERCURIC CYANIDE	0 (0.0)	1 (0.1)	1 (0.0)
ACONITUM SPP.	1 (0.1)	0 (0.0)	1 (0.0)
ACONITUM SPP.;ASARUM SPP.;EPHEDRA SPP.	1 (0.1)	0 (0.0)	1 (0.0)
ADENINE;CARNITINE;CYANOCOBALAMIN;LIVER;PYRIDOXINE;RIBOFLAVIN	1 (0.1)	0 (0.0)	1 (0.0)
AFLIBERCEPT	0 (0.0)	1 (0.1)	1 (0.0)
AFLOQUALONE	1 (0.1)	0 (0.0)	1 (0.0)
ALENDRONIC ACID;COLECALCIFEROL	0 (0.0)	1 (0.1)	1 (0.0)
ALGINIC ACID;ALUMINIUM HYDROXIDE;CALCIUM CARBONATE;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ALGINIC ACID;CALCIUM CARBONATE;SODIUM CARBONATE ANHYDROUS	0 (0.0)	1 (0.1)	1 (0.0)
ALGINIC ACID;PARAFFIN NOS;SQUALANE	0 (0.0)	1 (0.1)	1 (0.0)
ALGINIC ACID;POTASSIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
ALGINIC ACID;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ATRACTYLODES SPP.;NEOLITSEA CASSIA;POLYPORUS UMBELLATUS;PORIA COCOS	0 (0.0)	1 (0.1)	1 (0.0)
ALIZAPRIDE	0 (0.0)	1 (0.1)	1 (0.0)
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 (0.1)	0 (0.0)	1 (0.0)
ALLANTOIN;LIDOCAINE;PREDNISOLONE;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.0)
ALLERGENS NOS	1 (0.1)	0 (0.0)	1 (0.0)
ALLIUM CEPA	1 (0.1)	0 (0.0)	1 (0.0)
ALLIUM SATIVUM	0 (0.0)	1 (0.1)	1 (0.0)
ALOE VERA;APPLE FIBRE;ARCTIUM LAPPA;ASCORBIC ACID;CAMELLIA SINENSIS;CICHORIUM INTYBUS;DL-ALPHA TOCOPHEROL;FOLIC ACID;FRUCTOOLIGOSACCHARIDES;GLYCYRRHIZA GLABRA;LACTOBACILLUS ACIDOPHILUS;MALTODEXTRIN;	0 (0.0)	1 (0.1)	1 (0.0)
ALUMINIUM ACETATE;HYDROCORTISONE;LIDOCAINE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ALUMINIUM SILICATE;CALCIUM CARBONATE;DIASTASE;HERBAL EXTRACT NOS;SODIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.0)
ALUMINIUM SILICATE;OXETACAINE	1 (0.1)	0 (0.0)	1 (0.0)
AMINO ACIDS NOS;GANGLIOSIDE : GM1;HYPOXANTHINE;NITROGEN;POLYPEPTIDE NOS	1 (0.1)	0 (0.0)	1 (0.0)
AMINOBENZOIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
AMINOBENZOIC ACID;CYSTINE;KERATIN;PANTOTHENIC ACID;SACCHAROMYCES CEREVISIAE;THIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
AMINOCAPROIC ACID;CHLORPHENAMINE;CHONDROITIN;GLYCYRRHIZIC ACID;PYRIDOXINE;TAURINE;TETRYZOLINE	0 (0.0)	1 (0.1)	1 (0.0)
AMINOPHYLLINE;QUININE	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
AMISULPRIDE	0 (0.0)	1 (0.1)	1 (0.0)
AMLODIPINE;CANDESARTAN	1 (0.1)	0 (0.0)	1 (0.0)
AMLODIPINE;FIMASARTAN	1 (0.1)	0 (0.0)	1 (0.0)
AMLODIPINE;INDAPAMIDE	0 (0.0)	1 (0.1)	1 (0.0)
AMLODIPINE;IRBESARTAN	0 (0.0)	1 (0.1)	1 (0.0)
AMLODIPINE;LISINOPRIL	1 (0.1)	0 (0.0)	1 (0.0)
AMLODIPINE;RAMIPRIL	0 (0.0)	1 (0.1)	1 (0.0)
AMMONIUM CHLORIDE;CODEINE;DIPHENHYDRAMINE	0 (0.0)	1 (0.1)	1 (0.0)
AMMONIUM CHLORIDE;DIPHENHYDRAMINE;SODIUM CITRATE	1 (0.1)	0 (0.0)	1 (0.0)
AMMONIUM LACTATE	0 (0.0)	1 (0.1)	1 (0.0)
AMOROLFINE	0 (0.0)	1 (0.1)	1 (0.0)
ANEMARRHENA ASPHODELOIDES;CONIOSELINUM OFFICINALE;GLYCYRRHIZA SPP.;PORIA COCOS;ZIZIPHUS JUJUBA	0 (0.0)	1 (0.1)	1 (0.0)
ANGELICA ACUTILOBA;ANGELICA DAHURICA;ATRACTYLODES LANCEA;CITRUS SPP.;CITRUS X AURANTIUM;CONIOSELINUM OFFICINALE;EPHEDRA SPP.;GLYCYRRHIZA SPP.;MAGNOLIA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;	1 (0.1)	0 (0.0)	1 (0.0)
ANGELICA ACUTILOBA;ARECA CATECHU;ATRACTYLODES LANCEA;CONIOSELINUM OFFICINALE;COPTIS SPP.;CYPERUS ROTUNDUS;DOLOMIAEA COSTUS;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PANAX GINSENG;SCUTELLARIA BAICALENSIS;	0 (0.0)	1 (0.1)	1 (0.0)
ANGELICA ACUTILOBA;ASTRAGALUS SPP.;ATRACTYLODES SPP.;CITRUS X AURANTIUM;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PANAX GINSENG;POLYGALA TENUIFOLIA;PORIA COCOS;REHMANNIA GLUTINOSA;	1 (0.1)	0 (0.0)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ANGELICA ACUTILOBA;ATRACTYLODES LANCEA;BUPLEURUM FALCATUM;GARDENIA JASMINOIDES;GLYCYRRHIZA SPP.;MENTHA CANADENSIS;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;ZINGIBER OFFICINALE	0 (0.0)	1 (0.1)	1 (0.0)
ANGELICA ACUTILOBA;ATRACTYLODES SPP.;CALCIUM SULFATE;CONIOSELINUM OFFICINALE;EPHEDRA SPP.;FORSYTHIA SPP.;GARDENIA JASMINOIDES;GLYCYRRHIZA SPP.;MENTHA CANADENSIS;NEPETA TENUIFOLIA;PAEONIA LACTIFLORA;	0 (0.0)	1 (0.1)	1 (0.0)
ANIMAL UNSPECIFIED	0 (0.0)	1 (0.1)	1 (0.0)
ANTIALLERGIC AGENTS	0 (0.0)	1 (0.1)	1 (0.0)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS	0 (0.0)	1 (0.1)	1 (0.0)
APRONAL;CAFFEINE;IBUPROFEN	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;BETACAROTENE;LYCOPENE;SELENIUM;TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;BIOTIN;CALCIUM;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FOLIC ACID;IRON;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANAX GINSENG;PYRIDOXINE;RETINOL;RIBOFLAVIN;SELENIUM;THIAMINE;TOCOPHEROL;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;CUPRIC OXIDE;TOCOPHEROL;XANTOFYL;ZEAXANTHIN;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;CYANOCOBALAMIN;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;FISH OIL;SELENIUM;TOCOPHEROL;XANTOFYL;ZEAXANTHIN;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
ASTRAGALUS MONGHOLICUS;CODONOPSIS PILOSULA	1 (0.1)	0 (0.0)	1 (0.0)
ATOMOXETINE	0 (0.0)	1 (0.1)	1 (0.0)
ATORVASTATIN;IRBESARTAN	0 (0.0)	1 (0.1)	1 (0.0)
ATRACTYLODES LANCEA;CALCIUM SULFATE;EPHEDRA SPP.;GLYCYRRHIZA SPP.;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ATRACTYLODES SPP.	1 (0.1)	0 (0.0)	1 (0.0)
ATROPA BELLA-DONNA;ERGOTAMINE;PHENOBARBITAL	1 (0.1)	0 (0.0)	1 (0.0)
ATROPINE	0 (0.0)	1 (0.1)	1 (0.0)
ATROPINE;DIPHENOXYLATE	1 (0.1)	0 (0.0)	1 (0.0)
AZELAIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
AZELASTINE;FLUTICASONE	0 (0.0)	1 (0.1)	1 (0.0)
AZELNIDIPINE	1 (0.1)	0 (0.0)	1 (0.0)
AZELNIDIPINE;OLMESARTAN	0 (0.0)	1 (0.1)	1 (0.0)
AZILSARTAN;CHLORTALIDONE	1 (0.1)	0 (0.0)	1 (0.0)
BACITRACIN;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
BACTERIA NOS;HYDROCORTISONE	1 (0.1)	0 (0.0)	1 (0.0)
BALSALAZIDE	1 (0.1)	0 (0.0)	1 (0.0)
BARNIDIPINE	1 (0.1)	0 (0.0)	1 (0.0)
BAZEDOXIFENE	1 (0.1)	0 (0.0)	1 (0.0)
BECLOMETASONE;SALBUTAMOL	1 (0.1)	0 (0.0)	1 (0.0)
BENEXATE	0 (0.0)	1 (0.1)	1 (0.0)
BENFOTIAMINE	0 (0.0)	1 (0.1)	1 (0.0)
BENSERAZIDE;LEVODOPA	1 (0.1)	0 (0.0)	1 (0.0)
BENZALKONIUM;CAMPHOR;CINCHOCAINE;DIMETICONE;DIPHENHYDRAMINE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
BENZOCAINE;CHLOROTHYMOL;SODIUM MORRHUATE	1 (0.1)	0 (0.0)	1 (0.0)
BENZOCAINE;CHLORPHENAMINE	0 (0.0)	1 (0.1)	1 (0.0)
BENZONATATE	1 (0.1)	0 (0.0)	1 (0.0)
BENZOYL PEROXIDE	1 (0.1)	0 (0.0)	1 (0.0)
BENZOYL PEROXIDE;CLINDAMYCIN	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BENZYDAMINE	1 (0.1)	0 (0.0)	1 (0.0)
BETA-ACETYLDIGOXIN	0 (0.0)	1 (0.1)	1 (0.0)
BETAMETHASONE;CLIOQUINOL	0 (0.0)	1 (0.1)	1 (0.0)
BETAMETHASONE;FUSIDIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
BETAMETHASONE;LORATADINE	0 (0.0)	1 (0.1)	1 (0.0)
BETAMETHASONE;MAXACALCITOL	1 (0.1)	0 (0.0)	1 (0.0)
BETAMETHASONE;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
BEVACIZUMAB	0 (0.0)	1 (0.1)	1 (0.0)
BICYCLOL	0 (0.0)	1 (0.1)	1 (0.0)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM LACTIS;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS CASEI;LACTOBACILLUS LACTIS	0 (0.0)	1 (0.1)	1 (0.0)
BIFIDOBACTERIUM NOS	0 (0.0)	1 (0.1)	1 (0.0)
BILASTINE	0 (0.0)	1 (0.1)	1 (0.0)
BISABOLOL;CERESIN;PARAFFIN SOFT;PARAFFIN, LIQUID;WOOL ALCOHOLS	1 (0.1)	0 (0.0)	1 (0.0)
BISACODYL;SENNOSIDE A+B	0 (0.0)	1 (0.1)	1 (0.0)
BOSWELLIA SACRA	1 (0.1)	0 (0.0)	1 (0.0)
BOTULINUM TOXIN TYPE A	1 (0.1)	0 (0.0)	1 (0.0)
BREXPIPRAZOLE	0 (0.0)	1 (0.1)	1 (0.0)
BRINZOLAMIDE;TIMOLOL	1 (0.1)	0 (0.0)	1 (0.0)
BROMFENAC	0 (0.0)	1 (0.1)	1 (0.0)
BROMHEXINE	0 (0.0)	1 (0.1)	1 (0.0)
BROMISOVAL;CAFFEINE;ETHENZAMIDE;IBUPROFEN	0 (0.0)	1 (0.1)	1 (0.0)
BUCLIZINE;CODEINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
BUTALBITAL;CAFFEINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BUTAMIRATE	0 (0.0)	1 (0.1)	1 (0.0)
BUTYLSCOPOLAMINE	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;CARISOPRODOL;DICLOFENAC;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;CHLORPHENAMINE;DIHYDROCODEINE;GLYCYRRHIZA GLABRA;METHYLEPHEDRINE;PARACETAMOL;PROPYPHENAZONE	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;CODEINE;MEPROBAMATE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;CODEINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;ETHENZAMIDE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;IBUPROFEN	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;ISOMETHEPTENE;METAMIZOLE	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
CALCIFEDIOL	0 (0.0)	1 (0.1)	1 (0.0)
CALCIPOTRIOL	1 (0.1)	0 (0.0)	1 (0.0)
CALCITRIOL	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CARBONATE;CALCIUM PHOSPHATE;CHLOROPHYLLIN COPPER COMPLEX;MAGNESIUM HYDROXIDE;SCOPOLIA JAPONICA	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CARBONATE;CALCIUM PHOSPHATE;KAOLIN;MAGNESIUM CARBONATE;MAGNESIUM HYDROXIDE;MAGNESIUM OXIDE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CARBONATE;COLECALCIFEROL;MAGNESIUM CARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CARBONATE;ERGOCALCIFEROL	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM GLUCONATE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM PHOSPHATE;COLECALCIFEROL;PHOSPHORUS;SODIUM	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CALCIUM;COLECALCIFEROL;COPPER;MAGNESIUM;MANGANESE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM;COLECALCIFEROL;MAGNESIUM;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM;MAGNESIUM;VITAMIN D NOS	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM;VITAMINS NOS	0 (0.0)	1 (0.1)	1 (0.0)
CAMPHOR;DEXAMETHASONE;MENTHOL	1 (0.1)	0 (0.0)	1 (0.0)
CAMPHOR;ENOXOLONE;MENTHOL;SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
CAMPHOR;MENTHOL;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
CANNABIDIOL	1 (0.1)	0 (0.0)	1 (0.0)
CARBOMER;GLYCEROL;PARAFFIN, LIQUID;POLYCARBOPHIL	1 (0.1)	0 (0.0)	1 (0.0)
CARISOPRODOL;CYANOCOBALAMIN;METAMIZOLE;PYRIDOXINE;THIAMINE	0 (0.0)	1 (0.1)	1 (0.0)
CARNITINE;CYANOCOBALAMIN;CYPROHEPTADINE;LYSINE	0 (0.0)	1 (0.1)	1 (0.0)
CARPRONIUM	0 (0.0)	1 (0.1)	1 (0.0)
CARTHAMUS TINCTORIUS	1 (0.1)	0 (0.0)	1 (0.0)
CEFAZOLIN	1 (0.1)	0 (0.0)	1 (0.0)
CEFDINIR	1 (0.1)	0 (0.0)	1 (0.0)
CEFOTAXIME	0 (0.0)	1 (0.1)	1 (0.0)
CEFPODOXIME	1 (0.1)	0 (0.0)	1 (0.0)
CEFTEZOLE	1 (0.1)	0 (0.0)	1 (0.0)
CELIPROLOL	0 (0.0)	1 (0.1)	1 (0.0)
CETOMACROGOL 1000	1 (0.1)	0 (0.0)	1 (0.0)
CETOMACROGOL;CETOSTEARYL ALCOHOL;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	0 (0.0)	1 (0.1)	1 (0.0)
CETOMACROGOL;CHLOROCRESOL;GLYCEROL;PARAFFIN SOFT;PARAFFIN, LIQUID;PROPYLENE GLYCOL	1 (0.1)	0 (0.0)	1 (0.0)
CETYL ALCOHOL;GLYCEROL;PARAFFIN NOS	1 (0.1)	0 (0.0)	1 (0.0)
CETYL ALCOHOL;PARAFFIN NOS;PHENOXYETHANOL;STEARYL ALCOHOL	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CEVIMELINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORAMPHENICOL	1 (0.1)	0 (0.0)	1 (0.0)
CHLORDIAZEPOXIDE	0 (0.0)	1 (0.1)	1 (0.0)
CHLORHEXIDINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORHEXIDINE;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRINE	0 (0.0)	1 (0.1)	1 (0.0)
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL;PSEUDOEPHEDRINE	0 (0.0)	1 (0.1)	1 (0.0)
CHLORPHENAMINE;DIHYDROCODEINE;GUAIFENESIN;METHYLEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORZOXAZONE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
CHOLINE ALFOSCERATE	0 (0.0)	1 (0.1)	1 (0.0)
CHONDROITIN;ENOXOLONE;SORBITAN SESQUIOLEATE;TOCOPHEROL;TROLAMINE	0 (0.0)	1 (0.1)	1 (0.0)
CILAZAPRIL	1 (0.1)	0 (0.0)	1 (0.0)
CILNIDIPINE;VALSARTAN	0 (0.0)	1 (0.1)	1 (0.0)
CINCHOCAINE;PREDNISOLONE	1 (0.1)	0 (0.0)	1 (0.0)
CINOLAZEPAM	0 (0.0)	1 (0.1)	1 (0.0)
CIPROFIBRATE	0 (0.0)	1 (0.1)	1 (0.0)
CIPROFLOXACIN	1 (0.1)	0 (0.0)	1 (0.0)
CIPROFLOXACIN;HYDROCORTISONE	0 (0.0)	1 (0.1)	1 (0.0)
CITRUS SPP.	1 (0.1)	0 (0.0)	1 (0.0)
CLARITHROMYCIN	0 (0.0)	1 (0.1)	1 (0.0)
CLEBOPRIDE	0 (0.0)	1 (0.1)	1 (0.0)
CLEMATIS SPP.;PRUNELLA VULGARIS;TRICHOSANTHES KIRILOWII	1 (0.1)	0 (0.0)	1 (0.0)
CLOBAZAM	1 (0.1)	0 (0.0)	1 (0.0)
CLOBUTINOL;POLYVINYL ALCOHOL	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CLORAZEPIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
CODEINE;DOXYLAMINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
CODEINE;PROMETHAZINE	0 (0.0)	1 (0.1)	1 (0.0)
COIX LACRYMA-JOBI	1 (0.1)	0 (0.0)	1 (0.0)
COLECALCIFEROL;GLUCOSAMINE	1 (0.1)	0 (0.0)	1 (0.0)
COLESEVELAM	0 (0.0)	1 (0.1)	1 (0.0)
COLLAGEN	0 (0.0)	1 (0.1)	1 (0.0)
CORTICOSTEROIDS	0 (0.0)	1 (0.1)	1 (0.0)
CORTICOSTEROIDS, WEAK (GROUP I)	1 (0.1)	0 (0.0)	1 (0.0)
CORYDALIS YANHUSUO;IPOMOEA NIL	0 (0.0)	1 (0.1)	1 (0.0)
COUMARIN;TROXERUTIN	0 (0.0)	1 (0.1)	1 (0.0)
CROCUS SATIVUS	1 (0.1)	0 (0.0)	1 (0.0)
CROMOGLICIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
CROTAMITON	0 (0.0)	1 (0.1)	1 (0.0)
CYANOCOBALAMIN;LEVOGLUTAMIDE;SERINE	0 (0.0)	1 (0.1)	1 (0.0)
CYTIDINE;HYDROXOCOBALAMIN;URIDINE TRIPHOSPHATE	0 (0.0)	1 (0.1)	1 (0.0)
DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE	0 (0.0)	1 (0.1)	1 (0.0)
DESMOPRESSIN	1 (0.1)	0 (0.0)	1 (0.0)
DESONIDE	1 (0.1)	0 (0.0)	1 (0.0)
DESOXIMETASONE	1 (0.1)	0 (0.0)	1 (0.0)
DEXAMETHASONE;NEOMYCIN	0 (0.0)	1 (0.1)	1 (0.0)
DEXAMETHASONE;TOBRAMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
DEXPANTHENOL	0 (0.0)	1 (0.1)	1 (0.0)
DIMENHYDRINATE	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
DIPYRIDAMOLE	1 (0.1)	0 (0.0)	1 (0.0)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
DOCUSATE;SENNA ALEXANDRINA	0 (0.0)	1 (0.1)	1 (0.0)
DOXEPIN	1 (0.1)	0 (0.0)	1 (0.0)
DRONEDARONE	0 (0.0)	1 (0.1)	1 (0.0)
DRUGS FOR CONSTIPATION	1 (0.1)	0 (0.0)	1 (0.0)
EDOXABAN	0 (0.0)	1 (0.1)	1 (0.0)
EFINACONAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
EICOSAPENTAENOIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
ELCATONIN	0 (0.0)	1 (0.1)	1 (0.0)
ELUXADOLINE	0 (0.0)	1 (0.1)	1 (0.0)
EMPAGLIFLOZIN;METFORMIN	1 (0.1)	0 (0.0)	1 (0.0)
EMULSIFYING WAX;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	0 (0.0)	1 (0.1)	1 (0.0)
ENALAPRIL;INDAPAMIDE	0 (0.0)	1 (0.1)	1 (0.0)
ENEMAS	1 (0.1)	0 (0.0)	1 (0.0)
ENTECAVIR	1 (0.1)	0 (0.0)	1 (0.0)
EPALRESTAT	1 (0.1)	0 (0.0)	1 (0.0)
EPHEDRINE	0 (0.0)	1 (0.1)	1 (0.0)
EQUISETUM TELMATEIA;FUMARIA OFFICINALIS;GENTIANA LUTEA;GERANIUM ROBERTIANUM;JUGLANS REGIA;PINUS SYLVESTRIS;SCROPHULARIA NODOSA;SMILAX ARISTOLOCHIIFOLIA;TEUCRIUM SCORODONIA;TROPAEOLUM MAJUS	0 (0.0)	1 (0.1)	1 (0.0)
ERODIUM STEPHANIANUM	1 (0.1)	0 (0.0)	1 (0.0)
ERYTHROPOIETIN HUMAN	1 (0.1)	0 (0.0)	1 (0.0)
ESTRIOL	1 (0.1)	0 (0.0)	1 (0.0)

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Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ESTROGENS CONJUGATED	1 (0.1)	0 (0.0)	1 (0.0)
ETHYL LOFLAZEPATE	0 (0.0)	1 (0.1)	1 (0.0)
ETIFOXINE	0 (0.0)	1 (0.1)	1 (0.0)
ETOFENAMATE	1 (0.1)	0 (0.0)	1 (0.0)
ETRETINATE	1 (0.1)	0 (0.0)	1 (0.0)
FENOTEROL;IPRATROPIUM	1 (0.1)	0 (0.0)	1 (0.0)
FIBRE NOS	1 (0.1)	0 (0.0)	1 (0.0)
FLUDIAZEPAM	1 (0.1)	0 (0.0)	1 (0.0)
FLUDROXYCORTIDE	0 (0.0)	1 (0.1)	1 (0.0)
FLUNITRAZEPAM	0 (0.0)	1 (0.1)	1 (0.0)
FLUOROURACIL	0 (0.0)	1 (0.1)	1 (0.0)
FLUPENTIXOL;MELITRACEN	0 (0.0)	1 (0.1)	1 (0.0)
FLUVOXAMINE	0 (0.0)	1 (0.1)	1 (0.0)
FOLINIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
FORMOTEROL;MOMETASONE	1 (0.1)	0 (0.0)	1 (0.0)
FUMARIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
FUROSEMIDE;TRIAMTERENE	1 (0.1)	0 (0.0)	1 (0.0)
FUSIDIC ACID;HYDROCORTISONE	0 (0.0)	1 (0.1)	1 (0.0)
GARENOXACIN	0 (0.0)	1 (0.1)	1 (0.0)
GEMIGLIPTIN;METFORMIN	0 (0.0)	1 (0.1)	1 (0.0)
GLATIRAMER	1 (0.1)	0 (0.0)	1 (0.0)
GLICLAZIDE;METFORMIN	1 (0.1)	0 (0.0)	1 (0.0)
GLIPIZIDE;METFORMIN	1 (0.1)	0 (0.0)	1 (0.0)
GLIQUIDONE	1 (0.1)	0 (0.0)	1 (0.0)

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/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

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GLUTAMIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
GLYCEROL;HYPROMELLOSE;MACROGOL	0 (0.0)	1 (0.1)	1 (0.0)
GLYCEROL;NAPHAZOLINE	0 (0.0)	1 (0.1)	1 (0.0)
GLYCINE MAX;PERSEA AMERICANA	0 (0.0)	1 (0.1)	1 (0.0)
GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PRUNUS SPP.;RHEUM SPP.;SODIUM SULFATE	1 (0.1)	0 (0.0)	1 (0.0)
GLYCYRRHIZIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
GRANISETRON	0 (0.0)	1 (0.1)	1 (0.0)
GUAIFENESIN	1 (0.1)	0 (0.0)	1 (0.0)
GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.0)
GUALENIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
HEDERA HELIX;THYMUS VULGARIS	0 (0.0)	1 (0.1)	1 (0.0)
HERBAL POLLEN NOS	1 (0.1)	0 (0.0)	1 (0.0)
HERICIUM ERINACEUS	1 (0.1)	0 (0.0)	1 (0.0)
HIPPOPHAE RHAMNOIDES	1 (0.1)	0 (0.0)	1 (0.0)
HOMOCHLORCYCLIZINE	1 (0.1)	0 (0.0)	1 (0.0)
HYDROCHLOROTHIAZIDE;NEBIVOLOL	0 (0.0)	1 (0.1)	1 (0.0)
HYDROCORTISONE;SULFADIAZINE	1 (0.1)	0 (0.0)	1 (0.0)
HYDROTALCITE	1 (0.1)	0 (0.0)	1 (0.0)
HYDROXOCOBALAMIN	1 (0.1)	0 (0.0)	1 (0.0)
HYPERICUM PERFORATUM	0 (0.0)	1 (0.1)	1 (0.0)
IGURATIMOD	0 (0.0)	1 (0.1)	1 (0.0)
IMIDAFENACIN	1 (0.1)	0 (0.0)	1 (0.0)
IMIDAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
INULIN	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
IOHEXOL	1 (0.1)	0 (0.0)	1 (0.0)
IPRATROPIUM;SALBUTAMOL	0 (0.0)	1 (0.1)	1 (0.0)
IRSOGLADINE	1 (0.1)	0 (0.0)	1 (0.0)
KETAMINE	0 (0.0)	1 (0.1)	1 (0.0)
KETAZOLAM	0 (0.0)	1 (0.1)	1 (0.0)
L-CARBOCISTEINE	0 (0.0)	1 (0.1)	1 (0.0)
LABETALOL	0 (0.0)	1 (0.1)	1 (0.0)
LACOSAMIDE	0 (0.0)	1 (0.1)	1 (0.0)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS	0 (0.0)	1 (0.1)	1 (0.0)
LEFLUNOMIDE	0 (0.0)	1 (0.1)	1 (0.0)
LEMBOREXANT	0 (0.0)	1 (0.1)	1 (0.0)
LEVOCABASTINE	0 (0.0)	1 (0.1)	1 (0.0)
LEVOCARNITINE	1 (0.1)	0 (0.0)	1 (0.0)
LEVOCLOPERASTINE	1 (0.1)	0 (0.0)	1 (0.0)
LEVOMEPROMAZINE	0 (0.0)	1 (0.1)	1 (0.0)
LEVOSULPIRIDE	1 (0.1)	0 (0.0)	1 (0.0)
LIDOCAINE;RETINOL;SULFADIAZINE	1 (0.1)	0 (0.0)	1 (0.0)
LIMAPROST	1 (0.1)	0 (0.0)	1 (0.0)
LINACLOTIDE	1 (0.1)	0 (0.0)	1 (0.0)
LISDEXAMFETAMINE	0 (0.0)	1 (0.1)	1 (0.0)
LIVER THERAPY	1 (0.1)	0 (0.0)	1 (0.0)
LORATADINE;PSEUDOEPHEDRINE	1 (0.1)	0 (0.0)	1 (0.0)
LULICONAZOLE	0 (0.0)	1 (0.1)	1 (0.0)
LUSEOGLIFLOZIN	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
LYSOZYME	1 (0.1)	0 (0.0)	1 (0.0)
MACROGOL 400	1 (0.1)	0 (0.0)	1 (0.0)
MACROGOL 4000	1 (0.1)	0 (0.0)	1 (0.0)
MACROGOL;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
MAGIC MOUTHWASH	1 (0.1)	0 (0.0)	1 (0.0)
MAGNESIUM;MAGNESIUM CARBONATE;MAGNESIUM CITRATE;MAGNESIUM PHOSPHATE	0 (0.0)	1 (0.1)	1 (0.0)
MAGNESIUM;MAGNESIUM CITRATE;MAGNESIUM OXIDE	1 (0.1)	0 (0.0)	1 (0.0)
MAGNESIUM;PYRIDOXINE	0 (0.0)	1 (0.1)	1 (0.0)
MAGNOLIA OFFICINALIS	1 (0.1)	0 (0.0)	1 (0.0)
MAPROTILINE	1 (0.1)	0 (0.0)	1 (0.0)
MAXACALCITOL	1 (0.1)	0 (0.0)	1 (0.0)
MEBEVERINE	1 (0.1)	0 (0.0)	1 (0.0)
MEFENAMIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
MELILOTUS OFFICINALIS;RUTOSIDE	1 (0.1)	0 (0.0)	1 (0.0)
MENTHOL	0 (0.0)	1 (0.1)	1 (0.0)
MEQUITAZINE	0 (0.0)	1 (0.1)	1 (0.0)
MEROPENEM	1 (0.1)	0 (0.0)	1 (0.0)
METARAMINOL	0 (0.0)	1 (0.1)	1 (0.0)
METFORMIN;SAXAGLIPTIN	1 (0.1)	0 (0.0)	1 (0.0)
METHADONE	1 (0.1)	0 (0.0)	1 (0.0)
METHENAMINE	1 (0.1)	0 (0.0)	1 (0.0)
METHYLDOPA	0 (0.0)	1 (0.1)	1 (0.0)
METHYLPREDNISOLONE;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
METOLAZONE	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
MICONAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
MILRINONE	1 (0.1)	0 (0.0)	1 (0.0)
MINERAL OIL LIGHT;PARAFFIN NOS;PETROLATUM;WOOL ALCOHOLS	0 (0.0)	1 (0.1)	1 (0.0)
MINOCYCLINE	1 (0.1)	0 (0.0)	1 (0.0)
MINODRONIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
MINOXIDIL	1 (0.1)	0 (0.0)	1 (0.0)
MIROGABALIN	1 (0.1)	0 (0.0)	1 (0.0)
MITIGLINIDE	1 (0.1)	0 (0.0)	1 (0.0)
MOXIFLOXACIN	1 (0.1)	0 (0.0)	1 (0.0)
MYCOPHENOLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
NADOLOL	1 (0.1)	0 (0.0)	1 (0.0)
NAFTAZONE	0 (0.0)	1 (0.1)	1 (0.0)
NALDEMEDINE	0 (0.0)	1 (0.1)	1 (0.0)
NALOXEGOL	0 (0.0)	1 (0.1)	1 (0.0)
NALOXONE;OXYCODONE	1 (0.1)	0 (0.0)	1 (0.0)
NALOXONE;TILIDINE	0 (0.0)	1 (0.1)	1 (0.0)
NALTREXONE	1 (0.1)	0 (0.0)	1 (0.0)
NAPHAZOLINE	1 (0.1)	0 (0.0)	1 (0.0)
NAPROXEN;SUMATRIPTAN	0 (0.0)	1 (0.1)	1 (0.0)
NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;PORIA COCOS;PRUNUS SPP.	0 (0.0)	1 (0.1)	1 (0.0)
NEOSTIGMINE	1 (0.1)	0 (0.0)	1 (0.0)
NICAMETATE	1 (0.1)	0 (0.0)	1 (0.0)
NICERGOLINE	0 (0.0)	1 (0.1)	1 (0.0)
NICORANDIL	0 (0.0)	1 (0.1)	1 (0.0)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
NIMODIPINE	1 (0.1)	0 (0.0)	1 (0.0)
NITRAZEPAM	0 (0.0)	1 (0.1)	1 (0.0)
NITROGEN, LIQUID	1 (0.1)	0 (0.0)	1 (0.0)
NITROUS OXIDE	1 (0.1)	0 (0.0)	1 (0.0)
NIZATIDINE	0 (0.0)	1 (0.1)	1 (0.0)
NUTRIENTS NOS;VITAMINS NOS	0 (0.0)	1 (0.1)	1 (0.0)
OMALIZUMAB	1 (0.1)	0 (0.0)	1 (0.0)
ORLISTAT	0 (0.0)	1 (0.1)	1 (0.0)
ORPHENADRINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
OSELTAMIVIR	1 (0.1)	0 (0.0)	1 (0.0)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	1 (0.1)	0 (0.0)	1 (0.0)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	0 (0.0)	1 (0.1)	1 (0.0)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	0 (0.0)	1 (0.1)	1 (0.0)
OTHER ANTIPSORIATICS FOR TOPICAL USE	1 (0.1)	0 (0.0)	1 (0.0)
OTHER GYNECOLOGICALS	1 (0.1)	0 (0.0)	1 (0.0)
OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	0 (0.0)	1 (0.1)	1 (0.0)
OXYGEN	1 (0.1)	0 (0.0)	1 (0.0)
PARACETAMOL;PSEUDOEPHEDRINE	0 (0.0)	1 (0.1)	1 (0.0)
PARACETAMOL;PSEUDOEPHEDRINE;TRIPROLIDINE	0 (0.0)	1 (0.1)	1 (0.0)
PARAFFIN, LIQUID;POLYETHYLENE	0 (0.0)	1 (0.1)	1 (0.0)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	0 (0.0)	1 (0.1)	1 (0.0)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN;WOOL FAT	0 (0.0)	1 (0.1)	1 (0.0)
PARAMETHASONE	0 (0.0)	1 (0.1)	1 (0.0)
PASSIFLORA INCARNATA	0 (0.0)	1 (0.1)	1 (0.0)

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/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PEMAFIBRATE	1 (0.1)	0 (0.0)	1 (0.0)
PENICILLIN NOS	0 (0.0)	1 (0.1)	1 (0.0)
PHENYLEPHRINE	0 (0.0)	1 (0.1)	1 (0.0)
PINDOLOL	1 (0.1)	0 (0.0)	1 (0.0)
PIRIBEDIL	1 (0.1)	0 (0.0)	1 (0.0)
PLATYPHYLLINE	0 (0.0)	1 (0.1)	1 (0.0)
PORIA COCOS	1 (0.1)	0 (0.0)	1 (0.0)
PRAZOSIN	1 (0.1)	0 (0.0)	1 (0.0)
PROMESTRIENE	0 (0.0)	1 (0.1)	1 (0.0)
PROPYL GALLATE	1 (0.1)	0 (0.0)	1 (0.0)
PSYLLIUM HYDROPHILIC MUCILLOID	0 (0.0)	1 (0.1)	1 (0.0)
PYRIDOSTIGMINE	1 (0.1)	0 (0.0)	1 (0.0)
QUAZEPAM	0 (0.0)	1 (0.1)	1 (0.0)
RANIBIZUMAB	1 (0.1)	0 (0.0)	1 (0.0)
RASAGILINE	0 (0.0)	1 (0.1)	1 (0.0)
REBOXETINE	0 (0.0)	1 (0.1)	1 (0.0)
RESERPINE	1 (0.1)	0 (0.0)	1 (0.0)
RIVASTIGMINE	1 (0.1)	0 (0.0)	1 (0.0)
ROTIGOTINE	0 (0.0)	1 (0.1)	1 (0.0)
RUPATADINE	1 (0.1)	0 (0.0)	1 (0.0)
RUSCOGENIN;TRIMEBUTINE	1 (0.1)	0 (0.0)	1 (0.0)
SACUBITRIL;VALSARTAN	1 (0.1)	0 (0.0)	1 (0.0)
SALICYLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
SALMETEROL	1 (0.1)	0 (0.0)	1 (0.0)

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/t_gba_conmed_medical_history_event_posmp_saf3c1.rtf
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
SALVIA MILTIORRHIZA	1 (0.1)	0 (0.0)	1 (0.1)
SECUKINUMAB	1 (0.1)	0 (0.0)	1 (0.1)
SEVOFLURANE	1 (0.1)	0 (0.0)	1 (0.1)
SODA LIME	1 (0.1)	0 (0.0)	1 (0.1)
SOFT PARAFFIN AND FAT PRODUCTS	1 (0.1)	0 (0.0)	1 (0.1)
STREPTODORNASE;STREPTOKINASE	0 (0.0)	1 (0.1)	1 (0.1)
SUGAMMADEX	0 (0.0)	1 (0.1)	1 (0.1)
SULFACETAMIDE;SULFUR	0 (0.0)	1 (0.1)	1 (0.1)
SULFAMETHOXAZOLE;TRIMETHOPRIM	0 (0.0)	1 (0.1)	1 (0.1)
TEICOPLANIN	1 (0.1)	0 (0.0)	1 (0.1)
TENOXICAM	0 (0.0)	1 (0.1)	1 (0.1)
TERBUTALINE	1 (0.1)	0 (0.0)	1 (0.1)
TETRACYCLINE	1 (0.1)	0 (0.0)	1 (0.1)
THIOCOLCHICOSIDE	0 (0.0)	1 (0.1)	1 (0.1)
TIANEPTINE	0 (0.0)	1 (0.1)	1 (0.1)
TINZAPARIN	0 (0.0)	1 (0.1)	1 (0.1)
TOCOPHEROL;UBIDECARENONE;ZINC	1 (0.1)	0 (0.0)	1 (0.1)
TOCOPHERYL NICOTINATE	0 (0.0)	1 (0.1)	1 (0.1)
TOLPERISONE	0 (0.0)	1 (0.1)	1 (0.1)
TOPIROXOSTAT	0 (0.0)	1 (0.1)	1 (0.1)
TRADITIONAL CHINESE MEDICINE (TCM) DECOCTION	1 (0.1)	0 (0.0)	1 (0.1)
TRETINOIN	0 (0.0)	1 (0.1)	1 (0.1)
TRIMEBUTINE	0 (0.0)	1 (0.1)	1 (0.1)
TRIMETHOPRIM	1 (0.1)	0 (0.0)	1 (0.1)

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Medical History Event

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
TROPATEPINE	1 (0.1)	0 (0.0)	1 (0.0)
UREA	1 (0.1)	0 (0.0)	1 (0.0)
VARENICLINE	1 (0.1)	0 (0.0)	1 (0.0)
VITAMIN B NOS	0 (0.0)	1 (0.1)	1 (0.0)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12	0 (0.0)	1 (0.1)	1 (0.0)
VITAMIN K NOS	1 (0.1)	0 (0.0)	1 (0.0)
VITAMINS NOS	1 (0.1)	0 (0.0)	1 (0.0)
WHITE SOFT PARAFFIN	0 (0.0)	1 (0.1)	1 (0.0)
WITHANIA SOMNIFERA	0 (0.0)	1 (0.1)	1 (0.0)
WURFBAINIA VILLOSA	1 (0.1)	0 (0.0)	1 (0.0)
ZALEPLON	1 (0.1)	0 (0.0)	1 (0.0)
ZALTOPROFEN	1 (0.1)	0 (0.0)	1 (0.0)
ZINC	0 (0.0)	1 (0.1)	1 (0.0)
ZIPRASIDONE	1 (0.1)	0 (0.0)	1 (0.0)
ZOFENOPRIL	1 (0.1)	0 (0.0)	1 (0.0)
ZONISAMIDE	1 (0.1)	0 (0.0)	1 (0.0)

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Primary Study Condition

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
Subjects with >= 1 Medication	3 (0.2)	6 (0.5)	9 (0.4)
OXYCODONE	0 (0.0)	2 (0.2)	2 (0.1)
CINOBUFAGIN	0 (0.0)	1 (0.1)	1 (0.0)
CODEINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
CORDYCEPS SINENSIS;CORIDIUS CHINENSIS;CURCUMA LONGA;DOLOMIAEA COSTUS;FERULA SINKIANGENSIS;RHEUM PALMATUM;SYZYGIUM AROMATICUM;TERMINALIA CHEBULA	0 (0.0)	1 (0.1)	1 (0.0)
DULOXETINE	0 (0.0)	1 (0.1)	1 (0.0)
ERGOTAMINE	1 (0.1)	0 (0.0)	1 (0.0)
GABAPENTIN	0 (0.0)	1 (0.1)	1 (0.0)
LANSOPRAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
TRAMADOL	1 (0.1)	0 (0.0)	1 (0.0)

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Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_primary_study_condition_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 1 of 1
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis of Bone Loss

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
Subjects with >= 1 Medication	109 (8.5)	108 (8.5)	217 (8.5)
ZOLEDRONIC ACID	78 (6.1)	70 (5.5)	148 (5.8)
DENOSUMAB	12 (0.9)	20 (1.6)	32 (1.3)
ALENDRONIC ACID	10 (0.8)	14 (1.1)	24 (0.9)
RISEDRONIC ACID	5 (0.4)	3 (0.2)	8 (0.3)
IBANDRONIC ACID	3 (0.2)	4 (0.3)	7 (0.3)
ALENDRONIC ACID;COLECALCIFEROL	0 (0.0)	1 (0.1)	1 (0.0)
MINODRONIC ACID	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_of_bone_loss_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 1 of 1
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis of Bone Metastases

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
Subjects with >= 1 Medication	90 (7.0)	91 (7.2)	181 (7.1)
ZOLEDRONIC ACID	77 (6.0)	74 (5.9)	151 (5.9)
IBANDRONIC ACID	9 (0.7)	8 (0.6)	17 (0.7)
DENOSUMAB	4 (0.3)	5 (0.4)	9 (0.4)
ALENDRONIC ACID	3 (0.2)	5 (0.4)	8 (0.3)
CLODRONIC ACID	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_of_bone_metastases_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 1 of 48
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
Subjects with >= 1 Medication	823 (64.1)	781 (61.8)	1604 (63.0)
COLECALCIFEROL	106 (8.3)	127 (10.0)	233 (9.1)
COVID-19 VACCINE	93 (7.2)	81 (6.4)	174 (6.8)
CALCIUM CARBONATE;COLECALCIFEROL	79 (6.2)	92 (7.3)	171 (6.7)
VITAMIN D NOS	75 (5.8)	85 (6.7)	160 (6.3)
ACETYLSALICYLIC ACID	80 (6.2)	75 (5.9)	155 (6.1)
INFLUENZA VACCINE	77 (6.0)	67 (5.3)	144 (5.7)
LOPERAMIDE	128 (10.0)	4 (0.3)	132 (5.2)
PARACETAMOL	79 (6.2)	53 (4.2)	132 (5.2)
CALCIUM	62 (4.8)	64 (5.1)	126 (4.9)
OMEPRAZOLE	59 (4.6)	45 (3.6)	104 (4.1)
PANTOPRAZOLE	49 (3.8)	40 (3.2)	89 (3.5)
CALCIUM CARBONATE	46 (3.6)	38 (3.0)	84 (3.3)
ASCORBIC ACID	42 (3.3)	37 (2.9)	79 (3.1)
VITAMINS NOS	40 (3.1)	34 (2.7)	74 (2.9)
CALCIUM;COLECALCIFEROL	33 (2.6)	39 (3.1)	72 (2.8)
FISH OIL	31 (2.4)	35 (2.8)	66 (2.6)
VITAMIN B12 NOS	21 (1.6)	33 (2.6)	54 (2.1)
MAGNESIUM	21 (1.6)	32 (2.5)	53 (2.1)
CALCIUM;VITAMIN D NOS	22 (1.7)	30 (2.4)	52 (2.0)
ONDANSETRON	32 (2.5)	18 (1.4)	50 (2.0)
MULTIVITAMINS, PLAIN	24 (1.9)	25 (2.0)	49 (1.9)
VITAMIN B COMPLEX	25 (1.9)	24 (1.9)	49 (1.9)
ENOXAPARIN	31 (2.4)	17 (1.3)	48 (1.9)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BIOTIN	23 (1.8)	19 (1.5)	42 (1.6)
IBUPROFEN	27 (2.1)	15 (1.2)	42 (1.6)
ESOMEPRAZOLE	21 (1.6)	17 (1.3)	38 (1.5)
IRON	25 (1.9)	13 (1.0)	38 (1.5)
CEFALEXIN	21 (1.6)	14 (1.1)	35 (1.4)
CEFAZOLIN	18 (1.4)	17 (1.3)	35 (1.4)
RANITIDINE	22 (1.7)	13 (1.0)	35 (1.4)
POTASSIUM	21 (1.6)	12 (0.9)	33 (1.3)
CURCUMA LONGA	14 (1.1)	18 (1.4)	32 (1.3)
DEXAMETHASONE	19 (1.5)	12 (0.9)	31 (1.2)
LIDOCAINE	17 (1.3)	14 (1.1)	31 (1.2)
PNEUMOCOCCAL VACCINE	17 (1.3)	14 (1.1)	31 (1.2)
PROBIOTICS NOS	19 (1.5)	11 (0.9)	30 (1.2)
HEPARINOID	15 (1.2)	13 (1.0)	28 (1.1)
METOCLOPRAMIDE	16 (1.2)	12 (0.9)	28 (1.1)
PYRIDOXINE	17 (1.3)	11 (0.9)	28 (1.1)
REBAMIPIDE	12 (0.9)	16 (1.3)	28 (1.1)
FAMOTIDINE	14 (1.1)	13 (1.0)	27 (1.1)
FENTANYL	18 (1.4)	9 (0.7)	27 (1.1)
MIDAZOLAM	14 (1.1)	13 (1.0)	27 (1.1)
AMOXICILLIN	13 (1.0)	13 (1.0)	26 (1.0)
LANSOPRAZOLE	18 (1.4)	7 (0.6)	25 (1.0)
PROPOFOL	17 (1.3)	7 (0.6)	24 (0.9)
TOCOPHEROL	12 (0.9)	12 (0.9)	24 (0.9)

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Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CYANOCOBALAMIN	13 (1.0)	10 (0.8)	23 (0.9)
LORATADINE	11 (0.9)	11 (0.9)	22 (0.9)
SODIUM CHLORIDE	17 (1.3)	5 (0.4)	22 (0.9)
ZINC	10 (0.8)	12 (0.9)	22 (0.9)
CALCIUM CARBONATE;VITAMIN D NOS	6 (0.5)	15 (1.2)	21 (0.8)
HEPARIN	14 (1.1)	7 (0.6)	21 (0.8)
FOLIC ACID	17 (1.3)	3 (0.2)	20 (0.8)
GLUCOSAMINE	9 (0.7)	11 (0.9)	20 (0.8)
ERGOCALCIFEROL	11 (0.9)	8 (0.6)	19 (0.7)
METAMIZOLE	11 (0.9)	8 (0.6)	19 (0.7)
ATORVASTATIN	13 (1.0)	5 (0.4)	18 (0.7)
UBIDECARENONE	9 (0.7)	9 (0.7)	18 (0.7)
HERBAL PREPARATION	10 (0.8)	7 (0.6)	17 (0.7)
PROCHLORPERAZINE	10 (0.8)	7 (0.6)	17 (0.7)
VARICELLA ZOSTER VACCINE	9 (0.7)	8 (0.6)	17 (0.7)
DOCUSATE	7 (0.5)	9 (0.7)	16 (0.6)
LORAZEPAM	11 (0.9)	5 (0.4)	16 (0.6)
MINERALS NOS;VITAMINS NOS	7 (0.5)	9 (0.7)	16 (0.6)
PROMETHAZINE	11 (0.9)	5 (0.4)	16 (0.6)
TRAMADOL	9 (0.7)	7 (0.6)	16 (0.6)
ALPRAZOLAM	10 (0.8)	5 (0.4)	15 (0.6)
LIDOCAINE;PRILOCAINE	5 (0.4)	10 (0.8)	15 (0.6)
PLANTAGO OVATA	12 (0.9)	3 (0.2)	15 (0.6)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	7 (0.5)	8 (0.6)	15 (0.6)

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Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
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Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
VITAMIN E NOS	6 (0.5)	9 (0.7)	15 (0.6)
MAGNESIUM OXIDE	8 (0.6)	6 (0.5)	14 (0.5)
OXYCODONE	9 (0.7)	5 (0.4)	14 (0.5)
AMOXICILLIN;CLAVULANIC ACID	6 (0.5)	7 (0.6)	13 (0.5)
DIPHENHYDRAMINE	8 (0.6)	5 (0.4)	13 (0.5)
LACTULOSE	8 (0.6)	5 (0.4)	13 (0.5)
PREDNISOLONE	8 (0.6)	5 (0.4)	13 (0.5)
RABEPRAZOLE	9 (0.7)	4 (0.3)	13 (0.5)
RIVAROXABAN	8 (0.6)	5 (0.4)	13 (0.5)
CIPROFLOXACIN	8 (0.6)	4 (0.3)	12 (0.5)
DEXKETOPROFEN	8 (0.6)	4 (0.3)	12 (0.5)
LEVOTHYROXINE	4 (0.3)	8 (0.6)	12 (0.5)
TEPRENONE	4 (0.3)	8 (0.6)	12 (0.5)
CALCIUM CHLORIDE;POTASSIUM;SODIUM LACTATE	7 (0.5)	4 (0.3)	11 (0.4)
CEFCAPENE	4 (0.3)	7 (0.6)	11 (0.4)
DICLOFENAC	6 (0.5)	5 (0.4)	11 (0.4)
ZOLPIDEM	5 (0.4)	6 (0.5)	11 (0.4)
DIETARY SUPPLEMENT	6 (0.5)	4 (0.3)	10 (0.4)
IOHEXOL	4 (0.3)	6 (0.5)	10 (0.4)
PREGABALIN	4 (0.3)	6 (0.5)	10 (0.4)
SELENIUM	3 (0.2)	7 (0.6)	10 (0.4)
SIMETICONE	7 (0.5)	3 (0.2)	10 (0.4)
CELECOXIB	4 (0.3)	5 (0.4)	9 (0.4)
CHLORHEXIDINE	5 (0.4)	4 (0.3)	9 (0.4)

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Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CLINDAMYCIN	5 (0.4)	4 (0.3)	9 (0.4)
CLOPIDOGREL	5 (0.4)	4 (0.3)	9 (0.4)
CYANOCOBALAMIN;PYRIDOXINE;THIAMINE	6 (0.5)	3 (0.2)	9 (0.4)
EPINEPHRINE;LIDOCAINE	6 (0.5)	3 (0.2)	9 (0.4)
FEXOFENADINE	6 (0.5)	3 (0.2)	9 (0.4)
MULTIVITAMINS WITH MINERALS [UMBRELLA TERM]	4 (0.3)	5 (0.4)	9 (0.4)
ROCURONIUM	6 (0.5)	3 (0.2)	9 (0.4)
SACCHAROMYCES BOULARDII	8 (0.6)	1 (0.1)	9 (0.4)
SULFAMETHOXAZOLE;TRIMETHOPRIM	8 (0.6)	1 (0.1)	9 (0.4)
VITAMINS WITH MINERALS	5 (0.4)	4 (0.3)	9 (0.4)
APIXABAN	5 (0.4)	3 (0.2)	8 (0.3)
BISACODYL	7 (0.5)	1 (0.1)	8 (0.3)
CALCIFEDIOL	5 (0.4)	3 (0.2)	8 (0.3)
CEFUROXIME	3 (0.2)	5 (0.4)	8 (0.3)
CHLORPHENAMINE	5 (0.4)	3 (0.2)	8 (0.3)
CHONDROITIN;GLUCOSAMINE	4 (0.3)	4 (0.3)	8 (0.3)
CODEINE;PARACETAMOL	6 (0.5)	2 (0.2)	8 (0.3)
DIAZEPAM	2 (0.2)	6 (0.5)	8 (0.3)
ELDECALCITOL	5 (0.4)	3 (0.2)	8 (0.3)
FUROSEMIDE	7 (0.5)	1 (0.1)	8 (0.3)
HYALURONIC ACID	6 (0.5)	2 (0.2)	8 (0.3)
KETOPROFEN	5 (0.4)	3 (0.2)	8 (0.3)
MONTELUKAST	4 (0.3)	4 (0.3)	8 (0.3)
NAPROXEN	3 (0.2)	5 (0.4)	8 (0.3)

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Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
SIMVASTATIN	3 (0.2)	5 (0.4)	8 (0.3)
THIOCTIC ACID	4 (0.3)	4 (0.3)	8 (0.3)
VACCINIUM MACROCARPON	4 (0.3)	4 (0.3)	8 (0.3)
AZITHROMYCIN	5 (0.4)	2 (0.2)	7 (0.3)
CALCIUM CARBONATE;COLECALCIFEROL;SODIUM	4 (0.3)	3 (0.2)	7 (0.3)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	3 (0.2)	4 (0.3)	7 (0.3)
CEFADROXIL	4 (0.3)	3 (0.2)	7 (0.3)
CETIRIZINE	4 (0.3)	3 (0.2)	7 (0.3)
FLUCONAZOLE	4 (0.3)	3 (0.2)	7 (0.3)
HYDROMORPHONE	4 (0.3)	3 (0.2)	7 (0.3)
LACTOBACILLUS ACIDOPHILUS	3 (0.2)	4 (0.3)	7 (0.3)
MACROGOL 3350;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	3 (0.2)	4 (0.3)	7 (0.3)
MECOBALAMIN	5 (0.4)	2 (0.2)	7 (0.3)
MELATONIN	2 (0.2)	5 (0.4)	7 (0.3)
METFORMIN	4 (0.3)	3 (0.2)	7 (0.3)
MOSAPRIDE	2 (0.2)	5 (0.4)	7 (0.3)
OTHER EMOLLIENTS AND PROTECTIVES	3 (0.2)	4 (0.3)	7 (0.3)
PREDNISONE	5 (0.4)	2 (0.2)	7 (0.3)
ROSUVASTATIN	3 (0.2)	4 (0.3)	7 (0.3)
SEVOFLURANE	5 (0.4)	2 (0.2)	7 (0.3)
SULFADIAZINE	5 (0.4)	2 (0.2)	7 (0.3)
TINZAPARIN	6 (0.5)	1 (0.1)	7 (0.3)
VALACICLOVIR	6 (0.5)	1 (0.1)	7 (0.3)
VITAMINS, OTHER COMBINATIONS	6 (0.5)	1 (0.1)	7 (0.3)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ASCORBIC ACID;CALCIUM;MINERALS NOS;RETINOL;TOCOPHEROL;VITAMIN B NOS;VITAMINS NOS;ZINC	3 (0.2)	3 (0.2)	6 (0.2)
BISMUTH;RANITIDINE;SUCRALFATE	1 (0.1)	5 (0.4)	6 (0.2)
BISOPROLOL	4 (0.3)	2 (0.2)	6 (0.2)
BUTYLSCOPOLAMINE	6 (0.5)	0 (0.0)	6 (0.2)
CIMETIDINE	4 (0.3)	2 (0.2)	6 (0.2)
CLOSTRIDIUM BUTYRICUM	6 (0.5)	0 (0.0)	6 (0.2)
DIMETICONE	3 (0.2)	3 (0.2)	6 (0.2)
DOCUSATE;SENNOSIDE A+B	2 (0.2)	4 (0.3)	6 (0.2)
EPHEDRINE	4 (0.3)	2 (0.2)	6 (0.2)
FILGRASTIM	6 (0.5)	0 (0.0)	6 (0.2)
FLURBIPROFEN	2 (0.2)	4 (0.3)	6 (0.2)
FLUTICASONE	3 (0.2)	3 (0.2)	6 (0.2)
GENTAMICIN	4 (0.3)	2 (0.2)	6 (0.2)
HYDROCORTISONE	4 (0.3)	2 (0.2)	6 (0.2)
LEVOFLOXACIN	5 (0.4)	1 (0.1)	6 (0.2)
LYSINE	3 (0.2)	3 (0.2)	6 (0.2)
MAGNESIUM CITRATE	3 (0.2)	3 (0.2)	6 (0.2)
MAGNESIUM HYDROXIDE	3 (0.2)	3 (0.2)	6 (0.2)
NADROPARIN	2 (0.2)	4 (0.3)	6 (0.2)
PETHIDINE	4 (0.3)	2 (0.2)	6 (0.2)
SALBUTAMOL	2 (0.2)	4 (0.3)	6 (0.2)
SERTRALINE	4 (0.3)	2 (0.2)	6 (0.2)
SUGAMMADEX	5 (0.4)	1 (0.1)	6 (0.2)
ACETYLCYSTEINE	3 (0.2)	2 (0.2)	5 (0.2)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 8 of 48
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ACTAEA RACEMOSA	3 (0.2)	2 (0.2)	5 (0.2)
ALLOPURINOL	1 (0.1)	4 (0.3)	5 (0.2)
ANTIDIARRHEAL MICROORGANISMS	4 (0.3)	1 (0.1)	5 (0.2)
ASCORBIC ACID;CALCIUM PHOSPHATE;CITRIC ACID;COLECALCIFEROL	2 (0.2)	3 (0.2)	5 (0.2)
BACITRACIN	3 (0.2)	2 (0.2)	5 (0.2)
BETAMETHASONE	4 (0.3)	1 (0.1)	5 (0.2)
BUPIVACAINE	3 (0.2)	2 (0.2)	5 (0.2)
CALCIUM;ERGOCALCIFEROL	1 (0.1)	4 (0.3)	5 (0.2)
CANNABIS SATIVA	1 (0.1)	4 (0.3)	5 (0.2)
CEFTRIAXONE	5 (0.4)	0 (0.0)	5 (0.2)
CISATRACURIUM	4 (0.3)	1 (0.1)	5 (0.2)
COLLAGEN	2 (0.2)	3 (0.2)	5 (0.2)
CURCUMIN	2 (0.2)	3 (0.2)	5 (0.2)
DALTEPARIN	3 (0.2)	2 (0.2)	5 (0.2)
DOMPERIDONE	3 (0.2)	2 (0.2)	5 (0.2)
ESCITALOPRAM	2 (0.2)	3 (0.2)	5 (0.2)
ESTRADIOL	3 (0.2)	2 (0.2)	5 (0.2)
GADOTERIDOL	2 (0.2)	3 (0.2)	5 (0.2)
HYDROCHLOROTHIAZIDE	0 (0.0)	5 (0.4)	5 (0.2)
HYDROCODONE;PARACETAMOL	5 (0.4)	0 (0.0)	5 (0.2)
KETOROLAC	3 (0.2)	2 (0.2)	5 (0.2)
LEUCOGEN	3 (0.2)	2 (0.2)	5 (0.2)
LINUM USITATISSIMUM	1 (0.1)	4 (0.3)	5 (0.2)
LOXOPROFEN	2 (0.2)	3 (0.2)	5 (0.2)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
MACROGOL	3 (0.2)	2 (0.2)	5 (0.2)
MECLOZINE	3 (0.2)	2 (0.2)	5 (0.2)
METHYLPREDNISOLONE	2 (0.2)	3 (0.2)	5 (0.2)
MOMETASONE	2 (0.2)	3 (0.2)	5 (0.2)
MONASCUS PURPUREUS	2 (0.2)	3 (0.2)	5 (0.2)
MUPIROCIN	3 (0.2)	2 (0.2)	5 (0.2)
NICOTINE	1 (0.1)	4 (0.3)	5 (0.2)
OTHER OPHTHALMOLOGICALS	2 (0.2)	3 (0.2)	5 (0.2)
PARACETAMOL;TRAMADOL	4 (0.3)	1 (0.1)	5 (0.2)
PENTOXIFYLLINE	2 (0.2)	3 (0.2)	5 (0.2)
POLYSACCHARIDE-K	3 (0.2)	2 (0.2)	5 (0.2)
REMIFENTANIL	4 (0.3)	1 (0.1)	5 (0.2)
SODIUM BICARBONATE	2 (0.2)	3 (0.2)	5 (0.2)
SPIRONOLACTONE	2 (0.2)	3 (0.2)	5 (0.2)
TRANEXAMIC ACID	4 (0.3)	1 (0.1)	5 (0.2)
UREA	1 (0.1)	4 (0.3)	5 (0.2)
URSODEOXYCHOLIC ACID	3 (0.2)	2 (0.2)	5 (0.2)
WARFARIN	2 (0.2)	3 (0.2)	5 (0.2)
ACICLOVIR	4 (0.3)	0 (0.0)	4 (0.2)
AMITRIPTYLINE	3 (0.2)	1 (0.1)	4 (0.2)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHEROL;ZINC	3 (0.2)	1 (0.1)	4 (0.2)
ASCORBIC ACID;IRON	2 (0.2)	2 (0.2)	4 (0.2)
ATROPINE;DIPHENOXYLATE	3 (0.2)	1 (0.1)	4 (0.2)
BENZYDAMINE	2 (0.2)	2 (0.2)	4 (0.2)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BEZAFIBRATE	3 (0.2)	1 (0.1)	4 (0.2)
BIFIDOBACTERIUM NOS	3 (0.2)	1 (0.1)	4 (0.2)
BUDESONIDE	2 (0.2)	2 (0.2)	4 (0.2)
BUPROPION	1 (0.1)	3 (0.2)	4 (0.2)
CALCITRIOL;CALCIUM CARBONATE;ZINC	2 (0.2)	2 (0.2)	4 (0.2)
CITALOPRAM	2 (0.2)	2 (0.2)	4 (0.2)
COD-LIVER OIL	3 (0.2)	1 (0.1)	4 (0.2)
CYCLOBENZAPRINE	2 (0.2)	2 (0.2)	4 (0.2)
D-RIBOSE;PEPTIDES NOS	2 (0.2)	2 (0.2)	4 (0.2)
DEXCHLORPHENIRAMINE	3 (0.2)	1 (0.1)	4 (0.2)
DIOSMECTITE	4 (0.3)	0 (0.0)	4 (0.2)
DOXYCYCLINE	4 (0.3)	0 (0.0)	4 (0.2)
EPINEPHRINE	3 (0.2)	1 (0.1)	4 (0.2)
GLYCEROL	3 (0.2)	1 (0.1)	4 (0.2)
GLYCERYL TRINITRATE	2 (0.2)	2 (0.2)	4 (0.2)
GLYCOPYRRONIUM	3 (0.2)	1 (0.1)	4 (0.2)
HYDROXYZINE	3 (0.2)	1 (0.1)	4 (0.2)
HYOSCINE	2 (0.2)	2 (0.2)	4 (0.2)
HYPROMELLOSE	4 (0.3)	0 (0.0)	4 (0.2)
IODINE	1 (0.1)	3 (0.2)	4 (0.2)
IOPROMIDE	2 (0.2)	2 (0.2)	4 (0.2)
LAFUTIDINE	2 (0.2)	2 (0.2)	4 (0.2)
LORMETAZEPAM	1 (0.1)	3 (0.2)	4 (0.2)
MAGNESIUM CHLORIDE	1 (0.1)	3 (0.2)	4 (0.2)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
MAGNESIUM;PYRIDOXINE	1 (0.1)	3 (0.2)	4 (0.2)
METOPROLOL	3 (0.2)	1 (0.1)	4 (0.2)
METRONIDAZOLE	2 (0.2)	2 (0.2)	4 (0.2)
MORPHINE	2 (0.2)	2 (0.2)	4 (0.2)
MULTIVITAMINS, OTHER COMBINATIONS	1 (0.1)	3 (0.2)	4 (0.2)
NEOSTIGMINE	2 (0.2)	2 (0.2)	4 (0.2)
NITROFURANTOIN	2 (0.2)	2 (0.2)	4 (0.2)
NYSTATIN	1 (0.1)	3 (0.2)	4 (0.2)
OSELTAMIVIR	3 (0.2)	1 (0.1)	4 (0.2)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	3 (0.2)	1 (0.1)	4 (0.2)
OXYCODONE;PARACETAMOL	2 (0.2)	2 (0.2)	4 (0.2)
PANCREATIN	3 (0.2)	1 (0.1)	4 (0.2)
RAMIPRIL	3 (0.2)	1 (0.1)	4 (0.2)
RETINOL	2 (0.2)	2 (0.2)	4 (0.2)
ROPIVACAINE	4 (0.3)	0 (0.0)	4 (0.2)
SENNOSIDE A+B	2 (0.2)	2 (0.2)	4 (0.2)
SOTALOL	1 (0.1)	3 (0.2)	4 (0.2)
TEMAZEPAM	2 (0.2)	2 (0.2)	4 (0.2)
TRAZODONE	2 (0.2)	2 (0.2)	4 (0.2)
TRIAMCINOLONE	4 (0.3)	0 (0.0)	4 (0.2)
VITAMINS [UMBRELLA TERM]	1 (0.1)	3 (0.2)	4 (0.2)
VITIS VINIFERA	2 (0.2)	2 (0.2)	4 (0.2)
ACENOCOUMAROL	3 (0.2)	0 (0.0)	3 (0.1)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (0.2)	1 (0.1)	3 (0.1)

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ALBUMIN HUMAN	2 (0.2)	1 (0.1)	3 (0.1)
ALFACALCIDOL	2 (0.2)	1 (0.1)	3 (0.1)
ALLIUM SATIVUM	2 (0.2)	1 (0.1)	3 (0.1)
ALOE VERA	1 (0.1)	2 (0.2)	3 (0.1)
ALTEPLASE	1 (0.1)	2 (0.2)	3 (0.1)
AMLODIPINE	3 (0.2)	0 (0.0)	3 (0.1)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PHOSPHATE;CHROMIUM;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FOLIC ACID;IODINE;IRON;MAGNESIUM OXIDE;MANGANESE;MOLYBDENUM;NICOTINAMIDE;	3 (0.2)	0 (0.0)	3 (0.1)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CHROMIUM;COLECALCIFEROL;CUPRIC OXIDE;CYANOCOBALAMIN;DL-ALPHA TOCOPHEROL;FOLIC ACID;IRON;MAGNESIUM OXIDE;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;	2 (0.2)	1 (0.1)	3 (0.1)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;FURSULTIAMINE;IRON;NICOTINAMIDE;PYRIDOXINE;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC	2 (0.2)	1 (0.1)	3 (0.1)
ASCORBIC ACID;PANTOTHENIC ACID	0 (0.0)	3 (0.2)	3 (0.1)
ATROPINE	3 (0.2)	0 (0.0)	3 (0.1)
BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS	3 (0.2)	0 (0.0)	3 (0.1)
BIFIDOBACTERIUM LACTIS;COLOSTRUM;LACTOBACILLUS ACIDOPHILUS	2 (0.2)	1 (0.1)	3 (0.1)
BROMFENAC	2 (0.2)	1 (0.1)	3 (0.1)
BROMOPRIDE	1 (0.1)	2 (0.2)	3 (0.1)
CALCIUM CARBONATE;ERGOCALCIFEROL	1 (0.1)	2 (0.2)	3 (0.1)
CAMELLIA SINENSIS	0 (0.0)	3 (0.2)	3 (0.1)
CANNABIDIOL	1 (0.1)	2 (0.2)	3 (0.1)
CARBOMER	1 (0.1)	2 (0.2)	3 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CARMELLOSE	2 (0.2)	1 (0.1)	3 (0.1)
CEFALOTIN	2 (0.2)	1 (0.1)	3 (0.1)
CEFEPIME	3 (0.2)	0 (0.0)	3 (0.1)
CEFPIRAMIDE	2 (0.2)	1 (0.1)	3 (0.1)
CEFPODOXIME	2 (0.2)	1 (0.1)	3 (0.1)
CLOBETASOL	3 (0.2)	0 (0.0)	3 (0.1)
CLONAZEPAM	2 (0.2)	1 (0.1)	3 (0.1)
DESLORATADINE	1 (0.1)	2 (0.2)	3 (0.1)
DEXAMETHASONE;NEOMYCIN;POLYMYXIN B	2 (0.2)	1 (0.1)	3 (0.1)
DEXIBUPROFEN	1 (0.1)	2 (0.2)	3 (0.1)
DEXMEDETOMIDINE	2 (0.2)	1 (0.1)	3 (0.1)
DICYCLOVERINE	3 (0.2)	0 (0.0)	3 (0.1)
DIMENHYDRINATE;PYRIDOXINE	2 (0.2)	1 (0.1)	3 (0.1)
DIOSMIN;HESPERIDIN	2 (0.2)	1 (0.1)	3 (0.1)
DIPHENHYDRAMINE;PARACETAMOL	3 (0.2)	0 (0.0)	3 (0.1)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	3 (0.2)	0 (0.0)	3 (0.1)
DULOXETINE	1 (0.1)	2 (0.2)	3 (0.1)
ENTEROCOCCUS FAECALIS	1 (0.1)	2 (0.2)	3 (0.1)
ERYTHROPOIETIN	3 (0.2)	0 (0.0)	3 (0.1)
EZETIMIBE	2 (0.2)	1 (0.1)	3 (0.1)
FLUNARIZINE	1 (0.1)	2 (0.2)	3 (0.1)
GINKGO BILOBA	1 (0.1)	2 (0.2)	3 (0.1)
GLUCOSE	1 (0.1)	2 (0.2)	3 (0.1)
GRANISETRON	2 (0.2)	1 (0.1)	3 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
HYDROCODONE	2 (0.2)	1 (0.1)	3 (0.1)
IRON IN OTHER COMBINATIONS	2 (0.2)	1 (0.1)	3 (0.1)
ITOPRIDE	2 (0.2)	1 (0.1)	3 (0.1)
KETAMINE	2 (0.2)	1 (0.1)	3 (0.1)
KETOCONAZOLE	0 (0.0)	3 (0.2)	3 (0.1)
KRILL OIL	1 (0.1)	2 (0.2)	3 (0.1)
LEVETIRACETAM	1 (0.1)	2 (0.2)	3 (0.1)
LEVOCETIRIZINE	2 (0.2)	1 (0.1)	3 (0.1)
LEVOGLUTAMIDE	3 (0.2)	0 (0.0)	3 (0.1)
LEVOSULPIRIDE	2 (0.2)	1 (0.1)	3 (0.1)
LOTEPREDNOL	2 (0.2)	1 (0.1)	3 (0.1)
MACROGOL 3350	3 (0.2)	0 (0.0)	3 (0.1)
MACROGOL;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	2 (0.2)	1 (0.1)	3 (0.1)
MAGNESIUM;POTASSIUM ASPARTATE	1 (0.1)	2 (0.2)	3 (0.1)
MANNITOL	3 (0.2)	0 (0.0)	3 (0.1)
METHENAMINE	1 (0.1)	2 (0.2)	3 (0.1)
NALOXONE	2 (0.2)	1 (0.1)	3 (0.1)
NICOTINIC ACID	2 (0.2)	1 (0.1)	3 (0.1)
NIMESULIDE	2 (0.2)	1 (0.1)	3 (0.1)
OMEGA-3 FATTY ACIDS	2 (0.2)	1 (0.1)	3 (0.1)
OMEGA-3-ACID ETHYL ESTER	1 (0.1)	2 (0.2)	3 (0.1)
PAPAVERINE	3 (0.2)	0 (0.0)	3 (0.1)
PARAFFIN, LIQUID	1 (0.1)	2 (0.2)	3 (0.1)
PARECOXIB	2 (0.2)	1 (0.1)	3 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PHENIRAMINE	3 (0.2)	0 (0.0)	3 (0.1)
PHENYLEPHRINE	2 (0.2)	1 (0.1)	3 (0.1)
PHOSPHOLIPIDS	1 (0.1)	2 (0.2)	3 (0.1)
PIROXICAM	1 (0.1)	2 (0.2)	3 (0.1)
POVIDONE-IODINE	1 (0.1)	2 (0.2)	3 (0.1)
QUETIAPINE	2 (0.2)	1 (0.1)	3 (0.1)
SACCHAROMYCES CEREVISIAE	2 (0.2)	1 (0.1)	3 (0.1)
SILYBUM MARIANUM	0 (0.0)	3 (0.2)	3 (0.1)
SODIUM FLUORIDE	2 (0.2)	1 (0.1)	3 (0.1)
SUCRALFATE	2 (0.2)	1 (0.1)	3 (0.1)
SUXAMETHONIUM	2 (0.2)	1 (0.1)	3 (0.1)
TAPENTADOL	1 (0.1)	2 (0.2)	3 (0.1)
TRANILAST	0 (0.0)	3 (0.2)	3 (0.1)
VARENICLINE	0 (0.0)	3 (0.2)	3 (0.1)
VECURONIUM	1 (0.1)	2 (0.2)	3 (0.1)
VENLAFAXINE	2 (0.2)	1 (0.1)	3 (0.1)
VITAMIN B NOS	1 (0.1)	2 (0.2)	3 (0.1)
VONOPRAZAN	0 (0.0)	3 (0.2)	3 (0.1)
WHITE SOFT PARAFFIN	2 (0.2)	1 (0.1)	3 (0.1)
YEAST DRIED	3 (0.2)	0 (0.0)	3 (0.1)
ACETAZOLAMIDE	1 (0.1)	1 (0.1)	2 (0.1)
ADENINE;BIFENDATE;CARNITINE;CYANOCOBALAMIN;LIVER;PYRIDOXINE;RIBOFLAVIN	1 (0.1)	1 (0.1)	2 (0.1)
ALBENDAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
ALMAGATE	1 (0.1)	1 (0.1)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ALPHA-AMYLASE SWINE PANCREAS;CELLULASE;LIPASE;PROTEASE NOS	0 (0.0)	2 (0.2)	2 (0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	0 (0.0)	2 (0.2)	2 (0.1)
AMYGDALIN	0 (0.0)	2 (0.2)	2 (0.1)
AMYLASE;ASCORBIC ACID;CELLULASE;FOLIC ACID;LIPASE;PROTEASE NOS	1 (0.1)	1 (0.1)	2 (0.1)
APROTININ;CALCIUM CHLORIDE;FACTOR I (FIBRINOGEN);THROMBIN	2 (0.2)	0 (0.0)	2 (0.1)
ARTEMISIA ARGYI	1 (0.1)	1 (0.1)	2 (0.1)
ASCORBIC ACID;CYSTEINE;PANTOTHENIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
ASCORBIC ACID;DEXPANTHENOL;ERGOCALCIFEROL;NICOTINAMIDE;PYRIDOXINE;RETINOL;RIBOFLAVIN;THIAMINE;TOCOPHEROL	2 (0.2)	0 (0.0)	2 (0.1)
ASCORBIC ACID;HESPERIDIN;RUSCUS ACULEATUS	2 (0.2)	0 (0.0)	2 (0.1)
ASCORBIC ACID;THIAMINE	0 (0.0)	2 (0.2)	2 (0.1)
ASCORBIC ACID;VITAMIN D NOS	2 (0.2)	0 (0.0)	2 (0.1)
ATOVAQUONE;PROGUANIL	1 (0.1)	1 (0.1)	2 (0.1)
AZELASTINE	1 (0.1)	1 (0.1)	2 (0.1)
BACLOFEN	1 (0.1)	1 (0.1)	2 (0.1)
BATILOL	1 (0.1)	1 (0.1)	2 (0.1)
BECLOMETASONE;FORMOTEROL	1 (0.1)	1 (0.1)	2 (0.1)
BETAMETHASONE;GENTAMICIN	0 (0.0)	2 (0.2)	2 (0.1)
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM INFANTIS;BIFIDOBACTERIUM LONGUM;LACTIPLANTIBACILLUS PLANTARUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS PARACASEI;	1 (0.1)	1 (0.1)	2 (0.1)
BIOTIN;BROMELAINS;LECITHIN;PAPAIN;SELENIUM	0 (0.0)	2 (0.2)	2 (0.1)
BISMUTH	1 (0.1)	1 (0.1)	2 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BOSWELLIA SERRATA	1 (0.1)	1 (0.1)	2 (0.1)
BOTULINUM TOXIN TYPE A	1 (0.1)	1 (0.1)	2 (0.1)
BRASSICA OLERACEA	1 (0.1)	1 (0.1)	2 (0.1)
BROMELAINS	0 (0.0)	2 (0.2)	2 (0.1)
BUPRENORPHINE	2 (0.2)	0 (0.0)	2 (0.1)
BUSPIRONE	0 (0.0)	2 (0.2)	2 (0.1)
CAFFEINE;METAMIZOLE;ORPHENADRINE	2 (0.2)	0 (0.0)	2 (0.1)
CAFFEINE;PARACETAMOL;PROMETHAZINE;SALICYLAMIDE	0 (0.0)	2 (0.2)	2 (0.1)
CALCITRIOL	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL;COPPER;MAGNESIUM;MANGANESE;ZINC	2 (0.2)	0 (0.0)	2 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL;PHYTOMENADIONE	2 (0.2)	0 (0.0)	2 (0.1)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE	0 (0.0)	2 (0.2)	2 (0.1)
CALCIUM GLUCONATE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM PHOSPHATE;COLECALCIFEROL	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM;CALCIUM CARBONATE	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM;COLECALCIFEROL;MENAQUINONE-7	0 (0.0)	2 (0.2)	2 (0.1)
CALCIUM;VITAMIN D NOS;VITAMIN K NOS	1 (0.1)	1 (0.1)	2 (0.1)
CEFACLOR	0 (0.0)	2 (0.2)	2 (0.1)
CEFDINIR	1 (0.1)	1 (0.1)	2 (0.1)
CEFMETAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
CICLOSPORIN	2 (0.2)	0 (0.0)	2 (0.1)
CILOSTAZOL	1 (0.1)	1 (0.1)	2 (0.1)

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/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CLARITHROMYCIN	1 (0.1)	1 (0.1)	2 (0.1)
COCOS NUCIFERA	1 (0.1)	1 (0.1)	2 (0.1)
COLECALCIFEROL;MENAQUINONE	2 (0.2)	0 (0.0)	2 (0.1)
CORYDALIS YANHUSUO;IPOMOEA NIL	1 (0.1)	1 (0.1)	2 (0.1)
CYANOCOBALAMIN;FOLIC ACID	2 (0.2)	0 (0.0)	2 (0.1)
CYANOCOBALAMIN;FURSULTIAMINE;ORYZANOL;PYRIDOXINE;TOCOPHEROL	1 (0.1)	1 (0.1)	2 (0.1)
CYANOCOBALAMIN;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	1 (0.1)	2 (0.1)
DABIGATRAN	0 (0.0)	2 (0.2)	2 (0.1)
DEMANNOSE;VACCINIUM MACROCARPON	2 (0.2)	0 (0.0)	2 (0.1)
DEXTROMETHORPHAN	2 (0.2)	0 (0.0)	2 (0.1)
DIMENHYDRINATE	1 (0.1)	1 (0.1)	2 (0.1)
DIOSMIN	2 (0.2)	0 (0.0)	2 (0.1)
DIPHTHERIA VACCINE;TETANUS VACCINE	1 (0.1)	1 (0.1)	2 (0.1)
DOMPERIDONE;PANTOPRAZOLE	0 (0.0)	2 (0.2)	2 (0.1)
DROPERIDOL	1 (0.1)	1 (0.1)	2 (0.1)
ELWENDIA PERSICA	0 (0.0)	2 (0.2)	2 (0.1)
EMULSIFYING WAX;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (0.1)	1 (0.1)	2 (0.1)
ERGOCALCIFEROL;RETINOL	1 (0.1)	1 (0.1)	2 (0.1)
ESMOLOL	2 (0.2)	0 (0.0)	2 (0.1)
ETORICOXIB	1 (0.1)	1 (0.1)	2 (0.1)
EZETIMIBE;ROSUVASTATIN	0 (0.0)	2 (0.2)	2 (0.1)
FLUCLOXACILLIN	2 (0.2)	0 (0.0)	2 (0.1)
FLUMAZENIL	1 (0.1)	1 (0.1)	2 (0.1)
FLUOROMETHOLONE	2 (0.2)	0 (0.0)	2 (0.1)

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/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
FOLIC ACID;IRON	1 (0.1)	1 (0.1)	2 (0.1)
FUSIDIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
GABAPENTIN	1 (0.1)	1 (0.1)	2 (0.1)
GARCINIA GUMMI-GUTTA	1 (0.1)	1 (0.1)	2 (0.1)
GATIFLOXACIN	0 (0.0)	2 (0.2)	2 (0.1)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM CITRATE	2 (0.2)	0 (0.0)	2 (0.1)
GRAMICIDIN;NEOMYCIN;NYSTATIN;TRIAMCINOLONE	1 (0.1)	1 (0.1)	2 (0.1)
GRANULOCYTE COLONY STIMULATING FACTOR	0 (0.0)	2 (0.2)	2 (0.1)
GUAIAZULENE	1 (0.1)	1 (0.1)	2 (0.1)
GUALENIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
HEPATITIS A VACCINE	1 (0.1)	1 (0.1)	2 (0.1)
HEPATITIS VACCINES	1 (0.1)	1 (0.1)	2 (0.1)
HERBAL URINARY ANTISEPTICS AND ANTIINFECTIVES	1 (0.1)	1 (0.1)	2 (0.1)
HOMEOPATHIC PREPARATION	1 (0.1)	1 (0.1)	2 (0.1)
HYDRALAZINE	2 (0.2)	0 (0.0)	2 (0.1)
INDOCYANINE GREEN	2 (0.2)	0 (0.0)	2 (0.1)
INULIN	1 (0.1)	1 (0.1)	2 (0.1)
IPRATROPIUM	0 (0.0)	2 (0.2)	2 (0.1)
IRON PREPARATIONS	1 (0.1)	1 (0.1)	2 (0.1)
LACTOBACILLUS NOS	2 (0.2)	0 (0.0)	2 (0.1)
LACTOBACILLUS RHAMNOSUS	2 (0.2)	0 (0.0)	2 (0.1)
LAMIVUDINE	2 (0.2)	0 (0.0)	2 (0.1)
LATANOPROST	1 (0.1)	1 (0.1)	2 (0.1)
LISINOPRIL	1 (0.1)	1 (0.1)	2 (0.1)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
LORATADINE;PSEUDOEPHEDRINE	2 (0.2)	0 (0.0)	2 (0.1)
MACROGOL 400;PROPYLENE GLYCOL	2 (0.2)	0 (0.0)	2 (0.1)
MAGNESIUM CARBONATE;MAGNESIUM OXIDE	2 (0.2)	0 (0.0)	2 (0.1)
MAGNESIUM SULFATE	2 (0.2)	0 (0.0)	2 (0.1)
MALUS SPP.	0 (0.0)	2 (0.2)	2 (0.1)
MEGESTROL	2 (0.2)	0 (0.0)	2 (0.1)
MENAQUINONE	1 (0.1)	1 (0.1)	2 (0.1)
MENINGOCOCCAL VACCINE	1 (0.1)	1 (0.1)	2 (0.1)
METHYLSULFONYLMETHANE	0 (0.0)	2 (0.2)	2 (0.1)
MILNACIPRAN	2 (0.2)	0 (0.0)	2 (0.1)
MINOXIDIL	2 (0.2)	0 (0.0)	2 (0.1)
NALOXONE;OXYCODONE	1 (0.1)	1 (0.1)	2 (0.1)
NICARDIPINE	1 (0.1)	1 (0.1)	2 (0.1)
NITAZOXANIDE	2 (0.2)	0 (0.0)	2 (0.1)
NUTRIENTS NOS	2 (0.2)	0 (0.0)	2 (0.1)
OCTANOIC ACID	1 (0.1)	1 (0.1)	2 (0.1)
OENOTHERA BIENNIS	0 (0.0)	2 (0.2)	2 (0.1)
OFLOXACIN	1 (0.1)	1 (0.1)	2 (0.1)
OTILONIUM	2 (0.2)	0 (0.0)	2 (0.1)
OXETACAINE	0 (0.0)	2 (0.2)	2 (0.1)
PERINDOPRIL	2 (0.2)	0 (0.0)	2 (0.1)
PERIPLANETA AMERICANA	1 (0.1)	1 (0.1)	2 (0.1)
PHENAZOPYRIDINE	2 (0.2)	0 (0.0)	2 (0.1)
PHENOXYMETHYLPENICILLIN	2 (0.2)	0 (0.0)	2 (0.1)

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PLATYCODON GRANDIFLORUS	1 (0.1)	1 (0.1)	2 (0.1)
POLYENE PHOSPHATIDYLCHOLINE	1 (0.1)	1 (0.1)	2 (0.1)
POTASSIUM PHOSPHATE	1 (0.1)	1 (0.1)	2 (0.1)
PRAVASTATIN	0 (0.0)	2 (0.2)	2 (0.1)
PROPRANOLOL	1 (0.1)	1 (0.1)	2 (0.1)
PRUNUS CERASUS	0 (0.0)	2 (0.2)	2 (0.1)
PSEUDOEPHEDRINE	1 (0.1)	1 (0.1)	2 (0.1)
PYRIDOXAL	2 (0.2)	0 (0.0)	2 (0.1)
QUERCETIN	0 (0.0)	2 (0.2)	2 (0.1)
RAMOSETRON	2 (0.2)	0 (0.0)	2 (0.1)
SILICON DIOXIDE	1 (0.1)	1 (0.1)	2 (0.1)
SODIUM CITRATE;SODIUM LAURYL SULFOACETATE;SORBITOL	2 (0.2)	0 (0.0)	2 (0.1)
SODIUM PHOSPHATE	1 (0.1)	1 (0.1)	2 (0.1)
SODIUM PICOSULFATE	2 (0.2)	0 (0.0)	2 (0.1)
SPIRULINA SPP.	1 (0.1)	1 (0.1)	2 (0.1)
SULFAMETHOXAZOLE	1 (0.1)	1 (0.1)	2 (0.1)
THIAMINE	0 (0.0)	2 (0.2)	2 (0.1)
THROMBIN	2 (0.2)	0 (0.0)	2 (0.1)
TRAMETES VERSICOLOR	1 (0.1)	1 (0.1)	2 (0.1)
TYPHOID VACCINE	2 (0.2)	0 (0.0)	2 (0.1)
UBENIMEX	2 (0.2)	0 (0.0)	2 (0.1)
VACCINIUM SPP.	0 (0.0)	2 (0.2)	2 (0.1)
VANCOMYCIN	2 (0.2)	0 (0.0)	2 (0.1)
VISCUM ALBUM	2 (0.2)	0 (0.0)	2 (0.1)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 22 of 48
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
VITAMIN K NOS	1 (0.1)	1 (0.1)	2 (0.1)
WITHANIA SOMNIFERA	1 (0.1)	1 (0.1)	2 (0.1)
XANTOFYL	1 (0.1)	1 (0.1)	2 (0.1)
ZINGIBER OFFICINALE	0 (0.0)	2 (0.2)	2 (0.1)
ABSORBABLE GELATIN SPONGE	1 (0.1)	0 (0.0)	1 (0.0)
ACECLOFENAC	0 (0.0)	1 (0.1)	1 (0.0)
ACEMETACIN	0 (0.0)	1 (0.1)	1 (0.0)
ACETIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLCARNITINE;ASCORBIC ACID;PHENYLALANINE;TAURINE;TYROSINE	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLCARNITINE;GLYCEROPHOSPHOETHANOLAMINE;PYRIDOXINE;THIOCTIC ACID;VITAMIN E NOS	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLSALICYLIC ACID;ALUMINIUM HYDROXIDE;CAFFEINE;MEPYRAMINE	1 (0.1)	0 (0.0)	1 (0.0)
ACETYLSALICYLIC ACID;MAGNESIUM HYDROXIDE	0 (0.0)	1 (0.1)	1 (0.0)
ACHILLEA MILLEFOLIUM;ACONITUM NAPELLUS;ARNICA MONTANA;ATROPA BELLA-DONNA;BELLIS PERENNIS;CALCIUM SULFIDE;CALENDULA OFFICINALIS;ECHINACEA ANGUSTIFOLIA;ECHINACEA PURPUREA;HAMAMELIS VIRGINIANA;	0 (0.0)	1 (0.1)	1 (0.0)
ACONITUM SPP.;BRYONIA SPP.;FERROUS PHOSPHATE;GENTIANA SPP.;SARCOLACTIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
ADEMETIONINE	0 (0.0)	1 (0.1)	1 (0.0)
ADIPHENINE;METAMIZOLE;PROMETHAZINE	0 (0.0)	1 (0.1)	1 (0.0)
AGOMELATINE	0 (0.0)	1 (0.1)	1 (0.0)
ALANINE;ARGININE;ASPARTIC ACID;CYSTEINE;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN;TYROSINE;VALINE	1 (0.1)	0 (0.0)	1 (0.0)
ALANINE;ARGININE;CYSTEINE;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PHOSPHORIC ACID;PROLINE;SERINE;THREONINE;TRYPTOPHAN;VALINE	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 23 of 48
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ALANINE;ARGININE;CYSTEINE;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN;VALINE	1 (0.1)	0 (0.0)	1 (0.0)
ALDIOXA	1 (0.1)	0 (0.0)	1 (0.0)
ALDIOXA;SIMALDRATE	1 (0.1)	0 (0.0)	1 (0.0)
ALGINIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
ALGINIC ACID;ALUMINIUM HYDROXIDE;CALCIUM CARBONATE;SODIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.0)
ALGINIC ACID;POTASSIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
ALGINIC ACID;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ATRACTYLODES LANCEA;BUPLEURUM FALCATUM;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PANAX GINSENG;PINELLIA TERNATA;POLYPORUS UMBELLATUS;PORIA COCOS;	1 (0.1)	0 (0.0)	1 (0.0)
ALIZAPRIDE	1 (0.1)	0 (0.0)	1 (0.0)
ALLANTOIN;ALOE VERA;COLLAGEN;HYALURONIC ACID;LIDOCAINE	0 (0.0)	1 (0.1)	1 (0.0)
ALLANTOIN;ALUMINIUM HYDROXIDE	0 (0.0)	1 (0.1)	1 (0.0)
ALLANTOIN;DIETHYLENE GLYCOL MONOSTEARATE;DIMETICONE;ISOPROPYL MYRISTATE;LANOLIN OIL;PARAFFIN, LIQUID;PROPYLENE GLYCOL;STEARIC ACID;TOCOPHEROL;TROLAMINE	1 (0.1)	0 (0.0)	1 (0.0)
ALUMINIUM HYDROXIDE	1 (0.1)	0 (0.0)	1 (0.0)
ALUMINIUM HYDROXIDE-MAGNESIUM CARBONATE GEL;ALUMINIUM MAGNESIUM SILICATE;GLUCOSE;GLYCYRRHIZA GLABRA	1 (0.1)	0 (0.0)	1 (0.0)
ALUMINIUM HYDROXIDE;CALCIUM CARBONATE;MAGNESIUM CARBONATE;OXETACAINE	0 (0.0)	1 (0.1)	1 (0.0)
ALUMINIUM HYDROXIDE;MAGNESIUM CARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
ALVERINE	0 (0.0)	1 (0.1)	1 (0.0)
AMANTADINE	1 (0.1)	0 (0.0)	1 (0.0)
AMBROXOL	1 (0.1)	0 (0.0)	1 (0.0)

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Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 24 of 48
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
AMBROXOL ACEFYLLINATE	0 (0.0)	1 (0.1)	1 (0.0)
AMIKACIN	0 (0.0)	1 (0.1)	1 (0.0)
AMILORIDE;HYDROCHLOROTHIAZIDE	0 (0.0)	1 (0.1)	1 (0.0)
AMINO ACIDS NOS	1 (0.1)	0 (0.0)	1 (0.0)
AMINO ACIDS NOS;AMINOBENZOIC ACID;ASCORBIC ACID;BETAINE;BIOFLAVONOIDS NOS;BIOTIN;CHOLINE;DEOXYRIBONUCLEIC ACID;EQUISETUM ARVENSE;FOLIC ACID;INOSITOL;LECITHIN;MACROCYSTIS PYRIFERA;MINERALS NOS;	0 (0.0)	1 (0.1)	1 (0.0)
AMINO ACIDS NOS;CHLORAMPHENICOL;METHIONINE;RETINOL	1 (0.1)	0 (0.0)	1 (0.0)
AMINO ACIDS NOS;ENZYMES NOS;MINERALS NOS;NICOTINAMIDE;PROTEINS NOS;VITAMIN B NOS	1 (0.1)	0 (0.0)	1 (0.0)
AMINO ACIDS NOS;GLUCOSE;LIPIDS NOS	0 (0.0)	1 (0.1)	1 (0.0)
AMINO ACIDS NOS;HERBAL NOS;MINERALS NOS;VITAMINS NOS	1 (0.1)	0 (0.0)	1 (0.0)
AMINO ACIDS NOS;MINERALS NOS;VITAMINS NOS	0 (0.0)	1 (0.1)	1 (0.0)
AMINOBENZOIC ACID;ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE;CHOLINE;COLECALCIFEROL;CYANOCOBALAMIN;DL-ALPHA TOCOPHEROL;EQUISETUM ARVENSE;FOLIC ACID;GELATINE HYDROLYSATE;INOSITOL;MAGNESIUM OXIDE;	1 (0.1)	0 (0.0)	1 (0.0)
AMPICILLIN;PHENAZOPYRIDINE	1 (0.1)	0 (0.0)	1 (0.0)
ANANAS COMOSUS;COPPER;OENOTHERA BIENNIS;OMEGA-3 FATTY ACIDS;RETINOL;VITAMIN E NOS	1 (0.1)	0 (0.0)	1 (0.0)
ANDROGRAPHIS PANICULATA;ASCORBIC ACID;ECHINACEA PURPUREA;OLEA EUROPAEA;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ANEMARRHENA ASPHODELOIDES;CULLEN CORYLIFOLIUM;DIPSACUS ASPER;EPIMEDIUM SPP.;REHMANNIA GLUTINOSA;SALVIA MILTIORRHIZA	1 (0.1)	0 (0.0)	1 (0.0)
ANESTHETICS	0 (0.0)	1 (0.1)	1 (0.0)
ANNONA MURICATA	0 (0.0)	1 (0.1)	1 (0.0)
ANTIBIOTICS-RESISTANT LACTIC ACID BACTERIAE	0 (0.0)	1 (0.1)	1 (0.0)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	0 (0.0)	1 (0.1)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 25 of 48
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
APREPITANT	1 (0.1)	0 (0.0)	1 (0.0)
ARGININE	1 (0.1)	0 (0.0)	1 (0.0)
ARGININE;BETA-ALANINE;CYSTEINE;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN;VALINE	1 (0.1)	0 (0.0)	1 (0.0)
ARIPIPRAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
ARTICAINE;EPINEPHRINE	1 (0.1)	0 (0.0)	1 (0.0)
ASARUM SPP.;EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PINELLIA TERNATA;SCHISANDRA CHINENSIS;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.0)
ASCOPHYLLUM NODOSUM	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;BETACAROTENE;BIOTIN;BORIC ACID;CALCIUM PHOSPHATE;CHROMIUM;COLECALCIFEROL;CYANOCOBALAMIN;EQUISETUM ARVENSE;FOLIC ACID;IODINE;IRON;MAGNESIUM CHELATE;MOLYBDENUM;NICOTINAMIDE;	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PHOSPHATE;CHROMIUM;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;DL-ALPHA TOCOPHEROL;FOLIC ACID;IODINE;IRON;LYCOPENE;MAGNESIUM OXIDE;MANGANESE;	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CHLORIDE;CHROMIUM;COPPER;FOLIC ACID;IODINE;IRON;MAGNESIUM;MANGANESE;MOLYBDENUM;NICKEL;NICOTINIC ACID;PANTOTHENIC ACID;PHOSPHORUS;POTASSIUM;PYRIDOXINE;	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CHROMIUM;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FOLIC ACID;IODINE;IRON;MAGNESIUM;MANGANESE;MOLYBDENUM;NICOTINIC ACID;PANTOTHENIC ACID;PHOSPHORUS;PYRIDOXINE;	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;BETACAROTENE;BIOTIN;EQUISETUM ARVENSE;FOLIC ACID;IRON;MANGANESE;PANTOTHENIC ACID;SILICON DIOXIDE;ZINC	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 26 of 48
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ASCORBIC ACID;BETACAROTENE;CALCIUM CARBONATE;CALCIUM SILICATE;CELLULOSE MICROCRYSTALLINE;COLECALCIFEROL;CROSCARMELLOSE;CYANOCOBALAMIN;DEXTRIN;DL-ALPHA TOCOPHEROL;FOLIC ACID;GELATIN;GLUCOSE;	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;BETACAROTENE;COPPER;TOCOPHEROL;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;BIOFLAVONOIDS NOS;MAGNESIUM HYDROXIDE;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;BIOTIN;CALCIUM CARBONATE;CHROMIUM;COLECALCIFEROL;CUPRIC OXIDE;CYANOCOBALAMIN;FOLIC ACID;IODINE;IRON;MAGNESIUM HYDROXIDE;MANGANESE;MOLYBDENUM;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;BIOTIN;CHOLINE;COLECALCIFEROL;CYANOCOBALAMIN;DL-ALPHA TOCOPHEROL;FOLIC ACID;INOSITOL;INULIN;MAGNESIUM CITRATE;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RETINOL;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;BIOTIN;CHOLINE;CYANOCOBALAMIN;FOLIC ACID;INOSITOL;NICOTINAMIDE;PANTOTHENIC ACID;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;BIOTIN;DL-ALPHA TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;CENTAURIUM ERYTHRAEA;CRATAEGUS LAEVIGATA;ELYMUS REPENS;FOLIC ACID;IRON;MACROCYSTIS PYRIFERA;NICOTINAMIDE;PYRIDOXINE;RIBOFLAVIN;ROSA SPP.;SPINACIA OLERACEA;THIAMINE;URTICA DIOICA;	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;COLECALCIFEROL;CURCUMA LONGA;ZINGIBER OFFICINALE	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;COLECALCIFEROL;CYANOCOBALAMIN;MAGNESIUM OXIDE;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;COLLAGEN	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;CYANOCOBALAMIN;FOLIC ACID;IRON;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;CYANOCOBALAMIN;FOLIC ACID;IRON;NICOTINAMIDE;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0 (0.0)	1 (0.1)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 27 of 48
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ASCORBIC ACID;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;TOCOPHEROL	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;CYANOCOBALAMIN;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;DEMANNOSE;VACCINIUM MACROCARPON	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;MACROGOL 3350;POTASSIUM;SODIUM CHLORIDE;SODIUM SULFATE	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
ASCORBIC ACID;VACCINIUM MACROCARPON	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;VITAMIN B COMPLEX	0 (0.0)	1 (0.1)	1 (0.0)
ASCORBIC ACID;VITAMIN B NOS;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
ASTAXANTHIN	0 (0.0)	1 (0.1)	1 (0.0)
ASTRAGALUS MONGHOLICUS	0 (0.0)	1 (0.1)	1 (0.0)
ATRACTYLODES LANCEA;CITRUS RETICULATA;CITRUS SPP.;MAGNOLIA SPP.;PANAX GINSENG;PERILLA FRUTESCENS VAR. CRISPA;PINELLIA TERNATA;PORIA COCOS;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.0)
ATROPA BELLA-DONNA;ERGOTAMINE;PHENOBARBITAL	1 (0.1)	0 (0.0)	1 (0.0)
AZELASTINE;FLUTICASONE	0 (0.0)	1 (0.1)	1 (0.0)
AZILSARTAN	1 (0.1)	0 (0.0)	1 (0.0)
BACAMPICILLIN	1 (0.1)	0 (0.0)	1 (0.0)
BACILLUS CLAUSII	1 (0.1)	0 (0.0)	1 (0.0)
BACILLUS COAGULANS;INULIN	1 (0.1)	0 (0.0)	1 (0.0)
BACILLUS NOS	1 (0.1)	0 (0.0)	1 (0.0)
BACILLUS SUBTILIS;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS;STREPTOCOCCUS THERMOPHILUS	1 (0.1)	0 (0.0)	1 (0.0)
BACILLUS SUBTILIS;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BACILLUS SUBTILIS;LACTIPLANTIBACILLUS PLANTARUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS CASEI;LACTOBACILLUS PARACASEI;LACTOBACILLUS RHAMNOSUS;LACTOBACILLUS SALIVARIUS	1 (0.1)	0 (0.0)	1 (0.0)
BACITRACIN;LYSOZYME;PAPAIN	0 (0.0)	1 (0.1)	1 (0.0)
BACITRACIN;NEOMYCIN;POLYMYXIN B	0 (0.0)	1 (0.1)	1 (0.0)
BACOPA MONNIERI	1 (0.1)	0 (0.0)	1 (0.0)
BACTERIA LYSATE NOS	0 (0.0)	1 (0.1)	1 (0.0)
BARBITURATES, COMBINATIONS	0 (0.0)	1 (0.1)	1 (0.0)
BECLOMETASONE	0 (0.0)	1 (0.1)	1 (0.0)
BEMIPARIN	1 (0.1)	0 (0.0)	1 (0.0)
BENDROFLUMETHIAZIDE;MEDROXYPROGESTERONE;MEPROBAMATE	1 (0.1)	0 (0.0)	1 (0.0)
BENFOTIAMINE	0 (0.0)	1 (0.1)	1 (0.0)
BENFOTIAMINE;CYANOCOBALAMIN;PYRIDOXINE	1 (0.1)	0 (0.0)	1 (0.0)
BENZYL ALCOHOL;BENZYL BENZOATE;BENZYL CINNAMATE;WOOL FAT;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
BENZYLPENICILLIN	1 (0.1)	0 (0.0)	1 (0.0)
BEPOTASTINE	0 (0.0)	1 (0.1)	1 (0.0)
BERBERINE	0 (0.0)	1 (0.1)	1 (0.0)
BERBERINE;BERBERIS AQUIFOLIUM;COPTIS CHINENSIS;GLYCYRRHIZA URALENSIS;PHELLODENDRON CHINENSE;RHEUM OFFICINALE;SCUTELLARIA BAICALENSIS;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.0)
BETA GLUCAN	0 (0.0)	1 (0.1)	1 (0.0)
BETA-SITOSTEROL	1 (0.1)	0 (0.0)	1 (0.0)
BETACAROTENE	0 (0.0)	1 (0.1)	1 (0.0)
BETAHISTINE	1 (0.1)	0 (0.0)	1 (0.0)
BETAMETHASONE;DICLOFENAC;VITAMIN B12 NOS	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BETHANECHOL	1 (0.1)	0 (0.0)	1 (0.0)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM LACTIS;FRUCTOOLIGOSACCHARIDES;LACTOBACILLUS ACIDOPHILUS	1 (0.1)	0 (0.0)	1 (0.0)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS	0 (0.0)	1 (0.1)	1 (0.0)
BIFIDOBACTERIUM BIFIDUM;ESCHERICHIA COLI;LACTOBACILLUS ACIDOPHILUS	0 (0.0)	1 (0.1)	1 (0.0)
BIFIDOBACTERIUM BIFIDUM;LACTOBACILLUS ACIDOPHILUS	0 (0.0)	1 (0.1)	1 (0.0)
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM INFANTIS;FRUCTOOLIGOSACCHARIDES;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS CASEI;LACTOBACILLUS RHAMNOSUS;STREPTOCOCCUS THERMOPHILUS	1 (0.1)	0 (0.0)	1 (0.0)
BIFIDOBACTERIUM INFANTIS	0 (0.0)	1 (0.1)	1 (0.0)
BIFIDOBACTERIUM LACTIS	0 (0.0)	1 (0.1)	1 (0.0)
BIFIDOBACTERIUM LACTIS;FRUCTOOLIGOSACCHARIDES;INULIN;LACTOBACILLUS ACIDOPHILUS	1 (0.1)	0 (0.0)	1 (0.0)
BIFIDOBACTERIUM LACTIS;LACTOBACILLUS ACIDOPHILUS	1 (0.1)	0 (0.0)	1 (0.0)
BIFIDOBACTERIUM LONGUM;INULIN;LACTIPLANTIBACILLUS PLANTARUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS CASEI;LACTOBACILLUS REUTERI;LACTOBACILLUS RHAMNOSUS;STREPTOCOCCUS THERMOPHILUS	1 (0.1)	0 (0.0)	1 (0.0)
BILASTINE	1 (0.1)	0 (0.0)	1 (0.0)
BIMATOPROST	1 (0.1)	0 (0.0)	1 (0.0)
BIOFLAVONOIDS NOS	1 (0.1)	0 (0.0)	1 (0.0)
BIOTIN;CYANOCOBALAMIN;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
BISACODYL;DOCUSATE	0 (0.0)	1 (0.1)	1 (0.0)
BORIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
BORON;CALCIUM;COLECALCIFEROL;COPPER;MANGANESE;ZINC	1 (0.1)	0 (0.0)	1 (0.0)

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Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
BOSWELLIA SACRA	0 (0.0)	1 (0.1)	1 (0.0)
BRINZOLAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
BROMAZEPAM	0 (0.0)	1 (0.1)	1 (0.0)
BROMELAINS;CYSTEINE	1 (0.1)	0 (0.0)	1 (0.0)
BROMELAINS;PAPAIN;SELENIUM;VICIA LENS	0 (0.0)	1 (0.1)	1 (0.0)
BROTIZOLAM	1 (0.1)	0 (0.0)	1 (0.0)
BUMETANIDE	1 (0.1)	0 (0.0)	1 (0.0)
BUPIVACAINE;LIDOCAINE	1 (0.1)	0 (0.0)	1 (0.0)
BUTENAFINE	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;CARISOPRODOL;DICLOFENAC;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;CHLORPHENAMINE;PARACETAMOL;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.0)
CAFFEINE;CODEINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
CAFFEINE;PARACETAMOL;PROPYPHENAZONE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CARBONATE;CHONDROITIN;GLUCOSAMINE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM CARBONATE;COLECALCIFEROL;COPPER;MAGNESIUM CARBONATE;MAGNESIUM OXIDE;MANGANESE;PHYTOMENADIONE;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CARBONATE;COLECALCIFEROL;SACCHAROMYCES CEREVISIAE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CARBONATE;MAGNESIUM CARBONATE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM GLUCONATE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM PHOSPHATE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM PHOSPHATE;COLECALCIFEROL;PHOSPHORUS;SODIUM	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CALCIUM PHOSPHATE;COLECALCIFEROL;RETINOL	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM POLYSTYRENE SULFONATE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM;COLECALCIFEROL;COPPER;MAGNESIUM;MANGANESE;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM;COLECALCIFEROL;FOLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM;COLECALCIFEROL;MAGNESIUM OXIDE	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM;COLECALCIFEROL;MAGNESIUM;PHYTOMENADIONE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM;COLECALCIFEROL;MENAQUINONE	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM;MAGNESIUM;POTASSIUM	1 (0.1)	0 (0.0)	1 (0.0)
CALCIUM;MAGNESIUM;VITAMIN D NOS	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM;MAGNESIUM;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
CALENDULA OFFICINALIS;CHAMAEMELUM NOBILE;LAVANDULA ANGUSTIFOLIA;RETINOL;SALVIA ROSMARINUS;TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.0)
CAMPHOR;ENOXOLONE;MENTHOL;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
CAMPHOR;MENTHOL;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
CAPSAICIN	1 (0.1)	0 (0.0)	1 (0.0)
CARBAZOCHROME	1 (0.1)	0 (0.0)	1 (0.0)
CARBOCISTEINE	1 (0.1)	0 (0.0)	1 (0.0)
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEIN;VITAMINS NOS	1 (0.1)	0 (0.0)	1 (0.0)
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1 (0.1)	0 (0.0)	1 (0.0)
CARBOHYDRATES NOS;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	0 (0.0)	1 (0.1)	1 (0.0)
CARTEOLOL	0 (0.0)	1 (0.1)	1 (0.0)
CARVEDILOL	0 (0.0)	1 (0.1)	1 (0.0)
CEFAZEDONE	1 (0.1)	0 (0.0)	1 (0.0)
CEFDITOREN	1 (0.1)	0 (0.0)	1 (0.0)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CEFIXIME	1 (0.1)	0 (0.0)	1 (0.0)
CEFRADINE	1 (0.1)	0 (0.0)	1 (0.0)
CEFTEZOLE	1 (0.1)	0 (0.0)	1 (0.0)
CEREBROPROTEIN HYDROLYSATE	1 (0.1)	0 (0.0)	1 (0.0)
CERTOPARIN SODIUM	1 (0.1)	0 (0.0)	1 (0.0)
CETOMACROGOL	1 (0.1)	0 (0.0)	1 (0.0)
CETYLPYRIDINIUM;CHLORHEXIDINE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORAMPHENICOL	0 (0.0)	1 (0.1)	1 (0.0)
CHLORAMPHENICOL;DEXAMETHASONE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORAMPHENICOL;PREDNISOLONE	1 (0.1)	0 (0.0)	1 (0.0)
CHLORDIAZEPOXIDE;CLIDINIUM	1 (0.1)	0 (0.0)	1 (0.0)
CHLORPHENAMINE;PARACETAMOL	0 (0.0)	1 (0.1)	1 (0.0)
CHLORTALIDONE	0 (0.0)	1 (0.1)	1 (0.0)
CHOLERA VACCINE	0 (0.0)	1 (0.1)	1 (0.0)
CHOLINE;SILICON	0 (0.0)	1 (0.1)	1 (0.0)
CHONDROITIN	1 (0.1)	0 (0.0)	1 (0.0)
CHONDROITIN;GLUCOSAMINE;HYALURONIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
CHONDROITIN;GLUCOSAMINE;HYALURONIC ACID;METHYLSULFONYLMETHANE	1 (0.1)	0 (0.0)	1 (0.0)
CHONDROITIN;GLUCOSAMINE;METHYLSULFONYLMETHANE	0 (0.0)	1 (0.1)	1 (0.0)
CHROMIUM	0 (0.0)	1 (0.1)	1 (0.0)
CICLESONIDE	1 (0.1)	0 (0.0)	1 (0.0)
CILASTATIN;IMIPENEM	1 (0.1)	0 (0.0)	1 (0.0)
CILAZAPRIL	1 (0.1)	0 (0.0)	1 (0.0)
CINCHOCAINE;PREDNISOLONE	1 (0.1)	0 (0.0)	1 (0.0)

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CINNAMOMUM SPP.;CITRUS X AURANTIUM;COMMIPHORA MYRRHA;EUCALYPTUS SPP.;SALVIA ROSMARINUS;SYZYGIUM AROMATICUM	0 (0.0)	1 (0.1)	1 (0.0)
CINNARIZINE	1 (0.1)	0 (0.0)	1 (0.0)
CIPROFIBRATE	1 (0.1)	0 (0.0)	1 (0.0)
CIPROFLOXACIN;FLUOCINOLONE ACETONIDE	0 (0.0)	1 (0.1)	1 (0.0)
CITRIC ACID;MAGNESIUM OXIDE;SODIUM PICOSULFATE	1 (0.1)	0 (0.0)	1 (0.0)
CITRULLINE	0 (0.0)	1 (0.1)	1 (0.0)
CITRUS RETICULATA;CYPERUS ROTUNDUS;GLYCYRRHIZA SPP.;PERILLA FRUTESCENS VAR. CRISPA;ZINGIBER OFFICINALE	1 (0.1)	0 (0.0)	1 (0.0)
CITRUS X AURANTIUM;RUBUS FRUTICOSUS;VACCINIUM MYRTILLUS;VITIS VINIFERA	0 (0.0)	1 (0.1)	1 (0.0)
CITRUS X LIMON	1 (0.1)	0 (0.0)	1 (0.0)
CLAVULANIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
CLEBOPRIDE	1 (0.1)	0 (0.0)	1 (0.0)
CLEMASTINE	1 (0.1)	0 (0.0)	1 (0.0)
CLEMATIS VITALBA;HELIANTHEMUM NUMMULARIUM;IMPATIENS GLANDULIFERA;ORNITHOGALUM UMBELLATUM;PRUNUS CERASIFERA	1 (0.1)	0 (0.0)	1 (0.0)
CLOMIPRAMINE	1 (0.1)	0 (0.0)	1 (0.0)
CLONIDINE	1 (0.1)	0 (0.0)	1 (0.0)
CLOTIAZEPAM	1 (0.1)	0 (0.0)	1 (0.0)
CLOTRIMAZOLE	0 (0.0)	1 (0.1)	1 (0.0)
CODEINE	1 (0.1)	0 (0.0)	1 (0.0)
CODEINE;EPHEDRINE;PROMETHAZINE	0 (0.0)	1 (0.1)	1 (0.0)
CODEINE;GUAIFENESIN	0 (0.0)	1 (0.1)	1 (0.0)
CODEINE;IBUPROFEN;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CODEINE;PROMETHAZINE	0 (0.0)	1 (0.1)	1 (0.0)
COLECALCIFEROL;DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
COLECALCIFEROL;ERGOCALCIFEROL	1 (0.1)	0 (0.0)	1 (0.0)
COLECALCIFEROL;MENADIONE	1 (0.1)	0 (0.0)	1 (0.0)
COLECALCIFEROL;MENAQUINONE-7	0 (0.0)	1 (0.1)	1 (0.0)
COLECALCIFEROL;RETINOL	0 (0.0)	1 (0.1)	1 (0.0)
COLESEVELAM	1 (0.1)	0 (0.0)	1 (0.0)
COLESTYRAMINE	1 (0.1)	0 (0.0)	1 (0.0)
COLISTIN	1 (0.1)	0 (0.0)	1 (0.0)
COLLAGENASE	0 (0.0)	1 (0.1)	1 (0.0)
COLOSTRUM	0 (0.0)	1 (0.1)	1 (0.0)
COMBINATIONS OF VITAMINS	1 (0.1)	0 (0.0)	1 (0.0)
CONTACT LAXATIVES	1 (0.1)	0 (0.0)	1 (0.0)
COPPER;HYALURONIC ACID;MADECASSOSIDE;MANGANESE;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
CORTISONE	0 (0.0)	1 (0.1)	1 (0.0)
CROCUS SATIVUS	0 (0.0)	1 (0.1)	1 (0.0)
CROTAMITON	0 (0.0)	1 (0.1)	1 (0.0)
CURCUMA LONGA;PIPER NIGRUM	0 (0.0)	1 (0.1)	1 (0.0)
CURCUMIN;PIPERINE	0 (0.0)	1 (0.1)	1 (0.0)
CYANOCOBALAMIN;FOLIC ACID;PYRIDOXINE	1 (0.1)	0 (0.0)	1 (0.0)
CYANOCOBALAMIN;LEVOMEFOLIC ACID;MAGNESIUM;PYRIDOXINE;TAURINE	0 (0.0)	1 (0.1)	1 (0.0)
CYANOCOBALAMIN;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
CYANOCOBALAMIN;NICOTINAMIDE;PHOSPHOLIPIDS;PYRIDOXINE;RIBOFLAVIN;THIAMINE;TOCOPHEROL	0 (0.0)	1 (0.1)	1 (0.0)
CYCLIZINE	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
CYNARA CARDUNCULUS;HYDRASTIS CANADENSIS;SILYBUM MARIANUM;TARAXACUM SECT. TARAXACUM;TRIFOLIUM PRATENSE	1 (0.1)	0 (0.0)	1 (0.0)
CYSTEINE	1 (0.1)	0 (0.0)	1 (0.0)
CYSTINE;PYRIDOXINE	0 (0.0)	1 (0.1)	1 (0.0)
CYTOKINES	1 (0.1)	0 (0.0)	1 (0.0)
DAPSONE	0 (0.0)	1 (0.1)	1 (0.0)
DEANOL;HEPTAMINOL	0 (0.0)	1 (0.1)	1 (0.0)
DEFLAZACORT	1 (0.1)	0 (0.0)	1 (0.0)
DEOXYRIBONUCLEIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
DESFLURANE	1 (0.1)	0 (0.0)	1 (0.0)
DESONIDE	1 (0.1)	0 (0.0)	1 (0.0)
DESOXIMETASONE	0 (0.0)	1 (0.1)	1 (0.0)
DEXAMETHASONE;MOXIFLOXACIN	1 (0.1)	0 (0.0)	1 (0.0)
DEXAMETHASONE;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
DEXAMETHASONE;OXYTETRACYCLINE	1 (0.1)	0 (0.0)	1 (0.0)
DEXAMETHASONE;TOBRAMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
DEXRABEPRAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
DEXTRIN	1 (0.1)	0 (0.0)	1 (0.0)
DEXTROMETHORPHAN;DOXYLAMINE;EPHEDRINE;ETHANOL;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
DEXTROMETHORPHAN;LYSOZYME;POTASSIUM CRESOLSULFONATE	1 (0.1)	0 (0.0)	1 (0.0)
DIASTASE;LIPASE;URSODEOXYCHOLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
DICLOFENAC;THIOCOLCHICOSIDE	0 (0.0)	1 (0.1)	1 (0.0)
DICLOXACILLIN	0 (0.0)	1 (0.1)	1 (0.0)
DIFENIDOL	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
DILTIAZEM	1 (0.1)	0 (0.0)	1 (0.0)
DIMETICONE;METOCLOPRAMIDE;PEPSIN	0 (0.0)	1 (0.1)	1 (0.0)
DIMETINDENE;PHENYLEPHRINE	1 (0.1)	0 (0.0)	1 (0.0)
DIPHENHYDRAMINE;DIPROPHYLLINE	1 (0.1)	0 (0.0)	1 (0.0)
DOBESILIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;FISH OIL	1 (0.1)	0 (0.0)	1 (0.0)
DOCUSATE;SENNA ALEXANDRINA	1 (0.1)	0 (0.0)	1 (0.0)
DORZOLAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
DOXAZOSIN	1 (0.1)	0 (0.0)	1 (0.0)
DOXYLAMINE	1 (0.1)	0 (0.0)	1 (0.0)
DRUGS FOR ACID RELATED DISORDERS	1 (0.1)	0 (0.0)	1 (0.0)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	1 (0.1)	0 (0.0)	1 (0.0)
DULAGLUTIDE	1 (0.1)	0 (0.0)	1 (0.0)
EBASTINE	1 (0.1)	0 (0.0)	1 (0.0)
ECHINACEA SPP.	0 (0.0)	1 (0.1)	1 (0.0)
EDARAVONE	1 (0.1)	0 (0.0)	1 (0.0)
EDOXABAN	1 (0.1)	0 (0.0)	1 (0.0)
EICOSAPENTAENOIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
ELECTROLYTES NOS	1 (0.1)	0 (0.0)	1 (0.0)
ELECTROLYTES NOS;MACROGOL 3350	1 (0.1)	0 (0.0)	1 (0.0)
ELECTROLYTES NOS;MINERALS NOS;VITAMINS NOS	0 (0.0)	1 (0.1)	1 (0.0)
ENALAPRIL	0 (0.0)	1 (0.1)	1 (0.0)
ENTECAVIR	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
ENTEROCOCCUS FAECALIS INACTIVATED;ESCHERICHIA COLI INACTIVATED;KLEBSIELLA PNEUMONIAE INACTIVATED;MORGANELLA MORGANII INACTIVATED;PROTEUS MIRABILIS INACTIVATED	1 (0.1)	0 (0.0)	1 (0.0)
ENZYMES NOS	0 (0.0)	1 (0.1)	1 (0.0)
EPERISONE	0 (0.0)	1 (0.1)	1 (0.0)
EPHEDRA SPP.;GLYCYRRHIZA SPP.;NEOLITSEA CASSIA;PAEONIA LACTIFLORA;PUERARIA MONTANA VAR. LOBATA;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	1 (0.1)	0 (0.0)	1 (0.0)
ESCHERICHIA COLI	1 (0.1)	0 (0.0)	1 (0.0)
ESCIN	0 (0.0)	1 (0.1)	1 (0.0)
ESCULOSIDE;LATHYRUS OLERACEUS;PANCREATIN;PAPAIN;THYMUS GLAND	1 (0.1)	0 (0.0)	1 (0.0)
ESTROGENS CONJUGATED	0 (0.0)	1 (0.1)	1 (0.0)
ETHANOL;EUCALYPTUS SPP.;MENTHOL;PINUS SPP.;SALICYLIC ACID;THYMOL	0 (0.0)	1 (0.1)	1 (0.0)
ETHYL CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
ETIZOLAM	1 (0.1)	0 (0.0)	1 (0.0)
EUPATILIN	0 (0.0)	1 (0.1)	1 (0.0)
EZETIMIBE;SIMVASTATIN	0 (0.0)	1 (0.1)	1 (0.0)
FACTOR I (FIBRINOGEN);THROMBIN	1 (0.1)	0 (0.0)	1 (0.0)
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS, COMBINATIONS	1 (0.1)	0 (0.0)	1 (0.0)
FATTY ACIDS NOS	0 (0.0)	1 (0.1)	1 (0.0)
FENTICONAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
FENYRAMIDOL	0 (0.0)	1 (0.1)	1 (0.0)
FERRIC SUBSULFATE	1 (0.1)	0 (0.0)	1 (0.0)
FLAVINE ADENINE DINUCLEOTIDE;LIVER	1 (0.1)	0 (0.0)	1 (0.0)
FLUOCORTOLONE;NEOMYCIN;NYSTATIN	1 (0.1)	0 (0.0)	1 (0.0)
FLUORESCEIN	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
FOENICULUM VULGARE;MATRICARIA CHAMOMILLA;MENTHA X PIPERITA	0 (0.0)	1 (0.1)	1 (0.0)
FOLIC ACID;IRON;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE;VITAMIN B12 NOS;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
FOLIC ACID;MECOBALAMIN;PYRIDOXINE	1 (0.1)	0 (0.0)	1 (0.0)
FOLIC ACID;VITAMIN B NOS	0 (0.0)	1 (0.1)	1 (0.0)
FOLINIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
FONDAPARINUX	1 (0.1)	0 (0.0)	1 (0.0)
FRAMYCETIN	0 (0.0)	1 (0.1)	1 (0.0)
FRANGULA ALNUS;STERCULIA URENS	1 (0.1)	0 (0.0)	1 (0.0)
FUCOIDAN	0 (0.0)	1 (0.1)	1 (0.0)
GABAPENTIN;NORTRIPTYLINE	1 (0.1)	0 (0.0)	1 (0.0)
GANGLIOSIDE : GM1	1 (0.1)	0 (0.0)	1 (0.0)
GANODERMA LUCIDUM	1 (0.1)	0 (0.0)	1 (0.0)
GANODERMA SPP.	1 (0.1)	0 (0.0)	1 (0.0)
GELATINE HYDROLYSATE	1 (0.1)	0 (0.0)	1 (0.0)
GELSEMIUM SEMPERVIRENS	1 (0.1)	0 (0.0)	1 (0.0)
GINSENG NOS	0 (0.0)	1 (0.1)	1 (0.0)
GINSENG NOS;MINERALS NOS;VITAMINS NOS	0 (0.0)	1 (0.1)	1 (0.0)
GLIMEPIRIDE	1 (0.1)	0 (0.0)	1 (0.0)
GLIPIZIDE	0 (0.0)	1 (0.1)	1 (0.0)
GLUCONATE SODIUM;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM L-LACTATE	0 (0.0)	1 (0.1)	1 (0.0)
GLUCOSE;SODIUM CHLORIDE	1 (0.1)	0 (0.0)	1 (0.0)
GLYCINE MAX;OLEA EUROPAEA	0 (0.0)	1 (0.1)	1 (0.0)

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	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
GLYCINE MAX;PERSEA AMERICANA	0 (0.0)	1 (0.1)	1 (0.0)
GLYCOPYRRONIUM;INDACATEROL	0 (0.0)	1 (0.1)	1 (0.0)
GUAIFENESIN	1 (0.1)	0 (0.0)	1 (0.0)
GUALENIC ACID;LEVOGLUTAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
GUALENIC ACID;SODIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
HAEMOCOAGULASE	1 (0.1)	0 (0.0)	1 (0.0)
HEPATITIS B VACCINE	0 (0.0)	1 (0.1)	1 (0.0)
HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES	0 (0.0)	1 (0.1)	1 (0.0)
HERBAL NOS;VITAMINS NOS	1 (0.1)	0 (0.0)	1 (0.0)
HERBAL POLLEN NOS	0 (0.0)	1 (0.1)	1 (0.0)
HERBAL REMEDIES FOR IODINE THERAPY	0 (0.0)	1 (0.1)	1 (0.0)
HESPERIDIN	1 (0.1)	0 (0.0)	1 (0.0)
HONEY	0 (0.0)	1 (0.1)	1 (0.0)
HYDROCORTISONE;NATAMYCIN;NEOMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
HYDROQUINONE	1 (0.1)	0 (0.0)	1 (0.0)
HYDROXYAMFETAMINE;TROPICAMIDE	0 (0.0)	1 (0.1)	1 (0.0)
HYDROXYCHLOROQUINE	1 (0.1)	0 (0.0)	1 (0.0)
HYOSCINE;METAMIZOLE	1 (0.1)	0 (0.0)	1 (0.0)
HYPNOTICS AND SEDATIVES IN COMBINATION, EXCL. BARBITURATES	0 (0.0)	1 (0.1)	1 (0.0)
HYPOCHLOROUS ACID	1 (0.1)	0 (0.0)	1 (0.0)
INDOMETACIN	0 (0.0)	1 (0.1)	1 (0.0)
INFLUENZA VACCINES	0 (0.0)	1 (0.1)	1 (0.0)
INSULIN GLARGINE	0 (0.0)	1 (0.1)	1 (0.0)
INSULIN GLULISINE	1 (0.1)	0 (0.0)	1 (0.0)

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
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	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
INSULIN HUMAN	1 (0.1)	0 (0.0)	1 (0.0)
INSULIN LISPRO	0 (0.0)	1 (0.1)	1 (0.0)
IOPAMIDOL	1 (0.1)	0 (0.0)	1 (0.0)
IPRATROPIUM;SALBUTAMOL	1 (0.1)	0 (0.0)	1 (0.0)
ISONIAZID	1 (0.1)	0 (0.0)	1 (0.0)
ISOSORBIDE MONONITRATE	1 (0.1)	0 (0.0)	1 (0.0)
IVERMECTIN	1 (0.1)	0 (0.0)	1 (0.0)
KERATIN	1 (0.1)	0 (0.0)	1 (0.0)
LABETALOL	0 (0.0)	1 (0.1)	1 (0.0)
LACHESIS MUTA	0 (0.0)	1 (0.1)	1 (0.0)
LACTIPLANTIBACILLUS PLANTARUM	1 (0.1)	0 (0.0)	1 (0.0)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS	0 (0.0)	1 (0.1)	1 (0.0)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS	1 (0.1)	0 (0.0)	1 (0.0)
LACTOBACILLUS CASEI	1 (0.1)	0 (0.0)	1 (0.0)
LACTOBACILLUS REUTERI	1 (0.1)	0 (0.0)	1 (0.0)
LACTOBACILLUS RHAMNOSUS;MONASCUS PURPUREUS	1 (0.1)	0 (0.0)	1 (0.0)
LAUROMACROGOL 400;UREA	1 (0.1)	0 (0.0)	1 (0.0)
LIDOCAINE;TRIAMCINOLONE	0 (0.0)	1 (0.1)	1 (0.0)
LIDOCAINE;TRIBENOSIDE	1 (0.1)	0 (0.0)	1 (0.0)
LIMAPROST	0 (0.0)	1 (0.1)	1 (0.0)
LINACLOTIDE	1 (0.1)	0 (0.0)	1 (0.0)
LIOTHYRONINE	1 (0.1)	0 (0.0)	1 (0.0)
LIPID MODIFYING AGENTS, COMBINATIONS	0 (0.0)	1 (0.1)	1 (0.0)
LOSARTAN	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
LOSARTAN;RAMIPRIL	1 (0.1)	0 (0.0)	1 (0.1)
LOVASTATIN	0 (0.0)	1 (0.1)	1 (0.1)
MACROGOL 4000	1 (0.1)	0 (0.0)	1 (0.1)
MACROGOL 4000;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	1 (0.1)	0 (0.0)	1 (0.1)
MACROGOL;POTASSIUM;SODIUM BICARBONATE	0 (0.0)	1 (0.1)	1 (0.1)
MACROGOL;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	0 (0.0)	1 (0.1)	1 (0.1)
MAGNESIUM SULFATE;POTASSIUM SULFATE;SODIUM SULFATE	1 (0.1)	0 (0.0)	1 (0.1)
MAGNESIUM;PYRIDOXAL	0 (0.0)	1 (0.1)	1 (0.1)
MATRICARIA CHAMOMILLA	0 (0.0)	1 (0.1)	1 (0.1)
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	1 (0.1)	0 (0.0)	1 (0.1)
MEBENDAZOLE	0 (0.0)	1 (0.1)	1 (0.1)
MEBEVERINE	1 (0.1)	0 (0.0)	1 (0.1)
MECOBALAMIN;PREGABALIN	0 (0.0)	1 (0.1)	1 (0.1)
MELOXICAM	0 (0.0)	1 (0.1)	1 (0.1)
MENAQUINONE-7	1 (0.1)	0 (0.0)	1 (0.1)
MENTHA CANADENSIS	0 (0.0)	1 (0.1)	1 (0.1)
MENTHOL;OXYMETAZOLINE	0 (0.0)	1 (0.1)	1 (0.1)
MENTHOL;SALICYLIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
MEPIVACAINE	1 (0.1)	0 (0.0)	1 (0.1)
MEPYRAMINE	1 (0.1)	0 (0.0)	1 (0.1)
MESALAZINE	1 (0.1)	0 (0.0)	1 (0.1)
MESNA	1 (0.1)	0 (0.0)	1 (0.1)
METHOCARBAMOL	1 (0.1)	0 (0.0)	1 (0.1)
METHYLTHIONINIUM	1 (0.1)	0 (0.0)	1 (0.1)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
MIANSERIN	1 (0.1)	0 (0.0)	1 (0.0)
MICONAZOLE	1 (0.1)	0 (0.0)	1 (0.0)
MINERAL OIL LIGHT;PARAFFIN NOS;PETROLATUM;WOOL ALCOHOLS	0 (0.0)	1 (0.1)	1 (0.0)
MINOCYCLINE	1 (0.1)	0 (0.0)	1 (0.0)
MIRTAZAPINE	0 (0.0)	1 (0.1)	1 (0.0)
MISOPROSTOL	1 (0.1)	0 (0.0)	1 (0.0)
MIZOLASTINE	1 (0.1)	0 (0.0)	1 (0.0)
MOXIFLOXACIN	0 (0.0)	1 (0.1)	1 (0.0)
MOXONIDINE	1 (0.1)	0 (0.0)	1 (0.0)
NALBUPHINE	1 (0.1)	0 (0.0)	1 (0.0)
NASAL PREPARATIONS	0 (0.0)	1 (0.1)	1 (0.0)
NEOLITSEA CASSIA	0 (0.0)	1 (0.1)	1 (0.0)
NEOMYCIN;POLYMYXIN B	1 (0.1)	0 (0.0)	1 (0.0)
NEPAFENAC	1 (0.1)	0 (0.0)	1 (0.0)
NETUPITANT;PALONOSETRON	1 (0.1)	0 (0.0)	1 (0.0)
NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
NIGELLA SATIVA	0 (0.0)	1 (0.1)	1 (0.0)
NIMODIPINE	0 (0.0)	1 (0.1)	1 (0.0)
NORDAZEPAM	0 (0.0)	1 (0.1)	1 (0.0)
NYSTATIN;TRIAMCINOLONE	1 (0.1)	0 (0.0)	1 (0.0)
OLANZAPINE	1 (0.1)	0 (0.0)	1 (0.0)
OLOPATADINE	1 (0.1)	0 (0.0)	1 (0.0)
OMEGA-3 FATTY ACIDS;SELENIUM;ZINC	0 (0.0)	1 (0.1)	1 (0.0)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	1 (0.1)	0 (0.0)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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I3Y-MC-JPCF PDPM
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
OPIPRAMOL	1 (0.1)	0 (0.0)	1 (0.0)
ORNIDAZOLE	0 (0.0)	1 (0.1)	1 (0.0)
ORPHENADRINE;PARACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
OSMOTICALLY ACTING LAXATIVES	1 (0.1)	0 (0.0)	1 (0.0)
OTHER ANTIEMETICS	0 (0.0)	1 (0.1)	1 (0.0)
OTHER CARDIAC PREPARATIONS	0 (0.0)	1 (0.1)	1 (0.0)
OTHER DIAGNOSTIC AGENTS	1 (0.1)	0 (0.0)	1 (0.0)
OTHER LIPID MODIFYING AGENTS	0 (0.0)	1 (0.1)	1 (0.0)
OTHER MINERAL PRODUCTS	0 (0.0)	1 (0.1)	1 (0.0)
OTHER OTOLOGICALS	1 (0.1)	0 (0.0)	1 (0.0)
OTHER PLAIN VITAMIN PREPARATIONS	1 (0.1)	0 (0.0)	1 (0.0)
OTILONIUM;SIMETICONE	1 (0.1)	0 (0.0)	1 (0.0)
OXAZEPAM	1 (0.1)	0 (0.0)	1 (0.0)
OXIDISED CELLULOSE	1 (0.1)	0 (0.0)	1 (0.0)
OXYBUTYNIN	0 (0.0)	1 (0.1)	1 (0.0)
OXYTETRACYCLINE	1 (0.1)	0 (0.0)	1 (0.0)
OXYTETRACYCLINE;POLYMYXIN B	1 (0.1)	0 (0.0)	1 (0.0)
PALONOSETRON	0 (0.0)	1 (0.1)	1 (0.0)
PANCREATIN;SIMETICONE;URSODEOXYCHOLIC ACID	0 (0.0)	1 (0.1)	1 (0.0)
PARAFFIN NOS	0 (0.0)	1 (0.1)	1 (0.0)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (0.1)	0 (0.0)	1 (0.0)
PAROXETINE	0 (0.0)	1 (0.1)	1 (0.0)
PEGFILGRASTIM	1 (0.1)	0 (0.0)	1 (0.0)
PENICILLIN NOS	0 (0.0)	1 (0.1)	1 (0.0)

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
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Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PERMETHRIN	1 (0.1)	0 (0.0)	1 (0.0)
PHENIBUT	0 (0.0)	1 (0.1)	1 (0.0)
PHENTERMINE	1 (0.1)	0 (0.0)	1 (0.0)
PHYTOMENADIONE	0 (0.0)	1 (0.1)	1 (0.0)
PIPER NIGRUM;UBIDECARENONE	1 (0.1)	0 (0.0)	1 (0.0)
PIPERACILLIN	1 (0.1)	0 (0.0)	1 (0.0)
PIPERACILLIN;TAZOBACTAM	1 (0.1)	0 (0.0)	1 (0.0)
PLANTAGO SPP.	0 (0.0)	1 (0.1)	1 (0.0)
POTASSIUM PHOSPHATE;SODIUM PHOSPHATE	1 (0.1)	0 (0.0)	1 (0.0)
POTASSIUM;POTASSIUM BICARBONATE	1 (0.1)	0 (0.0)	1 (0.0)
PRANLUKAST	0 (0.0)	1 (0.1)	1 (0.0)
PREBIOTICS NOS	0 (0.0)	1 (0.1)	1 (0.0)
PREBIOTICS NOS;PROBIOTICS NOS	1 (0.1)	0 (0.0)	1 (0.0)
PREDNICARBATE	0 (0.0)	1 (0.1)	1 (0.0)
PRILOCAINE	0 (0.0)	1 (0.1)	1 (0.0)
PROCATEROL	1 (0.1)	0 (0.0)	1 (0.0)
PRONASE	0 (0.0)	1 (0.1)	1 (0.0)
PROPACETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
PROSULTIAMINE	1 (0.1)	0 (0.0)	1 (0.0)
PROSULTIAMINE;RIBOFLAVIN	0 (0.0)	1 (0.1)	1 (0.0)
PROTECTIVES AGAINST UV-RADIATION FOR TOPICAL USE	0 (0.0)	1 (0.1)	1 (0.0)
PROTEIN SUPPLEMENTS	0 (0.0)	1 (0.1)	1 (0.0)
PROTEINS NOS	1 (0.1)	0 (0.0)	1 (0.0)
PROXYMETACAINE	1 (0.1)	0 (0.0)	1 (0.0)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
PYRIDOSTIGMINE	1 (0.1)	0 (0.0)	1 (0.0)
QUININE	0 (0.0)	1 (0.1)	1 (0.0)
RABIES VACCINE	1 (0.1)	0 (0.0)	1 (0.0)
RACECADOTRIL	1 (0.1)	0 (0.0)	1 (0.0)
RADIOTHERAPY	0 (0.0)	1 (0.1)	1 (0.0)
RALOXIFENE	1 (0.1)	0 (0.0)	1 (0.0)
RED BLOOD CELLS	1 (0.1)	0 (0.0)	1 (0.0)
RESVERATROL	0 (0.0)	1 (0.1)	1 (0.0)
RHEUM RHAPONTICUM	1 (0.1)	0 (0.0)	1 (0.0)
RIBOFLAVIN	0 (0.0)	1 (0.1)	1 (0.0)
RIBONUCLEIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
RIFAXIMIN	1 (0.1)	0 (0.0)	1 (0.0)
RISPERIDONE	0 (0.0)	1 (0.1)	1 (0.0)
ROPINIROLE	0 (0.0)	1 (0.1)	1 (0.0)
RUPATADINE	1 (0.1)	0 (0.0)	1 (0.0)
SAMBUCUS NIGRA	1 (0.1)	0 (0.0)	1 (0.0)
SANGUISORBA OFFICINALIS	0 (0.0)	1 (0.1)	1 (0.0)
SELENIUM;ZINC	1 (0.1)	0 (0.0)	1 (0.0)
SENNA ALEXANDRINA	0 (0.0)	1 (0.1)	1 (0.0)
SENNA SPP.	0 (0.0)	1 (0.1)	1 (0.0)
SERRAPEPTASE	1 (0.1)	0 (0.0)	1 (0.0)
SESAMUM INDICUM	0 (0.0)	1 (0.1)	1 (0.0)
SILICONES NOS	1 (0.1)	0 (0.0)	1 (0.0)
SILVER	0 (0.0)	1 (0.1)	1 (0.0)

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
SOLUTIONS FOR PARENTERAL NUTRITION	0 (0.0)	1 (0.1)	1 (0.0)
SORBITOL	1 (0.1)	0 (0.0)	1 (0.0)
SOY PROTEIN	0 (0.0)	1 (0.1)	1 (0.0)
STREPTOCOCCUS SALIVARIUS	1 (0.1)	0 (0.0)	1 (0.0)
STREPTODORNASE;STREPTOKINASE	1 (0.1)	0 (0.0)	1 (0.0)
SULFASALAZINE	1 (0.1)	0 (0.0)	1 (0.0)
SULINDAC	0 (0.0)	1 (0.1)	1 (0.0)
SUMATRIPTAN	1 (0.1)	0 (0.0)	1 (0.0)
SUPLATAST TOSILATE	0 (0.0)	1 (0.1)	1 (0.0)
TACROLIMUS	1 (0.1)	0 (0.0)	1 (0.0)
TAFLUPROST	0 (0.0)	1 (0.1)	1 (0.0)
TAGETES SPP.	0 (0.0)	1 (0.1)	1 (0.0)
TALC	0 (0.0)	1 (0.1)	1 (0.0)
TANNIC ACID	1 (0.1)	0 (0.0)	1 (0.0)
TECHNETIUM TC 99M	0 (0.0)	1 (0.1)	1 (0.0)
TEGOPRAZAN	0 (0.0)	1 (0.1)	1 (0.0)
TEICOPLANIN	1 (0.1)	0 (0.0)	1 (0.0)
TENOXICAM	0 (0.0)	1 (0.1)	1 (0.0)
TETANUS VACCINE	1 (0.1)	0 (0.0)	1 (0.0)
THEOPHYLLINE	1 (0.1)	0 (0.0)	1 (0.0)
THIOPENTAL	0 (0.0)	1 (0.1)	1 (0.0)
THYMALFASIN	1 (0.1)	0 (0.0)	1 (0.0)
THYROID	1 (0.1)	0 (0.0)	1 (0.0)
TIANEPTINE	1 (0.1)	0 (0.0)	1 (0.0)

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I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
TIMOLOL;TRAVOPROST	1 (0.1)	0 (0.0)	1 (0.0)
TIMONACIC	1 (0.1)	0 (0.0)	1 (0.0)
TIOTROPIUM	0 (0.0)	1 (0.1)	1 (0.0)
TIZANIDINE	0 (0.0)	1 (0.1)	1 (0.0)
TOBRAMYCIN	1 (0.1)	0 (0.0)	1 (0.0)
TOCOTRIENOLS NOS	1 (0.1)	0 (0.0)	1 (0.0)
TRETINOIN	0 (0.0)	1 (0.1)	1 (0.0)
TRIMEBUTINE	0 (0.0)	1 (0.1)	1 (0.0)
TRIMETAZIDINE	0 (0.0)	1 (0.1)	1 (0.0)
TRIMETHOPRIM	1 (0.1)	0 (0.0)	1 (0.0)
TRITICUM AESTIVUM	1 (0.1)	0 (0.0)	1 (0.0)
TROMETAMOL	1 (0.1)	0 (0.0)	1 (0.0)
TROSPIUM	0 (0.0)	1 (0.1)	1 (0.0)
TROXERUTIN	0 (0.0)	1 (0.1)	1 (0.0)
UBIDECARENONE;VITAMIN E NOS	0 (0.0)	1 (0.1)	1 (0.0)
VARICELLA ZOSTER VACCINES	0 (0.0)	1 (0.1)	1 (0.0)
VASOPRESSIN	1 (0.1)	0 (0.0)	1 (0.0)
VINPOCETINE	0 (0.0)	1 (0.1)	1 (0.0)
VISCUM ALBUM SUBSP. ABIETIS	1 (0.1)	0 (0.0)	1 (0.0)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12	1 (0.1)	0 (0.0)	1 (0.0)
VITAMIN D AND ANALOGUES	0 (0.0)	1 (0.1)	1 (0.0)
VORTIOXETINE	1 (0.1)	0 (0.0)	1 (0.0)
WHEY PROTEIN	1 (0.1)	0 (0.0)	1 (0.0)
XYLITOL	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Concomitant Medications and Therapies [by Decreasing Frequency] Page 48 of 48
Cohort 1 Population - Safety - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

Indication: Prophylaxis

	LY2835219-150 mg+EDT*a (N=1283) n (%)	EDT*a (N=1264) n (%)	Total (N=2547) n (%)
YELLOW FEVER VACCINE	0 (0.0)	1 (0.1)	1 (0.0)
ZALTOPROFEN	0 (0.0)	1 (0.1)	1 (0.0)
ZOPICLONE	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects who received medication.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_conmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1
/t_gba_conmed_prophylaxis_posmp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.2: Vortherapien

Anhang 4-G1.2.1: Jegliche Vortherapien (Prämenopausale Patientinnen)

Summary of Prior Medication and Therapy Page 1 of 4
Cohort 1 Population - ITT - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=777) n	(%)	EDT*a (N=728) n	(%)	Total (N=1505) n	(%)
Prior anti-cancer therapy						
Surgical procedure	776	(99.9)	728	(100.0)	1504	(99.9)
Radiotherapy	757	(97.4)	701	(96.3)	1458	(96.9)
Systemic therapy	773	(99.5)	725	(99.6)	1498	(99.5)
Surgical procedure: intent						
CURATIVE INTENT	776	(99.9)	728	(100.0)	1504	(99.9)
Radiotherapy: reason						
NEOADJUVANT	14	(1.8)	21	(2.9)	35	(2.3)
ADJUVANT	744	(95.8)	685	(94.1)	1429	(95.0)
Systemic therapy: reason and type						
NEO-ADJUVANT	319	(41.1)	313	(43.0)	632	(42.0)
Chemo	311	(40.0)	310	(42.6)	621	(41.3)
Endocrine	31	(4.0)	23	(3.2)	54	(3.6)
Other	2	(0.3)	0	(0.0)	2	(0.1)
Target	1	(0.1)	2	(0.3)	3	(0.2)
ADJUVANT	705	(90.7)	652	(89.6)	1357	(90.2)
Chemo	484	(62.3)	442	(60.7)	926	(61.5)
Endocrine	519	(66.8)	490	(67.3)	1009	(67.0)
Target	0	(0.0)	1	(0.1)	1	(0.1)
Systemic therapy: medication						
ANASTROZOLE	31	(4.0)	26	(3.6)	57	(3.8)
BEVACIZUMAB	1	(0.1)	0	(0.0)	1	(0.1)
CAPECITABINE	19	(2.4)	14	(1.9)	33	(2.2)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_priormed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_priormed_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Prior Medication and Therapy Page 2 of 4
Cohort 1 Population - ITT - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=777) n (%)	EDT*a (N=728) n (%)	Total (N=1505) n (%)
CARBOPLATIN	11 (1.4)	6 (0.8)	17 (1.1)
CISPLATIN	4 (0.5)	3 (0.4)	7 (0.5)
CYCLOPHOSPHAMIDE	732 (94.2)	695 (95.5)	1427 (94.8)
DOCETAXEL	336 (43.2)	322 (44.2)	658 (43.7)
DOXORUBICIN	402 (51.7)	390 (53.6)	792 (52.6)
EPIRUBICIN	337 (43.4)	313 (43.0)	650 (43.2)
EXEMESTANE	11 (1.4)	9 (1.2)	20 (1.3)
FLUOROURACIL	101 (13.0)	106 (14.6)	207 (13.8)
GONADORELIN	0 (0.0)	2 (0.3)	2 (0.1)
GOSERELIN	139 (17.9)	128 (17.6)	267 (17.7)
LETROZOLE	58 (7.5)	45 (6.2)	103 (6.8)
LEUPRORELIN	68 (8.8)	52 (7.1)	120 (8.0)
METHOTREXATE	1 (0.1)	2 (0.3)	3 (0.2)
PACLITAXEL	410 (52.8)	378 (51.9)	788 (52.4)
PEMBROLIZUMAB	2 (0.3)	0 (0.0)	2 (0.1)
PERTUZUMAB	0 (0.0)	1 (0.1)	1 (0.1)
PIRARUBICIN	2 (0.3)	5 (0.7)	7 (0.5)
SUNITINIB	0 (0.0)	1 (0.1)	1 (0.1)
TAMOXIFEN	393 (50.6)	374 (51.4)	767 (51.0)
TOREMIFENE	2 (0.3)	3 (0.4)	5 (0.3)
TRASTUZUMAB	0 (0.0)	1 (0.1)	1 (0.1)
TRIPTORELIN	15 (1.9)	18 (2.5)	33 (2.2)
VINORELBINE	3 (0.4)	3 (0.4)	6 (0.4)
Systemic therapy: reason and medication			
NEO-ADJUVANT	319 (41.1)	313 (43.0)	632 (42.0)
BEVACIZUMAB	1 (0.1)	0 (0.0)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_priormed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_priormed_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Prior Medication and Therapy — Page 3 of 4
Cohort 1 Population - ITT - Premenopausal — 03:32 27OCT2025
I3Y-MC-JPCF — PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=777) n	(%)	EDT*a (N=728) n	(%)	Total (N=1505) n	(%)
CAPECITABINE	1	(0.1)	4	(0.5)	5	(0.3)
CARBOPLATIN	7	(0.9)	4	(0.5)	11	(0.7)
CISPLATIN	4	(0.5)	2	(0.3)	6	(0.4)
CYCLOPHOSPHAMIDE	289	(37.2)	295	(40.5)	584	(38.8)
DOCETAXEL	133	(17.1)	118	(16.2)	251	(16.7)
DOXORUBICIN	166	(21.4)	165	(22.7)	331	(22.0)
EPIRUBICIN	136	(17.5)	139	(19.1)	275	(18.3)
FLUOROURACIL	37	(4.8)	37	(5.1)	74	(4.9)
GOSERELIN	14	(1.8)	8	(1.1)	22	(1.5)
LETROZOLE	3	(0.4)	2	(0.3)	5	(0.3)
LEUPRORELIN	8	(1.0)	8	(1.1)	16	(1.1)
PACLITAXEL	164	(21.1)	175	(24.0)	339	(22.5)
PEMBROLIZUMAB	2	(0.3)	0	(0.0)	2	(0.1)
PERTUZUMAB	0	(0.0)	1	(0.1)	1	(0.1)
PIRARUBICIN	1	(0.1)	2	(0.3)	3	(0.2)
SUNITINIB	0	(0.0)	1	(0.1)	1	(0.1)
TAMOXIFEN	10	(1.3)	5	(0.7)	15	(1.0)
TRASTUZUMAB	0	(0.0)	1	(0.1)	1	(0.1)
TRIPTORELIN	0	(0.0)	1	(0.1)	1	(0.1)
VINORELBINE	1	(0.1)	3	(0.4)	4	(0.3)
ADJUVANT	705	(90.7)	652	(89.6)	1357	(90.2)
ANASTROZOLE	31	(4.0)	26	(3.6)	57	(3.8)
CAPECITABINE	19	(2.4)	10	(1.4)	29	(1.9)
CARBOPLATIN	4	(0.5)	2	(0.3)	6	(0.4)
CISPLATIN	0	(0.0)	1	(0.1)	1	(0.1)
CYCLOPHOSPHAMIDE	447	(57.5)	408	(56.0)	855	(56.8)
DOCETAXEL	209	(26.9)	209	(28.7)	418	(27.8)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_priormed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_priormed_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Prior Medication and Therapy — Page 4 of 4
Cohort 1 Population - ITT - Premenopausal — 03:32 27OCT2025
I3Y-MC-JPCF — PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=777) n	(%)	EDT*a (N=728) n	(%)	Total (N=1505) n	(%)
DOXORUBICIN	238	(30.6)	228	(31.3)	466	(31.0)
EPIRUBICIN	204	(26.3)	178	(24.5)	382	(25.4)
EXEMESTANE	11	(1.4)	9	(1.2)	20	(1.3)
FLUOROURACIL	64	(8.2)	69	(9.5)	133	(8.8)
GONADORELIN	0	(0.0)	2	(0.3)	2	(0.1)
GOSERELIN	136	(17.5)	128	(17.6)	264	(17.5)
LETROZOLE	58	(7.5)	45	(6.2)	103	(6.8)
LEUPRORELIN	67	(8.6)	51	(7.0)	118	(7.8)
METHOTREXATE	1	(0.1)	2	(0.3)	3	(0.2)
PACLITAXEL	246	(31.7)	206	(28.3)	452	(30.0)
PERTUZUMAB	0	(0.0)	1	(0.1)	1	(0.1)
PIRARUBICIN	1	(0.1)	3	(0.4)	4	(0.3)
TAMOXIFEN	389	(50.1)	371	(51.0)	760	(50.5)
TOREMIFENE	2	(0.3)	3	(0.4)	5	(0.3)
TRASTUZUMAB	0	(0.0)	1	(0.1)	1	(0.1)
TRIPTORELIN	15	(1.9)	18	(2.5)	33	(2.2)
VINORELBINE	2	(0.3)	0	(0.0)	2	(0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_priormed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_priormed_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.2.2: Jegliche Vortherapien (Postmenopausale Patientinnen)

Summary of Prior Medication and Therapy Page 1 of 5
Cohort 1 Population - ITT - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n	(%)	EDT*a (N=1263) n	(%)	Total (N=2547) n	(%)
Prior anti-cancer therapy						
Surgical procedure	1282	(99.8)	1263	(100.0)	2545	(99.9)
Radiotherapy	1223	(95.2)	1213	(96.0)	2436	(95.6)
Systemic therapy	1244	(96.9)	1222	(96.8)	2466	(96.8)
Surgical procedure: intent						
CURATIVE INTENT	1282	(99.8)	1263	(100.0)	2545	(99.9)
Radiotherapy: reason						
NEOADJUVANT	32	(2.5)	25	(2.0)	57	(2.2)
ADJUVANT	1196	(93.1)	1188	(94.1)	2384	(93.6)
Systemic therapy: reason and type						
NEO-ADJUVANT	438	(34.1)	429	(34.0)	867	(34.0)
Chemo	423	(32.9)	407	(32.2)	830	(32.6)
Endocrine	27	(2.1)	39	(3.1)	66	(2.6)
Other	0	(0.0)	1	(0.1)	1	(0.0)
Target	4	(0.3)	0	(0.0)	4	(0.2)
ADJUVANT	1096	(85.4)	1080	(85.5)	2176	(85.4)
Chemo	817	(63.6)	800	(63.3)	1617	(63.5)
Endocrine	765	(59.6)	737	(58.4)	1502	(59.0)
Target	1	(0.1)	0	(0.0)	1	(0.0)
Term to be coded	1	(0.1)	0	(0.0)	1	(0.0)
Term to be coded	1	(0.1)	0	(0.0)	1	(0.0)
Systemic therapy: medication						
ANASTROZOLE	246	(19.2)	209	(16.5)	455	(17.9)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_priormed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_priormed_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Prior Medication and Therapy Page 2 of 5
Cohort 1 Population - ITT - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
AZD 9496	1 (0.1)	0 (0.0)	1 (0.0)
BEVACIZUMAB	3 (0.2)	0 (0.0)	3 (0.1)
CAPECITABINE	10 (0.8)	18 (1.4)	28 (1.1)
CARBOPLATIN	9 (0.7)	15 (1.2)	24 (0.9)
CISPLATIN	1 (0.1)	5 (0.4)	6 (0.2)
CYCLOPHOSPHAMIDE	1133 (88.2)	1113 (88.1)	2246 (88.2)
DOCETAXEL	481 (37.5)	470 (37.2)	951 (37.3)
DOXORUBICIN	640 (49.8)	635 (50.3)	1275 (50.1)
EPIRUBICIN	467 (36.4)	456 (36.1)	923 (36.2)
ERIBULIN	1 (0.1)	1 (0.1)	2 (0.1)
EXEMESTANE	5 (0.4)	5 (0.4)	10 (0.4)
FLUOROURACIL	147 (11.4)	139 (11.0)	286 (11.2)
FULVESTRANT	2 (0.2)	2 (0.2)	4 (0.2)
GEMCITABINE	0 (0.0)	1 (0.1)	1 (0.0)
GOSERELIN	13 (1.0)	9 (0.7)	22 (0.9)
INVESTIGATIONAL DRUG	0 (0.0)	1 (0.1)	1 (0.0)
LADIRATUZUMAB VEDOTIN	0 (0.0)	1 (0.1)	1 (0.0)
LETROZOLE	447 (34.8)	431 (34.1)	878 (34.5)
LEUPRORELIN	5 (0.4)	4 (0.3)	9 (0.4)
METHOTREXATE	9 (0.7)	10 (0.8)	19 (0.7)
MITOXANTRONE	2 (0.2)	0 (0.0)	2 (0.1)
PACLITAXEL	673 (52.4)	656 (51.9)	1329 (52.2)
PERTUZUMAB	1 (0.1)	0 (0.0)	1 (0.0)
PIRARUBICIN	5 (0.4)	0 (0.0)	5 (0.2)
TAMOXIFEN	84 (6.5)	112 (8.9)	196 (7.7)
TOREMIFENE	0 (0.0)	1 (0.1)	1 (0.0)
TRASTUZUMAB	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_priormed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_priormed_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Prior Medication and Therapy — Page 3 of 5
Cohort 1 Population - ITT - Postmenopausal — 03:32 27OCT2025
I3Y-MC-JPCF — PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n	(%)	EDT*a (N=1263) n	(%)	Total (N=2547) n	(%)
TRIPTORELIN	2	(0.2)	2	(0.2)	4	(0.2)
Term to be coded	1	(0.1)	0	(0.0)	1	(0.0)
VINORELBINE	1	(0.1)	4	(0.3)	5	(0.2)
Systemic therapy: reason and medication						
NEO-ADJUVANT	438	(34.1)	429	(34.0)	867	(34.0)
ANASTROZOLE	8	(0.6)	10	(0.8)	18	(0.7)
AZD 9496	1	(0.1)	0	(0.0)	1	(0.0)
BEVACIZUMAB	3	(0.2)	0	(0.0)	3	(0.1)
CAPECITABINE	0	(0.0)	1	(0.1)	1	(0.0)
CARBOPLATIN	3	(0.2)	5	(0.4)	8	(0.3)
CISPLATIN	0	(0.0)	4	(0.3)	4	(0.2)
CYCLOPHOSPHAMIDE	390	(30.4)	376	(29.8)	766	(30.1)
DOCETAXEL	146	(11.4)	160	(12.7)	306	(12.0)
DOXORUBICIN	241	(18.8)	243	(19.2)	484	(19.0)
EPIRUBICIN	162	(12.6)	143	(11.3)	305	(12.0)
EXEMESTANE	2	(0.2)	1	(0.1)	3	(0.1)
FLUOROURACIL	38	(3.0)	39	(3.1)	77	(3.0)
FULVESTRANT	2	(0.2)	2	(0.2)	4	(0.2)
GOSERELIN	1	(0.1)	3	(0.2)	4	(0.2)
INVESTIGATIONAL DRUG	0	(0.0)	1	(0.1)	1	(0.0)
LADIRATUZUMAB VEDOTIN	0	(0.0)	1	(0.1)	1	(0.0)
LETROZOLE	14	(1.1)	17	(1.3)	31	(1.2)
METHOTREXATE	0	(0.0)	1	(0.1)	1	(0.0)
PACLITAXEL	244	(19.0)	228	(18.1)	472	(18.5)
PERTUZUMAB	1	(0.1)	0	(0.0)	1	(0.0)
PIRARUBICIN	1	(0.1)	0	(0.0)	1	(0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_priormed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_priormed_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - ITT - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
TAMOXIFEN	1 (0.1)	7 (0.6)	8 (0.3)
TOREMIFENE	0 (0.0)	1 (0.1)	1 (0.0)
TRASTUZUMAB	1 (0.1)	0 (0.0)	1 (0.0)
VINORELBINE	0 (0.0)	2 (0.2)	2 (0.1)
ADJUVANT	1096 (85.4)	1080 (85.5)	2176 (85.4)
ANASTROZOLE	244 (19.0)	206 (16.3)	450 (17.7)
CAPECITABINE	10 (0.8)	17 (1.3)	27 (1.1)
CARBOPLATIN	6 (0.5)	10 (0.8)	16 (0.6)
CISPLATIN	1 (0.1)	1 (0.1)	2 (0.1)
CYCLOPHOSPHAMIDE	750 (58.4)	745 (59.0)	1495 (58.7)
DOCETAXEL	345 (26.9)	317 (25.1)	662 (26.0)
DOXORUBICIN	405 (31.5)	395 (31.3)	800 (31.4)
EPIRUBICIN	307 (23.9)	316 (25.0)	623 (24.5)
ERIBULIN	1 (0.1)	1 (0.1)	2 (0.1)
EXEMESTANE	3 (0.2)	4 (0.3)	7 (0.3)
FLUOROURACIL	110 (8.6)	101 (8.0)	211 (8.3)
GEMCITABINE	0 (0.0)	1 (0.1)	1 (0.0)
GOSERELIN	13 (1.0)	8 (0.6)	21 (0.8)
LETROZOLE	446 (34.7)	427 (33.8)	873 (34.3)
LEUPRORELIN	5 (0.4)	4 (0.3)	9 (0.4)
METHOTREXATE	9 (0.7)	9 (0.7)	18 (0.7)
MITOXANTRONE	2 (0.2)	0 (0.0)	2 (0.1)
PACLITAXEL	433 (33.7)	433 (34.3)	866 (34.0)
PERTUZUMAB	1 (0.1)	0 (0.0)	1 (0.0)
PIRARUBICIN	4 (0.3)	0 (0.0)	4 (0.2)
TAMOXIFEN	84 (6.5)	109 (8.6)	193 (7.6)
TRASTUZUMAB	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_priormed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_priormed_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Prior Medication and Therapy Page 5 of 5
Cohort 1 Population - ITT - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
TRIPTORELIN	2 (0.2)	2 (0.2)	4 (0.2)
VINORELBINE	1 (0.1)	3 (0.2)	4 (0.2)
Term to be coded	1 (0.1)	0 (0.0)	1 (0.0)
Term to be coded	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_priormed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_priormed_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.3: Folgetherapien

Anhang 4-G1.3.1: Jegliche Folgetherapien (Prämenopausale Patientinnen)

Summary of Post Discontinuation Therapy — Page 1 of 4
Cohort 1 Population - ITT - Premenopausal — 03:32 27OCT2025
I3Y-MC-JPCF — PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=777) n	(%)	EDT*a (N=728) n	(%)	Total (N=1505) n	(%)
Surgical procedure	28	(3.6)	37	(5.1)	65	(4.3)
Radiotherapy	29	(3.7)	33	(4.5)	62	(4.1)
Systemic Therapy						
Overall	725	(93.3)	675	(92.7)	1400	(93.0)
Chemo	59	(7.6)	86	(11.8)	145	(9.6)
AZACITIDINE	0	(0.0)	1	(0.1)	1	(0.1)
CAPECITABINE	28	(3.6)	47	(6.5)	75	(5.0)
CARBOPLATIN	12	(1.5)	14	(1.9)	26	(1.7)
CARMUSTINE	0	(0.0)	1	(0.1)	1	(0.1)
CISPLATIN	5	(0.6)	8	(1.1)	13	(0.9)
CYCLOPHOSPHAMIDE	9	(1.2)	7	(1.0)	16	(1.1)
CYTARABINE	0	(0.0)	1	(0.1)	1	(0.1)
DATOPOTAMAB DERUXTECAN	0	(0.0)	1	(0.1)	1	(0.1)
DAUNORUBICIN	0	(0.0)	1	(0.1)	1	(0.1)
DECITABINE	0	(0.0)	1	(0.1)	1	(0.1)
DOCETAXEL	7	(0.9)	13	(1.8)	20	(1.3)
DOXORUBICIN	7	(0.9)	6	(0.8)	13	(0.9)
EPIRUBICIN	4	(0.5)	2	(0.3)	6	(0.4)
ERIBULIN	11	(1.4)	18	(2.5)	29	(1.9)
ETOPOSIDE	0	(0.0)	1	(0.1)	1	(0.1)
FLUOROURACIL	3	(0.4)	0	(0.0)	3	(0.2)
GEMCITABINE	11	(1.4)	17	(2.3)	28	(1.9)
GIMERACIL;OTERACIL;TEGAFUR	1	(0.1)	3	(0.4)	4	(0.3)
HYDROXYCARBAMIDE	0	(0.0)	1	(0.1)	1	(0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_postmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Post Discontinuation Therapy — Page 2 of 4
Cohort 1 Population - ITT - Premenopausal — 03:32 27OCT2025
I3Y-MC-JPCF — PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=777) n (%)	EDT*a (N=728) n (%)	Total (N=1505) n (%)
IRINOTECAN	0 (0.0)	1 (0.1)	1 (0.1)
IXABEPILONE	0 (0.0)	1 (0.1)	1 (0.1)
METHOTREXATE	2 (0.3)	1 (0.1)	3 (0.2)
MITOMYCIN	2 (0.3)	0 (0.0)	2 (0.1)
MITOXANTRONE	1 (0.1)	0 (0.0)	1 (0.1)
OTERACIL	1 (0.1)	0 (0.0)	1 (0.1)
OXALIPLATIN	1 (0.1)	0 (0.0)	1 (0.1)
PACLITAXEL	26 (3.3)	42 (5.8)	68 (4.5)
SACITUZUMAB GOVITECAN	10 (1.3)	4 (0.5)	14 (0.9)
TEGAFUR	1 (0.1)	0 (0.0)	1 (0.1)
TESETAXEL	1 (0.1)	0 (0.0)	1 (0.1)
VINCRISTINE	1 (0.1)	0 (0.0)	1 (0.1)
VINORELBINE	5 (0.6)	8 (1.1)	13 (0.9)
Endocrine	712 (91.6)	655 (90.0)	1367 (90.8)
ANASTROZOLE	115 (14.8)	86 (11.8)	201 (13.4)
ELACESTRANT	0 (0.0)	1 (0.1)	1 (0.1)
EXEMESTANE	44 (5.7)	44 (6.0)	88 (5.8)
FULVESTRANT	42 (5.4)	63 (8.7)	105 (7.0)
GIREDESTRANT	0 (0.0)	2 (0.3)	2 (0.1)
GOSERELIN	170 (21.9)	154 (21.2)	324 (21.5)
IMLUNESTRANT	5 (0.6)	5 (0.7)	10 (0.7)
LETROZOLE	235 (30.2)	229 (31.5)	464 (30.8)
LEUPRORELIN	104 (13.4)	98 (13.5)	202 (13.4)
MEDROXYPROGESTERONE	1 (0.1)	0 (0.0)	1 (0.1)
SELECTIVE ESTROGEN RECEPTOR MODULATORS	0 (0.0)	1 (0.1)	1 (0.1)
TAMOXIFEN	485 (62.4)	439 (60.3)	924 (61.4)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_postmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

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Cohort 1 Population - ITT - Premenopausal — 03:32 27OCT2025
I3Y-MC-JPCF — PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=777) n (%)	EDT*a (N=728) n (%)	Total (N=1505) n (%)
TRIPTORELIN	20 (2.6)	19 (2.6)	39 (2.6)
Other	12 (1.5)	14 (1.9)	26 (1.7)
ATEZOLIZUMAB	1 (0.1)	2 (0.3)	3 (0.2)
DENOSUMAB	0 (0.0)	3 (0.4)	3 (0.2)
ETHANOL	1 (0.1)	0 (0.0)	1 (0.1)
GIMERACIL	1 (0.1)	0 (0.0)	1 (0.1)
INVESTIGATIONAL DRUG	6 (0.8)	5 (0.7)	11 (0.7)
OTHER ANTINEOPLASTIC AGENTS	0 (0.0)	1 (0.1)	1 (0.1)
PEMBROLIZUMAB	2 (0.3)	3 (0.4)	5 (0.3)
ZOLEDRONIC ACID	1 (0.1)	0 (0.0)	1 (0.1)
Target	70 (9.0)	127 (17.4)	197 (13.1)
ABEMACICLIB	10 (1.3)	43 (5.9)	53 (3.5)
ALPELISIB	2 (0.3)	4 (0.5)	6 (0.4)
BEVACIZUMAB	9 (1.2)	16 (2.2)	25 (1.7)
CAPIVASERTIB	0 (0.0)	3 (0.4)	3 (0.2)
CHIDAMIDE	1 (0.1)	0 (0.0)	1 (0.1)
DALPICICLIB	1 (0.1)	0 (0.0)	1 (0.1)
EVEROLIMUS	4 (0.5)	7 (1.0)	11 (0.7)
OLAPARIB	3 (0.4)	2 (0.3)	5 (0.3)
PALBOCICLIB	18 (2.3)	32 (4.4)	50 (3.3)
PERTUZUMAB	3 (0.4)	3 (0.4)	6 (0.4)
PROTEIN KINASE INHIBITORS	0 (0.0)	1 (0.1)	1 (0.1)
RIBOCICLIB	27 (3.5)	47 (6.5)	74 (4.9)
TALAZOPARIB	1 (0.1)	4 (0.5)	5 (0.3)
TORIPALIMAB	1 (0.1)	0 (0.0)	1 (0.1)
TRASTUZUMAB	5 (0.6)	3 (0.4)	8 (0.5)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_postmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Post Discontinuation Therapy Page 4 of 4
Cohort 1 Population - ITT - Premenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=777) n (%)	EDT*a (N=728) n (%)	Total (N=1505) n (%)
TRASTUZUMAB DERUXTECAN	5 (0.6)	10 (1.4)	15 (1.0)
TRASTUZUMAB EMTANSINE	1 (0.1)	0 (0.0)	1 (0.1)
VENADAPARIB	0 (0.0)	1 (0.1)	1 (0.1)
VENETOCLAX	0 (0.0)	1 (0.1)	1 (0.1)
XENTUZUMAB	0 (0.0)	1 (0.1)	1 (0.1)
Term to be coded	3 (0.4)	2 (0.3)	5 (0.3)
ACTINOMYCINES	1 (0.1)	0 (0.0)	1 (0.1)
BEBT 209	0 (0.0)	1 (0.1)	1 (0.1)
BEBT 908	0 (0.0)	1 (0.1)	1 (0.1)
EVEROLIMUS;EXEMESTANE	1 (0.1)	0 (0.0)	1 (0.1)
LUCICEBTIDE	0 (0.0)	1 (0.1)	1 (0.1)
POLYENE PHOSPHATIDYLCHOLINE	1 (0.1)	0 (0.0)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_postmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.3.2: Jegliche Folgetherapien (Postmenopausale Patientinnen)

Summary of Post Discontinuation Therapy Page 1 of 4
Cohort 1 Population - ITT - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
Surgical procedure	27 (2.1)	47 (3.7)	74 (2.9)
Radiotherapy	43 (3.3)	69 (5.5)	112 (4.4)
Systemic Therapy			
Overall	1172 (91.3)	1167 (92.4)	2339 (91.8)
Chemo	104 (8.1)	148 (11.7)	252 (9.9)
ALBUMIN HUMAN;PACLITAXEL	0 (0.0)	1 (0.1)	1 (0.0)
AZACITIDINE	2 (0.2)	0 (0.0)	2 (0.1)
CAPECITABINE	46 (3.6)	70 (5.5)	116 (4.6)
CARBOPLATIN	21 (1.6)	26 (2.1)	47 (1.8)
CISPLATIN	5 (0.4)	10 (0.8)	15 (0.6)
CYCLOPHOSPHAMIDE	13 (1.0)	10 (0.8)	23 (0.9)
DOCETAXEL	6 (0.5)	18 (1.4)	24 (0.9)
DOXORUBICIN	6 (0.5)	11 (0.9)	17 (0.7)
EPIRUBICIN	2 (0.2)	4 (0.3)	6 (0.2)
ERIBULIN	23 (1.8)	19 (1.5)	42 (1.6)
FLUOROURACIL	3 (0.2)	5 (0.4)	8 (0.3)
FLUOROURACIL;FOLINIC ACID;OXALIPLATIN	1 (0.1)	0 (0.0)	1 (0.0)
GEMCITABINE	22 (1.7)	27 (2.1)	49 (1.9)
GIMERACIL;OTERACIL;TEGAFUR	2 (0.2)	8 (0.6)	10 (0.4)
IRINOTECAN	1 (0.1)	1 (0.1)	2 (0.1)
METHOTREXATE	5 (0.4)	3 (0.2)	8 (0.3)
MITOMYCIN	2 (0.2)	0 (0.0)	2 (0.1)
MITOXANTRONE	3 (0.2)	0 (0.0)	3 (0.1)
NEDAPLATIN	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_postmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Post Discontinuation Therapy Page 2 of 4
Cohort 1 Population - ITT - Postmenopausal 03:32 27OCT2025
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
OXALIPLATIN	0 (0.0)	1 (0.1)	1 (0.0)
PACLITAXEL	39 (3.0)	52 (4.1)	91 (3.6)
SACITUZUMAB GOVITECAN	11 (0.9)	14 (1.1)	25 (1.0)
TEMOZOLOMIDE	1 (0.1)	2 (0.2)	3 (0.1)
TESETAXEL	0 (0.0)	1 (0.1)	1 (0.0)
VINCRISTINE	2 (0.2)	0 (0.0)	2 (0.1)
VINORELBINE	9 (0.7)	13 (1.0)	22 (0.9)
Endocrine	1145 (89.2)	1136 (89.9)	2281 (89.6)
AMCENESTRANT	0 (0.0)	1 (0.1)	1 (0.0)
ANASTROZOLE	389 (30.3)	396 (31.4)	785 (30.8)
BICALUTAMIDE	1 (0.1)	0 (0.0)	1 (0.0)
CAMIZESTRANT	1 (0.1)	0 (0.0)	1 (0.0)
ELACESTRANT	0 (0.0)	6 (0.5)	6 (0.2)
EXEMESTANE	46 (3.6)	52 (4.1)	98 (3.8)
FULVESTRANT	81 (6.3)	149 (11.8)	230 (9.0)
GIREDESTRANT	0 (0.0)	1 (0.1)	1 (0.0)
GOSERELIN	15 (1.2)	22 (1.7)	37 (1.5)
IMLUNESTRANT	6 (0.5)	5 (0.4)	11 (0.4)
LETROZOLE	669 (52.1)	630 (49.9)	1299 (51.0)
LEUPRORELIN	2 (0.2)	6 (0.5)	8 (0.3)
TAMOXIFEN	129 (10.0)	145 (11.5)	274 (10.8)
TOREMIFENE	2 (0.2)	0 (0.0)	2 (0.1)
TRIPTORELIN	2 (0.2)	0 (0.0)	2 (0.1)
Other	19 (1.5)	19 (1.5)	38 (1.5)
ATEZOLIZUMAB	2 (0.2)	2 (0.2)	4 (0.2)
DENDRITIC CELLS CYTOKINE INDUCED KILLER CELLS	1 (0.1)	0 (0.0)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_postmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Post Discontinuation Therapy — Page 3 of 4
Cohort 1 Population - ITT - Postmenopausal — 03:32 27OCT2025
I3Y-MC-JPCF — PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
DENOSUMAB	3 (0.2)	3 (0.2)	6 (0.2)
DEXAMETHASONE	1 (0.1)	0 (0.0)	1 (0.0)
DURVALUMAB	0 (0.0)	1 (0.1)	1 (0.0)
IMMUNOTHERAPY	1 (0.1)	0 (0.0)	1 (0.0)
INVESTIGATIONAL DRUG	4 (0.3)	4 (0.3)	8 (0.3)
IODINE (131 I)	0 (0.0)	1 (0.1)	1 (0.0)
KL A167	1 (0.1)	0 (0.0)	1 (0.0)
PEMBROLIZUMAB	6 (0.5)	5 (0.4)	11 (0.4)
PREDNISOLONE	1 (0.1)	1 (0.1)	2 (0.1)
RITUXIMAB	1 (0.1)	0 (0.0)	1 (0.0)
ZOLEDRONIC ACID	1 (0.1)	2 (0.2)	3 (0.1)
Target	94 (7.3)	183 (14.5)	277 (10.9)
ABEMACICLIB	10 (0.8)	61 (4.8)	71 (2.8)
ALPELISIB	5 (0.4)	2 (0.2)	7 (0.3)
BEVACIZUMAB	10 (0.8)	16 (1.3)	26 (1.0)
CAPIVASERTIB	1 (0.1)	2 (0.2)	3 (0.1)
DALPICICLIB	0 (0.0)	2 (0.2)	2 (0.1)
EVEROLIMUS	5 (0.4)	21 (1.7)	26 (1.0)
FELMETATUG VEDOTIN	0 (0.0)	1 (0.1)	1 (0.0)
FUZULOPARIB	0 (0.0)	1 (0.1)	1 (0.0)
INAVOLISIB	1 (0.1)	0 (0.0)	1 (0.0)
NIRAPARIB	2 (0.2)	0 (0.0)	2 (0.1)
OLAPARIB	2 (0.2)	3 (0.2)	5 (0.2)
PALBOCICLIB	29 (2.3)	76 (6.0)	105 (4.1)
PERTUZUMAB	4 (0.3)	4 (0.3)	8 (0.3)
PERTUZUMAB;TRASTUZUMAB	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_postmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of Post Discontinuation Therapy — Page 4 of 4
Cohort 1 Population - ITT - Postmenopausal — 03:32 27OCT2025
I3Y-MC-JPCF — PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
RIBOCICLIB	34 (2.6)	47 (3.7)	81 (3.2)
SACITUZUMAB TIRUMOTECAN	1 (0.1)	0 (0.0)	1 (0.0)
SELPERCATINIB	0 (0.0)	1 (0.1)	1 (0.0)
TRASTUZUMAB	5 (0.4)	6 (0.5)	11 (0.4)
TRASTUZUMAB DERUXTECAN	15 (1.2)	13 (1.0)	28 (1.1)
TRASTUZUMAB EMTANSINE	1 (0.1)	2 (0.2)	3 (0.1)
TUCATINIB	1 (0.1)	0 (0.0)	1 (0.0)
Term to be coded	2 (0.2)	3 (0.2)	5 (0.2)
BT 8009	0 (0.0)	1 (0.1)	1 (0.0)
CALCIUM CARBONATE;COLECALCIFEROL	1 (0.1)	0 (0.0)	1 (0.0)
CARBOPLATIN;ETOPOSIDE	0 (0.0)	1 (0.1)	1 (0.0)
ENFORTUMAB VEDOTIN	0 (0.0)	1 (0.1)	1 (0.0)
GRANISETRON	1 (0.1)	0 (0.0)	1 (0.0)
PEMIGATINIB	0 (0.0)	1 (0.1)	1 (0.0)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_postmed.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.3.3: Erste Folgetherapien (Prämenopausale Patientinnen)

Summary of First Subsequent Post Discontinuation Anti-Cancer Therapy Page 1 of 2
Cohort 1 Population - ITT - Premenopausal 04:02 29JAN2026
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=777) n (%)	EDT*a (N=728) n (%)	Total (N=1505) n (%)
Systemic Therapy			
Overall	725 (93.3)	675 (92.7)	1400 (93.0)
Chemo	18 (2.3)	22 (3.0)	40 (2.7)
CAPECITABINE	5 (0.6)	11 (1.5)	16 (1.1)
CARBOPLATIN	2 (0.3)	2 (0.3)	4 (0.3)
CISPLATIN	1 (0.1)	1 (0.1)	2 (0.1)
CYCLOPHOSPHAMIDE	2 (0.3)	1 (0.1)	3 (0.2)
DOCETAXEL	3 (0.4)	5 (0.7)	8 (0.5)
GEMCITABINE	3 (0.4)	0 (0.0)	3 (0.2)
PACLITAXEL	7 (0.9)	6 (0.8)	13 (0.9)
VINORELBINE	0 (0.0)	2 (0.3)	2 (0.1)
Endocrine	707 (91.0)	648 (89.0)	1355 (90.0)
ANASTROZOLE	71 (9.1)	50 (6.9)	121 (8.0)
EXEMESTANE	18 (2.3)	19 (2.6)	37 (2.5)
FULVESTRANT	4 (0.5)	17 (2.3)	21 (1.4)
GOSERELIN	132 (17.0)	114 (15.7)	246 (16.3)
LETROZOLE	137 (17.6)	122 (16.8)	259 (17.2)
LEUPRORELIN	80 (10.3)	79 (10.9)	159 (10.6)
TAMOXIFEN	465 (59.8)	428 (58.8)	893 (59.3)
TRIPTORELIN	17 (2.2)	17 (2.3)	34 (2.3)
Other	0 (0.0)	1 (0.1)	1 (0.1)
OTHER ANTINEOPLASTIC AGENTS	0 (0.0)	1 (0.1)	1 (0.1)
Target	8 (1.0)	36 (4.9)	44 (2.9)
ABEMACICLIB	0 (0.0)	10 (1.4)	10 (0.7)
ALPELISIB	0 (0.0)	1 (0.1)	1 (0.1)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_postmed1.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed1_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of First Subsequent Post Discontinuation Anti-Cancer Therapy Page 2 of 2
Cohort 1 Population - ITT - Premenopausal 04:02 29JAN2026
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=777) n (%)	EDT*a (N=728) n (%)	Total (N=1505) n (%)
BEVACIZUMAB	1 (0.1)	3 (0.4)	4 (0.3)
OLAPARIB	0 (0.0)	1 (0.1)	1 (0.1)
PALBOCICLIB	3 (0.4)	9 (1.2)	12 (0.8)
PERTUZUMAB	2 (0.3)	2 (0.3)	4 (0.3)
RIBOCICLIB	1 (0.1)	9 (1.2)	10 (0.7)
TALAZOPARIB	1 (0.1)	1 (0.1)	2 (0.1)
TRASTUZUMAB	2 (0.3)	2 (0.3)	4 (0.3)

*a According to appropriate comparator by G-BA:
Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_postmed1.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed1_premp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G1.3.4: Erste Folgetherapien (Postmenopausale Patientinnen)

Summary of First Subsequent Post Discontinuation Anti-Cancer Therapy Page 1 of 2
Cohort 1 Population - ITT - Postmenopausal 04:02 29JAN2026
I3Y-MC-JPCF PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
Systemic Therapy			
Overall	1172 (91.3)	1167 (92.4)	2339 (91.8)
Chemo	29 (2.3)	37 (2.9)	66 (2.6)
ALBUMIN HUMAN;PACLITAXEL	0 (0.0)	1 (0.1)	1 (0.0)
CAPECITABINE	8 (0.6)	9 (0.7)	17 (0.7)
CARBOPLATIN	2 (0.2)	8 (0.6)	10 (0.4)
CISPLATIN	2 (0.2)	1 (0.1)	3 (0.1)
CYCLOPHOSPHAMIDE	2 (0.2)	5 (0.4)	7 (0.3)
DOCETAXEL	0 (0.0)	6 (0.5)	6 (0.2)
DOXORUBICIN	1 (0.1)	0 (0.0)	1 (0.0)
EPIRUBICIN	0 (0.0)	2 (0.2)	2 (0.1)
ERIBULIN	6 (0.5)	0 (0.0)	6 (0.2)
FLUOROURACIL	1 (0.1)	4 (0.3)	5 (0.2)
GEMCITABINE	3 (0.2)	6 (0.5)	9 (0.4)
GIMERACIL;OTERACIL;TEGAFUR	0 (0.0)	1 (0.1)	1 (0.0)
METHOTREXATE	3 (0.2)	1 (0.1)	4 (0.2)
MITOMYCIN	2 (0.2)	0 (0.0)	2 (0.1)
MITOXANTRONE	2 (0.2)	0 (0.0)	2 (0.1)
OXALIPLATIN	0 (0.0)	1 (0.1)	1 (0.0)
PACLITAXEL	6 (0.5)	8 (0.6)	14 (0.5)
SACITUZUMAB GOVITECAN	1 (0.1)	0 (0.0)	1 (0.0)
TEMOZOLOMIDE	0 (0.0)	1 (0.1)	1 (0.0)
VINCRISTINE	1 (0.1)	0 (0.0)	1 (0.0)
VINORELBINE	0 (0.0)	2 (0.2)	2 (0.1)
Endocrine	1139 (88.7)	1126 (89.2)	2265 (88.9)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed1_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Summary of First Subsequent Post Discontinuation Anti-Cancer Therapy — Page 2 of 2
Cohort 1 Population - ITT - Postmenopausal — 04:02 29JAN2026
I3Y-MC-JPCF — PDPM
Data cutoff: 15JUL2025

	LY2835219-150 mg+EDT*a (N=1284) n (%)	EDT*a (N=1263) n (%)	Total (N=2547) n (%)
ANASTROZOLE	372 (29.0)	369 (29.2)	741 (29.1)
CAMIZESTRANT	1 (0.1)	0 (0.0)	1 (0.0)
EXEMESTANE	9 (0.7)	9 (0.7)	18 (0.7)
FULVESTRANT	14 (1.1)	31 (2.5)	45 (1.8)
GOSERELIN	11 (0.9)	17 (1.3)	28 (1.1)
LETROZOLE	639 (49.8)	599 (47.4)	1238 (48.6)
LEUPRORELIN	2 (0.2)	2 (0.2)	4 (0.2)
TAMOXIFEN	103 (8.0)	115 (9.1)	218 (8.6)
TOREMIFENE	1 (0.1)	0 (0.0)	1 (0.0)
TRIPTORELIN	2 (0.2)	0 (0.0)	2 (0.1)
Other	0 (0.0)	2 (0.2)	2 (0.1)
ATEZOLIZUMAB	0 (0.0)	1 (0.1)	1 (0.0)
PEMBROLIZUMAB	0 (0.0)	1 (0.1)	1 (0.0)
Target	13 (1.0)	35 (2.8)	48 (1.9)
ABEMACICLIB	0 (0.0)	5 (0.4)	5 (0.2)
ALPELISIB	1 (0.1)	0 (0.0)	1 (0.0)
BEVACIZUMAB	2 (0.2)	2 (0.2)	4 (0.2)
OLAPARIB	1 (0.1)	1 (0.1)	2 (0.1)
PALBOCICLIB	4 (0.3)	22 (1.7)	26 (1.0)
PERTUZUMAB	1 (0.1)	2 (0.2)	3 (0.1)
RIBOCICLIB	4 (0.3)	3 (0.2)	7 (0.3)
TRASTUZUMAB	0 (0.0)	2 (0.2)	2 (0.1)

*a According to appropriate comparator by G-BA:
Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen
Abbreviations: N = number of subjects in analysis population; n = number of subjects in the specified category.
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t_gba_postmed1_posmp_itt3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba

Anhang 4-G2: Ergänzende Ergebnisdarstellung des finalen Datenschnitts vom 15.07.2025

Anhang 4-G2.1: Gesamtüberleben

Anhang 4-G2.1.1: Subgruppenanalysen nicht-interagierender Subgruppen

Tabelle 101.1.2: Subgruppen für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - ITT - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9995)					
Neoadjuvante Chemotherapie	41/315 (13,0)	NE [NE; NE]	57/305 (18,7)	90,9 [NE; NE]	0,67 [0,45; 0,99] 0,0457
Adjuvante Chemotherapie	24/452 (5,3)	NE [NE; NE]	32/416 (7,7)	NE [NE; NE]	0,66 [0,39; 1,12] 0,1235
Keine Chemotherapie	0/10 (0,0)	NE [NE; NE]	1/7 (14,3)	NE [68,38; NE]	0,00 [0,00; NE] 0,3173
Region (p-Wert des Interaktionsterms: 0,6476)					
Nordamerika / Europa	34/348 (9,8)	NE [NE; NE]	42/308 (13,6)	NE [90,87; NE]	0,70 [0,45; 1,10] 0,1218
Asien	9/239 (3,8)	NE [NE; NE]	18/226 (8,0)	NE [NE; NE]	0,46 [0,21; 1,03] 0,0521
Andere	22/190 (11,6)	NE [NE; NE]	30/194 (15,5)	NE [NE; NE]	0,69 [0,40; 1,19] 0,1762
Primärtumorgröße (p-Wert des Interaktionsterms: 0,1047)					
< 20 mm	11/205 (5,4)	NE [NE; NE]	26/188 (13,8)	NE [NE; NE]	0,38 [0,19; 0,76] 0,0046
≥ 20 bis < 50 mm	28/360 (7,8)	NE [NE; NE]	43/346 (12,4)	NE [90,87; NE]	0,62 [0,39; 1,00] 0,0490
≥ 50 mm	23/194 (11,9)	NE [NE; NE]	20/185 (10,8)	NE [NE; NE]	1,02 [0,56; 1,86] 0,9510
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,2670)					
0-3	24/269 (8,9)	NE [NE; NE]	26/269 (9,7)	NE [NE; NE]	0,91 [0,52; 1,59] 0,7506
4-9	22/354 (6,2)	NE [NE; NE]	41/325 (12,6)	NE [90,87; NE]	0,48 [0,29; 0,81] 0,0051
≥ 10	19/154 (12,3)	NE [NE; NE]	23/134 (17,2)	NE [NE; NE]	0,65 [0,35; 1,19] 0,1557
Tumorstadium (p-Wert des Interaktionsterms: 0,9795)					
IIA	6/79 (7,6)	NE [NE; NE]	8/77 (10,4)	NE [NE; NE]	0,70 [0,24; 2,03] 0,5132
IIB	4/73 (5,5)	NE [87,75; NE]	9/93 (9,7)	NE [NE; NE]	0,62 [0,19; 2,02] 0,4229

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
IIIA	24/346 (6,9)	NE [NE; NE]	30/293 (10,2)	NE [NE; NE]	0,67 [0,39; 1,15] 0,1419
IIIB	3/22 (13,6)	NE [NE; NE]	3/19 (15,8)	90,9 [NE; NE]	0,88 [0,18; 4,36] 0,8732
IIIC	26/253 (10,3)	NE [NE; NE]	40/245 (16,3)	NE [NE; NE]	0,56 [0,34; 0,93] 0,0216
Tumorgrading (p-Wert des Interaktionsterms: 0,2531)					
G1	1/63 (1,6)	NE [NE; NE]	4/52 (7,7)	NE [NE; NE]	0,20 [0,02; 1,76] 0,1052
G2	26/349 (7,4)	NE [NE; NE]	32/323 (9,9)	NE [90,87; NE]	0,73 [0,44; 1,23] 0,2400
G3	37/318 (11,6)	NE [NE; NE]	47/311 (15,1)	NE [NE; NE]	0,74 [0,48; 1,14] 0,1739
GX	1/44 (2,3)	NE [NE; NE]	7/40 (17,5)	NE [NE; NE]	0,12 [0,01; 0,98] 0,0182
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5600)					
Negativ	7/67 (10,4)	NE [NE; NE]	14/62 (22,6)	NE [NE; NE]	0,40 [0,16; 0,98] 0,0390
Positiv	55/679 (8,1)	NE [NE; NE]	74/646 (11,5)	NE [90,87; NE]	0,68 [0,48; 0,97] 0,0314
Unbekannt	0/8 (0,0)	NE [NE; NE]	1/8 (12,5)	NE [68,68; NE]	0,00 [0,00; NE] 0,3173
Ethnizität (p-Wert des Interaktionsterms: 0,4502)					
Weiß	51/462 (11,0)	NE [NE; NE]	62/439 (14,1)	NE [90,87; NE]	0,75 [0,52; 1,09] 0,1351
Asiatisch	11/273 (4,0)	NE [NE; NE]	20/243 (8,2)	NE [NE; NE]	0,47 [0,22; 0,98] 0,0380
Andere	3/30 (10,0)	NE [NE; NE]	7/34 (20,6)	NE [NE; NE]	0,52 [0,13; 1,99] 0,3282
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,9149)					
Tamoxifen	46/553 (8,3)	NE [NE; NE]	66/534 (12,4)	NE [NE; NE]	0,65 [0,44; 0,94] 0,0228
Aromatase-Inhibitor	19/224 (8,5)	NE [NE; NE]	24/194 (12,4)	NE [90,87; NE]	0,67 [0,37; 1,23] 0,1969
ECOG-PS (p-Wert des Interaktionsterms: 0,1240)					

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
ECOG-PS 0	62/686 (9,0)	NE [NE; NE]	80/648 (12,3)	NE [90,87; NE]	0,71 [0,51; 0,98] 0,0385
ECOG-PS 1	3/91 (3,3)	NE [NE; NE]	10/80 (12,5)	NE [NE; NE]	0,25 [0,07; 0,92] 0,0237

Datenschnitt: 15.07.2025
ITT-Population
1: Aus Log-rank-Test; 2: In Monaten; 3: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl verstorbener Patienten; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte, kontrollierte Studie.

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Tabelle 101.2.2: Subgruppen für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - ITT - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
Alter (p-Wert des Interaktionsterms: 0,9893)					
< 65 Jahre	113/918 (12,3)	NE [NE; NE]	139/936 (14,9)	NE [NE; NE]	0,83 [0,65; 1,06] 0,1406
≥ 65 Jahre	62/366 (16,9)	NE [NE; NE]	69/327 (21,1)	NE [NE; NE]	0,83 [0,59; 1,17] 0,2776
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,6184)					
Neoadjuvante Chemotherapie	69/430 (16,0)	NE [NE; NE]	90/415 (21,7)	NE [NE; NE]	0,76 [0,56; 1,05] 0,0921
Adjuvante Chemotherapie	94/785 (12,0)	NE [NE; NE]	100/767 (13,0)	NE [NE; NE]	0,92 [0,70; 1,22] 0,5828
Keine Chemotherapie	12/69 (17,4)	NE [NE; NE]	18/81 (22,2)	NE [84,20; NE]	0,72 [0,34; 1,49] 0,3690
Region (p-Wert des Interaktionsterms: 0,8571)					
Nordamerika / Europa	94/679 (13,8)	NE [NE; NE]	102/648 (15,7)	NE [NE; NE]	0,88 [0,67; 1,17] 0,3889
Asien	18/203 (8,9)	NE [NE; NE]	23/201 (11,4)	NE [NE; NE]	0,77 [0,41; 1,42] 0,3934
Andere	63/402 (15,7)	NE [NE; NE]	83/414 (20,0)	NE [NE; NE]	0,80 [0,58; 1,12] 0,1910
Primärtumorgröße (p-Wert des Interaktionsterms: 0,4707)					
< 20 mm	34/332 (10,2)	NE [NE; NE]	50/333 (15,0)	NE [NE; NE]	0,67 [0,43; 1,04] 0,0725
≥ 20 bis < 50 mm	85/646 (13,2)	NE [NE; NE]	101/653 (15,5)	NE [NE; NE]	0,86 [0,65; 1,15] 0,3197
≥ 50 mm	56/289 (19,4)	NE [NE; NE]	56/265 (21,1)	NE [NE; NE]	0,96 [0,66; 1,39] 0,8189
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,1166)					
0-3	44/427 (10,3)	NE [NE; NE]	57/418 (13,6)	NE [NE; NE]	0,76 [0,51; 1,13] 0,1695
4-9	73/548 (13,3)	NE [NE; NE]	68/543 (12,5)	NE [NE; NE]	1,09 [0,78; 1,52] 0,6107
≥ 10	58/309 (18,8)	NE [NE; NE]	83/302 (27,5)	NE [85,51; NE]	0,68 [0,48; 0,95] 0,0213

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
Tumorgrading (p-Wert des Interaktionsterms: 0,1009)					
G1	13/91 (14,3)	NE [NE; NE]	12/93 (12,9)	NE [NE; NE]	1,16 [0,53; 2,54] 0,7106
G2	89/613 (14,5)	NE [NE; NE]	94/601 (15,6)	NE [NE; NE]	0,95 [0,71; 1,28] 0,7551
G3	71/528 (13,4)	NE [NE; NE]	87/505 (17,2)	NE [NE; NE]	0,78 [0,57; 1,06] 0,1118
GX	2/50 (4,0)	NE [NE; NE]	14/60 (23,3)	NE [84,49; NE]	0,16 [0,04; 0,71] 0,0060
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5488)					
Negativ	29/157 (18,5)	NE [NE; NE]	47/168 (28,0)	NE [85,64; NE]	0,67 [0,42; 1,07] 0,0899
Positiv	141/1089 (12,9)	NE [NE; NE]	156/1066 (14,6)	NE [NE; NE]	0,89 [0,71; 1,12] 0,3228
Unbekannt	1/10 (10,0)	NE [66,08; NE]	1/7 (14,3)	NE [84,49; NE]	>100 [0,00; NE] 0,3496
Ethnizität (p-Wert des Interaktionsterms: 0,7329)					
Weiß	145/958 (15,1)	NE [NE; NE]	164/943 (17,4)	NE [NE; NE]	0,88 [0,70; 1,10] 0,2643
Asiatisch	21/250 (8,4)	NE [NE; NE]	29/242 (12,0)	NE [NE; NE]	0,69 [0,39; 1,21] 0,1964
Andere	8/63 (12,7)	NE [NE; NE]	11/63 (17,5)	NE [NE; NE]	0,77 [0,31; 1,91] 0,5694
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,1845)					
Tamoxifen	10/114 (8,8)	NE [89,33; NE]	21/132 (15,9)	NE [NE; NE]	0,51 [0,24; 1,09] 0,0752
Aromatase-Inhibitor	165/1170 (14,1)	NE [NE; NE]	187/1131 (16,5)	NE [NE; NE]	0,87 [0,71; 1,07] 0,1900
ECOG-PS (p-Wert des Interaktionsterms: 0,0704)					
ECOG-PS 0	139/1070 (13,0)	NE [NE; NE]	172/1019 (16,9)	NE [NE; NE]	0,77 [0,61; 0,96] 0,0205
ECOG-PS 1	36/214 (16,8)	NE [NE; NE]	36/244 (14,8)	NE [NE; NE]	1,24 [0,78; 1,97] 0,3614

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
Datenschnitt: 15.07.2025 ITT-Population 1: Aus Log-rank-Test; 2: In Monaten; 3: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen. Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl verstorbener Patienten; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte, kontrollierte Studie.					

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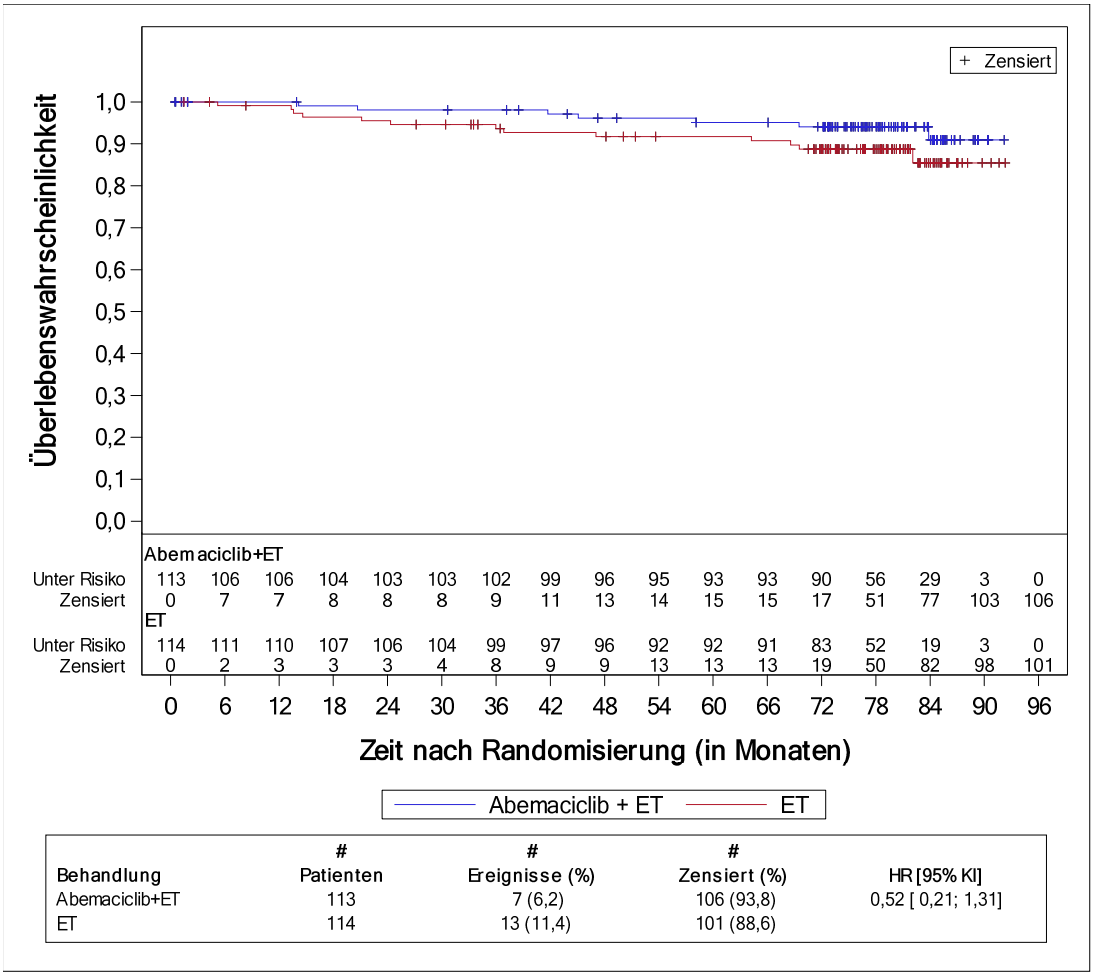
Anhang 4-G2.1.2: Kaplan-Meier-Kurven interagierender Subgruppen

Kaplan-Meier-Kurven - Gesamtüberleben
Kohorte 1 Population - ITT - Postmenopausal
Tumorstadium: IIA



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	113	7 (6,2)	106 (93,8)	0,52 [0,21; 1,31]
ET	114	13 (11,4)	101 (88,6)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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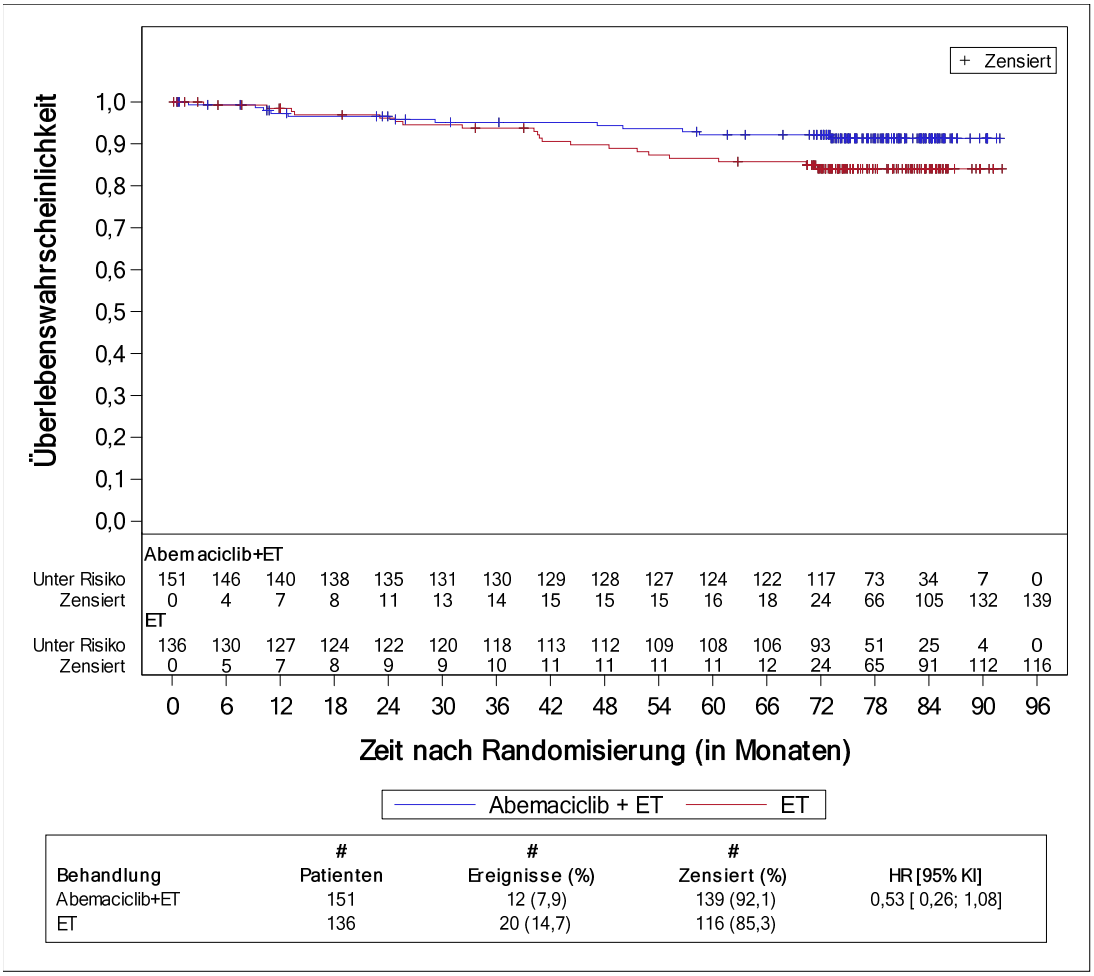
Kaplan-Meier-Kurven - Gesamtüberleben
Kohorte 1 Population - ITT - Postmenopausal
Tumorstadium: IIB



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	151	12 (7,9)	139 (92,1)	0,53 [0,26; 1,08]
ET	136	20 (14,7)	116 (85,3)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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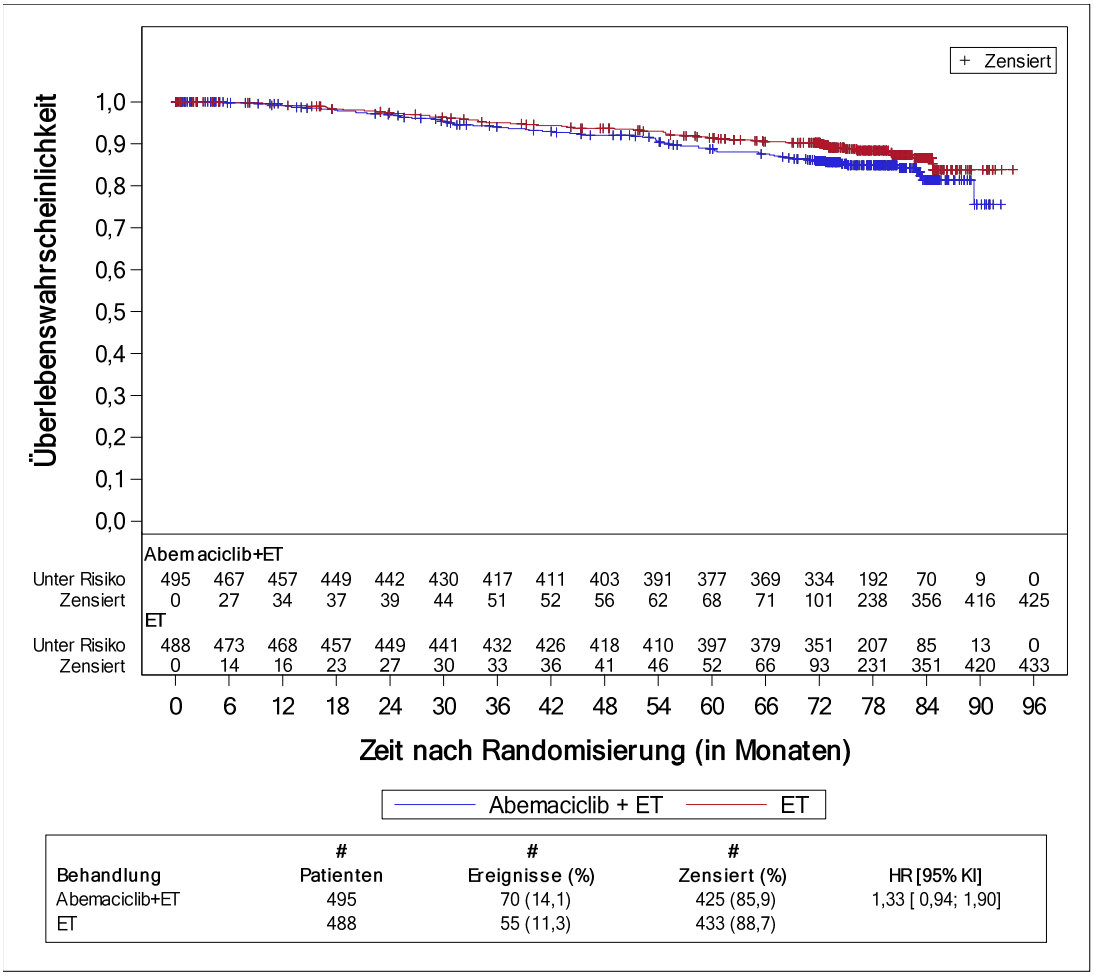
Kaplan-Meier-Kurven - Gesamtüberleben
Kohorte 1 Population - ITT - Postmenopausal
Tumorstadium: IIIA



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	495	70 (14,1)	425 (85,9)	1,33 [0,94; 1,90]
ET	488	55 (11,3)	433 (88,7)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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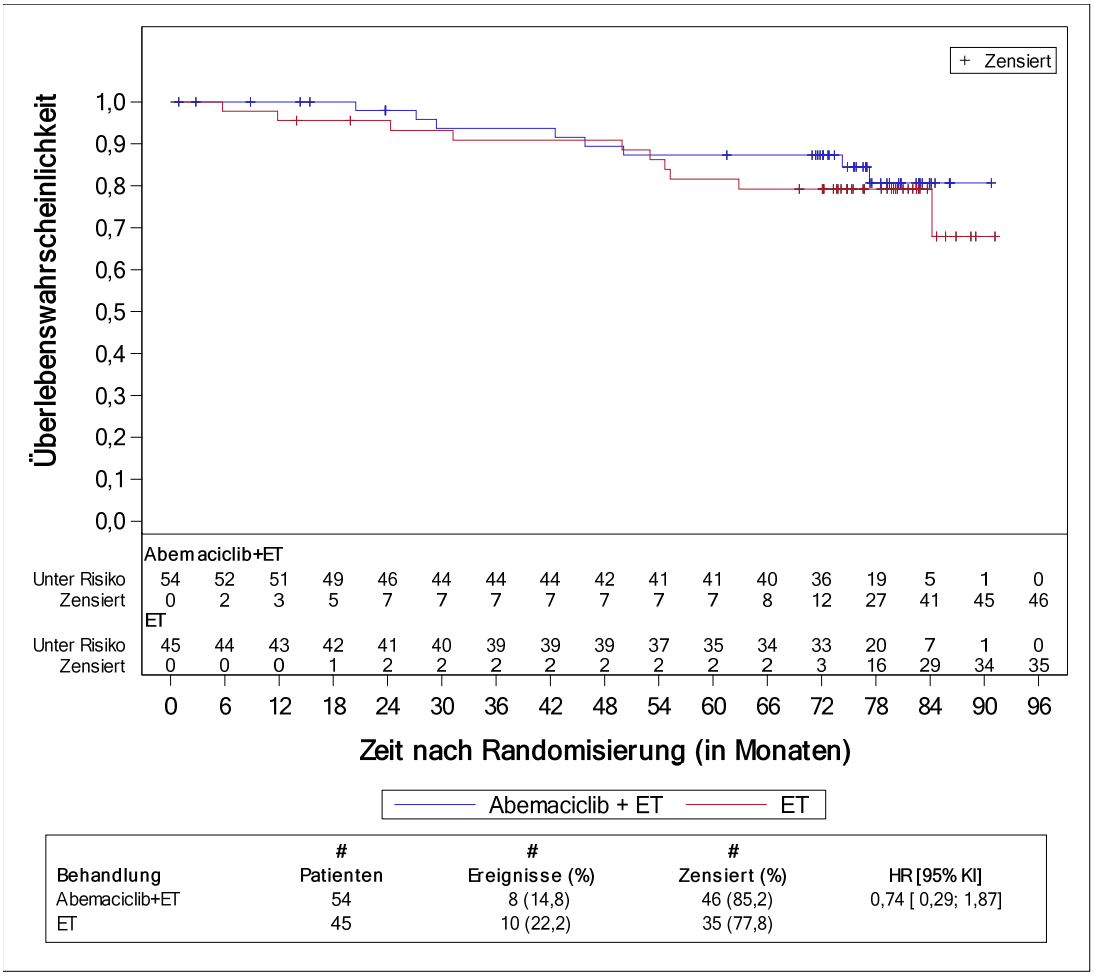
Kaplan-Meier-Kurven - Gesamtüberleben
Kohorte 1 Population - ITT - Postmenopausal
Tumorstadium: IIIB



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	54	8 (14,8)	46 (85,2)	0,74 [0,29; 1,87]
ET	45	10 (22,2)	35 (77,8)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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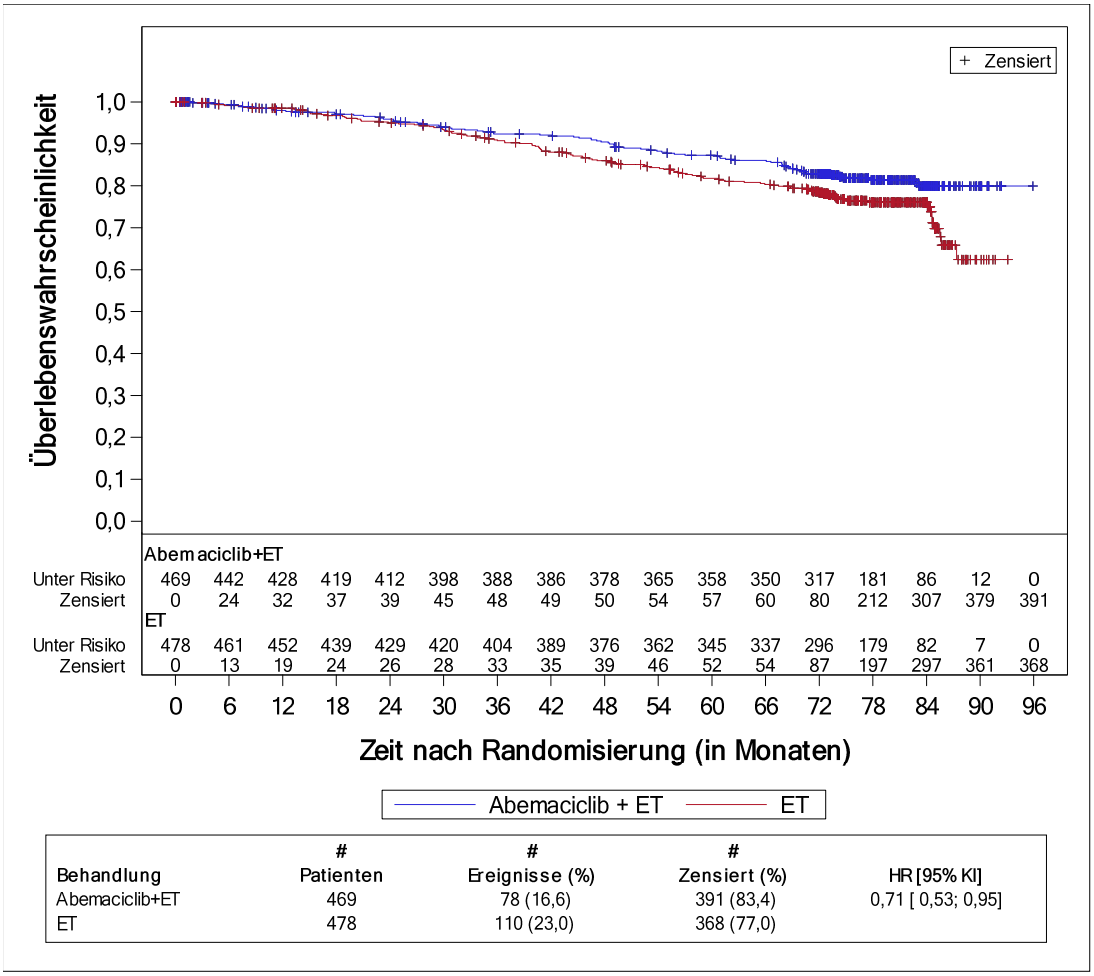
Kaplan-Meier-Kurven - Gesamtüberleben
Kohorte 1 Population - ITT - Postmenopausal
Tumorstadium: IIIC



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	469	78 (16,6)	391 (83,4)	0,71 [0,53; 0,95]
ET	478	110 (23,0)	368 (77,0)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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Anhang 4-G2.2: Invasives krankheitsfreies Überleben

Anhang 4-G2.2.1: Subgruppenanalysen nicht-interagierender Subgruppen

Tabelle 102.1.2: Subgruppen für IDFS aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - ITT - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,2791)					
Neoadjuvante Chemotherapie	78/315 (24,8)	NE [NE; NE]	124/305 (40,7)	87,3 [87,29; NE]	0,52 [0,39; 0,70] <,0001
Adjuvante Chemotherapie	59/452 (13,1)	NE [NE; NE]	81/416 (19,5)	NE [NE; NE]	0,63 [0,45; 0,88] 0,0061
Keine Chemotherapie	3/10 (30,0)	NE [14,24; NE]	1/7 (14,3)	NE [62,14; NE]	2,68 [0,28; 25,82] 0,3755
Region (p-Wert des Interaktionsterms: 0,9038)					
Nordamerika / Europa	65/348 (18,7)	NE [NE; NE]	89/308 (28,9)	NE [NE; NE]	0,59 [0,43; 0,81] 0,0011
Asien	36/239 (15,1)	NE [NE; NE]	58/226 (25,7)	NE [87,29; NE]	0,54 [0,35; 0,81] 0,0028
Andere	39/190 (20,5)	NE [NE; NE]	59/194 (30,4)	NE [NE; NE]	0,60 [0,40; 0,90] 0,0124
Primärtumorgröße (p-Wert des Interaktionsterms: 0,2921)					
< 20 mm	30/205 (14,6)	NE [NE; NE]	51/188 (27,1)	NE [NE; NE]	0,50 [0,32; 0,78] 0,0019
≥ 20 bis < 50 mm	69/360 (19,2)	NE [NE; NE]	92/346 (26,6)	NE [NE; NE]	0,68 [0,50; 0,93] 0,0150
≥ 50 mm	37/194 (19,1)	NE [NE; NE]	62/185 (33,5)	NE [85,64; NE]	0,47 [0,32; 0,71] 0,0002
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,2806)					
0-3	47/269 (17,5)	NE [NE; NE]	62/269 (23,0)	NE [NE; NE]	0,73 [0,50; 1,06] 0,0975
4-9	55/354 (15,5)	NE [NE; NE]	95/325 (29,2)	NE [NE; NE]	0,48 [0,34; 0,67] <,0001
≥ 10	38/154 (24,7)	NE [NE; NE]	49/134 (36,6)	NE [82,82; NE]	0,56 [0,37; 0,86] 0,0065
Tumorstadium (p-Wert des Interaktionsterms: 0,6260)					
IIA	10/79 (12,7)	NE [NE; NE]	18/77 (23,4)	NE [NE; NE]	0,50 [0,23; 1,09] 0,0756
IIB	12/73 (16,4)	NE [NE; NE]	17/93 (18,3)	NE [NE; NE]	1,01 [0,48; 2,13] 0,9782

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
IIIA	54/346 (15,6)	NE [NE; NE]	78/293 (26,6)	NE [NE; NE]	0,54 [0,38; 0,77] 0,0004
IIIB	5/22 (22,7)	NE [37,71; NE]	6/19 (31,6)	NE [40,54; NE]	0,70 [0,21; 2,30] 0,5558
IIIC	57/253 (22,5)	NE [NE; NE]	87/245 (35,5)	NE [85,64; NE]	0,52 [0,37; 0,73] 0,0001
Tumorgrading (p-Wert des Interaktionsterms: 0,4788)					
G1	5/63 (7,9)	NE [NE; NE]	9/52 (17,3)	NE [NE; NE]	0,46 [0,15; 1,37] 0,1506
G2	57/349 (16,3)	NE [NE; NE]	89/323 (27,6)	NE [87,29; NE]	0,52 [0,38; 0,73] 0,0001
G3	72/318 (22,6)	NE [NE; NE]	95/311 (30,5)	NE [NE; NE]	0,68 [0,50; 0,92] 0,0126
GX	6/44 (13,6)	NE [NE; NE]	13/40 (32,5)	NE [69,83; NE]	0,35 [0,13; 0,93] 0,0272
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,3308)					
Negativ	16/67 (23,9)	NE [NE; NE]	31/62 (50,0)	73,4 [36,56; NE]	0,39 [0,21; 0,71] 0,0014
Positiv	121/679 (17,8)	NE [NE; NE]	170/646 (26,3)	NE [NE; NE]	0,62 [0,49; 0,78] <,0001
Unbekannt	0/8 (0,0)	NE [NE; NE]	2/8 (25,0)	NE [37,68; NE]	0,00 [0,00; NE] 0,1711
Ethnizität (p-Wert des Interaktionsterms: 0,6524)					
Weiß	91/462 (19,7)	NE [NE; NE]	124/439 (28,2)	NE [NE; NE]	0,64 [0,49; 0,83] 0,0010
Asiatisch	41/273 (15,0)	NE [NE; NE]	64/243 (26,3)	NE [87,29; NE]	0,51 [0,35; 0,76] 0,0007
Andere	8/30 (26,7)	NE [57,34; NE]	14/34 (41,2)	NE [36,56; NE]	0,61 [0,26; 1,45] 0,2582
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,9830)					
Tamoxifen	104/553 (18,8)	NE [NE; NE]	156/534 (29,2)	NE [NE; NE]	0,58 [0,45; 0,74] <,0001
Aromatase-Inhibitor	36/224 (16,1)	NE [NE; NE]	50/194 (25,8)	NE [NE; NE]	0,58 [0,38; 0,89] 0,0108
ECOG-PS (p-Wert des Interaktionsterms: 0,9518)					

Subgruppe	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
ECOG-PS 0	123/686 (17,9)	NE [NE; NE]	181/648 (27,9)	NE [NE; NE]	0,58 [0,46; 0,73] <,0001
ECOG-PS 1	17/91 (18,7)	NE [NE; NE]	25/80 (31,3)	NE [NE; NE]	0,56 [0,30; 1,04] 0,0621

Datenschnitt: 15.07.2025
ITT-Population
1: Aus Log-rank-Test; 2: In Monaten; 3: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; IDFS: Invasives krankheitsfreies Überleben (invasive disease-free survival); ITT: Intention to Treat; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte, kontrollierte Studie.

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Tabelle 102.2.2: Subgruppen für IDFS aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - ITT - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
Alter (p-Wert des Interaktionsterms: 0,3233)					
< 65 Jahre	188/918 (20,5)	NE [NE; NE]	264/936 (28,2)	NE [NE; NE]	0,71 [0,59; 0,85] 0,0002
≥ 65 Jahre	98/366 (26,8)	NE [NE; NE]	106/327 (32,4)	NE [NE; NE]	0,83 [0,63; 1,09] 0,1889
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,7842)					
Neoadjuvante Chemotherapie	114/430 (26,5)	NE [NE; NE]	151/415 (36,4)	NE [NE; NE]	0,72 [0,57; 0,92] 0,0087
Adjuvante Chemotherapie	154/785 (19,6)	NE [NE; NE]	190/767 (24,8)	NE [NE; NE]	0,78 [0,63; 0,96] 0,0216
Keine Chemotherapie	18/69 (26,1)	NE [85,71; NE]	29/81 (35,8)	NE [64,57; NE]	0,65 [0,36; 1,17] 0,1466
Region (p-Wert des Interaktionsterms: 0,9114)					
Nordamerika / Europa	145/679 (21,4)	NE [NE; NE]	187/648 (28,9)	NE [NE; NE]	0,73 [0,58; 0,90] 0,0037
Asien	44/203 (21,7)	NE [NE; NE]	56/201 (27,9)	NE [NE; NE]	0,74 [0,50; 1,10] 0,1302
Andere	97/402 (24,1)	NE [NE; NE]	127/414 (30,7)	NE [NE; NE]	0,79 [0,60; 1,02] 0,0738
Primärtumorgröße (p-Wert des Interaktionsterms: 0,4582)					
< 20 mm	54/332 (16,3)	NE [NE; NE]	83/333 (24,9)	NE [NE; NE]	0,64 [0,45; 0,90] 0,0090
≥ 20 bis < 50 mm	151/646 (23,4)	NE [NE; NE]	187/653 (28,6)	NE [NE; NE]	0,81 [0,65; 1,00] 0,0476
≥ 50 mm	76/289 (26,3)	NE [NE; NE]	97/265 (36,6)	NE [84,20; NE]	0,71 [0,52; 0,95] 0,0222
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7071)					
0-3	69/427 (16,2)	NE [NE; NE]	98/418 (23,4)	NE [NE; NE]	0,68 [0,50; 0,92] 0,0130
4-9	111/548 (20,3)	NE [NE; NE]	138/543 (25,4)	NE [NE; NE]	0,80 [0,62; 1,03] 0,0773
≥ 10	106/309 (34,3)	NE [85,58; NE]	134/302 (44,4)	84,0 [71,87; NE]	0,72 [0,56; 0,93] 0,0117

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
Tumorstadium (p-Wert des Interaktionsterms: 0,6084)					
IIA	12/113 (10,6)	NE [NE; NE]	24/114 (21,1)	NE [NE; NE]	0,48 [0,24; 0,97] 0,0363
IIB	26/151 (17,2)	NE [NE; NE]	28/136 (20,6)	NE [NE; NE]	0,81 [0,48; 1,39] 0,4441
IIIA	96/495 (19,4)	NE [NE; NE]	118/488 (24,2)	NE [NE; NE]	0,83 [0,63; 1,08] 0,1697
IIIB	17/54 (31,5)	NE [77,29; NE]	16/45 (35,6)	NE [59,64; NE]	0,90 [0,45; 1,78] 0,7623
IIIC	135/469 (28,8)	NE [NE; NE]	184/478 (38,5)	NE [84,62; NE]	0,70 [0,56; 0,87] 0,0016
Tumorgrading (p-Wert des Interaktionsterms: 0,7192)					
G1	18/91 (19,8)	NE [NE; NE]	26/93 (28,0)	NE [NE; NE]	0,69 [0,38; 1,26] 0,2276
G2	139/613 (22,7)	NE [NE; NE]	173/601 (28,8)	NE [NE; NE]	0,78 [0,63; 0,98] 0,0325
G3	116/528 (22,0)	NE [NE; NE]	144/505 (28,5)	NE [NE; NE]	0,75 [0,59; 0,96] 0,0234
GX	13/50 (26,0)	NE [78,08; NE]	26/60 (43,3)	NE [47,34; NE]	0,53 [0,27; 1,02] 0,0547
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,7346)					
Negativ	50/157 (31,8)	NE [NE; NE]	72/168 (42,9)	84,6 [64,70; NE]	0,70 [0,49; 1,00] 0,0513
Positiv	228/1089 (20,9)	NE [NE; NE]	290/1066 (27,2)	NE [NE; NE]	0,76 [0,64; 0,90] 0,0019
Unbekannt	3/10 (30,0)	NE [47,24; NE]	2/7 (28,6)	NE [62,93; NE]	1,90 [0,30; 11,87] 0,4879
Ethnizität (p-Wert des Interaktionsterms: 0,6063)					
Weiß	216/958 (22,5)	NE [NE; NE]	282/943 (29,9)	NE [NE; NE]	0,74 [0,62; 0,89] 0,0009
Asiatisch	52/250 (20,8)	NE [NE; NE]	69/242 (28,5)	NE [NE; NE]	0,70 [0,49; 1,00] 0,0493
Andere	15/63 (23,8)	NE [NE; NE]	15/63 (23,8)	NE [NE; NE]	1,03 [0,50; 2,11] 0,9313
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,1038)					

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
Tamoxifen	17/114 (14,9)	NE [NE; NE]	37/132 (28,0)	NE [NE; NE]	0,48 [0,27; 0,86] 0,0108
Aromatase-Inhibitor	269/1170 (23,0)	NE [NE; NE]	333/1131 (29,4)	NE [NE; NE]	0,77 [0,66; 0,91] 0,0018
ECOG-PS (p-Wert des Interaktionsterms: 0,0795)					
ECOG-PS 0	231/1070 (21,6)	NE [NE; NE]	303/1019 (29,7)	NE [NE; NE]	0,70 [0,59; 0,83] <,0001
ECOG-PS 1	55/214 (25,7)	NE [85,58; NE]	67/244 (27,5)	NE [NE; NE]	1,00 [0,70; 1,43] 0,9983

Datenschnitt: 15.07.2025
ITT-Population
1: Aus Log-rank-Test; 2: In Monaten; 3: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; HR: Hazard Ratio; IDFS: Invasives krankheitsfreies Überleben (invasive disease-free survival); ITT: Intention to Treat; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte, kontrollierte Studie.

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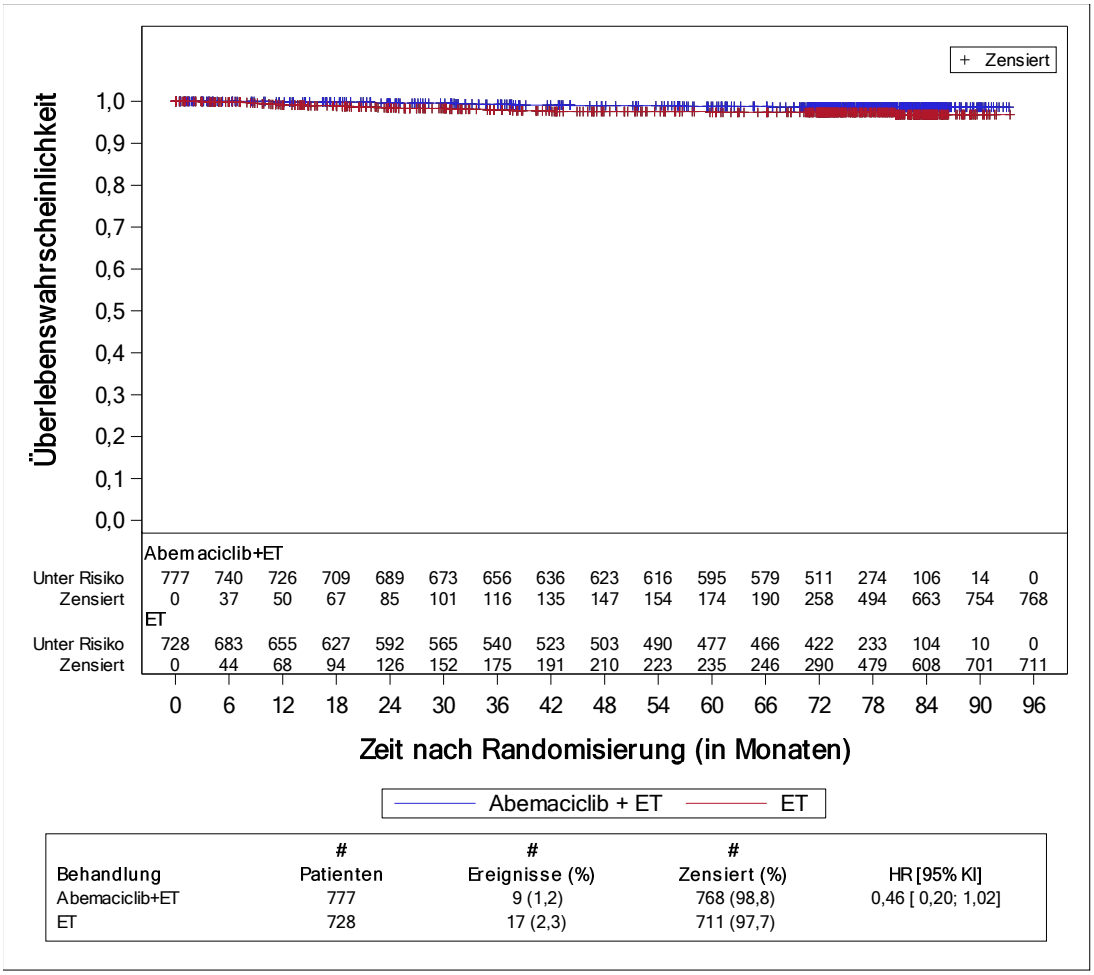
Anhang 4-G2.2.2: Kaplan-Meier-Kurven der Einzelkomponenten des IDFS

Kaplan-Meier-Kurven - lokales Brustkrebsrezidiv
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	9 (1,2)	768 (98,8)	0,46 [0,20; 1,02]
ET	728	17 (2,3)	711 (97,7)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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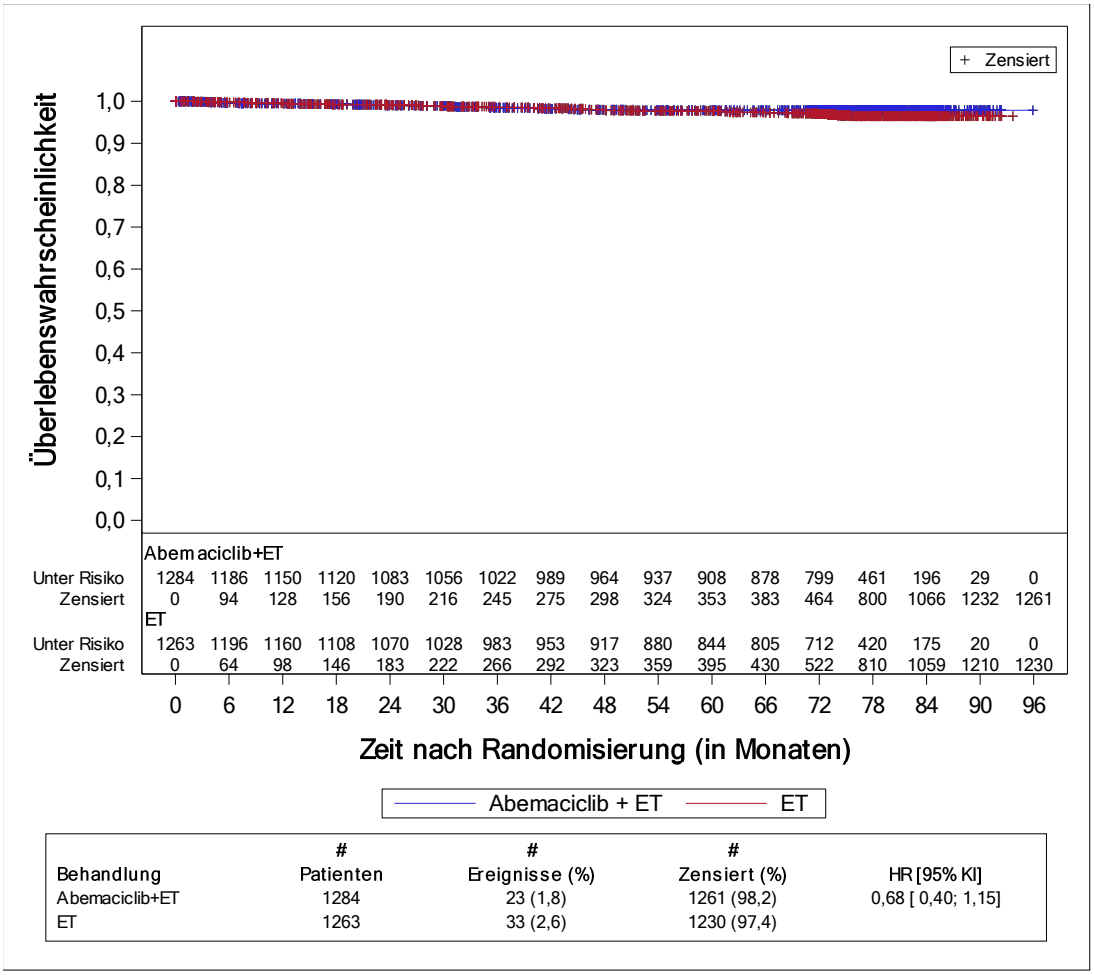
Kaplan-Meier-Kurven - lokales Brustkrebsrezidiv
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	23 (1,8)	1261 (98,2)	0,68 [0,40; 1,15]
ET	1263	33 (2,6)	1230 (97,4)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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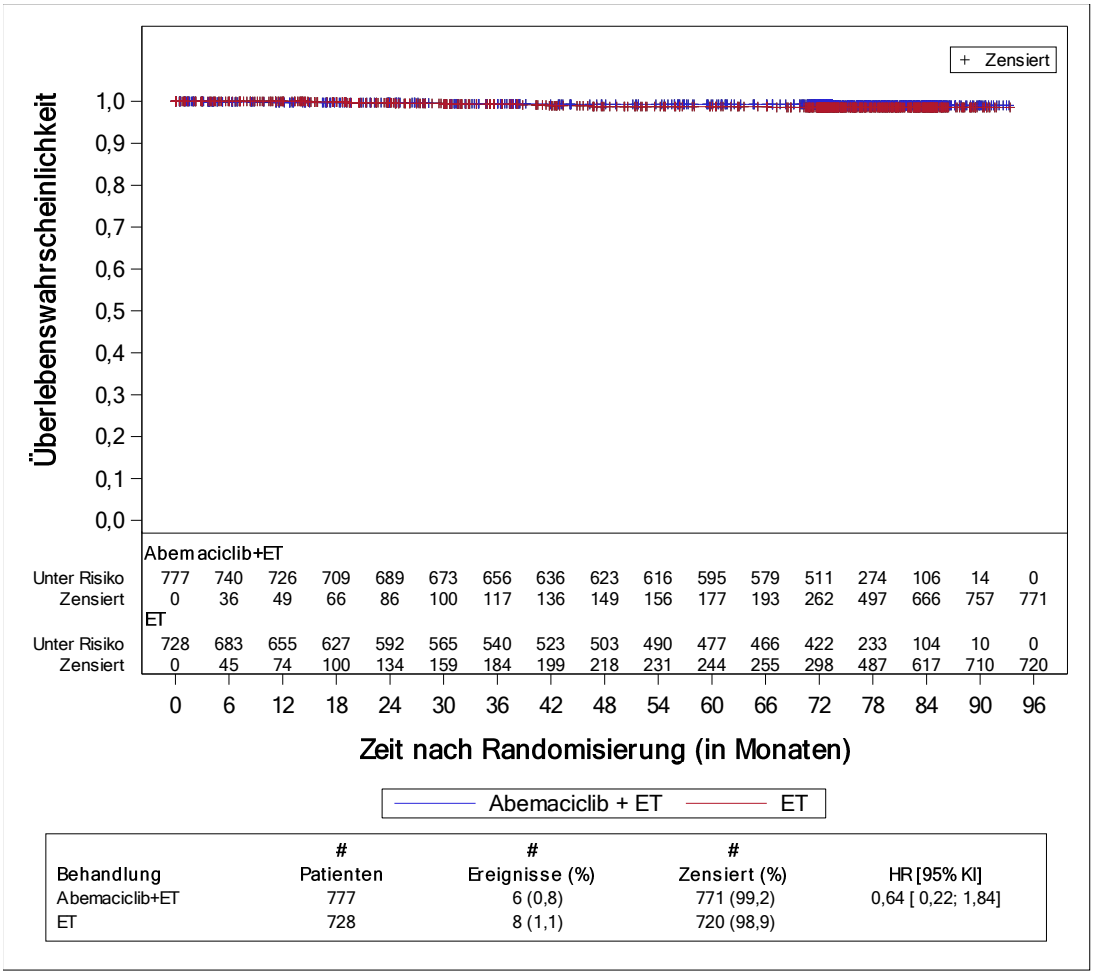
Kaplan-Meier-Kurven - regionäres invasives Brustkrebsrezidiv
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	6 (0,8)	771 (99,2)	0,64 [0,22; 1,84]
ET	728	8 (1,1)	720 (98,9)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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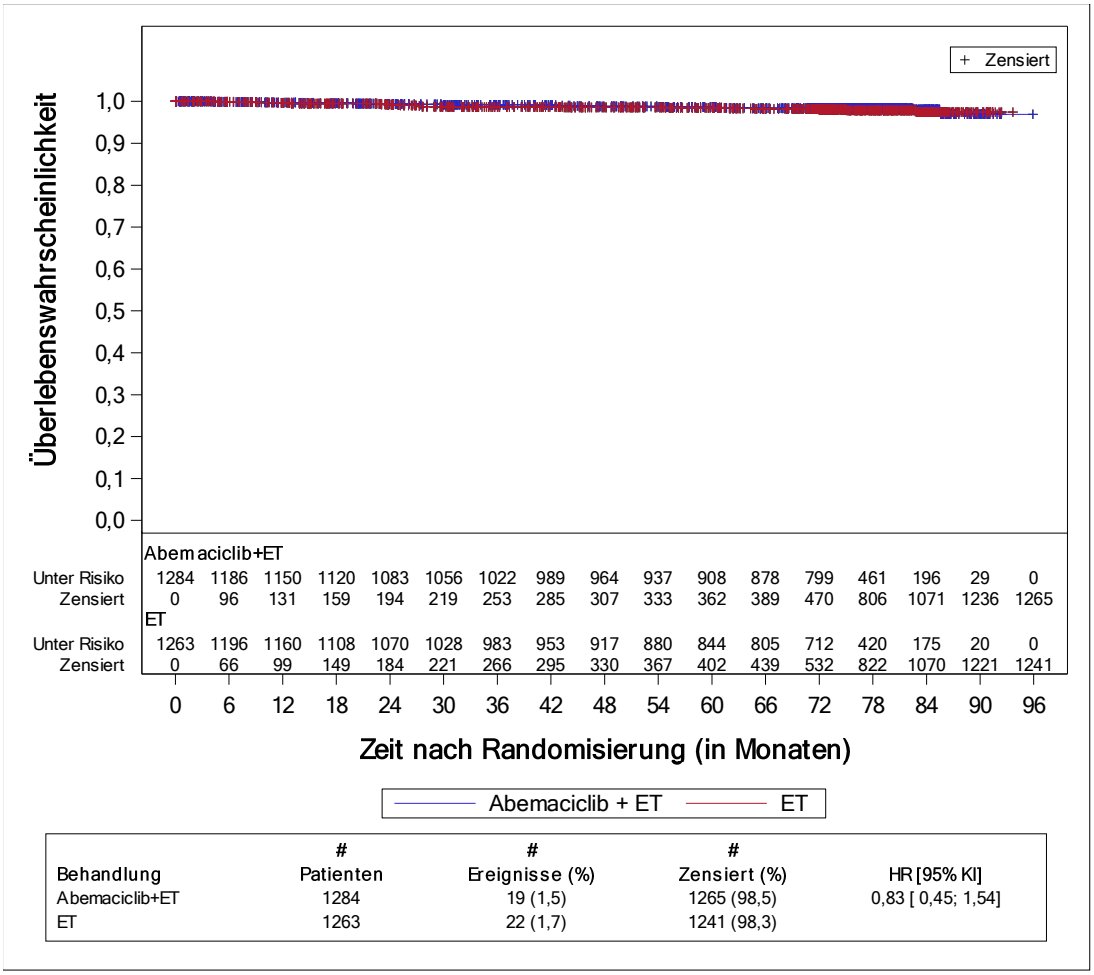
Kaplan-Meier-Kurven - regionäres invasives Brustkrebsrezidiv
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	19 (1,5)	1265 (98,5)	0,83 [0,45; 1,54]
ET	1263	22 (1,7)	1241 (98,3)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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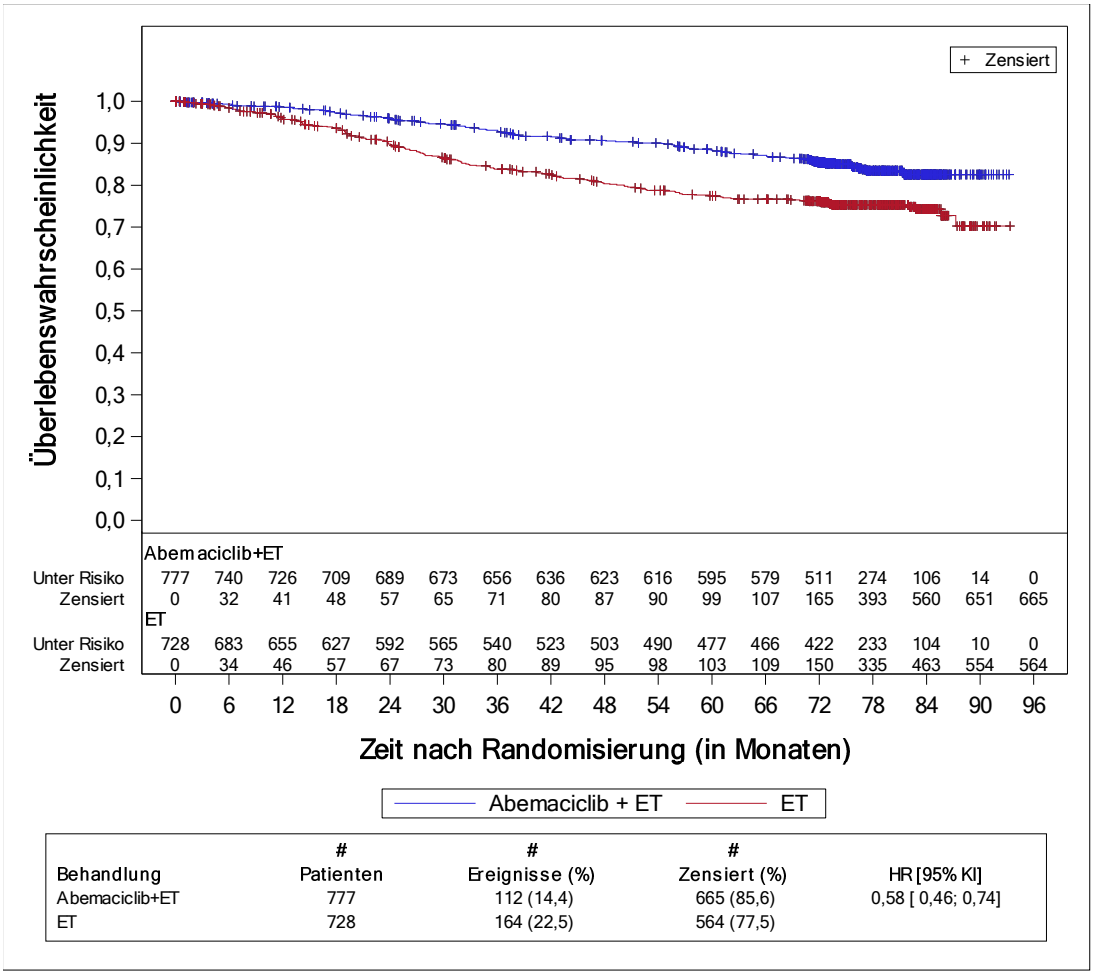
Kaplan-Meier-Kurven - Fernrezidiv
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	112 (14,4)	665 (85,6)	0,58 [0,46; 0,74]
ET	728	164 (22,5)	564 (77,5)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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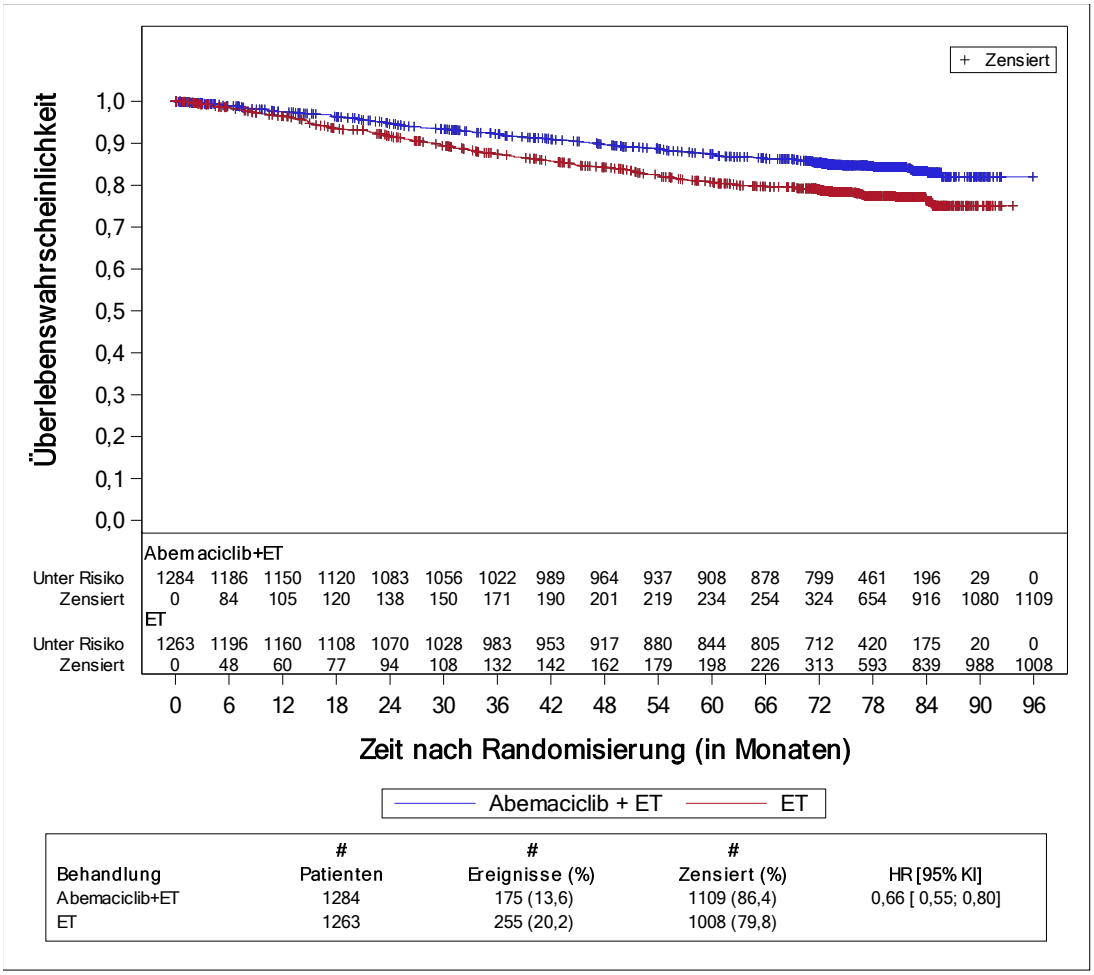
Kaplan-Meier-Kurven - Fernrezidiv
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	175 (13,6)	1109 (86,4)	0,66 [0,55; 0,80]
ET	1263	255 (20,2)	1008 (79,8)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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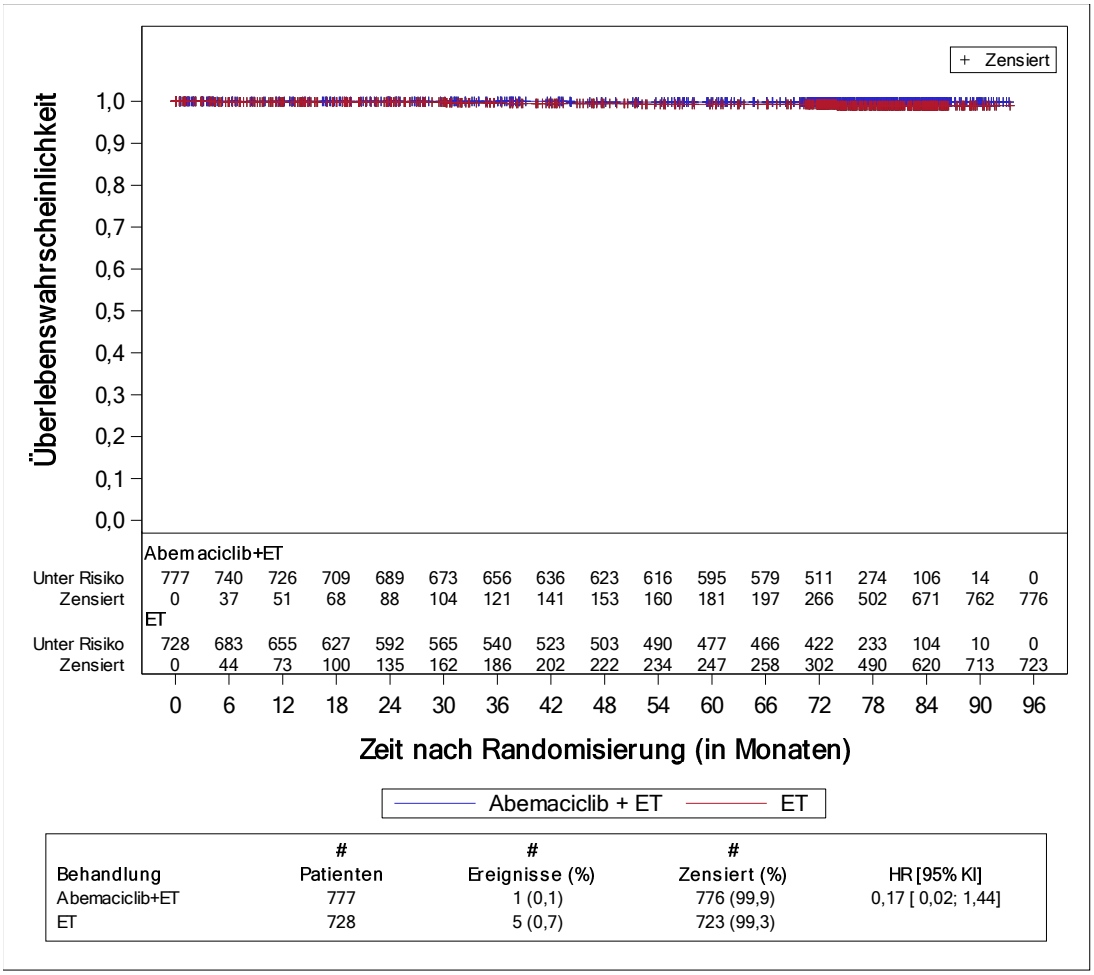
Kaplan-Meier-Kurven - Tod jeglicher Ursache
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	1 (0,1)	776 (99,9)	0,17 [0,02; 1,44]
ET	728	5 (0,7)	723 (99,3)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/f_gba3c1_km_eff.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/f_km_idfs_dth_premp_itt3c1.rtf
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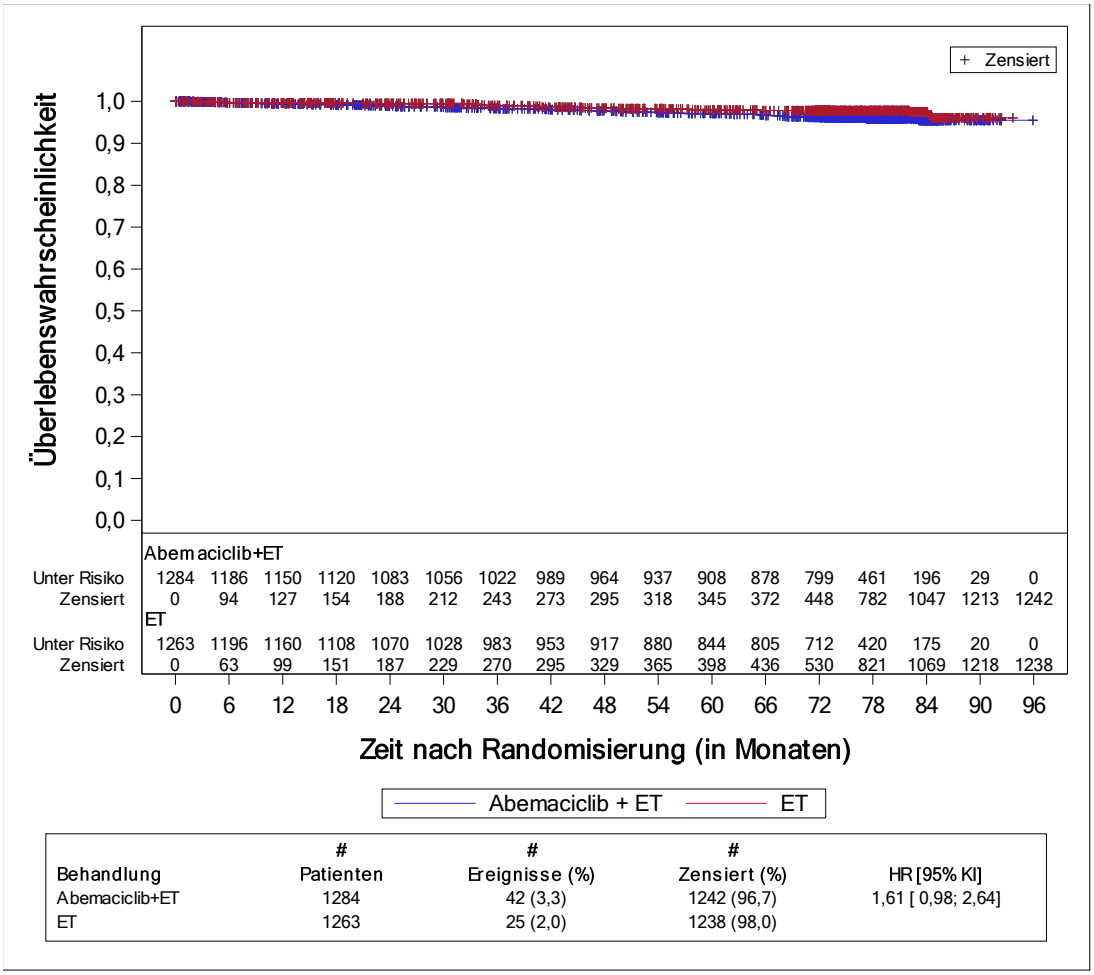
27OCT2025 / 03:32

Kaplan-Meier-Kurven - Tod jeglicher Ursache
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	42 (3,3)	1242 (96,7)	1,61 [0,98; 2,64]
ET	1263	25 (2,0)	1238 (98,0)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/f_gba3c1_km_eff.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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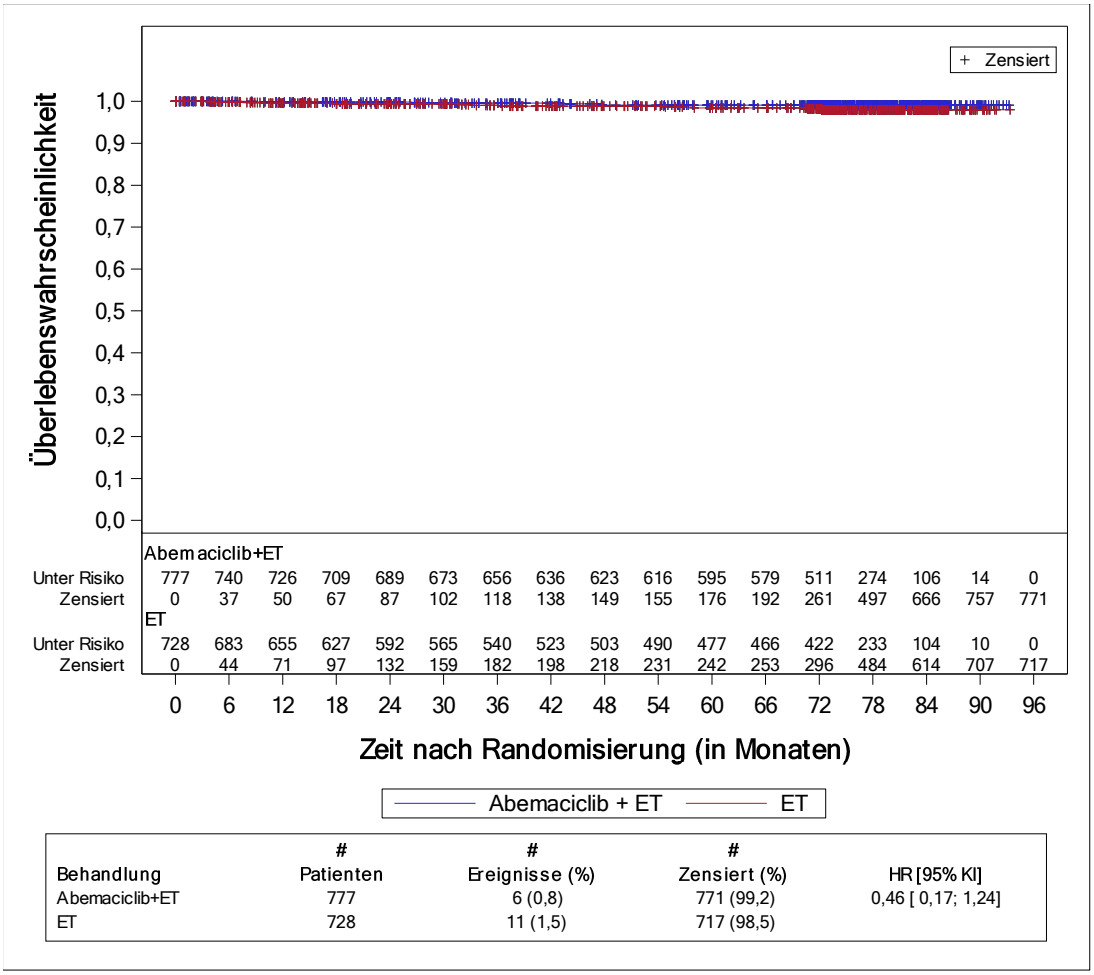
Kaplan-Meier-Kurven - kontralateraler invasiver Brustkrebs
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	6 (0,8)	771 (99,2)	0,46 [0,17; 1,24]
ET	728	11 (1,5)	717 (98,5)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/f_gba3c1_km_eff.sas
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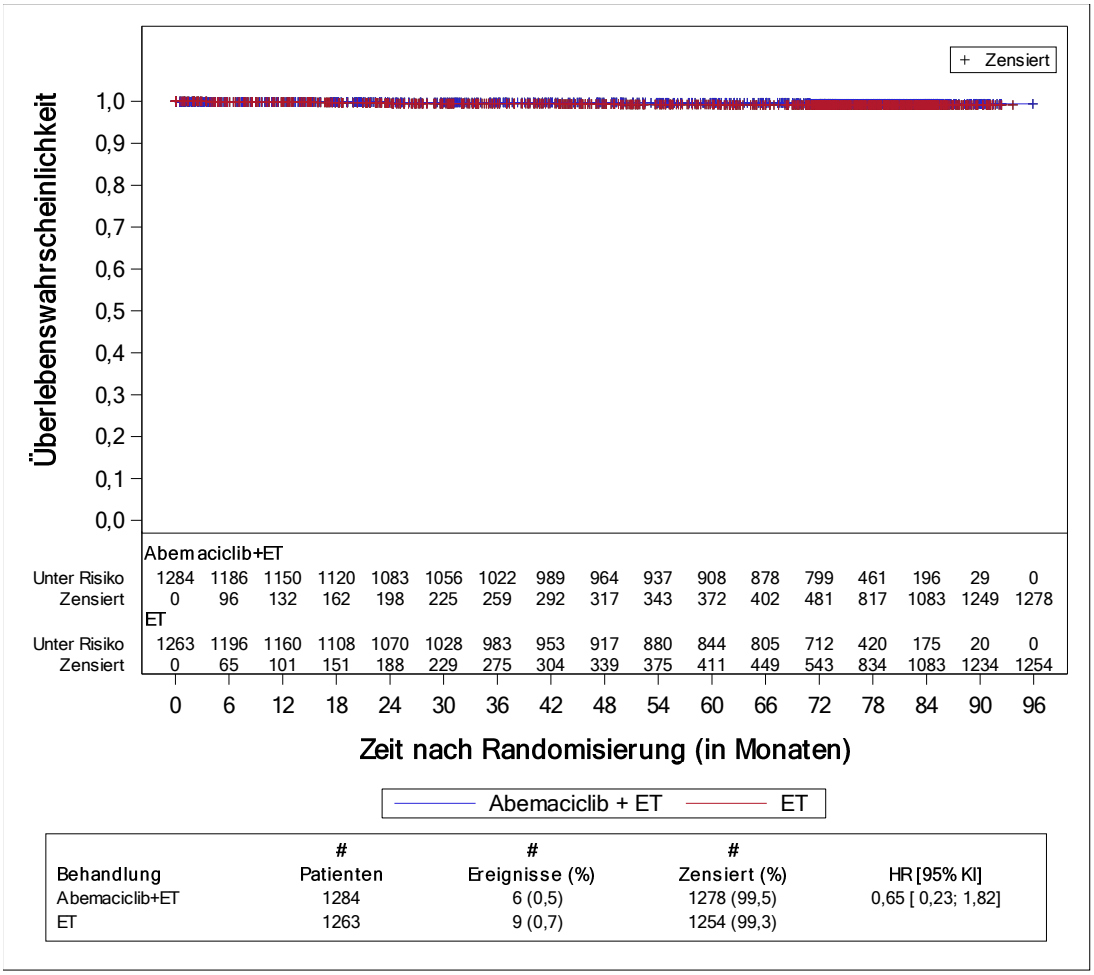
Kaplan-Meier-Kurven - kontralateraler invasiver Brustkrebs
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	6 (0,5)	1278 (99,5)	0,65 [0,23; 1,82]
ET	1263	9 (0,7)	1254 (99,3)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/f_gba3c1_km_eff.sas
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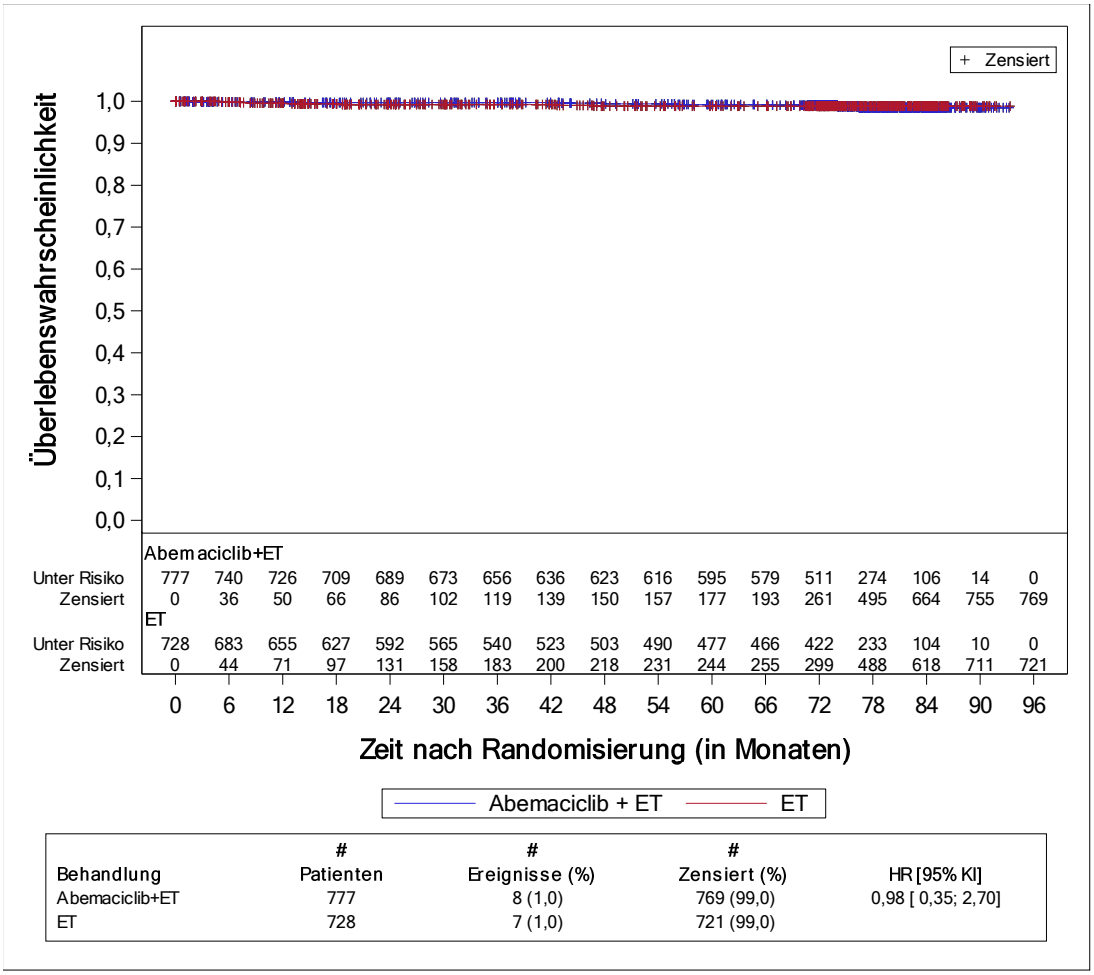
Kaplan-Meier-Kurven - Sekundäres Primärkarzinom (kein Brustkrebs)
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	8 (1,0)	769 (99,0)	0,98 [0,35; 2,70]
ET	728	7 (1,0)	721 (99,0)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/f_gba3c1_km_eff.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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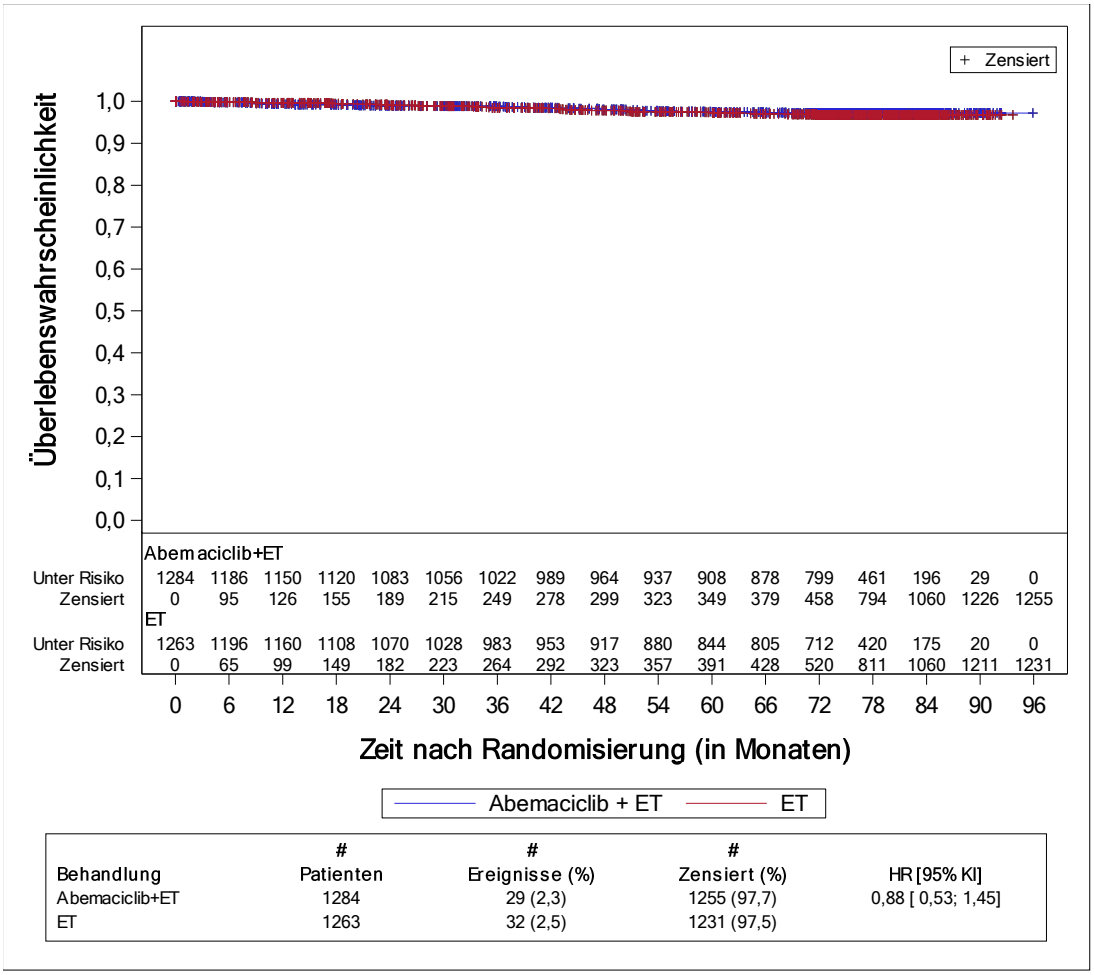
Kaplan-Meier-Kurven - Sekundäres Primärkarzinom (kein Brustkrebs)
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	29 (2,3)	1255 (97,7)	0,88 [0,53; 1,45]
ET	1263	32 (2,5)	1231 (97,5)	

Datenschnitt: 15.07.2025
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/f_gba3c1_km_eff.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/f_km_idfs_sec_posmp_itt3c1.rtf
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Anhang 4-G2.3: Fernmetastasenfreies Überleben

Anhang 4-G2.3.1: Subgruppenanalysen nicht-interagierender Subgruppen

Tabelle 103.1.2: Subgruppen für DRFS aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - ITT - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,4619)					
Neoadjuvante Chemotherapie	67/315 (21,3)	NE [NE; NE]	109/305 (35,7)	NE [87,29; NE]	0,52 [0,39; 0,71] <,0001
Adjuvante Chemotherapie	54/452 (11,9)	NE [NE; NE]	72/416 (17,3)	NE [NE; NE]	0,65 [0,46; 0,92] 0,0150
Keine Chemotherapie	2/10 (20,0)	NE [64,73; NE]	1/7 (14,3)	NE [62,14; NE]	1,60 [0,14; 17,67] 0,6988
Region (p-Wert des Interaktionsterms: 0,9816)					
Nordamerika / Europa	55/348 (15,8)	NE [NE; NE]	76/308 (24,7)	NE [NE; NE]	0,59 [0,42; 0,84] 0,0030
Asien	34/239 (14,2)	NE [NE; NE]	52/226 (23,0)	NE [87,29; NE]	0,57 [0,37; 0,88] 0,0099
Andere	34/190 (17,9)	NE [NE; NE]	54/194 (27,8)	NE [NE; NE]	0,57 [0,37; 0,87] 0,0091
Primärtumorgröße (p-Wert des Interaktionsterms: 0,6111)					
< 20 mm	26/205 (12,7)	NE [NE; NE]	43/188 (22,9)	NE [NE; NE]	0,52 [0,32; 0,84] 0,0070
≥ 20 bis < 50 mm	60/360 (16,7)	NE [NE; NE]	84/346 (24,3)	NE [NE; NE]	0,65 [0,47; 0,90] 0,0098
≥ 50 mm	34/194 (17,5)	NE [NE; NE]	54/185 (29,2)	NE [85,64; NE]	0,51 [0,33; 0,79] 0,0020
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,6186)					
0-3	38/269 (14,1)	NE [NE; NE]	55/269 (20,4)	NE [NE; NE]	0,66 [0,44; 1,00] 0,0503
4-9	49/354 (13,8)	NE [NE; NE]	82/325 (25,2)	NE [NE; NE]	0,50 [0,35; 0,71] <,0001
≥ 10	36/154 (23,4)	NE [NE; NE]	45/134 (33,6)	NE [85,64; NE]	0,58 [0,37; 0,90] 0,0141
Tumorstadium (p-Wert des Interaktionsterms: 0,8338)					
IIA	10/79 (12,7)	NE [NE; NE]	15/77 (19,5)	NE [NE; NE]	0,62 [0,28; 1,37] 0,2296
IIB	10/73 (13,7)	NE [NE; NE]	16/93 (17,2)	NE [NE; NE]	0,89 [0,40; 1,97] 0,7665

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
IIIA	47/346 (13,6)	NE [NE; NE]	68/293 (23,2)	NE [NE; NE]	0,55 [0,38; 0,79] 0,0012
IIIB	3/22 (13,6)	NE [NE; NE]	6/19 (31,6)	NE [40,54; NE]	0,40 [0,10; 1,61] 0,1815
IIIC	51/253 (20,2)	NE [NE; NE]	77/245 (31,4)	NE [85,64; NE]	0,53 [0,38; 0,76] 0,0004
Tumorgrading (p-Wert des Interaktionsterms: 0,5540)					
G1	4/63 (6,3)	NE [NE; NE]	9/52 (17,3)	NE [NE; NE]	0,37 [0,11; 1,19] 0,0804
G2	52/349 (14,9)	NE [NE; NE]	79/323 (24,5)	NE [87,29; NE]	0,54 [0,38; 0,77] 0,0005
G3	61/318 (19,2)	NE [NE; NE]	82/311 (26,4)	NE [NE; NE]	0,67 [0,48; 0,94] 0,0184
GX	6/44 (13,6)	NE [NE; NE]	12/40 (30,0)	NE [NE; NE]	0,38 [0,14; 1,02] 0,0472
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,7986)					
Negativ	15/67 (22,4)	NE [NE; NE]	24/62 (38,7)	87,3 [56,42; NE]	0,47 [0,25; 0,90] 0,0189
Positiv	105/679 (15,5)	NE [NE; NE]	155/646 (24,0)	NE [NE; NE]	0,59 [0,46; 0,76] <,0001
Unbekannt	0/8 (0,0)	NE [NE; NE]	1/8 (12,5)	NE [68,88; NE]	0,00 [0,00; NE] 0,2801
Ethnizität (p-Wert des Interaktionsterms: 0,8338)					
Weiß	76/462 (16,5)	NE [NE; NE]	111/439 (25,3)	NE [NE; NE]	0,60 [0,44; 0,80] 0,0004
Asiatisch	39/273 (14,3)	NE [NE; NE]	57/243 (23,5)	NE [87,29; NE]	0,55 [0,37; 0,83] 0,0039
Andere	8/30 (26,7)	NE [57,34; NE]	12/34 (35,3)	NE [40,54; NE]	0,73 [0,30; 1,79] 0,4908
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,9700)					
Tamoxifen	91/553 (16,5)	NE [NE; NE]	138/534 (25,8)	NE [NE; NE]	0,58 [0,44; 0,76] <,0001
Aromatase-Inhibitor	32/224 (14,3)	NE [NE; NE]	44/194 (22,7)	NE [NE; NE]	0,59 [0,37; 0,93] 0,0204
ECOG-PS (p-Wert des Interaktionsterms: 0,4715)					

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
ECOG-PS 0	109/686 (15,9)	NE [NE; NE]	157/648 (24,2)	NE [NE; NE]	0,60 [0,47; 0,77] <,0001
ECOG-PS 1	14/91 (15,4)	NE [NE; NE]	25/80 (31,3)	NE [NE; NE]	0,46 [0,24; 0,88] 0,0165

Datenschnitt: 15.07.2025
ITT-Population
1: Aus Log-rank-Test; 2: In Monaten; 3: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; DRFS: Fernmetastasenfreies Überleben (distant relapse-free survival); GnRH: Gonadotropin-Releasing Hormon; ITT: Intention to Treat; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte, kontrollierte Studie.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Tabelle 103.2.2: Subgruppen für DRFS aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - ITT - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
Alter (p-Wert des Interaktionsterms: 0,4336)					
< 65 Jahre	165/918 (18,0)	NE [NE; NE]	230/936 (24,6)	NE [NE; NE]	0,71 [0,58; 0,87] 0,0009
≥ 65 Jahre	84/366 (23,0)	NE [NE; NE]	93/327 (28,4)	NE [NE; NE]	0,82 [0,61; 1,10] 0,1853
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,7945)					
Neoadjuvante Chemotherapie	101/430 (23,5)	NE [NE; NE]	134/415 (32,3)	NE [NE; NE]	0,72 [0,56; 0,93] 0,0120
Adjuvante Chemotherapie	134/785 (17,1)	NE [NE; NE]	166/767 (21,6)	NE [NE; NE]	0,78 [0,62; 0,98] 0,0349
Keine Chemotherapie	14/69 (20,3)	NE [85,71; NE]	23/81 (28,4)	NE [84,20; NE]	0,65 [0,33; 1,25] 0,1929
Region (p-Wert des Interaktionsterms: 0,7672)					
Nordamerika / Europa	128/679 (18,9)	NE [NE; NE]	162/648 (25,0)	NE [NE; NE]	0,74 [0,59; 0,94] 0,0118
Asien	34/203 (16,7)	NE [NE; NE]	49/201 (24,4)	NE [NE; NE]	0,66 [0,43; 1,02] 0,0616
Andere	87/402 (21,6)	NE [NE; NE]	112/414 (27,1)	NE [NE; NE]	0,80 [0,61; 1,06] 0,1242
Primärtumorgröße (p-Wert des Interaktionsterms: 0,4179)					
< 20 mm	45/332 (13,6)	NE [NE; NE]	74/333 (22,2)	NE [NE; NE]	0,59 [0,41; 0,86] 0,0053
≥ 20 bis < 50 mm	128/646 (19,8)	NE [NE; NE]	165/653 (25,3)	NE [NE; NE]	0,78 [0,62; 0,98] 0,0301
≥ 50 mm	71/289 (24,6)	NE [NE; NE]	81/265 (30,6)	NE [NE; NE]	0,80 [0,58; 1,10] 0,1675
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7176)					
0-3	55/427 (12,9)	NE [NE; NE]	78/418 (18,7)	NE [NE; NE]	0,68 [0,48; 0,96] 0,0286
4-9	98/548 (17,9)	NE [NE; NE]	122/543 (22,5)	NE [NE; NE]	0,80 [0,62; 1,05] 0,1062
≥ 10	96/309 (31,1)	NE [NE; NE]	123/302 (40,7)	NE [80,58; NE]	0,71 [0,55; 0,93] 0,0122

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
Tumorstadium (p-Wert des Interaktionsterms: 0,6087)					
IIA	9/113 (8,0)	NE [NE; NE]	17/114 (14,9)	NE [NE; NE]	0,51 [0,23; 1,15] 0,0964
IIB	19/151 (12,6)	NE [NE; NE]	24/136 (17,6)	NE [NE; NE]	0,69 [0,38; 1,26] 0,2265
IIIA	84/495 (17,0)	NE [NE; NE]	99/488 (20,3)	NE [NE; NE]	0,87 [0,65; 1,16] 0,3483
IIIB	15/54 (27,8)	NE [77,29; NE]	14/45 (31,1)	NE [84,20; NE]	0,94 [0,45; 1,94] 0,8619
IIIC	122/469 (26,0)	NE [NE; NE]	169/478 (35,4)	NE [NE; NE]	0,69 [0,55; 0,87] 0,0019
Tumorgrading (p-Wert des Interaktionsterms: 0,7149)					
G1	18/91 (19,8)	NE [NE; NE]	20/93 (21,5)	NE [NE; NE]	0,92 [0,49; 1,74] 0,7997
G2	125/613 (20,4)	NE [NE; NE]	158/601 (26,3)	NE [NE; NE]	0,77 [0,61; 0,97] 0,0280
G3	95/528 (18,0)	NE [NE; NE]	121/505 (24,0)	NE [NE; NE]	0,74 [0,57; 0,97] 0,0270
GX	11/50 (22,0)	NE [NE; NE]	23/60 (38,3)	NE [67,46; NE]	0,54 [0,26; 1,10] 0,0835
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6854)					
Negativ	42/157 (26,8)	NE [NE; NE]	64/168 (38,1)	NE [84,62; NE]	0,68 [0,46; 1,00] 0,0509
Positiv	199/1089 (18,3)	NE [NE; NE]	252/1066 (23,6)	NE [NE; NE]	0,76 [0,63; 0,92] 0,0043
Unbekannt	3/10 (30,0)	NE [47,24; NE]	2/7 (28,6)	84,5 [62,93; NE]	3,02 [0,31; 29,13] 0,3142
Ethnizität (p-Wert des Interaktionsterms: 0,3712)					
Weiß	193/958 (20,1)	NE [NE; NE]	243/943 (25,8)	NE [NE; NE]	0,77 [0,64; 0,93] 0,0074
Asiatisch	40/250 (16,0)	NE [NE; NE]	61/242 (25,2)	NE [NE; NE]	0,61 [0,41; 0,91] 0,0149
Andere	15/63 (23,8)	NE [NE; NE]	15/63 (23,8)	NE [NE; NE]	1,04 [0,51; 2,12] 0,9227
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,1220)					

Subgruppe	Abemaciclib+ET[3] Pat. mit Ereignis n/N (%)	Abemaciclib+ET[3] Mediane Ereigniszeit[2] [95% KI]	ET[3] Pat. mit Ereignis n/N (%)	ET[3] Mediane Ereigniszeit[2] [95% KI]	Abemaciclib+ET vs. ET[3] HR [95% KI] p-Wert[1]
Tamoxifen	15/114 (13,2)	NE [NE; NE]	33/132 (25,0)	NE [NE; NE]	0,48 [0,26; 0,89] 0,0166
Aromatase-Inhibitor	234/1170 (20,0)	NE [NE; NE]	290/1131 (25,6)	NE [NE; NE]	0,78 [0,65; 0,92] 0,0040
ECOG-PS (p-Wert des Interaktionsterms: 0,1844)					
ECOG-PS 0	203/1070 (19,0)	NE [NE; NE]	264/1019 (25,9)	NE [NE; NE]	0,71 [0,59; 0,85] 0,0002
ECOG-PS 1	46/214 (21,5)	NE [NE; NE]	59/244 (24,2)	NE [NE; NE]	0,95 [0,65; 1,40] 0,7901

Datenschnitt: 15.07.2025
ITT-Population
1: Aus Log-rank-Test; 2: In Monaten; 3: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; HR: Hazard Ratio; DRFS: Fernmetastasenfreies Überleben (distant relapse-free survival); ITT: Intention to Treat; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte, kontrollierte Studie.

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Anhang 4-G2.4: Unerwünschte Ereignisse

Anhang 4-G2.4.1: Unerwünschte Ereignisse (Gesamtraten) - Subgruppenanalysen nicht-interagierender Subgruppen (Prämenopausale Patientinnen)

Tabelle 116.1.2: Subgruppen - Unerwünschtes Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Region (p-Wert des Interaktionsterms: 0,2950)					
Nordamerika / Europa	344/347 (99,1)	280/309 (90,6)	1,09 [1,05; 1,14] <,0001[2]	11,88 [3,58; 39,39] <,0001[3]	8,5 [5,1; 11,9] <,0001[3]
Asien	238/239 (99,6)	204/226 (90,3)	1,10 [1,06; 1,15] <,0001[2]	25,67 [3,43; 192,08] <,0001[3]	9,3 [5,4; 13,3] <,0001[3]
Andere	179/190 (94,2)	156/194 (80,4)	1,17 [1,08; 1,27] <,0001[2]	3,96 [1,96; 8,02] <,0001[3]	13,8 [7,3; 20,3] <,0001[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,5113)					
< 20 mm	200/204 (98,0)	169/189 (89,4)	1,10 [1,04; 1,16] 0,0006[2]	5,92 [1,98; 17,65] 0,0004[3]	8,6 [3,8; 13,4] 0,0004[3]
≥ 20 bis < 50 mm	352/360 (97,8)	298/346 (86,1)	1,14 [1,09; 1,19] <,0001[2]	7,09 [3,30; 15,22] <,0001[3]	11,7 [7,7; 15,6] <,0001[3]
≥ 50 mm	191/194 (98,5)	166/185 (89,7)	1,10 [1,04; 1,16] 0,0005[2]	7,29 [2,12; 25,06] 0,0003[3]	8,7 [4,0; 13,4] 0,0003[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,6508)					
0-3	265/269 (98,5)	239/269 (88,8)	1,11 [1,06; 1,16] <,0001[2]	8,32 [2,89; 23,95] <,0001[3]	9,7 [5,6; 13,7] <,0001[3]
4-9	345/353 (97,7)	287/326 (88,0)	1,11 [1,06; 1,16] <,0001[2]	5,86 [2,70; 12,74] <,0001[3]	9,7 [5,8; 13,5] <,0001[3]
≥ 10	151/154 (98,1)	114/134 (85,1)	1,15 [1,07; 1,24] 0,0002[2]	8,83 [2,56; 30,44] <,0001[3]	13,0 [6,6; 19,4] <,0001[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,1662)					
IIA	78/79 (98,7)	69/77 (89,6)	1,10 [1,02; 1,19] 0,0176[2]	9,04 [1,10; 74,14] 0,0170[4]	9,1 [1,9; 16,4] 0,0170[4]
IIB	71/73 (97,3)	81/93 (87,1)	1,12 [1,02; 1,22] 0,0131[2]	5,26 [1,14; 24,30] 0,0193[3]	10,2 [2,4; 17,9] 0,0193[3]
IIIA	336/345 (97,4)	265/294 (90,1)	1,08 [1,04; 1,13] 0,0003[2]	4,09 [1,90; 8,78] 0,0001[3]	7,3 [3,5; 11,1] 0,0001[3]
IIIB	22/22 (100,0)	17/19 (89,5)	1,12 [0,94; 1,33] 0,2154[2]	6,43 [0,29; 142,70] 0,2085[4]	10,5 [-3,3; 24,3] 0,2085[4]
IIIC	250/253 (98,8)	207/245 (84,5)	1,17 [1,11; 1,24] <,0001[2]	15,30 [4,66; 50,27] <,0001[3]	14,3 [9,6; 19,0] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,1482)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
G1	61/63 (96,8)	46/52 (88,5)	1,09 [0,98; 1,22] 0,1007[2]	3,98 [0,77; 20,62] 0,1379[4]	8,4 [-1,3; 18,1] 0,1379[4]
G2	342/349 (98,0)	283/323 (87,6)	1,12 [1,07; 1,17] <,0001[2]	6,91 [3,05; 15,65] <,0001[3]	10,4 [6,5; 14,3] <,0001[3]
G3	313/317 (98,7)	271/312 (86,9)	1,14 [1,09; 1,19] <,0001[2]	11,84 [4,19; 33,48] <,0001[3]	11,9 [7,9; 15,8] <,0001[3]
GX	42/44 (95,5)	38/40 (95,0)	1,00 [0,91; 1,11] 0,9224[2]	1,11 [0,15; 8,24] 1,0000[4]	0,5 [-8,7; 9,6] 1,0000[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,1739)					
Tamoxifen	543/553 (98,2)	464/534 (86,9)	1,13 [1,09; 1,17] <,0001[2]	8,19 [4,17; 16,07] <,0001[3]	11,3 [8,2; 14,4] <,0001[3]
Aromatase-Inhibitor	218/223 (97,8)	176/195 (90,3)	1,08 [1,03; 1,14] 0,0018[2]	4,71 [1,72; 12,86] 0,0010[3]	7,5 [2,9; 12,1] 0,0010[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 117.1.2: Subgruppen - Schwerwiegendes unerwünschtes Ereignis aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9349)					
Neoadjuvante Chemotherapie	37/314 (11,8)	23/306 (7,5)	1,57 [0,95; 2,57] 0,0756[2]	1,64 [0,95; 2,84] 0,0724[3]	4,3 [-0,4; 8,9] 0,0724[3]
Adjuvante Chemotherapie	56/452 (12,4)	37/416 (8,9)	1,39 [0,94; 2,06] 0,0986[2]	1,45 [0,93; 2,25] 0,0963[3]	3,5 [-0,6; 7,6] 0,0963[3]
Keine Chemotherapie	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]
Region (p-Wert des Interaktionsterms: 0,6515)					
Nordamerika / Europa	47/347 (13,5)	32/309 (10,4)	1,31 [0,86; 2,00] 0,2128[2]	1,36 [0,84; 2,19] 0,2104[3]	3,2 [-1,8; 8,1] 0,2104[3]
Asien	27/239 (11,3)	16/226 (7,1)	1,60 [0,88; 2,88] 0,1212[2]	1,67 [0,88; 3,19] 0,1166[3]	4,2 [-1,0; 9,4] 0,1166[3]
Andere	22/190 (11,6)	12/194 (6,2)	1,87 [0,95; 3,67] 0,0684[2]	1,99 [0,95; 4,14] 0,0629[3]	5,4 [-0,3; 11,1] 0,0629[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3759)					
< 20 mm	22/204 (10,8)	18/189 (9,5)	1,13 [0,63; 2,04] 0,6800[2]	1,15 [0,60; 2,22] 0,6797[3]	1,3 [-4,7; 7,2] 0,6797[3]
≥ 20 bis < 50 mm	39/360 (10,8)	26/346 (7,5)	1,44 [0,90; 2,32] 0,1302[2]	1,50 [0,89; 2,51] 0,1273[3]	3,3 [-0,9; 7,6] 0,1273[3]
≥ 50 mm	32/194 (16,5)	15/185 (8,1)	2,03 [1,14; 3,63] 0,0163[2]	2,24 [1,17; 4,29] 0,0133[3]	8,4 [1,8; 14,9] 0,0133[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,2513)					
0-3	37/269 (13,8)	19/269 (7,1)	1,95 [1,15; 3,30] 0,0131[2]	2,10 [1,17; 3,75] 0,0110[3]	6,7 [1,6; 11,8] 0,0110[3]
4-9	44/353 (12,5)	27/326 (8,3)	1,50 [0,95; 2,37] 0,0782[2]	1,58 [0,95; 2,61] 0,0752[3]	4,2 [-0,4; 8,7] 0,0752[3]
≥ 10	15/154 (9,7)	14/134 (10,4)	0,93 [0,47; 1,86] 0,8423[2]	0,92 [0,43; 1,99] 0,8423[3]	-0,7 [-7,7; 6,3] 0,8423[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,4128)					
IIA	5/79 (6,3)	6/77 (7,8)	0,81 [0,26; 2,55] 0,7218[2]	0,80 [0,23; 2,74] 0,7212[3]	-1,5 [-9,5; 6,6] 0,7212[3]
IIB	6/73 (8,2)	5/93 (5,4)	1,53 [0,49; 4,81] 0,4681[2]	1,58 [0,46; 5,38] 0,5380[4]	2,8 [-4,9; 10,6] 0,5380[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIA	53/345 (15,4)	22/294 (7,5)	2,05 [1,28; 3,29] 0,0028[2]	2,24 [1,33; 3,79] 0,0020[3]	7,9 [3,0; 12,7] 0,0020[3]
IIIB	1/22 (4,5)	1/19 (5,3)	0,86 [0,06; 12,89] 0,9153[2]	0,86 [0,05; 14,71] 1,0000[4]	-0,7 [-14,0; 12,6] 1,0000[4]
IIIC	30/253 (11,9)	25/245 (10,2)	1,16 [0,70; 1,92] 0,5567[2]	1,18 [0,67; 2,08] 0,5561[3]	1,7 [-3,8; 7,2] 0,5561[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,7599)					
G1	11/63 (17,5)	4/52 (7,7)	2,27 [0,77; 6,71] 0,1383[2]	2,54 [0,76; 8,51] 0,1216[3]	9,8 [-2,1; 21,6] 0,1216[3]
G2	44/349 (12,6)	31/323 (9,6)	1,31 [0,85; 2,03] 0,2179[2]	1,36 [0,84; 2,21] 0,2157[3]	3,0 [-1,7; 7,7] 0,2157[3]
G3	35/317 (11,0)	23/312 (7,4)	1,50 [0,91; 2,48] 0,1150[2]	1,56 [0,90; 2,71] 0,1118[3]	3,7 [-0,8; 8,2] 0,1118[3]
GX	5/44 (11,4)	2/40 (5,0)	2,27 [0,47; 11,07] 0,3094[2]	2,44 [0,45; 13,33] 0,4367[4]	6,4 [-5,2; 17,9] 0,4367[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5758)					
Negativ	10/67 (14,9)	9/62 (14,5)	1,03 [0,45; 2,36] 0,9478[2]	1,03 [0,39; 2,74] 0,9478[3]	0,4 [-11,8; 12,6] 0,9478[3]
Positiv	82/678 (12,1)	47/647 (7,3)	1,66 [1,18; 2,34] 0,0035[2]	1,76 [1,21; 2,56] 0,0030[3]	4,8 [1,7; 8,0] 0,0030[3]
Unbekannt	0/8 (0,0)	1/8 (12,5)	0,33 [0,02; 7,14] 0,4823[2]	0,29 [0,01; 8,37] 1,0000[4]	-12,5 [-35,4; 10,4] 1,0000[4]
Ethnizität (p-Wert des Interaktionsterms: 0,7200)					
Weiß	55/461 (11,9)	38/440 (8,6)	1,38 [0,93; 2,04] 0,1064[2]	1,43 [0,93; 2,22] 0,1042[3]	3,3 [-0,7; 7,2] 0,1042[3]
Asiatisch	33/273 (12,1)	16/243 (6,6)	1,84 [1,04; 3,25] 0,0372[2]	1,95 [1,05; 3,64] 0,0333[3]	5,5 [0,5; 10,5] 0,0333[3]
Andere	5/30 (16,7)	4/34 (11,8)	1,42 [0,42; 4,80] 0,5757[2]	1,50 [0,36; 6,19] 0,7231[4]	4,9 [-12,3; 22,1] 0,7231[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,5248)					
Tamoxifen	64/553 (11,6)	44/534 (8,2)	1,40 [0,98; 2,02] 0,0681[2]	1,46 [0,97; 2,18] 0,0662[3]	3,3 [-0,2; 6,9] 0,0662[3]
Aromatase-Inhibitor	32/223 (14,3)	16/195 (8,2)	1,75 [0,99; 3,09] 0,0540[2]	1,87 [0,99; 3,53] 0,0493[3]	6,1 [0,1; 12,1] 0,0493[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,4815)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	84/685 (12,3)	55/649 (8,5)	1,45 [1,05; 2,00] 0,0248[2]	1,51 [1,05; 2,16] 0,0236[3]	3,8 [0,5; 7,0] 0,0236[3]
ECOG-PS 1	12/91 (13,2)	5/80 (6,3)	2,11 [0,78; 5,73] 0,1430[2]	2,28 [0,77; 6,78] 0,1304[3]	6,9 [-1,8; 15,7] 0,1304[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 118.1.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9050)					
Neoadjuvante Chemotherapie	164/314 (52,2)	52/306 (17,0)	3,07 [2,35; 4,02] <,0001[2]	5,34 [3,68; 7,74] <,0001[3]	35,2 [28,3; 42,2] <,0001[3]
Adjuvante Chemotherapie	203/452 (44,9)	56/416 (13,5)	3,34 [2,56; 4,35] <,0001[2]	5,24 [3,74; 7,34] <,0001[3]	31,4 [25,8; 37,1] <,0001[3]
Keine Chemotherapie	4/10 (40,0)	1/7 (14,3)	2,80 [0,39; 20,02] 0,3049[2]	4,00 [0,34; 47,11] 0,3382[4]	25,7 [-14,2; 65,6] 0,3382[4]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3070)					
< 20 mm	102/204 (50,0)	32/189 (16,9)	2,95 [2,09; 4,17] <,0001[2]	4,91 [3,07; 7,84] <,0001[3]	33,1 [24,4; 41,8] <,0001[3]
≥ 20 bis < 50 mm	169/360 (46,9)	43/346 (12,4)	3,78 [2,80; 5,10] <,0001[2]	6,23 [4,26; 9,12] <,0001[3]	34,5 [28,3; 40,7] <,0001[3]
≥ 50 mm	93/194 (47,9)	33/185 (17,8)	2,69 [1,91; 3,78] <,0001[2]	4,24 [2,65; 6,79] <,0001[3]	30,1 [21,2; 39,0] <,0001[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7578)					
0-3	140/269 (52,0)	40/269 (14,9)	3,50 [2,57; 4,76] <,0001[2]	6,21 [4,11; 9,38] <,0001[3]	37,2 [29,8; 44,5] <,0001[3]
4-9	152/353 (43,1)	47/326 (14,4)	2,99 [2,23; 3,99] <,0001[2]	4,49 [3,09; 6,53] <,0001[3]	28,6 [22,2; 35,1] <,0001[3]
≥ 10	79/154 (51,3)	22/134 (16,4)	3,12 [2,07; 4,72] <,0001[2]	5,36 [3,08; 9,35] <,0001[3]	34,9 [24,8; 45,0] <,0001[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,6459)					
IIA	43/79 (54,4)	12/77 (15,6)	3,49 [2,00; 6,10] <,0001[2]	6,47 [3,03; 13,81] <,0001[3]	38,8 [25,2; 52,5] <,0001[3]
IIB	37/73 (50,7)	17/93 (18,3)	2,77 [1,71; 4,51] <,0001[2]	4,59 [2,29; 9,23] <,0001[3]	32,4 [18,5; 46,3] <,0001[3]
IIIA	152/345 (44,1)	45/294 (15,3)	2,88 [2,15; 3,86] <,0001[2]	4,36 [2,97; 6,39] <,0001[3]	28,8 [22,1; 35,4] <,0001[3]
IIIB	11/22 (50,0)	1/19 (5,3)	9,50 [1,35; 66,97] 0,0239[2]	18,00 [2,03; 159,27] 0,0017[3]	44,7 [21,6; 67,9] 0,0017[3]
IIIC	125/253 (49,4)	34/245 (13,9)	3,56 [2,54; 4,98] <,0001[2]	6,06 [3,91; 9,39] <,0001[3]	35,5 [28,0; 43,1] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,6418)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
G1	34/63 (54,0)	10/52 (19,2)	2,81 [1,54; 5,12] 0,0008[2]	4,92 [2,11; 11,51] 0,0001[3]	34,7 [18,4; 51,1] 0,0001[3]
G2	158/349 (45,3)	51/323 (15,8)	2,87 [2,17; 3,78] <,0001[2]	4,41 [3,06; 6,36] <,0001[3]	29,5 [22,9; 36,0] <,0001[3]
G3	155/317 (48,9)	44/312 (14,1)	3,47 [2,58; 4,66] <,0001[2]	5,83 [3,96; 8,59] <,0001[3]	34,8 [28,1; 41,5] <,0001[3]
GX	21/44 (47,7)	4/40 (10,0)	4,77 [1,79; 12,71] 0,0018[2]	8,22 [2,50; 27,02] 0,0002[3]	37,7 [20,3; 55,2] 0,0002[3]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5322)					
Negativ	40/67 (59,7)	14/62 (22,6)	2,64 [1,60; 4,36] 0,0001[2]	5,08 [2,35; 10,97] <,0001[3]	37,1 [21,4; 52,8] <,0001[3]
Positiv	319/678 (47,1)	90/647 (13,9)	3,38 [2,75; 4,16] <,0001[2]	5,50 [4,20; 7,20] <,0001[3]	33,1 [28,5; 37,7] <,0001[3]
Unbekannt	4/8 (50,0)	2/8 (25,0)	2,00 [0,50; 8,00] 0,3270[2]	3,00 [0,36; 24,92] 0,6084[4]	25,0 [-20,8; 70,8] 0,6084[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,6470)					
Tamoxifen	243/553 (43,9)	76/534 (14,2)	3,09 [2,46; 3,88] <,0001[2]	4,72 [3,52; 6,35] <,0001[3]	29,7 [24,6; 34,8] <,0001[3]
Aromatase-Inhibitor	128/223 (57,4)	33/195 (16,9)	3,39 [2,44; 4,72] <,0001[2]	6,61 [4,18; 10,47] <,0001[3]	40,5 [32,1; 48,8] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,8234)					
ECOG-PS 0	337/685 (49,2)	99/649 (15,3)	3,23 [2,65; 3,93] <,0001[2]	5,38 [4,14; 6,99] <,0001[3]	33,9 [29,3; 38,6] <,0001[3]
ECOG-PS 1	34/91 (37,4)	10/80 (12,5)	2,99 [1,58; 5,66] 0,0008[2]	4,18 [1,90; 9,17] 0,0002[3]	24,9 [12,6; 37,2] 0,0002[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 119.1.2: Subgruppen - Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,8225)					
Neoadjuvante Chemotherapie	33/314 (10,5)	3/306 (1,0)	10,72 [3,32; 34,59] <,0001[2]	11,86 [3,60; 39,11] <,0001[3]	9,5 [6,0; 13,1] <,0001[3]
Adjuvante Chemotherapie	59/452 (13,1)	3/416 (0,7)	18,10 [5,72; 57,30] <,0001[2]	20,67 [6,43; 66,47] <,0001[3]	12,3 [9,1; 15,5] <,0001[3]
Keine Chemotherapie	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Region (p-Wert des Interaktionsterms: 0,6083)					
Nordamerika / Europa	53/347 (15,3)	3/309 (1,0)	15,73 [4,97; 49,84] <,0001[2]	18,39 [5,68; 59,49] <,0001[3]	14,3 [10,4; 18,2] <,0001[3]
Asien	26/239 (10,9)	1/226 (0,4)	24,59 [3,36; 179,68] 0,0016[2]	27,46 [3,69; 204,17] <,0001[3]	10,4 [6,4; 14,5] <,0001[3]
Andere	15/190 (7,9)	2/194 (1,0)	7,66 [1,78; 33,03] 0,0063[2]	8,23 [1,86; 36,49] 0,0011[3]	6,9 [2,8; 11,0] 0,0011[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,6579)					
< 20 mm	21/204 (10,3)	2/189 (1,1)	9,73 [2,31; 40,93] 0,0019[2]	10,73 [2,48; 46,42] <,0001[3]	9,2 [4,8; 13,7] <,0001[3]
≥ 20 bis < 50 mm	48/360 (13,3)	2/346 (0,6)	23,07 [5,65; 94,17] <,0001[2]	26,46 [6,38; 109,78] <,0001[3]	12,8 [9,2; 16,4] <,0001[3]
≥ 50 mm	23/194 (11,9)	2/185 (1,1)	10,97 [2,62; 45,86] 0,0010[2]	12,31 [2,86; 52,99] <,0001[3]	10,8 [6,0; 15,6] <,0001[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,9919)					
0-3	40/269 (14,9)	3/269 (1,1)	13,33 [4,18; 42,58] <,0001[2]	15,49 [4,73; 50,73] <,0001[3]	13,8 [9,3; 18,2] <,0001[3]
4-9	39/353 (11,0)	3/326 (0,9)	12,01 [3,75; 38,47] <,0001[2]	13,37 [4,09; 43,72] <,0001[3]	10,1 [6,7; 13,6] <,0001[3]
≥ 10	15/154 (9,7)	0/134 (0,0)	27,00 [1,63; 446,99] 0,0214[2]	29,89 [1,77; 504,51] 0,0002[3]	9,7 [5,1; 14,4] 0,0002[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,8147)					
IIA	9/79 (11,4)	1/77 (1,3)	8,77 [1,14; 67,60] 0,0371[2]	9,77 [1,21; 79,11] 0,0178[4]	10,1 [2,6; 17,5] 0,0178[4]
IIB	11/73 (15,1)	2/93 (2,2)	7,01 [1,60; 30,63] 0,0097[2]	8,07 [1,73; 37,69] 0,0021[3]	12,9 [4,2; 21,6] 0,0021[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIA	38/345 (11,0)	2/294 (0,7)	16,19 [3,94; 66,54] 0,0001[2]	18,07 [4,32; 75,58] <,0001[3]	10,3 [6,9; 13,8] <,0001[3]
IIIB	4/22 (18,2)	1/19 (5,3)	3,45 [0,42; 28,31] 0,2481[2]	4,00 [0,41; 39,37] 0,3499[4]	12,9 [-6,1; 31,9] 0,3499[4]
IIIC	31/253 (12,3)	0/245 (0,0)	61,02 [3,75; 991,62] 0,0039[2]	69,51 [4,23; 1142,65] <,0001[3]	12,3 [8,2; 16,3] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,5979)					
G1	8/63 (12,7)	0/52 (0,0)	14,08 [0,83; 238,28] 0,0669[2]	16,08 [0,91; 285,62] 0,0078[4]	12,7 [4,5; 20,9] 0,0078[4]
G2	44/349 (12,6)	5/323 (1,5)	8,14 [3,27; 20,28] <,0001[2]	9,18 [3,59; 23,45] <,0001[3]	11,1 [7,3; 14,8] <,0001[3]
G3	38/317 (12,0)	1/312 (0,3)	37,40 [5,17; 270,73] 0,0003[2]	42,36 [5,78; 310,54] <,0001[3]	11,7 [8,0; 15,3] <,0001[3]
GX	4/44 (9,1)	0/40 (0,0)	8,20 [0,46; 147,68] 0,1537[2]	9,00 [0,47; 172,65] 0,1177[4]	9,1 [0,6; 17,6] 0,1177[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6932)					
Negativ	7/67 (10,4)	1/62 (1,6)	6,48 [0,82; 51,16] 0,0764[2]	7,12 [0,85; 59,61] 0,0635[4]	8,8 [0,9; 16,8] 0,0635[4]
Positiv	74/678 (10,9)	4/647 (0,6)	17,65 [6,49; 48,01] <,0001[2]	19,69 [7,16; 54,19] <,0001[3]	10,3 [7,9; 12,7] <,0001[3]
Unbekannt	3/8 (37,5)	0/8 (0,0)	7,00 [0,42; 116,91] 0,1755[2]	10,82 [0,46; 252,79] 0,2000[4]	37,5 [4,0; 71,0] 0,2000[4]
Ethnizität (p-Wert des Interaktionsterms: 0,8150)					
Weiß	56/461 (12,1)	4/440 (0,9)	13,36 [4,89; 36,54] <,0001[2]	15,07 [5,42; 41,94] <,0001[3]	11,2 [8,1; 14,3] <,0001[3]
Asiatisch	31/273 (11,4)	1/243 (0,4)	27,59 [3,80; 200,61] 0,0010[2]	31,00 [4,20; 228,90] <,0001[3]	10,9 [7,1; 14,8] <,0001[3]
Andere	5/30 (16,7)	0/34 (0,0)	12,42 [0,72; 215,65] 0,0837[2]	14,88 [0,79; 281,50] 0,0187[4]	16,7 [3,3; 30,0] 0,0187[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,6569)					
Tamoxifen	69/553 (12,5)	5/534 (0,9)	13,33 [5,42; 32,77] <,0001[2]	15,08 [6,03; 37,70] <,0001[3]	11,5 [8,7; 14,4] <,0001[3]
Aromatase-Inhibitor	25/223 (11,2)	1/195 (0,5)	21,86 [2,99; 159,85] 0,0024[2]	24,49 [3,29; 182,55] <,0001[3]	10,7 [6,4; 15,0] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,9762)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	86/685 (12,6)	6/649 (0,9)	13,58 [5,98; 30,85] <,0001[2]	15,39 [6,68; 35,46] <,0001[3]	11,6 [9,0; 14,2] <,0001[3]
ECOG-PS 1	8/91 (8,8)	0/80 (0,0)	14,97 [0,88; 255,28] 0,0615[2]	16,39 [0,93; 288,64] 0,0074[4]	8,8 [3,0; 14,6] 0,0074[4]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Anhang 4-G2.4.2: Unerwünschte Ereignisse (Gesamtraten) - Subgruppenanalysen nicht-interagierender Subgruppen

Tabelle 116.2.2: Subgruppen - Unerwünschtes Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,9379)					
< 65 Jahre	900/918 (98,0)	827/936 (88,4)	1,11 [1,08; 1,14] <,0001[2]	6,59 [3,97; 10,95] <,0001[3]	9,7 [7,4; 11,9] <,0001[3]
≥ 65 Jahre	360/365 (98,6)	291/328 (88,7)	1,11 [1,07; 1,16] <,0001[2]	9,15 [3,55; 23,59] <,0001[3]	9,9 [6,3; 13,5] <,0001[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,0772)					
Neoadjuvante Chemotherapie	420/430 (97,7)	376/415 (90,6)	1,08 [1,04; 1,12] <,0001[2]	4,36 [2,14; 8,85] <,0001[3]	7,1 [3,9; 10,2] <,0001[3]
Adjuvante Chemotherapie	773/784 (98,6)	677/768 (88,2)	1,12 [1,09; 1,15] <,0001[2]	9,45 [5,01; 17,81] <,0001[3]	10,4 [8,0; 12,9] <,0001[3]
Keine Chemotherapie	67/69 (97,1)	65/81 (80,2)	1,21 [1,08; 1,36] 0,0012[2]	8,25 [1,82; 37,29] 0,0015[3]	16,9 [7,3; 26,4] 0,0015[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,1171)					
< 20 mm	324/331 (97,9)	296/334 (88,6)	1,10 [1,06; 1,15] <,0001[2]	5,94 [2,61; 13,51] <,0001[3]	9,3 [5,5; 13,0] <,0001[3]
≥ 20 bis < 50 mm	636/646 (98,5)	568/653 (87,0)	1,13 [1,10; 1,17] <,0001[2]	9,52 [4,89; 18,51] <,0001[3]	11,5 [8,7; 14,2] <,0001[3]
≥ 50 mm	283/289 (97,9)	242/265 (91,3)	1,07 [1,03; 1,12] 0,0008[2]	4,48 [1,80; 11,19] 0,0005[3]	6,6 [2,8; 10,4] 0,0005[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,5403)					
0-3	420/427 (98,4)	375/418 (89,7)	1,10 [1,06; 1,14] <,0001[2]	6,88 [3,06; 15,48] <,0001[3]	8,6 [5,5; 11,8] <,0001[3]
4-9	536/549 (97,6)	477/542 (88,0)	1,11 [1,07; 1,15] <,0001[2]	5,62 [3,06; 10,32] <,0001[3]	9,6 [6,6; 12,6] <,0001[3]
≥ 10	304/307 (99,0)	266/304 (87,5)	1,13 [1,08; 1,18] <,0001[2]	14,48 [4,42; 47,44] <,0001[3]	11,5 [7,6; 15,4] <,0001[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,5151)					
IIA	111/113 (98,2)	104/114 (91,2)	1,08 [1,01; 1,15] 0,0195[2]	5,34 [1,14; 24,93] 0,0184[3]	7,0 [1,3; 12,7] 0,0184[3]
IIB	149/151 (98,7)	123/136 (90,4)	1,09 [1,03; 1,16] 0,0031[2]	7,87 [1,74; 35,56] 0,0018[3]	8,2 [3,0; 13,5] 0,0018[3]
IIIA	482/495 (97,4)	424/488 (86,9)	1,12 [1,08; 1,16] <,0001[2]	5,60 [3,04; 10,30] <,0001[3]	10,5 [7,2; 13,8] <,0001[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIB	53/54 (98,1)	42/45 (93,3)	1,05 [0,96; 1,15] 0,2530[2]	3,79 [0,38; 37,73] 0,3271[4]	4,8 [-3,3; 12,9] 0,3271[4]
IIIC	463/468 (98,9)	423/479 (88,3)	1,12 [1,08; 1,16] <,0001[2]	12,26 [4,86; 30,89] <,0001[3]	10,6 [7,6; 13,6] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,1714)					
G1	89/91 (97,8)	82/93 (88,2)	1,11 [1,02; 1,20] 0,0117[2]	5,97 [1,28; 27,74] 0,0108[3]	9,6 [2,4; 16,9] 0,0108[3]
G2	600/612 (98,0)	543/602 (90,2)	1,09 [1,06; 1,12] <,0001[2]	5,43 [2,89; 10,22] <,0001[3]	7,8 [5,2; 10,5] <,0001[3]
G3	519/527 (98,5)	442/506 (87,4)	1,13 [1,09; 1,17] <,0001[2]	9,39 [4,46; 19,80] <,0001[3]	11,1 [8,1; 14,2] <,0001[3]
GX	50/51 (98,0)	47/59 (79,7)	1,23 [1,08; 1,41] 0,0025[2]	12,77 [1,60; 102,03] 0,0029[3]	18,4 [7,4; 29,3] 0,0029[3]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,3313)					
Negativ	154/156 (98,7)	155/169 (91,7)	1,08 [1,03; 1,13] 0,0031[2]	6,95 [1,55; 31,12] 0,0036[3]	7,0 [2,5; 11,5] 0,0036[3]
Positiv	1070/1089 (98,3)	936/1066 (87,8)	1,12 [1,09; 1,15] <,0001[2]	7,82 [4,80; 12,76] <,0001[3]	10,5 [8,3; 12,6] <,0001[3]
Unbekannt	9/10 (90,0)	5/7 (71,4)	1,26 [0,76; 2,10] 0,3764[2]	3,60 [0,26; 50,33] 0,5368[4]	18,6 [-19,7; 56,9] 0,5368[4]
Ethnizität (p-Wert des Interaktionsterms: 0,8418)					
Weiß	940/958 (98,1)	833/943 (88,3)	1,11 [1,08; 1,14] <,0001[2]	6,90 [4,15; 11,45] <,0001[3]	9,8 [7,6; 12,0] <,0001[3]
Asiatisch	246/250 (98,4)	213/242 (88,0)	1,12 [1,06; 1,17] <,0001[2]	8,37 [2,90; 24,20] <,0001[3]	10,4 [6,0; 14,8] <,0001[3]
Andere	61/62 (98,4)	58/64 (90,6)	1,09 [1,00; 1,18] 0,0581[2]	6,31 [0,74; 54,03] 0,1148[4]	7,8 [-0,0; 15,6] 0,1148[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,3260)					
Tamoxifen	113/114 (99,1)	114/132 (86,4)	1,15 [1,07; 1,23] 0,0001[2]	17,84 [2,34; 135,91] 0,0002[3]	12,8 [6,7; 18,9] 0,0002[3]
Aromatase-Inhibitor	1147/1169 (98,1)	1004/1132 (88,7)	1,11 [1,08; 1,13] <,0001[2]	6,65 [4,20; 10,53] <,0001[3]	9,4 [7,4; 11,4] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,9206)					
ECOG-PS 0	1051/1070 (98,2)	901/1019 (88,4)	1,11 [1,08; 1,14] <,0001[2]	7,24 [4,43; 11,86] <,0001[3]	9,8 [7,7; 11,9] <,0001[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 1	209/213 (98,1)	217/245 (88,6)	1,11 [1,06; 1,16] <,0001[2]	6,74 [2,32; 19,55] <,0001[3]	9,6 [5,2; 13,9] <,0001[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 117.2.2: Subgruppen - Schwerwiegendes unerwünschtes Ereignis aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Subgruppe	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,5152)					
< 65 Jahre	124/918 (13,5)	85/936 (9,1)	1,49 [1,15; 1,93] 0,0028[2]	1,56 [1,17; 2,09] 0,0026[3]	4,4 [1,5; 7,3] 0,0026[3]
≥ 65 Jahre	82/365 (22,5)	43/328 (13,1)	1,71 [1,22; 2,40] 0,0018[2]	1,92 [1,28; 2,88] 0,0014[3]	9,4 [3,7; 15,0] 0,0014[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,8892)					
Neoadjuvante Chemotherapie	70/430 (16,3)	41/415 (9,9)	1,65 [1,15; 2,36] 0,0067[2]	1,77 [1,18; 2,68] 0,0059[3]	6,4 [1,9; 10,9] 0,0059[3]
Adjuvante Chemotherapie	122/784 (15,6)	78/768 (10,2)	1,53 [1,17; 2,00] 0,0017[2]	1,63 [1,20; 2,21] 0,0015[3]	5,4 [2,1; 8,7] 0,0015[3]
Keine Chemotherapie	14/69 (20,3)	9/81 (11,1)	1,83 [0,84; 3,96] 0,1270[2]	2,04 [0,82; 5,05] 0,1199[3]	9,2 [-2,5; 20,9] 0,1199[3]
Region (p-Wert des Interaktionsterms: 0,2371)					
Nordamerika / Europa	118/678 (17,4)	81/649 (12,5)	1,39 [1,07; 1,81] 0,0127[2]	1,48 [1,09; 2,01] 0,0120[3]	4,9 [1,1; 8,7] 0,0120[3]
Asien	40/203 (19,7)	25/201 (12,4)	1,58 [1,00; 2,51] 0,0500[2]	1,73 [1,00; 2,97] 0,0469[3]	7,3 [0,1; 14,4] 0,0469[3]
Andere	48/402 (11,9)	22/414 (5,3)	2,25 [1,38; 3,65] 0,0011[2]	2,42 [1,43; 4,08] 0,0007[3]	6,6 [2,8; 10,5] 0,0007[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3865)					
< 20 mm	46/331 (13,9)	34/334 (10,2)	1,37 [0,90; 2,07] 0,1428[2]	1,42 [0,89; 2,28] 0,1406[3]	3,7 [-1,2; 8,7] 0,1406[3]
≥ 20 bis < 50 mm	106/646 (16,4)	71/653 (10,9)	1,51 [1,14; 2,00] 0,0040[2]	1,61 [1,17; 2,22] 0,0036[3]	5,5 [1,8; 9,3] 0,0036[3]
≥ 50 mm	52/289 (18,0)	23/265 (8,7)	2,07 [1,31; 3,29] 0,0020[2]	2,31 [1,37; 3,89] 0,0014[3]	9,3 [3,7; 14,9] 0,0014[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,1428)					
0-3	75/427 (17,6)	41/418 (9,8)	1,79 [1,25; 2,56] 0,0013[2]	1,96 [1,30; 2,94] 0,0011[3]	7,8 [3,2; 12,4] 0,0011[3]
4-9	71/549 (12,9)	57/542 (10,5)	1,23 [0,89; 1,71] 0,2162[2]	1,26 [0,87; 1,83] 0,2150[3]	2,4 [-1,4; 6,2] 0,2150[3]
≥ 10	60/307 (19,5)	30/304 (9,9)	1,98 [1,32; 2,98] 0,0010[2]	2,22 [1,39; 3,55] 0,0007[3]	9,7 [4,1; 15,2] 0,0007[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,5958)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIA	14/113 (12,4)	13/114 (11,4)	1,09 [0,53; 2,21] 0,8186[2]	1,10 [0,49; 2,46] 0,8185[3]	1,0 [-7,4; 9,4] 0,8185[3]
IIB	26/151 (17,2)	13/136 (9,6)	1,80 [0,97; 3,36] 0,0646[2]	1,97 [0,97; 4,01] 0,0586[3]	7,7 [-0,1; 15,4] 0,0586[3]
IIIA	76/495 (15,4)	49/488 (10,0)	1,53 [1,09; 2,14] 0,0134[2]	1,63 [1,11; 2,38] 0,0124[3]	5,3 [1,2; 9,5] 0,0124[3]
IIIB	7/54 (13,0)	6/45 (13,3)	0,97 [0,35; 2,69] 0,9567[2]	0,97 [0,30; 3,12] 0,9567[3]	-0,4 [-13,7; 13,0] 0,9567[3]
IIIC	83/468 (17,7)	47/479 (9,8)	1,81 [1,29; 2,53] 0,0005[2]	1,98 [1,35; 2,91] 0,0004[3]	7,9 [3,6; 12,3] 0,0004[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,6692)					
G1	16/91 (17,6)	15/93 (16,1)	1,09 [0,57; 2,07] 0,7924[2]	1,11 [0,51; 2,40] 0,7923[3]	1,5 [-9,4; 12,3] 0,7923[3]
G2	104/612 (17,0)	61/602 (10,1)	1,68 [1,25; 2,25] 0,0006[2]	1,82 [1,29; 2,55] 0,0005[3]	6,9 [3,0; 10,7] 0,0005[3]
G3	78/527 (14,8)	46/506 (9,1)	1,63 [1,15; 2,30] 0,0054[2]	1,74 [1,18; 2,56] 0,0048[3]	5,7 [1,8; 9,6] 0,0048[3]
GX	7/51 (13,7)	6/59 (10,2)	1,35 [0,48; 3,76] 0,5660[2]	1,41 [0,44; 4,49] 0,5645[3]	3,6 [-8,6; 15,7] 0,5645[3]
Ethnizität (p-Wert des Interaktionsterms: 0,7948)					
Weiß	149/958 (15,6)	94/943 (10,0)	1,56 [1,22; 1,99] 0,0003[2]	1,66 [1,26; 2,19] 0,0003[3]	5,6 [2,6; 8,6] 0,0003[3]
Asiatisch	46/250 (18,4)	28/242 (11,6)	1,59 [1,03; 2,46] 0,0367[2]	1,72 [1,04; 2,86] 0,0341[3]	6,8 [0,6; 13,1] 0,0341[3]
Andere	9/62 (14,5)	4/64 (6,3)	2,32 [0,75; 7,15] 0,1420[2]	2,55 [0,74; 8,75] 0,1273[3]	8,3 [-2,3; 18,9] 0,1273[3]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,1119)					
Tamoxifen	20/114 (17,5)	8/132 (6,1)	2,89 [1,33; 6,32] 0,0076[2]	3,30 [1,39; 7,81] 0,0047[3]	11,5 [3,4; 19,6] 0,0047[3]
Aromatase-Inhibitor	186/1169 (15,9)	120/1132 (10,6)	1,50 [1,21; 1,86] 0,0002[2]	1,60 [1,25; 2,04] 0,0002[3]	5,3 [2,6; 8,1] 0,0002[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,1566)					
ECOG-PS 0	155/1070 (14,5)	100/1019 (9,8)	1,48 [1,17; 1,87] 0,0012[2]	1,56 [1,19; 2,03] 0,0011[3]	4,7 [1,9; 7,5] 0,0011[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 1	51/213 (23,9)	28/245 (11,4)	2,10 [1,37; 3,20] 0,0006[2]	2,44 [1,47; 4,04] 0,0004[3]	12,5 [5,5; 19,5] 0,0004[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 118.2.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,2111)					
< 65 Jahre	446/918 (48,6)	149/936 (15,9)	3,05 [2,60; 3,59] <,0001[2]	4,99 [4,01; 6,21] <,0001[3]	32,7 [28,7; 36,7] <,0001[3]
≥ 65 Jahre	202/365 (55,3)	71/328 (21,6)	2,56 [2,04; 3,20] <,0001[2]	4,49 [3,21; 6,27] <,0001[3]	33,7 [26,9; 40,5] <,0001[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,7019)					
Neoadjuvante Chemotherapie	234/430 (54,4)	72/415 (17,3)	3,14 [2,50; 3,94] <,0001[2]	5,69 [4,14; 7,81] <,0001[3]	37,1 [31,1; 43,0] <,0001[3]
Adjuvante Chemotherapie	380/784 (48,5)	134/768 (17,4)	2,78 [2,34; 3,29] <,0001[2]	4,45 [3,52; 5,62] <,0001[3]	31,0 [26,6; 35,4] <,0001[3]
Keine Chemotherapie	34/69 (49,3)	14/81 (17,3)	2,85 [1,67; 4,86] 0,0001[2]	4,65 [2,21; 9,79] <,0001[3]	32,0 [17,6; 46,4] <,0001[3]
Region (p-Wert des Interaktionsterms: 0,1930)					
Nordamerika / Europa	335/678 (49,4)	124/649 (19,1)	2,59 [2,17; 3,08] <,0001[2]	4,14 [3,23; 5,29] <,0001[3]	30,3 [25,5; 35,1] <,0001[3]
Asien	126/203 (62,1)	38/201 (18,9)	3,28 [2,42; 4,46] <,0001[2]	7,02 [4,46; 11,04] <,0001[3]	43,2 [34,6; 51,8] <,0001[3]
Andere	187/402 (46,5)	58/414 (14,0)	3,32 [2,56; 4,31] <,0001[2]	5,34 [3,80; 7,50] <,0001[3]	32,5 [26,6; 38,4] <,0001[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,4463)					
< 20 mm	156/331 (47,1)	56/334 (16,8)	2,81 [2,16; 3,66] <,0001[2]	4,43 [3,09; 6,34] <,0001[3]	30,4 [23,7; 37,1] <,0001[3]
≥ 20 bis < 50 mm	330/646 (51,1)	121/653 (18,5)	2,76 [2,31; 3,29] <,0001[2]	4,59 [3,57; 5,90] <,0001[3]	32,6 [27,7; 37,4] <,0001[3]
≥ 50 mm	154/289 (53,3)	41/265 (15,5)	3,44 [2,55; 4,66] <,0001[2]	6,23 [4,16; 9,35] <,0001[3]	37,8 [30,6; 45,0] <,0001[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,8105)					
0-3	218/427 (51,1)	70/418 (16,7)	3,05 [2,41; 3,85] <,0001[2]	5,19 [3,77; 7,14] <,0001[3]	34,3 [28,4; 40,2] <,0001[3]
4-9	260/549 (47,4)	93/542 (17,2)	2,76 [2,25; 3,39] <,0001[2]	4,34 [3,29; 5,74] <,0001[3]	30,2 [25,0; 35,4] <,0001[3]
≥ 10	170/307 (55,4)	57/304 (18,8)	2,95 [2,29; 3,81] <,0001[2]	5,38 [3,73; 7,75] <,0001[3]	36,6 [29,5; 43,7] <,0001[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,2234)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIA	46/113 (40,7)	21/114 (18,4)	2,21 [1,41; 3,45] 0,0005[2]	3,04 [1,66; 5,56] 0,0002[3]	22,3 [10,8; 33,8] 0,0002[3]
IIB	78/151 (51,7)	23/136 (16,9)	3,05 [2,04; 4,57] <,0001[2]	5,25 [3,03; 9,10] <,0001[3]	34,7 [24,6; 44,9] <,0001[3]
IIIA	239/495 (48,3)	79/488 (16,2)	2,98 [2,39; 3,72] <,0001[2]	4,83 [3,59; 6,51] <,0001[3]	32,1 [26,6; 37,6] <,0001[3]
IIIB	24/54 (44,4)	12/45 (26,7)	1,67 [0,94; 2,94] 0,0784[2]	2,20 [0,94; 5,15] 0,0671[3]	17,8 [-0,7; 36,3] 0,0671[3]
IIIC	260/468 (55,6)	85/479 (17,7)	3,13 [2,54; 3,86] <,0001[2]	5,79 [4,31; 7,80] <,0001[3]	37,8 [32,2; 43,5] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,8473)					
G1	48/91 (52,7)	18/93 (19,4)	2,73 [1,72; 4,31] <,0001[2]	4,65 [2,41; 8,99] <,0001[3]	33,4 [20,4; 46,4] <,0001[3]
G2	307/612 (50,2)	101/602 (16,8)	2,99 [2,46; 3,63] <,0001[2]	4,99 [3,83; 6,52] <,0001[3]	33,4 [28,4; 38,3] <,0001[3]
G3	266/527 (50,5)	88/506 (17,4)	2,90 [2,36; 3,57] <,0001[2]	4,84 [3,64; 6,45] <,0001[3]	33,1 [27,7; 38,5] <,0001[3]
GX	26/51 (51,0)	13/59 (22,0)	2,31 [1,33; 4,01] 0,0028[2]	3,68 [1,61; 8,40] 0,0016[3]	28,9 [11,6; 46,3] 0,0016[3]
Ethnizität (p-Wert des Interaktionsterms: 0,2863)					
Weiß	469/958 (49,0)	162/943 (17,2)	2,85 [2,44; 3,33] <,0001[2]	4,62 [3,74; 5,71] <,0001[3]	31,8 [27,8; 35,8] <,0001[3]
Asiatisch	143/250 (57,2)	40/242 (16,5)	3,46 [2,56; 4,68] <,0001[2]	6,75 [4,43; 10,29] <,0001[3]	40,7 [33,0; 48,4] <,0001[3]
Andere	32/62 (51,6)	15/64 (23,4)	2,20 [1,33; 3,65] 0,0021[2]	3,48 [1,62; 7,48] 0,0011[3]	28,2 [12,0; 44,4] 0,0011[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,6465)					
ECOG-PS 0	531/1070 (49,6)	171/1019 (16,8)	2,96 [2,55; 3,43] <,0001[2]	4,89 [3,99; 5,99] <,0001[3]	32,8 [29,1; 36,6] <,0001[3]
ECOG-PS 1	117/213 (54,9)	49/245 (20,0)	2,75 [2,08; 3,63] <,0001[2]	4,88 [3,22; 7,37] <,0001[3]	34,9 [26,6; 43,3] <,0001[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Datenschnitt: 15.07.2025 Safety-Population 1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test. Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.					

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Tabelle 119.2.2: Subgruppen - Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,2261)					
< 65 Jahre	149/918 (16,2)	6/936 (0,6)	25,32 [11,25; 56,98] <,0001[2]	30,03 [13,21; 68,30] <,0001[3]	15,6 [13,2; 18,0] <,0001[3]
≥ 65 Jahre	133/365 (36,4)	9/328 (2,7)	13,28 [6,87; 25,65] <,0001[2]	20,32 [10,13; 40,75] <,0001[3]	33,7 [28,5; 38,9] <,0001[3]
Region (p-Wert des Interaktionsterms: 0,9396)					
Nordamerika / Europa	181/678 (26,7)	12/649 (1,8)	14,44 [8,13; 25,64] <,0001[2]	19,33 [10,65; 35,08] <,0001[3]	24,8 [21,4; 28,3] <,0001[3]
Asien	48/203 (23,6)	0/201 (0,0)	96,05 [5,96; 1547,07] 0,0013[2]	125,69 [7,69; 2054,44] <,0001[3]	23,6 [17,8; 29,5] <,0001[3]
Andere	53/402 (13,2)	3/414 (0,7)	18,19 [5,73; 57,75] <,0001[2]	20,81 [6,45; 67,16] <,0001[3]	12,5 [9,1; 15,9] <,0001[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,4830)					
< 20 mm	68/331 (20,5)	2/334 (0,6)	34,31 [8,48; 138,83] <,0001[2]	42,92 [10,42; 176,75] <,0001[3]	19,9 [15,5; 24,4] <,0001[3]
≥ 20 bis < 50 mm	144/646 (22,3)	8/653 (1,2)	18,20 [9,00; 36,77] <,0001[2]	23,13 [11,24; 47,58] <,0001[3]	21,1 [17,7; 24,4] <,0001[3]
≥ 50 mm	68/289 (23,5)	5/265 (1,9)	12,47 [5,11; 30,45] <,0001[2]	16,00 [6,34; 40,38] <,0001[3]	21,6 [16,5; 26,8] <,0001[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,2487)					
IIA	25/113 (22,1)	1/114 (0,9)	25,22 [3,48; 183,00] 0,0014[2]	32,10 [4,27; 241,54] <,0001[3]	21,2 [13,4; 29,1] <,0001[3]
IIB	37/151 (24,5)	2/136 (1,5)	16,66 [4,09; 67,83] <,0001[2]	21,75 [5,13; 92,21] <,0001[3]	23,0 [15,9; 30,2] <,0001[3]
IIIA	117/495 (23,6)	2/488 (0,4)	57,67 [14,33; 232,03] <,0001[2]	75,21 [18,47; 306,28] <,0001[3]	23,2 [19,4; 27,0] <,0001[3]
IIIB	8/54 (14,8)	1/45 (2,2)	6,67 [0,87; 51,32] 0,0685[2]	7,65 [0,92; 63,72] 0,0374[4]	12,6 [2,2; 23,0] 0,0374[4]
IIIC	95/468 (20,3)	9/479 (1,9)	10,80 [5,52; 21,15] <,0001[2]	13,30 [6,63; 26,70] <,0001[3]	18,4 [14,6; 22,3] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,5765)					
G1	18/91 (19,8)	2/93 (2,2)	9,20 [2,20; 38,51] 0,0024[2]	11,22 [2,52; 49,93] 0,0001[3]	17,6 [8,9; 26,3] 0,0001[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
G2	137/612 (22,4)	5/602 (0,8)	26,95 [11,12; 65,32] <,0001[2]	34,44 [13,99; 84,74] <,0001[3]	21,6 [18,2; 24,9] <,0001[3]
G3	118/527 (22,4)	7/506 (1,4)	16,19 [7,63; 34,35] <,0001[2]	20,57 [9,49; 44,58] <,0001[3]	21,0 [17,3; 24,7] <,0001[3]
GX	9/51 (17,6)	1/59 (1,7)	10,41 [1,37; 79,41] 0,0238[2]	12,43 [1,52; 101,88] 0,0054[4]	16,0 [5,0; 26,9] 0,0054[4]
Ethnizität (p-Wert des Interaktionsterms: 0,8565)					
Weiß	214/958 (22,3)	14/943 (1,5)	15,05 [8,83; 25,64] <,0001[2]	19,09 [11,02; 33,06] <,0001[3]	20,9 [18,1; 23,6] <,0001[3]
Asiatisch	55/250 (22,0)	0/242 (0,0)	107,46 [6,68; 1729,89] 0,0010[2]	137,69 [8,45; 2243,07] <,0001[3]	22,0 [16,9; 27,1] <,0001[3]
Andere	8/62 (12,9)	1/64 (1,6)	8,26 [1,06; 64,10] 0,0435[2]	9,33 [1,13; 77,01] 0,0160[4]	11,3 [2,5; 20,2] 0,0160[4]
ECOG-PS (p-Wert des Interaktionsterms: 0,0515)					
ECOG-PS 0	224/1070 (20,9)	8/1019 (0,8)	26,67 [13,24; 53,70] <,0001[2]	33,46 [16,43; 68,13] <,0001[3]	20,1 [17,7; 22,6] <,0001[3]
ECOG-PS 1	58/213 (27,2)	7/245 (2,9)	9,53 [4,45; 20,43] <,0001[2]	12,72 [5,66; 28,60] <,0001[3]	24,4 [18,0; 30,7] <,0001[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Anhang 4-G2.4.3: Unerwünschte Ereignisse von speziellem Interesse - Subgruppenanalysen nicht-interagierender Subgruppen (Prämenopausale Patientinnen)

Tabelle 121.1.2: Subgruppen - Unerwünschtes Ereignis: PT Neutropenie und erniedrigte Neutrophilenzahl (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,0976)					
Neoadjuvante Chemotherapie	129/314 (41,1)	32/306 (10,5)	3,93 [2,76; 5,60] <,0001[2]	5,97 [3,89; 9,18] <,0001[3]	30,6 [24,2; 37,1] <,0001[3]
Adjuvante Chemotherapie	229/452 (50,7)	31/416 (7,5)	6,80 [4,79; 9,65] <,0001[2]	12,75 [8,47; 19,21] <,0001[3]	43,2 [38,0; 48,5] <,0001[3]
Keine Chemotherapie	4/10 (40,0)	0/7 (0,0)	6,55 [0,41; 105,10] 0,1847[2]	10,38 [0,47; 231,63] 0,1029[4]	40,0 [9,6; 70,4] 0,1029[4]
Region (p-Wert des Interaktionsterms: 0,4824)					
Nordamerika / Europa	117/347 (33,7)	17/309 (5,5)	6,13 [3,77; 9,95] <,0001[2]	8,74 [5,11; 14,95] <,0001[3]	28,2 [22,6; 33,8] <,0001[3]
Asien	157/239 (65,7)	32/226 (14,2)	4,64 [3,32; 6,48] <,0001[2]	11,61 [7,33; 18,38] <,0001[3]	51,5 [44,0; 59,1] <,0001[3]
Andere	88/190 (46,3)	14/194 (7,2)	6,42 [3,79; 10,87] <,0001[2]	11,09 [6,00; 20,50] <,0001[3]	39,1 [31,1; 47,1] <,0001[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,5143)					
< 20 mm	94/204 (46,1)	17/189 (9,0)	5,12 [3,18; 8,26] <,0001[2]	8,65 [4,89; 15,28] <,0001[3]	37,1 [29,1; 45,0] <,0001[3]
≥ 20 bis < 50 mm	167/360 (46,4)	33/346 (9,5)	4,86 [3,45; 6,85] <,0001[2]	8,21 [5,42; 12,42] <,0001[3]	36,9 [30,8; 42,9] <,0001[3]
≥ 50 mm	90/194 (46,4)	12/185 (6,5)	7,15 [4,05; 12,62] <,0001[2]	12,48 [6,52; 23,89] <,0001[3]	39,9 [32,0; 47,8] <,0001[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,3662)					
0-3	115/269 (42,8)	16/269 (5,9)	7,19 [4,38; 11,79] <,0001[2]	11,81 [6,74; 20,67] <,0001[3]	36,8 [30,3; 43,4] <,0001[3]
4-9	168/353 (47,6)	33/326 (10,1)	4,70 [3,34; 6,62] <,0001[2]	8,06 [5,32; 12,22] <,0001[3]	37,5 [31,3; 43,6] <,0001[3]
≥ 10	79/154 (51,3)	14/134 (10,4)	4,91 [2,92; 8,25] <,0001[2]	9,03 [4,77; 17,08] <,0001[3]	40,9 [31,4; 50,3] <,0001[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,8915)					
IIA	30/79 (38,0)	6/77 (7,8)	4,87 [2,15; 11,05] 0,0001[2]	7,24 [2,80; 18,72] <,0001[3]	30,2 [17,9; 42,4] <,0001[3]
IIB	32/73 (43,8)	5/93 (5,4)	8,15 [3,34; 19,88] <,0001[2]	13,74 [4,99; 37,82] <,0001[3]	38,5 [26,2; 50,7] <,0001[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIA	165/345 (47,8)	27/294 (9,2)	5,21 [3,58; 7,58] <,0001[2]	9,06 [5,79; 14,20] <,0001[3]	38,6 [32,4; 44,9] <,0001[3]
IIIB	8/22 (36,4)	1/19 (5,3)	6,91 [0,95; 50,35] 0,0565[2]	10,29 [1,15; 92,19] 0,0238[4]	31,1 [8,6; 53,6] 0,0238[4]
IIIC	123/253 (48,6)	24/245 (9,8)	4,96 [3,32; 7,41] <,0001[2]	8,71 [5,35; 14,19] <,0001[3]	38,8 [31,6; 46,0] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,5175)					
G1	27/63 (42,9)	2/52 (3,8)	11,14 [2,78; 44,67] 0,0007[2]	18,75 [4,19; 83,93] <,0001[3]	39,0 [25,7; 52,3] <,0001[3]
G2	158/349 (45,3)	26/323 (8,0)	5,62 [3,82; 8,28] <,0001[2]	9,45 [6,01; 14,86] <,0001[3]	37,2 [31,2; 43,2] <,0001[3]
G3	146/317 (46,1)	27/312 (8,7)	5,32 [3,64; 7,78] <,0001[2]	9,01 [5,73; 14,17] <,0001[3]	37,4 [31,1; 43,7] <,0001[3]
GX	28/44 (63,6)	7/40 (17,5)	3,64 [1,79; 7,39] 0,0004[2]	8,25 [2,97; 22,90] <,0001[3]	46,1 [27,7; 64,6] <,0001[3]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9890)					
Negativ	33/67 (49,3)	6/62 (9,7)	5,09 [2,29; 11,31] <,0001[2]	9,06 [3,44; 23,86] <,0001[3]	39,6 [25,5; 53,6] <,0001[3]
Positiv	318/678 (46,9)	56/647 (8,7)	5,42 [4,17; 7,05] <,0001[2]	9,32 [6,82; 12,75] <,0001[3]	38,2 [33,9; 42,6] <,0001[3]
Unbekannt	4/8 (50,0)	0/8 (0,0)	9,00 [0,56; 143,89] 0,1203[2]	17,00 [0,74; 391,68] 0,0769[4]	50,0 [15,4; 84,6] 0,0769[4]
Ethnizität (p-Wert des Interaktionsterms: 0,3894)					
Weiß	186/461 (40,3)	28/440 (6,4)	6,34 [4,36; 9,23] <,0001[2]	9,95 [6,50; 15,23] <,0001[3]	34,0 [29,0; 39,0] <,0001[3]
Asiatisch	160/273 (58,6)	32/243 (13,2)	4,45 [3,17; 6,24] <,0001[2]	9,34 [5,99; 14,54] <,0001[3]	45,4 [38,2; 52,7] <,0001[3]
Andere	14/30 (46,7)	3/34 (8,8)	5,29 [1,68; 16,64] 0,0044[2]	9,04 [2,26; 36,13] 0,0006[3]	37,8 [17,6; 58,1] 0,0006[3]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,1934)					
Tamoxifen	238/553 (43,0)	38/534 (7,1)	6,05 [4,39; 8,34] <,0001[2]	9,86 [6,81; 14,28] <,0001[3]	35,9 [31,3; 40,6] <,0001[3]
Aromatase-Inhibitor	124/223 (55,6)	25/195 (12,8)	4,34 [2,95; 6,37] <,0001[2]	8,52 [5,19; 13,99] <,0001[3]	42,8 [34,8; 50,8] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,3619)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	326/685 (47,6)	55/649 (8,5)	5,62 [4,31; 7,32] <,0001[2]	9,81 [7,16; 13,43] <,0001[3]	39,1 [34,8; 43,4] <,0001[3]
ECOG-PS 1	36/91 (39,6)	8/80 (10,0)	3,96 [1,96; 8,00] 0,0001[2]	5,89 [2,54; 13,68] <,0001[3]	29,6 [17,6; 41,6] <,0001[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; PT: Preferred Term; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 122.1.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3: PT Neutropenie und erniedrigte Neutrophilenzahl aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,2435)					
Neoadjuvante Chemotherapie	64/314 (20,4)	8/306 (2,6)	7,80 [3,80; 15,98] <,0001[2]	9,54 [4,49; 20,27] <,0001[3]	17,8 [13,0; 22,6] <,0001[3]
Adjuvante Chemotherapie	81/452 (17,9)	3/416 (0,7)	24,85 [7,91; 78,06] <,0001[2]	30,06 [9,41; 95,96] <,0001[3]	17,2 [13,6; 20,8] <,0001[3]
Keine Chemotherapie	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (p-Wert des Interaktionsterms: 0,5133)					
Nordamerika / Europa	51/347 (14,7)	5/309 (1,6)	9,08 [3,67; 22,47] <,0001[2]	10,48 [4,12; 26,61] <,0001[3]	13,1 [9,1; 17,1] <,0001[3]
Asien	63/239 (26,4)	5/226 (2,2)	11,91 [4,88; 29,08] <,0001[2]	15,82 [6,23; 40,18] <,0001[3]	24,1 [18,2; 30,1] <,0001[3]
Andere	32/190 (16,8)	1/194 (0,5)	32,67 [4,51; 236,71] 0,0006[2]	39,09 [5,28; 289,24] <,0001[3]	16,3 [10,9; 21,7] <,0001[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,1983)					
< 20 mm	38/204 (18,6)	5/189 (2,6)	7,04 [2,83; 17,51] <,0001[2]	8,42 [3,24; 21,91] <,0001[3]	16,0 [10,2; 21,8] <,0001[3]
≥ 20 bis < 50 mm	67/360 (18,6)	2/346 (0,6)	32,20 [7,95; 130,39] <,0001[2]	39,33 [9,55; 161,91] <,0001[3]	18,0 [13,9; 22,1] <,0001[3]
≥ 50 mm	40/194 (20,6)	4/185 (2,2)	9,54 [3,48; 26,13] <,0001[2]	11,75 [4,11; 33,59] <,0001[3]	18,5 [12,4; 24,5] <,0001[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,4216)					
0-3	53/269 (19,7)	2/269 (0,7)	26,50 [6,52; 107,64] <,0001[2]	32,76 [7,89; 135,95] <,0001[3]	19,0 [14,1; 23,8] <,0001[3]
4-9	60/353 (17,0)	6/326 (1,8)	9,24 [4,04; 21,09] <,0001[2]	10,92 [4,65; 25,66] <,0001[3]	15,2 [11,0; 19,3] <,0001[3]
≥ 10	33/154 (21,4)	3/134 (2,2)	9,57 [3,00; 30,50] 0,0001[2]	11,91 [3,56; 39,84] <,0001[3]	19,2 [12,2; 26,1] <,0001[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,9490)					
IIA	12/79 (15,2)	2/77 (2,6)	5,85 [1,35; 25,27] 0,0180[2]	6,72 [1,45; 31,10] 0,0059[3]	12,6 [3,9; 21,3] 0,0059[3]
IIB	16/73 (21,9)	0/93 (0,0)	41,92 [2,56; 687,25] 0,0088[2]	53,66 [3,16; 911,68] <,0001[3]	21,9 [12,4; 31,4] <,0001[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIA	59/345 (17,1)	4/294 (1,4)	12,57 [4,62; 34,19] <,0001[2]	14,96 [5,36; 41,72] <,0001[3]	15,7 [11,6; 19,9] <,0001[3]
IIIB	6/22 (27,3)	0/19 (0,0)	11,30 [0,68; 188,39] 0,0911[2]	15,36 [0,80; 293,60] 0,0226[4]	27,3 [8,7; 45,9] 0,0226[4]
IIIC	52/253 (20,6)	5/245 (2,0)	10,07 [4,09; 24,79] <,0001[2]	12,42 [4,87; 31,68] <,0001[3]	18,5 [13,2; 23,8] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,6791)					
G1	17/63 (27,0)	0/52 (0,0)	28,98 [1,78; 470,70] 0,0179[2]	39,52 [2,31; 675,47] <,0001[3]	27,0 [16,0; 37,9] <,0001[3]
G2	66/349 (18,9)	7/323 (2,2)	8,73 [4,06; 18,74] <,0001[2]	10,53 [4,75; 23,32] <,0001[3]	16,7 [12,3; 21,1] <,0001[3]
G3	56/317 (17,7)	3/312 (1,0)	18,37 [5,81; 58,08] <,0001[2]	22,10 [6,84; 71,43] <,0001[3]	16,7 [12,4; 21,0] <,0001[3]
GX	6/44 (13,6)	1/40 (2,5)	5,45 [0,69; 43,37] 0,1088[2]	6,16 [0,71; 53,59] 0,1122[4]	11,1 [-0,1; 22,4] 0,1122[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9986)					
Negativ	14/67 (20,9)	1/62 (1,6)	12,96 [1,75; 95,64] 0,0120[2]	16,11 [2,05; 126,66] 0,0006[3]	19,3 [9,1; 29,5] 0,0006[3]
Positiv	129/678 (19,0)	10/647 (1,5)	12,31 [6,53; 23,21] <,0001[2]	14,97 [7,79; 28,77] <,0001[3]	17,5 [14,4; 20,6] <,0001[3]
Unbekannt	2/8 (25,0)	0/8 (0,0)	5,00 [0,28; 90,18] 0,2754[2]	6,54 [0,27; 160,97] 0,4667[4]	25,0 [-5,0; 55,0] 0,4667[4]
Ethnizität (p-Wert des Interaktionsterms: 0,8740)					
Weiß	73/461 (15,8)	5/440 (1,1)	13,93 [5,68; 34,16] <,0001[2]	16,37 [6,55; 40,92] <,0001[3]	14,7 [11,2; 18,2] <,0001[3]
Asiatisch	65/273 (23,8)	5/243 (2,1)	11,57 [4,74; 28,26] <,0001[2]	14,88 [5,88; 37,64] <,0001[3]	21,8 [16,4; 27,1] <,0001[3]
Andere	7/30 (23,3)	1/34 (2,9)	7,93 [1,03; 60,83] 0,0463[2]	10,04 [1,16; 87,25] 0,0211[4]	20,4 [4,2; 36,6] 0,0211[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,1680)					
Tamoxifen	99/553 (17,9)	10/534 (1,9)	9,56 [5,04; 18,12] <,0001[2]	11,43 [5,89; 22,16] <,0001[3]	16,0 [12,6; 19,4] <,0001[3]
Aromatase-Inhibitor	47/223 (21,1)	1/195 (0,5)	41,10 [5,72; 295,11] 0,0002[2]	51,81 [7,07; 379,44] <,0001[3]	20,6 [15,1; 26,0] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,3175)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	132/685 (19,3)	9/649 (1,4)	13,90 [7,13; 27,06] <,0001[2]	16,97 [8,56; 33,66] <,0001[3]	17,9 [14,8; 21,0] <,0001[3]
ECOG-PS 1	14/91 (15,4)	2/80 (2,5)	6,15 [1,44; 26,26] 0,0141[2]	7,09 [1,56; 32,25] 0,0039[3]	12,9 [4,7; 21,0] 0,0039[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; PT: Preferred Term; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 125.1.2: Subgruppen - Unerwünschtes Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,3097)					
Neoadjuvante Chemotherapie	164/314 (52,2)	133/306 (43,5)	1,20 [1,02; 1,42] 0,0300[2]	1,42 [1,04; 1,95] 0,0289[3]	8,8 [0,9; 16,6] 0,0289[3]
Adjuvante Chemotherapie	255/452 (56,4)	168/416 (40,4)	1,40 [1,21; 1,61] <,0001[2]	1,91 [1,46; 2,50] <,0001[3]	16,0 [9,5; 22,6] <,0001[3]
Keine Chemotherapie	6/10 (60,0)	2/7 (28,6)	2,10 [0,59; 7,52] 0,2544[2]	3,75 [0,47; 29,75] 0,3348[4]	31,4 [-13,8; 76,6] 0,3348[4]
Region (p-Wert des Interaktionsterms: 0,7806)					
Nordamerika / Europa	190/347 (54,8)	132/309 (42,7)	1,28 [1,09; 1,51] 0,0025[2]	1,62 [1,19; 2,21] 0,0021[3]	12,0 [4,4; 19,6] 0,0021[3]
Asien	146/239 (61,1)	107/226 (47,3)	1,29 [1,09; 1,53] 0,0034[2]	1,75 [1,21; 2,52] 0,0029[3]	13,7 [4,8; 22,7] 0,0029[3]
Andere	89/190 (46,8)	64/194 (33,0)	1,42 [1,10; 1,83] 0,0063[2]	1,79 [1,18; 2,71] 0,0056[3]	13,9 [4,2; 23,6] 0,0056[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,2848)					
< 20 mm	117/204 (57,4)	77/189 (40,7)	1,41 [1,14; 1,73] 0,0013[2]	1,96 [1,31; 2,92] 0,0010[3]	16,6 [6,9; 26,4] 0,0010[3]
≥ 20 bis < 50 mm	187/360 (51,9)	149/346 (43,1)	1,21 [1,03; 1,41] 0,0190[2]	1,43 [1,06; 1,92] 0,0182[3]	8,9 [1,5; 16,2] 0,0182[3]
≥ 50 mm	112/194 (57,7)	73/185 (39,5)	1,46 [1,18; 1,81] 0,0005[2]	2,10 [1,39; 3,16] 0,0004[3]	18,3 [8,4; 28,2] 0,0004[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7057)					
0-3	148/269 (55,0)	113/269 (42,0)	1,31 [1,10; 1,56] 0,0028[2]	1,69 [1,20; 2,37] 0,0025[3]	13,0 [4,6; 21,4] 0,0025[3]
4-9	186/353 (52,7)	135/326 (41,4)	1,27 [1,08; 1,50] 0,0037[2]	1,58 [1,16; 2,13] 0,0033[3]	11,3 [3,8; 18,7] 0,0033[3]
≥ 10	91/154 (59,1)	55/134 (41,0)	1,44 [1,13; 1,83] 0,0031[2]	2,07 [1,30; 3,32] 0,0022[3]	18,0 [6,7; 29,4] 0,0022[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,7993)					
IIA	45/79 (57,0)	28/77 (36,4)	1,57 [1,10; 2,23] 0,0125[2]	2,32 [1,22; 4,41] 0,0099[3]	20,6 [5,3; 35,9] 0,0099[3]
IIB	39/73 (53,4)	43/93 (46,2)	1,16 [0,85; 1,57] 0,3554[2]	1,33 [0,72; 2,47] 0,3579[3]	7,2 [-8,1; 22,5] 0,3579[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIA	182/345 (52,8)	117/294 (39,8)	1,33 [1,12; 1,58] 0,0014[2]	1,69 [1,23; 2,31] 0,0011[3]	13,0 [5,3; 20,6] 0,0011[3]
IIIB	12/22 (54,5)	8/19 (42,1)	1,30 [0,68; 2,48] 0,4356[2]	1,65 [0,48; 5,69] 0,4268[3]	12,4 [-18,0; 42,9] 0,4268[3]
IIIC	144/253 (56,9)	107/245 (43,7)	1,30 [1,09; 1,56] 0,0036[2]	1,70 [1,20; 2,43] 0,0031[3]	13,2 [4,5; 22,0] 0,0031[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,5439)					
G1	34/63 (54,0)	17/52 (32,7)	1,65 [1,05; 2,59] 0,0297[2]	2,41 [1,13; 5,17] 0,0223[3]	21,3 [3,6; 39,0] 0,0223[3]
G2	189/349 (54,2)	131/323 (40,6)	1,34 [1,13; 1,57] 0,0005[2]	1,73 [1,27; 2,35] 0,0004[3]	13,6 [6,1; 21,1] 0,0004[3]
G3	174/317 (54,9)	131/312 (42,0)	1,31 [1,11; 1,54] 0,0014[2]	1,68 [1,23; 2,30] 0,0012[3]	12,9 [5,2; 20,6] 0,0012[3]
GX	26/44 (59,1)	22/40 (55,0)	1,07 [0,74; 1,56] 0,7061[2]	1,18 [0,50; 2,81] 0,7051[3]	4,1 [-17,1; 25,3] 0,7051[3]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,0634)					
Negativ	30/67 (44,8)	30/62 (48,4)	0,93 [0,64; 1,34] 0,6811[2]	0,86 [0,43; 1,73] 0,6812[3]	-3,6 [-20,8; 13,6] 0,6812[3]
Positiv	377/678 (55,6)	259/647 (40,0)	1,39 [1,24; 1,56] <,0001[2]	1,88 [1,51; 2,33] <,0001[3]	15,6 [10,3; 20,9] <,0001[3]
Unbekannt	4/8 (50,0)	5/8 (62,5)	0,80 [0,33; 1,92] 0,6178[2]	0,60 [0,08; 4,40] 1,0000[4]	-12,5 [-60,7; 35,7] 1,0000[4]
Ethnizität (p-Wert des Interaktionsterms: 0,6211)					
Weiß	243/461 (52,7)	172/440 (39,1)	1,35 [1,17; 1,56] <,0001[2]	1,74 [1,33; 2,26] <,0001[3]	13,6 [7,2; 20,1] <,0001[3]
Asiatisch	159/273 (58,2)	109/243 (44,9)	1,30 [1,09; 1,54] 0,0029[2]	1,71 [1,21; 2,43] 0,0024[3]	13,4 [4,8; 21,9] 0,0024[3]
Andere	17/30 (56,7)	18/34 (52,9)	1,07 [0,69; 1,67] 0,7647[2]	1,16 [0,43; 3,12] 0,7651[3]	3,7 [-20,7; 28,1] 0,7651[3]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,9299)					
Tamoxifen	302/553 (54,6)	222/534 (41,6)	1,31 [1,16; 1,49] <,0001[2]	1,69 [1,33; 2,15] <,0001[3]	13,0 [7,1; 18,9] <,0001[3]
Aromatase-Inhibitor	123/223 (55,2)	81/195 (41,5)	1,33 [1,08; 1,63] 0,0065[2]	1,73 [1,17; 2,55] 0,0055[3]	13,6 [4,1; 23,1] 0,0055[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,0635)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	385/685 (56,2)	267/649 (41,1)	1,37 [1,22; 1,53] <,0001[2]	1,84 [1,48; 2,28] <,0001[3]	15,1 [9,8; 20,4] <,0001[3]
ECOG-PS 1	40/91 (44,0)	36/80 (45,0)	0,98 [0,70; 1,37] 0,8909[2]	0,96 [0,52; 1,75] 0,8910[3]	-1,0 [-16,0; 13,9] 0,8910[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.

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Tabelle 126.1.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Region (p-Wert des Interaktionsterms: 0,3145)					
Nordamerika / Europa	23/347 (6,6)	8/309 (2,6)	2,56 [1,16; 5,64] 0,0196[2]	2,67 [1,18; 6,06] 0,0149[3]	4,0 [0,9; 7,2] 0,0149[3]
Asien	6/239 (2,5)	6/226 (2,7)	0,95 [0,31; 2,89] 0,9218[2]	0,94 [0,30; 2,97] 0,9218[3]	-0,1 [-3,0; 2,7] 0,9218[3]
Andere	8/190 (4,2)	3/194 (1,5)	2,72 [0,73; 10,11] 0,1345[2]	2,80 [0,73; 10,71] 0,1176[3]	2,7 [-0,7; 6,0] 0,1176[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3893)					
< 20 mm	7/204 (3,4)	6/189 (3,2)	1,08 [0,37; 3,16] 0,8870[2]	1,08 [0,36; 3,28] 0,8869[3]	0,3 [-3,3; 3,8] 0,8869[3]
≥ 20 bis < 50 mm	18/360 (5,0)	6/346 (1,7)	2,88 [1,16; 7,18] 0,0229[2]	2,98 [1,17; 7,60] 0,0167[3]	3,3 [0,6; 5,9] 0,0167[3]
≥ 50 mm	11/194 (5,7)	5/185 (2,7)	2,10 [0,74; 5,92] 0,1617[2]	2,16 [0,74; 6,35] 0,1510[3]	3,0 [-1,0; 7,0] 0,1510[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,4249)					
0-3	10/269 (3,7)	7/269 (2,6)	1,43 [0,55; 3,70] 0,4623[2]	1,45 [0,54; 3,85] 0,4597[3]	1,1 [-1,8; 4,1] 0,4597[3]
4-9	18/353 (5,1)	5/326 (1,5)	3,32 [1,25; 8,85] 0,0162[2]	3,45 [1,27; 9,40] 0,0103[3]	3,6 [0,9; 6,2] 0,0103[3]
≥ 10	9/154 (5,8)	5/134 (3,7)	1,57 [0,54; 4,56] 0,4105[2]	1,60 [0,52; 4,90] 0,4056[3]	2,1 [-2,8; 7,0] 0,4056[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,2541)					
IIA	1/79 (1,3)	4/77 (5,2)	0,24 [0,03; 2,13] 0,2019[2]	0,23 [0,03; 2,14] 0,2068[4]	-3,9 [-9,5; 1,6] 0,2068[4]
IIB	2/73 (2,7)	0/93 (0,0)	6,35 [0,31; 130,28] 0,2304[2]	6,54 [0,31; 138,33] 0,1919[4]	2,7 [-1,0; 6,5] 0,1919[4]
IIIA	19/345 (5,5)	4/294 (1,4)	4,05 [1,39; 11,76] 0,0102[2]	4,23 [1,42; 12,56] 0,0050[3]	4,1 [1,4; 6,9] 0,0050[3]
IIIB	0/22 (0,0)	1/19 (5,3)	0,29 [0,01; 6,72] 0,4401[2]	0,27 [0,01; 7,13] 0,4634[4]	-5,3 [-15,3; 4,8] 0,4634[4]
IIIC	15/253 (5,9)	8/245 (3,3)	1,82 [0,78; 4,21] 0,1639[2]	1,87 [0,78; 4,49] 0,1568[3]	2,7 [-1,0; 6,3] 0,1568[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,6332)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
G1	4/63 (6,3)	1/52 (1,9)	3,30 [0,38; 28,64] 0,2785[2]	3,46 [0,37; 31,93] 0,3757[4]	4,4 [-2,7; 11,5] 0,3757[4]
G2	19/349 (5,4)	7/323 (2,2)	2,51 [1,07; 5,90] 0,0344[2]	2,60 [1,08; 6,27] 0,0278[3]	3,3 [0,4; 6,1] 0,0278[3]
G3	11/317 (3,5)	9/312 (2,9)	1,20 [0,51; 2,86] 0,6762[2]	1,21 [0,49; 2,96] 0,6757[3]	0,6 [-2,2; 3,3] 0,6757[3]
GX	3/44 (6,8)	0/40 (0,0)	6,38 [0,34; 119,78] 0,2156[2]	6,83 [0,34; 136,48] 0,2427[4]	6,8 [-0,6; 14,3] 0,2427[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5496)					
Negativ	3/67 (4,5)	3/62 (4,8)	0,93 [0,19; 4,42] 0,9225[2]	0,92 [0,18; 4,75] 1,0000[4]	-0,4 [-7,6; 6,9] 1,0000[4]
Positiv	30/678 (4,4)	12/647 (1,9)	2,39 [1,23; 4,62] 0,0099[2]	2,45 [1,24; 4,83] 0,0076[3]	2,6 [0,7; 4,4] 0,0076[3]
Unbekannt	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Ethnizität (p-Wert des Interaktionsterms: 0,2647)					
Weiß	28/461 (6,1)	10/440 (2,3)	2,67 [1,31; 5,44] 0,0067[2]	2,78 [1,33; 5,79] 0,0045[3]	3,8 [1,2; 6,4] 0,0045[3]
Asiatisch	6/273 (2,2)	6/243 (2,5)	0,89 [0,29; 2,72] 0,8383[2]	0,89 [0,28; 2,79] 0,8383[3]	-0,3 [-2,9; 2,3] 0,8383[3]
Andere	2/30 (6,7)	1/34 (2,9)	2,27 [0,22; 23,76] 0,4949[2]	2,36 [0,20; 27,39] 0,5961[4]	3,7 [-6,9; 14,3] 0,5961[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,9802)					
Tamoxifen	21/553 (3,8)	10/534 (1,9)	2,03 [0,96; 4,27] 0,0624[2]	2,07 [0,96; 4,43] 0,0567[3]	1,9 [-0,0; 3,9] 0,0567[3]
Aromatase-Inhibitor	16/223 (7,2)	7/195 (3,6)	2,00 [0,84; 4,76] 0,1175[2]	2,08 [0,84; 5,16] 0,1088[3]	3,6 [-0,7; 7,9] 0,1088[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,3725)					
ECOG-PS 0	35/685 (5,1)	15/649 (2,3)	2,21 [1,22; 4,01] 0,0090[2]	2,28 [1,23; 4,21] 0,0072[3]	2,8 [0,8; 4,8] 0,0072[3]
ECOG-PS 1	2/91 (2,2)	2/80 (2,5)	0,88 [0,13; 6,10] 0,8963[2]	0,88 [0,12; 6,37] 1,0000[4]	-0,3 [-4,9; 4,3] 1,0000[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Datenschnitt: 15.07.2025 Safety-Population 1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test. Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.					

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Tabelle 127.1.2: Subgruppen - Schwerwiegendes unerwünschtes Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Region (p-Wert des Interaktionsterms: 0,6729)					
Nordamerika / Europa	17/347 (4,9)	11/309 (3,6)	1,38 [0,65; 2,89] 0,3994[2]	1,40 [0,64; 3,03] 0,3970[3]	1,3 [-1,7; 4,4] 0,3970[3]
Asien	9/239 (3,8)	5/226 (2,2)	1,70 [0,58; 5,00] 0,3335[2]	1,73 [0,57; 5,24] 0,3272[3]	1,6 [-1,5; 4,6] 0,3272[3]
Andere	8/190 (4,2)	3/194 (1,5)	2,72 [0,73; 10,11] 0,1345[2]	2,80 [0,73; 10,71] 0,1176[3]	2,7 [-0,7; 6,0] 0,1176[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,1048)					
< 20 mm	4/204 (2,0)	7/189 (3,7)	0,53 [0,16; 1,78] 0,3039[2]	0,52 [0,15; 1,81] 0,2953[3]	-1,7 [-5,0; 1,6] 0,2953[3]
≥ 20 bis < 50 mm	18/360 (5,0)	9/346 (2,6)	1,92 [0,88; 4,22] 0,1034[2]	1,97 [0,87; 4,45] 0,0966[3]	2,4 [-0,4; 5,2] 0,0966[3]
≥ 50 mm	10/194 (5,2)	3/185 (1,6)	3,18 [0,89; 11,37] 0,0753[2]	3,30 [0,89; 12,18] 0,0589[3]	3,5 [-0,1; 7,1] 0,0589[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,8011)					
0-3	12/269 (4,5)	8/269 (3,0)	1,50 [0,62; 3,61] 0,3657[2]	1,52 [0,61; 3,79] 0,3620[3]	1,5 [-1,7; 4,7] 0,3620[3]
4-9	14/353 (4,0)	6/326 (1,8)	2,15 [0,84; 5,54] 0,1111[2]	2,20 [0,84; 5,80] 0,1017[3]	2,1 [-0,4; 4,6] 0,1017[3]
≥ 10	8/154 (5,2)	5/134 (3,7)	1,39 [0,47; 4,15] 0,5530[2]	1,41 [0,45; 4,43] 0,5507[3]	1,5 [-3,3; 6,2] 0,5507[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,2518)					
IIA	1/79 (1,3)	4/77 (5,2)	0,24 [0,03; 2,13] 0,2019[2]	0,23 [0,03; 2,14] 0,2068[4]	-3,9 [-9,5; 1,6] 0,2068[4]
IIB	3/73 (4,1)	1/93 (1,1)	3,82 [0,41; 35,98] 0,2412[2]	3,94 [0,40; 38,72] 0,3210[4]	3,0 [-2,0; 8,0] 0,3210[4]
IIIA	16/345 (4,6)	4/294 (1,4)	3,41 [1,15; 10,08] 0,0267[2]	3,53 [1,17; 10,67] 0,0177[3]	3,3 [0,7; 5,9] 0,0177[3]
IIIB	0/22 (0,0)	1/19 (5,3)	0,29 [0,01; 6,72] 0,4401[2]	0,27 [0,01; 7,13] 0,4634[4]	-5,3 [-15,3; 4,8] 0,4634[4]
IIIC	13/253 (5,1)	9/245 (3,7)	1,40 [0,61; 3,21] 0,4289[2]	1,42 [0,60; 3,39] 0,4264[3]	1,5 [-2,1; 5,1] 0,4264[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,9418)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
G1	2/63 (3,2)	1/52 (1,9)	1,65 [0,15; 17,70] 0,6788[2]	1,67 [0,15; 18,98] 1,0000[4]	1,3 [-4,5; 7,0] 1,0000[4]
G2	16/349 (4,6)	8/323 (2,5)	1,85 [0,80; 4,27] 0,1484[2]	1,89 [0,80; 4,48] 0,1413[3]	2,1 [-0,7; 4,9] 0,1413[3]
G3	13/317 (4,1)	10/312 (3,2)	1,28 [0,57; 2,87] 0,5507[2]	1,29 [0,56; 2,99] 0,5495[3]	0,9 [-2,0; 3,8] 0,5495[3]
GX	3/44 (6,8)	0/40 (0,0)	6,38 [0,34; 119,78] 0,2156[2]	6,83 [0,34; 136,48] 0,2427[4]	6,8 [-0,6; 14,3] 0,2427[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6814)					
Negativ	4/67 (6,0)	5/62 (8,1)	0,74 [0,21; 2,63] 0,6422[2]	0,72 [0,19; 2,83] 0,7371[4]	-2,1 [-10,9; 6,7] 0,7371[4]
Positiv	27/678 (4,0)	12/647 (1,9)	2,15 [1,10; 4,20] 0,0257[2]	2,19 [1,10; 4,37] 0,0220[3]	2,1 [0,3; 3,9] 0,0220[3]
Unbekannt	0/8 (0,0)	0/8 (0,0)	NB	NB	NB
Ethnizität (p-Wert des Interaktionsterms: 0,6406)					
Weiß	23/461 (5,0)	12/440 (2,7)	1,83 [0,92; 3,63] 0,0843[2]	1,87 [0,92; 3,81] 0,0790[3]	2,3 [-0,2; 4,8] 0,0790[3]
Asiatisch	10/273 (3,7)	5/243 (2,1)	1,78 [0,62; 5,14] 0,2860[2]	1,81 [0,61; 5,37] 0,2786[3]	1,6 [-1,2; 4,5] 0,2786[3]
Andere	1/30 (3,3)	2/34 (5,9)	0,57 [0,05; 5,94] 0,6357[2]	0,55 [0,05; 6,41] 1,0000[4]	-2,5 [-12,7; 7,6] 1,0000[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,6827)					
Tamoxifen	19/553 (3,4)	10/534 (1,9)	1,83 [0,86; 3,91] 0,1158[2]	1,86 [0,86; 4,05] 0,1099[3]	1,6 [-0,3; 3,5] 0,1099[3]
Aromatase-Inhibitor	15/223 (6,7)	9/195 (4,6)	1,46 [0,65; 3,26] 0,3584[2]	1,49 [0,64; 3,49] 0,3547[3]	2,1 [-2,3; 6,5] 0,3547[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,9556)					
ECOG-PS 0	30/685 (4,4)	17/649 (2,6)	1,67 [0,93; 3,00] 0,0852[2]	1,70 [0,93; 3,12] 0,0814[3]	1,8 [-0,2; 3,7] 0,0814[3]
ECOG-PS 1	4/91 (4,4)	2/80 (2,5)	1,76 [0,33; 9,35] 0,5079[2]	1,79 [0,32; 10,06] 0,6859[4]	1,9 [-3,5; 7,3] 0,6859[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Datenschnitt: 15.07.2025 Safety-Population 1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test. Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.					

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Tabelle 129.1.2: Subgruppen - Unerwünschtes Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9299)					
Neoadjuvante Chemotherapie	260/314 (82,8)	17/306 (5,6)	14,90 [9,36; 23,72] <,0001[2]	81,85 [46,28; 144,77] <,0001[3]	77,2 [72,3; 82,1] <,0001[3]
Adjuvante Chemotherapie	375/452 (83,0)	26/416 (6,3)	13,27 [9,13; 19,30] <,0001[2]	73,05 [45,81; 116,49] <,0001[3]	76,7 [72,5; 80,9] <,0001[3]
Keine Chemotherapie	7/10 (70,0)	0/7 (0,0)	10,91 [0,72; 164,61] 0,0844[2]	32,14 [1,40; 736,17] 0,0098[4]	70,0 [41,6; 98,4] 0,0098[4]
Region (p-Wert des Interaktionsterms: 0,0732)					
Nordamerika / Europa	295/347 (85,0)	26/309 (8,4)	10,10 [6,98; 14,63] <,0001[2]	61,75 [37,52; 101,63] <,0001[3]	76,6 [71,7; 81,5] <,0001[3]
Asien	220/239 (92,1)	12/226 (5,3)	17,34 [9,98; 30,10] <,0001[2]	206,49 [97,85; 435,75] <,0001[3]	86,7 [82,2; 91,2] <,0001[3]
Andere	127/190 (66,8)	5/194 (2,6)	25,93 [10,86; 61,96] <,0001[2]	76,20 [29,83; 194,68] <,0001[3]	64,3 [57,2; 71,3] <,0001[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,9076)					
0-3	221/269 (82,2)	17/269 (6,3)	13,00 [8,18; 20,66] <,0001[2]	68,25 [38,14; 122,13] <,0001[3]	75,8 [70,4; 81,3] <,0001[3]
4-9	293/353 (83,0)	18/326 (5,5)	15,03 [9,57; 23,61] <,0001[2]	83,56 [48,19; 144,90] <,0001[3]	77,5 [72,8; 82,1] <,0001[3]
≥ 10	128/154 (83,1)	8/134 (6,0)	13,92 [7,08; 27,36] <,0001[2]	77,54 [33,82; 177,77] <,0001[3]	77,1 [70,0; 84,3] <,0001[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,4576)					
IIA	66/79 (83,5)	5/77 (6,5)	12,87 [5,48; 30,20] <,0001[2]	73,11 [24,72; 216,17] <,0001[3]	77,1 [67,2; 86,9] <,0001[3]
IIB	56/73 (76,7)	9/93 (9,7)	7,93 [4,21; 14,94] <,0001[2]	30,75 [12,81; 73,82] <,0001[3]	67,0 [55,6; 78,4] <,0001[3]
IIIA	284/345 (82,3)	15/294 (5,1)	16,13 [9,83; 26,48] <,0001[2]	86,60 [48,07; 155,99] <,0001[3]	77,2 [72,5; 82,0] <,0001[3]
IIIB	19/22 (86,4)	1/19 (5,3)	16,41 [2,42; 111,36] 0,0042[2]	114,00 [10,84; 1199,18] <,0001[3]	81,1 [63,6; 98,6] <,0001[3]
IIIC	214/253 (84,6)	13/245 (5,3)	15,94 [9,37; 27,13] <,0001[2]	97,93 [50,89; 188,44] <,0001[3]	79,3 [74,0; 84,5] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,8964)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
G1	52/63 (82,5)	2/52 (3,8)	21,46 [5,49; 83,93] <,0001[2]	118,18 [24,94; 560,07] <,0001[3]	78,7 [68,0; 89,4] <,0001[3]
G2	298/349 (85,4)	19/323 (5,9)	14,52 [9,36; 22,50] <,0001[2]	93,49 [53,91; 162,12] <,0001[3]	79,5 [75,0; 84,0] <,0001[3]
G3	258/317 (81,4)	20/312 (6,4)	12,70 [8,28; 19,46] <,0001[2]	63,84 [37,43; 108,91] <,0001[3]	75,0 [69,9; 80,1] <,0001[3]
GX	31/44 (70,5)	2/40 (5,0)	14,09 [3,60; 55,14] 0,0001[2]	45,31 [9,50; 216,14] <,0001[3]	65,5 [50,4; 80,5] <,0001[3]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,2314)					
Negativ	57/67 (85,1)	6/62 (9,7)	8,79 [4,08; 18,93] <,0001[2]	53,20 [18,12; 156,22] <,0001[3]	75,4 [64,1; 86,7] <,0001[3]
Positiv	562/678 (82,9)	33/647 (5,1)	16,25 [11,64; 22,70] <,0001[2]	90,14 [60,23; 134,92] <,0001[3]	77,8 [74,5; 81,1] <,0001[3]
Unbekannt	6/8 (75,0)	1/8 (12,5)	6,00 [0,92; 39,18] 0,0613[2]	21,00 [1,50; 293,25] 0,0406[4]	62,5 [24,7; 100,0] 0,0406[4]
Ethnizität (p-Wert des Interaktionsterms: 0,4560)					
Weiß	364/461 (79,0)	27/440 (6,1)	12,87 [8,90; 18,60] <,0001[2]	57,40 [36,63; 89,95] <,0001[3]	72,8 [68,5; 77,2] <,0001[3]
Asiatisch	242/273 (88,6)	12/243 (4,9)	17,95 [10,32; 31,21] <,0001[2]	150,27 [75,35; 299,70] <,0001[3]	83,7 [79,1; 88,4] <,0001[3]
Andere	24/30 (80,0)	3/34 (8,8)	9,07 [3,03; 27,11] <,0001[2]	41,33 [9,36; 182,45] <,0001[3]	71,2 [54,0; 88,4] <,0001[3]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,6520)					
Tamoxifen	445/553 (80,5)	32/534 (6,0)	13,43 [9,57; 18,84] <,0001[2]	64,64 [42,70; 97,85] <,0001[3]	74,5 [70,6; 78,3] <,0001[3]
Aromatase-Inhibitor	197/223 (88,3)	11/195 (5,6)	15,66 [8,80; 27,86] <,0001[2]	126,74 [60,89; 263,80] <,0001[3]	82,7 [77,4; 88,0] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,1549)					
ECOG-PS 0	574/685 (83,8)	36/649 (5,5)	15,11 [10,98; 20,79] <,0001[2]	88,05 [59,45; 130,42] <,0001[3]	78,2 [75,0; 81,5] <,0001[3]
ECOG-PS 1	68/91 (74,7)	7/80 (8,8)	8,54 [4,17; 17,50] <,0001[2]	30,83 [12,43; 76,46] <,0001[3]	66,0 [55,1; 76,8] <,0001[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Datenschnitt: 15.07.2025 Safety-Population 1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test. Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; PT: Preferred Term; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.					

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Tabelle 130.1.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9028)					
Neoadjuvante Chemotherapie	20/314 (6,4)	1/306 (0,3)	19,49 [2,63; 144,33] 0,0036[2]	20,75 [2,77; 155,59] <,0001[3]	6,0 [3,3; 8,8] <,0001[3]
Adjuvante Chemotherapie	24/452 (5,3)	2/416 (0,5)	11,04 [2,63; 46,44] 0,0010[2]	11,61 [2,73; 49,43] <,0001[3]	4,8 [2,7; 7,0] <,0001[3]
Keine Chemotherapie	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Region (p-Wert des Interaktionsterms: 0,8410)					
Nordamerika / Europa	24/347 (6,9)	1/309 (0,3)	21,37 [2,91; 157,05] 0,0026[2]	22,89 [3,08; 170,20] <,0001[3]	6,6 [3,8; 9,3] <,0001[3]
Asien	13/239 (5,4)	1/226 (0,4)	12,29 [1,62; 93,21] 0,0152[2]	12,94 [1,68; 99,77] 0,0016[3]	5,0 [2,0; 8,0] 0,0016[3]
Andere	9/190 (4,7)	1/194 (0,5)	9,19 [1,18; 71,83] 0,0345[2]	9,60 [1,20; 76,50] 0,0101[4]	4,2 [1,0; 7,4] 0,0101[4]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,9261)					
< 20 mm	15/204 (7,4)	2/189 (1,1)	6,95 [1,61; 29,98] 0,0094[2]	7,42 [1,67; 32,90] 0,0022[3]	6,3 [2,4; 10,2] 0,0022[3]
≥ 20 bis < 50 mm	17/360 (4,7)	0/346 (0,0)	33,64 [2,03; 557,27] 0,0141[2]	35,31 [2,11; 589,41] <,0001[3]	4,7 [2,5; 6,9] <,0001[3]
≥ 50 mm	12/194 (6,2)	1/185 (0,5)	11,44 [1,50; 87,13] 0,0186[2]	12,13 [1,56; 94,26] 0,0025[3]	5,6 [2,1; 9,2] 0,0025[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7486)					
0-3	16/269 (5,9)	1/269 (0,4)	16,00 [2,14; 119,80] 0,0069[2]	16,95 [2,23; 128,74] 0,0002[3]	5,6 [2,7; 8,5] 0,0002[3]
4-9	16/353 (4,5)	0/326 (0,0)	30,48 [1,84; 506,05] 0,0171[2]	31,92 [1,91; 534,31] 0,0001[3]	4,5 [2,4; 6,7] 0,0001[3]
≥ 10	14/154 (9,1)	2/134 (1,5)	6,09 [1,41; 26,32] 0,0155[2]	6,60 [1,47; 29,60] 0,0050[3]	7,6 [2,6; 12,6] 0,0050[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,9947)					
IIA	7/79 (8,9)	1/77 (1,3)	6,82 [0,86; 54,16] 0,0693[2]	7,39 [0,89; 61,55] 0,0635[4]	7,6 [0,8; 14,3] 0,0635[4]
IIB	2/73 (2,7)	0/93 (0,0)	6,35 [0,31; 130,28] 0,2304[2]	6,54 [0,31; 138,33] 0,1919[4]	2,7 [-1,0; 6,5] 0,1919[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIA	15/345 (4,3)	0/294 (0,0)	26,43 [1,59; 439,83] 0,0225[2]	27,62 [1,65; 463,68] 0,0003[3]	4,3 [2,2; 6,5] 0,0003[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NB	NB	NB
IIIC	20/253 (7,9)	2/245 (0,8)	9,68 [2,29; 40,99] 0,0020[2]	10,43 [2,41; 45,12] 0,0001[3]	7,1 [3,6; 10,6] 0,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,9385)					
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	20/349 (5,7)	2/323 (0,6)	9,26 [2,18; 39,28] 0,0026[2]	9,76 [2,26; 42,08] 0,0002[3]	5,1 [2,5; 7,7] 0,0002[3]
G3	21/317 (6,6)	1/312 (0,3)	20,67 [2,80; 152,72] 0,0030[2]	22,06 [2,95; 165,07] <,0001[3]	6,3 [3,5; 9,1] <,0001[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9981)					
Negativ	4/67 (6,0)	0/62 (0,0)	8,34 [0,46; 151,78] 0,1520[2]	8,86 [0,47; 167,99] 0,1203[4]	6,0 [0,3; 11,6] 0,1203[4]
Positiv	40/678 (5,9)	2/647 (0,3)	19,09 [4,63; 78,65] <,0001[2]	20,22 [4,87; 84,01] <,0001[3]	5,6 [3,8; 7,4] <,0001[3]
Unbekannt	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Ethnizität (p-Wert des Interaktionsterms: 0,1705)					
Weiß	30/461 (6,5)	1/440 (0,2)	28,63 [3,92; 209,07] 0,0009[2]	30,56 [4,15; 225,06] <,0001[3]	6,3 [4,0; 8,6] <,0001[3]
Asiatisch	13/273 (4,8)	1/243 (0,4)	11,57 [1,52; 87,81] 0,0179[2]	12,10 [1,57; 93,19] 0,0024[3]	4,4 [1,7; 7,0] 0,0024[3]
Andere	1/30 (3,3)	1/34 (2,9)	1,13 [0,07; 17,34] 0,9283[2]	1,14 [0,07; 19,02] 1,0000[4]	0,4 [-8,2; 9,0] 1,0000[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,9780)					
Tamoxifen	30/553 (5,4)	2/534 (0,4)	14,48 [3,48; 60,31] 0,0002[2]	15,26 [3,63; 64,17] <,0001[3]	5,1 [3,1; 7,0] <,0001[3]
Aromatase-Inhibitor	16/223 (7,2)	1/195 (0,5)	13,99 [1,87; 104,54] 0,0101[2]	15,00 [1,97; 114,15] 0,0006[3]	6,7 [3,1; 10,2] 0,0006[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,9807)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	45/685 (6,6)	3/649 (0,5)	14,21 [4,44; 45,50] <,0001[2]	15,14 [4,68; 48,97] <,0001[3]	6,1 [4,2; 8,0] <,0001[3]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; PT: Preferred Term; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 133.1.2: Subgruppen - Unerwünschtes Ereignis: Hepatische Ereignisse (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,5840)					
Neoadjuvante Chemotherapie	57/314 (18,2)	30/306 (9,8)	1,85 [1,23; 2,80] 0,0035[2]	2,04 [1,27; 3,28] 0,0028[3]	8,3 [2,9; 13,8] 0,0028[3]
Adjuvante Chemotherapie	89/452 (19,7)	55/416 (13,2)	1,49 [1,09; 2,03] 0,0114[2]	1,61 [1,12; 2,32] 0,0105[3]	6,5 [1,6; 11,4] 0,0105[3]
Keine Chemotherapie	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Region (p-Wert des Interaktionsterms: 0,1525)					
Nordamerika / Europa	38/347 (11,0)	12/309 (3,9)	2,82 [1,50; 5,30] 0,0013[2]	3,04 [1,56; 5,94] 0,0007[3]	7,1 [3,1; 11,0] 0,0007[3]
Asien	64/239 (26,8)	41/226 (18,1)	1,48 [1,04; 2,09] 0,0280[2]	1,65 [1,06; 2,57] 0,0260[3]	8,6 [1,1; 16,2] 0,0260[3]
Andere	45/190 (23,7)	33/194 (17,0)	1,39 [0,93; 2,08] 0,1067[2]	1,51 [0,92; 2,50] 0,1041[3]	6,7 [-1,4; 14,7] 0,1041[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,6307)					
< 20 mm	46/204 (22,5)	22/189 (11,6)	1,94 [1,21; 3,09] 0,0056[2]	2,21 [1,27; 3,84] 0,0043[3]	10,9 [3,6; 18,2] 0,0043[3]
≥ 20 bis < 50 mm	64/360 (17,8)	42/346 (12,1)	1,46 [1,02; 2,10] 0,0379[2]	1,56 [1,03; 2,38] 0,0360[3]	5,6 [0,4; 10,9] 0,0360[3]
≥ 50 mm	30/194 (15,5)	19/185 (10,3)	1,51 [0,88; 2,58] 0,1361[2]	1,60 [0,87; 2,95] 0,1320[3]	5,2 [-1,5; 11,9] 0,1320[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,3404)					
0-3	48/269 (17,8)	23/269 (8,6)	2,09 [1,31; 3,33] 0,0020[2]	2,32 [1,37; 3,94] 0,0014[3]	9,3 [3,6; 15,0] 0,0014[3]
4-9	70/353 (19,8)	43/326 (13,2)	1,50 [1,06; 2,13] 0,0219[2]	1,63 [1,08; 2,46] 0,0203[3]	6,6 [1,1; 12,2] 0,0203[3]
≥ 10	29/154 (18,8)	20/134 (14,9)	1,26 [0,75; 2,12] 0,3814[2]	1,32 [0,71; 2,47] 0,3789[3]	3,9 [-4,7; 12,5] 0,3789[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,7828)					
IIA	17/79 (21,5)	7/77 (9,1)	2,37 [1,04; 5,39] 0,0400[2]	2,74 [1,07; 7,05] 0,0315[3]	12,4 [1,3; 23,5] 0,0315[3]
IIB	15/73 (20,5)	11/93 (11,8)	1,74 [0,85; 3,55] 0,1301[2]	1,93 [0,83; 4,50] 0,1249[3]	8,7 [-2,6; 20,1] 0,1249[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIA	67/345 (19,4)	42/294 (14,3)	1,36 [0,96; 1,93] 0,0882[2]	1,45 [0,95; 2,20] 0,0855[3]	5,1 [-0,6; 10,9] 0,0855[3]
IIIB	2/22 (9,1)	1/19 (5,3)	1,73 [0,17; 17,59] 0,6444[2]	1,80 [0,15; 21,57] 1,0000[4]	3,8 [-11,8; 19,5] 1,0000[4]
IIIC	43/253 (17,0)	25/245 (10,2)	1,67 [1,05; 2,64] 0,0299[2]	1,80 [1,06; 3,06] 0,0273[3]	6,8 [0,8; 12,8] 0,0273[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,3484)					
G1	15/63 (23,8)	5/52 (9,6)	2,48 [0,96; 6,36] 0,0595[2]	2,94 [0,99; 8,73] 0,0456[3]	14,2 [1,0; 27,4] 0,0456[3]
G2	52/349 (14,9)	36/323 (11,1)	1,34 [0,90; 1,99] 0,1519[2]	1,40 [0,89; 2,20] 0,1495[3]	3,8 [-1,3; 8,8] 0,1495[3]
G3	63/317 (19,9)	40/312 (12,8)	1,55 [1,08; 2,23] 0,0183[2]	1,69 [1,10; 2,60] 0,0168[3]	7,1 [1,3; 12,8] 0,0168[3]
GX	16/44 (36,4)	5/40 (12,5)	2,91 [1,17; 7,21] 0,0212[2]	4,00 [1,30; 12,26] 0,0116[3]	23,9 [6,3; 41,4] 0,0116[3]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,8535)					
Negativ	15/67 (22,4)	7/62 (11,3)	1,98 [0,87; 4,54] 0,1051[2]	2,27 [0,86; 6,00] 0,0941[3]	11,1 [-1,6; 23,8] 0,0941[3]
Positiv	128/678 (18,9)	79/647 (12,2)	1,55 [1,19; 2,00] 0,0010[2]	1,67 [1,23; 2,27] 0,0008[3]	6,7 [2,8; 10,5] 0,0008[3]
Unbekannt	2/8 (25,0)	0/8 (0,0)	5,00 [0,28; 90,18] 0,2754[2]	6,54 [0,27; 160,97] 0,4667[4]	25,0 [-5,0; 55,0] 0,4667[4]
Ethnizität (p-Wert des Interaktionsterms: 0,5140)					
Weiß	71/461 (15,4)	37/440 (8,4)	1,83 [1,26; 2,67] 0,0016[2]	1,98 [1,30; 3,02] 0,0012[3]	7,0 [2,8; 11,2] 0,0012[3]
Asiatisch	68/273 (24,9)	41/243 (16,9)	1,48 [1,04; 2,09] 0,0277[2]	1,63 [1,06; 2,52] 0,0256[3]	8,0 [1,1; 15,0] 0,0256[3]
Andere	8/30 (26,7)	8/34 (23,5)	1,13 [0,49; 2,65] 0,7724[2]	1,18 [0,38; 3,67] 0,7724[3]	3,1 [-18,2; 24,4] 0,7724[3]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,4332)					
Tamoxifen	80/553 (14,5)	53/534 (9,9)	1,46 [1,05; 2,02] 0,0236[2]	1,53 [1,06; 2,22] 0,0224[3]	4,5 [0,7; 8,4] 0,0224[3]
Aromatase-Inhibitor	67/223 (30,0)	33/195 (16,9)	1,78 [1,23; 2,57] 0,0024[2]	2,11 [1,32; 3,38] 0,0017[3]	13,1 [5,1; 21,1] 0,0017[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,4746)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	132/685 (19,3)	80/649 (12,3)	1,56 [1,21; 2,02] 0,0006[2]	1,70 [1,26; 2,29] 0,0005[3]	6,9 [3,1; 10,8] 0,0005[3]
ECOG-PS 1	15/91 (16,5)	6/80 (7,5)	2,20 [0,90; 5,39] 0,0856[2]	2,43 [0,90; 6,61] 0,0741[3]	9,0 [-0,6; 18,5] 0,0741[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 134.1.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3: Hepatische Ereignisse aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Region (p-Wert des Interaktionsterms: 0,9350)					
Nordamerika / Europa	6/347 (1,7)	1/309 (0,3)	5,34 [0,65; 44,13] 0,1198[2]	5,42 [0,65; 45,27] 0,1274[4]	1,4 [-0,1; 2,9] 0,1274[4]
Asien	16/239 (6,7)	2/226 (0,9)	7,56 [1,76; 32,53] 0,0065[2]	8,04 [1,83; 35,36] 0,0012[3]	5,8 [2,4; 9,2] 0,0012[3]
Andere	9/190 (4,7)	1/194 (0,5)	9,19 [1,18; 71,83] 0,0345[2]	9,60 [1,20; 76,50] 0,0101[4]	4,2 [1,0; 7,4] 0,0101[4]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,8217)					
< 20 mm	9/204 (4,4)	2/189 (1,1)	4,17 [0,91; 19,05] 0,0655[2]	4,32 [0,92; 20,24] 0,0440[3]	3,4 [0,2; 6,5] 0,0440[3]
≥ 20 bis < 50 mm	17/360 (4,7)	2/346 (0,6)	8,17 [1,90; 35,10] 0,0047[2]	8,52 [1,95; 37,18] 0,0007[3]	4,1 [1,8; 6,5] 0,0007[3]
≥ 50 mm	4/194 (2,1)	0/185 (0,0)	8,58 [0,47; 158,35] 0,1483[2]	8,76 [0,47; 163,92] 0,1234[4]	2,1 [0,1; 4,1] 0,1234[4]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,3258)					
0-3	10/269 (3,7)	0/269 (0,0)	21,00 [1,24; 356,57] 0,0351[2]	21,81 [1,27; 374,09] 0,0014[3]	3,7 [1,5; 6,0] 0,0014[3]
4-9	14/353 (4,0)	1/326 (0,3)	12,93 [1,71; 97,77] 0,0132[2]	13,42 [1,75; 102,65] 0,0012[3]	3,7 [1,5; 5,8] 0,0012[3]
≥ 10	7/154 (4,5)	3/134 (2,2)	2,03 [0,54; 7,70] 0,2976[2]	2,08 [0,53; 8,21] 0,3472[4]	2,3 [-1,8; 6,4] 0,3472[4]
Tumorstadium (p-Wert des Interaktionsterms: 0,9265)					
IIA	6/79 (7,6)	0/77 (0,0)	12,68 [0,73; 221,21] 0,0817[2]	13,71 [0,76; 247,65] 0,0284[4]	7,6 [1,8; 13,4] 0,0284[4]
IIB	2/73 (2,7)	0/93 (0,0)	6,35 [0,31; 130,28] 0,2304[2]	6,54 [0,31; 138,33] 0,1919[4]	2,7 [-1,0; 6,5] 0,1919[4]
IIIA	12/345 (3,5)	1/294 (0,3)	10,23 [1,34; 78,18] 0,0251[2]	10,56 [1,36; 81,69] 0,0051[3]	3,1 [1,1; 5,2] 0,0051[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NB	NB	NB
IIIC	10/253 (4,0)	3/245 (1,2)	3,23 [0,90; 11,59] 0,0724[2]	3,32 [0,90; 12,21] 0,0563[3]	2,7 [-0,0; 5,5] 0,0563[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,9987)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	11/349 (3,2)	3/323 (0,9)	3,39 [0,96; 12,05] 0,0589[2]	3,47 [0,96; 12,56] 0,0438[3]	2,2 [0,1; 4,3] 0,0438[3]
G3	14/317 (4,4)	0/312 (0,0)	28,54 [1,71; 476,43] 0,0196[2]	29,86 [1,77; 502,77] 0,0002[3]	4,4 [2,2; 6,7] 0,0002[3]
GX	3/44 (6,8)	1/40 (2,5)	2,73 [0,30; 25,17] 0,3762[2]	2,85 [0,28; 28,61] 0,6176[4]	4,3 [-4,6; 13,2] 0,6176[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,8317)					
Negativ	4/67 (6,0)	1/62 (1,6)	3,70 [0,43; 32,22] 0,2359[2]	3,87 [0,42; 35,64] 0,3671[4]	4,4 [-2,1; 10,8] 0,3671[4]
Positiv	25/678 (3,7)	3/647 (0,5)	7,95 [2,41; 26,21] 0,0007[2]	8,22 [2,47; 27,35] <,0001[3]	3,2 [1,7; 4,7] <,0001[3]
Unbekannt	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Ethnizität (p-Wert des Interaktionsterms: 0,7514)					
Weiß	11/461 (2,4)	1/440 (0,2)	10,50 [1,36; 80,98] 0,0241[2]	10,73 [1,38; 83,47] 0,0047[3]	2,2 [0,7; 3,6] 0,0047[3]
Asiatisch	17/273 (6,2)	2/243 (0,8)	7,57 [1,77; 32,41] 0,0064[2]	8,00 [1,83; 35,00] 0,0011[3]	5,4 [2,3; 8,5] 0,0011[3]
Andere	3/30 (10,0)	1/34 (2,9)	3,40 [0,37; 30,97] 0,2776[2]	3,67 [0,36; 37,30] 0,3334[4]	7,1 [-5,1; 19,2] 0,3334[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,2945)					
Tamoxifen	16/553 (2,9)	1/534 (0,2)	15,45 [2,06; 116,09] 0,0078[2]	15,88 [2,10; 120,17] 0,0003[3]	2,7 [1,3; 4,2] 0,0003[3]
Aromatase-Inhibitor	15/223 (6,7)	3/195 (1,5)	4,37 [1,28; 14,88] 0,0182[2]	4,62 [1,32; 16,19] 0,0091[3]	5,2 [1,5; 8,9] 0,0091[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,2241)					
ECOG-PS 0	29/685 (4,2)	3/649 (0,5)	9,16 [2,80; 29,92] 0,0002[2]	9,52 [2,89; 31,40] <,0001[3]	3,8 [2,2; 5,4] <,0001[3]
ECOG-PS 1	2/91 (2,2)	1/80 (1,3)	1,76 [0,16; 19,03] 0,6424[2]	1,78 [0,16; 19,95] 1,0000[4]	0,9 [-2,9; 4,8] 1,0000[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Datenschnitt: 15.07.2025 Safety-Population 1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test. Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.					

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Tabelle 137.1.2: Subgruppen - Unerwünschtes Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,5633)					
Neoadjuvante Chemotherapie	8/314 (2,5)	2/306 (0,7)	3,90 [0,83; 18,21] 0,0837[2]	3,97 [0,84; 18,87] 0,1068[4]	1,9 [-0,1; 3,9] 0,1068[4]
Adjuvante Chemotherapie	6/452 (1,3)	3/416 (0,7)	1,84 [0,46; 7,31] 0,3860[2]	1,85 [0,46; 7,45] 0,5089[4]	0,6 [-0,7; 1,9] 0,5089[4]
Keine Chemotherapie	0/10 (0,0)	0/7 (0,0)	NB	NB	NB
Region (p-Wert des Interaktionsterms: 0,2416)					
Nordamerika / Europa	12/347 (3,5)	1/309 (0,3)	10,69 [1,40; 81,71] 0,0225[2]	11,03 [1,43; 85,35] 0,0040[3]	3,1 [1,1; 5,2] 0,0040[3]
Asien	2/239 (0,8)	2/226 (0,9)	0,95 [0,13; 6,66] 0,9552[2]	0,95 [0,13; 6,77] 1,0000[4]	-0,0 [-1,7; 1,6] 1,0000[4]
Andere	0/190 (0,0)	2/194 (1,0)	0,20 [0,01; 4,23] 0,3041[2]	0,20 [0,01; 4,24] 0,4987[4]	-1,0 [-2,5; 0,4] 0,4987[4]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,9448)					
0-3	8/269 (3,0)	3/269 (1,1)	2,67 [0,72; 9,94] 0,1441[2]	2,72 [0,71; 10,36] 0,1277[3]	1,9 [-0,5; 4,2] 0,1277[3]
4-9	4/353 (1,1)	2/326 (0,6)	1,85 [0,34; 10,02] 0,4769[2]	1,86 [0,34; 10,21] 0,6876[4]	0,5 [-0,9; 1,9] 0,6876[4]
≥ 10	2/154 (1,3)	0/134 (0,0)	4,35 [0,21; 89,92] 0,3409[2]	4,41 [0,21; 92,67] 0,5007[4]	1,3 [-0,5; 3,1] 0,5007[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9533)					
Negativ	2/67 (3,0)	0/62 (0,0)	4,63 [0,23; 94,63] 0,3193[2]	4,77 [0,22; 101,36] 0,4969[4]	3,0 [-1,1; 7,1] 0,4969[4]
Positiv	11/678 (1,6)	5/647 (0,8)	2,10 [0,73; 6,01] 0,1669[2]	2,12 [0,73; 6,13] 0,1570[3]	0,8 [-0,3; 2,0] 0,1570[3]
Unbekannt	0/8 (0,0)	0/8 (0,0)	NB	NB	NB
Ethnizität (p-Wert des Interaktionsterms: 0,3691)					
Weiß	11/461 (2,4)	2/440 (0,5)	5,25 [1,17; 23,55] 0,0304[2]	5,35 [1,18; 24,29] 0,0151[3]	1,9 [0,4; 3,5] 0,0151[3]
Asiatisch	2/273 (0,7)	2/243 (0,8)	0,89 [0,13; 6,27] 0,9070[2]	0,89 [0,12; 6,36] 1,0000[4]	-0,1 [-1,6; 1,4] 1,0000[4]
Andere	0/30 (0,0)	0/34 (0,0)	NB	NB	NB

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,9765)					
Tamoxifen	12/553 (2,2)	5/534 (0,9)	2,32 [0,82; 6,53] 0,1120[2]	2,35 [0,82; 6,71] 0,1013[3]	1,2 [-0,2; 2,7] 0,1013[3]
Aromatase-Inhibitor	2/223 (0,9)	0/195 (0,0)	4,38 [0,21; 90,58] 0,3398[2]	4,41 [0,21; 92,48] 0,5010[4]	0,9 [-0,3; 2,1] 0,5010[4]
ECOG-PS (p-Wert des Interaktionsterms: 0,9743)					
ECOG-PS 0	11/685 (1,6)	5/649 (0,8)	2,08 [0,73; 5,97] 0,1711[2]	2,10 [0,73; 6,08] 0,1612[3]	0,8 [-0,3; 2,0] 0,1612[3]
ECOG-PS 1	3/91 (3,3)	0/80 (0,0)	6,16 [0,32; 117,53] 0,2267[2]	6,37 [0,32; 125,17] 0,2487[4]	3,3 [-0,4; 7,0] 0,2487[4]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 141.1.2: Subgruppen - Unerwünschtes Ereignis: ILD/Pneumonitis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,0838)					
Neoadjuvante Chemotherapie	11/314 (3,5)	7/306 (2,3)	1,53 [0,60; 3,90] 0,3714[2]	1,55 [0,59; 4,05] 0,3674[3]	1,2 [-1,4; 3,9] 0,3674[3]
Adjuvante Chemotherapie	23/452 (5,1)	7/416 (1,7)	3,02 [1,31; 6,97] 0,0094[2]	3,13 [1,33; 7,38] 0,0061[3]	3,4 [1,0; 5,8] 0,0061[3]
Keine Chemotherapie	0/10 (0,0)	0/7 (0,0)	NB	NB	NB
Region (p-Wert des Interaktionsterms: 0,5152)					
Nordamerika / Europa	8/347 (2,3)	2/309 (0,6)	3,56 [0,76; 16,65] 0,1064[2]	3,62 [0,76; 17,19] 0,1126[4]	1,7 [-0,2; 3,5] 0,1126[4]
Asien	23/239 (9,6)	9/226 (4,0)	2,42 [1,14; 5,11] 0,0209[2]	2,57 [1,16; 5,68] 0,0163[3]	5,6 [1,1; 10,2] 0,0163[3]
Andere	3/190 (1,6)	3/194 (1,5)	1,02 [0,21; 5,00] 0,9795[2]	1,02 [0,20; 5,12] 1,0000[4]	0,0 [-2,4; 2,5] 1,0000[4]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,7192)					
< 20 mm	8/204 (3,9)	2/189 (1,1)	3,71 [0,80; 17,23] 0,0948[2]	3,82 [0,80; 18,20] 0,1075[4]	2,9 [-0,2; 5,9] 0,1075[4]
≥ 20 bis < 50 mm	15/360 (4,2)	7/346 (2,0)	2,06 [0,85; 4,99] 0,1096[2]	2,11 [0,85; 5,23] 0,1013[3]	2,1 [-0,4; 4,7] 0,1013[3]
≥ 50 mm	9/194 (4,6)	5/185 (2,7)	1,72 [0,59; 5,03] 0,3244[2]	1,75 [0,58; 5,33] 0,3177[3]	1,9 [-1,8; 5,7] 0,3177[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,3525)					
0-3	7/269 (2,6)	6/269 (2,2)	1,17 [0,40; 3,43] 0,7791[2]	1,17 [0,39; 3,53] 0,7789[3]	0,4 [-2,2; 3,0] 0,7789[3]
4-9	21/353 (5,9)	6/326 (1,8)	3,23 [1,32; 7,91] 0,0102[2]	3,37 [1,34; 8,47] 0,0062[3]	4,1 [1,2; 7,0] 0,0062[3]
≥ 10	6/154 (3,9)	2/134 (1,5)	2,61 [0,54; 12,72] 0,2350[2]	2,68 [0,53; 13,49] 0,2918[4]	2,4 [-1,3; 6,1] 0,2918[4]
Tumorstadium (p-Wert des Interaktionsterms: 0,6652)					
IIA	0/79 (0,0)	0/77 (0,0)	NB	NB	NB
IIB	1/73 (1,4)	3/93 (3,2)	0,42 [0,05; 4,00] 0,4541[2]	0,42 [0,04; 4,09] 0,6315[4]	-1,9 [-6,3; 2,6] 0,6315[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIA	20/345 (5,8)	6/294 (2,0)	2,84 [1,16; 6,98] 0,0228[2]	2,95 [1,17; 7,46] 0,0166[3]	3,8 [0,8; 6,7] 0,0166[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NB	NB	NB
IIIC	12/253 (4,7)	5/245 (2,0)	2,32 [0,83; 6,50] 0,1080[2]	2,39 [0,83; 6,89] 0,0969[3]	2,7 [-0,5; 5,9] 0,0969[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,9588)					
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	19/349 (5,4)	8/323 (2,5)	2,20 [0,98; 4,95] 0,0573[2]	2,27 [0,98; 5,25] 0,0503[3]	3,0 [0,0; 5,9] 0,0503[3]
G3	8/317 (2,5)	5/312 (1,6)	1,57 [0,52; 4,76] 0,4211[2]	1,59 [0,51; 4,91] 0,4169[3]	0,9 [-1,3; 3,1] 0,4169[3]
GX	3/44 (6,8)	1/40 (2,5)	2,73 [0,30; 25,17] 0,3762[2]	2,85 [0,28; 28,61] 0,6176[4]	4,3 [-4,6; 13,2] 0,6176[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6201)					
Negativ	2/67 (3,0)	1/62 (1,6)	1,85 [0,17; 19,91] 0,6115[2]	1,88 [0,17; 21,23] 1,0000[4]	1,4 [-3,8; 6,5] 1,0000[4]
Positiv	30/678 (4,4)	13/647 (2,0)	2,20 [1,16; 4,18] 0,0159[2]	2,26 [1,17; 4,37] 0,0131[3]	2,4 [0,5; 4,3] 0,0131[3]
Unbekannt	0/8 (0,0)	0/8 (0,0)	NB	NB	NB
Ethnizität (p-Wert des Interaktionsterms: 0,8749)					
Weiß	9/461 (2,0)	4/440 (0,9)	2,15 [0,67; 6,92] 0,2006[2]	2,17 [0,66; 7,10] 0,1893[3]	1,0 [-0,5; 2,6] 0,1893[3]
Asiatisch	24/273 (8,8)	9/243 (3,7)	2,37 [1,13; 5,01] 0,0232[2]	2,51 [1,14; 5,50] 0,0184[3]	5,1 [1,0; 9,2] 0,0184[3]
Andere	1/30 (3,3)	1/34 (2,9)	1,13 [0,07; 17,34] 0,9283[2]	1,14 [0,07; 19,02] 1,0000[4]	0,4 [-8,2; 9,0] 1,0000[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,4486)					
Tamoxifen	17/553 (3,1)	9/534 (1,7)	1,82 [0,82; 4,06] 0,1405[2]	1,85 [0,82; 4,19] 0,1341[3]	1,4 [-0,4; 3,2] 0,1341[3]
Aromatase-Inhibitor	17/223 (7,6)	5/195 (2,6)	2,97 [1,12; 7,91] 0,0291[2]	3,14 [1,13; 8,67] 0,0208[3]	5,1 [0,9; 9,2] 0,0208[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,8689)					
ECOG-PS 0	27/685 (3,9)	11/649 (1,7)	2,33 [1,16; 4,65] 0,0170[2]	2,38 [1,17; 4,84] 0,0137[3]	2,2 [0,5; 4,0] 0,0137[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 1	7/91 (7,7)	3/80 (3,8)	2,05 [0,55; 7,67] 0,2856[2]	2,14 [0,53; 8,57] 0,3396[4]	3,9 [-2,9; 10,8] 0,3396[4]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; ILD: Interstitial Lung Disease; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 145.1.2: Subgruppen - Unerwünschtes Ereignis: Erkrankungen der Nieren und Harnwege (SOC) (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9993)					
Neoadjuvante Chemotherapie	22/314 (7,0)	14/306 (4,6)	1,53 [0,80; 2,94] 0,1997[2]	1,57 [0,79; 3,13] 0,1956[3]	2,4 [-1,2; 6,1] 0,1956[3]
Adjuvante Chemotherapie	32/452 (7,1)	19/416 (4,6)	1,55 [0,89; 2,69] 0,1195[2]	1,59 [0,89; 2,85] 0,1159[3]	2,5 [-0,6; 5,6] 0,1159[3]
Keine Chemotherapie	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (p-Wert des Interaktionsterms: 0,4208)					
Nordamerika / Europa	30/347 (8,6)	13/309 (4,2)	2,05 [1,09; 3,87] 0,0256[2]	2,15 [1,10; 4,21] 0,0219[3]	4,4 [0,7; 8,1] 0,0219[3]
Asien	15/239 (6,3)	10/226 (4,4)	1,42 [0,65; 3,09] 0,3793[2]	1,45 [0,64; 3,29] 0,3763[3]	1,9 [-2,2; 5,9] 0,3763[3]
Andere	10/190 (5,3)	10/194 (5,2)	1,02 [0,43; 2,40] 0,9618[2]	1,02 [0,42; 2,51] 0,9618[3]	0,1 [-4,3; 4,6] 0,9618[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,2633)					
< 20 mm	17/204 (8,3)	9/189 (4,8)	1,75 [0,80; 3,83] 0,1615[2]	1,82 [0,79; 4,18] 0,1547[3]	3,6 [-1,3; 8,4] 0,1547[3]
≥ 20 bis < 50 mm	21/360 (5,8)	19/346 (5,5)	1,06 [0,58; 1,94] 0,8443[2]	1,07 [0,56; 2,02] 0,8442[3]	0,3 [-3,1; 3,8] 0,8442[3]
≥ 50 mm	14/194 (7,2)	5/185 (2,7)	2,67 [0,98; 7,27] 0,0545[2]	2,80 [0,99; 7,94] 0,0441[3]	4,5 [0,2; 8,8] 0,0441[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,9222)					
0-3	23/269 (8,6)	16/269 (5,9)	1,44 [0,78; 2,66] 0,2477[2]	1,48 [0,76; 2,87] 0,2445[3]	2,6 [-1,8; 7,0] 0,2445[3]
4-9	22/353 (6,2)	12/326 (3,7)	1,69 [0,85; 3,37] 0,1331[2]	1,74 [0,85; 3,57] 0,1278[3]	2,6 [-0,7; 5,8] 0,1278[3]
≥ 10	10/154 (6,5)	5/134 (3,7)	1,74 [0,61; 4,96] 0,3002[2]	1,79 [0,60; 5,38] 0,2927[3]	2,8 [-2,3; 7,8] 0,2927[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,1686)					
IIA	9/79 (11,4)	4/77 (5,2)	2,19 [0,70; 6,82] 0,1752[2]	2,35 [0,69; 7,97] 0,1614[3]	6,2 [-2,4; 14,8] 0,1614[3]
IIB	2/73 (2,7)	8/93 (8,6)	0,32 [0,07; 1,45] 0,1398[2]	0,30 [0,06; 1,45] 0,1880[4]	-5,9 [-12,7; 1,0] 0,1880[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIA	29/345 (8,4)	10/294 (3,4)	2,47 [1,23; 4,99] 0,0115[2]	2,61 [1,25; 5,44] 0,0084[3]	5,0 [1,4; 8,6] 0,0084[3]
IIIB	2/22 (9,1)	1/19 (5,3)	1,73 [0,17; 17,59] 0,6444[2]	1,80 [0,15; 21,57] 1,0000[4]	3,8 [-11,8; 19,5] 1,0000[4]
IIIC	13/253 (5,1)	10/245 (4,1)	1,26 [0,56; 2,82] 0,5753[2]	1,27 [0,55; 2,96] 0,5743[3]	1,1 [-2,6; 4,7] 0,5743[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,8218)					
G1	7/63 (11,1)	3/52 (5,8)	1,93 [0,52; 7,08] 0,3237[2]	2,04 [0,50; 8,33] 0,5082[4]	5,3 [-4,7; 15,4] 0,5082[4]
G2	26/349 (7,4)	13/323 (4,0)	1,85 [0,97; 3,54] 0,0627[2]	1,92 [0,97; 3,80] 0,0578[3]	3,4 [-0,1; 6,9] 0,0578[3]
G3	20/317 (6,3)	16/312 (5,1)	1,23 [0,65; 2,33] 0,5247[2]	1,25 [0,63; 2,45] 0,5238[3]	1,2 [-2,4; 4,8] 0,5238[3]
GX	2/44 (4,5)	1/40 (2,5)	1,82 [0,17; 19,29] 0,6198[2]	1,86 [0,16; 21,30] 1,0000[4]	2,0 [-5,8; 9,9] 1,0000[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6341)					
Negativ	5/67 (7,5)	1/62 (1,6)	4,63 [0,56; 38,51] 0,1565[2]	4,92 [0,56; 43,34] 0,2098[4]	5,8 [-1,2; 12,9] 0,2098[4]
Positiv	49/678 (7,2)	29/647 (4,5)	1,61 [1,03; 2,52] 0,0359[2]	1,66 [1,04; 2,66] 0,0338[3]	2,7 [0,2; 5,3] 0,0338[3]
Unbekannt	0/8 (0,0)	3/8 (37,5)	0,14 [0,01; 2,39] 0,1755[2]	0,09 [0,00; 2,16] 0,2000[4]	-37,5 [-71,0; -4,0] 0,2000[4]
Ethnizität (p-Wert des Interaktionsterms: 0,8749)					
Weiß	35/461 (7,6)	20/440 (4,5)	1,67 [0,98; 2,85] 0,0595[2]	1,73 [0,98; 3,04] 0,0562[3]	3,0 [-0,1; 6,2] 0,0562[3]
Asiatisch	17/273 (6,2)	11/243 (4,5)	1,38 [0,66; 2,88] 0,3973[2]	1,40 [0,64; 3,05] 0,3947[3]	1,7 [-2,2; 5,6] 0,3947[3]
Andere	2/30 (6,7)	1/34 (2,9)	2,27 [0,22; 23,76] 0,4949[2]	2,36 [0,20; 27,39] 0,5961[4]	3,7 [-6,9; 14,3] 0,5961[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,3254)					
Tamoxifen	37/553 (6,7)	26/534 (4,9)	1,37 [0,84; 2,24] 0,2011[2]	1,40 [0,84; 2,35] 0,1988[3]	1,8 [-0,9; 4,6] 0,1988[3]
Aromatase-Inhibitor	18/223 (8,1)	7/195 (3,6)	2,25 [0,96; 5,27] 0,0622[2]	2,36 [0,96; 5,77] 0,0539[3]	4,5 [0,1; 8,9] 0,0539[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,5483)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	47/685 (6,9)	27/649 (4,2)	1,65 [1,04; 2,62] 0,0334[2]	1,70 [1,04; 2,76] 0,0312[3]	2,7 [0,3; 5,1] 0,0312[3]
ECOG-PS 1	8/91 (8,8)	6/80 (7,5)	1,17 [0,42; 3,23] 0,7590[2]	1,19 [0,39; 3,59] 0,7586[3]	1,3 [-6,9; 9,5] 0,7586[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.

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Anhang 4-G2.4.4: Unerwünschte Ereignisse von speziellem Interesse - Subgruppenanalysen nicht-interagierender Subgruppen (Postmenopausale Patientinnen)

Tabelle 121.2.2: Subgruppen - Unerwünschtes Ereignis: PT Neutropenie und erniedrigte Neutrophilenzahl (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,1278)					
< 65 Jahre	405/918 (44,1)	43/936 (4,6)	9,60 [7,11; 12,97] <,0001[2]	16,40 [11,76; 22,86] <,0001[3]	39,5 [36,0; 43,0] <,0001[3]
≥ 65 Jahre	154/365 (42,2)	8/328 (2,4)	17,30 [8,63; 34,66] <,0001[2]	29,19 [14,05; 60,68] <,0001[3]	39,8 [34,4; 45,1] <,0001[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,3518)					
Neoadjuvante Chemotherapie	203/430 (47,2)	24/415 (5,8)	8,16 [5,47; 12,19] <,0001[2]	14,57 [9,26; 22,93] <,0001[3]	41,4 [36,2; 46,7] <,0001[3]
Adjuvante Chemotherapie	338/784 (43,1)	27/768 (3,5)	12,26 [8,39; 17,92] <,0001[2]	20,80 [13,81; 31,31] <,0001[3]	39,6 [35,9; 43,3] <,0001[3]
Keine Chemotherapie	18/69 (26,1)	0/81 (0,0)	43,34 [2,66; 706,27] 0,0081[2]	58,55 [3,45; 992,81] <,0001[3]	26,1 [15,7; 36,4] <,0001[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,4029)					
< 20 mm	140/331 (42,3)	17/334 (5,1)	8,31 [5,14; 13,43] <,0001[2]	13,67 [8,01; 23,32] <,0001[3]	37,2 [31,4; 43,0] <,0001[3]
≥ 20 bis < 50 mm	282/646 (43,7)	23/653 (3,5)	12,39 [8,22; 18,69] <,0001[2]	21,22 [13,61; 33,09] <,0001[3]	40,1 [36,1; 44,2] <,0001[3]
≥ 50 mm	125/289 (43,3)	9/265 (3,4)	12,74 [6,61; 24,53] <,0001[2]	21,68 [10,72; 43,85] <,0001[3]	39,9 [33,7; 46,0] <,0001[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,8673)					
0-3	174/427 (40,7)	14/418 (3,3)	12,17 [7,18; 20,62] <,0001[2]	19,85 [11,26; 34,98] <,0001[3]	37,4 [32,4; 42,4] <,0001[3]
4-9	249/549 (45,4)	24/542 (4,4)	10,24 [6,85; 15,31] <,0001[2]	17,91 [11,51; 27,88] <,0001[3]	40,9 [36,4; 45,4] <,0001[3]
≥ 10	136/307 (44,3)	13/304 (4,3)	10,36 [6,00; 17,89] <,0001[2]	17,80 [9,78; 32,42] <,0001[3]	40,0 [34,0; 46,0] <,0001[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,8935)					
IIA	43/113 (38,1)	4/114 (3,5)	10,85 [4,03; 29,21] <,0001[2]	16,89 [5,81; 49,12] <,0001[3]	34,5 [25,0; 44,1] <,0001[3]
IIB	69/151 (45,7)	5/136 (3,7)	12,43 [5,17; 29,90] <,0001[2]	22,05 [8,54; 56,93] <,0001[3]	42,0 [33,5; 50,6] <,0001[3]
IIIA	213/495 (43,0)	17/488 (3,5)	12,35 [7,66; 19,92] <,0001[2]	20,93 [12,50; 35,04] <,0001[3]	39,5 [34,9; 44,2] <,0001[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIB	27/54 (50,0)	3/45 (6,7)	7,50 [2,43; 23,11] 0,0004[2]	14,00 [3,87; 50,71] <,0001[3]	43,3 [28,1; 58,5] <,0001[3]
IIIC	206/468 (44,0)	22/479 (4,6)	9,58 [6,29; 14,60] <,0001[2]	16,33 [10,26; 26,00] <,0001[3]	39,4 [34,6; 44,3] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,5647)					
G1	33/91 (36,3)	2/93 (2,2)	16,86 [4,17; 68,23] <,0001[2]	25,89 [5,98; 112,01] <,0001[3]	34,1 [23,8; 44,4] <,0001[3]
G2	257/612 (42,0)	25/602 (4,2)	10,11 [6,81; 15,01] <,0001[2]	16,71 [10,85; 25,72] <,0001[3]	37,8 [33,6; 42,1] <,0001[3]
G3	240/527 (45,5)	19/506 (3,8)	12,13 [7,73; 19,04] <,0001[2]	21,43 [13,14; 34,96] <,0001[3]	41,8 [37,2; 46,3] <,0001[3]
GX	28/51 (54,9)	5/59 (8,5)	6,48 [2,70; 15,54] <,0001[2]	13,15 [4,51; 38,31] <,0001[3]	46,4 [31,0; 61,8] <,0001[3]
Ethnizität (p-Wert des Interaktionsterms: 0,5880)					
Weiß	372/958 (38,8)	36/943 (3,8)	10,17 [7,31; 14,15] <,0001[2]	15,99 [11,19; 22,87] <,0001[3]	35,0 [31,7; 38,3] <,0001[3]
Asiatisch	155/250 (62,0)	14/242 (5,8)	10,72 [6,39; 17,98] <,0001[2]	26,57 [14,63; 48,27] <,0001[3]	56,2 [49,5; 62,9] <,0001[3]
Andere	28/62 (45,2)	1/64 (1,6)	28,90 [4,06; 205,98] 0,0008[2]	51,88 [6,76; 398,13] <,0001[3]	43,6 [30,8; 56,4] <,0001[3]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,6212)					
Tamoxifen	46/114 (40,4)	6/132 (4,5)	8,88 [3,94; 20,01] <,0001[2]	14,21 [5,77; 34,96] <,0001[3]	35,8 [26,1; 45,5] <,0001[3]
Aromatase-Inhibitor	513/1169 (43,9)	45/1132 (4,0)	11,04 [8,23; 14,81] <,0001[2]	18,89 [13,72; 26,01] <,0001[3]	39,9 [36,8; 43,0] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,4410)					
ECOG-PS 0	467/1070 (43,6)	39/1019 (3,8)	11,40 [8,32; 15,63] <,0001[2]	19,46 [13,82; 27,40] <,0001[3]	39,8 [36,6; 43,0] <,0001[3]
ECOG-PS 1	92/213 (43,2)	12/245 (4,9)	8,82 [4,97; 15,64] <,0001[2]	14,76 [7,78; 28,01] <,0001[3]	38,3 [31,1; 45,5] <,0001[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; PT: Preferred Term; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 122.2.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3: PT Neutropenie und erniedrigte Neutrophilenzahl aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,4248)					
< 65 Jahre	188/918 (20,5)	5/936 (0,5)	38,34 [15,85; 92,74] <,0001[2]	47,95 [19,63; 117,17] <,0001[3]	19,9 [17,3; 22,6] <,0001[3]
≥ 65 Jahre	71/365 (19,5)	3/328 (0,9)	21,27 [6,76; 66,87] <,0001[2]	26,16 [8,15; 83,95] <,0001[3]	18,5 [14,3; 22,7] <,0001[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9871)					
Neoadjuvante Chemotherapie	102/430 (23,7)	3/415 (0,7)	32,81 [10,49; 102,62] <,0001[2]	42,71 [13,43; 135,86] <,0001[3]	23,0 [18,9; 27,1] <,0001[3]
Adjuvante Chemotherapie	149/784 (19,0)	5/768 (0,7)	29,19 [12,04; 70,77] <,0001[2]	35,81 [14,60; 87,83] <,0001[3]	18,4 [15,5; 21,2] <,0001[3]
Keine Chemotherapie	8/69 (11,6)	0/81 (0,0)	19,91 [1,17; 338,90] 0,0386[2]	22,53 [1,28; 397,86] 0,0016[4]	11,6 [4,0; 19,1] 0,0016[4]
Region (p-Wert des Interaktionsterms: 0,9337)					
Nordamerika / Europa	109/678 (16,1)	3/649 (0,5)	34,78 [11,10; 108,96] <,0001[2]	41,25 [13,03; 130,61] <,0001[3]	15,6 [12,8; 18,4] <,0001[3]
Asien	81/203 (39,9)	3/201 (1,5)	26,73 [8,59; 83,23] <,0001[2]	43,82 [13,54; 141,78] <,0001[3]	38,4 [31,5; 45,4] <,0001[3]
Andere	69/402 (17,2)	2/414 (0,5)	35,53 [8,77; 143,96] <,0001[2]	42,68 [10,39; 175,40] <,0001[3]	16,7 [12,9; 20,4] <,0001[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,7394)					
< 20 mm	67/331 (20,2)	2/334 (0,6)	33,80 [8,35; 136,83] <,0001[2]	42,13 [10,23; 173,54] <,0001[3]	19,6 [15,2; 24,0] <,0001[3]
≥ 20 bis < 50 mm	126/646 (19,5)	5/653 (0,8)	25,47 [10,49; 61,85] <,0001[2]	31,40 [12,75; 77,33] <,0001[3]	18,7 [15,6; 21,9] <,0001[3]
≥ 50 mm	64/289 (22,1)	1/265 (0,4)	58,69 [8,20; 420,04] <,0001[2]	75,09 [10,33; 545,63] <,0001[3]	21,8 [16,9; 26,6] <,0001[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,6623)					
0-3	88/427 (20,6)	2/418 (0,5)	43,07 [10,67; 173,81] <,0001[2]	53,99 [13,20; 220,91] <,0001[3]	20,1 [16,2; 24,0] <,0001[3]
4-9	110/549 (20,0)	3/542 (0,6)	36,20 [11,57; 113,27] <,0001[2]	45,02 [14,20; 142,72] <,0001[3]	19,5 [16,1; 22,9] <,0001[3]
≥ 10	61/307 (19,9)	3/304 (1,0)	20,13 [6,39; 63,47] <,0001[2]	24,88 [7,71; 80,26] <,0001[3]	18,9 [14,3; 23,5] <,0001[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Tumorstadium (p-Wert des Interaktionsterms: 0,4752)					
IIA	20/113 (17,7)	0/114 (0,0)	41,36 [2,53; 675,69] 0,0090[2]	50,21 [3,00; 841,23] <,0001[3]	17,7 [10,7; 24,7] <,0001[3]
IIB	36/151 (23,8)	1/136 (0,7)	32,42 [4,51; 233,30] 0,0006[2]	42,26 [5,71; 313,05] <,0001[3]	23,1 [16,2; 30,1] <,0001[3]
IIIA	99/495 (20,0)	1/488 (0,2)	97,60 [13,67; 696,97] <,0001[2]	121,75 [16,91; 876,79] <,0001[3]	19,8 [16,2; 23,3] <,0001[3]
IIIB	9/54 (16,7)	1/45 (2,2)	7,50 [0,99; 56,98] 0,0515[2]	8,80 [1,07; 72,39] 0,0202[4]	14,4 [3,6; 25,3] 0,0202[4]
IIIC	94/468 (20,1)	5/479 (1,0)	19,24 [7,90; 46,88] <,0001[2]	23,83 [9,59; 59,17] <,0001[3]	19,0 [15,3; 22,8] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,8734)					
G1	11/91 (12,1)	0/93 (0,0)	23,50 [1,41; 392,99] 0,0280[2]	26,71 [1,55; 460,48] 0,0005[3]	12,1 [5,4; 18,8] 0,0005[3]
G2	120/612 (19,6)	3/602 (0,5)	39,35 [12,58; 123,04] <,0001[2]	48,70 [15,39; 154,08] <,0001[3]	19,1 [15,9; 22,3] <,0001[3]
G3	115/527 (21,8)	4/506 (0,8)	27,60 [10,26; 74,24] <,0001[2]	35,03 [12,82; 95,73] <,0001[3]	21,0 [17,4; 24,6] <,0001[3]
GX	13/51 (25,5)	1/59 (1,7)	15,04 [2,04; 111,03] 0,0079[2]	19,84 [2,49; 157,98] 0,0002[3]	23,8 [11,4; 36,2] 0,0002[3]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9962)					
Negativ	41/156 (26,3)	0/169 (0,0)	89,87 [5,58; 1448,66] 0,0015[2]	121,81 [7,42; 1999,97] <,0001[3]	26,3 [19,4; 33,2] <,0001[3]
Positiv	216/1089 (19,8)	7/1066 (0,7)	30,21 [14,30; 63,81] <,0001[2]	37,43 [17,54; 79,88] <,0001[3]	19,2 [16,8; 21,6] <,0001[3]
Unbekannt	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Ethnizität (p-Wert des Interaktionsterms: 0,9940)					
Weiß	156/958 (16,3)	5/943 (0,5)	30,71 [12,66; 74,48] <,0001[2]	36,49 [14,90; 89,34] <,0001[3]	15,8 [13,4; 18,1] <,0001[3]
Asiatisch	88/250 (35,2)	3/242 (1,2)	28,39 [9,11; 88,52] <,0001[2]	43,28 [13,46; 139,14] <,0001[3]	34,0 [27,9; 40,0] <,0001[3]
Andere	14/62 (22,6)	0/64 (0,0)	29,92 [1,82; 490,96] 0,0173[2]	38,57 [2,24; 662,55] <,0001[3]	22,6 [12,2; 33,0] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,6181)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	219/1070 (20,5)	6/1019 (0,6)	34,76 [15,52; 77,86] <,0001[2]	43,45 [19,21; 98,27] <,0001[3]	19,9 [17,4; 22,3] <,0001[3]
ECOG-PS 1	40/213 (18,8)	2/245 (0,8)	23,00 [5,63; 94,06] <,0001[2]	28,09 [6,70; 117,80] <,0001[3]	18,0 [12,6; 23,3] <,0001[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; PT: Preferred Term; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 125.2.2: Subgruppen - Unerwünschtes Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,4121)					
< 65 Jahre	447/918 (48,7)	345/936 (36,9)	1,32 [1,19; 1,47] <,0001[2]	1,63 [1,35; 1,96] <,0001[3]	11,8 [7,4; 16,3] <,0001[3]
≥ 65 Jahre	160/365 (43,8)	119/328 (36,3)	1,21 [1,00; 1,45] 0,0445[2]	1,37 [1,01; 1,86] 0,0429[3]	7,6 [0,3; 14,8] 0,0429[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,5060)					
Neoadjuvante Chemotherapie	203/430 (47,2)	142/415 (34,2)	1,38 [1,17; 1,63] 0,0002[2]	1,72 [1,30; 2,27] 0,0001[3]	13,0 [6,4; 19,6] 0,0001[3]
Adjuvante Chemotherapie	374/784 (47,7)	297/768 (38,7)	1,23 [1,10; 1,38] 0,0004[2]	1,45 [1,18; 1,77] 0,0003[3]	9,0 [4,1; 13,9] 0,0003[3]
Keine Chemotherapie	30/69 (43,5)	25/81 (30,9)	1,41 [0,92; 2,15] 0,1120[2]	1,72 [0,88; 3,37] 0,1101[3]	12,6 [-2,8; 28,0] 0,1101[3]
Region (p-Wert des Interaktionsterms: 0,0671)					
Nordamerika / Europa	352/678 (51,9)	270/649 (41,6)	1,25 [1,11; 1,40] 0,0002[2]	1,52 [1,22; 1,88] 0,0002[3]	10,3 [5,0; 15,7] 0,0002[3]
Asien	102/203 (50,2)	92/201 (45,8)	1,10 [0,90; 1,35] 0,3688[2]	1,20 [0,81; 1,77] 0,3680[3]	4,5 [-5,3; 14,2] 0,3680[3]
Andere	153/402 (38,1)	102/414 (24,6)	1,54 [1,25; 1,91] <,0001[2]	1,88 [1,39; 2,54] <,0001[3]	13,4 [7,1; 19,7] <,0001[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,2662)					
< 20 mm	156/331 (47,1)	107/334 (32,0)	1,47 [1,21; 1,79] <,0001[2]	1,89 [1,38; 2,59] <,0001[3]	15,1 [7,7; 22,4] <,0001[3]
≥ 20 bis < 50 mm	285/646 (44,1)	238/653 (36,4)	1,21 [1,06; 1,38] 0,0050[2]	1,38 [1,10; 1,72] 0,0048[3]	7,7 [2,4; 13,0] 0,0048[3]
≥ 50 mm	158/289 (54,7)	112/265 (42,3)	1,29 [1,09; 1,54] 0,0041[2]	1,65 [1,18; 2,31] 0,0035[3]	12,4 [4,1; 20,7] 0,0035[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,9777)					
0-3	203/427 (47,5)	152/418 (36,4)	1,31 [1,11; 1,54] 0,0011[2]	1,59 [1,20; 2,09] 0,0010[3]	11,2 [4,6; 17,8] 0,0010[3]
4-9	254/549 (46,3)	196/542 (36,2)	1,28 [1,11; 1,48] 0,0008[2]	1,52 [1,19; 1,94] 0,0007[3]	10,1 [4,3; 15,9] 0,0007[3]
≥ 10	150/307 (48,9)	116/304 (38,2)	1,28 [1,07; 1,54] 0,0082[2]	1,55 [1,12; 2,14] 0,0076[3]	10,7 [2,9; 18,5] 0,0076[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Tumorstadium (p-Wert des Interaktionsterms: 0,8804)					
IIA	58/113 (51,3)	44/114 (38,6)	1,33 [0,99; 1,78] 0,0565[2]	1,68 [0,99; 2,84] 0,0539[3]	12,7 [-0,1; 25,6] 0,0539[3]
IIB	68/151 (45,0)	49/136 (36,0)	1,25 [0,94; 1,66] 0,1250[2]	1,45 [0,90; 2,34] 0,1212[3]	9,0 [-2,3; 20,3] 0,1212[3]
IIIA	237/495 (47,9)	171/488 (35,0)	1,37 [1,17; 1,59] <,0001[2]	1,70 [1,32; 2,20] <,0001[3]	12,8 [6,7; 18,9] <,0001[3]
IIIB	23/54 (42,6)	16/45 (35,6)	1,20 [0,73; 1,98] 0,4796[2]	1,34 [0,60; 3,04] 0,4755[3]	7,0 [-12,2; 26,3] 0,4755[3]
IIIC	219/468 (46,8)	183/479 (38,2)	1,22 [1,05; 1,42] 0,0078[2]	1,42 [1,10; 1,84] 0,0075[3]	8,6 [2,3; 14,9] 0,0075[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,6696)					
G1	42/91 (46,2)	27/93 (29,0)	1,59 [1,08; 2,34] 0,0191[2]	2,10 [1,14; 3,85] 0,0165[3]	17,1 [3,3; 30,9] 0,0165[3]
G2	291/612 (47,5)	224/602 (37,2)	1,28 [1,12; 1,46] 0,0003[2]	1,53 [1,22; 1,92] 0,0003[3]	10,3 [4,8; 15,9] 0,0003[3]
G3	247/527 (46,9)	190/506 (37,5)	1,25 [1,08; 1,44] 0,0026[2]	1,47 [1,14; 1,88] 0,0024[3]	9,3 [3,3; 15,3] 0,0024[3]
GX	26/51 (51,0)	21/59 (35,6)	1,43 [0,93; 2,22] 0,1064[2]	1,88 [0,88; 4,04] 0,1038[3]	15,4 [-3,0; 33,8] 0,1038[3]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6164)					
Negativ	78/156 (50,0)	71/169 (42,0)	1,19 [0,94; 1,51] 0,1494[2]	1,38 [0,89; 2,14] 0,1488[3]	8,0 [-2,8; 18,8] 0,1488[3]
Positiv	513/1089 (47,1)	378/1066 (35,5)	1,33 [1,20; 1,47] <,0001[2]	1,62 [1,36; 1,93] <,0001[3]	11,6 [7,5; 15,8] <,0001[3]
Unbekannt	6/10 (60,0)	4/7 (57,1)	1,05 [0,46; 2,38] 0,9068[2]	1,13 [0,16; 7,99] 1,0000[4]	2,9 [-44,7; 50,5] 1,0000[4]
Ethnizität (p-Wert des Interaktionsterms: 0,0799)					
Weiß	451/958 (47,1)	345/943 (36,6)	1,29 [1,16; 1,43] <,0001[2]	1,54 [1,28; 1,85] <,0001[3]	10,5 [6,1; 14,9] <,0001[3]
Asiatisch	117/250 (46,8)	96/242 (39,7)	1,18 [0,96; 1,45] 0,1122[2]	1,34 [0,94; 1,91] 0,1105[3]	7,1 [-1,6; 15,9] 0,1105[3]
Andere	32/62 (51,6)	15/64 (23,4)	2,20 [1,33; 3,65] 0,0021[2]	3,48 [1,62; 7,48] 0,0011[3]	28,2 [12,0; 44,4] 0,0011[3]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,9358)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Tamoxifen	63/114 (55,3)	57/132 (43,2)	1,28 [0,99; 1,65] 0,0590[2]	1,63 [0,98; 2,69] 0,0587[3]	12,1 [-0,4; 24,5] 0,0587[3]
Aromatase-Inhibitor	544/1169 (46,5)	407/1132 (36,0)	1,29 [1,17; 1,43] <,0001[2]	1,55 [1,31; 1,83] <,0001[3]	10,6 [6,6; 14,6] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,5846)					
ECOG-PS 0	504/1070 (47,1)	377/1019 (37,0)	1,27 [1,15; 1,41] <,0001[2]	1,52 [1,27; 1,81] <,0001[3]	10,1 [5,9; 14,3] <,0001[3]
ECOG-PS 1	103/213 (48,4)	87/245 (35,5)	1,36 [1,09; 1,69] 0,0056[2]	1,70 [1,17; 2,47] 0,0054[3]	12,8 [3,8; 21,8] 0,0054[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.

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Tabelle 126.2.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,6823)					
< 65 Jahre	46/918 (5,0)	25/936 (2,7)	1,88 [1,16; 3,03] 0,0099[2]	1,92 [1,17; 3,16] 0,0087[3]	2,3 [0,6; 4,1] 0,0087[3]
≥ 65 Jahre	25/365 (6,8)	10/328 (3,0)	2,25 [1,10; 4,61] 0,0271[2]	2,34 [1,11; 4,95] 0,0225[3]	3,8 [0,6; 7,0] 0,0225[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,2742)					
Neoadjuvante Chemotherapie	24/430 (5,6)	12/415 (2,9)	1,93 [0,98; 3,81] 0,0579[2]	1,99 [0,98; 4,02] 0,0529[3]	2,7 [-0,0; 5,4] 0,0529[3]
Adjuvante Chemotherapie	44/784 (5,6)	18/768 (2,3)	2,39 [1,40; 4,11] 0,0015[2]	2,48 [1,42; 4,33] 0,0010[3]	3,3 [1,3; 5,2] 0,0010[3]
Keine Chemotherapie	3/69 (4,3)	5/81 (6,2)	0,70 [0,17; 2,84] 0,6224[2]	0,69 [0,16; 3,00] 0,7264[4]	-1,8 [-8,9; 5,3] 0,7264[4]
Region (p-Wert des Interaktionsterms: 0,1753)					
Nordamerika / Europa	48/678 (7,1)	24/649 (3,7)	1,91 [1,19; 3,09] 0,0078[2]	1,98 [1,20; 3,28] 0,0066[3]	3,4 [1,0; 5,8] 0,0066[3]
Asien	7/203 (3,4)	7/201 (3,5)	0,99 [0,35; 2,77] 0,9850[2]	0,99 [0,34; 2,87] 0,9850[3]	-0,0 [-3,6; 3,5] 0,9850[3]
Andere	16/402 (4,0)	4/414 (1,0)	4,12 [1,39; 12,22] 0,0107[2]	4,25 [1,41; 12,82] 0,0054[3]	3,0 [0,9; 5,1] 0,0054[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,6632)					
0-3	27/427 (6,3)	15/418 (3,6)	1,76 [0,95; 3,26] 0,0718[2]	1,81 [0,95; 3,46] 0,0674[3]	2,7 [-0,2; 5,7] 0,0674[3]
4-9	22/549 (4,0)	12/542 (2,2)	1,81 [0,90; 3,62] 0,0935[2]	1,84 [0,90; 3,76] 0,0883[3]	1,8 [-0,3; 3,8] 0,0883[3]
≥ 10	22/307 (7,2)	8/304 (2,6)	2,72 [1,23; 6,02] 0,0133[2]	2,86 [1,25; 6,52] 0,0095[3]	4,5 [1,1; 7,9] 0,0095[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,5516)					
IIA	6/113 (5,3)	3/114 (2,6)	2,02 [0,52; 7,87] 0,3122[2]	2,07 [0,51; 8,51] 0,3327[4]	2,7 [-2,4; 7,8] 0,3327[4]
IIB	10/151 (6,6)	9/136 (6,6)	1,00 [0,42; 2,39] 0,9987[2]	1,00 [0,39; 2,54] 0,9987[3]	0,0 [-5,8; 5,8] 0,9987[3]
IIIA	25/495 (5,1)	10/488 (2,0)	2,46 [1,20; 5,08] 0,0144[2]	2,54 [1,21; 5,35] 0,0111[3]	3,0 [0,7; 5,3] 0,0111[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIB	2/54 (3,7)	1/45 (2,2)	1,67 [0,16; 17,79] 0,6724[2]	1,69 [0,15; 19,30] 1,0000[4]	1,5 [-5,1; 8,1] 1,0000[4]
IIIC	28/468 (6,0)	12/479 (2,5)	2,39 [1,23; 4,64] 0,0102[2]	2,48 [1,24; 4,93] 0,0078[3]	3,5 [0,9; 6,0] 0,0078[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,0891)					
G1	5/91 (5,5)	4/93 (4,3)	1,28 [0,35; 4,61] 0,7083[2]	1,29 [0,34; 4,98] 0,7457[4]	1,2 [-5,0; 7,4] 0,7457[4]
G2	35/612 (5,7)	9/602 (1,5)	3,83 [1,85; 7,89] 0,0003[2]	4,00 [1,90; 8,39] <,0001[3]	4,2 [2,1; 6,3] <,0001[3]
G3	27/527 (5,1)	21/506 (4,2)	1,23 [0,71; 2,15] 0,4586[2]	1,25 [0,70; 2,24] 0,4576[3]	1,0 [-1,6; 3,5] 0,4576[3]
GX	3/51 (5,9)	1/59 (1,7)	3,47 [0,37; 32,34] 0,2745[2]	3,63 [0,37; 35,99] 0,3349[4]	4,2 [-3,1; 11,4] 0,3349[4]
Ethnizität (p-Wert des Interaktionsterms: 0,8038)					
Weiß	56/958 (5,8)	28/943 (3,0)	1,97 [1,26; 3,07] 0,0028[2]	2,03 [1,28; 3,22] 0,0023[3]	2,9 [1,0; 4,7] 0,0023[3]
Asiatisch	10/250 (4,0)	7/242 (2,9)	1,38 [0,54; 3,57] 0,5035[2]	1,40 [0,52; 3,74] 0,5013[3]	1,1 [-2,1; 4,3] 0,5013[3]
Andere	5/62 (8,1)	0/64 (0,0)	11,35 [0,64; 201,02] 0,0976[2]	12,34 [0,67; 228,05] 0,0265[4]	8,1 [1,3; 14,8] 0,0265[4]
ECOG-PS (p-Wert des Interaktionsterms: 0,7773)					
ECOG-PS 0	55/1070 (5,1)	25/1019 (2,5)	2,10 [1,32; 3,34] 0,0018[2]	2,15 [1,33; 3,48] 0,0014[3]	2,7 [1,1; 4,3] 0,0014[3]
ECOG-PS 1	16/213 (7,5)	10/245 (4,1)	1,84 [0,85; 3,97] 0,1198[2]	1,91 [0,85; 4,30] 0,1136[3]	3,4 [-0,9; 7,8] 0,1136[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.

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Tabelle 127.2.2: Subgruppen - Schwerwiegendes unerwünschtes Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,5578)					
< 65 Jahre	45/918 (4,9)	24/936 (2,6)	1,91 [1,17; 3,11] 0,0091[2]	1,96 [1,18; 3,24] 0,0078[3]	2,3 [0,6; 4,1] 0,0078[3]
≥ 65 Jahre	25/365 (6,8)	9/328 (2,7)	2,50 [1,18; 5,27] 0,0164[2]	2,61 [1,20; 5,67] 0,0125[3]	4,1 [1,0; 7,2] 0,0125[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,1862)					
Neoadjuvante Chemotherapie	26/430 (6,0)	11/415 (2,7)	2,28 [1,14; 4,56] 0,0195[2]	2,36 [1,15; 4,85] 0,0159[3]	3,4 [0,7; 6,1] 0,0159[3]
Adjuvante Chemotherapie	43/784 (5,5)	18/768 (2,3)	2,34 [1,36; 4,02] 0,0021[2]	2,42 [1,38; 4,23] 0,0015[3]	3,1 [1,2; 5,1] 0,0015[3]
Keine Chemotherapie	1/69 (1,4)	4/81 (4,9)	0,29 [0,03; 2,56] 0,2677[2]	0,28 [0,03; 2,59] 0,3747[4]	-3,5 [-9,0; 2,0] 0,3747[4]
Region (p-Wert des Interaktionsterms: 0,1491)					
Nordamerika / Europa	43/678 (6,3)	24/649 (3,7)	1,72 [1,05; 2,79] 0,0302[2]	1,76 [1,06; 2,94] 0,0279[3]	2,6 [0,3; 5,0] 0,0279[3]
Asien	7/203 (3,4)	5/201 (2,5)	1,39 [0,45; 4,30] 0,5714[2]	1,40 [0,44; 4,49] 0,5695[3]	1,0 [-2,3; 4,3] 0,5695[3]
Andere	20/402 (5,0)	4/414 (1,0)	5,15 [1,78; 14,93] 0,0026[2]	5,37 [1,82; 15,84] 0,0007[3]	4,0 [1,7; 6,3] 0,0007[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7659)					
0-3	25/427 (5,9)	14/418 (3,3)	1,75 [0,92; 3,32] 0,0873[2]	1,79 [0,92; 3,50] 0,0826[3]	2,5 [-0,3; 5,3] 0,0826[3]
4-9	27/549 (4,9)	12/542 (2,2)	2,22 [1,14; 4,34] 0,0195[2]	2,28 [1,15; 4,56] 0,0162[3]	2,7 [0,5; 4,9] 0,0162[3]
≥ 10	18/307 (5,9)	7/304 (2,3)	2,55 [1,08; 6,01] 0,0329[2]	2,64 [1,09; 6,42] 0,0263[3]	3,6 [0,4; 6,7] 0,0263[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,1866)					
IIA	5/113 (4,4)	2/114 (1,8)	2,52 [0,50; 12,73] 0,2628[2]	2,59 [0,49; 13,65] 0,2803[4]	2,7 [-1,8; 7,2] 0,2803[4]
IIB	8/151 (5,3)	9/136 (6,6)	0,80 [0,32; 2,02] 0,6370[2]	0,79 [0,30; 2,11] 0,6363[3]	-1,3 [-6,8; 4,2] 0,6363[3]
IIIA	31/495 (6,3)	9/488 (1,8)	3,40 [1,63; 7,06] 0,0011[2]	3,56 [1,67; 7,55] 0,0005[3]	4,4 [2,0; 6,9] 0,0005[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIB	3/54 (5,6)	2/45 (4,4)	1,25 [0,22; 7,16] 0,8021[2]	1,26 [0,20; 7,92] 1,0000[4]	1,1 [-7,5; 9,7] 1,0000[4]
IIIC	23/468 (4,9)	11/479 (2,3)	2,14 [1,06; 4,34] 0,0350[2]	2,20 [1,06; 4,56] 0,0304[3]	2,6 [0,2; 5,0] 0,0304[3]
Ethnizität (p-Wert des Interaktionsterms: 0,9144)					
Weiß	56/958 (5,8)	27/943 (2,9)	2,04 [1,30; 3,20] 0,0019[2]	2,11 [1,32; 3,36] 0,0015[3]	3,0 [1,2; 4,8] 0,0015[3]
Asiatisch	10/250 (4,0)	6/242 (2,5)	1,61 [0,60; 4,37] 0,3469[2]	1,64 [0,59; 4,58] 0,3418[3]	1,5 [-1,6; 4,6] 0,3418[3]
Andere	4/62 (6,5)	0/64 (0,0)	9,29 [0,51; 168,95] 0,1322[2]	9,92 [0,52; 188,28] 0,0557[4]	6,5 [0,3; 12,6] 0,0557[4]
ECOG-PS (p-Wert des Interaktionsterms: 0,6915)					
ECOG-PS 0	53/1070 (5,0)	25/1019 (2,5)	2,02 [1,26; 3,22] 0,0032[2]	2,07 [1,28; 3,36] 0,0026[3]	2,5 [0,9; 4,1] 0,0026[3]
ECOG-PS 1	17/213 (8,0)	8/245 (3,3)	2,44 [1,08; 5,55] 0,0327[2]	2,57 [1,09; 6,08] 0,0267[3]	4,7 [0,5; 9,0] 0,0267[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.

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Tabelle 129.2.2: Subgruppen - Unerwünschtes Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,7077)					
Neoadjuvante Chemotherapie	352/430 (81,9)	38/415 (9,2)	8,94 [6,58; 12,14] <,0001[2]	44,77 [29,59; 67,74] <,0001[3]	72,7 [68,1; 77,3] <,0001[3]
Adjuvante Chemotherapie	652/784 (83,2)	68/768 (8,9)	9,39 [7,47; 11,81] <,0001[2]	50,85 [37,24; 69,42] <,0001[3]	74,3 [71,0; 77,6] <,0001[3]
Keine Chemotherapie	56/69 (81,2)	5/81 (6,2)	13,15 [5,58; 30,97] <,0001[2]	65,48 [22,07; 194,28] <,0001[3]	75,0 [64,4; 85,6] <,0001[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,4738)					
< 20 mm	272/331 (82,2)	27/334 (8,1)	10,17 [7,06; 14,64] <,0001[2]	52,42 [32,31; 85,03] <,0001[3]	74,1 [69,0; 79,1] <,0001[3]
≥ 20 bis < 50 mm	528/646 (81,7)	53/653 (8,1)	10,07 [7,76; 13,07] <,0001[2]	50,66 [35,89; 71,49] <,0001[3]	73,6 [70,0; 77,3] <,0001[3]
≥ 50 mm	248/289 (85,8)	29/265 (10,9)	7,84 [5,54; 11,09] <,0001[2]	49,22 [29,62; 81,80] <,0001[3]	74,9 [69,4; 80,4] <,0001[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7530)					
0-3	347/427 (81,3)	33/418 (7,9)	10,29 [7,40; 14,33] <,0001[2]	50,60 [32,90; 77,84] <,0001[3]	73,4 [68,9; 77,9] <,0001[3]
4-9	462/549 (84,2)	52/542 (9,6)	8,77 [6,76; 11,39] <,0001[2]	50,04 [34,69; 72,18] <,0001[3]	74,6 [70,6; 78,5] <,0001[3]
≥ 10	251/307 (81,8)	26/304 (8,6)	9,56 [6,59; 13,86] <,0001[2]	47,92 [29,20; 78,66] <,0001[3]	73,2 [67,9; 78,5] <,0001[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,3755)					
IIA	87/113 (77,0)	11/114 (9,6)	7,98 [4,51; 14,12] <,0001[2]	31,33 [14,65; 67,03] <,0001[3]	67,3 [57,9; 76,8] <,0001[3]
IIB	122/151 (80,8)	8/136 (5,9)	13,74 [6,98; 27,02] <,0001[2]	67,31 [29,61; 152,99] <,0001[3]	74,9 [67,5; 82,3] <,0001[3]
IIIA	422/495 (85,3)	39/488 (8,0)	10,67 [7,88; 14,45] <,0001[2]	66,55 [44,13; 100,37] <,0001[3]	77,3 [73,3; 81,2] <,0001[3]
IIIB	41/54 (75,9)	6/45 (13,3)	5,69 [2,66; 12,17] <,0001[2]	20,50 [7,09; 59,29] <,0001[3]	62,6 [47,5; 77,7] <,0001[3]
IIIC	387/468 (82,7)	46/479 (9,6)	8,61 [6,52; 11,37] <,0001[2]	44,97 [30,54; 66,22] <,0001[3]	73,1 [68,8; 77,4] <,0001[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,4036)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
G1	78/91 (85,7)	8/93 (8,6)	9,96 [5,11; 19,43] <,0001[2]	63,75 [25,08; 162,03] <,0001[3]	77,1 [67,9; 86,3] <,0001[3]
G2	516/612 (84,3)	57/602 (9,5)	8,90 [6,94; 11,43] <,0001[2]	51,39 [36,25; 72,87] <,0001[3]	74,8 [71,1; 78,6] <,0001[3]
G3	422/527 (80,1)	44/506 (8,7)	9,21 [6,92; 12,25] <,0001[2]	42,20 [28,98; 61,46] <,0001[3]	71,4 [67,2; 75,6] <,0001[3]
GX	42/51 (82,4)	1/59 (1,7)	48,59 [6,93; 340,64] <,0001[2]	270,67 [33,02; 2218,73] <,0001[3]	80,7 [69,7; 91,6] <,0001[3]
Ethnizität (p-Wert des Interaktionsterms: 0,0514)					
Weiß	792/958 (82,7)	93/943 (9,9)	8,38 [6,90; 10,19] <,0001[2]	43,61 [33,23; 57,22] <,0001[3]	72,8 [69,7; 75,9] <,0001[3]
Asiatisch	204/250 (81,6)	11/242 (4,5)	17,95 [10,05; 32,07] <,0001[2]	93,13 [46,98; 184,61] <,0001[3]	77,1 [71,6; 82,5] <,0001[3]
Andere	52/62 (83,9)	6/64 (9,4)	8,95 [4,14; 19,31] <,0001[2]	50,27 [17,09; 147,89] <,0001[3]	74,5 [62,9; 86,1] <,0001[3]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,3933)					
Tamoxifen	86/114 (75,4)	8/132 (6,1)	12,45 [6,31; 24,56] <,0001[2]	47,61 [20,71; 109,45] <,0001[3]	69,4 [60,5; 78,3] <,0001[3]
Aromatase-Inhibitor	974/1169 (83,3)	103/1132 (9,1)	9,16 [7,60; 11,03] <,0001[2]	49,90 [38,70; 64,35] <,0001[3]	74,2 [71,5; 76,9] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,5566)					
ECOG-PS 0	894/1070 (83,6)	93/1019 (9,1)	9,15 [7,53; 11,13] <,0001[2]	50,58 [38,70; 66,09] <,0001[3]	74,4 [71,6; 77,3] <,0001[3]
ECOG-PS 1	166/213 (77,9)	18/245 (7,3)	10,61 [6,76; 16,64] <,0001[2]	44,54 [24,96; 79,47] <,0001[3]	70,6 [64,1; 77,0] <,0001[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; PT: Preferred Term; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 130.2.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,6740)					
< 65 Jahre	77/918 (8,4)	1/936 (0,1)	78,51 [10,94; 563,28] <,0001[2]	85,61 [11,88; 616,84] <,0001[3]	8,3 [6,5; 10,1] <,0001[3]
≥ 65 Jahre	48/365 (13,2)	1/328 (0,3)	43,13 [5,99; 310,74] 0,0002[2]	49,51 [6,79; 360,88] <,0001[3]	12,8 [9,3; 16,4] <,0001[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9543)					
Neoadjuvante Chemotherapie	48/430 (11,2)	1/415 (0,2)	46,33 [6,42; 334,08] 0,0001[2]	52,02 [7,15; 378,72] <,0001[3]	10,9 [7,9; 13,9] <,0001[3]
Adjuvante Chemotherapie	73/784 (9,3)	1/768 (0,1)	71,51 [9,96; 513,20] <,0001[2]	78,75 [10,92; 568,07] <,0001[3]	9,2 [7,1; 11,2] <,0001[3]
Keine Chemotherapie	4/69 (5,8)	0/81 (0,0)	10,54 [0,58; 192,43] 0,1119[2]	11,20 [0,59; 211,78] 0,0427[4]	5,8 [0,3; 11,3] 0,0427[4]
Region (p-Wert des Interaktionsterms: 0,9994)					
Nordamerika / Europa	67/678 (9,9)	2/649 (0,3)	32,07 [7,89; 130,34] <,0001[2]	35,47 [8,65; 145,41] <,0001[3]	9,6 [7,3; 11,9] <,0001[3]
Asien	13/203 (6,4)	0/201 (0,0)	26,74 [1,60; 446,72] 0,0222[2]	28,56 [1,69; 483,76] 0,0003[3]	6,4 [3,0; 9,8] 0,0003[3]
Andere	45/402 (11,2)	0/414 (0,0)	93,71 [5,79; 1515,99] 0,0014[2]	105,51 [6,48; 1718,80] <,0001[3]	11,2 [8,1; 14,3] <,0001[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,7882)					
< 20 mm	27/331 (8,2)	0/334 (0,0)	55,50 [3,40; 906,05] 0,0048[2]	60,42 [3,67; 994,75] <,0001[3]	8,2 [5,2; 11,1] <,0001[3]
≥ 20 bis < 50 mm	68/646 (10,5)	1/653 (0,2)	68,74 [9,57; 493,54] <,0001[2]	76,71 [10,62; 554,17] <,0001[3]	10,4 [8,0; 12,8] <,0001[3]
≥ 50 mm	28/289 (9,7)	1/265 (0,4)	25,67 [3,52; 187,39] 0,0014[2]	28,32 [3,83; 209,69] <,0001[3]	9,3 [5,8; 12,8] <,0001[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,9946)					
0-3	51/427 (11,9)	1/418 (0,2)	49,93 [6,93; 359,61] 0,0001[2]	56,56 [7,78; 411,30] <,0001[3]	11,7 [8,6; 14,8] <,0001[3]
4-9	44/549 (8,0)	1/542 (0,2)	43,44 [6,01; 314,16] 0,0002[2]	47,14 [6,47; 343,39] <,0001[3]	7,8 [5,5; 10,1] <,0001[3]
≥ 10	30/307 (9,8)	0/304 (0,0)	60,41 [3,71; 983,42] 0,0040[2]	66,94 [4,07; 1099,81] <,0001[3]	9,8 [6,5; 13,1] <,0001[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Tumorstadium (p-Wert des Interaktionsterms: 0,9968)					
IIA	11/113 (9,7)	0/114 (0,0)	23,20 [1,38; 389,08] 0,0288[2]	25,69 [1,50; 441,49] 0,0006[3]	9,7 [4,3; 15,2] 0,0006[3]
IIB	16/151 (10,6)	0/136 (0,0)	29,74 [1,80; 491,08] 0,0177[2]	33,24 [1,97; 559,68] <,0001[3]	10,6 [5,7; 15,5] <,0001[3]
IIIA	35/495 (7,1)	1/488 (0,2)	34,51 [4,75; 250,87] 0,0005[2]	37,05 [5,06; 271,57] <,0001[3]	6,9 [4,6; 9,2] <,0001[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	60/468 (12,8)	1/479 (0,2)	61,41 [8,55; 441,29] <,0001[2]	70,29 [9,70; 509,45] <,0001[3]	12,6 [9,6; 15,7] <,0001[3]
Ethnizität (p-Wert des Interaktionsterms: 0,9998)					
Weiß	103/958 (10,8)	2/943 (0,2)	50,69 [12,55; 204,83] <,0001[2]	56,68 [13,94; 230,39] <,0001[3]	10,5 [8,6; 12,5] <,0001[3]
Asiatisch	14/250 (5,6)	0/242 (0,0)	28,08 [1,68; 468,05] 0,0202[2]	29,74 [1,76; 501,31] 0,0002[3]	5,6 [2,7; 8,5] 0,0002[3]
Andere	6/62 (9,7)	0/64 (0,0)	13,41 [0,77; 233,15] 0,0748[2]	14,84 [0,82; 269,32] 0,0125[4]	9,7 [2,3; 17,0] 0,0125[4]
ECOG-PS (p-Wert des Interaktionsterms: 0,9752)					
ECOG-PS 0	105/1070 (9,8)	2/1019 (0,2)	50,00 [12,37; 202,02] <,0001[2]	55,33 [13,62; 224,78] <,0001[3]	9,6 [7,8; 11,4] <,0001[3]
ECOG-PS 1	20/213 (9,4)	0/245 (0,0)	47,13 [2,87; 774,60] 0,0070[2]	52,02 [3,13; 865,51] <,0001[3]	9,4 [5,5; 13,3] <,0001[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; PT: Preferred Term; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 133.2.2: Subgruppen - Unerwünschtes Ereignis: Hepatische Ereignisse (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,9876)					
< 65 Jahre	170/918 (18,5)	119/936 (12,7)	1,46 [1,17; 1,81] 0,0006[2]	1,56 [1,21; 2,01] 0,0006[3]	5,8 [2,5; 9,1] 0,0006[3]
≥ 65 Jahre	63/365 (17,3)	39/328 (11,9)	1,45 [1,00; 2,10] 0,0486[2]	1,55 [1,00; 2,38] 0,0463[3]	5,4 [0,1; 10,6] 0,0463[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,5250)					
Neoadjuvante Chemotherapie	85/430 (19,8)	55/415 (13,3)	1,49 [1,09; 2,04] 0,0118[2]	1,61 [1,11; 2,33] 0,0109[3]	6,5 [1,5; 11,5] 0,0109[3]
Adjuvante Chemotherapie	133/784 (17,0)	95/768 (12,4)	1,37 [1,07; 1,75] 0,0111[2]	1,45 [1,09; 1,92] 0,0106[3]	4,6 [1,1; 8,1] 0,0106[3]
Keine Chemotherapie	15/69 (21,7)	8/81 (9,9)	2,20 [0,99; 4,88] 0,0520[2]	2,53 [1,00; 6,41] 0,0445[3]	11,9 [0,2; 23,6] 0,0445[3]
Region (p-Wert des Interaktionsterms: 0,0719)					
Nordamerika / Europa	87/678 (12,8)	53/649 (8,2)	1,57 [1,14; 2,17] 0,0063[2]	1,66 [1,15; 2,37] 0,0057[3]	4,7 [1,4; 7,9] 0,0057[3]
Asien	61/203 (30,0)	30/201 (14,9)	2,01 [1,36; 2,98] 0,0005[2]	2,45 [1,50; 4,00] 0,0003[3]	15,1 [7,1; 23,1] 0,0003[3]
Andere	85/402 (21,1)	75/414 (18,1)	1,17 [0,88; 1,54] 0,2767[2]	1,21 [0,86; 1,71] 0,2760[3]	3,0 [-2,4; 8,5] 0,2760[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,6027)					
< 20 mm	60/331 (18,1)	39/334 (11,7)	1,55 [1,07; 2,26] 0,0210[2]	1,67 [1,08; 2,59] 0,0195[3]	6,5 [1,1; 11,8] 0,0195[3]
≥ 20 bis < 50 mm	119/646 (18,4)	89/653 (13,6)	1,35 [1,05; 1,74] 0,0192[2]	1,43 [1,06; 1,93] 0,0185[3]	4,8 [0,8; 8,8] 0,0185[3]
≥ 50 mm	49/289 (17,0)	26/265 (9,8)	1,73 [1,11; 2,70] 0,0161[2]	1,88 [1,13; 3,12] 0,0141[3]	7,1 [1,5; 12,8] 0,0141[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,2558)					
0-3	76/427 (17,8)	40/418 (9,6)	1,86 [1,30; 2,66] 0,0007[2]	2,05 [1,36; 3,08] 0,0005[3]	8,2 [3,6; 12,8] 0,0005[3]
4-9	104/549 (18,9)	76/542 (14,0)	1,35 [1,03; 1,77] 0,0295[2]	1,43 [1,04; 1,98] 0,0285[3]	4,9 [0,5; 9,3] 0,0285[3]
≥ 10	53/307 (17,3)	42/304 (13,8)	1,25 [0,86; 1,81] 0,2411[2]	1,30 [0,84; 2,02] 0,2396[3]	3,4 [-2,3; 9,2] 0,2396[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Tumorstadium (p-Wert des Interaktionsterms: 0,7209)					
IIA	23/113 (20,4)	10/114 (8,8)	2,32 [1,16; 4,65] 0,0177[2]	2,66 [1,20; 5,88] 0,0133[3]	11,6 [2,5; 20,6] 0,0133[3]
IIB	21/151 (13,9)	14/136 (10,3)	1,35 [0,72; 2,55] 0,3534[2]	1,41 [0,69; 2,89] 0,3503[3]	3,6 [-3,9; 11,1] 0,3503[3]
IIIA	94/495 (19,0)	66/488 (13,5)	1,40 [1,05; 1,87] 0,0213[2]	1,50 [1,06; 2,11] 0,0203[3]	5,5 [0,9; 10,1] 0,0203[3]
IIIB	10/54 (18,5)	5/45 (11,1)	1,67 [0,61; 4,52] 0,3157[2]	1,82 [0,57; 5,78] 0,3061[3]	7,4 [-6,4; 21,3] 0,3061[3]
IIIC	84/468 (17,9)	63/479 (13,2)	1,36 [1,01; 1,84] 0,0428[2]	1,44 [1,01; 2,06] 0,0416[3]	4,8 [0,2; 9,4] 0,0416[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,1847)					
G1	14/91 (15,4)	11/93 (11,8)	1,30 [0,62; 2,71] 0,4832[2]	1,36 [0,58; 3,17] 0,4815[3]	3,6 [-6,3; 13,5] 0,4815[3]
G2	102/612 (16,7)	84/602 (14,0)	1,19 [0,92; 1,56] 0,1904[2]	1,23 [0,90; 1,69] 0,1894[3]	2,7 [-1,3; 6,8] 0,1894[3]
G3	103/527 (19,5)	53/506 (10,5)	1,87 [1,37; 2,54] <,0001[2]	2,08 [1,45; 2,97] <,0001[3]	9,1 [4,8; 13,4] <,0001[3]
GX	13/51 (25,5)	9/59 (15,3)	1,67 [0,78; 3,58] 0,1871[2]	1,90 [0,74; 4,91] 0,1808[3]	10,2 [-4,8; 25,3] 0,1808[3]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,7791)					
Negativ	27/156 (17,3)	22/169 (13,0)	1,33 [0,79; 2,23] 0,2822[2]	1,40 [0,76; 2,58] 0,2802[3]	4,3 [-3,5; 12,1] 0,2802[3]
Positiv	204/1089 (18,7)	133/1066 (12,5)	1,50 [1,23; 1,84] <,0001[2]	1,62 [1,28; 2,05] <,0001[3]	6,3 [3,2; 9,3] <,0001[3]
Unbekannt	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Ethnizität (p-Wert des Interaktionsterms: 0,2720)					
Weiß	156/958 (16,3)	118/943 (12,5)	1,30 [1,04; 1,62] 0,0198[2]	1,36 [1,05; 1,76] 0,0193[3]	3,8 [0,6; 6,9] 0,0193[3]
Asiatisch	62/250 (24,8)	32/242 (13,2)	1,88 [1,27; 2,77] 0,0015[2]	2,16 [1,35; 3,46] 0,0011[3]	11,6 [4,7; 18,4] 0,0011[3]
Andere	12/62 (19,4)	8/64 (12,5)	1,55 [0,68; 3,53] 0,2981[2]	1,68 [0,64; 4,44] 0,2925[3]	6,9 [-5,9; 19,6] 0,2925[3]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,4847)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Tamoxifen	9/114 (7,9)	5/132 (3,8)	2,08 [0,72; 6,04] 0,1762[2]	2,18 [0,71; 6,70] 0,1656[3]	4,1 [-1,8; 10,0] 0,1656[3]
Aromatase-Inhibitor	224/1169 (19,2)	153/1132 (13,5)	1,42 [1,17; 1,71] 0,0003[2]	1,52 [1,21; 1,90] 0,0003[3]	5,6 [2,6; 8,7] 0,0003[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,4080)					
ECOG-PS 0	199/1070 (18,6)	126/1019 (12,4)	1,50 [1,22; 1,85] 0,0001[2]	1,62 [1,27; 2,06] <,0001[3]	6,2 [3,1; 9,3] <,0001[3]
ECOG-PS 1	34/213 (16,0)	32/245 (13,1)	1,22 [0,78; 1,91] 0,3785[2]	1,26 [0,75; 2,13] 0,3779[3]	2,9 [-3,6; 9,4] 0,3779[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 134.2.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3: Hepatische Ereignisse aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,2672)					
< 65 Jahre	41/918 (4,5)	12/936 (1,3)	3,48 [1,84; 6,59] 0,0001[2]	3,60 [1,88; 6,89] <,0001[3]	3,2 [1,7; 4,7] <,0001[3]
≥ 65 Jahre	19/365 (5,2)	2/328 (0,6)	8,54 [2,00; 36,37] 0,0037[2]	8,95 [2,07; 38,73] 0,0004[3]	4,6 [2,2; 7,0] 0,0004[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,8675)					
Neoadjuvante Chemotherapie	25/430 (5,8)	5/415 (1,2)	4,83 [1,87; 12,49] 0,0012[2]	5,06 [1,92; 13,35] 0,0003[3]	4,6 [2,2; 7,1] 0,0003[3]
Adjuvante Chemotherapie	26/784 (3,3)	7/768 (0,9)	3,64 [1,59; 8,33] 0,0023[2]	3,73 [1,61; 8,64] 0,0010[3]	2,4 [1,0; 3,8] 0,0010[3]
Keine Chemotherapie	9/69 (13,0)	2/81 (2,5)	5,28 [1,18; 23,63] 0,0294[2]	5,93 [1,23; 28,44] 0,0133[3]	10,6 [1,9; 19,2] 0,0133[3]
Region (p-Wert des Interaktionsterms: 0,7625)					
Nordamerika / Europa	24/678 (3,5)	4/649 (0,6)	5,74 [2,00; 16,46] 0,0011[2]	5,92 [2,04; 17,15] 0,0002[3]	2,9 [1,4; 4,4] 0,0002[3]
Asien	16/203 (7,9)	4/201 (2,0)	3,96 [1,35; 11,64] 0,0123[2]	4,21 [1,38; 12,83] 0,0063[3]	5,9 [1,7; 10,1] 0,0063[3]
Andere	20/402 (5,0)	6/414 (1,4)	3,43 [1,39; 8,46] 0,0074[2]	3,56 [1,41; 8,96] 0,0041[3]	3,5 [1,1; 5,9] 0,0041[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,8143)					
< 20 mm	11/331 (3,3)	3/334 (0,9)	3,70 [1,04; 13,14] 0,0431[2]	3,79 [1,05; 13,72] 0,0294[3]	2,4 [0,2; 4,6] 0,0294[3]
≥ 20 bis < 50 mm	36/646 (5,6)	7/653 (1,1)	5,20 [2,33; 11,60] <,0001[2]	5,45 [2,41; 12,33] <,0001[3]	4,5 [2,6; 6,4] <,0001[3]
≥ 50 mm	11/289 (3,8)	3/265 (1,1)	3,36 [0,95; 11,92] 0,0604[2]	3,46 [0,95; 12,52] 0,0451[3]	2,7 [0,1; 5,2] 0,0451[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,1683)					
0-3	23/427 (5,4)	2/418 (0,5)	11,26 [2,67; 47,45] 0,0010[2]	11,84 [2,77; 50,55] <,0001[3]	4,9 [2,7; 7,1] <,0001[3]
4-9	21/549 (3,8)	5/542 (0,9)	4,15 [1,57; 10,92] 0,0040[2]	4,27 [1,60; 11,41] 0,0017[3]	2,9 [1,1; 4,7] 0,0017[3]
≥ 10	16/307 (5,2)	7/304 (2,3)	2,26 [0,94; 5,42] 0,0670[2]	2,33 [0,95; 5,75] 0,0589[3]	2,9 [-0,1; 5,9] 0,0589[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Tumorstadium (p-Wert des Interaktionsterms: 0,9233)					
IIA	3/113 (2,7)	1/114 (0,9)	3,03 [0,32; 28,66] 0,3343[2]	3,08 [0,32; 30,08] 0,3695[4]	1,8 [-1,6; 5,2] 0,3695[4]
IIB	6/151 (4,0)	1/136 (0,7)	5,40 [0,66; 44,32] 0,1161[2]	5,59 [0,66; 47,00] 0,1240[4]	3,2 [-0,2; 6,7] 0,1240[4]
IIIA	19/495 (3,8)	3/488 (0,6)	6,24 [1,86; 20,96] 0,0030[2]	6,45 [1,90; 21,95] 0,0006[3]	3,2 [1,4; 5,1] 0,0006[3]
IIIB	6/54 (11,1)	1/45 (2,2)	5,00 [0,62; 40,01] 0,1293[2]	5,50 [0,64; 47,51] 0,1226[4]	8,9 [-0,5; 18,3] 0,1226[4]
IIIC	26/468 (5,6)	8/479 (1,7)	3,33 [1,52; 7,27] 0,0026[2]	3,46 [1,55; 7,73] 0,0013[3]	3,9 [1,5; 6,3] 0,0013[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,3749)					
G1	4/91 (4,4)	0/93 (0,0)	9,20 [0,50; 168,39] 0,1348[2]	9,62 [0,51; 181,24] 0,0578[4]	4,4 [0,2; 8,6] 0,0578[4]
G2	27/612 (4,4)	11/602 (1,8)	2,41 [1,21; 4,82] 0,0125[2]	2,48 [1,22; 5,05] 0,0097[3]	2,6 [0,6; 4,5] 0,0097[3]
G3	26/527 (4,9)	3/506 (0,6)	8,32 [2,53; 27,32] 0,0005[2]	8,70 [2,62; 28,93] <,0001[3]	4,3 [2,4; 6,3] <,0001[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,1179)					
Negativ	7/156 (4,5)	2/169 (1,2)	3,79 [0,80; 17,98] 0,0933[2]	3,92 [0,80; 19,18] 0,0932[4]	3,3 [-0,3; 6,9] 0,0932[4]
Positiv	53/1089 (4,9)	12/1066 (1,1)	4,32 [2,32; 8,04] <,0001[2]	4,49 [2,39; 8,46] <,0001[3]	3,7 [2,3; 5,2] <,0001[3]
Unbekannt	0/10 (0,0)	0/7 (0,0)	NB	NB	NB
Ethnizität (p-Wert des Interaktionsterms: 0,6529)					
Weiß	38/958 (4,0)	7/943 (0,7)	5,34 [2,40; 11,91] <,0001[2]	5,52 [2,45; 12,43] <,0001[3]	3,2 [1,9; 4,6] <,0001[3]
Asiatisch	16/250 (6,4)	5/242 (2,1)	3,10 [1,15; 8,32] 0,0250[2]	3,24 [1,17; 8,99] 0,0174[3]	4,3 [0,8; 7,9] 0,0174[3]
Andere	6/62 (9,7)	2/64 (3,1)	3,10 [0,65; 14,76] 0,1560[2]	3,32 [0,64; 17,13] 0,1606[4]	6,6 [-2,0; 15,1] 0,1606[4]
ECOG-PS (p-Wert des Interaktionsterms: 0,7693)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	51/1070 (4,8)	12/1019 (1,2)	4,05 [2,17; 7,55] <,0001[2]	4,20 [2,23; 7,92] <,0001[3]	3,6 [2,2; 5,0] <,0001[3]
ECOG-PS 1	9/213 (4,2)	2/245 (0,8)	5,18 [1,13; 23,69] 0,0341[2]	5,36 [1,15; 25,09] 0,0175[3]	3,4 [0,5; 6,3] 0,0175[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 137.2.2: Subgruppen - Unerwünschtes Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,8761)					
Neoadjuvante Chemotherapie	15/430 (3,5)	4/415 (1,0)	3,62 [1,21; 10,81] 0,0213[2]	3,71 [1,22; 11,28] 0,0133[3]	2,5 [0,6; 4,5] 0,0133[3]
Adjuvante Chemotherapie	27/784 (3,4)	5/768 (0,7)	5,29 [2,05; 13,66] 0,0006[2]	5,44 [2,09; 14,21] 0,0001[3]	2,8 [1,4; 4,2] 0,0001[3]
Keine Chemotherapie	3/69 (4,3)	0/81 (0,0)	8,20 [0,43; 156,04] 0,1615[2]	8,58 [0,44; 169,04] 0,0950[4]	4,3 [-0,5; 9,2] 0,0950[4]
Region (p-Wert des Interaktionsterms: 0,7403)					
Nordamerika / Europa	25/678 (3,7)	7/649 (1,1)	3,42 [1,49; 7,85] 0,0037[2]	3,51 [1,51; 8,18] 0,0020[3]	2,6 [1,0; 4,2] 0,0020[3]
Asien	7/203 (3,4)	0/201 (0,0)	14,85 [0,85; 258,34] 0,0641[2]	15,38 [0,87; 271,14] 0,0148[4]	3,4 [0,9; 6,0] 0,0148[4]
Andere	13/402 (3,2)	2/414 (0,5)	6,69 [1,52; 29,48] 0,0119[2]	6,88 [1,54; 30,70] 0,0035[3]	2,8 [0,9; 4,6] 0,0035[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,6128)					
< 20 mm	10/331 (3,0)	3/334 (0,9)	3,36 [0,93; 12,11] 0,0635[2]	3,44 [0,94; 12,60] 0,0480[3]	2,1 [0,0; 4,2] 0,0480[3]
≥ 20 bis < 50 mm	27/646 (4,2)	4/653 (0,6)	6,82 [2,40; 19,39] 0,0003[2]	7,08 [2,46; 20,34] <,0001[3]	3,6 [1,9; 5,2] <,0001[3]
≥ 50 mm	7/289 (2,4)	2/265 (0,8)	3,21 [0,67; 15,31] 0,1436[2]	3,26 [0,67; 15,85] 0,1798[4]	1,7 [-0,4; 3,7] 0,1798[4]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,8545)					
0-3	14/427 (3,3)	2/418 (0,5)	6,85 [1,57; 29,97] 0,0106[2]	7,05 [1,59; 31,22] 0,0028[3]	2,8 [1,0; 4,6] 0,0028[3]
4-9	19/549 (3,5)	4/542 (0,7)	4,69 [1,61; 13,69] 0,0047[2]	4,82 [1,63; 14,27] 0,0017[3]	2,7 [1,0; 4,4] 0,0017[3]
≥ 10	12/307 (3,9)	3/304 (1,0)	3,96 [1,13; 13,90] 0,0316[2]	4,08 [1,14; 14,61] 0,0196[3]	2,9 [0,5; 5,4] 0,0196[3]
Tumorstadium (p-Wert des Interaktionsterms: 0,9986)					
IIA	4/113 (3,5)	1/114 (0,9)	4,04 [0,46; 35,55] 0,2089[2]	4,15 [0,46; 37,69] 0,2125[4]	2,7 [-1,2; 6,5] 0,2125[4]
IIB	5/151 (3,3)	0/136 (0,0)	9,91 [0,55; 177,65] 0,1192[2]	10,25 [0,56; 187,10] 0,0620[4]	3,3 [0,5; 6,2] 0,0620[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IIIA	20/495 (4,0)	4/488 (0,8)	4,93 [1,70; 14,32] 0,0034[2]	5,09 [1,73; 15,02] 0,0011[3]	3,2 [1,3; 5,1] 0,0011[3]
IIIB	1/54 (1,9)	0/45 (0,0)	2,51 [0,10; 60,13] 0,5703[2]	2,55 [0,10; 64,17] 1,0000[4]	1,9 [-1,7; 5,4] 1,0000[4]
IIIC	15/468 (3,2)	4/479 (0,8)	3,84 [1,28; 11,48] 0,0161[2]	3,93 [1,30; 11,94] 0,0093[3]	2,4 [0,6; 4,2] 0,0093[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,7764)					
G1	2/91 (2,2)	1/93 (1,1)	2,04 [0,19; 22,15] 0,5565[2]	2,07 [0,18; 23,21] 0,6189[4]	1,1 [-2,5; 4,8] 0,6189[4]
G2	25/612 (4,1)	6/602 (1,0)	4,10 [1,69; 9,92] 0,0018[2]	4,23 [1,72; 10,39] 0,0006[3]	3,1 [1,3; 4,8] 0,0006[3]
G3	17/527 (3,2)	2/506 (0,4)	8,16 [1,90; 35,14] 0,0048[2]	8,40 [1,93; 36,55] 0,0007[3]	2,8 [1,2; 4,4] 0,0007[3]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9607)					
Negativ	7/156 (4,5)	0/169 (0,0)	16,24 [0,94; 282,05] 0,0556[2]	17,01 [0,96; 300,29] 0,0055[4]	4,5 [1,2; 7,7] 0,0055[4]
Positiv	37/1089 (3,4)	8/1066 (0,8)	4,53 [2,12; 9,68] <,0001[2]	4,65 [2,16; 10,04] <,0001[3]	2,6 [1,5; 3,8] <,0001[3]
Unbekannt	0/10 (0,0)	0/7 (0,0)	NB	NB	NB
Ethnizität (p-Wert des Interaktionsterms: 0,2939)					
Weiß	34/958 (3,5)	6/943 (0,6)	5,58 [2,35; 13,22] <,0001[2]	5,75 [2,40; 13,75] <,0001[3]	2,9 [1,6; 4,2] <,0001[3]
Asiatisch	9/250 (3,6)	0/242 (0,0)	18,39 [1,08; 314,31] 0,0443[2]	19,08 [1,10; 329,63] 0,0037[4]	3,6 [1,3; 5,9] 0,0037[4]
Andere	2/62 (3,2)	2/64 (3,1)	1,03 [0,15; 7,10] 0,9743[2]	1,03 [0,14; 7,57] 1,0000[4]	0,1 [-6,0; 6,2] 1,0000[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,8769)					
Tamoxifen	5/114 (4,4)	1/132 (0,8)	5,79 [0,69; 48,83] 0,1065[2]	6,01 [0,69; 52,21] 0,0988[4]	3,6 [-0,4; 7,7] 0,0988[4]
Aromatase-Inhibitor	40/1169 (3,4)	8/1132 (0,7)	4,84 [2,28; 10,30] <,0001[2]	4,98 [2,32; 10,68] <,0001[3]	2,7 [1,6; 3,9] <,0001[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,8674)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
ECOG-PS 0	33/1070 (3,1)	6/1019 (0,6)	5,24 [2,20; 12,45] 0,0002[2]	5,37 [2,24; 12,88] <,0001[3]	2,5 [1,4; 3,6] <,0001[3]
ECOG-PS 1	12/213 (5,6)	3/245 (1,2)	4,60 [1,32; 16,09] 0,0169[2]	4,82 [1,34; 17,30] 0,0082[3]	4,4 [1,0; 7,8] 0,0082[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 138.2.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9628)					
Neoadjuvante Chemotherapie	5/430 (1,2)	0/415 (0,0)	10,62 [0,59; 191,41] 0,1093[2]	10,74 [0,59; 194,87] 0,0620[4]	1,2 [0,1; 2,2] 0,0620[4]
Adjuvante Chemotherapie	8/784 (1,0)	4/768 (0,5)	1,96 [0,59; 6,48] 0,2704[2]	1,97 [0,59; 6,57] 0,2613[3]	0,5 [-0,4; 1,4] 0,2613[3]
Keine Chemotherapie	2/69 (2,9)	0/81 (0,0)	5,86 [0,29; 119,97] 0,2512[2]	6,04 [0,28; 127,91] 0,2099[4]	2,9 [-1,1; 6,9] 0,2099[4]
Region (p-Wert des Interaktionsterms: 0,3049)					
Nordamerika / Europa	10/678 (1,5)	2/649 (0,3)	4,79 [1,05; 21,76] 0,0427[2]	4,84 [1,06; 22,19] 0,0248[3]	1,2 [0,2; 2,2] 0,0248[3]
Asien	4/203 (2,0)	0/201 (0,0)	8,91 [0,48; 164,45] 0,1414[2]	9,09 [0,49; 169,95] 0,1232[4]	2,0 [0,1; 3,9] 0,1232[4]
Andere	1/402 (0,2)	2/414 (0,5)	0,51 [0,05; 5,66] 0,5873[2]	0,51 [0,05; 5,69] 1,0000[4]	-0,2 [-1,1; 0,6] 1,0000[4]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,6674)					
< 20 mm	3/331 (0,9)	0/334 (0,0)	7,06 [0,37; 136,21] 0,1954[2]	7,13 [0,37; 138,53] 0,1228[4]	0,9 [-0,1; 1,9] 0,1228[4]
≥ 20 bis < 50 mm	11/646 (1,7)	3/653 (0,5)	3,71 [1,04; 13,22] 0,0435[2]	3,75 [1,04; 13,52] 0,0300[3]	1,2 [0,1; 2,4] 0,0300[3]
≥ 50 mm	1/289 (0,3)	1/265 (0,4)	0,92 [0,06; 14,59] 0,9510[2]	0,92 [0,06; 14,73] 1,0000[4]	-0,0 [-1,0; 1,0] 1,0000[4]
Tumorgrading (p-Wert des Interaktionsterms: 0,9996)					
G1	0/91 (0,0)	0/93 (0,0)	NB	NB	NB
G2	6/612 (1,0)	4/602 (0,7)	1,48 [0,42; 5,20] 0,5452[2]	1,48 [0,42; 5,27] 0,7530[4]	0,3 [-0,7; 1,3] 0,7530[4]
G3	9/527 (1,7)	0/506 (0,0)	18,24 [1,06; 312,64] 0,0452[2]	18,56 [1,08; 319,73] 0,0038[4]	1,7 [0,6; 2,8] 0,0038[4]
GX	0/51 (0,0)	0/59 (0,0)	NB	NB	NB
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9632)					
Negativ	3/156 (1,9)	0/169 (0,0)	7,58 [0,39; 145,58] 0,1792[2]	7,73 [0,40; 150,85] 0,1095[4]	1,9 [-0,2; 4,1] 0,1095[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Positiv	12/1089 (1,1)	3/1066 (0,3)	3,92 [1,11; 13,84] 0,0341[2]	3,95 [1,11; 14,03] 0,0220[3]	0,8 [0,1; 1,5] 0,0220[3]
Unbekannt	0/10 (0,0)	0/7 (0,0)	NB	NB	NB
Ethnizität (p-Wert des Interaktionsterms: 0,9813)					
Weiß	9/958 (0,9)	4/943 (0,4)	2,21 [0,68; 7,17] 0,1845[2]	2,23 [0,68; 7,25] 0,1729[3]	0,5 [-0,2; 1,3] 0,1729[3]
Asiatisch	6/250 (2,4)	0/242 (0,0)	12,59 [0,71; 222,20] 0,0838[2]	12,89 [0,72; 230,13] 0,0304[4]	2,4 [0,5; 4,3] 0,0304[4]
Andere	0/62 (0,0)	0/64 (0,0)	NB	NB	NB
ECOG-PS (p-Wert des Interaktionsterms: 0,9715)					
ECOG-PS 0	10/1070 (0,9)	4/1019 (0,4)	2,38 [0,75; 7,57] 0,1415[2]	2,39 [0,75; 7,66] 0,1291[3]	0,5 [-0,2; 1,2] 0,1291[3]
ECOG-PS 1	5/213 (2,3)	0/245 (0,0)	12,64 [0,70; 227,35] 0,0852[2]	12,95 [0,71; 235,61] 0,0212[4]	2,3 [0,3; 4,4] 0,0212[4]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 139.2.2: Subgruppen - Schwerwiegendes unerwünschtes Ereignis: Venöse Thromboembolie aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,5325)					
Neoadjuvante Chemotherapie	8/430 (1,9)	1/415 (0,2)	7,72 [0,97; 61,46] 0,0535[2]	7,85 [0,98; 63,03] 0,0383[4]	1,6 [0,3; 3,0] 0,0383[4]
Adjuvante Chemotherapie	8/784 (1,0)	4/768 (0,5)	1,96 [0,59; 6,48] 0,2704[2]	1,97 [0,59; 6,57] 0,2613[3]	0,5 [-0,4; 1,4] 0,2613[3]
Keine Chemotherapie	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Region (p-Wert des Interaktionsterms: 0,8110)					
Nordamerika / Europa	10/678 (1,5)	3/649 (0,5)	3,19 [0,88; 11,54] 0,0769[2]	3,22 [0,88; 11,77] 0,0612[3]	1,0 [-0,0; 2,1] 0,0612[3]
Asien	4/203 (2,0)	0/201 (0,0)	8,91 [0,48; 164,45] 0,1414[2]	9,09 [0,49; 169,95] 0,1232[4]	2,0 [0,1; 3,9] 0,1232[4]
Andere	3/402 (0,7)	2/414 (0,5)	1,54 [0,26; 9,20] 0,6328[2]	1,55 [0,26; 9,32] 0,6822[4]	0,3 [-0,8; 1,3] 0,6822[4]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,8627)					
< 20 mm	4/331 (1,2)	1/334 (0,3)	4,04 [0,45; 35,92] 0,2109[2]	4,07 [0,45; 36,64] 0,2152[4]	0,9 [-0,4; 2,2] 0,2152[4]
≥ 20 bis < 50 mm	11/646 (1,7)	3/653 (0,5)	3,71 [1,04; 13,22] 0,0435[2]	3,75 [1,04; 13,52] 0,0300[3]	1,2 [0,1; 2,4] 0,0300[3]
≥ 50 mm	2/289 (0,7)	1/265 (0,4)	1,83 [0,17; 20,11] 0,6196[2]	1,84 [0,17; 20,41] 1,0000[4]	0,3 [-0,9; 1,5] 1,0000[4]
Tumorstadium (p-Wert des Interaktionsterms: 0,8672)					
IIA	1/113 (0,9)	0/114 (0,0)	3,03 [0,12; 73,51] 0,4963[2]	3,05 [0,12; 75,75] 0,4978[4]	0,9 [-0,8; 2,6] 0,4978[4]
IIB	3/151 (2,0)	0/136 (0,0)	6,31 [0,33; 121,05] 0,2217[2]	6,43 [0,33; 125,70] 0,2494[4]	2,0 [-0,2; 4,2] 0,2494[4]
IIIA	5/495 (1,0)	3/488 (0,6)	1,64 [0,39; 6,84] 0,4949[2]	1,65 [0,39; 6,94] 0,7255[4]	0,4 [-0,7; 1,5] 0,7255[4]
IIIB	0/54 (0,0)	0/45 (0,0)	NB	NB	NB
IIIC	8/468 (1,7)	2/479 (0,4)	4,09 [0,87; 19,18] 0,0736[2]	4,15 [0,88; 19,64] 0,0613[4]	1,3 [-0,0; 2,6] 0,0613[4]
Tumorgrading (p-Wert des Interaktionsterms: 0,8468)					

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
G1	1/91 (1,1)	1/93 (1,1)	1,02 [0,06; 16,09] 0,9877[2]	1,02 [0,06; 16,59] 1,0000[4]	0,0 [-3,0; 3,0] 1,0000[4]
G2	10/612 (1,6)	4/602 (0,7)	2,46 [0,78; 7,80] 0,1265[2]	2,48 [0,77; 7,96] 0,1137[3]	1,0 [-0,2; 2,2] 0,1137[3]
G3	6/527 (1,1)	0/506 (0,0)	12,48 [0,71; 221,01] 0,0851[2]	12,63 [0,71; 224,71] 0,0310[4]	1,1 [0,2; 2,0] 0,0310[4]
GX	0/51 (0,0)	0/59 (0,0)	NB	NB	NB
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9644)					
Negativ	2/156 (1,3)	0/169 (0,0)	5,41 [0,26; 111,90] 0,2744[2]	5,49 [0,26; 115,15] 0,2296[4]	1,3 [-0,5; 3,0] 0,2296[4]
Positiv	15/1089 (1,4)	4/1066 (0,4)	3,67 [1,22; 11,02] 0,0205[2]	3,71 [1,23; 11,21] 0,0128[3]	1,0 [0,2; 1,8] 0,0128[3]
Unbekannt	0/10 (0,0)	0/7 (0,0)	NB	NB	NB
Ethnizität (p-Wert des Interaktionsterms: 0,9997)					
Weiß	11/958 (1,1)	4/943 (0,4)	2,71 [0,87; 8,47] 0,0871[2]	2,73 [0,87; 8,59] 0,0744[3]	0,7 [-0,1; 1,5] 0,0744[3]
Asiatisch	5/250 (2,0)	0/242 (0,0)	10,65 [0,59; 191,56] 0,1086[2]	10,87 [0,60; 197,57] 0,0614[4]	2,0 [0,3; 3,7] 0,0614[4]
Andere	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
ECOG-PS (p-Wert des Interaktionsterms: 0,9784)					
ECOG-PS 0	14/1070 (1,3)	4/1019 (0,4)	3,33 [1,10; 10,09] 0,0332[2]	3,36 [1,10; 10,25] 0,0236[3]	0,9 [0,1; 1,7] 0,0236[3]
ECOG-PS 1	3/213 (1,4)	1/245 (0,4)	3,45 [0,36; 32,93] 0,2818[2]	3,49 [0,36; 33,76] 0,3420[4]	1,0 [-0,8; 2,8] 0,3420[4]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 141.2.2: Subgruppen - Unerwünschtes Ereignis: ILD/Pneumonitis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,5506)					
< 65 Jahre	22/918 (2,4)	13/936 (1,4)	1,73 [0,87; 3,40] 0,1156[2]	1,74 [0,87; 3,48] 0,1110[3]	1,0 [-0,2; 2,2] 0,1110[3]
≥ 65 Jahre	9/365 (2,5)	3/328 (0,9)	2,70 [0,74; 9,87] 0,1343[2]	2,74 [0,74; 10,20] 0,1181[3]	1,6 [-0,3; 3,4] 0,1181[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,4119)					
Neoadjuvante Chemotherapie	12/430 (2,8)	9/415 (2,2)	1,29 [0,55; 3,02] 0,5626[2]	1,30 [0,54; 3,11] 0,5615[3]	0,6 [-1,5; 2,7] 0,5615[3]
Adjuvante Chemotherapie	18/784 (2,3)	6/768 (0,8)	2,94 [1,17; 7,36] 0,0214[2]	2,98 [1,18; 7,56] 0,0156[3]	1,5 [0,3; 2,7] 0,0156[3]
Keine Chemotherapie	1/69 (1,4)	1/81 (1,2)	1,17 [0,07; 18,42] 0,9091[2]	1,18 [0,07; 19,17] 1,0000[4]	0,2 [-3,5; 3,9] 1,0000[4]
Region (p-Wert des Interaktionsterms: 0,7985)					
Nordamerika / Europa	17/678 (2,5)	7/649 (1,1)	2,32 [0,97; 5,57] 0,0584[2]	2,36 [0,97; 5,73] 0,0509[3]	1,4 [0,0; 2,8] 0,0509[3]
Asien	9/203 (4,4)	6/201 (3,0)	1,49 [0,54; 4,10] 0,4447[2]	1,51 [0,53; 4,32] 0,4414[3]	1,4 [-2,2; 5,1] 0,4414[3]
Andere	5/402 (1,2)	3/414 (0,7)	1,72 [0,41; 7,13] 0,4574[2]	1,73 [0,41; 7,27] 0,4998[4]	0,5 [-0,8; 1,9] 0,4998[4]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3701)					
< 20 mm	8/331 (2,4)	2/334 (0,6)	4,04 [0,86; 18,87] 0,0761[2]	4,11 [0,87; 19,51] 0,0625[4]	1,8 [-0,0; 3,7] 0,0625[4]
≥ 20 bis < 50 mm	17/646 (2,6)	9/653 (1,4)	1,91 [0,86; 4,25] 0,1133[2]	1,93 [0,86; 4,37] 0,1068[3]	1,3 [-0,3; 2,8] 0,1068[3]
≥ 50 mm	4/289 (1,4)	4/265 (1,5)	0,92 [0,23; 3,63] 0,9017[2]	0,92 [0,23; 3,70] 1,0000[4]	-0,1 [-2,1; 1,9] 1,0000[4]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7854)					
0-3	12/427 (2,8)	6/418 (1,4)	1,96 [0,74; 5,17] 0,1749[2]	1,99 [0,74; 5,34] 0,1664[3]	1,4 [-0,6; 3,3] 0,1664[3]
4-9	7/549 (1,3)	5/542 (0,9)	1,38 [0,44; 4,33] 0,5784[2]	1,39 [0,44; 4,40] 0,5767[3]	0,4 [-0,9; 1,6] 0,5767[3]
≥ 10	12/307 (3,9)	5/304 (1,6)	2,38 [0,85; 6,66] 0,0999[2]	2,43 [0,85; 6,99] 0,0889[3]	2,3 [-0,3; 4,9] 0,0889[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Tumorstadium (p-Wert des Interaktionsterms: 0,8611)					
IIA	5/113 (4,4)	1/114 (0,9)	5,04 [0,60; 42,50] 0,1367[2]	5,23 [0,60; 45,51] 0,1192[4]	3,5 [-0,6; 7,7] 0,1192[4]
IIB	4/151 (2,6)	3/136 (2,2)	1,20 [0,27; 5,27] 0,8083[2]	1,21 [0,27; 5,49] 1,0000[4]	0,4 [-3,1; 4,0] 1,0000[4]
IIIA	6/495 (1,2)	4/488 (0,8)	1,48 [0,42; 5,21] 0,5425[2]	1,48 [0,42; 5,29] 0,7527[4]	0,4 [-0,9; 1,6] 0,7527[4]
IIIB	0/54 (0,0)	0/45 (0,0)	NB	NB	NB
IIIC	15/468 (3,2)	8/479 (1,7)	1,92 [0,82; 4,48] 0,1322[2]	1,95 [0,82; 4,64] 0,1250[3]	1,5 [-0,4; 3,5] 0,1250[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,9819)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	12/612 (2,0)	8/602 (1,3)	1,48 [0,61; 3,58] 0,3903[2]	1,49 [0,60; 3,66] 0,3872[3]	0,6 [-0,8; 2,1] 0,3872[3]
G3	14/527 (2,7)	7/506 (1,4)	1,92 [0,78; 4,72] 0,1549[2]	1,95 [0,78; 4,86] 0,1472[3]	1,3 [-0,4; 3,0] 0,1472[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,3966)					
Negativ	4/156 (2,6)	2/169 (1,2)	2,17 [0,40; 11,66] 0,3680[2]	2,20 [0,40; 12,17] 0,4323[4]	1,4 [-1,6; 4,3] 0,4323[4]
Positiv	27/1089 (2,5)	14/1066 (1,3)	1,89 [1,00; 3,58] 0,0516[2]	1,91 [1,00; 3,66] 0,0476[3]	1,2 [0,0; 2,3] 0,0476[3]
Unbekannt	0/10 (0,0)	0/7 (0,0)	NB	NB	NB
Ethnizität (p-Wert des Interaktionsterms: 0,7144)					
Weiß	19/958 (2,0)	8/943 (0,8)	2,34 [1,03; 5,31] 0,0427[2]	2,36 [1,03; 5,43] 0,0365[3]	1,1 [0,1; 2,2] 0,0365[3]
Asiatisch	10/250 (4,0)	7/242 (2,9)	1,38 [0,54; 3,57] 0,5035[2]	1,40 [0,52; 3,74] 0,5013[3]	1,1 [-2,1; 4,3] 0,5013[3]
Andere	2/62 (3,2)	0/64 (0,0)	5,16 [0,25; 105,34] 0,2864[2]	5,33 [0,25; 113,30] 0,2401[4]	3,2 [-1,2; 7,6] 0,2401[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,2478)					
Tamoxifen	3/114 (2,6)	4/132 (3,0)	0,87 [0,20; 3,80] 0,8514[2]	0,86 [0,19; 3,95] 1,0000[4]	-0,4 [-4,5; 3,7] 1,0000[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Aromatase-Inhibitor	28/1169 (2,4)	12/1132 (1,1)	2,26 [1,15; 4,42] 0,0173[2]	2,29 [1,16; 4,53] 0,0143[3]	1,3 [0,3; 2,4] 0,0143[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,2849)					
ECOG-PS 0	25/1070 (2,3)	10/1019 (1,0)	2,38 [1,15; 4,93] 0,0196[2]	2,41 [1,15; 5,05] 0,0159[3]	1,4 [0,3; 2,4] 0,0159[3]
ECOG-PS 1	6/213 (2,8)	6/245 (2,4)	1,15 [0,38; 3,51] 0,8059[2]	1,15 [0,37; 3,63] 0,8058[3]	0,4 [-2,6; 3,3] 0,8058[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; ILD: Interstitial Lung Disease; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 145.2.2: Subgruppen - Unerwünschtes Ereignis: Erkrankungen der Nieren und Harnwege (SOC) (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Alter (p-Wert des Interaktionsterms: 0,6782)					
< 65 Jahre	63/918 (6,9)	46/936 (4,9)	1,40 [0,97; 2,02] 0,0762[2]	1,43 [0,96; 2,11] 0,0746[3]	1,9 [-0,2; 4,1] 0,0746[3]
≥ 65 Jahre	39/365 (10,7)	22/328 (6,7)	1,59 [0,97; 2,63] 0,0684[2]	1,66 [0,96; 2,87] 0,0650[3]	4,0 [-0,2; 8,1] 0,0650[3]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,2380)					
Neoadjuvante Chemotherapie	31/430 (7,2)	15/415 (3,6)	1,99 [1,09; 3,64] 0,0245[2]	2,07 [1,10; 3,90] 0,0213[3]	3,6 [0,6; 6,6] 0,0213[3]
Adjuvante Chemotherapie	62/784 (7,9)	49/768 (6,4)	1,24 [0,86; 1,78] 0,2440[2]	1,26 [0,85; 1,86] 0,2429[3]	1,5 [-1,0; 4,1] 0,2429[3]
Keine Chemotherapie	9/69 (13,0)	4/81 (4,9)	2,64 [0,85; 8,20] 0,0930[2]	2,89 [0,85; 9,83] 0,0787[3]	8,1 [-1,1; 17,3] 0,0787[3]
Region (p-Wert des Interaktionsterms: 0,7533)					
Nordamerika / Europa	64/678 (9,4)	42/649 (6,5)	1,46 [1,00; 2,12] 0,0479[2]	1,51 [1,00; 2,26] 0,0462[3]	3,0 [0,1; 5,9] 0,0462[3]
Asien	13/203 (6,4)	11/201 (5,5)	1,17 [0,54; 2,55] 0,6925[2]	1,18 [0,52; 2,70] 0,6921[3]	0,9 [-3,7; 5,5] 0,6921[3]
Andere	25/402 (6,2)	15/414 (3,6)	1,72 [0,92; 3,21] 0,0904[2]	1,76 [0,92; 3,40] 0,0860[3]	2,6 [-0,4; 5,6] 0,0860[3]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,1276)					
< 20 mm	31/331 (9,4)	14/334 (4,2)	2,23 [1,21; 4,12] 0,0101[2]	2,36 [1,23; 4,53] 0,0079[3]	5,2 [1,4; 9,0] 0,0079[3]
≥ 20 bis < 50 mm	47/646 (7,3)	43/653 (6,6)	1,10 [0,74; 1,65] 0,6243[2]	1,11 [0,73; 1,71] 0,6241[3]	0,7 [-2,1; 3,5] 0,6241[3]
≥ 50 mm	22/289 (7,6)	11/265 (4,2)	1,83 [0,91; 3,71] 0,0915[2]	1,90 [0,90; 4,00] 0,0855[3]	3,5 [-0,4; 7,3] 0,0855[3]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,4969)					
0-3	31/427 (7,3)	26/418 (6,2)	1,17 [0,71; 1,93] 0,5473[2]	1,18 [0,69; 2,02] 0,5468[3]	1,0 [-2,3; 4,4] 0,5468[3]
4-9	45/549 (8,2)	28/542 (5,2)	1,59 [1,01; 2,50] 0,0475[2]	1,64 [1,01; 2,67] 0,0452[3]	3,0 [0,1; 6,0] 0,0452[3]
≥ 10	26/307 (8,5)	14/304 (4,6)	1,84 [0,98; 3,45] 0,0581[2]	1,92 [0,98; 3,75] 0,0535[3]	3,9 [-0,0; 7,8] 0,0535[3]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Tumorstadium (p-Wert des Interaktionsterms: 0,2382)					
IIA	11/113 (9,7)	5/114 (4,4)	2,22 [0,80; 6,18] 0,1272[2]	2,35 [0,79; 7,00] 0,1155[3]	5,3 [-1,3; 12,0] 0,1155[3]
IIB	10/151 (6,6)	10/136 (7,4)	0,90 [0,39; 2,10] 0,8083[2]	0,89 [0,36; 2,22] 0,8083[3]	-0,7 [-6,6; 5,2] 0,8083[3]
IIIA	38/495 (7,7)	24/488 (4,9)	1,56 [0,95; 2,56] 0,0782[2]	1,61 [0,95; 2,72] 0,0752[3]	2,8 [-0,3; 5,8] 0,0752[3]
IIIB	1/54 (1,9)	4/45 (8,9)	0,21 [0,02; 1,80] 0,1537[2]	0,19 [0,02; 1,80] 0,1738[4]	-7,0 [-16,1; 2,0] 0,1738[4]
IIIC	42/468 (9,0)	25/479 (5,2)	1,72 [1,07; 2,77] 0,0264[2]	1,79 [1,07; 2,99] 0,0242[3]	3,8 [0,5; 7,0] 0,0242[3]
Tumorgrading (p-Wert des Interaktionsterms: 0,9972)					
G1	6/91 (6,6)	4/93 (4,3)	1,53 [0,45; 5,25] 0,4966[2]	1,57 [0,43; 5,76] 0,5339[4]	2,3 [-4,3; 8,8] 0,5339[4]
G2	45/612 (7,4)	30/602 (5,0)	1,48 [0,94; 2,31] 0,0888[2]	1,51 [0,94; 2,44] 0,0864[3]	2,4 [-0,3; 5,1] 0,0864[3]
G3	48/527 (9,1)	32/506 (6,3)	1,44 [0,94; 2,21] 0,0966[2]	1,48 [0,93; 2,36] 0,0942[3]	2,8 [-0,5; 6,0] 0,0942[3]
GX	3/51 (5,9)	2/59 (3,4)	1,74 [0,30; 9,98] 0,5369[2]	1,78 [0,29; 11,10] 0,6613[4]	2,5 [-5,4; 10,4] 0,6613[4]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,6585)					
Tamoxifen	6/114 (5,3)	6/132 (4,5)	1,16 [0,38; 3,49] 0,7946[2]	1,17 [0,37; 3,72] 0,7944[3]	0,7 [-4,7; 6,1] 0,7944[3]
Aromatase-Inhibitor	96/1169 (8,2)	62/1132 (5,5)	1,50 [1,10; 2,04] 0,0101[2]	1,54 [1,11; 2,15] 0,0095[3]	2,7 [0,7; 4,8] 0,0095[3]
ECOG-PS (p-Wert des Interaktionsterms: 0,5177)					
ECOG-PS 0	83/1070 (7,8)	56/1019 (5,5)	1,41 [1,02; 1,96] 0,0394[2]	1,45 [1,02; 2,05] 0,0382[3]	2,3 [0,1; 4,4] 0,0382[3]
ECOG-PS 1	19/213 (8,9)	12/245 (4,9)	1,82 [0,91; 3,66] 0,0928[2]	1,90 [0,90; 4,02] 0,0874[3]	4,0 [-0,7; 8,7] 0,0874[3]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_ae_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t145_bp_ae_saf3c1_posmp_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
30OCT2025 / 02:19

Tabelle 146.2.2: Subgruppen - Unerwünschtes Ereignis CTCAE Grad ≥ 3: Erkrankungen der Nieren und Harnwege (SOC) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Region (p-Wert des Interaktionsterms: 0,5905)					
Nordamerika / Europa	10/678 (1,5)	2/649 (0,3)	4,79 [1,05; 21,76] 0,0427[2]	4,84 [1,06; 22,19] 0,0248[3]	1,2 [0,2; 2,2] 0,0248[3]
Asien	2/203 (1,0)	1/201 (0,5)	1,98 [0,18; 21,67] 0,5757[2]	1,99 [0,18; 22,12] 1,0000[4]	0,5 [-1,2; 2,2] 1,0000[4]
Andere	1/402 (0,2)	1/414 (0,2)	1,03 [0,06; 16,41] 0,9834[2]	1,03 [0,06; 16,52] 1,0000[4]	0,0 [-0,7; 0,7] 1,0000[4]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,8618)					
< 20 mm	3/331 (0,9)	1/334 (0,3)	3,03 [0,32; 28,95] 0,3363[2]	3,05 [0,32; 29,43] 0,3716[4]	0,6 [-0,6; 1,8] 0,3716[4]
≥ 20 bis < 50 mm	8/646 (1,2)	2/653 (0,3)	4,04 [0,86; 18,97] 0,0765[2]	4,08 [0,86; 19,29] 0,0631[4]	0,9 [-0,0; 1,9] 0,0631[4]
≥ 50 mm	2/289 (0,7)	1/265 (0,4)	1,83 [0,17; 20,11] 0,6196[2]	1,84 [0,17; 20,41] 1,0000[4]	0,3 [-0,9; 1,5] 1,0000[4]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9998)					
Negativ	0/156 (0,0)	0/169 (0,0)	NB	NB	NB
Positiv	13/1089 (1,2)	4/1066 (0,4)	3,18 [1,04; 9,73] 0,0424[2]	3,21 [1,04; 9,87] 0,0318[3]	0,8 [0,1; 1,6] 0,0318[3]
Unbekannt	0/10 (0,0)	0/7 (0,0)	NB	NB	NB
Ethnizität (p-Wert des Interaktionsterms: 0,8444)					
Weiß	8/958 (0,8)	2/943 (0,2)	3,94 [0,84; 18,49] 0,0825[2]	3,96 [0,84; 18,71] 0,1086[4]	0,6 [-0,0; 1,3] 0,1086[4]
Asiatisch	2/250 (0,8)	1/242 (0,4)	1,94 [0,18; 21,21] 0,5886[2]	1,94 [0,18; 21,57] 1,0000[4]	0,4 [-1,0; 1,8] 1,0000[4]
Andere	2/62 (3,2)	1/64 (1,6)	2,06 [0,19; 22,19] 0,5497[2]	2,10 [0,19; 23,77] 0,6160[4]	1,7 [-3,7; 7,0] 0,6160[4]
ECOG-PS (p-Wert des Interaktionsterms: 0,9718)					
ECOG-PS 0	9/1070 (0,8)	4/1019 (0,4)	2,14 [0,66; 6,94] 0,2035[2]	2,15 [0,66; 7,01] 0,1925[3]	0,4 [-0,2; 1,1] 0,1925[3]
ECOG-PS 1	4/213 (1,9)	0/245 (0,0)	10,35 [0,56; 191,06] 0,1163[2]	10,55 [0,56; 197,03] 0,0461[4]	1,9 [0,1; 3,7] 0,0461[4]

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Datenschnitt: 15.07.2025 Safety-Population 1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test. Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; mm: Millimeter; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.					

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_ae_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t146_bp_ae_saf3c1_posmp_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Tabelle 147.2.2: Subgruppen - Schwerwiegendes unerwünschtes Ereignis: Erkrankungen der Nieren und Harnwege (SOC) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

Subgruppe	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9655)					
Negativ	1/156 (0,6)	0/169 (0,0)	3,25 [0,13; 79,16] 0,4696[2]	3,27 [0,13; 80,87] 0,4800[4]	0,6 [-0,6; 1,9] 0,4800[4]
Positiv	8/1089 (0,7)	4/1066 (0,4)	1,96 [0,59; 6,48] 0,2714[2]	1,96 [0,59; 6,54] 0,2623[3]	0,4 [-0,3; 1,0] 0,2623[3]
Unbekannt	0/10 (0,0)	0/7 (0,0)	NB	NB	NB
ECOG-PS (p-Wert des Interaktionsterms: 0,9728)					
ECOG-PS 0	7/1070 (0,7)	4/1019 (0,4)	1,67 [0,49; 5,68] 0,4140[2]	1,67 [0,49; 5,73] 0,4088[3]	0,3 [-0,4; 0,9] 0,4088[3]
ECOG-PS 1	2/213 (0,9)	0/245 (0,0)	5,75 [0,28; 119,06] 0,2581[2]	5,80 [0,28; 121,56] 0,2157[4]	0,9 [-0,4; 2,2] 0,2157[4]

Datenschnitt: 15.07.2025
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_ae_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/output/shared/tfl/german_dossier/gba3c1/t147_bp_ae_saf3c1_posmp_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Anhang 4-G2.4.5: Häufige unerwünschte Ereignisse nach SOC und PT

Table 057.1: Results from binary analysis for adverse events according PT - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Abdominal distension				
24/776 (3,1)	7/729 (1,0)	3,22 [1,40; 7,43] 0,0061[2]	3,29 [1,41; 7,69] 0,0036[3]	2,1 [0,7; 3,5] 0,0036[3]
Abdominal pain				
207/776 (26,7)	35/729 (4,8)	5,56 [3,94; 7,83] <,0001[2]	7,21 [4,96; 10,50] <,0001[3]	21,9 [18,4; 25,4] <,0001[3]
Abdominal pain upper				
97/776 (12,5)	25/729 (3,4)	3,65 [2,38; 5,59] <,0001[2]	4,02 [2,56; 6,32] <,0001[3]	9,1 [6,4; 11,7] <,0001[3]
Alanine aminotransferase increased				
85/776 (11,0)	38/729 (5,2)	2,10 [1,45; 3,04] <,0001[2]	2,24 [1,50; 3,33] <,0001[3]	5,7 [3,0; 8,5] <,0001[3]
Alopecia				
73/776 (9,4)	13/729 (1,8)	5,28 [2,95; 9,43] <,0001[2]	5,72 [3,14; 10,41] <,0001[3]	7,6 [5,4; 9,9] <,0001[3]
Anaemia				
159/776 (20,5)	30/729 (4,1)	4,98 [3,42; 7,26] <,0001[2]	6,00 [4,01; 9,00] <,0001[3]	16,4 [13,2; 19,6] <,0001[3]
Anxiety				
31/776 (4,0)	37/729 (5,1)	0,79 [0,49; 1,25] 0,3144[2]	0,78 [0,48; 1,27] 0,3131[3]	-1,1 [-3,2; 1,0] 0,3131[3]
Arthralgia				
171/776 (22,0)	227/729 (31,1)	0,71 [0,60; 0,84] <,0001[2]	0,63 [0,50; 0,79] <,0001[3]	-9,1 [-13,6; -4,7] <,0001[3]
Aspartate aminotransferase increased				
90/776 (11,6)	32/729 (4,4)	2,64 [1,79; 3,90] <,0001[2]	2,86 [1,88; 4,34] <,0001[3]	7,2 [4,5; 9,9] <,0001[3]
Asthenia				
77/776 (9,9)	33/729 (4,5)	2,19 [1,48; 3,25] <,0001[2]	2,32 [1,52; 3,54] <,0001[3]	5,4 [2,8; 8,0] <,0001[3]
Axillary pain				
11/776 (1,4)	8/729 (1,1)	1,29 [0,52; 3,19] 0,5794[2]	1,30 [0,52; 3,24] 0,5783[3]	0,3 [-0,8; 1,4] 0,5783[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Back pain				
83/776 (10,7)	91/729 (12,5)	0,86 [0,65; 1,13] 0,2791[2]	0,84 [0,61; 1,15] 0,2786[3]	-1,8 [-5,0; 1,5] 0,2786[3]
Blood alkaline phosphatase increased				
25/776 (3,2)	13/729 (1,8)	1,81 [0,93; 3,50] 0,0802[2]	1,83 [0,93; 3,61] 0,0755[3]	1,4 [-0,1; 3,0] 0,0755[3]
Blood cholesterol increased				
20/776 (2,6)	17/729 (2,3)	1,11 [0,58; 2,09] 0,7588[2]	1,11 [0,58; 2,13] 0,7587[3]	0,2 [-1,3; 1,8] 0,7587[3]
Blood creatinine increased				
71/776 (9,1)	3/729 (0,4)	22,23 [7,03; 70,27] <,0001[2]	24,37 [7,64; 77,73] <,0001[3]	8,7 [6,7; 10,8] <,0001[3]
Bone pain				
12/776 (1,5)	19/729 (2,6)	0,59 [0,29; 1,21] 0,1528[2]	0,59 [0,28; 1,22] 0,1480[3]	-1,1 [-2,5; 0,4] 0,1480[3]
Breast pain				
34/776 (4,4)	33/729 (4,5)	0,97 [0,61; 1,55] 0,8914[2]	0,97 [0,59; 1,58] 0,8914[3]	-0,1 [-2,2; 1,9] 0,8914[3]
Breast reconstruction				
11/776 (1,4)	10/729 (1,4)	1,03 [0,44; 2,42] 0,9397[2]	1,03 [0,44; 2,45] 0,9397[3]	0,0 [-1,1; 1,2] 0,9397[3]
COVID-19				
11/776 (1,4)	5/729 (0,7)	2,07 [0,72; 5,92] 0,1763[2]	2,08 [0,72; 6,02] 0,1666[3]	0,7 [-0,3; 1,8] 0,1666[3]
Cellulitis				
21/776 (2,7)	6/729 (0,8)	3,29 [1,33; 8,10] 0,0097[2]	3,35 [1,35; 8,35] 0,0059[3]	1,9 [0,6; 3,2] 0,0059[3]
Chest discomfort				
10/776 (1,3)	5/729 (0,7)	1,88 [0,65; 5,47] 0,2474[2]	1,89 [0,64; 5,56] 0,2394[3]	0,6 [-0,4; 1,6] 0,2394[3]
Chest pain				
14/776 (1,8)	8/729 (1,1)	1,64 [0,69; 3,90] 0,2587[2]	1,66 [0,69; 3,97] 0,2536[3]	0,7 [-0,5; 1,9] 0,2536[3]
Chills				
18/776 (2,3)	2/729 (0,3)	8,45 [1,97; 36,31] 0,0041[2]	8,63 [2,00; 37,33] 0,0005[3]	2,0 [0,9; 3,2] 0,0005[3]
Conjunctivitis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
15/776 (1,9)	5/729 (0,7)	2,82 [1,03; 7,72] 0,0437[2]	2,85 [1,03; 7,89] 0,0347[3]	1,2 [0,1; 2,4] 0,0347[3]
Constipation				
99/776 (12,8)	47/729 (6,4)	1,98 [1,42; 2,76] <,0001[2]	2,12 [1,48; 3,05] <,0001[3]	6,3 [3,4; 9,3] <,0001[3]
Contusion				
11/776 (1,4)	11/729 (1,5)	0,94 [0,41; 2,15] 0,8827[2]	0,94 [0,40; 2,18] 0,8826[3]	-0,1 [-1,3; 1,1] 0,8826[3]
Cough				
90/776 (11,6)	42/729 (5,8)	2,01 [1,42; 2,86] <,0001[2]	2,15 [1,47; 3,14] <,0001[3]	5,8 [3,0; 8,7] <,0001[3]
Cystitis				
22/776 (2,8)	11/729 (1,5)	1,88 [0,92; 3,85] 0,0846[2]	1,90 [0,92; 3,96] 0,0791[3]	1,3 [-0,1; 2,8] 0,0791[3]
Decreased appetite				
70/776 (9,0)	10/729 (1,4)	6,58 [3,42; 12,66] <,0001[2]	7,13 [3,65; 13,94] <,0001[3]	7,6 [5,5; 9,8] <,0001[3]
Depression				
34/776 (4,4)	24/729 (3,3)	1,33 [0,80; 2,22] 0,2745[2]	1,35 [0,79; 2,29] 0,2726[3]	1,1 [-0,8; 3,0] 0,2726[3]
Diarrhoea				
642/776 (82,7)	43/729 (5,9)	14,03 [10,48; 18,78] <,0001[2]	76,43 [53,33; 109,55] <,0001[3]	76,8 [73,7; 80,0] <,0001[3]
Dizziness				
74/776 (9,5)	49/729 (6,7)	1,42 [1,00; 2,01] 0,0479[2]	1,46 [1,00; 2,13] 0,0464[3]	2,8 [0,1; 5,6] 0,0464[3]
Dry eye				
26/776 (3,4)	12/729 (1,6)	2,04 [1,03; 4,00] 0,0395[2]	2,07 [1,04; 4,14] 0,0352[3]	1,7 [0,1; 3,3] 0,0352[3]
Dry mouth				
19/776 (2,4)	4/729 (0,5)	4,46 [1,53; 13,05] 0,0063[2]	4,55 [1,54; 13,44] 0,0027[3]	1,9 [0,7; 3,1] 0,0027[3]
Dry skin				
40/776 (5,2)	17/729 (2,3)	2,21 [1,26; 3,86] 0,0054[2]	2,28 [1,28; 4,05] 0,0041[3]	2,8 [0,9; 4,7] 0,0041[3]
Dysgeusia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
20/776 (2,6)	1/729 (0,1)	18,79 [2,53; 139,64] 0,0042[2]	19,26 [2,58; 143,87] <,0001[3]	2,4 [1,3; 3,6] <,0001[3]
Dyspepsia				
69/776 (8,9)	17/729 (2,3)	3,81 [2,26; 6,42] <,0001[2]	4,09 [2,38; 7,02] <,0001[3]	6,6 [4,3; 8,8] <,0001[3]
Dyspnoea				
43/776 (5,5)	17/729 (2,3)	2,38 [1,37; 4,13] 0,0021[2]	2,46 [1,39; 4,35] 0,0015[3]	3,2 [1,3; 5,2] 0,0015[3]
Dysuria				
11/776 (1,4)	11/729 (1,5)	0,94 [0,41; 2,15] 0,8827[2]	0,94 [0,40; 2,18] 0,8826[3]	-0,1 [-1,3; 1,1] 0,8826[3]
Eczema				
6/776 (0,8)	14/729 (1,9)	0,40 [0,16; 1,04] 0,0608[2]	0,40 [0,15; 1,04] 0,0521[3]	-1,1 [-2,3; 0,0] 0,0521[3]
Epistaxis				
10/776 (1,3)	1/729 (0,1)	9,39 [1,21; 73,20] 0,0325[2]	9,50 [1,21; 74,43] 0,0088[3]	1,2 [0,3; 2,0] 0,0088[3]
Erythema				
16/776 (2,1)	3/729 (0,4)	5,01 [1,47; 17,12] 0,0102[2]	5,09 [1,48; 17,56] 0,0042[3]	1,7 [0,5; 2,8] 0,0042[3]
Fall				
10/776 (1,3)	4/729 (0,5)	2,35 [0,74; 7,46] 0,1474[2]	2,37 [0,74; 7,58] 0,1351[3]	0,7 [-0,2; 1,7] 0,1351[3]
Fatigue				
202/776 (26,0)	86/729 (11,8)	2,21 [1,75; 2,78] <,0001[2]	2,63 [2,00; 3,47] <,0001[3]	14,2 [10,4; 18,1] <,0001[3]
Flatulence				
13/776 (1,7)	2/729 (0,3)	6,11 [1,38; 26,97] 0,0170[2]	6,19 [1,39; 27,54] 0,0063[3]	1,4 [0,4; 2,4] 0,0063[3]
Gamma-glutamyltransferase increased				
28/776 (3,6)	8/729 (1,1)	3,29 [1,51; 7,17] 0,0028[2]	3,37 [1,53; 7,45] 0,0014[3]	2,5 [1,0; 4,0] 0,0014[3]
Gastritis				
22/776 (2,8)	7/729 (1,0)	2,95 [1,27; 6,87] 0,0120[2]	3,01 [1,28; 7,09] 0,0082[3]	1,9 [0,5; 3,2] 0,0082[3]
Gastroenteritis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
17/776 (2,2)	8/729 (1,1)	2,00 [0,87; 4,60] 0,1043[2]	2,02 [0,87; 4,71] 0,0972[3]	1,1 [-0,2; 2,4] 0,0972[3]
Gastrooesophageal reflux disease				
18/776 (2,3)	11/729 (1,5)	1,54 [0,73; 3,23] 0,2568[2]	1,55 [0,73; 3,30] 0,2529[3]	0,8 [-0,6; 2,2] 0,2529[3]
Haemorrhoids				
28/776 (3,6)	11/729 (1,5)	2,39 [1,20; 4,77] 0,0133[2]	2,44 [1,21; 4,94] 0,0104[3]	2,1 [0,5; 3,7] 0,0104[3]
Headache				
156/776 (20,1)	128/729 (17,6)	1,14 [0,93; 1,41] 0,2081[2]	1,18 [0,91; 1,53] 0,2073[3]	2,5 [-1,4; 6,5] 0,2073[3]
Hepatic steatosis				
15/776 (1,9)	12/729 (1,6)	1,17 [0,55; 2,49] 0,6755[2]	1,18 [0,55; 2,53] 0,6752[3]	0,3 [-1,1; 1,6] 0,6752[3]
Herpes zoster				
9/776 (1,2)	10/729 (1,4)	0,85 [0,35; 2,07] 0,7132[2]	0,84 [0,34; 2,09] 0,7128[3]	-0,2 [-1,3; 0,9] 0,7128[3]
Hot flush				
132/776 (17,0)	174/729 (23,9)	0,71 [0,58; 0,87] 0,0010[2]	0,65 [0,51; 0,84] 0,0010[3]	-6,9 [-10,9; -2,8] 0,0010[3]
Hypercalcaemia				
11/776 (1,4)	5/729 (0,7)	2,07 [0,72; 5,92] 0,1763[2]	2,08 [0,72; 6,02] 0,1666[3]	0,7 [-0,3; 1,8] 0,1666[3]
Hyperglycaemia				
11/776 (1,4)	14/729 (1,9)	0,74 [0,34; 1,62] 0,4473[2]	0,73 [0,33; 1,63] 0,4455[3]	-0,5 [-1,8; 0,8] 0,4455[3]
Hypertension				
44/776 (5,7)	36/729 (4,9)	1,15 [0,75; 1,76] 0,5275[2]	1,16 [0,74; 1,82] 0,5271[3]	0,7 [-1,5; 3,0] 0,5271[3]
Hypertriglyceridaemia				
28/776 (3,6)	12/729 (1,6)	2,19 [1,12; 4,28] 0,0214[2]	2,24 [1,13; 4,43] 0,0180[3]	2,0 [0,4; 3,6] 0,0180[3]
Hyperuricaemia				
10/776 (1,3)	1/729 (0,1)	9,39 [1,21; 73,20] 0,0325[2]	9,50 [1,21; 74,43] 0,0088[3]	1,2 [0,3; 2,0] 0,0088[3]
Hypokalaemia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
25/776 (3,2)	6/729 (0,8)	3,91 [1,62; 9,49] 0,0025[2]	4,01 [1,64; 9,84] 0,0011[3]	2,4 [1,0; 3,8] 0,0011[3]
Hypothyroidism				
10/776 (1,3)	16/729 (2,2)	0,59 [0,27; 1,29] 0,1829[2]	0,58 [0,26; 1,29] 0,1776[3]	-0,9 [-2,2; 0,4] 0,1776[3]
Influenza				
43/776 (5,5)	35/729 (4,8)	1,15 [0,75; 1,78] 0,5179[2]	1,16 [0,74; 1,84] 0,5174[3]	0,7 [-1,5; 3,0] 0,5174[3]
Influenza like illness				
60/776 (7,7)	39/729 (5,3)	1,45 [0,98; 2,14] 0,0644[2]	1,48 [0,98; 2,25] 0,0625[3]	2,4 [-0,1; 4,9] 0,0625[3]
Insomnia				
80/776 (10,3)	71/729 (9,7)	1,06 [0,78; 1,43] 0,7131[2]	1,07 [0,76; 1,49] 0,7130[3]	0,6 [-2,5; 3,6] 0,7130[3]
Irritability				
4/776 (0,5)	10/729 (1,4)	0,38 [0,12; 1,19] 0,0968[2]	0,37 [0,12; 1,19] 0,0838[3]	-0,9 [-1,8; 0,1] 0,0838[3]
Lacrimation increased				
36/776 (4,6)	2/729 (0,3)	16,91 [4,09; 69,98] <,0001[2]	17,68 [4,24; 73,71] <,0001[3]	4,4 [2,8; 5,9] <,0001[3]
Leukopenia				
84/776 (10,8)	15/729 (2,1)	5,26 [3,07; 9,03] <,0001[2]	5,78 [3,30; 10,11] <,0001[3]	8,8 [6,4; 11,2] <,0001[3]
Libido decreased				
10/776 (1,3)	11/729 (1,5)	0,85 [0,36; 2,00] 0,7161[2]	0,85 [0,36; 2,02] 0,7158[3]	-0,2 [-1,4; 1,0] 0,7158[3]
Lymphocyte count decreased				
76/776 (9,8)	25/729 (3,4)	2,86 [1,84; 4,44] <,0001[2]	3,06 [1,92; 4,86] <,0001[3]	6,4 [3,9; 8,8] <,0001[3]
Lymphoedema				
105/776 (13,5)	67/729 (9,2)	1,47 [1,10; 1,97] 0,0088[2]	1,55 [1,12; 2,14] 0,0082[3]	4,3 [1,1; 7,5] 0,0082[3]
Lymphopenia				
33/776 (4,3)	13/729 (1,8)	2,38 [1,27; 4,49] 0,0072[2]	2,45 [1,28; 4,69] 0,0054[3]	2,5 [0,8; 4,2] 0,0054[3]
Malaise				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
30/776 (3,9)	11/729 (1,5)	2,56 [1,29; 5,07] 0,0070[2]	2,62 [1,31; 5,28] 0,0050[3]	2,4 [0,7; 4,0] 0,0050[3]
Mastitis				
10/776 (1,3)	10/729 (1,4)	0,94 [0,39; 2,24] 0,8882[2]	0,94 [0,39; 2,27] 0,8881[3]	-0,1 [-1,2; 1,1] 0,8881[3]
Memory impairment				
10/776 (1,3)	8/729 (1,1)	1,17 [0,47; 2,96] 0,7333[2]	1,18 [0,46; 3,00] 0,7330[3]	0,2 [-0,9; 1,3] 0,7330[3]
Mouth ulceration				
13/776 (1,7)	1/729 (0,1)	12,21 [1,60; 93,12] 0,0158[2]	12,40 [1,62; 95,06] 0,0019[3]	1,5 [0,6; 2,5] 0,0019[3]
Mucosal inflammation				
18/776 (2,3)	6/729 (0,8)	2,82 [1,12; 7,06] 0,0270[2]	2,86 [1,13; 7,25] 0,0205[3]	1,5 [0,3; 2,7] 0,0205[3]
Muscle spasms				
46/776 (5,9)	33/729 (4,5)	1,31 [0,85; 2,02] 0,2250[2]	1,33 [0,84; 2,10] 0,2232[3]	1,4 [-0,8; 3,6] 0,2232[3]
Musculoskeletal chest pain				
19/776 (2,4)	15/729 (2,1)	1,19 [0,61; 2,32] 0,6106[2]	1,19 [0,60; 2,37] 0,6101[3]	0,4 [-1,1; 1,9] 0,6101[3]
Myalgia				
50/776 (6,4)	45/729 (6,2)	1,04 [0,71; 1,54] 0,8293[2]	1,05 [0,69; 1,59] 0,8293[3]	0,3 [-2,2; 2,7] 0,8293[3]
Nail disorder				
18/776 (2,3)	2/729 (0,3)	8,45 [1,97; 36,31] 0,0041[2]	8,63 [2,00; 37,33] 0,0005[3]	2,0 [0,9; 3,2] 0,0005[3]
Nasopharyngitis				
97/776 (12,5)	67/729 (9,2)	1,36 [1,01; 1,83] 0,0407[2]	1,41 [1,02; 1,96] 0,0395[3]	3,3 [0,2; 6,4] 0,0395[3]
Nausea				
211/776 (27,2)	55/729 (7,5)	3,60 [2,73; 4,76] <,0001[2]	4,58 [3,33; 6,28] <,0001[3]	19,6 [16,0; 23,3] <,0001[3]
Neck pain				
20/776 (2,6)	11/729 (1,5)	1,71 [0,82; 3,54] 0,1499[2]	1,73 [0,82; 3,63] 0,1447[3]	1,1 [-0,4; 2,5] 0,1447[3]
Neuropathy peripheral				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
14/776 (1,8)	10/729 (1,4)	1,32 [0,59; 2,94] 0,5048[2]	1,32 [0,58; 2,99] 0,5034[3]	0,4 [-0,8; 1,7] 0,5034[3]
Neutropenia				
155/776 (20,0)	25/729 (3,4)	5,82 [3,86; 8,78] <,0001[2]	7,03 [4,54; 10,87] <,0001[3]	16,5 [13,4; 19,7] <,0001[3]
Neutrophil count decreased				
216/776 (27,8)	41/729 (5,6)	4,95 [3,60; 6,80] <,0001[2]	6,47 [4,55; 9,20] <,0001[3]	22,2 [18,6; 25,8] <,0001[3]
Night sweats				
11/776 (1,4)	8/729 (1,1)	1,29 [0,52; 3,19] 0,5794[2]	1,30 [0,52; 3,24] 0,5783[3]	0,3 [-0,8; 1,4] 0,5783[3]
Oedema				
13/776 (1,7)	3/729 (0,4)	4,07 [1,16; 14,23] 0,0279[2]	4,12 [1,17; 14,53] 0,0169[3]	1,3 [0,2; 2,3] 0,0169[3]
Oedema peripheral				
55/776 (7,1)	34/729 (4,7)	1,52 [1,00; 2,30] 0,0484[2]	1,56 [1,00; 2,42] 0,0464[3]	2,4 [0,1; 4,8] 0,0464[3]
Onychoclasis				
18/776 (2,3)	4/729 (0,5)	4,23 [1,44; 12,43] 0,0088[2]	4,30 [1,45; 12,78] 0,0042[3]	1,8 [0,6; 3,0] 0,0042[3]
Oropharyngeal pain				
40/776 (5,2)	23/729 (3,2)	1,63 [0,99; 2,70] 0,0557[2]	1,67 [0,99; 2,81] 0,0529[3]	2,0 [-0,0; 4,0] 0,0529[3]
Osteopenia				
12/776 (1,5)	4/729 (0,5)	2,82 [0,91; 8,70] 0,0716[2]	2,85 [0,91; 8,87] 0,0593[3]	1,0 [-0,0; 2,0] 0,0593[3]
Osteoporosis				
17/776 (2,2)	21/729 (2,9)	0,76 [0,40; 1,43] 0,3954[2]	0,76 [0,40; 1,44] 0,3939[3]	-0,7 [-2,3; 0,9] 0,3939[3]
Pain				
21/776 (2,7)	14/729 (1,9)	1,41 [0,72; 2,75] 0,3147[2]	1,42 [0,72; 2,82] 0,3121[3]	0,8 [-0,7; 2,3] 0,3121[3]
Pain in extremity				
75/776 (9,7)	75/729 (10,3)	0,94 [0,69; 1,27] 0,6868[2]	0,93 [0,67; 1,31] 0,6867[3]	-0,6 [-3,7; 2,4] 0,6867[3]
Palpitations				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
10/776 (1,3)	1/729 (0,1)	9,39 [1,21; 73,20] 0,0325[2]	9,50 [1,21; 74,43] 0,0088[3]	1,2 [0,3; 2,0] 0,0088[3]
Paraesthesia				
10/776 (1,3)	11/729 (1,5)	0,85 [0,36; 2,00] 0,7161[2]	0,85 [0,36; 2,02] 0,7158[3]	-0,2 [-1,4; 1,0] 0,7158[3]
Peripheral sensory neuropathy				
14/776 (1,8)	15/729 (2,1)	0,88 [0,43; 1,80] 0,7209[2]	0,87 [0,42; 1,82] 0,7207[3]	-0,3 [-1,6; 1,1] 0,7207[3]
Peripheral swelling				
11/776 (1,4)	11/729 (1,5)	0,94 [0,41; 2,15] 0,8827[2]	0,94 [0,40; 2,18] 0,8826[3]	-0,1 [-1,3; 1,1] 0,8826[3]
Pharyngitis				
9/776 (1,2)	12/729 (1,6)	0,70 [0,30; 1,66] 0,4240[2]	0,70 [0,29; 1,67] 0,4215[3]	-0,5 [-1,7; 0,7] 0,4215[3]
Platelet count decreased				
59/776 (7,6)	12/729 (1,6)	4,62 [2,50; 8,52] <,0001[2]	4,92 [2,62; 9,22] <,0001[3]	6,0 [3,9; 8,0] <,0001[3]
Pneumonia				
21/776 (2,7)	9/729 (1,2)	2,19 [1,01; 4,75] 0,0470[2]	2,23 [1,01; 4,89] 0,0412[3]	1,5 [0,1; 2,9] 0,0412[3]
Pneumonitis				
16/776 (2,1)	3/729 (0,4)	5,01 [1,47; 17,12] 0,0102[2]	5,09 [1,48; 17,56] 0,0042[3]	1,7 [0,5; 2,8] 0,0042[3]
Procedural pain				
27/776 (3,5)	17/729 (2,3)	1,49 [0,82; 2,71] 0,1900[2]	1,51 [0,82; 2,79] 0,1867[3]	1,1 [-0,5; 2,8] 0,1867[3]
Productive cough				
14/776 (1,8)	4/729 (0,5)	3,29 [1,09; 9,94] 0,0350[2]	3,33 [1,09; 10,16] 0,0252[3]	1,3 [0,2; 2,3] 0,0252[3]
Pruritus				
70/776 (9,0)	32/729 (4,4)	2,06 [1,37; 3,08] 0,0005[2]	2,16 [1,40; 3,32] 0,0004[3]	4,6 [2,1; 7,1] 0,0004[3]
Pyrexia				
86/776 (11,1)	36/729 (4,9)	2,24 [1,54; 3,27] <,0001[2]	2,40 [1,60; 3,59] <,0001[3]	6,1 [3,4; 8,9] <,0001[3]
Radiation pneumonitis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
12/776 (1,5)	8/729 (1,1)	1,41 [0,58; 3,43] 0,4495[2]	1,42 [0,58; 3,48] 0,4471[3]	0,4 [-0,7; 1,6] 0,4471[3]
Rash				
63/776 (8,1)	24/729 (3,3)	2,47 [1,56; 3,90] 0,0001[2]	2,60 [1,60; 4,20] <,0001[3]	4,8 [2,5; 7,1] <,0001[3]
Rash maculo-papular				
11/776 (1,4)	4/729 (0,5)	2,58 [0,83; 8,08] 0,1027[2]	2,61 [0,83; 8,22] 0,0899[3]	0,9 [-0,1; 1,9] 0,0899[3]
Rectal haemorrhage				
14/776 (1,8)	2/729 (0,3)	6,58 [1,50; 28,83] 0,0125[2]	6,68 [1,51; 29,49] 0,0038[3]	1,5 [0,5; 2,5] 0,0038[3]
Rhinitis allergic				
16/776 (2,1)	13/729 (1,8)	1,16 [0,56; 2,39] 0,6947[2]	1,16 [0,55; 2,43] 0,6944[3]	0,3 [-1,1; 1,7] 0,6944[3]
Rhinorrhoea				
10/776 (1,3)	6/729 (0,8)	1,57 [0,57; 4,29] 0,3829[2]	1,57 [0,57; 4,35] 0,3788[3]	0,5 [-0,6; 1,5] 0,3788[3]
Seasonal allergy				
10/776 (1,3)	6/729 (0,8)	1,57 [0,57; 4,29] 0,3829[2]	1,57 [0,57; 4,35] 0,3788[3]	0,5 [-0,6; 1,5] 0,3788[3]
Sinusitis				
29/776 (3,7)	9/729 (1,2)	3,03 [1,44; 6,35] 0,0034[2]	3,11 [1,46; 6,61] 0,0020[3]	2,5 [0,9; 4,1] 0,0020[3]
Skin infection				
13/776 (1,7)	6/729 (0,8)	2,04 [0,78; 5,33] 0,1476[2]	2,05 [0,78; 5,43] 0,1389[3]	0,9 [-0,3; 2,0] 0,1389[3]
Stomatitis				
58/776 (7,5)	13/729 (1,8)	4,19 [2,32; 7,58] <,0001[2]	4,45 [2,42; 8,19] <,0001[3]	5,7 [3,6; 7,8] <,0001[3]
Thrombocytopenia				
28/776 (3,6)	9/729 (1,2)	2,92 [1,39; 6,15] 0,0047[2]	2,99 [1,40; 6,39] 0,0030[3]	2,4 [0,8; 3,9] 0,0030[3]
Toothache				
25/776 (3,2)	13/729 (1,8)	1,81 [0,93; 3,50] 0,0802[2]	1,83 [0,93; 3,61] 0,0755[3]	1,4 [-0,1; 3,0] 0,0755[3]
Upper respiratory tract infection				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
90/776 (11,6)	71/729 (9,7)	1,19 [0,89; 1,60] 0,2447[2]	1,22 [0,88; 1,69] 0,2437[3]	1,9 [-1,3; 5,0] 0,2437[3]
Urinary tract infection				
68/776 (8,8)	33/729 (4,5)	1,94 [1,29; 2,90] 0,0013[2]	2,03 [1,32; 3,11] 0,0010[3]	4,2 [1,7; 6,7] 0,0010[3]
Urticaria				
12/776 (1,5)	5/729 (0,7)	2,25 [0,80; 6,37] 0,1249[2]	2,27 [0,80; 6,49] 0,1144[3]	0,9 [-0,2; 1,9] 0,1144[3]
Vaginal discharge				
11/776 (1,4)	26/729 (3,6)	0,40 [0,20; 0,80] 0,0095[2]	0,39 [0,19; 0,79] 0,0071[3]	-2,1 [-3,7; -0,6] 0,0071[3]
Vaginal haemorrhage				
14/776 (1,8)	9/729 (1,2)	1,46 [0,64; 3,36] 0,3711[2]	1,47 [0,63; 3,42] 0,3680[3]	0,6 [-0,7; 1,8] 0,3680[3]
Vaginal infection				
14/776 (1,8)	10/729 (1,4)	1,32 [0,59; 2,94] 0,5048[2]	1,32 [0,58; 2,99] 0,5034[3]	0,4 [-0,8; 1,7] 0,5034[3]
Vertigo				
23/776 (3,0)	13/729 (1,8)	1,66 [0,85; 3,26] 0,1387[2]	1,68 [0,85; 3,35] 0,1341[3]	1,2 [-0,4; 2,7] 0,1341[3]
Viral infection				
11/776 (1,4)	5/729 (0,7)	2,07 [0,72; 5,92] 0,1763[2]	2,08 [0,72; 6,02] 0,1666[3]	0,7 [-0,3; 1,8] 0,1666[3]
Vision blurred				
12/776 (1,5)	8/729 (1,1)	1,41 [0,58; 3,43] 0,4495[2]	1,42 [0,58; 3,48] 0,4471[3]	0,4 [-0,7; 1,6] 0,4471[3]
Vitamin D deficiency				
10/776 (1,3)	13/729 (1,8)	0,72 [0,32; 1,64] 0,4365[2]	0,72 [0,31; 1,65] 0,4344[3]	-0,5 [-1,7; 0,8] 0,4344[3]
Vomiting				
125/776 (16,1)	23/729 (3,2)	5,11 [3,31; 7,87] <,0001[2]	5,89 [3,73; 9,31] <,0001[3]	13,0 [10,1; 15,8] <,0001[3]
Vulvovaginal dryness				
40/776 (5,2)	42/729 (5,8)	0,89 [0,59; 1,36] 0,6045[2]	0,89 [0,57; 1,39] 0,6043[3]	-0,6 [-2,9; 1,7] 0,6043[3]
Weight decreased				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
20/776 (2,6)	11/729 (1,5)	1,71 [0,82; 3,54] 0,1499[2]	1,73 [0,82; 3,63] 0,1447[3]	1,1 [-0,4; 2,5] 0,1447[3]
Weight increased				
19/776 (2,4)	14/729 (1,9)	1,27 [0,64; 2,52] 0,4857[2]	1,28 [0,64; 2,58] 0,4845[3]	0,5 [-0,9; 2,0] 0,4845[3]
White blood cell count decreased				
215/776 (27,7)	56/729 (7,7)	3,61 [2,74; 4,75] <,0001[2]	4,61 [3,36; 6,31] <,0001[3]	20,0 [16,3; 23,7] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; GnRH: Gonadotropine releasing hormone; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aesocpt.sas
Output Location:
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
31OCT2025 / 03:24

Table 057.2: Results from binary analysis for adverse events according PT - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Abdominal discomfort				
19/1283 (1,5)	7/1264 (0,6)	2,67 [1,13; 6,34] 0,0255[2]	2,70 [1,13; 6,44] 0,0199[3]	0,9 [0,1; 1,7] 0,0199[3]
Abdominal distension				
34/1283 (2,7)	12/1264 (0,9)	2,79 [1,45; 5,37] 0,0021[2]	2,84 [1,46; 5,51] 0,0013[3]	1,7 [0,7; 2,7] 0,0013[3]
Abdominal pain				
312/1283 (24,3)	64/1264 (5,1)	4,80 [3,71; 6,21] <,0001[2]	6,02 [4,54; 7,99] <,0001[3]	19,3 [16,6; 21,9] <,0001[3]
Abdominal pain upper				
124/1283 (9,7)	45/1264 (3,6)	2,71 [1,95; 3,78] <,0001[2]	2,90 [2,04; 4,11] <,0001[3]	6,1 [4,2; 8,0] <,0001[3]
Alanine aminotransferase increased				
156/1283 (12,2)	68/1264 (5,4)	2,26 [1,72; 2,97] <,0001[2]	2,43 [1,81; 3,27] <,0001[3]	6,8 [4,6; 9,0] <,0001[3]
Alopecia				
152/1283 (11,8)	36/1264 (2,8)	4,16 [2,92; 5,93] <,0001[2]	4,58 [3,16; 6,65] <,0001[3]	9,0 [7,0; 11,0] <,0001[3]
Anaemia				
333/1283 (26,0)	48/1264 (3,8)	6,83 [5,10; 9,16] <,0001[2]	8,88 [6,49; 12,16] <,0001[3]	22,2 [19,5; 24,8] <,0001[3]
Anxiety				
37/1283 (2,9)	55/1264 (4,4)	0,66 [0,44; 1,00] 0,0489[2]	0,65 [0,43; 1,00] 0,0472[3]	-1,5 [-2,9; -0,0] 0,0472[3]
Arthralgia				
344/1283 (26,8)	497/1264 (39,3)	0,68 [0,61; 0,76] <,0001[2]	0,57 [0,48; 0,67] <,0001[3]	-12,5 [-16,1; -8,9] <,0001[3]
Arthritis				
11/1283 (0,9)	18/1264 (1,4)	0,60 [0,29; 1,27] 0,1825[2]	0,60 [0,28; 1,27] 0,1777[3]	-0,6 [-1,4; 0,3] 0,1777[3]
Aspartate aminotransferase increased				
147/1283 (11,5)	65/1264 (5,1)	2,23 [1,68; 2,95] <,0001[2]	2,39 [1,76; 3,23] <,0001[3]	6,3 [4,2; 8,4] <,0001[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Asthenia				
147/1283 (11,5)	69/1264 (5,5)	2,10 [1,59; 2,76] <,0001[2]	2,24 [1,66; 3,02] <,0001[3]	6,0 [3,9; 8,1] <,0001[3]
Axillary pain				
24/1283 (1,9)	19/1264 (1,5)	1,24 [0,69; 2,26] 0,4726[2]	1,25 [0,68; 2,29] 0,4717[3]	0,4 [-0,6; 1,4] 0,4717[3]
Back pain				
115/1283 (9,0)	148/1264 (11,7)	0,77 [0,61; 0,96] 0,0233[2]	0,74 [0,57; 0,96] 0,0228[3]	-2,7 [-5,1; -0,4] 0,0228[3]
Blood alkaline phosphatase increased				
61/1283 (4,8)	39/1264 (3,1)	1,54 [1,04; 2,29] 0,0316[2]	1,57 [1,04; 2,36] 0,0301[3]	1,7 [0,2; 3,2] 0,0301[3]
Blood bilirubin increased				
17/1283 (1,3)	8/1264 (0,6)	2,09 [0,91; 4,83] 0,0835[2]	2,11 [0,91; 4,90] 0,0765[3]	0,7 [-0,1; 1,5] 0,0765[3]
Blood cholesterol increased				
16/1283 (1,2)	22/1264 (1,7)	0,72 [0,38; 1,36] 0,3067[2]	0,71 [0,37; 1,36] 0,3044[3]	-0,5 [-1,4; 0,4] 0,3044[3]
Blood creatinine increased				
150/1283 (11,7)	15/1264 (1,2)	9,85 [5,83; 16,66] <,0001[2]	11,02 [6,44; 18,86] <,0001[3]	10,5 [8,6; 12,4] <,0001[3]
Bone pain				
33/1283 (2,6)	49/1264 (3,9)	0,66 [0,43; 1,02] 0,0642[2]	0,65 [0,42; 1,02] 0,0622[3]	-1,3 [-2,7; 0,1] 0,0622[3]
Breast pain				
44/1283 (3,4)	59/1264 (4,7)	0,73 [0,50; 1,08] 0,1143[2]	0,73 [0,49; 1,08] 0,1127[3]	-1,2 [-2,8; 0,3] 0,1127[3]
Bronchitis				
24/1283 (1,9)	30/1264 (2,4)	0,79 [0,46; 1,34] 0,3797[2]	0,78 [0,46; 1,35] 0,3785[3]	-0,5 [-1,6; 0,6] 0,3785[3]
COVID-19				
37/1283 (2,9)	8/1264 (0,6)	4,56 [2,13; 9,75] <,0001[2]	4,66 [2,16; 10,05] <,0001[3]	2,3 [1,2; 3,3] <,0001[3]
Cataract				
27/1283 (2,1)	10/1264 (0,8)	2,66 [1,29; 5,47] 0,0079[2]	2,70 [1,30; 5,59] 0,0056[3]	1,3 [0,4; 2,2] 0,0056[3]
Cellulitis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
27/1283 (2,1)	20/1264 (1,6)	1,33 [0,75; 2,36] 0,3293[2]	1,34 [0,75; 2,40] 0,3276[3]	0,5 [-0,5; 1,6] 0,3276[3]
Chest pain				
27/1283 (2,1)	25/1264 (2,0)	1,06 [0,62; 1,82] 0,8213[2]	1,07 [0,61; 1,85] 0,8213[3]	0,1 [-1,0; 1,2] 0,8213[3]
Chills				
19/1283 (1,5)	11/1264 (0,9)	1,70 [0,81; 3,56] 0,1583[2]	1,71 [0,81; 3,61] 0,1532[3]	0,6 [-0,2; 1,4] 0,1532[3]
Conjunctivitis				
22/1283 (1,7)	13/1264 (1,0)	1,67 [0,84; 3,29] 0,1414[2]	1,68 [0,84; 3,35] 0,1369[3]	0,7 [-0,2; 1,6] 0,1369[3]
Constipation				
154/1283 (12,0)	72/1264 (5,7)	2,11 [1,61; 2,76] <,0001[2]	2,26 [1,69; 3,02] <,0001[3]	6,3 [4,1; 8,5] <,0001[3]
Contusion				
21/1283 (1,6)	17/1264 (1,3)	1,22 [0,65; 2,30] 0,5442[2]	1,22 [0,64; 2,32] 0,5435[3]	0,3 [-0,6; 1,2] 0,5435[3]
Cough				
185/1283 (14,4)	111/1264 (8,8)	1,64 [1,31; 2,05] <,0001[2]	1,75 [1,36; 2,25] <,0001[3]	5,6 [3,2; 8,1] <,0001[3]
Cystitis				
37/1283 (2,9)	32/1264 (2,5)	1,14 [0,71; 1,82] 0,5844[2]	1,14 [0,71; 1,85] 0,5841[3]	0,4 [-0,9; 1,6] 0,5841[3]
Decreased appetite				
164/1283 (12,8)	43/1264 (3,4)	3,76 [2,71; 5,21] <,0001[2]	4,16 [2,95; 5,88] <,0001[3]	9,4 [7,3; 11,5] <,0001[3]
Deep vein thrombosis				
21/1283 (1,6)	3/1264 (0,2)	6,90 [2,06; 23,06] 0,0017[2]	6,99 [2,08; 23,51] 0,0003[3]	1,4 [0,7; 2,1] 0,0003[3]
Dehydration				
26/1283 (2,0)	3/1264 (0,2)	8,54 [2,59; 28,14] 0,0004[2]	8,69 [2,62; 28,80] <,0001[3]	1,8 [1,0; 2,6] <,0001[3]
Depression				
50/1283 (3,9)	48/1264 (3,8)	1,03 [0,70; 1,51] 0,8960[2]	1,03 [0,69; 1,54] 0,8960[3]	0,1 [-1,4; 1,6] 0,8960[3]
Dermatitis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
19/1283 (1,5)	7/1264 (0,6)	2,67 [1,13; 6,34] 0,0255[2]	2,70 [1,13; 6,44] 0,0199[3]	0,9 [0,1; 1,7] 0,0199[3]
Diarrhoea				
1060/1283 (82,6)	111/1264 (8,8)	9,41 [7,86; 11,26] <,0001[2]	49,38 [38,74; 62,92] <,0001[3]	73,8 [71,2; 76,4] <,0001[3]
Dizziness				
138/1283 (10,8)	85/1264 (6,7)	1,60 [1,23; 2,07] 0,0004[2]	1,67 [1,26; 2,22] 0,0003[3]	4,0 [1,8; 6,2] 0,0003[3]
Dry eye				
38/1283 (3,0)	11/1264 (0,9)	3,40 [1,75; 6,63] 0,0003[2]	3,48 [1,77; 6,83] 0,0001[3]	2,1 [1,0; 3,2] 0,0001[3]
Dry mouth				
45/1283 (3,5)	17/1264 (1,3)	2,61 [1,50; 4,53] 0,0007[2]	2,67 [1,52; 4,68] 0,0004[3]	2,2 [1,0; 3,4] 0,0004[3]
Dry skin				
51/1283 (4,0)	25/1264 (2,0)	2,01 [1,25; 3,22] 0,0038[2]	2,05 [1,26; 3,33] 0,0031[3]	2,0 [0,7; 3,3] 0,0031[3]
Dysgeusia				
60/1283 (4,7)	6/1264 (0,5)	9,85 [4,27; 22,72] <,0001[2]	10,29 [4,43; 23,90] <,0001[3]	4,2 [3,0; 5,4] <,0001[3]
Dyspepsia				
96/1283 (7,5)	32/1264 (2,5)	2,96 [2,00; 4,38] <,0001[2]	3,11 [2,07; 4,68] <,0001[3]	5,0 [3,3; 6,6] <,0001[3]
Dyspnoea				
95/1283 (7,4)	50/1264 (4,0)	1,87 [1,34; 2,61] 0,0002[2]	1,94 [1,37; 2,76] 0,0002[3]	3,4 [1,7; 5,2] 0,0002[3]
Dysuria				
26/1283 (2,0)	13/1264 (1,0)	1,97 [1,02; 3,82] 0,0444[2]	1,99 [1,02; 3,89] 0,0403[3]	1,0 [0,0; 1,9] 0,0403[3]
Eczema				
13/1283 (1,0)	16/1264 (1,3)	0,80 [0,39; 1,66] 0,5489[2]	0,80 [0,38; 1,67] 0,5480[3]	-0,3 [-1,1; 0,6] 0,5480[3]
Epistaxis				
23/1283 (1,8)	3/1264 (0,2)	7,55 [2,27; 25,09] 0,0010[2]	7,67 [2,30; 25,62] <,0001[3]	1,6 [0,8; 2,3] <,0001[3]
Erythema				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
17/1283 (1,3)	16/1264 (1,3)	1,05 [0,53; 2,06] 0,8949[2]	1,05 [0,53; 2,08] 0,8949[3]	0,1 [-0,8; 0,9] 0,8949[3]
Fall				
45/1283 (3,5)	27/1264 (2,1)	1,64 [1,03; 2,63] 0,0390[2]	1,67 [1,03; 2,70] 0,0368[3]	1,4 [0,1; 2,7] 0,0368[3]
Fatigue				
397/1283 (30,9)	150/1264 (11,9)	2,61 [2,20; 3,09] <,0001[2]	3,33 [2,70; 4,10] <,0001[3]	19,1 [16,0; 22,2] <,0001[3]
Flatulence				
42/1283 (3,3)	9/1264 (0,7)	4,60 [2,25; 9,41] <,0001[2]	4,72 [2,29; 9,74] <,0001[3]	2,6 [1,5; 3,6] <,0001[3]
Gamma-glutamyltransferase increased				
42/1283 (3,3)	17/1264 (1,3)	2,43 [1,39; 4,25] 0,0018[2]	2,48 [1,41; 4,38] 0,0012[3]	1,9 [0,8; 3,1] 0,0012[3]
Gastritis				
30/1283 (2,3)	21/1264 (1,7)	1,41 [0,81; 2,44] 0,2251[2]	1,42 [0,81; 2,49] 0,2227[3]	0,7 [-0,4; 1,8] 0,2227[3]
Gastroenteritis				
18/1283 (1,4)	13/1264 (1,0)	1,36 [0,67; 2,77] 0,3908[2]	1,37 [0,67; 2,81] 0,3888[3]	0,4 [-0,5; 1,2] 0,3888[3]
Gastrointestinal pain				
17/1283 (1,3)	1/1264 (0,1)	16,75 [2,23; 125,66] 0,0061[2]	16,96 [2,25; 127,63] 0,0002[3]	1,2 [0,6; 1,9] 0,0002[3]
Gastrooesophageal reflux disease				
41/1283 (3,2)	25/1264 (2,0)	1,62 [0,99; 2,64] 0,0556[2]	1,64 [0,99; 2,71] 0,0531[3]	1,2 [-0,0; 2,4] 0,0531[3]
Haemorrhoids				
28/1283 (2,2)	13/1264 (1,0)	2,12 [1,10; 4,08] 0,0240[2]	2,15 [1,11; 4,16] 0,0207[3]	1,2 [0,2; 2,1] 0,0207[3]
Headache				
224/1283 (17,5)	149/1264 (11,8)	1,48 [1,22; 1,79] <,0001[2]	1,58 [1,27; 1,98] <,0001[3]	5,7 [2,9; 8,4] <,0001[3]
Hepatic steatosis				
23/1283 (1,8)	22/1264 (1,7)	1,03 [0,58; 1,84] 0,9204[2]	1,03 [0,57; 1,86] 0,9204[3]	0,1 [-1,0; 1,1] 0,9204[3]
Herpes zoster				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
23/1283 (1,8)	23/1264 (1,8)	0,99 [0,56; 1,75] 0,9593[2]	0,98 [0,55; 1,76] 0,9593[3]	-0,0 [-1,1; 1,0] 0,9593[3]
Hot flush				
147/1283 (11,5)	216/1264 (17,1)	0,67 [0,55; 0,81] <,0001[2]	0,63 [0,50; 0,79] <,0001[3]	-5,6 [-8,3; -2,9] <,0001[3]
Hypercalcaemia				
27/1283 (2,1)	18/1264 (1,4)	1,48 [0,82; 2,67] 0,1955[2]	1,49 [0,82; 2,72] 0,1925[3]	0,7 [-0,3; 1,7] 0,1925[3]
Hypercholesterolaemia				
15/1283 (1,2)	24/1264 (1,9)	0,62 [0,32; 1,17] 0,1378[2]	0,61 [0,32; 1,17] 0,1338[3]	-0,7 [-1,7; 0,2] 0,1338[3]
Hyperglycaemia				
20/1283 (1,6)	30/1264 (2,4)	0,66 [0,38; 1,15] 0,1415[2]	0,65 [0,37; 1,15] 0,1384[3]	-0,8 [-1,9; 0,3] 0,1384[3]
Hyperhidrosis				
17/1283 (1,3)	21/1264 (1,7)	0,80 [0,42; 1,50] 0,4848[2]	0,79 [0,42; 1,51] 0,4838[3]	-0,3 [-1,3; 0,6] 0,4838[3]
Hyperkalaemia				
14/1283 (1,1)	9/1264 (0,7)	1,53 [0,67; 3,53] 0,3156[2]	1,54 [0,66; 3,57] 0,3118[3]	0,4 [-0,4; 1,1] 0,3118[3]
Hypersensitivity				
13/1283 (1,0)	11/1264 (0,9)	1,16 [0,52; 2,59] 0,7091[2]	1,17 [0,52; 2,61] 0,7088[3]	0,1 [-0,6; 0,9] 0,7088[3]
Hypertension				
56/1283 (4,4)	72/1264 (5,7)	0,77 [0,55; 1,08] 0,1254[2]	0,76 [0,53; 1,08] 0,1241[3]	-1,3 [-3,0; 0,4] 0,1241[3]
Hypertriglyceridaemia				
25/1283 (1,9)	28/1264 (2,2)	0,88 [0,52; 1,50] 0,6376[2]	0,88 [0,51; 1,51] 0,6374[3]	-0,3 [-1,4; 0,8] 0,6374[3]
Hyperuricaemia				
20/1283 (1,6)	10/1264 (0,8)	1,97 [0,93; 4,19] 0,0783[2]	1,99 [0,93; 4,26] 0,0726[3]	0,8 [-0,1; 1,6] 0,0726[3]
Hypoalbuminaemia				
14/1283 (1,1)	8/1264 (0,6)	1,72 [0,73; 4,10] 0,2172[2]	1,73 [0,72; 4,14] 0,2114[3]	0,5 [-0,3; 1,2] 0,2114[3]
Hypokalaemia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
57/1283 (4,4)	15/1264 (1,2)	3,74 [2,13; 6,58] <,0001[2]	3,87 [2,18; 6,87] <,0001[3]	3,3 [2,0; 4,5] <,0001[3]
Hyponatraemia				
19/1283 (1,5)	9/1264 (0,7)	2,08 [0,94; 4,58] 0,0690[2]	2,10 [0,94; 4,65] 0,0628[3]	0,8 [-0,0; 1,6] 0,0628[3]
Hypotension				
24/1283 (1,9)	7/1264 (0,6)	3,38 [1,46; 7,81] 0,0044[2]	3,42 [1,47; 7,97] 0,0024[3]	1,3 [0,5; 2,2] 0,0024[3]
Hypothyroidism				
15/1283 (1,2)	19/1264 (1,5)	0,78 [0,40; 1,52] 0,4639[2]	0,78 [0,39; 1,53] 0,4627[3]	-0,3 [-1,2; 0,6] 0,4627[3]
Influenza				
47/1283 (3,7)	43/1264 (3,4)	1,08 [0,72; 1,62] 0,7210[2]	1,08 [0,71; 1,65] 0,7209[3]	0,3 [-1,2; 1,7] 0,7209[3]
Influenza like illness				
56/1283 (4,4)	43/1264 (3,4)	1,28 [0,87; 1,89] 0,2101[2]	1,30 [0,86; 1,94] 0,2087[3]	1,0 [-0,5; 2,5] 0,2087[3]
Insomnia				
96/1283 (7,5)	92/1264 (7,3)	1,03 [0,78; 1,35] 0,8439[2]	1,03 [0,77; 1,39] 0,8439[3]	0,2 [-1,8; 2,2] 0,8439[3]
Joint stiffness				
14/1283 (1,1)	30/1264 (2,4)	0,46 [0,24; 0,86] 0,0156[2]	0,45 [0,24; 0,86] 0,0130[3]	-1,3 [-2,3; -0,3] 0,0130[3]
Lacrimation increased				
72/1283 (5,6)	5/1264 (0,4)	14,19 [5,75; 35,00] <,0001[2]	14,97 [6,03; 37,19] <,0001[3]	5,2 [3,9; 6,5] <,0001[3]
Leukopenia				
188/1283 (14,7)	25/1264 (2,0)	7,41 [4,92; 11,16] <,0001[2]	8,51 [5,56; 13,02] <,0001[3]	12,7 [10,6; 14,8] <,0001[3]
Lymphocyte count decreased				
112/1283 (8,7)	28/1264 (2,2)	3,94 [2,62; 5,92] <,0001[2]	4,22 [2,77; 6,44] <,0001[3]	6,5 [4,8; 8,3] <,0001[3]
Lymphoedema				
155/1283 (12,1)	105/1264 (8,3)	1,45 [1,15; 1,84] 0,0018[2]	1,52 [1,17; 1,97] 0,0017[3]	3,8 [1,4; 6,1] 0,0017[3]
Lymphopenia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
69/1283 (5,4)	10/1264 (0,8)	6,80 [3,52; 13,13] <,0001[2]	7,13 [3,65; 13,90] <,0001[3]	4,6 [3,3; 5,9] <,0001[3]
Malaise				
33/1283 (2,6)	12/1264 (0,9)	2,71 [1,41; 5,22] 0,0029[2]	2,75 [1,42; 5,36] 0,0019[3]	1,6 [0,6; 2,6] 0,0019[3]
Mastitis				
10/1283 (0,8)	18/1264 (1,4)	0,55 [0,25; 1,18] 0,1246[2]	0,54 [0,25; 1,18] 0,1188[3]	-0,6 [-1,5; 0,2] 0,1188[3]
Memory impairment				
17/1283 (1,3)	10/1264 (0,8)	1,67 [0,77; 3,64] 0,1934[2]	1,68 [0,77; 3,69] 0,1884[3]	0,5 [-0,3; 1,3] 0,1884[3]
Mucosal inflammation				
37/1283 (2,9)	9/1264 (0,7)	4,05 [1,96; 8,36] 0,0002[2]	4,14 [1,99; 8,62] <,0001[3]	2,2 [1,1; 3,2] <,0001[3]
Muscle spasms				
73/1283 (5,7)	49/1264 (3,9)	1,47 [1,03; 2,09] 0,0334[2]	1,50 [1,03; 2,17] 0,0322[3]	1,8 [0,2; 3,5] 0,0322[3]
Muscular weakness				
18/1283 (1,4)	8/1264 (0,6)	2,22 [0,97; 5,08] 0,0599[2]	2,23 [0,97; 5,16] 0,0532[3]	0,8 [-0,0; 1,5] 0,0532[3]
Musculoskeletal chest pain				
38/1283 (3,0)	30/1264 (2,4)	1,25 [0,78; 2,00] 0,3581[2]	1,26 [0,77; 2,04] 0,3570[3]	0,6 [-0,7; 1,8] 0,3570[3]
Musculoskeletal pain				
13/1283 (1,0)	15/1264 (1,2)	0,85 [0,41; 1,79] 0,6750[2]	0,85 [0,40; 1,80] 0,6747[3]	-0,2 [-1,0; 0,6] 0,6747[3]
Musculoskeletal stiffness				
16/1283 (1,2)	18/1264 (1,4)	0,88 [0,45; 1,71] 0,6974[2]	0,87 [0,44; 1,72] 0,6972[3]	-0,2 [-1,1; 0,7] 0,6972[3]
Myalgia				
74/1283 (5,8)	83/1264 (6,6)	0,88 [0,65; 1,19] 0,4024[2]	0,87 [0,63; 1,20] 0,4020[3]	-0,8 [-2,7; 1,1] 0,4020[3]
Nail disorder				
23/1283 (1,8)	2/1264 (0,2)	11,33 [2,68; 47,95] 0,0010[2]	11,52 [2,71; 48,96] <,0001[3]	1,6 [0,9; 2,4] <,0001[3]
Nasal congestion				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
17/1283 (1,3)	13/1264 (1,0)	1,29 [0,63; 2,64] 0,4892[2]	1,29 [0,63; 2,67] 0,4880[3]	0,3 [-0,5; 1,1] 0,4880[3]
Nasopharyngitis				
106/1283 (8,3)	90/1264 (7,1)	1,16 [0,89; 1,52] 0,2803[2]	1,17 [0,88; 1,57] 0,2798[3]	1,1 [-0,9; 3,2] 0,2798[3]
Nausea				
385/1283 (30,0)	97/1264 (7,7)	3,91 [3,17; 4,82] <,0001[2]	5,16 [4,06; 6,55] <,0001[3]	22,3 [19,4; 25,2] <,0001[3]
Neck pain				
28/1283 (2,2)	32/1264 (2,5)	0,86 [0,52; 1,42] 0,5616[2]	0,86 [0,51; 1,44] 0,5612[3]	-0,3 [-1,5; 0,8] 0,5612[3]
Neuropathy peripheral				
39/1283 (3,0)	36/1264 (2,8)	1,07 [0,68; 1,67] 0,7749[2]	1,07 [0,68; 1,69] 0,7748[3]	0,2 [-1,1; 1,5] 0,7748[3]
Neutropenia				
297/1283 (23,1)	29/1264 (2,3)	10,09 [6,95; 14,66] <,0001[2]	12,83 [8,68; 18,95] <,0001[3]	20,9 [18,4; 23,3] <,0001[3]
Neutrophil count decreased				
282/1283 (22,0)	22/1264 (1,7)	12,63 [8,24; 19,35] <,0001[2]	15,90 [10,22; 24,74] <,0001[3]	20,2 [17,9; 22,6] <,0001[3]
Night sweats				
10/1283 (0,8)	14/1264 (1,1)	0,70 [0,31; 1,58] 0,3939[2]	0,70 [0,31; 1,58] 0,3914[3]	-0,3 [-1,1; 0,4] 0,3914[3]
Oedema				
16/1283 (1,2)	8/1264 (0,6)	1,97 [0,85; 4,59] 0,1157[2]	1,98 [0,85; 4,65] 0,1087[3]	0,6 [-0,1; 1,4] 0,1087[3]
Oedema peripheral				
93/1283 (7,2)	49/1264 (3,9)	1,87 [1,33; 2,62] 0,0003[2]	1,94 [1,36; 2,76] 0,0002[3]	3,4 [1,6; 5,1] 0,0002[3]
Onychoclasis				
21/1283 (1,6)	3/1264 (0,2)	6,90 [2,06; 23,06] 0,0017[2]	6,99 [2,08; 23,51] 0,0003[3]	1,4 [0,7; 2,1] 0,0003[3]
Oral herpes				
16/1283 (1,2)	5/1264 (0,4)	3,15 [1,16; 8,58] 0,0246[2]	3,18 [1,16; 8,71] 0,0175[3]	0,9 [0,2; 1,6] 0,0175[3]
Oropharyngeal pain				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
49/1283 (3,8)	32/1264 (2,5)	1,51 [0,97; 2,34] 0,0662[2]	1,53 [0,97; 2,40] 0,0641[3]	1,3 [-0,1; 2,6] 0,0641[3]
Osteoarthritis				
15/1283 (1,2)	26/1264 (2,1)	0,57 [0,30; 1,07] 0,0792[2]	0,56 [0,30; 1,07] 0,0751[3]	-0,9 [-1,9; 0,1] 0,0751[3]
Osteopenia				
23/1283 (1,8)	25/1264 (2,0)	0,91 [0,52; 1,59] 0,7312[2]	0,90 [0,51; 1,60] 0,7311[3]	-0,2 [-1,2; 0,9] 0,7311[3]
Osteoporosis				
30/1283 (2,3)	47/1264 (3,7)	0,63 [0,40; 0,99] 0,0440[2]	0,62 [0,39; 0,99] 0,0420[3]	-1,4 [-2,7; -0,0] 0,0420[3]
Pain				
29/1283 (2,3)	30/1264 (2,4)	0,95 [0,58; 1,58] 0,8496[2]	0,95 [0,57; 1,59] 0,8495[3]	-0,1 [-1,3; 1,1] 0,8495[3]
Pain in extremity				
128/1283 (10,0)	141/1264 (11,2)	0,89 [0,71; 1,12] 0,3336[2]	0,88 [0,69; 1,14] 0,3333[3]	-1,2 [-3,6; 1,2] 0,3333[3]
Palpitations				
27/1283 (2,1)	12/1264 (0,9)	2,22 [1,13; 4,36] 0,0209[2]	2,24 [1,13; 4,45] 0,0176[3]	1,2 [0,2; 2,1] 0,0176[3]
Paraesthesia				
32/1283 (2,5)	30/1264 (2,4)	1,05 [0,64; 1,72] 0,8433[2]	1,05 [0,64; 1,74] 0,8433[3]	0,1 [-1,1; 1,3] 0,8433[3]
Paronychia				
15/1283 (1,2)	4/1264 (0,3)	3,69 [1,23; 11,10] 0,0199[2]	3,73 [1,23; 11,26] 0,0124[3]	0,9 [0,2; 1,5] 0,0124[3]
Peripheral sensory neuropathy				
16/1283 (1,2)	13/1264 (1,0)	1,21 [0,59; 2,51] 0,6037[2]	1,22 [0,58; 2,54] 0,6031[3]	0,2 [-0,6; 1,0] 0,6031[3]
Peripheral swelling				
30/1283 (2,3)	25/1264 (2,0)	1,18 [0,70; 2,00] 0,5320[2]	1,19 [0,69; 2,03] 0,5315[3]	0,4 [-0,8; 1,5] 0,5315[3]
Platelet count decreased				
116/1283 (9,0)	9/1264 (0,7)	12,70 [6,47; 24,91] <,0001[2]	13,86 [7,00; 27,44] <,0001[3]	8,3 [6,7; 10,0] <,0001[3]
Pneumonia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
31/1283 (2,4)	19/1264 (1,5)	1,61 [0,91; 2,83] 0,1001[2]	1,62 [0,91; 2,89] 0,0968[3]	0,9 [-0,2; 2,0] 0,0968[3]
Pneumonitis				
18/1283 (1,4)	3/1264 (0,2)	5,91 [1,75; 20,02] 0,0043[2]	5,98 [1,76; 20,36] 0,0011[3]	1,2 [0,5; 1,9] 0,0011[3]
Procedural pain				
36/1283 (2,8)	26/1264 (2,1)	1,36 [0,83; 2,25] 0,2221[2]	1,37 [0,83; 2,29] 0,2201[3]	0,7 [-0,4; 1,9] 0,2201[3]
Productive cough				
21/1283 (1,6)	13/1264 (1,0)	1,59 [0,80; 3,16] 0,1852[2]	1,60 [0,80; 3,21] 0,1811[3]	0,6 [-0,3; 1,5] 0,1811[3]
Pruritus				
109/1283 (8,5)	59/1264 (4,7)	1,82 [1,34; 2,47] 0,0001[2]	1,90 [1,37; 2,63] <,0001[3]	3,8 [1,9; 5,7] <,0001[3]
Pyrexia				
99/1283 (7,7)	45/1264 (3,6)	2,17 [1,54; 3,06] <,0001[2]	2,27 [1,58; 3,25] <,0001[3]	4,2 [2,4; 5,9] <,0001[3]
Rash				
113/1283 (8,8)	37/1264 (2,9)	3,01 [2,09; 4,33] <,0001[2]	3,20 [2,19; 4,68] <,0001[3]	5,9 [4,1; 7,7] <,0001[3]
Rash maculo-papular				
21/1283 (1,6)	3/1264 (0,2)	6,90 [2,06; 23,06] 0,0017[2]	6,99 [2,08; 23,51] 0,0003[3]	1,4 [0,7; 2,1] 0,0003[3]
Respiratory tract infection				
15/1283 (1,2)	9/1264 (0,7)	1,64 [0,72; 3,74] 0,2375[2]	1,65 [0,72; 3,78] 0,2325[3]	0,5 [-0,3; 1,2] 0,2325[3]
Rhinitis allergic				
23/1283 (1,8)	24/1264 (1,9)	0,94 [0,54; 1,66] 0,8424[2]	0,94 [0,53; 1,68] 0,8424[3]	-0,1 [-1,2; 0,9] 0,8424[3]
Sciatica				
13/1283 (1,0)	15/1264 (1,2)	0,85 [0,41; 1,79] 0,6750[2]	0,85 [0,40; 1,80] 0,6747[3]	-0,2 [-1,0; 0,6] 0,6747[3]
Seroma				
16/1283 (1,2)	5/1264 (0,4)	3,15 [1,16; 8,58] 0,0246[2]	3,18 [1,16; 8,71] 0,0175[3]	0,9 [0,2; 1,6] 0,0175[3]
Sinusitis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
30/1283 (2,3)	32/1264 (2,5)	0,92 [0,56; 1,51] 0,7516[2]	0,92 [0,56; 1,53] 0,7515[3]	-0,2 [-1,4; 1,0] 0,7515[3]
Stomatitis				
68/1283 (5,3)	12/1264 (0,9)	5,58 [3,04; 10,26] <,0001[2]	5,84 [3,15; 10,84] <,0001[3]	4,4 [3,0; 5,7] <,0001[3]
Syncope				
14/1283 (1,1)	8/1264 (0,6)	1,72 [0,73; 4,10] 0,2172[2]	1,73 [0,72; 4,14] 0,2114[3]	0,5 [-0,3; 1,2] 0,2114[3]
Taste disorder				
21/1283 (1,6)	2/1264 (0,2)	10,34 [2,43; 44,03] 0,0016[2]	10,50 [2,46; 44,87] <,0001[3]	1,5 [0,8; 2,2] <,0001[3]
Tendonitis				
10/1283 (0,8)	18/1264 (1,4)	0,55 [0,25; 1,18] 0,1246[2]	0,54 [0,25; 1,18] 0,1188[3]	-0,6 [-1,5; 0,2] 0,1188[3]
Thrombocytopenia				
86/1283 (6,7)	9/1264 (0,7)	9,41 [4,76; 18,62] <,0001[2]	10,02 [5,02; 20,00] <,0001[3]	6,0 [4,5; 7,4] <,0001[3]
Tooth extraction				
8/1283 (0,6)	13/1264 (1,0)	0,61 [0,25; 1,46] 0,2636[2]	0,60 [0,25; 1,46] 0,2585[3]	-0,4 [-1,1; 0,3] 0,2585[3]
Toothache				
18/1283 (1,4)	19/1264 (1,5)	0,93 [0,49; 1,77] 0,8327[2]	0,93 [0,49; 1,78] 0,8326[3]	-0,1 [-1,0; 0,8] 0,8326[3]
Tremor				
15/1283 (1,2)	6/1264 (0,5)	2,46 [0,96; 6,33] 0,0612[2]	2,48 [0,96; 6,41] 0,0526[3]	0,7 [-0,0; 1,4] 0,0526[3]
Trigger finger				
13/1283 (1,0)	14/1264 (1,1)	0,91 [0,43; 1,94] 0,8162[2]	0,91 [0,43; 1,95] 0,8162[3]	-0,1 [-0,9; 0,7] 0,8162[3]
Upper respiratory tract infection				
107/1283 (8,3)	88/1264 (7,0)	1,20 [0,91; 1,57] 0,1918[2]	1,22 [0,91; 1,63] 0,1910[3]	1,4 [-0,7; 3,4] 0,1910[3]
Urinary tract infection				
118/1283 (9,2)	68/1264 (5,4)	1,71 [1,28; 2,28] 0,0003[2]	1,78 [1,31; 2,43] 0,0002[3]	3,8 [1,8; 5,8] 0,0002[3]
Urticaria				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
13/1283 (1,0)	10/1264 (0,8)	1,28 [0,56; 2,91] 0,5546[2]	1,28 [0,56; 2,94] 0,5535[3]	0,2 [-0,5; 1,0] 0,5535[3]
Vertigo				
40/1283 (3,1)	27/1264 (2,1)	1,46 [0,90; 2,36] 0,1241[2]	1,47 [0,90; 2,42] 0,1217[3]	1,0 [-0,3; 2,2] 0,1217[3]
Viral infection				
15/1283 (1,2)	2/1264 (0,2)	7,39 [1,69; 32,24] 0,0078[2]	7,46 [1,70; 32,71] 0,0017[3]	1,0 [0,4; 1,6] 0,0017[3]
Vision blurred				
29/1283 (2,3)	10/1264 (0,8)	2,86 [1,40; 5,84] 0,0040[2]	2,90 [1,41; 5,98] 0,0025[3]	1,5 [0,5; 2,4] 0,0025[3]
Vitamin B12 deficiency				
16/1283 (1,2)	4/1264 (0,3)	3,94 [1,32; 11,75] 0,0139[2]	3,98 [1,33; 11,93] 0,0078[3]	0,9 [0,2; 1,6] 0,0078[3]
Vitamin D deficiency				
16/1283 (1,2)	15/1264 (1,2)	1,05 [0,52; 2,12] 0,8895[2]	1,05 [0,52; 2,14] 0,8895[3]	0,1 [-0,8; 0,9] 0,8895[3]
Vomiting				
222/1283 (17,3)	53/1264 (4,2)	4,13 [3,09; 5,51] <,0001[2]	4,78 [3,50; 6,52] <,0001[3]	13,1 [10,8; 15,5] <,0001[3]
Vulvovaginal dryness				
27/1283 (2,1)	40/1264 (3,2)	0,67 [0,41; 1,08] 0,0971[2]	0,66 [0,40; 1,08] 0,0946[3]	-1,1 [-2,3; 0,2] 0,0946[3]
Weight decreased				
59/1283 (4,6)	15/1264 (1,2)	3,88 [2,21; 6,79] <,0001[2]	4,01 [2,26; 7,11] <,0001[3]	3,4 [2,1; 4,7] <,0001[3]
Weight increased				
19/1283 (1,5)	33/1264 (2,6)	0,57 [0,32; 0,99] 0,0468[2]	0,56 [0,32; 0,99] 0,0438[3]	-1,1 [-2,2; -0,0] 0,0438[3]
White blood cell count decreased				
287/1283 (22,4)	51/1264 (4,0)	5,54 [4,16; 7,39] <,0001[2]	6,85 [5,03; 9,34] <,0001[3]	18,3 [15,8; 20,9] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aesocpt.sas
Output Location:
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
31OCT2025 / 03:24

Table 058.1: Results from binary analysis for adverse events according SOC - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Blood and lymphatic system disorders				
286/776 (36,9)	80/729 (11,0)	3,36 [2,68; 4,21] <,0001[2]	4,74 [3,60; 6,23] <,0001[3]	25,9 [21,8; 30,0] <,0001[3]
Cardiac disorders				
30/776 (3,9)	20/729 (2,7)	1,41 [0,81; 2,46] 0,2272[2]	1,43 [0,80; 2,53] 0,2246[3]	1,1 [-0,7; 2,9] 0,2246[3]
Ear and labyrinth disorders				
40/776 (5,2)	36/729 (4,9)	1,04 [0,67; 1,62] 0,8481[2]	1,05 [0,66; 1,66] 0,8481[3]	0,2 [-2,0; 2,4] 0,8481[3]
Endocrine disorders				
14/776 (1,8)	27/729 (3,7)	0,49 [0,26; 0,92] 0,0270[2]	0,48 [0,25; 0,92] 0,0237[3]	-1,9 [-3,6; -0,2] 0,0237[3]
Eye disorders				
105/776 (13,5)	48/729 (6,6)	2,06 [1,48; 2,85] <,0001[2]	2,22 [1,55; 3,17] <,0001[3]	6,9 [3,9; 10,0] <,0001[3]
Gastrointestinal disorders				
698/776 (89,9)	225/729 (30,9)	2,91 [2,61; 3,26] <,0001[2]	20,05 [15,12; 26,57] <,0001[3]	59,1 [55,1; 63,0] <,0001[3]
General disorders and administration site conditions				
422/776 (54,4)	232/729 (31,8)	1,71 [1,51; 1,93] <,0001[2]	2,55 [2,07; 3,15] <,0001[3]	22,6 [17,7; 27,4] <,0001[3]
Hepatobiliary disorders				
43/776 (5,5)	25/729 (3,4)	1,62 [1,00; 2,62] 0,0513[2]	1,65 [1,00; 2,73] 0,0487[3]	2,1 [0,0; 4,2] 0,0487[3]
Immune system disorders				
15/776 (1,9)	13/729 (1,8)	1,08 [0,52; 2,26] 0,8300[2]	1,09 [0,51; 2,30] 0,8299[3]	0,1 [-1,2; 1,5] 0,8299[3]
Infections and infestations				
425/776 (54,8)	303/729 (41,6)	1,32 [1,18; 1,47] <,0001[2]	1,70 [1,39; 2,09] <,0001[3]	13,2 [8,2; 18,2] <,0001[3]
Injury, poisoning and procedural complications				
123/776 (15,9)	98/729 (13,4)	1,18 [0,92; 1,51] 0,1882[2]	1,21 [0,91; 1,62] 0,1873[3]	2,4 [-1,2; 6,0] 0,1873[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Investigations				
405/776 (52,2)	159/729 (21,8)	2,39 [2,05; 2,79] <,0001[2]	3,91 [3,12; 4,90] <,0001[3]	30,4 [25,8; 35,0] <,0001[3]
Metabolism and nutrition disorders				
175/776 (22,6)	85/729 (11,7)	1,93 [1,52; 2,46] <,0001[2]	2,21 [1,66; 2,92] <,0001[3]	10,9 [7,1; 14,6] <,0001[3]
Musculoskeletal and connective tissue disorders				
365/776 (47,0)	390/729 (53,5)	0,88 [0,79; 0,97] 0,0123[2]	0,77 [0,63; 0,95] 0,0122[3]	-6,5 [-11,5; -1,4] 0,0122[3]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
21/776 (2,7)	24/729 (3,3)	0,82 [0,46; 1,46] 0,5054[2]	0,82 [0,45; 1,48] 0,5047[3]	-0,6 [-2,3; 1,1] 0,5047[3]
Nervous system disorders				
283/776 (36,5)	216/729 (29,6)	1,23 [1,06; 1,42] 0,0051[2]	1,36 [1,10; 1,69] 0,0049[3]	6,8 [2,1; 11,6] 0,0049[3]
Psychiatric disorders				
163/776 (21,0)	152/729 (20,9)	1,01 [0,83; 1,23] 0,9412[2]	1,01 [0,79; 1,29] 0,9412[3]	0,2 [-4,0; 4,3] 0,9412[3]
Renal and urinary disorders				
55/776 (7,1)	33/729 (4,5)	1,57 [1,03; 2,38] 0,0362[2]	1,61 [1,03; 2,51] 0,0343[3]	2,6 [0,2; 4,9] 0,0343[3]
Reproductive system and breast disorders				
144/776 (18,6)	153/729 (21,0)	0,88 [0,72; 1,08] 0,2366[2]	0,86 [0,67; 1,11] 0,2363[3]	-2,4 [-6,5; 1,6] 0,2363[3]
Respiratory, thoracic and mediastinal disorders				
217/776 (28,0)	113/729 (15,5)	1,80 [1,47; 2,21] <,0001[2]	2,12 [1,64; 2,73] <,0001[3]	12,5 [8,4; 16,6] <,0001[3]
Skin and subcutaneous tissue disorders				
305/776 (39,3)	145/729 (19,9)	1,98 [1,67; 2,34] <,0001[2]	2,61 [2,07; 3,29] <,0001[3]	19,4 [14,9; 23,9] <,0001[3]
Surgical and medical procedures				
45/776 (5,8)	41/729 (5,6)	1,03 [0,68; 1,56] 0,8839[2]	1,03 [0,67; 1,60] 0,8839[3]	0,2 [-2,2; 2,5] 0,8839[3]
Vascular disorders				
265/776 (34,1)	261/729 (35,8)	0,95 [0,83; 1,09] 0,5014[2]	0,93 [0,75; 1,15] 0,5015[3]	-1,7 [-6,5; 3,2] 0,5015[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; GnRH: Gonadotropine releasing hormone; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.				

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Table 058.2: Results from binary analysis for adverse events according SOC - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Blood and lymphatic system disorders				
591/1283 (46,1)	114/1264 (9,0)	5,11 [4,25; 6,14] <,0001[2]	8,62 [6,90; 10,75] <,0001[3]	37,0 [33,9; 40,2] <,0001[3]
Cardiac disorders				
90/1283 (7,0)	60/1264 (4,7)	1,48 [1,08; 2,03] 0,0158[2]	1,51 [1,08; 2,12] 0,0151[3]	2,3 [0,4; 4,1] 0,0151[3]
Ear and labyrinth disorders				
52/1283 (4,1)	56/1264 (4,4)	0,91 [0,63; 1,32] 0,6366[2]	0,91 [0,62; 1,34] 0,6365[3]	-0,4 [-1,9; 1,2] 0,6365[3]
Endocrine disorders				
24/1283 (1,9)	31/1264 (2,5)	0,76 [0,45; 1,29] 0,3140[2]	0,76 [0,44; 1,30] 0,3124[3]	-0,6 [-1,7; 0,5] 0,3124[3]
Eye disorders				
197/1283 (15,4)	66/1264 (5,2)	2,94 [2,25; 3,84] <,0001[2]	3,29 [2,46; 4,40] <,0001[3]	10,1 [7,8; 12,5] <,0001[3]
Gastrointestinal disorders				
1142/1283 (89,0)	412/1264 (32,6)	2,73 [2,52; 2,96] <,0001[2]	16,75 [13,57; 20,68] <,0001[3]	56,4 [53,3; 59,5] <,0001[3]
General disorders and administration site conditions				
716/1283 (55,8)	412/1264 (32,6)	1,71 [1,56; 1,88] <,0001[2]	2,61 [2,22; 3,07] <,0001[3]	23,2 [19,5; 27,0] <,0001[3]
Hepatobiliary disorders				
62/1283 (4,8)	56/1264 (4,4)	1,09 [0,77; 1,55] 0,6295[2]	1,10 [0,76; 1,59] 0,6294[3]	0,4 [-1,2; 2,0] 0,6294[3]
Immune system disorders				
30/1283 (2,3)	30/1264 (2,4)	0,99 [0,60; 1,62] 0,9534[2]	0,98 [0,59; 1,64] 0,9534[3]	-0,0 [-1,2; 1,1] 0,9534[3]
Infections and infestations				
607/1283 (47,3)	464/1264 (36,7)	1,29 [1,17; 1,41] <,0001[2]	1,55 [1,32; 1,81] <,0001[3]	10,6 [6,8; 14,4] <,0001[3]
Injury, poisoning and procedural complications				
221/1283 (17,2)	187/1264 (14,8)	1,16 [0,97; 1,39] 0,0950[2]	1,20 [0,97; 1,48] 0,0944[3]	2,4 [-0,4; 5,3] 0,0944[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Investigations				
623/1283 (48,6)	281/1264 (22,2)	2,18 [1,94; 2,46] <,0001[2]	3,30 [2,78; 3,92] <,0001[3]	26,3 [22,8; 29,9] <,0001[3]
Metabolism and nutrition disorders				
363/1283 (28,3)	211/1264 (16,7)	1,69 [1,46; 1,97] <,0001[2]	1,97 [1,63; 2,38] <,0001[3]	11,6 [8,4; 14,8] <,0001[3]
Musculoskeletal and connective tissue disorders				
631/1283 (49,2)	745/1264 (58,9)	0,83 [0,78; 0,90] <,0001[2]	0,67 [0,58; 0,79] <,0001[3]	-9,8 [-13,6; -5,9] <,0001[3]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
39/1283 (3,0)	38/1264 (3,0)	1,01 [0,65; 1,57] 0,9607[2]	1,01 [0,64; 1,59] 0,9607[3]	0,0 [-1,3; 1,4] 0,9607[3]
Nervous system disorders				
500/1283 (39,0)	347/1264 (27,5)	1,42 [1,27; 1,59] <,0001[2]	1,69 [1,43; 1,99] <,0001[3]	11,5 [7,9; 15,1] <,0001[3]
Psychiatric disorders				
204/1283 (15,9)	214/1264 (16,9)	0,94 [0,79; 1,12] 0,4829[2]	0,93 [0,75; 1,14] 0,4828[3]	-1,0 [-3,9; 1,8] 0,4828[3]
Renal and urinary disorders				
102/1283 (8,0)	68/1264 (5,4)	1,48 [1,10; 1,99] 0,0099[2]	1,52 [1,11; 2,09] 0,0094[3]	2,6 [0,6; 4,5] 0,0094[3]
Reproductive system and breast disorders				
125/1283 (9,7)	169/1264 (13,4)	0,73 [0,59; 0,91] 0,0044[2]	0,70 [0,55; 0,89] 0,0042[3]	-3,6 [-6,1; -1,1] 0,0042[3]
Respiratory, thoracic and mediastinal disorders				
376/1283 (29,3)	248/1264 (19,6)	1,49 [1,30; 1,72] <,0001[2]	1,70 [1,41; 2,04] <,0001[3]	9,7 [6,4; 13,0] <,0001[3]
Skin and subcutaneous tissue disorders				
508/1283 (39,6)	283/1264 (22,4)	1,77 [1,56; 2,00] <,0001[2]	2,27 [1,91; 2,70] <,0001[3]	17,2 [13,7; 20,7] <,0001[3]
Surgical and medical procedures				
67/1283 (5,2)	71/1264 (5,6)	0,93 [0,67; 1,29] 0,6598[2]	0,93 [0,66; 1,30] 0,6598[3]	-0,4 [-2,2; 1,4] 0,6598[3]
Vascular disorders				
393/1283 (30,6)	375/1264 (29,7)	1,03 [0,92; 1,16] 0,5963[2]	1,05 [0,88; 1,24] 0,5962[3]	1,0 [-2,6; 4,5] 0,5962[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.				

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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Anhang 4-G2.4.6: Häufige schwerwiegende unerwünschte Ereignisse nach SOC und PT

Table 059.1: Results from binary analysis for serious adverse events according PT - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
No events in category				
-	-	-	-	-

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 059.2: Results from binary analysis for serious adverse events according PT - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Pneumonia				
15/1283 (1,2)	7/1264 (0,6)	2,11 [0,86; 5,16] 0,1013[2]	2,12 [0,86; 5,23] 0,0934[3]	0,6 [-0,1; 1,3] 0,0934[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aesocpt.sas
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Table 060.1: Results from binary analysis for serious adverse events according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Hepatobiliary disorders				
10/776 (1,3)	1/729 (0,1)	9,39 [1,21; 73,20] 0,0325[2]	9,50 [1,21; 74,43] 0,0088[3]	1,2 [0,3; 2,0] 0,0088[3]
Infections and infestations				
34/776 (4,4)	19/729 (2,6)	1,68 [0,97; 2,92] 0,0652[2]	1,71 [0,97; 3,03] 0,0619[3]	1,8 [-0,1; 3,6] 0,0619[3]
Reproductive system and breast disorders				
6/776 (0,8)	10/729 (1,4)	0,56 [0,21; 1,54] 0,2645[2]	0,56 [0,20; 1,55] 0,2578[3]	-0,6 [-1,6; 0,4] 0,2578[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 060.2: Results from binary analysis for serious adverse events according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Cardiac disorders				
17/1283 (1,3)	8/1264 (0,6)	2,09 [0,91; 4,83] 0,0835[2]	2,11 [0,91; 4,90] 0,0765[3]	0,7 [-0,1; 1,5] 0,0765[3]
Gastrointestinal disorders				
31/1283 (2,4)	14/1264 (1,1)	2,18 [1,17; 4,08] 0,0146[2]	2,21 [1,17; 4,18] 0,0122[3]	1,3 [0,3; 2,3] 0,0122[3]
Infections and infestations				
70/1283 (5,5)	33/1264 (2,6)	2,09 [1,39; 3,14] 0,0004[2]	2,15 [1,41; 3,28] 0,0003[3]	2,8 [1,3; 4,4] 0,0003[3]
Injury, poisoning and procedural complications				
18/1283 (1,4)	17/1264 (1,3)	1,04 [0,54; 2,01] 0,8999[2]	1,04 [0,54; 2,03] 0,8999[3]	0,1 [-0,8; 1,0] 0,8999[3]
Metabolism and nutrition disorders				
13/1283 (1,0)	4/1264 (0,3)	3,20 [1,05; 9,79] 0,0413[2]	3,22 [1,05; 9,92] 0,0308[3]	0,7 [0,1; 1,3] 0,0308[3]
Nervous system disorders				
14/1283 (1,1)	13/1264 (1,0)	1,06 [0,50; 2,25] 0,8772[2]	1,06 [0,50; 2,27] 0,8772[3]	0,1 [-0,7; 0,9] 0,8772[3]
Respiratory, thoracic and mediastinal disorders				
16/1283 (1,2)	8/1264 (0,6)	1,97 [0,85; 4,59] 0,1157[2]	1,98 [0,85; 4,65] 0,1087[3]	0,6 [-0,1; 1,4] 0,1087[3]
Vascular disorders				
16/1283 (1,2)	6/1264 (0,5)	2,63 [1,03; 6,69] 0,0429[2]	2,65 [1,03; 6,79] 0,0352[3]	0,8 [0,1; 1,5] 0,0352[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.

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Anhang 4-G2.4.7: Häufige schwere unerwünschte Ereignisse (CTCAE Grade >=3) nach SOC und PT

Table 061.1: Results from binary analysis for adverse events with CTCAE Grade ≥ 3 according PT - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Alanine aminotransferase increased				
21/776 (2,7)	3/729 (0,4)	6,58 [1,97; 21,95] 0,0022[2]	6,73 [2,00; 22,66] 0,0004[3]	2,3 [1,1; 3,5] 0,0004[3]
Aspartate aminotransferase increased				
16/776 (2,1)	2/729 (0,3)	7,52 [1,73; 32,57] 0,0070[2]	7,65 [1,75; 33,40] 0,0014[3]	1,8 [0,7; 2,9] 0,0014[3]
Diarrhoea				
46/776 (5,9)	3/729 (0,4)	14,40 [4,50; 46,11] <,0001[2]	15,25 [4,72; 49,25] <,0001[3]	5,5 [3,8; 7,2] <,0001[3]
Fatigue				
10/776 (1,3)	0/729 (0,0)	19,73 [1,16; 336,08] 0,0393[2]	19,99 [1,17; 341,69] 0,0020[4]	1,3 [0,5; 2,1] 0,0020[4]
Gamma-glutamyltransferase increased				
11/776 (1,4)	0/729 (0,0)	21,61 [1,28; 366,03] 0,0333[2]	21,92 [1,29; 372,62] 0,0013[3]	1,4 [0,6; 2,2] 0,0013[3]
Hypertension				
10/776 (1,3)	10/729 (1,4)	0,94 [0,39; 2,24] 0,8882[2]	0,94 [0,39; 2,27] 0,8881[3]	-0,1 [-1,2; 1,1] 0,8881[3]
Leukopenia				
22/776 (2,8)	0/729 (0,0)	42,28 [2,57; 695,67] 0,0088[2]	43,51 [2,63; 718,56] <,0001[3]	2,8 [1,7; 4,0] <,0001[3]
Lymphocyte count decreased				
34/776 (4,4)	2/729 (0,3)	15,97 [3,85; 66,24] 0,0001[2]	16,66 [3,99; 69,58] <,0001[3]	4,1 [2,6; 5,6] <,0001[3]
Lymphopenia				
12/776 (1,5)	3/729 (0,4)	3,76 [1,06; 13,26] 0,0396[2]	3,80 [1,07; 13,52] 0,0268[3]	1,1 [0,2; 2,1] 0,0268[3]
Neutropenia				
60/776 (7,7)	5/729 (0,7)	11,27 [4,55; 27,91] <,0001[2]	12,13 [4,84; 30,39] <,0001[3]	7,0 [5,1; 9,0] <,0001[3]
Neutrophil count decreased				
87/776 (11,2)	6/729 (0,8)	13,62 [5,99; 30,96] <,0001[2]	15,22 [6,61; 35,03] <,0001[3]	10,4 [8,1; 12,7] <,0001[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
White blood cell count decreased				
68/776 (8,8)	6/729 (0,8)	10,65 [4,65; 24,38] <,0001[2]	11,57 [4,99; 26,84] <,0001[3]	7,9 [5,8; 10,0] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; GnRH: Gonadotropine releasing hormone; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

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Output Location:
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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 061.2: Results from binary analysis for adverse events with CTCAE Grade ≥ 3 according PT - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Alanine aminotransferase increased				
35/1283 (2,7)	7/1264 (0,6)	4,93 [2,20; 11,05] 0,0001[2]	5,04 [2,23; 11,38] <,0001[3]	2,2 [1,2; 3,2] <,0001[3]
Anaemia				
39/1283 (3,0)	6/1264 (0,5)	6,40 [2,72; 15,07] <,0001[2]	6,57 [2,77; 15,58] <,0001[3]	2,6 [1,6; 3,6] <,0001[3]
Aspartate aminotransferase increased				
22/1283 (1,7)	4/1264 (0,3)	5,42 [1,87; 15,68] 0,0018[2]	5,50 [1,89; 15,99] 0,0004[3]	1,4 [0,6; 2,2] 0,0004[3]
Diarrhoea				
125/1283 (9,7)	2/1264 (0,2)	61,57 [15,26; 248,40] <,0001[2]	68,11 [16,81; 276,00] <,0001[3]	9,6 [7,9; 11,2] <,0001[3]
Fatigue				
34/1283 (2,7)	2/1264 (0,2)	16,75 [4,03; 69,56] 0,0001[2]	17,18 [4,12; 71,65] <,0001[3]	2,5 [1,6; 3,4] <,0001[3]
Gamma-glutamyltransferase increased				
20/1283 (1,6)	5/1264 (0,4)	3,94 [1,48; 10,47] 0,0059[2]	3,99 [1,49; 10,66] 0,0029[3]	1,2 [0,4; 1,9] 0,0029[3]
Hypertension				
17/1283 (1,3)	21/1264 (1,7)	0,80 [0,42; 1,50] 0,4848[2]	0,79 [0,42; 1,51] 0,4838[3]	-0,3 [-1,3; 0,6] 0,4838[3]
Hypokalaemia				
18/1283 (1,4)	4/1264 (0,3)	4,43 [1,50; 13,06] 0,0069[2]	4,48 [1,51; 13,28] 0,0030[3]	1,1 [0,4; 1,8] 0,0030[3]
Leukopenia				
48/1283 (3,7)	2/1264 (0,2)	23,64 [5,76; 97,07] <,0001[2]	24,52 [5,95; 101,12] <,0001[3]	3,6 [2,5; 4,6] <,0001[3]
Lymphocyte count decreased				
42/1283 (3,3)	5/1264 (0,4)	8,28 [3,28; 20,85] <,0001[2]	8,52 [3,36; 21,61] <,0001[3]	2,9 [1,8; 3,9] <,0001[3]
Lymphopenia				
22/1283 (1,7)	2/1264 (0,2)	10,84 [2,55; 45,99] 0,0012[2]	11,01 [2,58; 46,91] <,0001[3]	1,6 [0,8; 2,3] <,0001[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Neutropenia				
140/1283 (10,9)	4/1264 (0,3)	34,48 [12,80; 92,88] <,0001[2]	38,58 [14,23; 104,58] <,0001[3]	10,6 [8,9; 12,3] <,0001[3]
Neutrophil count decreased				
129/1283 (10,1)	4/1264 (0,3)	31,77 [11,78; 85,68] <,0001[2]	35,21 [12,98; 95,55] <,0001[3]	9,7 [8,1; 11,4] <,0001[3]
Platelet count decreased				
13/1283 (1,0)	0/1264 (0,0)	26,60 [1,58; 446,99] 0,0227[2]	26,87 [1,60; 452,53] 0,0003[3]	1,0 [0,5; 1,6] 0,0003[3]
White blood cell count decreased				
99/1283 (7,7)	3/1264 (0,2)	32,51 [10,34; 102,26] <,0001[2]	35,15 [11,11; 111,15] <,0001[3]	7,5 [6,0; 9,0] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

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/lillyce/prd/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 062.1: Results from binary analysis for adverse events with CTCAE Grade ≥ 3 according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Blood and lymphatic system disorders				
91/776 (11,7)	14/729 (1,9)	6,11 [3,51; 10,62] <,0001[2]	6,78 [3,83; 12,03] <,0001[3]	9,8 [7,3; 12,3] <,0001[3]
Gastrointestinal disorders				
62/776 (8,0)	7/729 (1,0)	8,32 [3,83; 18,06] <,0001[2]	8,96 [4,07; 19,70] <,0001[3]	7,0 [5,0; 9,1] <,0001[3]
General disorders and administration site conditions				
16/776 (2,1)	5/729 (0,7)	3,01 [1,11; 8,16] 0,0308[2]	3,05 [1,11; 8,36] 0,0229[3]	1,4 [0,2; 2,5] 0,0229[3]
Hepatobiliary disorders				
11/776 (1,4)	2/729 (0,3)	5,17 [1,15; 23,23] 0,0323[2]	5,23 [1,15; 23,66] 0,0166[3]	1,1 [0,2; 2,1] 0,0166[3]
Infections and infestations				
37/776 (4,8)	17/729 (2,3)	2,04 [1,16; 3,60] 0,0131[2]	2,10 [1,17; 3,76] 0,0111[3]	2,4 [0,6; 4,3] 0,0111[3]
Investigations				
162/776 (20,9)	14/729 (1,9)	10,87 [6,36; 18,59] <,0001[2]	13,47 [7,72; 23,51] <,0001[3]	19,0 [15,9; 22,0] <,0001[3]
Metabolism and nutrition disorders				
16/776 (2,1)	6/729 (0,8)	2,51 [0,99; 6,37] 0,0537[2]	2,54 [0,99; 6,52] 0,0454[3]	1,2 [0,0; 2,4] 0,0454[3]
Musculoskeletal and connective tissue disorders				
6/776 (0,8)	10/729 (1,4)	0,56 [0,21; 1,54] 0,2645[2]	0,56 [0,20; 1,55] 0,2578[3]	-0,6 [-1,6; 0,4] 0,2578[3]
Nervous system disorders				
11/776 (1,4)	6/729 (0,8)	1,72 [0,64; 4,63] 0,2816[2]	1,73 [0,64; 4,71] 0,2754[3]	0,6 [-0,5; 1,7] 0,2754[3]
Reproductive system and breast disorders				
5/776 (0,6)	13/729 (1,8)	0,36 [0,13; 1,01] 0,0519[2]	0,36 [0,13; 1,01] 0,0422[3]	-1,1 [-2,3; -0,0] 0,0422[3]
Respiratory, thoracic and mediastinal disorders				
10/776 (1,3)	1/729 (0,1)	9,39 [1,21; 73,20] 0,0325[2]	9,50 [1,21; 74,43] 0,0088[3]	1,2 [0,3; 2,0] 0,0088[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Surgical and medical procedures				
9/776 (1,2)	10/729 (1,4)	0,85 [0,35; 2,07] 0,7132[2]	0,84 [0,34; 2,09] 0,7128[3]	-0,2 [-1,3; 0,9] 0,7128[3]
Vascular disorders				
14/776 (1,8)	15/729 (2,1)	0,88 [0,43; 1,80] 0,7209[2]	0,87 [0,42; 1,82] 0,7207[3]	-0,3 [-1,6; 1,1] 0,7207[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 062.2: Results from binary analysis for adverse events with CTCAE Grade ≥ 3 according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Blood and lymphatic system disorders				
210/1283 (16,4)	15/1264 (1,2)	13,79 [8,22; 23,15] <,0001[2]	16,30 [9,59; 27,69] <,0001[3]	15,2 [13,1; 17,3] <,0001[3]
Cardiac disorders				
14/1283 (1,1)	11/1264 (0,9)	1,25 [0,57; 2,75] 0,5726[2]	1,26 [0,57; 2,78] 0,5717[3]	0,2 [-0,5; 1,0] 0,5717[3]
Eye disorders				
15/1283 (1,2)	6/1264 (0,5)	2,46 [0,96; 6,33] 0,0612[2]	2,48 [0,96; 6,41] 0,0526[3]	0,7 [-0,0; 1,4] 0,0526[3]
Gastrointestinal disorders				
148/1283 (11,5)	18/1264 (1,4)	8,10 [5,00; 13,13] <,0001[2]	9,03 [5,50; 14,82] <,0001[3]	10,1 [8,2; 12,0] <,0001[3]
General disorders and administration site conditions				
53/1283 (4,1)	7/1264 (0,6)	7,46 [3,40; 16,34] <,0001[2]	7,74 [3,50; 17,09] <,0001[3]	3,6 [2,4; 4,7] <,0001[3]
Infections and infestations				
71/1283 (5,5)	35/1264 (2,8)	2,00 [1,34; 2,97] 0,0006[2]	2,06 [1,36; 3,11] 0,0005[3]	2,8 [1,2; 4,3] 0,0005[3]
Injury, poisoning and procedural complications				
17/1283 (1,3)	19/1264 (1,5)	0,88 [0,46; 1,69] 0,7035[2]	0,88 [0,46; 1,70] 0,7033[3]	-0,2 [-1,1; 0,7] 0,7033[3]
Investigations				
246/1283 (19,2)	30/1264 (2,4)	8,08 [5,57; 11,71] <,0001[2]	9,76 [6,62; 14,38] <,0001[3]	16,8 [14,5; 19,1] <,0001[3]
Metabolism and nutrition disorders				
65/1283 (5,1)	25/1264 (2,0)	2,56 [1,63; 4,04] <,0001[2]	2,64 [1,66; 4,22] <,0001[3]	3,1 [1,7; 4,5] <,0001[3]
Musculoskeletal and connective tissue disorders				
15/1283 (1,2)	25/1264 (2,0)	0,59 [0,31; 1,12] 0,1049[2]	0,59 [0,31; 1,12] 0,1007[3]	-0,8 [-1,8; 0,2] 0,1007[3]
Nervous system disorders				
26/1283 (2,0)	17/1264 (1,3)	1,51 [0,82; 2,76] 0,1851[2]	1,52 [0,82; 2,81] 0,1819[3]	0,7 [-0,3; 1,7] 0,1819[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Renal and urinary disorders				
13/1283 (1,0)	4/1264 (0,3)	3,20 [1,05; 9,79] 0,0413[2]	3,22 [1,05; 9,92] 0,0308[3]	0,7 [0,1; 1,3] 0,0308[3]
Respiratory, thoracic and mediastinal disorders				
23/1283 (1,8)	9/1264 (0,7)	2,52 [1,17; 5,42] 0,0183[2]	2,55 [1,17; 5,52] 0,0144[3]	1,1 [0,2; 1,9] 0,0144[3]
Surgical and medical procedures				
14/1283 (1,1)	9/1264 (0,7)	1,53 [0,67; 3,53] 0,3156[2]	1,54 [0,66; 3,57] 0,3118[3]	0,4 [-0,4; 1,1] 0,3118[3]
Vascular disorders				
29/1283 (2,3)	31/1264 (2,5)	0,92 [0,56; 1,52] 0,7492[2]	0,92 [0,55; 1,54] 0,7491[3]	-0,2 [-1,4; 1,0] 0,7491[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.

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Anhang 4-G2.4.8: Häufige unerwünschte Ereignisse nach SOC und PT - Ergebnis des Interaktionsterms der Subgruppenanalysen

Table 200.1: Interaction term results of the subgroup analysis for adverse events according SOC/PT - from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Endpoint	Subgroup										
	Age group	ECOG PS	First endocrine therapy	Number of positive lymph nodes	Prior chemo-therapy	Progesterone receptor status	Race	Region	Tumor grade	Primary tumor size	Tumor stage
Adverse events according PT - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm											
Abdominal distension	NE	0,9749	0,2994	0,9952	0,1576	0,9994	0,9993	0,9991	0,5047	0,7059	0,8141
Abdominal pain	NE	0,5689	0,7054	0,5164	**0,0410**	0,9836	**0,0024**	0,0828	0,8185	0,5429	0,4569
Abdominal pain upper	NE	0,5989	0,1244	0,2404	0,9352	**0,0174**	**0,0487**	0,1560	0,8874	0,2801	0,3018
Alanine aminotransferase increased	NE	0,7732	0,0772	0,2287	0,5174	0,9179	0,3734	0,2624	0,8823	0,5339	0,5549
Alopecia	NE	0,4703	0,3621	0,3544	0,5273	**0,0003**	0,6034	0,4911	**0,0437**	0,3959	0,6597
Anaemia	NE	0,4061	0,2314	0,1507	0,3187	**<,0001**	0,6346	0,1783	0,1869	0,6519	0,0557
Arthralgia	NE	0,4130	0,6983	0,7824	0,1995	0,2428	0,3559	0,1151	0,6382	0,1520	0,7827
Aspartate aminotransferase increased	NE	0,3972	0,0811	0,7950	0,3444	0,5494	0,6777	0,3837	0,4162	0,3502	0,8875
Asthenia	NE	0,9403	0,1800	0,6436	0,3817	0,1469	0,9312	0,1029	0,5909	0,1398	0,5461
Blood creatinine increased	NE	0,9764	0,7839	0,9996	0,9738	0,9981	0,6836	0,8537	0,9628	0,9996	0,9999
Cellulitis	NE	0,8370	0,6183	0,2327	0,8833	0,9598	0,8353	0,9845	0,6917	0,2022	0,6794
Chills	NE	0,9779	0,9772	0,9995	0,1799	0,9996	0,7777	0,7627	NE	NE	1,0000
Conjunctivitis	NE	0,9771	0,9742	NE	0,1756	0,9607	0,8394	0,8656	0,9506	NE	NE
Constipation	NE	0,8935	0,1125	0,9100	0,9611	**<,0001**	**0,0231**	**0,0168**	0,1906	0,2117	0,9430
Cough	NE	**0,0171**	0,2821	0,3563	0,9313	**<,0001**	0,3753	0,5611	0,8244	0,9392	0,2677
Decreased appetite	NE	0,0653	0,8178	0,4751	**0,0219**	0,9749	0,9961	0,5139	0,8186	0,7692	0,4443
Diarrhoea	NE	0,1549	0,6520	0,9076	0,9299	0,2314	0,4560	0,0732	0,8964	**0,0213**	0,4576
Dizziness	NE	**0,0182**	0,7003	0,2504	0,3554	0,2695	0,7941	0,8732	0,4603	0,3767	0,3739
Dry eye	NE	0,4202	0,0636	0,1493	0,4815	0,9993	0,2707	0,2978	0,3957	0,0962	0,1088
Dry mouth	NE	0,9765	0,9749	0,6145	0,2951	0,4377	0,9993	0,9994	0,6829	0,3385	0,9751
Dry skin	NE	0,7762	0,2509	0,7943	0,9892	0,9208	0,8628	0,9222	0,9651	0,9948	0,7705

Endpoint	Subgroup										
	Age group	ECOG PS	First endocrine therapy	Number of positive lymph nodes	Prior chemo-therapy	Progesterone receptor status	Race	Region	Tumor grade	Primary tumor size	Tumor stage
Dysgeusia	NE	0,9796	0,9783	NE	0,9890	0,9582	0,9995	NE	0,9997	0,9998	NE
Dyspepsia	NE	0,7731	0,6493	0,8494	0,2431	0,3084	0,3446	0,3606	0,9870	0,8623	0,3545
Dyspnoea	NE	0,6402	0,1247	0,8838	0,8941	0,9994	0,3714	0,7709	0,2782	0,9198	0,6791
Epistaxis	NE	0,9796	NE	NE	NE	0,9497	NE	NE	NE	NE	NE
Erythema	NE	0,9784	0,9768	0,7499	NE	0,9516	0,8583	0,9480	NE	NE	0,8030
Fatigue	NE	0,4331	0,7907	0,8385	0,1913	0,2382	0,0536	0,1195	0,3369	0,0625	**0,0152**
Flatulence	NE	0,9771	0,9763	NE	NE	0,9497	0,9824	NE	NE	NE	NE
Gamma-glutamyltransferase increased	NE	0,9775	0,7417	0,9941	0,2375	0,9993	0,9289	0,7552	0,9970	0,5112	0,9920
Gastritis	NE	0,9169	0,5451	0,9370	0,3963	0,0834	0,9554	0,7991	0,8078	0,6214	0,7615
Haemorrhoids	NE	0,9768	0,7302	0,8540	0,7822	**0,0012**	0,6737	0,5559	0,9997	0,0693	0,9124
Hot flush	NE	0,5462	0,2179	0,1592	0,8513	0,2188	0,0765	0,1078	0,1425	0,3309	0,6537
Hypertriglyceridaemia	NE	0,9729	0,5804	0,2230	0,5722	0,6222	0,6460	0,6736	0,9989	0,5144	0,6328
Hyperuricaemia	NE	0,9796	NE	NE	NE	NE	NE	NE	NE	NE	NE
Hypokalaemia	NE	0,9763	**0,0243**	0,0514	0,2843	0,1138	0,2377	0,5365	0,7002	0,6993	0,7786
Lacrimation increased	NE	0,9786	0,3015	0,9582	0,9261	**0,0063**	0,9994	0,8885	**<,0001**	0,9729	0,9992
Leukopenia	NE	0,4747	0,3175	0,6584	0,8114	0,9577	0,8036	0,7714	0,8748	0,1054	0,9798
Lymphocyte count decreased	NE	0,8508	0,0940	0,1076	0,5242	0,9994	0,4094	0,2482	0,1942	0,7277	0,5623
Lymphoedema	NE	**0,0490**	0,8123	0,3751	0,2865	0,1615	0,7673	0,4596	0,3462	0,0697	0,8083
Lymphopenia	NE	0,9753	0,3889	0,7906	**<,0001**	**0,0019**	0,9516	0,9527	0,8831	0,8311	0,1797
Malaise	NE	0,2532	0,9835	0,9800	0,9623	0,9998	0,3324	0,2323	0,9901	0,7054	0,9849
Mouth ulceration	NE	0,9786	NE	NE	NE	0,9996	NE	NE	NE	NE	NE
Mucosal inflammation	NE	0,1978	0,4046	0,7157	0,3760	0,9599	0,9818	0,9994	0,2908	0,5842	0,8617
Nail disorder	NE	**<,0001**	0,9772	0,9738	0,9116	0,9971	0,9824	0,9979	0,9999	0,9690	NE
Nasopharyngitis	NE	0,2878	0,2374	0,9899	0,6918	0,5961	0,9406	0,8162	0,5497	0,7601	0,8468
Nausea	NE	0,5381	0,7822	0,1591	0,6506	0,8436	0,5776	0,5455	0,9336	**0,0205**	0,3345
Neutropenia	NE	0,3793	0,5420	0,7948	0,1848	0,7158	0,3015	0,2830	0,9326	0,3030	0,7844

Endpoint	Subgroup										
	Age group	**ECOG PS**	**First endocrine therapy**	**Number of positive lymph nodes**	**Prior chemo-therapy**	**Progesterone receptor status**	**Race**	**Region**	**Tumor grade**	**Primary tumor size**	**Tumor stage**
Neutrophil count decreased	NE	0,8864	0,1064	0,1498	0,6705	0,5220	0,6283	0,7519	0,3274	0,6542	0,8258
Oedema	NE	0,9779	0,6598	0,9656	NE	0,9996	NE	NE	NE	NE	NE
Oedema peripheral	NE	0,2122	0,1815	0,5547	0,4247	**<,0001**	0,3062	0,5508	0,8078	**0,0485**	0,5022
Onychoclasis	NE	0,9692	0,9758	0,5816	0,9965	1,0000	0,9995	0,5382	0,3857	NE	NE
Palpitations	NE	**<,0001**	NE	NE	NE	0,9712	NE	NE	NE	NE	NE
Platelet count decreased	NE	0,0791	0,9989	0,6633	0,8195	0,9295	0,8334	0,6051	0,9447	**0,0271**	0,9502
Pneumonia	NE	0,0543	0,9712	0,3319	0,4432	0,1409	0,6384	0,7736	0,9735	0,8494	0,2715
Pneumonitis	NE	0,4381	0,8317	0,3840	0,0719	0,9533	0,9026	0,8612	0,2448	NE	NE
Productive cough	NE	0,9747	0,8204	NE	0,6297	0,9533	NE	NE	NE	NE	NE
Pruritus	NE	0,9360	0,1894	0,8483	0,2953	**0,0002**	0,8082	0,7085	0,8711	0,9851	0,9823
Pyrexia	NE	**0,0079**	0,9875	0,6060	0,8650	0,8815	0,3164	0,5562	0,4158	0,4917	0,3615
Rash	NE	0,7731	0,8038	0,9990	0,9786	0,9753	0,3565	0,1353	0,9977	**0,0128**	0,8085
Rectal haemorrhage	NE	0,1309	0,9773	NE	0,9903	0,9494	0,9937	0,3018	NE	NE	NE
Sinusitis	NE	0,9773	0,6897	0,6822	0,1176	0,9236	0,7848	0,9979	0,4467	0,3540	0,2886
Stomatitis	NE	0,9741	0,9648	0,6742	0,9995	0,0888	0,4493	0,6495	0,9283	0,4412	0,4564
Thrombocytopenia	NE	0,8568	0,5232	0,5955	0,8685	0,9602	0,6096	0,5227	0,6009	0,5343	0,7102
Urinary tract infection	NE	0,0981	0,5227	0,7998	0,9968	0,1501	0,3600	0,5449	0,9781	0,4052	0,6759
Vaginal discharge	NE	0,9734	0,3272	0,9922	0,3204	0,9967	0,5835	0,4351	0,7358	0,4243	0,8051
Vomiting	NE	0,9653	0,8018	**0,0433**	0,4678	0,9749	0,7398	0,6485	0,7245	0,0503	0,5092
White blood cell count decreased	NE	0,3539	0,1239	0,2887	0,8275	0,8590	0,3412	0,5759	0,2817	0,6729	0,3305
Adverse events according SOC - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm											
Blood and lymphatic system disorders	NE	0,8949	0,6856	0,1104	0,8061	0,9724	0,4330	0,1999	0,4940	0,3344	0,2052
Endocrine disorders	NE	0,1162	0,3343	0,4514	0,8018	0,0998	0,6967	0,0976	0,8602	0,7845	0,6166
Eye disorders	NE	0,4575	0,1187	0,6226	0,4248	0,7952	0,9805	0,8575	0,2197	0,4950	0,8315

Endpoint	Subgroup										
	Age group	ECOG PS	First endocrine therapy	Number of positive lymph nodes	Prior chemo-therapy	Progesterone receptor status	Race	Region	Tumor grade	Primary tumor size	Tumor stage
Gastrointestinal disorders	NE	0,6866	**0,0457**	0,7715	0,1266	0,2773	0,9342	0,2866	0,1374	0,2085	NE
General disorders and administration site conditions	NE	**0,0112**	0,1923	0,4045	0,2811	0,7168	0,7624	0,8668	0,4348	0,8575	0,5269
Infections and infestations	NE	0,0635	0,9299	0,7057	0,3097	0,0634	0,6211	0,7806	0,5439	0,2848	0,7993
Investigations	NE	0,8223	0,0854	0,1083	0,6591	0,8930	0,5376	0,0763	0,3705	0,5241	0,6185
Metabolism and nutrition disorders	NE	0,8014	0,3256	0,4420	0,5275	0,4543	0,3021	0,5152	0,3735	0,8106	0,8384
Musculoskeletal and connective tissue disorders	NE	0,6239	0,6228	0,1914	0,8768	0,8972	0,7908	**0,0367**	0,0742	0,0901	0,5886
Nervous system disorders	NE	**0,0005**	0,4805	0,4873	0,0696	0,4146	**0,0060**	0,0799	0,5928	0,1566	0,5773
Renal and urinary disorders	NE	0,5483	0,3254	0,9222	0,9993	0,6341	0,8749	0,4208	0,8218	0,2633	0,1686
Respiratory, thoracic and mediastinal disorders	NE	0,1031	0,1269	0,4074	0,9279	0,8312	0,8350	0,2013	0,6186	0,9283	0,2393
Skin and subcutaneous tissue disorders	NE	0,6325	0,8086	0,9599	0,4069	0,6519	0,5605	0,6462	0,3465	0,3529	0,4647
Serious adverse events according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm											
Hepatobiliary disorders	NE	NE	NE	NE	NE	0,9497	NE	NE	NE	NE	NE
Adverse events with CTCAE Grade ≥ 3 according PT - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm											
Alanine aminotransferase increased	NE	0,2515	0,4932	0,6825	0,0565	0,3738	0,5884	0,9966	0,9988	0,9935	0,9960
Aspartate aminotransferase increased	NE	0,1107	0,6845	0,7580	NE	0,9533	0,9996	0,9742	NE	0,9999	NE
Diarrhoea	NE	0,9807	0,9780	0,7486	0,9028	0,9981	0,1705	0,8410	0,9385	0,9261	0,9947
Fatigue	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gamma-glutamyltransferase increased	NE	**<,0001**	NE	NE	NE	NE	NE	NE	NE	NE	NE
Leukopenia	NE	**<,0001**	**<,0001**	NE	0,9586	0,9894	0,9996	**<,0001**	1,0000	**<,0001**	NE

Endpoint	Subgroup										
	Age group	**ECOG PS**	**First endocrine therapy**	**Number of positive lymph nodes**	**Prior chemo-therapy**	**Progesterone receptor status**	**Race**	**Region**	**Tumor grade**	**Primary tumor size**	**Tumor stage**
Lymphocyte count decreased	NE	0,9784	0,9724	0,9992	0,1799	0,0510	0,9993	0,6084	0,5067	0,9979	1,0000
Lymphopenia	NE	0,9777	NE	NE	NE	0,9562	0,9994	NE	NE	NE	NE
Neutropenia	NE	0,0855	0,9746	0,5722	**0,0045**	0,9996	0,3304	0,6027	0,7321	0,4467	0,9907
Neutrophil count decreased	NE	0,9763	0,4352	0,4958	0,4579	0,8348	0,8779	0,6983	0,7373	0,5329	0,9644
White blood cell count decreased	NE	0,6754	0,4191	0,7492	**<,0001**	0,9516	0,9242	0,7274	0,7215	0,4587	0,9979
Adverse events with CTCAE Grade ≥ 3 according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm											
Blood and lymphatic system disorders	NE	0,6468	0,3193	0,9600	**0,0025**	0,9140	0,1885	0,1640	0,9930	0,9249	0,4964
Gastrointestinal disorders	NE	0,9780	0,6091	0,5621	0,5011	0,9715	**0,0149**	0,4955	0,9593	0,9716	0,3591
General disorders and administration site conditions	NE	0,9756	0,3964	0,6713	0,6171	0,9618	0,9996	0,9632	0,9647	0,6593	NE
Hepatobiliary disorders	NE	0,9767	0,3200	NE	NE	0,9497	NE	NE	NE	NE	NE
Infections and infestations	NE	0,3725	0,9802	0,4249	**0,0088**	0,5496	0,2647	0,3145	0,6332	0,3893	0,2541
Investigations	NE	0,4764	0,8671	0,1009	0,0586	0,7962	0,8801	0,7353	0,3787	0,3239	0,7781
Respiratory, thoracic and mediastinal disorders	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Data cut-off: 15.07.2025
The table shows p-values of the interaction term of subgroup factor and treatment group from logistic regression model: event = treatment, subgroup, treatment*subgroup. Only endpoints with z-test p-value < 0.05 for relative risk in the main analysis are included.
NE: not evaluable/not calculated. If fewer than 10 patients with an event occur in a subgroup category, an interaction test is not performed.
Abbreviations: CTCAE: common terminology criteria for adverse events; PT: preferred term; RCT: randomized, controlled study; SOC: system organ class.

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Table 200.2: Interaction term results of the subgroup analysis for adverse events according SOC/PT - from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Endpoint	Subgroup										
	Age group	ECOG PS	First endocrine therapy	Number of positive lymph nodes	Prior chemo-therapy	Progesterone receptor status	Race	Region	Tumor grade	Primary tumor size	Tumor stage
Adverse events according PT - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm											
Abdominal discomfort	0,4105	0,1766	0,8968	NE	**<,0001**	0,3408	0,9772	0,9968	**<,0001**	0,1587	0,8921
Abdominal distension	0,9487	0,5259	0,6296	**0,0495**	0,6706	0,0896	0,5662	0,7139	0,1449	0,6950	0,3805
Abdominal pain	0,5588	0,7874	0,1945	0,7770	0,9400	**<,0001**	0,9490	0,6716	0,8821	0,1568	0,7670
Abdominal pain upper	0,8999	0,9810	0,1037	0,4527	0,3012	0,9898	0,9550	0,0584	0,9324	0,8707	0,2805
Alanine aminotransferase increased	0,9544	0,8265	0,8343	0,2158	0,5797	0,6586	0,4004	0,6835	0,1531	0,5544	0,3399
Alopecia	0,1301	0,5286	**<,0001**	0,0816	0,3704	**<,0001**	0,3632	0,2488	0,6649	0,1084	0,5394
Anaemia	0,9107	0,2517	0,2577	0,5811	0,9646	**<,0001**	0,3669	0,2981	0,6706	0,7665	0,3013
Anxiety	**0,0226**	0,3875	0,2940	0,2018	0,4022	**<,0001**	0,3935	0,9637	**<,0001**	0,9666	0,6017
Arthralgia	0,7570	0,8579	0,2590	0,2323	0,6455	0,4111	0,9736	0,7911	0,3195	0,9249	0,7008
Aspartate aminotransferase increased	0,6289	0,5640	0,9436	0,3268	0,2937	0,5767	0,5151	0,3038	0,2171	0,6069	0,9973
Asthenia	0,5200	0,8689	0,6054	0,7582	0,4313	**<,0001**	0,7393	0,5850	0,6557	0,3605	0,7770
Back pain	0,3546	0,2169	0,9770	0,0847	0,6229	0,7913	0,8310	0,5465	0,4024	0,8443	0,1205
Blood alkaline phosphatase increased	0,5976	**0,0174**	0,4193	0,5587	0,8767	**0,0477**	0,6060	0,5048	0,2420	0,5358	0,9806
Blood creatinine increased	0,5103	0,8776	**<,0001**	0,8624	0,3624	**<,0001**	0,4758	0,3151	0,9969	0,7755	0,5171
COVID-19	0,7504	0,9713	0,9903	0,4720	**<,0001**	0,3322	0,9997	0,3691	0,1362	0,8811	1,0000
Cataract	0,9434	0,4131	0,1870	0,5206	0,5732	**<,0001**	0,9155	0,5419	0,0630	0,6804	0,7289
Constipation	**0,0019**	0,1650	0,3408	0,0866	0,1854	**<,0001**	0,5995	0,9930	0,8049	0,1221	0,3622
Cough	0,7182	**0,0210**	0,6772	0,8143	0,2570	**<,0001**	0,7752	0,5785	0,7171	0,3798	0,2307
Decreased appetite	0,1491	0,3949	0,7694	0,3645	0,7519	**<,0001**	0,1493	0,4443	0,8069	0,1413	**0,0438**
Deep vein thrombosis	**<,0001**	0,2792	**<,0001**	NE	0,9411	0,9633	0,2492	0,9091	0,1855	0,9550	0,9877

Endpoint	Subgroup										
	Age group	ECOG PS	First endocrine therapy	Number of positive lymph nodes	Prior chemo-therapy	Progesterone receptor status	Race	Region	Tumor grade	Primary tumor size	Tumor stage
Dehydration	**<,0001**	0,9744	**<,0001**	0,8241	0,8270	0,2718	0,9997	0,9111	0,8960	0,4448	0,9799
Dermatitis	0,8072	0,2238	0,3482	0,5331	0,8069	0,9998	0,6415	0,3321	0,7827	0,2891	0,8994
Diarrhoea	**0,0006**	0,5566	0,3933	0,7530	0,7077	**<,0001**	0,0514	**0,0032**	0,4036	0,4738	0,3755
Dizziness	0,7591	0,8368	0,3204	0,5556	0,3869	**0,0072**	0,8984	0,6923	0,9502	0,4405	0,7881
Dry eye	0,5410	**0,0478**	0,6245	0,5057	0,9901	0,2710	0,9642	0,6962	0,4789	0,8832	0,5145
Dry mouth	0,4649	0,5821	0,5869	0,2561	0,5442	0,9617	0,6216	0,4423	0,3093	0,1122	0,6980
Dry skin	0,5109	0,3664	0,6420	**0,0379**	0,7983	0,1223	0,5629	0,4606	0,2920	0,4331	0,1579
Dysgeusia	0,3072	0,9729	**0,0257**	0,3471	0,5816	0,9979	0,6370	0,7785	0,9986	0,6822	0,9908
Dyspepsia	**0,0171**	0,3026	0,5444	0,9936	0,1740	**<,0001**	**0,0222**	**0,0245**	0,9062	0,2058	0,8913
Dyspnoea	0,7885	0,5583	0,4829	0,7501	0,7259	**<,0001**	0,2394	0,1227	0,6495	0,3587	0,8872
Dysuria	0,8628	0,7128	0,8879	0,2065	0,3165	0,6151	0,3724	0,9332	0,6036	0,2659	0,2775
Epistaxis	**<,0001**	0,9729	**<,0001**	0,6657	0,9887	0,2732	0,3168	0,3984	0,6207	0,9937	NE
Fall	0,2556	0,4934	**<,0001**	0,7196	0,3364	0,5246	0,8359	0,8173	0,9753	0,2966	0,7764
Fatigue	0,5725	0,1324	0,2999	0,9746	0,3466	0,6989	0,3784	0,1480	0,9895	0,5456	0,2119
Flatulence	**0,0459**	0,3222	0,9953	0,1701	0,6259	0,5419	0,9996	0,9993	0,4280	0,7675	0,6794
Gamma-glutamyltransferase increased	0,8367	0,5582	**<,0001**	0,8442	0,6676	0,9972	0,8695	0,7449	0,8658	0,9898	0,8851
Gastrointestinal pain	**<,0001**	0,9793	**<,0001**	NE	0,9638	0,9621	0,9920	NE	NE	0,9991	NE
Haemorrhoids	0,7499	0,1457	**<,0001**	0,4419	0,9096	0,2688	0,8648	0,8266	0,5528	0,4866	0,9451
Headache	0,2780	0,6280	0,8990	0,7943	0,9702	**<,0001**	0,9997	0,6096	0,2585	0,6283	0,9600
Hot flush	0,2231	0,9862	0,2601	0,8553	0,2986	**<,0001**	0,5133	0,2172	0,6548	0,8321	0,6133
Hypokalaemia	0,9634	0,8542	0,4015	0,7892	0,5340	0,1714	0,8627	0,9345	0,9338	0,8800	0,2019
Hypotension	0,9947	0,4362	0,7427	0,9696	0,9585	0,2220	0,9909	0,1822	0,3177	0,5052	0,8569
Joint stiffness	0,5481	0,8813	0,1656	0,3010	0,9763	0,6142	0,8242	0,1941	0,6809	0,4611	0,9010
Lacrimation increased	0,1332	0,9054	0,6607	0,9973	0,6987	0,9588	0,9997	0,9703	0,3823	0,7043	0,7221
Leukopenia	0,6756	0,1872	**<,0001**	0,8757	0,9377	0,5536	0,7761	0,2470	0,6126	0,5781	0,9491
Lymphocyte count decreased	0,5167	0,1097	0,1159	0,9934	0,9336	**<,0001**	0,9474	0,8395	0,3919	0,8893	0,8284

	Subgroup										
Endpoint	**Age group**	**ECOG PS**	**First endocrine therapy**	**Number of positive lymph nodes**	**Prior chemo-therapy**	**Progesterone receptor status**	**Race**	**Region**	**Tumor grade**	**Primary tumor size**	**Tumor stage**
Lymphoedema	0,2668	0,6391	**0,0035**	0,3646	0,3956	**<,0001**	0,2679	0,0942	0,2535	0,4585	0,4473
Lymphopenia	0,3583	0,1364	**<,0001**	0,8581	0,1115	**<,0001**	0,5271	0,9477	0,9860	0,8694	0,8402
Malaise	0,5659	0,8133	0,3669	0,7573	0,8826	0,9617	0,7580	0,6895	0,6829	0,4421	0,9395
Mucosal inflammation	0,6616	0,8936	**<,0001**	0,8521	0,2723	0,1007	0,9885	0,9719	0,8854	0,3830	0,9887
Muscle spasms	0,1693	0,1440	0,1720	0,8500	0,9607	**<,0001**	0,6415	0,7747	0,6990	0,0980	0,1186
Nail disorder	**<,0001**	0,0958	**<,0001**	0,9645	0,9811	0,9634	0,9993	0,2870	0,9999	0,9210	0,6122
Nausea	0,8548	0,2836	0,5281	0,0811	0,4973	0,9325	0,4255	0,2960	0,1385	0,9728	0,3074
Neutropenia	0,4765	0,2779	0,4874	0,7461	0,9895	**<,0001**	0,3674	**0,0082**	0,1854	0,9297	0,5933
Neutrophil count decreased	0,1703	0,8210	0,1073	0,8230	0,1821	**<,0001**	0,4760	0,2979	0,1338	0,1639	0,8304
Oedema peripheral	0,7980	0,7036	0,7438	0,8809	0,6719	**<,0001**	0,8178	0,6722	0,5910	0,6935	0,7276
Onychoclasis	0,6526	0,3380	0,3336	0,8371	0,9848	0,9644	0,9852	0,9779	0,9991	0,8159	0,9599
Oral herpes	0,6298	0,9325	0,5292	0,6509	0,9996	0,9624	0,9578	**<,0001**	**<,0001**	0,7506	NE
Osteoporosis	0,5287	0,3265	0,9518	0,5430	0,8719	0,2964	0,9355	0,6253	0,5675	0,7436	0,3867
Palpitations	0,3711	0,9584	**<,0001**	0,9511	0,7686	0,6594	0,4462	0,5768	0,9992	0,6056	0,9422
Paronychia	0,8267	0,9731	**<,0001**	NE	0,9664	0,5742	0,9737	0,9932	NE	NE	NE
Platelet count decreased	0,8788	0,6414	0,4631	0,4747	0,9965	**<,0001**	0,2780	0,1252	0,5938	0,1525	0,4743
Pneumonitis	**<,0001**	**<,0001**	**<,0001**	NE	0,7212	0,3906	0,7758	0,7878	0,9955	0,5329	NE
Pruritus	0,5667	**0,0159**	0,5911	0,3794	0,1400	**<,0001**	0,0779	0,1887	0,2686	0,1664	0,2314
Pyrexia	0,8454	0,2473	0,7409	0,1466	0,7315	**<,0001**	0,8684	0,8380	0,1420	0,3460	0,2090
Rash	0,5579	0,5858	0,9436	0,5830	0,1768	0,3015	0,6848	0,8347	0,7146	0,3991	0,8973
Rash maculo-papular	**<,0001**	0,8318	**<,0001**	0,9518	0,9127	0,9645	0,9997	0,9994	0,9758	0,9163	0,8790
Seroma	0,6298	0,7040	**<,0001**	NE	0,3496	**<,0001**	0,9909	0,7179	**0,0009**	NE	0,7479
Stomatitis	0,6410	0,4489	0,3279	0,2772	0,7134	0,9384	0,8239	0,9290	0,5400	0,3263	0,9978
Taste disorder	0,7795	0,5162	0,2949	0,8184	0,9720	0,2089	0,9867	0,9756	0,5170	0,9210	1,0000
Thrombocytopenia	0,1111	0,4654	**<,0001**	0,3425	0,9425	0,5703	0,1628	0,5761	0,9986	0,6590	0,9663
Urinary tract infection	0,9075	0,5950	0,1329	0,8554	0,0838	**<,0001**	0,7490	0,6528	0,7168	0,9063	0,6520

Endpoint	Subgroup										
	Age group	**ECOG PS**	**First endocrine therapy**	**Number of positive lymph nodes**	**Prior chemo-therapy**	**Progesterone receptor status**	**Race**	**Region**	**Tumor grade**	**Primary tumor size**	**Tumor stage**
Viral infection	0,2126	0,9757	**<,0001**	NE	0,9831	0,9634	0,9853	0,9779	0,5765	NE	NE
Vision blurred	0,1761	0,7866	0,9969	0,9371	0,7756	0,2115	0,9528	0,5704	0,7465	0,2525	0,5697
Vitamin B12 deficiency	0,0713	0,8919	**<,0001**	NE	**<,0001**	0,5735	0,9844	0,5278	0,8827	0,8845	1,0000
Vomiting	0,5692	0,0935	0,3697	**0,0197**	0,9715	**<,0001**	0,3570	0,0767	0,7813	0,7226	0,0567
Weight decreased	0,5196	0,5643	0,6712	0,9193	0,8371	0,9996	0,5561	0,6278	0,3837	0,0928	0,9905
Weight increased	0,4643	0,5085	0,4277	**0,0122**	0,7461	0,9349	0,2337	0,2086	0,9707	**0,0098**	0,0913
White blood cell count decreased	0,2324	0,5827	0,4062	0,9559	0,5861	**<,0001**	0,8863	0,7141	0,7340	0,6181	0,6302
Adverse events according SOC - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm											
Blood and lymphatic system disorders	0,1802	0,2663	**0,0167**	0,5649	0,9497	0,0524	**0,0364**	**0,0026**	0,7317	0,7181	0,4358
Cardiac disorders	0,7120	0,7539	0,1847	**0,0121**	0,9186	0,0648	0,3399	0,6115	0,9086	0,0615	0,7507
Eye disorders	0,9405	0,3337	0,2874	0,7523	0,7241	**<,0001**	0,3433	0,3707	0,3739	0,7086	0,4593
Gastrointestinal disorders	0,1125	0,1697	0,8103	0,3014	0,7415	0,5509	0,1567	**0,0005**	0,0766	**0,0491**	0,0509
General disorders and administration site conditions	0,9855	0,8806	0,5172	0,7037	0,6483	0,7816	0,6356	**0,0324**	0,1050	0,7328	0,4629
Infections and infestations	0,4121	0,5846	0,9358	0,9777	0,5060	0,6164	0,0799	0,0671	0,6696	0,2662	0,8804
Investigations	0,2502	0,2042	0,3696	0,1933	0,7095	0,8306	0,1390	**0,0484**	0,9394	0,4280	0,3128
Metabolism and nutrition disorders	0,5004	0,9942	0,2740	0,3288	0,3862	0,7745	0,2320	**0,0020**	0,2028	**0,0128**	0,4066
Musculoskeletal and connective tissue disorders	0,0579	0,8173	0,2749	0,1676	0,9299	0,5508	0,8828	0,9341	0,4186	0,7852	0,3708
Nervous system disorders	0,5067	0,3469	0,2637	0,9421	0,3910	0,3126	0,8761	0,4024	0,1380	0,8622	0,7476
Renal and urinary disorders	0,6782	0,5177	0,6585	0,4969	0,2380	**0,0003**	**0,0220**	0,7533	0,9972	0,1276	0,2382
Reproductive system and breast disorders	0,4085	0,2007	0,8277	0,7449	0,9432	0,3519	0,6551	0,8801	0,2540	0,9390	0,6235
Respiratory, thoracic and mediastinal disorders	0,3302	0,0600	0,6671	0,7357	0,6911	**<,0001**	0,7148	0,6902	0,3587	0,9638	0,7141

Endpoint	Subgroup										
	Age group	**ECOG PS**	**First endocrine therapy**	**Number of positive lymph nodes**	**Prior chemo-therapy**	**Progesterone receptor status**	**Race**	**Region**	**Tumor grade**	**Primary tumor size**	**Tumor stage**
Skin and subcutaneous tissue disorders	0,1076	0,4558	0,5676	0,8102	0,0952	0,5689	0,1582	**0,0175**	0,1881	0,7453	0,9949
Serious adverse events according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm											
Gastrointestinal disorders	**0,0458**	0,1446	**<,0001**	0,2721	0,9571	**<,0001**	0,8621	0,5637	0,2747	0,9408	0,9734
Infections and infestations	0,5578	0,6915	**<,0001**	0,7659	0,1862	**0,0132**	0,9144	0,1491	**0,0206**	**0,0218**	0,1866
Metabolism and nutrition disorders	NE	0,7629	**<,0001**	NE	NE	0,9655	0,9997	NE	NE	NE	NE
Vascular disorders	0,7519	0,4066	0,5754	NE	0,7215	0,5571	0,9997	0,9315	0,8559	0,3037	0,7379
Adverse events with CTCAE Grade ≥ 3 according PT - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm											
Alanine aminotransferase increased	0,4360	0,9733	**<,0001**	0,4551	0,4166	0,4288	0,5663	0,9345	0,8374	0,6182	0,9619
Anaemia	0,9746	0,9706	**<,0001**	0,5751	0,9809	0,6390	0,9889	0,9070	0,9903	0,9311	0,9611
Aspartate aminotransferase increased	0,8653	0,6693	**<,0001**	0,7696	0,2493	0,3666	0,1050	0,8121	0,7851	0,9040	0,9711
Diarrhoea	0,6740	0,9752	**<,0001**	0,9946	0,9543	**<,0001**	0,9998	0,9994	**<,0001**	0,7882	0,9968
Fatigue	0,9307	0,9742	**<,0001**	0,9979	0,8091	0,9606	0,9864	0,9995	1,0000	0,9993	0,9982
Gamma-glutamyltransferase increased	**<,0001**	0,8795	**<,0001**	0,2457	0,8567	0,9644	0,9288	0,9495	0,8949	0,0936	NE
Hypokalaemia	0,7515	0,8062	**<,0001**	0,3954	0,4368	0,9583	0,9968	0,9244	NE	0,8010	0,9974
Leukopenia	0,5705	0,5302	**<,0001**	0,9762	0,9718	0,9595	0,9997	0,9992	0,9991	0,9996	1,0000
Lymphocyte count decreased	0,9118	0,9727	**<,0001**	0,8207	0,8981	**<,0001**	0,6891	0,5953	0,9018	0,9875	0,9172
Lymphopenia	0,8343	**<,0001**	**<,0001**	0,9175	0,9512	0,9631	0,5468	0,8267	0,9999	0,6739	0,9998
Neutropenia	0,9139	0,9020	**<,0001**	0,9108	0,8359	0,9279	0,9997	0,9784	**<,0001**	0,9309	0,5902
Neutrophil count decreased	0,3246	0,4896	**<,0001**	0,6017	0,9404	0,9965	0,6907	0,8027	0,9525	0,7147	1,0000
Platelet count decreased	NE	**<,0001**	**<,0001**	NE	NE	0,9724	NE	NE	NE	NE	NE
White blood cell count decreased	0,1256	0,9749	**<,0001**	0,5299	0,9482	0,9999	0,8722	0,9680	0,6983	0,9636	1,0000

Endpoint	Subgroup										
	Age group	ECOG PS	First endocrine therapy	Number of positive lymph nodes	Prior chemo-therapy	Progesterone receptor status	Race	Region	Tumor grade	Primary tumor size	Tumor stage
Adverse events with CTCAE Grade ≥ 3 according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm											
Blood and lymphatic system disorders	0,7919	0,9058	**<,0001**	0,6933	0,8821	0,8104	0,5217	0,9879	**<,0001**	0,2541	0,9920
Gastrointestinal disorders	0,2066	0,7567	**<,0001**	0,4922	0,7016	**<,0001**	0,9915	0,3028	0,2053	0,8652	0,8903
General disorders and administration site conditions	0,7481	0,2392	0,4917	0,6966	0,4960	**0,0442**	0,9844	0,4836	0,9167	0,6870	0,4381
Infections and infestations	0,6823	0,7773	**<,0001**	0,6632	0,2742	**0,0145**	0,8038	0,1753	0,0891	**0,0489**	0,5516
Investigations	0,2217	0,6450	0,8445	**0,0360**	0,3027	**<,0001**	0,7382	0,3604	0,6117	0,8444	0,5619
Metabolism and nutrition disorders	0,8935	0,9291	0,6905	0,8170	0,3638	0,1624	0,4109	0,2285	**<,0001**	0,2806	0,4388
Renal and urinary disorders	NE	0,9718	**<,0001**	NE	NE	0,9998	0,8444	0,5905	**<,0001**	0,8618	NE
Respiratory, thoracic and mediastinal disorders	0,1373	0,1515	**<,0001**	0,9150	0,7322	0,2934	0,6777	0,9634	**<,0001**	0,5459	0,9587

Data cut-off: 15.07.2025
The table shows p-values of the interaction term of subgroup factor and treatment group from logistic regression model: event = treatment, subgroup, treatment*subgroup. Only endpoints with z-test p-value < 0.05 for relative risk in the main analysis are included.
NE: not evaluable/not calculated. If fewer than 10 patients with an event occur in a subgroup category, an interaction test is not performed.
Abbreviations: CTCAE: common terminology criteria for adverse events; PT: preferred term; RCT: randomized, controlled study; SOC: system organ class.

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Anhang 4-G2.4.9: Häufige unerwünschte Ereignisse nach Schweregrad und nach SOC und PT - Subgruppenanalyse interagierender Subgruppen (Prämenopausale Patientinnen)

Table 202.1.1: Interacting subgroups - adverse events according PT Abdominal pain from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,0410)					
Neoadjuvant chemotherapy	88/314 (28,0)	16/306 (5,2)	5,36 [3,22; 8,92] <,0001[2]	7,06 [4,03; 12,36] <,0001[3]	22,8 [17,2; 28,4] <,0001[3]
Adjuvant chemotherapy	118/452 (26,1)	17/416 (4,1)	6,39 [3,91; 10,44] <,0001[2]	8,29 [4,89; 14,07] <,0001[3]	22,0 [17,5; 26,5] <,0001[3]
No chemotherapy	1/10 (10,0)	2/7 (28,6)	0,35 [0,04; 3,15] 0,3491[2]	0,28 [0,02; 3,88] 0,5368[4]	-18,6 [-56,9; 19,7] 0,5368[4]
Race (Interaction p-value: 0,0024)					
White	146/461 (31,7)	25/440 (5,7)	5,57 [3,72; 8,35] <,0001[2]	7,69 [4,91; 12,05] <,0001[3]	26,0 [21,2; 30,8] <,0001[3]
Asian	52/273 (19,0)	3/243 (1,2)	15,43 [4,88; 48,77] <,0001[2]	18,82 [5,80; 61,14] <,0001[3]	17,8 [13,0; 22,7] <,0001[3]
Other	6/30 (20,0)	6/34 (17,6)	1,13 [0,41; 3,14] 0,8099[2]	1,17 [0,33; 4,10] 0,8098[3]	2,4 [-16,9; 21,6] 0,8098[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 203.1.1: Interacting subgroups - adverse events according PT Abdominal pain upper from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,0174)					
Negative	13/67 (19,4)	1/62 (1,6)	12,03 [1,62; 89,28] 0,0150[2]	14,69 [1,86; 115,99] 0,0012[3]	17,8 [7,8; 27,8] 0,0012[3]
Positive	83/678 (12,2)	24/647 (3,7)	3,30 [2,12; 5,13] <,0001[2]	3,62 [2,27; 5,78] <,0001[3]	8,5 [5,7; 11,4] <,0001[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,0487)					
White	68/461 (14,8)	12/440 (2,7)	5,41 [2,97; 9,85] <,0001[2]	6,17 [3,29; 11,57] <,0001[3]	12,0 [8,4; 15,6] <,0001[3]
Asian	20/273 (7,3)	10/243 (4,1)	1,78 [0,85; 3,73] 0,1262[2]	1,84 [0,84; 4,02] 0,1198[3]	3,2 [-0,8; 7,2] 0,1198[3]
Other	8/30 (26,7)	1/34 (2,9)	9,07 [1,20; 68,35] 0,0324[2]	12,00 [1,40; 102,78] 0,0096[4]	23,7 [6,9; 40,5] 0,0096[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 205.1.1: Interacting subgroups - adverse events according PT Alopecia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor grade (Interaction p-value: 0,0437)					
G1	7/63 (11,1)	5/52 (9,6)	1,16 [0,39; 3,43] 0,7944[2]	1,18 [0,35; 3,95] 0,7940[3]	1,5 [-9,7; 12,7] 0,7940[3]
G2	35/349 (10,0)	3/323 (0,9)	10,80 [3,35; 34,77] <,0001[2]	11,89 [3,62; 39,06] <,0001[3]	9,1 [5,8; 12,4] <,0001[3]
G3	27/317 (8,5)	5/312 (1,6)	5,31 [2,07; 13,62] 0,0005[2]	5,72 [2,17; 15,04] <,0001[3]	6,9 [3,5; 10,3] <,0001[3]
GX	4/44 (9,1)	0/40 (0,0)	8,20 [0,46; 147,68] 0,1537[2]	9,00 [0,47; 172,65] 0,1177[4]	9,1 [0,6; 17,6] 0,1177[4]
Progesterone receptor status (Interaction p-value: 0,0003)					
Negative	6/67 (9,0)	1/62 (1,6)	5,55 [0,69; 44,83] 0,1077[2]	6,00 [0,70; 51,33] 0,1167[4]	7,3 [-0,2; 14,9] 0,1167[4]
Positive	64/678 (9,4)	11/647 (1,7)	5,55 [2,96; 10,43] <,0001[2]	6,03 [3,15; 11,54] <,0001[3]	7,7 [5,3; 10,2] <,0001[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 206.1.1: Interacting subgroups - adverse events according PT Anaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	13/67 (19,4)	4/62 (6,5)	3,01 [1,04; 8,73] 0,0429[2]	3,49 [1,07; 11,36] 0,0298[3]	13,0 [1,7; 24,2] 0,0298[3]
Positive	144/678 (21,2)	25/647 (3,9)	5,50 [3,65; 8,29] <,0001[2]	6,71 [4,32; 10,42] <,0001[3]	17,4 [14,0; 20,8] <,0001[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 214.1.1: Interacting subgroups - adverse events according PT Constipation from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,0168)					
North America / Europe	66/347 (19,0)	22/309 (7,1)	2,67 [1,69; 4,22] <,0001[2]	3,06 [1,84; 5,10] <,0001[3]	11,9 [6,9; 16,9] <,0001[3]
Asia	18/239 (7,5)	19/226 (8,4)	0,90 [0,48; 1,66] 0,7274[2]	0,89 [0,45; 1,74] 0,7273[3]	-0,9 [-5,8; 4,1] 0,7273[3]
Other	15/190 (7,9)	6/194 (3,1)	2,55 [1,01; 6,44] 0,0472[2]	2,69 [1,02; 7,08] 0,0385[3]	4,8 [0,3; 9,3] 0,0385[3]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	11/67 (16,4)	6/62 (9,7)	1,70 [0,67; 4,31] 0,2667[2]	1,83 [0,63; 5,30] 0,2581[3]	6,7 [-4,8; 18,3] 0,2581[3]
Positive	82/678 (12,1)	41/647 (6,3)	1,91 [1,33; 2,73] 0,0004[2]	2,03 [1,37; 3,01] 0,0003[3]	5,8 [2,7; 8,8] 0,0003[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,0231)					
White	70/461 (15,2)	24/440 (5,5)	2,78 [1,78; 4,34] <,0001[2]	3,10 [1,91; 5,03] <,0001[3]	9,7 [5,8; 13,6] <,0001[3]
Asian	22/273 (8,1)	19/243 (7,8)	1,03 [0,57; 1,86] 0,9200[2]	1,03 [0,55; 1,96] 0,9200[3]	0,2 [-4,4; 4,9] 0,9200[3]
Other	4/30 (13,3)	1/34 (2,9)	4,53 [0,54; 38,36] 0,1654[2]	5,08 [0,53; 48,21] 0,1774[4]	10,4 [-3,0; 23,8] 0,1774[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 215.1.1: Interacting subgroups - adverse events according PT Cough from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	7/67 (10,4)	4/62 (6,5)	1,62 [0,50; 5,26] 0,4229[2]	1,69 [0,47; 6,09] 0,4168[3]	4,0 [-5,5; 13,5] 0,4168[3]
Positive	76/678 (11,2)	36/647 (5,6)	2,01 [1,38; 2,95] 0,0003[2]	2,14 [1,42; 3,24] 0,0002[3]	5,6 [2,7; 8,6] 0,0002[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,0171)					
ECOG-PS 0	78/685 (11,4)	30/649 (4,6)	2,46 [1,64; 3,70] <,0001[2]	2,65 [1,71; 4,10] <,0001[3]	6,8 [3,9; 9,6] <,0001[3]
ECOG-PS 1	12/91 (13,2)	12/80 (15,0)	0,88 [0,42; 1,85] 0,7335[2]	0,86 [0,36; 2,04] 0,7334[3]	-1,8 [-12,3; 8,7] 0,7334[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 216.1.1: Interacting subgroups - adverse events according PT Decreased appetite from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,0219)					
Neoadjuvant chemotherapy	30/314 (9,6)	3/306 (1,0)	9,75 [3,01; 31,60] 0,0001[2]	10,67 [3,22; 35,34] <,0001[3]	8,6 [5,1; 12,0] <,0001[3]
Adjuvant chemotherapy	40/452 (8,8)	7/416 (1,7)	5,26 [2,38; 11,61] <,0001[2]	5,67 [2,51; 12,81] <,0001[3]	7,2 [4,3; 10,1] <,0001[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 217.1.1: Interacting subgroups - adverse events according PT Diarrhoea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Primary tumor size (Interaction p-value: 0,0213)					
< 20 mm	171/204 (83,8)	9/189 (4,8)	17,60 [9,28; 33,40] <,0001[2]	103,64 [48,17; 222,98] <,0001[3]	79,1 [73,2; 85,0] <,0001[3]
≥ 20 but < 50 mm	290/360 (80,6)	29/346 (8,4)	9,61 [6,76; 13,67] <,0001[2]	45,29 [28,55; 71,82] <,0001[3]	72,2 [67,2; 77,2] <,0001[3]
≥ 50 mm	167/194 (86,1)	5/185 (2,7)	31,85 [13,39; 75,75] <,0001[2]	222,67 [83,80; 591,62] <,0001[3]	83,4 [78,0; 88,8] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 218.1.1: Interacting subgroups - adverse events according PT Dizziness from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: 0,0182)					
ECOG-PS 0	70/685 (10,2)	40/649 (6,2)	1,66 [1,14; 2,41] 0,0079[2]	1,73 [1,16; 2,60] 0,0071[3]	4,1 [1,1; 7,0] 0,0071[3]
ECOG-PS 1	4/91 (4,4)	9/80 (11,3)	0,39 [0,13; 1,22] 0,1058[2]	0,36 [0,11; 1,23] 0,0915[3]	-6,9 [-15,0; 1,3] 0,0915[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 227.1.1: Interacting subgroups - adverse events according PT Fatigue from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,0152)					
IIA	23/79 (29,1)	20/77 (26,0)	1,12 [0,67; 1,87] 0,6613[2]	1,17 [0,58; 2,37] 0,6608[3]	3,1 [-10,9; 17,1] 0,6608[3]
IIB	20/73 (27,4)	8/93 (8,6)	3,18 [1,49; 6,81] 0,0028[2]	4,01 [1,65; 9,75] 0,0013[3]	18,8 [7,1; 30,5] 0,0013[3]
IIIA	92/345 (26,7)	34/294 (11,6)	2,31 [1,61; 3,31] <,0001[2]	2,78 [1,81; 4,27] <,0001[3]	15,1 [9,2; 21,0] <,0001[3]
IIIB	5/22 (22,7)	5/19 (26,3)	0,86 [0,29; 2,54] 0,7896[2]	0,82 [0,20; 3,43] 1,0000[4]	-3,6 [-30,0; 22,8] 1,0000[4]
IIIC	61/253 (24,1)	19/245 (7,8)	3,11 [1,92; 5,04] <,0001[2]	3,78 [2,18; 6,55] <,0001[3]	16,4 [10,1; 22,6] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 231.1.1: Interacting subgroups - adverse events according PT Haemorrhoids from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,0012)					
Negative	2/67 (3,0)	1/62 (1,6)	1,85 [0,17; 19,91] 0,6115[2]	1,88 [0,17; 21,23] 1,0000[4]	1,4 [-3,8; 6,5] 1,0000[4]
Positive	26/678 (3,8)	10/647 (1,5)	2,48 [1,21; 5,10] 0,0135[2]	2,54 [1,22; 5,31] 0,0104[3]	2,3 [0,6; 4,0] 0,0104[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 235.1.1: Interacting subgroups - adverse events according PT Hypokalaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: 0,0243)					
Tamoxifen	18/553 (3,3)	1/534 (0,2)	17,38 [2,33; 129,74] 0,0054[2]	17,93 [2,39; 134,81] 0,0001[3]	3,1 [1,5; 4,6] 0,0001[3]
Aromatase inhibitor	7/223 (3,1)	5/195 (2,6)	1,22 [0,39; 3,80] 0,7260[2]	1,23 [0,38; 3,94] 0,7255[3]	0,6 [-2,6; 3,8] 0,7255[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 236.1.1: Interacting subgroups - adverse events according PT Lacrimation increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor grade (Interaction p-value: <,0001)					
G1	6/63 (9,5)	1/52 (1,9)	4,95 [0,62; 39,84] 0,1326[2]	5,37 [0,63; 46,11] 0,1256[4]	7,6 [-0,6; 15,8] 0,1256[4]
G2	12/349 (3,4)	0/323 (0,0)	23,14 [1,38; 389,30] 0,0291[2]	23,96 [1,41; 406,39] 0,0008[3]	3,4 [1,5; 5,4] 0,0008[3]
G3	16/317 (5,0)	1/312 (0,3)	15,75 [2,10; 118,03] 0,0073[2]	16,53 [2,18; 125,43] 0,0003[3]	4,7 [2,2; 7,2] 0,0003[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,0063)					
Negative	3/67 (4,5)	1/62 (1,6)	2,78 [0,30; 25,99] 0,3709[2]	2,86 [0,29; 28,24] 0,6202[4]	2,9 [-3,0; 8,7] 0,6202[4]
Positive	33/678 (4,9)	1/647 (0,2)	31,49 [4,32; 229,57] 0,0007[2]	33,05 [4,51; 242,37] <,0001[3]	4,7 [3,1; 6,4] <,0001[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 239.1.1: Interacting subgroups - adverse events according PT Lymphoedema from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: 0,0490)					
ECOG-PS 0	98/685 (14,3)	57/649 (8,8)	1,63 [1,20; 2,22] 0,0019[2]	1,73 [1,23; 2,45] 0,0017[3]	5,5 [2,1; 8,9] 0,0017[3]
ECOG-PS 1	7/91 (7,7)	10/80 (12,5)	0,62 [0,25; 1,54] 0,2999[2]	0,58 [0,21; 1,61] 0,2945[3]	-4,8 [-13,9; 4,3] 0,2945[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 240.1.1: Interacting subgroups - adverse events according PT Lymphopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: <,0001)					
Neoadjuvant chemotherapy	15/314 (4,8)	6/306 (2,0)	2,44 [0,96; 6,20] 0,0616[2]	2,51 [0,96; 6,55] 0,0526[3]	2,8 [-0,0; 5,6] 0,0526[3]
Adjuvant chemotherapy	18/452 (4,0)	7/416 (1,7)	2,37 [1,00; 5,61] 0,0504[2]	2,42 [1,00; 5,86] 0,0430[3]	2,3 [0,1; 4,5] 0,0430[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,0019)					
Negative	2/67 (3,0)	1/62 (1,6)	1,85 [0,17; 19,91] 0,6115[2]	1,88 [0,17; 21,23] 1,0000[4]	1,4 [-3,8; 6,5] 1,0000[4]
Positive	31/678 (4,6)	12/647 (1,9)	2,47 [1,28; 4,76] 0,0072[2]	2,54 [1,29; 4,98] 0,0053[3]	2,7 [0,8; 4,6] 0,0053[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 244.1.1: Interacting subgroups - adverse events according PT Nail disorder from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: <,0001)					
ECOG-PS 0	18/685 (2,6)	2/649 (0,3)	8,53 [1,99; 36,60] 0,0039[2]	8,73 [2,02; 37,78] 0,0005[3]	2,3 [1,0; 3,6] 0,0005[3]
ECOG-PS 1	0/91 (0,0)	0/80 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 246.1.1: Interacting subgroups - adverse events according PT Nausea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Primary tumor size (Interaction p-value: 0,0205)					
< 20 mm	54/204 (26,5)	15/189 (7,9)	3,34 [1,95; 5,70] <,0001[2]	4,18 [2,26; 7,70] <,0001[3]	18,5 [11,4; 25,7] <,0001[3]
≥ 20 but < 50 mm	82/360 (22,8)	31/346 (9,0)	2,54 [1,73; 3,74] <,0001[2]	3,00 [1,92; 4,67] <,0001[3]	13,8 [8,5; 19,1] <,0001[3]
≥ 50 mm	67/194 (34,5)	8/185 (4,3)	7,99 [3,95; 16,16] <,0001[2]	11,67 [5,42; 25,15] <,0001[3]	30,2 [22,9; 37,5] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 250.1.1: Interacting subgroups - adverse events according PT Oedema peripheral from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Primary tumor size (Interaction p-value: 0,0485)					
< 20 mm	22/204 (10,8)	8/189 (4,2)	2,55 [1,16; 5,58] 0,0195[2]	2,73 [1,19; 6,30] 0,0145[3]	6,6 [1,4; 11,7] 0,0145[3]
≥ 20 but < 50 mm	20/360 (5,6)	21/346 (6,1)	0,92 [0,51; 1,66] 0,7705[2]	0,91 [0,48; 1,71] 0,7704[3]	-0,5 [-4,0; 2,9] 0,7704[3]
≥ 50 mm	13/194 (6,7)	4/185 (2,2)	3,10 [1,03; 9,33] 0,0443[2]	3,25 [1,04; 10,16] 0,0329[3]	4,5 [0,4; 8,6] 0,0329[3]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	6/67 (9,0)	2/62 (3,2)	2,78 [0,58; 13,25] 0,2003[2]	2,95 [0,57; 15,20] 0,2765[4]	5,7 [-2,4; 13,9] 0,2765[4]
Positive	48/678 (7,1)	31/647 (4,8)	1,48 [0,95; 2,29] 0,0810[2]	1,51 [0,95; 2,41] 0,0787[3]	2,3 [-0,2; 4,8] 0,0787[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 252.1.1: Interacting subgroups - adverse events according PT Palpitations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: <,0001)					
ECOG-PS 0	10/685 (1,5)	1/649 (0,2)	9,47 [1,22; 73,80] 0,0318[2]	9,60 [1,23; 75,20] 0,0084[3]	1,3 [0,4; 2,3] 0,0084[3]
ECOG-PS 1	0/91 (0,0)	0/80 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 253.1.1: Interacting subgroups - adverse events according PT Platelet count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Primary tumor size (Interaction p-value: 0,0271)					
< 20 mm	11/204 (5,4)	3/189 (1,6)	3,40 [0,96; 11,99] 0,0574[2]	3,53 [0,97; 12,87] 0,0420[3]	3,8 [0,2; 7,4] 0,0420[3]
≥ 20 but < 50 mm	34/360 (9,4)	3/346 (0,9)	10,89 [3,38; 35,14] <,0001[2]	11,92 [3,63; 39,20] <,0001[3]	8,6 [5,4; 11,8] <,0001[3]
≥ 50 mm	8/194 (4,1)	6/185 (3,2)	1,27 [0,45; 3,59] 0,6505[2]	1,28 [0,44; 3,77] 0,6496[3]	0,9 [-2,9; 4,7] 0,6496[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 257.1.1: Interacting subgroups - adverse events according PT Pruritus from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,0002)					
Negative	5/67 (7,5)	3/62 (4,8)	1,54 [0,38; 6,19] 0,5410[2]	1,59 [0,36; 6,93] 0,7195[4]	2,6 [-5,6; 10,9] 0,7195[4]
Positive	64/678 (9,4)	29/647 (4,5)	2,11 [1,38; 3,22] 0,0006[2]	2,22 [1,41; 3,49] 0,0004[3]	5,0 [2,2; 7,7] 0,0004[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 258.1.1: Interacting subgroups - adverse events according PT Pyrexia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: 0,0079)					
ECOG-PS 0	79/685 (11,5)	27/649 (4,2)	2,77 [1,82; 4,23] <,0001[2]	3,00 [1,91; 4,71] <,0001[3]	7,4 [4,5; 10,2] <,0001[3]
ECOG-PS 1	7/91 (7,7)	9/80 (11,3)	0,68 [0,27; 1,75] 0,4285[2]	0,66 [0,23; 1,85] 0,4254[3]	-3,6 [-12,4; 5,3] 0,4254[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 259.1.1: Interacting subgroups - adverse events according PT Rash from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Primary tumor size (Interaction p-value: 0,0128)					
< 20 mm	22/204 (10,8)	3/189 (1,6)	6,79 [2,07; 22,33] 0,0016[2]	7,49 [2,20; 25,47] 0,0002[3]	9,2 [4,6; 13,8] 0,0002[3]
≥ 20 but < 50 mm	24/360 (6,7)	18/346 (5,2)	1,28 [0,71; 2,32] 0,4124[2]	1,30 [0,69; 2,44] 0,4109[3]	1,5 [-2,0; 4,9] 0,4109[3]
≥ 50 mm	17/194 (8,8)	3/185 (1,6)	5,40 [1,61; 18,13] 0,0063[2]	5,83 [1,68; 20,23] 0,0019[3]	7,1 [2,8; 11,5] 0,0019[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 266.1.1: Interacting subgroups - adverse events according PT Vomiting from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Number of positive lymph nodes (Interaction p-value: 0,0433)					
0-3	55/269 (20,4)	5/269 (1,9)	11,00 [4,47; 27,05] <,0001[2]	13,57 [5,34; 34,50] <,0001[3]	18,6 [13,5; 23,7] <,0001[3]
4-9	48/353 (13,6)	15/326 (4,6)	2,96 [1,69; 5,17] 0,0001[2]	3,26 [1,79; 5,95] <,0001[3]	9,0 [4,8; 13,2] <,0001[3]
≥ 10	22/154 (14,3)	3/134 (2,2)	6,38 [1,95; 20,85] 0,0022[2]	7,28 [2,13; 24,91] 0,0003[3]	12,0 [6,0; 18,1] 0,0003[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 271.1.1: Interacting subgroups - adverse events according SOC Gastrointestinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: 0,0457)					
Tamoxifen	496/553 (89,7)	176/534 (33,0)	2,72 [2,40; 3,08] <,0001[2]	17,70 [12,75; 24,58] <,0001[3]	56,7 [52,0; 61,5] <,0001[3]
Aromatase inhibitor	202/223 (90,6)	49/195 (25,1)	3,60 [2,82; 4,61] <,0001[2]	28,66 [16,47; 49,86] <,0001[3]	65,5 [58,3; 72,6] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pre.sas
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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 272.1.1: Interacting subgroups - adverse events according SOC General disorders and administration site conditions from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: 0,0112)					
ECOG-PS 0	378/685 (55,2)	198/649 (30,5)	1,81 [1,58; 2,07] <,0001[2]	2,80 [2,24; 3,51] <,0001[3]	24,7 [19,5; 29,8] <,0001[3]
ECOG-PS 1	44/91 (48,4)	34/80 (42,5)	1,14 [0,82; 1,59] 0,4460[2]	1,27 [0,69; 2,32] 0,4433[3]	5,9 [-9,1; 20,8] 0,4433[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 276.1.1: Interacting subgroups - adverse events according SOC Musculoskeletal and connective tissue disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,0367)					
North America / Europe	206/347 (59,4)	186/309 (60,2)	0,99 [0,87; 1,12] 0,8290[2]	0,97 [0,71; 1,32] 0,8291[3]	-0,8 [-8,3; 6,7] 0,8291[3]
Asia	93/239 (38,9)	110/226 (48,7)	0,80 [0,65; 0,98] 0,0347[2]	0,67 [0,46; 0,97] 0,0339[3]	-9,8 [-18,7; -0,8] 0,0339[3]
Other	66/190 (34,7)	94/194 (48,5)	0,72 [0,56; 0,91] 0,0073[2]	0,57 [0,38; 0,85] 0,0064[3]	-13,7 [-23,5; -4,0] 0,0064[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 277.1.1: Interacting subgroups - adverse events according SOC Nervous system disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Race (Interaction p-value: 0,0060)					
White	167/461 (36,2)	135/440 (30,7)	1,18 [0,98; 1,42] 0,0792[2]	1,28 [0,97; 1,69] 0,0781[3]	5,5 [-0,6; 11,7] 0,0781[3]
Asian	100/273 (36,6)	56/243 (23,0)	1,59 [1,20; 2,10] 0,0011[2]	1,93 [1,31; 2,84] 0,0008[3]	13,6 [5,8; 21,4] 0,0008[3]
Other	9/30 (30,0)	19/34 (55,9)	0,54 [0,29; 1,00] 0,0503[2]	0,34 [0,12; 0,95] 0,0373[3]	-25,9 [-49,3; -2,5] 0,0373[3]
ECOG-PS (Interaction p-value: 0,0005)					
ECOG-PS 0	260/685 (38,0)	182/649 (28,0)	1,35 [1,16; 1,58] 0,0001[2]	1,57 [1,25; 1,98] 0,0001[3]	9,9 [4,9; 14,9] 0,0001[3]
ECOG-PS 1	23/91 (25,3)	34/80 (42,5)	0,59 [0,38; 0,92] 0,0194[2]	0,46 [0,24; 0,87] 0,0171[3]	-17,2 [-31,3; -3,2] 0,0171[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 286.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥ 3 according PT Gamma-glutamyltransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: <,0001)					
ECOG-PS 0	11/685 (1,6)	0/649 (0,0)	21,79 [1,29; 369,07] 0,0328[2]	22,15 [1,30; 376,61] 0,0012[3]	1,6 [0,7; 2,5] 0,0012[3]
ECOG-PS 1	0/91 (0,0)	0/80 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 290.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥ 3 according PT Neutropenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,0045)					
Neoadjuvant chemotherapy	32/314 (10,2)	4/306 (1,3)	7,80 [2,79; 21,78] <,0001[2]	8,57 [2,99; 24,53] <,0001[3]	8,9 [5,3; 12,5] <,0001[3]
Adjuvant chemotherapy	28/452 (6,2)	1/416 (0,2)	25,77 [3,52; 188,56] 0,0014[2]	27,41 [3,71; 202,35] <,0001[3]	6,0 [3,7; 8,2] <,0001[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 292.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥ 3 according PT White blood cell count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: <,0001)					
Neoadjuvant chemotherapy	34/314 (10,8)	3/306 (1,0)	11,04 [3,43; 35,58] <,0001[2]	12,26 [3,73; 40,38] <,0001[3]	9,8 [6,2; 13,5] <,0001[3]
Adjuvant chemotherapy	33/452 (7,3)	3/416 (0,7)	10,12 [3,13; 32,76] 0,0001[2]	10,84 [3,30; 35,63] <,0001[3]	6,6 [4,0; 9,1] <,0001[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 293.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC Blood and lymphatic system disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,0025)					
Neoadjuvant chemotherapy	42/314 (13,4)	6/306 (2,0)	6,82 [2,94; 15,81] <,0001[2]	7,72 [3,23; 18,45] <,0001[3]	11,4 [7,3; 15,5] <,0001[3]
Adjuvant chemotherapy	49/452 (10,8)	8/416 (1,9)	5,64 [2,70; 11,76] <,0001[2]	6,20 [2,90; 13,26] <,0001[3]	8,9 [5,8; 12,1] <,0001[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 294.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC Gastrointestinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Race (Interaction p-value: 0,0149)					
White	42/461 (9,1)	3/440 (0,7)	13,36 [4,17; 42,80] <,0001[2]	14,60 [4,49; 47,47] <,0001[3]	8,4 [5,7; 11,2] <,0001[3]
Asian	17/273 (6,2)	1/243 (0,4)	15,13 [2,03; 112,86] 0,0080[2]	16,07 [2,12; 121,68] 0,0003[3]	5,8 [2,8; 8,8] 0,0003[3]
Other	1/30 (3,3)	3/34 (8,8)	0,38 [0,04; 3,44] 0,3878[2]	0,36 [0,04; 3,62] 0,6159[4]	-5,5 [-17,0; 6,0] 0,6159[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 297.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC Infections and infestations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,0088)					
Neoadjuvant chemotherapy	17/314 (5,4)	7/306 (2,3)	2,37 [1,00; 5,63] 0,0512[2]	2,44 [1,00; 5,98] 0,0436[3]	3,1 [0,1; 6,1] 0,0436[3]
Adjuvant chemotherapy	20/452 (4,4)	10/416 (2,4)	1,84 [0,87; 3,89] 0,1096[2]	1,88 [0,87; 4,06] 0,1035[3]	2,0 [-0,4; 4,4] 0,1035[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Anhang 4-G2.4.10: Häufige unerwünschte Ereignisse nach Schweregrad und nach SOC und PT - Subgruppenanalyse interagierender Subgruppen (Postmenopausale Patientinnen)

Table 300.1.1: Interacting subgroups - adverse events according PT Abdominal discomfort from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: <,0001)					
Neoadjuvant chemotherapy	7/430 (1,6)	4/415 (1,0)	1,69 [0,50; 5,73] 0,4002[2]	1,70 [0,49; 5,85] 0,3946[3]	0,7 [-0,9; 2,2] 0,3946[3]
Adjuvant chemotherapy	12/784 (1,5)	3/768 (0,4)	3,92 [1,11; 13,83] 0,0338[2]	3,96 [1,11; 14,10] 0,0217[3]	1,1 [0,2; 2,1] 0,0217[3]
No chemotherapy	0/69 (0,0)	0/81 (0,0)	NE	NE	NE
Tumor grade (Interaction p-value: <,0001)					
G1	0/91 (0,0)	0/93 (0,0)	NE	NE	NE
G2	8/612 (1,3)	4/602 (0,7)	1,97 [0,60; 6,50] 0,2670[2]	1,98 [0,59; 6,61] 0,2577[3]	0,6 [-0,5; 1,8] 0,2577[3]
G3	11/527 (2,1)	3/506 (0,6)	3,52 [0,99; 12,55] 0,0522[2]	3,57 [0,99; 12,89] 0,0378[3]	1,5 [0,1; 2,9] 0,0378[3]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 301.1.1: Interacting subgroups - adverse events according PT Abdominal distension from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Number of positive lymph nodes (Interaction p-value: 0,0495)					
0-3	14/427 (3,3)	6/418 (1,4)	2,28 [0,89; 5,89] 0,0873[2]	2,33 [0,89; 6,12] 0,0780[3]	1,8 [-0,2; 3,9] 0,0780[3]
4-9	16/549 (2,9)	1/542 (0,2)	15,80 [2,10; 118,69] 0,0073[2]	16,24 [2,15; 122,89] 0,0003[3]	2,7 [1,3; 4,2] 0,0003[3]
≥ 10	4/307 (1,3)	5/304 (1,6)	0,79 [0,21; 2,92] 0,7265[2]	0,79 [0,21; 2,97] 0,7511[4]	-0,3 [-2,3; 1,6] 0,7511[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pos.sas
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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 302.1.1: Interacting subgroups - adverse events according PT Abdominal pain from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	36/156 (23,1)	8/169 (4,7)	4,88 [2,34; 10,16] <,0001[2]	6,04 [2,71; 13,46] <,0001[3]	18,3 [11,0; 25,7] <,0001[3]
Positive	257/1089 (23,6)	53/1066 (5,0)	4,75 [3,58; 6,30] <,0001[2]	5,90 [4,33; 8,05] <,0001[3]	18,6 [15,8; 21,5] <,0001[3]
Unknown	4/10 (40,0)	0/7 (0,0)	6,55 [0,41; 105,10] 0,1847[2]	10,38 [0,47; 231,63] 0,1029[4]	40,0 [9,6; 70,4] 0,1029[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 305.1.1: Interacting subgroups - adverse events according PT Alopecia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	20/156 (12,8)	8/169 (4,7)	2,71 [1,23; 5,97] 0,0135[2]	2,96 [1,26; 6,93] 0,0094[3]	8,1 [1,9; 14,2] 0,0094[3]
Positive	125/1089 (11,5)	27/1066 (2,5)	4,53 [3,02; 6,81] <,0001[2]	4,99 [3,26; 7,63] <,0001[3]	8,9 [6,8; 11,1] <,0001[3]
Unknown	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	8/114 (7,0)	0/132 (0,0)	19,66 [1,15; 336,92] 0,0399[2]	21,15 [1,21; 370,63] 0,0019[4]	7,0 [2,3; 11,7] 0,0019[4]
Aromatase inhibitor	144/1169 (12,3)	36/1132 (3,2)	3,87 [2,71; 5,53] <,0001[2]	4,28 [2,94; 6,22] <,0001[3]	9,1 [7,0; 11,3] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 306.1.1: Interacting subgroups - adverse events according PT Anaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	42/156 (26,9)	7/169 (4,1)	6,50 [3,01; 14,04] <,0001[2]	8,53 [3,70; 19,66] <,0001[3]	22,8 [15,2; 30,4] <,0001[3]
Positive	287/1089 (26,4)	40/1066 (3,8)	7,02 [5,10; 9,67] <,0001[2]	9,18 [6,51; 12,94] <,0001[3]	22,6 [19,7; 25,5] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 307.1.1: Interacting subgroups - adverse events according PT Anxiety from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,0226)					
< 65 years	32/918 (3,5)	37/936 (4,0)	0,88 [0,55; 1,40] 0,5955[2]	0,88 [0,54; 1,42] 0,5952[3]	-0,5 [-2,2; 1,3] 0,5952[3]
≥ 65 years	5/365 (1,4)	18/328 (5,5)	0,25 [0,09; 0,66] 0,0055[2]	0,24 [0,09; 0,65] 0,0025[3]	-4,1 [-6,9; -1,4] 0,0025[3]
Tumor grade (Interaction p-value: <,0001)					
G1	2/91 (2,2)	5/93 (5,4)	0,41 [0,08; 2,05] 0,2774[2]	0,40 [0,07; 2,09] 0,4442[4]	-3,2 [-8,7; 2,3] 0,4442[4]
G2	18/612 (2,9)	37/602 (6,1)	0,48 [0,28; 0,83] 0,0089[2]	0,46 [0,26; 0,82] 0,0073[3]	-3,2 [-5,5; -0,9] 0,0073[3]
G3	17/527 (3,2)	13/506 (2,6)	1,26 [0,62; 2,56] 0,5308[2]	1,26 [0,61; 2,63] 0,5298[3]	0,7 [-1,4; 2,7] 0,5298[3]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	5/156 (3,2)	7/169 (4,1)	0,77 [0,25; 2,39] 0,6556[2]	0,77 [0,24; 2,47] 0,6545[3]	-0,9 [-5,0; 3,1] 0,6545[3]
Positive	30/1089 (2,8)	48/1066 (4,5)	0,61 [0,39; 0,96] 0,0317[2]	0,60 [0,38; 0,96] 0,0298[3]	-1,7 [-3,3; -0,2] 0,0298[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 310.1.1: Interacting subgroups - adverse events according PT Asthenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	18/156 (11,5)	15/169 (8,9)	1,30 [0,68; 2,49] 0,4287[2]	1,34 [0,65; 2,76] 0,4272[3]	2,7 [-3,9; 9,3] 0,4272[3]
Positive	129/1089 (11,8)	52/1066 (4,9)	2,43 [1,78; 3,31] <,0001[2]	2,62 [1,88; 3,66] <,0001[3]	7,0 [4,7; 9,3] <,0001[3]
Unknown	0/10 (0,0)	1/7 (14,3)	0,24 [0,01; 5,21] 0,3654[2]	0,21 [0,01; 5,86] 0,4118[4]	-14,3 [-40,2; 11,6] 0,4118[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 312.1.1: Interacting subgroups - adverse events according PT Blood alkaline phosphatase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,0477)					
Negative	9/156 (5,8)	6/169 (3,6)	1,63 [0,59; 4,46] 0,3460[2]	1,66 [0,58; 4,79] 0,3408[3]	2,2 [-2,4; 6,8] 0,3408[3]
Positive	52/1089 (4,8)	31/1066 (2,9)	1,64 [1,06; 2,54] 0,0260[2]	1,67 [1,06; 2,63] 0,0243[3]	1,9 [0,2; 3,5] 0,0243[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,0174)					
ECOG-PS 0	44/1070 (4,1)	35/1019 (3,4)	1,20 [0,77; 1,85] 0,4179[2]	1,21 [0,77; 1,90] 0,4172[3]	0,7 [-1,0; 2,3] 0,4172[3]
ECOG-PS 1	17/213 (8,0)	4/245 (1,6)	4,89 [1,67; 14,30] 0,0038[2]	5,23 [1,73; 15,78] 0,0012[3]	6,3 [2,4; 10,3] 0,0012[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 313.1.1: Interacting subgroups - adverse events according PT Blood creatinine increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	23/156 (14,7)	1/169 (0,6)	24,92 [3,41; 182,33] 0,0015[2]	29,05 [3,87; 217,92] <,0001[3]	14,2 [8,5; 19,8] <,0001[3]
Positive	118/1089 (10,8)	14/1066 (1,3)	8,25 [4,77; 14,27] <,0001[2]	9,13 [5,21; 16,00] <,0001[3]	9,5 [7,6; 11,5] <,0001[3]
Unknown	4/10 (40,0)	0/7 (0,0)	6,55 [0,41; 105,10] 0,1847[2]	10,38 [0,47; 231,63] 0,1029[4]	40,0 [9,6; 70,4] 0,1029[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	8/114 (7,0)	0/132 (0,0)	19,66 [1,15; 336,92] 0,0399[2]	21,15 [1,21; 370,63] 0,0019[4]	7,0 [2,3; 11,7] 0,0019[4]
Aromatase inhibitor	142/1169 (12,1)	15/1132 (1,3)	9,17 [5,42; 15,51] <,0001[2]	10,30 [6,01; 17,65] <,0001[3]	10,8 [8,8; 12,8] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 314.1.1: Interacting subgroups - adverse events according PT COVID-19 from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: <,0001)					
Neoadjuvant chemotherapy	13/430 (3,0)	2/415 (0,5)	6,27 [1,42; 27,63] 0,0152[2]	6,44 [1,44; 28,70] 0,0052[3]	2,5 [0,8; 4,3] 0,0052[3]
Adjuvant chemotherapy	24/784 (3,1)	6/768 (0,8)	3,92 [1,61; 9,53] 0,0026[2]	4,01 [1,63; 9,87] 0,0011[3]	2,3 [0,9; 3,6] 0,0011[3]
No chemotherapy	0/69 (0,0)	0/81 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 315.1.1: Interacting subgroups - adverse events according PT Cataract from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	3/156 (1,9)	1/169 (0,6)	3,25 [0,34; 30,92] 0,3051[2]	3,29 [0,34; 32,00] 0,3537[4]	1,3 [-1,1; 3,8] 0,3537[4]
Positive	23/1089 (2,1)	9/1066 (0,8)	2,50 [1,16; 5,38] 0,0190[2]	2,53 [1,17; 5,50] 0,0150[3]	1,3 [0,3; 2,3] 0,0150[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 316.1.1: Interacting subgroups - adverse events according PT Constipation from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,0019)					
< 65 years	112/918 (12,2)	40/936 (4,3)	2,85 [2,01; 4,05] <,0001[2]	3,11 [2,14; 4,52] <,0001[3]	7,9 [5,4; 10,4] <,0001[3]
≥ 65 years	42/365 (11,5)	32/328 (9,8)	1,18 [0,76; 1,82] 0,4571[2]	1,20 [0,74; 1,96] 0,4562[3]	1,8 [-2,8; 6,3] 0,4562[3]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	23/156 (14,7)	10/169 (5,9)	2,49 [1,23; 5,07] 0,0117[2]	2,75 [1,26; 5,98] 0,0085[3]	8,8 [2,2; 15,4] 0,0085[3]
Positive	120/1089 (11,0)	61/1066 (5,7)	1,93 [1,43; 2,59] <,0001[2]	2,04 [1,48; 2,81] <,0001[3]	5,3 [3,0; 7,6] <,0001[3]
Unknown	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 317.1.1: Interacting subgroups - adverse events according PT Cough from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	23/156 (14,7)	13/169 (7,7)	1,92 [1,01; 3,65] 0,0478[2]	2,08 [1,01; 4,26] 0,0430[3]	7,1 [0,2; 13,9] 0,0430[3]
Positive	156/1089 (14,3)	95/1066 (8,9)	1,61 [1,26; 2,04] 0,0001[2]	1,71 [1,30; 2,24] <,0001[3]	5,4 [2,7; 8,1] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
ECOG-PS (Interaction p-value: 0,0210)					
ECOG-PS 0	139/1070 (13,0)	92/1019 (9,0)	1,44 [1,12; 1,85] 0,0042[2]	1,50 [1,14; 1,99] 0,0039[3]	4,0 [1,3; 6,6] 0,0039[3]
ECOG-PS 1	46/213 (21,6)	19/245 (7,8)	2,78 [1,69; 4,60] <,0001[2]	3,28 [1,85; 5,80] <,0001[3]	13,8 [7,4; 20,3] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 318.1.1: Interacting subgroups - adverse events according PT Decreased appetite from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,0438)					
IIA	8/113 (7,1)	7/114 (6,1)	1,15 [0,43; 3,07] 0,7760[2]	1,16 [0,41; 3,33] 0,7758[3]	0,9 [-5,5; 7,4] 0,7758[3]
IIB	18/151 (11,9)	2/136 (1,5)	8,11 [1,92; 34,29] 0,0045[2]	9,07 [2,06; 39,85] 0,0005[3]	10,4 [4,9; 16,0] 0,0005[3]
IIIA	69/495 (13,9)	13/488 (2,7)	5,23 [2,93; 9,34] <,0001[2]	5,92 [3,23; 10,86] <,0001[3]	11,3 [7,9; 14,6] <,0001[3]
IIIB	5/54 (9,3)	3/45 (6,7)	1,39 [0,35; 5,50] 0,6397[2]	1,43 [0,32; 6,34] 0,7248[4]	2,6 [-8,0; 13,2] 0,7248[4]
IIIC	63/468 (13,5)	18/479 (3,8)	3,58 [2,16; 5,95] <,0001[2]	3,98 [2,32; 6,84] <,0001[3]	9,7 [6,2; 13,2] <,0001[3]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	26/156 (16,7)	6/169 (3,6)	4,69 [1,99; 11,10] 0,0004[2]	5,43 [2,17; 13,59] <,0001[3]	13,1 [6,6; 19,6] <,0001[3]
Positive	133/1089 (12,2)	35/1066 (3,3)	3,72 [2,59; 5,35] <,0001[2]	4,10 [2,80; 6,01] <,0001[3]	8,9 [6,7; 11,1] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 319.1.1: Interacting subgroups - adverse events according PT Deep vein thrombosis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: <,0001)					
< 65 years	12/918 (1,3)	3/936 (0,3)	4,08 [1,15; 14,41] 0,0290[2]	4,12 [1,16; 14,65] 0,0177[3]	1,0 [0,2; 1,8] 0,0177[3]
≥ 65 years	9/365 (2,5)	0/328 (0,0)	17,08 [1,00; 292,30] 0,0502[2]	17,51 [1,01; 301,99] 0,0041[4]	2,5 [0,9; 4,1] 0,0041[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	3/114 (2,6)	0/132 (0,0)	8,10 [0,42; 155,09] 0,1651[2]	8,32 [0,43; 162,77] 0,0981[4]	2,6 [-0,3; 5,6] 0,0981[4]
Aromatase inhibitor	18/1169 (1,5)	3/1132 (0,3)	5,81 [1,72; 19,67] 0,0047[2]	5,89 [1,73; 20,03] 0,0013[3]	1,3 [0,5; 2,0] 0,0013[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 320.1.1: Interacting subgroups - adverse events according PT Dehydration from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: <,0001)					
< 65 years	11/918 (1,2)	3/936 (0,3)	3,74 [1,05; 13,36] 0,0424[2]	3,77 [1,05; 13,56] 0,0291[3]	0,9 [0,1; 1,7] 0,0291[3]
≥ 65 years	15/365 (4,1)	0/328 (0,0)	27,87 [1,67; 463,88] 0,0204[2]	29,05 [1,73; 487,53] 0,0002[3]	4,1 [2,1; 6,1] 0,0002[3]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	0/114 (0,0)	0/132 (0,0)	NE	NE	NE
Aromatase inhibitor	26/1169 (2,2)	3/1132 (0,3)	8,39 [2,55; 27,65] 0,0005[2]	8,56 [2,58; 28,36] <,0001[3]	2,0 [1,1; 2,9] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 322.1.1: Interacting subgroups - adverse events according PT Diarrhoea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,0006)					
< 65 years	769/918 (83,8)	68/936 (7,3)	11,53 [9,16; 14,52] <,0001[2]	65,88 [48,67; 89,18] <,0001[3]	76,5 [73,6; 79,4] <,0001[3]
≥ 65 years	291/365 (79,7)	43/328 (13,1)	6,08 [4,58; 8,07] <,0001[2]	26,06 [17,30; 39,27] <,0001[3]	66,6 [61,1; 72,1] <,0001[3]
Region (Interaction p-value: 0,0032)					
North America / Europe	585/678 (86,3)	77/649 (11,9)	7,27 [5,88; 8,99] <,0001[2]	46,73 [33,82; 64,56] <,0001[3]	74,4 [70,8; 78,0] <,0001[3]
Asia	176/203 (86,7)	10/201 (5,0)	17,43 [9,50; 31,96] <,0001[2]	124,50 [58,58; 264,60] <,0001[3]	81,7 [76,2; 87,3] <,0001[3]
Other	299/402 (74,4)	24/414 (5,8)	12,83 [8,66; 19,00] <,0001[2]	47,17 [29,51; 75,41] <,0001[3]	68,6 [63,8; 73,4] <,0001[3]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	126/156 (80,8)	15/169 (8,9)	9,10 [5,58; 14,84] <,0001[2]	43,12 [22,22; 83,68] <,0001[3]	71,9 [64,4; 79,4] <,0001[3]
Positive	901/1089 (82,7)	93/1066 (8,7)	9,48 [7,80; 11,54] <,0001[2]	50,14 [38,49; 65,32] <,0001[3]	74,0 [71,2; 76,8] <,0001[3]
Unknown	8/10 (80,0)	0/7 (0,0)	12,36 [0,83; 184,49] 0,0682[2]	51,00 [2,10; 1240,17] 0,0023[4]	80,0 [55,2; 100,0] 0,0023[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 323.1.1: Interacting subgroups - adverse events according PT Dizziness from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,0072)					
Negative	19/156 (12,2)	11/169 (6,5)	1,87 [0,92; 3,81] 0,0837[2]	1,99 [0,92; 4,33] 0,0777[3]	5,7 [-0,7; 12,0] 0,0777[3]
Positive	118/1089 (10,8)	72/1066 (6,8)	1,60 [1,21; 2,12] 0,0010[2]	1,68 [1,24; 2,28] 0,0008[3]	4,1 [1,7; 6,5] 0,0008[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 324.1.1: Interacting subgroups - adverse events according PT Dry eye from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: 0,0478)					
ECOG-PS 0	33/1070 (3,1)	6/1019 (0,6)	5,24 [2,20; 12,45] 0,0002[2]	5,37 [2,24; 12,88] <,0001[3]	2,5 [1,4; 3,6] <,0001[3]
ECOG-PS 1	5/213 (2,3)	5/245 (2,0)	1,15 [0,34; 3,92] 0,8229[2]	1,15 [0,33; 4,04] 1,0000[4]	0,3 [-2,4; 3,0] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 326.1.1: Interacting subgroups - adverse events according PT Dry skin from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Number of positive lymph nodes (Interaction p-value: 0,0379)					
0-3	13/427 (3,0)	13/418 (3,1)	0,98 [0,46; 2,09] 0,9560[2]	0,98 [0,45; 2,14] 0,9560[3]	-0,1 [-2,4; 2,3] 0,9560[3]
4-9	27/549 (4,9)	6/542 (1,1)	4,44 [1,85; 10,67] 0,0009[2]	4,62 [1,89; 11,28] 0,0002[3]	3,8 [1,8; 5,8] 0,0002[3]
≥ 10	11/307 (3,6)	6/304 (2,0)	1,82 [0,68; 4,85] 0,2340[2]	1,85 [0,67; 5,06] 0,2265[3]	1,6 [-1,0; 4,2] 0,2265[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pos.sas
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Table 327.1.1: Interacting subgroups - adverse events according PT Dysgeusia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: 0,0257)					
Tamoxifen	2/114 (1,8)	2/132 (1,5)	1,16 [0,17; 8,09] 0,8825[2]	1,16 [0,16; 8,37] 1,0000[4]	0,2 [-2,9; 3,4] 1,0000[4]
Aromatase inhibitor	58/1169 (5,0)	4/1132 (0,4)	14,04 [5,11; 38,55] <,0001[2]	14,72 [5,33; 40,69] <,0001[3]	4,6 [3,3; 5,9] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pos.sas
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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 328.1.1: Interacting subgroups - adverse events according PT Dyspepsia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,0171)					
< 65 years	75/918 (8,2)	19/936 (2,0)	4,02 [2,45; 6,60] <,0001[2]	4,29 [2,57; 7,16] <,0001[3]	6,1 [4,2; 8,1] <,0001[3]
≥ 65 years	21/365 (5,8)	13/328 (4,0)	1,45 [0,74; 2,85] 0,2795[2]	1,48 [0,73; 3,00] 0,2760[3]	1,8 [-1,4; 5,0] 0,2760[3]
Region (Interaction p-value: 0,0245)					
North America / Europe	69/678 (10,2)	18/649 (2,8)	3,67 [2,21; 6,09] <,0001[2]	3,97 [2,34; 6,75] <,0001[3]	7,4 [4,8; 10,0] <,0001[3]
Asia	10/203 (4,9)	10/201 (5,0)	0,99 [0,42; 2,33] 0,9819[2]	0,99 [0,40; 2,43] 0,9819[3]	-0,0 [-4,3; 4,2] 0,9819[3]
Other	17/402 (4,2)	4/414 (1,0)	4,38 [1,49; 12,90] 0,0074[2]	4,53 [1,51; 13,57] 0,0033[3]	3,3 [1,1; 5,4] 0,0033[3]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	12/156 (7,7)	8/169 (4,7)	1,63 [0,68; 3,87] 0,2728[2]	1,68 [0,67; 4,22] 0,2675[3]	3,0 [-2,3; 8,2] 0,2675[3]
Positive	80/1089 (7,3)	23/1066 (2,2)	3,40 [2,16; 5,37] <,0001[2]	3,60 [2,24; 5,76] <,0001[3]	5,2 [3,4; 7,0] <,0001[3]
Unknown	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Race (Interaction p-value: 0,0222)					
White	82/958 (8,6)	21/943 (2,2)	3,84 [2,40; 6,15] <,0001[2]	4,11 [2,52; 6,70] <,0001[3]	6,3 [4,3; 8,3] <,0001[3]
Asian	10/250 (4,0)	10/242 (4,1)	0,97 [0,41; 2,28] 0,9408[2]	0,97 [0,40; 2,37] 0,9408[3]	-0,1 [-3,6; 3,4] 0,9408[3]
Other	3/62 (4,8)	1/64 (1,6)	3,10 [0,33; 28,97] 0,3218[2]	3,20 [0,32; 31,66] 0,3610[4]	3,3 [-2,9; 9,4] 0,3610[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pos.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 329.1.1: Interacting subgroups - adverse events according PT Dyspnoea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	13/156 (8,3)	7/169 (4,1)	2,01 [0,82; 4,91] 0,1248[2]	2,10 [0,82; 5,42] 0,1162[3]	4,2 [-1,1; 9,5] 0,1162[3]
Positive	76/1089 (7,0)	41/1066 (3,8)	1,81 [1,25; 2,63] 0,0016[2]	1,88 [1,27; 2,77] 0,0013[3]	3,1 [1,2; 5,0] 0,0013[3]
Unknown	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 331.1.1: Interacting subgroups - adverse events according PT Epistaxis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: <,0001)					
< 65 years	15/918 (1,6)	3/936 (0,3)	5,10 [1,48; 17,55] 0,0098[2]	5,17 [1,49; 17,91] 0,0039[3]	1,3 [0,4; 2,2] 0,0039[3]
≥ 65 years	8/365 (2,2)	0/328 (0,0)	15,28 [0,89; 263,73] 0,0606[2]	15,62 [0,90; 271,70] 0,0081[4]	2,2 [0,7; 3,7] 0,0081[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	3/114 (2,6)	0/132 (0,0)	8,10 [0,42; 155,09] 0,1651[2]	8,32 [0,43; 162,77] 0,0981[4]	2,6 [-0,3; 5,6] 0,0981[4]
Aromatase inhibitor	20/1169 (1,7)	3/1132 (0,3)	6,46 [1,92; 21,66] 0,0025[2]	6,55 [1,94; 22,11] 0,0005[3]	1,4 [0,6; 2,2] 0,0005[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 332.1.1: Interacting subgroups - adverse events according PT Fall from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	4/114 (3,5)	0/132 (0,0)	10,41 [0,57; 191,27] 0,1147[2]	10,79 [0,57; 202,64] 0,0448[4]	3,5 [0,1; 6,9] 0,0448[4]
Aromatase inhibitor	41/1169 (3,5)	27/1132 (2,4)	1,47 [0,91; 2,37] 0,1145[2]	1,49 [0,91; 2,43] 0,1121[3]	1,1 [-0,3; 2,5] 0,1121[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pos.sas
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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 334.1.1: Interacting subgroups - adverse events according PT Flatulence from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,0459)					
< 65 years	32/918 (3,5)	4/936 (0,4)	8,16 [2,90; 22,97] <,0001[2]	8,42 [2,96; 23,89] <,0001[3]	3,1 [1,8; 4,3] <,0001[3]
≥ 65 years	10/365 (2,7)	5/328 (1,5)	1,80 [0,62; 5,20] 0,2798[2]	1,82 [0,62; 5,38] 0,2723[3]	1,2 [-0,9; 3,4] 0,2723[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pos.sas
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Table 335.1.1: Interacting subgroups - adverse events according PT
Gamma-glutamyltransferase increased from RCT with medical drug to be assessed - Cohort 1
Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	1/114 (0,9)	0/132 (0,0)	3,47 [0,14; 84,34] 0,4448[2]	3,50 [0,14; 86,82] 0,4634[4]	0,9 [-0,8; 2,6] 0,4634[4]
Aromatase inhibitor	41/1169 (3,5)	17/1132 (1,5)	2,34 [1,33; 4,09] 0,0030[2]	2,38 [1,35; 4,22] 0,0022[3]	2,0 [0,7; 3,3] 0,0022[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pos.sas
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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 336.1.1: Interacting subgroups - adverse events according PT Gastrointestinal pain from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: <,0001)					
< 65 years	12/918 (1,3)	1/936 (0,1)	12,24 [1,59; 93,91] 0,0160[2]	12,38 [1,61; 95,44] 0,0020[3]	1,2 [0,4; 2,0] 0,0020[3]
≥ 65 years	5/365 (1,4)	0/328 (0,0)	9,89 [0,55; 178,14] 0,1204[2]	10,02 [0,55; 181,97] 0,0634[4]	1,4 [0,2; 2,6] 0,0634[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	1/114 (0,9)	0/132 (0,0)	3,47 [0,14; 84,34] 0,4448[2]	3,50 [0,14; 86,82] 0,4634[4]	0,9 [-0,8; 2,6] 0,4634[4]
Aromatase inhibitor	16/1169 (1,4)	1/1132 (0,1)	15,49 [2,06; 116,64] 0,0078[2]	15,69 [2,08; 118,54] 0,0003[3]	1,3 [0,6; 2,0] 0,0003[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 337.1.1: Interacting subgroups - adverse events according PT Haemorrhoids from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	0/114 (0,0)	0/132 (0,0)	NE	NE	NE
Aromatase inhibitor	28/1169 (2,4)	13/1132 (1,1)	2,09 [1,09; 4,01] 0,0273[2]	2,11 [1,09; 4,10] 0,0238[3]	1,2 [0,2; 2,3] 0,0238[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 338.1.1: Interacting subgroups - adverse events according PT Headache from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	26/156 (16,7)	20/169 (11,8)	1,41 [0,82; 2,42] 0,2146[2]	1,49 [0,79; 2,79] 0,2118[3]	4,8 [-2,8; 12,4] 0,2118[3]
Positive	189/1089 (17,4)	128/1066 (12,0)	1,45 [1,17; 1,78] 0,0005[2]	1,54 [1,21; 1,96] 0,0005[3]	5,3 [2,4; 8,3] 0,0005[3]
Unknown	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 339.1.1: Interacting subgroups - adverse events according PT Hot flush from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	20/156 (12,8)	31/169 (18,3)	0,70 [0,42; 1,17] 0,1755[2]	0,65 [0,36; 1,20] 0,1715[3]	-5,5 [-13,4; 2,3] 0,1715[3]
Positive	121/1089 (11,1)	179/1066 (16,8)	0,66 [0,53; 0,82] 0,0002[2]	0,62 [0,48; 0,79] 0,0001[3]	-5,7 [-8,6; -2,8] 0,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 344.1.1: Interacting subgroups - adverse events according PT Leukopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	22/114 (19,3)	0/132 (0,0)	52,04 [3,19; 848,42] 0,0055[2]	64,46 [3,86; 1076,02] <,0001[3]	19,3 [12,1; 26,5] <,0001[3]
Aromatase inhibitor	166/1169 (14,2)	25/1132 (2,2)	6,43 [4,26; 9,71] <,0001[2]	7,33 [4,77; 11,26] <,0001[3]	12,0 [9,8; 14,2] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 345.1.1: Interacting subgroups - adverse events according PT Lymphocyte count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	13/156 (8,3)	5/169 (3,0)	2,82 [1,03; 7,72] 0,0441[2]	2,98 [1,04; 8,57] 0,0343[3]	5,4 [0,3; 10,4] 0,0343[3]
Positive	95/1089 (8,7)	21/1066 (2,0)	4,43 [2,78; 7,05] <,0001[2]	4,76 [2,94; 7,69] <,0001[3]	6,8 [4,9; 8,6] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 346.1.1: Interacting subgroups - adverse events according PT Lymphoedema from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	21/156 (13,5)	15/169 (8,9)	1,52 [0,81; 2,84] 0,1921[2]	1,60 [0,79; 3,22] 0,1882[3]	4,6 [-2,3; 11,4] 0,1882[3]
Positive	128/1089 (11,8)	88/1066 (8,3)	1,42 [1,10; 1,84] 0,0073[2]	1,48 [1,11; 1,97] 0,0069[3]	3,5 [1,0; 6,0] 0,0069[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,0035)					
Tamoxifen	6/114 (5,3)	17/132 (12,9)	0,41 [0,17; 1,00] 0,0504[2]	0,38 [0,14; 0,99] 0,0408[3]	-7,6 [-14,6; -0,6] 0,0408[3]
Aromatase inhibitor	149/1169 (12,7)	88/1132 (7,8)	1,64 [1,28; 2,11] 0,0001[2]	1,73 [1,31; 2,29] <,0001[3]	5,0 [2,5; 7,4] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 347.1.1: Interacting subgroups - adverse events according PT Lymphopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	6/156 (3,8)	2/169 (1,2)	3,25 [0,67; 15,86] 0,1451[2]	3,34 [0,66; 16,80] 0,1598[4]	2,7 [-0,8; 6,1] 0,1598[4]
Positive	63/1089 (5,8)	7/1066 (0,7)	8,81 [4,05; 19,15] <,0001[2]	9,29 [4,23; 20,38] <,0001[3]	5,1 [3,7; 6,6] <,0001[3]
Unknown	0/10 (0,0)	1/7 (14,3)	0,24 [0,01; 5,21] 0,3654[2]	0,21 [0,01; 5,86] 0,4118[4]	-14,3 [-40,2; 11,6] 0,4118[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	6/114 (5,3)	0/132 (0,0)	15,03 [0,86; 264,00] 0,0638[2]	15,88 [0,88; 284,97] 0,0092[4]	5,3 [1,2; 9,4] 0,0092[4]
Aromatase inhibitor	63/1169 (5,4)	10/1132 (0,9)	6,10 [3,15; 11,83] <,0001[2]	6,39 [3,26; 12,52] <,0001[3]	4,5 [3,1; 5,9] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 349.1.1: Interacting subgroups - adverse events according PT Mucosal inflammation from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	5/114 (4,4)	0/132 (0,0)	12,72 [0,71; 227,60] 0,0839[2]	13,31 [0,73; 243,39] 0,0204[4]	4,4 [0,6; 8,1] 0,0204[4]
Aromatase inhibitor	32/1169 (2,7)	9/1132 (0,8)	3,44 [1,65; 7,18] 0,0010[2]	3,51 [1,67; 7,39] 0,0004[3]	1,9 [0,9; 3,0] 0,0004[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 350.1.1: Interacting subgroups - adverse events according PT Muscle spasms from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	12/156 (7,7)	2/169 (1,2)	6,50 [1,48; 28,58] 0,0132[2]	6,96 [1,53; 31,61] 0,0039[3]	6,5 [2,0; 11,0] 0,0039[3]
Positive	58/1089 (5,3)	45/1066 (4,2)	1,26 [0,86; 1,85] 0,2307[2]	1,28 [0,86; 1,90] 0,2295[3]	1,1 [-0,7; 2,9] 0,2295[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 351.1.1: Interacting subgroups - adverse events according PT Nail disorder from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: <,0001)					
< 65 years	15/918 (1,6)	2/936 (0,2)	7,65 [1,75; 33,35] 0,0068[2]	7,76 [1,77; 34,02] 0,0013[3]	1,4 [0,5; 2,3] 0,0013[3]
≥ 65 years	8/365 (2,2)	0/328 (0,0)	15,28 [0,89; 263,73] 0,0606[2]	15,62 [0,90; 271,70] 0,0081[4]	2,2 [0,7; 3,7] 0,0081[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	2/114 (1,8)	0/132 (0,0)	5,78 [0,28; 119,22] 0,2557[2]	5,89 [0,28; 123,94] 0,2137[4]	1,8 [-0,7; 4,2] 0,2137[4]
Aromatase inhibitor	21/1169 (1,8)	2/1132 (0,2)	10,17 [2,39; 43,26] 0,0017[2]	10,34 [2,42; 44,18] <,0001[3]	1,6 [0,8; 2,4] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 353.1.1: Interacting subgroups - adverse events according PT Neutropenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,0082)					
North America / Europe	146/678 (21,5)	6/649 (0,9)	23,29 [10,37; 52,32] <,0001[2]	29,41 [12,90; 67,08] <,0001[3]	20,6 [17,4; 23,8] <,0001[3]
Asia	24/203 (11,8)	1/201 (0,5)	23,76 [3,25; 173,99] 0,0018[2]	26,82 [3,59; 200,24] <,0001[3]	11,3 [6,8; 15,9] <,0001[3]
Other	127/402 (31,6)	22/414 (5,3)	5,95 [3,86; 9,15] <,0001[2]	8,23 [5,10; 13,27] <,0001[3]	26,3 [21,2; 31,3] <,0001[3]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	38/156 (24,4)	3/169 (1,8)	13,72 [4,32; 43,56] <,0001[2]	17,82 [5,37; 59,09] <,0001[3]	22,6 [15,6; 29,6] <,0001[3]
Positive	257/1089 (23,6)	26/1066 (2,4)	9,68 [6,52; 14,35] <,0001[2]	12,36 [8,17; 18,68] <,0001[3]	21,2 [18,5; 23,8] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 354.1.1: Interacting subgroups - adverse events according PT Neutrophil count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	37/156 (23,7)	4/169 (2,4)	10,02 [3,66; 27,47] <,0001[2]	12,83 [4,45; 36,95] <,0001[3]	21,4 [14,3; 28,4] <,0001[3]
Positive	233/1089 (21,4)	17/1066 (1,6)	13,42 [8,26; 21,79] <,0001[2]	16,80 [10,18; 27,71] <,0001[3]	19,8 [17,3; 22,4] <,0001[3]
Unknown	4/10 (40,0)	0/7 (0,0)	6,55 [0,41; 105,10] 0,1847[2]	10,38 [0,47; 231,63] 0,1029[4]	40,0 [9,6; 70,4] 0,1029[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pos.sas
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Table 355.1.1: Interacting subgroups - adverse events according PT Oedema peripheral from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	15/156 (9,6)	10/169 (5,9)	1,63 [0,75; 3,51] 0,2165[2]	1,69 [0,74; 3,89] 0,2113[3]	3,7 [-2,1; 9,5] 0,2113[3]
Positive	76/1089 (7,0)	39/1066 (3,7)	1,91 [1,31; 2,78] 0,0008[2]	1,98 [1,33; 2,93] 0,0006[3]	3,3 [1,4; 5,2] 0,0006[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 357.1.1: Interacting subgroups - adverse events according PT Oral herpes from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: <,0001)					
North America / Europe	13/678 (1,9)	3/649 (0,5)	4,15 [1,19; 14,49] 0,0258[2]	4,21 [1,19; 14,84] 0,0152[3]	1,5 [0,3; 2,6] 0,0152[3]
Asia	3/203 (1,5)	1/201 (0,5)	2,97 [0,31; 28,32] 0,3440[2]	3,00 [0,31; 29,09] 0,6232[4]	1,0 [-0,9; 2,9] 0,6232[4]
Other	0/402 (0,0)	1/414 (0,2)	0,34 [0,01; 8,40] 0,5122[2]	0,34 [0,01; 8,43] 1,0000[4]	-0,2 [-0,7; 0,2] 1,0000[4]
Tumor grade (Interaction p-value: <,0001)					
G1	1/91 (1,1)	0/93 (0,0)	3,07 [0,13; 74,28] 0,4910[2]	3,10 [0,12; 77,08] 0,4946[4]	1,1 [-1,0; 3,2] 0,4946[4]
G2	8/612 (1,3)	3/602 (0,5)	2,62 [0,70; 9,84] 0,1528[2]	2,64 [0,70; 10,02] 0,1370[3]	0,8 [-0,3; 1,9] 0,1370[3]
G3	7/527 (1,3)	2/506 (0,4)	3,36 [0,70; 16,10] 0,1294[2]	3,39 [0,70; 16,41] 0,1786[4]	0,9 [-0,2; 2,1] 0,1786[4]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 359.1.1: Interacting subgroups - adverse events according PT Palpitations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	2/114 (1,8)	0/132 (0,0)	5,78 [0,28; 119,22] 0,2557[2]	5,89 [0,28; 123,94] 0,2137[4]	1,8 [-0,7; 4,2] 0,2137[4]
Aromatase inhibitor	25/1169 (2,1)	12/1132 (1,1)	2,02 [1,02; 4,00] 0,0442[2]	2,04 [1,02; 4,08] 0,0398[3]	1,1 [0,1; 2,1] 0,0398[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 360.1.1: Interacting subgroups - adverse events according PT Paronychia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	0/114 (0,0)	1/132 (0,8)	0,39 [0,02; 9,37] 0,5582[2]	0,38 [0,02; 9,49] 1,0000[4]	-0,8 [-2,2; 0,7] 1,0000[4]
Aromatase inhibitor	15/1169 (1,3)	3/1132 (0,3)	4,84 [1,41; 16,68] 0,0124[2]	4,89 [1,41; 16,94] 0,0056[3]	1,0 [0,3; 1,7] 0,0056[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 361.1.1: Interacting subgroups - adverse events according PT Platelet count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	9/156 (5,8)	1/169 (0,6)	9,75 [1,25; 76,08] 0,0298[2]	10,29 [1,29; 82,15] 0,0082[4]	5,2 [1,3; 9,0] 0,0082[4]
Positive	103/1089 (9,5)	8/1066 (0,8)	12,60 [6,17; 25,75] <,0001[2]	13,82 [6,69; 28,51] <,0001[3]	8,7 [6,9; 10,5] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 362.1.1: Interacting subgroups - adverse events according PT Pneumonitis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: <,0001)					
< 65 years	11/918 (1,2)	3/936 (0,3)	3,74 [1,05; 13,36] 0,0424[2]	3,77 [1,05; 13,56] 0,0291[3]	0,9 [0,1; 1,7] 0,0291[3]
≥ 65 years	7/365 (1,9)	0/328 (0,0)	13,48 [0,77; 235,17] 0,0745[2]	13,74 [0,78; 241,60] 0,0161[4]	1,9 [0,5; 3,3] 0,0161[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	1/114 (0,9)	0/132 (0,0)	3,47 [0,14; 84,34] 0,4448[2]	3,50 [0,14; 86,82] 0,4634[4]	0,9 [-0,8; 2,6] 0,4634[4]
Aromatase inhibitor	17/1169 (1,5)	3/1132 (0,3)	5,49 [1,61; 18,67] 0,0064[2]	5,55 [1,62; 19,00] 0,0021[3]	1,2 [0,4; 1,9] 0,0021[3]
ECOG-PS (Interaction p-value: <,0001)					
ECOG-PS 0	13/1070 (1,2)	0/1019 (0,0)	25,71 [1,53; 432,00] 0,0241[2]	26,03 [1,55; 438,44] 0,0004[3]	1,2 [0,6; 1,9] 0,0004[3]
ECOG-PS 1	5/213 (2,3)	3/245 (1,2)	1,92 [0,46; 7,93] 0,3689[2]	1,94 [0,46; 8,21] 0,4813[4]	1,1 [-1,3; 3,6] 0,4813[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 363.1.1: Interacting subgroups - adverse events according PT Pruritus from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	11/156 (7,1)	12/169 (7,1)	0,99 [0,45; 2,19] 0,9862[2]	0,99 [0,42; 2,32] 0,9862[3]	-0,0 [-5,6; 5,5] 0,9862[3]
Positive	95/1089 (8,7)	46/1066 (4,3)	2,02 [1,44; 2,85] <,0001[2]	2,12 [1,47; 3,05] <,0001[3]	4,4 [2,3; 6,5] <,0001[3]
Unknown	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]
ECOG-PS (Interaction p-value: 0,0159)					
ECOG-PS 0	80/1070 (7,5)	51/1019 (5,0)	1,49 [1,06; 2,10] 0,0209[2]	1,53 [1,07; 2,20] 0,0198[3]	2,5 [0,4; 4,5] 0,0198[3]
ECOG-PS 1	29/213 (13,6)	8/245 (3,3)	4,17 [1,95; 8,92] 0,0002[2]	4,67 [2,09; 10,45] <,0001[3]	10,3 [5,2; 15,5] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 364.1.1: Interacting subgroups - adverse events according PT Pyrexia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	14/156 (9,0)	7/169 (4,1)	2,17 [0,90; 5,23] 0,0853[2]	2,28 [0,90; 5,81] 0,0767[3]	4,8 [-0,6; 10,2] 0,0767[3]
Positive	83/1089 (7,6)	38/1066 (3,6)	2,14 [1,47; 3,11] <,0001[2]	2,23 [1,51; 3,31] <,0001[3]	4,1 [2,1; 6,0] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 366.1.1: Interacting subgroups - adverse events according PT Rash maculo-papular from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: <,0001)					
< 65 years	16/918 (1,7)	3/936 (0,3)	5,44 [1,59; 18,60] 0,0070[2]	5,52 [1,60; 19,00] 0,0024[3]	1,4 [0,5; 2,3] 0,0024[3]
≥ 65 years	5/365 (1,4)	0/328 (0,0)	9,89 [0,55; 178,14] 0,1204[2]	10,02 [0,55; 181,97] 0,0634[4]	1,4 [0,2; 2,6] 0,0634[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	2/114 (1,8)	0/132 (0,0)	5,78 [0,28; 119,22] 0,2557[2]	5,89 [0,28; 123,94] 0,2137[4]	1,8 [-0,7; 4,2] 0,2137[4]
Aromatase inhibitor	19/1169 (1,6)	3/1132 (0,3)	6,13 [1,82; 20,67] 0,0034[2]	6,22 [1,83; 21,07] 0,0008[3]	1,4 [0,6; 2,1] 0,0008[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 367.1.1: Interacting subgroups - adverse events according PT Seroma from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor grade (Interaction p-value: 0,0009)					
G1	3/91 (3,3)	0/93 (0,0)	7,15 [0,37; 136,54] 0,1910[2]	7,40 [0,38; 145,22] 0,1189[4]	3,3 [-0,4; 7,0] 0,1189[4]
G2	8/612 (1,3)	4/602 (0,7)	1,97 [0,60; 6,50] 0,2670[2]	1,98 [0,59; 6,61] 0,2577[3]	0,6 [-0,5; 1,8] 0,2577[3]
G3	5/527 (0,9)	1/506 (0,2)	4,80 [0,56; 40,95] 0,1515[2]	4,84 [0,56; 41,55] 0,2180[4]	0,8 [-0,2; 1,7] 0,2180[4]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	2/156 (1,3)	1/169 (0,6)	2,17 [0,20; 23,66] 0,5261[2]	2,18 [0,20; 24,30] 0,6093[4]	0,7 [-1,4; 2,8] 0,6093[4]
Positive	13/1089 (1,2)	4/1066 (0,4)	3,18 [1,04; 9,73] 0,0424[2]	3,21 [1,04; 9,87] 0,0318[3]	0,8 [0,1; 1,6] 0,0318[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	0/114 (0,0)	0/132 (0,0)	NE	NE	NE
Aromatase inhibitor	16/1169 (1,4)	5/1132 (0,4)	3,10 [1,14; 8,43] 0,0268[2]	3,13 [1,14; 8,57] 0,0194[3]	0,9 [0,2; 1,7] 0,0194[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 370.1.1: Interacting subgroups - adverse events according PT Thrombocytopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	5/114 (4,4)	0/132 (0,0)	12,72 [0,71; 227,60] 0,0839[2]	13,31 [0,73; 243,39] 0,0204[4]	4,4 [0,6; 8,1] 0,0204[4]
Aromatase inhibitor	81/1169 (6,9)	9/1132 (0,8)	8,72 [4,40; 17,27] <,0001[2]	9,29 [4,64; 18,59] <,0001[3]	6,1 [4,6; 7,7] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 371.1.1: Interacting subgroups - adverse events according PT Urinary tract infection from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	13/156 (8,3)	7/169 (4,1)	2,01 [0,82; 4,91] 0,1248[2]	2,10 [0,82; 5,42] 0,1162[3]	4,2 [-1,1; 9,5] 0,1162[3]
Positive	102/1089 (9,4)	59/1066 (5,5)	1,69 [1,24; 2,31] 0,0009[2]	1,76 [1,27; 2,46] 0,0007[3]	3,8 [1,6; 6,0] 0,0007[3]
Unknown	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 372.1.1: Interacting subgroups - adverse events according PT Viral infection from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	3/114 (2,6)	0/132 (0,0)	8,10 [0,42; 155,09] 0,1651[2]	8,32 [0,43; 162,77] 0,0981[4]	2,6 [-0,3; 5,6] 0,0981[4]
Aromatase inhibitor	12/1169 (1,0)	2/1132 (0,2)	5,81 [1,30; 25,90] 0,0210[2]	5,86 [1,31; 26,24] 0,0088[3]	0,8 [0,2; 1,5] 0,0088[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 374.1.1: Interacting subgroups - adverse events according PT Vitamin B12 deficiency from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: <,0001)					
Neoadjuvant chemotherapy	5/430 (1,2)	1/415 (0,2)	4,83 [0,57; 41,13] 0,1500[2]	4,87 [0,57; 41,87] 0,2175[4]	0,9 [-0,2; 2,0] 0,2175[4]
Adjuvant chemotherapy	11/784 (1,4)	3/768 (0,4)	3,59 [1,01; 12,82] 0,0489[2]	3,63 [1,01; 13,06] 0,0349[3]	1,0 [0,1; 1,9] 0,0349[3]
No chemotherapy	0/69 (0,0)	0/81 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	2/114 (1,8)	0/132 (0,0)	5,78 [0,28; 119,22] 0,2557[2]	5,89 [0,28; 123,94] 0,2137[4]	1,8 [-0,7; 4,2] 0,2137[4]
Aromatase inhibitor	14/1169 (1,2)	4/1132 (0,4)	3,39 [1,12; 10,27] 0,0309[2]	3,42 [1,12; 10,42] 0,0216[3]	0,8 [0,1; 1,6] 0,0216[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 375.1.1: Interacting subgroups - adverse events according PT Vomiting from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Number of positive lymph nodes (Interaction p-value: 0,0197)					
0-3	74/427 (17,3)	17/418 (4,1)	4,26 [2,56; 7,09] <,0001[2]	4,94 [2,86; 8,54] <,0001[3]	13,3 [9,2; 17,3] <,0001[3]
4-9	86/549 (15,7)	30/542 (5,5)	2,83 [1,90; 4,21] <,0001[2]	3,17 [2,05; 4,89] <,0001[3]	10,1 [6,5; 13,7] <,0001[3]
≥ 10	62/307 (20,2)	6/304 (2,0)	10,23 [4,49; 23,30] <,0001[2]	12,57 [5,35; 29,55] <,0001[3]	18,2 [13,5; 23,0] <,0001[3]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	28/156 (17,9)	12/169 (7,1)	2,53 [1,33; 4,80] 0,0045[2]	2,86 [1,40; 5,85] 0,0029[3]	10,8 [3,7; 18,0] 0,0029[3]
Positive	184/1089 (16,9)	41/1066 (3,8)	4,39 [3,17; 6,10] <,0001[2]	5,08 [3,58; 7,21] <,0001[3]	13,1 [10,5; 15,6] <,0001[3]
Unknown	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 377.1.1: Interacting subgroups - adverse events according PT Weight increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Primary tumor size (Interaction p-value: 0,0098)					
< 20 mm	12/331 (3,6)	7/334 (2,1)	1,73 [0,69; 4,34] 0,2428[2]	1,76 [0,68; 4,52] 0,2365[3]	1,5 [-1,0; 4,1] 0,2365[3]
≥ 20 but < 50 mm	5/646 (0,8)	14/653 (2,1)	0,36 [0,13; 1,00] 0,0492[2]	0,36 [0,13; 0,99] 0,0397[3]	-1,4 [-2,7; -0,1] 0,0397[3]
≥ 50 mm	2/289 (0,7)	12/265 (4,5)	0,15 [0,03; 0,68] 0,0133[2]	0,15 [0,03; 0,66] 0,0041[3]	-3,8 [-6,5; -1,2] 0,0041[3]
Number of positive lymph nodes (Interaction p-value: 0,0122)					
0-3	10/427 (2,3)	4/418 (1,0)	2,45 [0,77; 7,74] 0,1277[2]	2,48 [0,77; 7,98] 0,1148[3]	1,4 [-0,3; 3,1] 0,1148[3]
4-9	5/549 (0,9)	16/542 (3,0)	0,31 [0,11; 0,84] 0,0208[2]	0,30 [0,11; 0,83] 0,0141[3]	-2,0 [-3,7; -0,4] 0,0141[3]
≥ 10	4/307 (1,3)	13/304 (4,3)	0,30 [0,10; 0,92] 0,0358[2]	0,30 [0,10; 0,92] 0,0255[3]	-3,0 [-5,6; -0,4] 0,0255[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 378.1.1: Interacting subgroups - adverse events according PT White blood cell count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	32/156 (20,5)	11/169 (6,5)	3,15 [1,65; 6,03] 0,0005[2]	3,71 [1,80; 7,65] 0,0002[3]	14,0 [6,7; 21,4] 0,0002[3]
Positive	249/1089 (22,9)	40/1066 (3,8)	6,09 [4,41; 8,42] <,0001[2]	7,60 [5,38; 10,75] <,0001[3]	19,1 [16,4; 21,9] <,0001[3]
Unknown	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 379.1.1: Interacting subgroups - adverse events according SOC Blood and lymphatic system disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,0026)					
North America / Europe	271/678 (40,0)	42/649 (6,5)	6,18 [4,55; 8,39] <,0001[2]	9,62 [6,79; 13,63] <,0001[3]	33,5 [29,4; 37,6] <,0001[3]
Asia	98/203 (48,3)	10/201 (5,0)	9,70 [5,22; 18,05] <,0001[2]	17,83 [8,92; 35,64] <,0001[3]	43,3 [35,8; 50,8] <,0001[3]
Other	222/402 (55,2)	62/414 (15,0)	3,69 [2,88; 4,72] <,0001[2]	7,00 [5,01; 9,78] <,0001[3]	40,2 [34,3; 46,2] <,0001[3]
Race (Interaction p-value: 0,0364)					
White	434/958 (45,3)	91/943 (9,7)	4,69 [3,82; 5,78] <,0001[2]	7,75 [6,03; 9,97] <,0001[3]	35,7 [32,0; 39,3] <,0001[3]
Asian	117/250 (46,8)	12/242 (5,0)	9,44 [5,35; 16,64] <,0001[2]	16,86 [8,97; 31,70] <,0001[3]	41,8 [35,1; 48,6] <,0001[3]
Other	33/62 (53,2)	10/64 (15,6)	3,41 [1,84; 6,30] <,0001[2]	6,14 [2,66; 14,22] <,0001[3]	37,6 [22,3; 52,9] <,0001[3]
First endocrine therapy (Interaction p-value: 0,0167)					
Tamoxifen	50/114 (43,9)	3/132 (2,3)	19,30 [6,19; 60,21] <,0001[2]	33,59 [10,09; 111,87] <,0001[3]	41,6 [32,1; 51,0] <,0001[3]
Aromatase inhibitor	541/1169 (46,3)	111/1132 (9,8)	4,72 [3,91; 5,69] <,0001[2]	7,92 [6,31; 9,94] <,0001[3]	36,5 [33,1; 39,8] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 380.1.1: Interacting subgroups - adverse events according SOC Cardiac disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Number of positive lymph nodes (Interaction p-value: 0,0121)					
0-3	39/427 (9,1)	13/418 (3,1)	2,94 [1,59; 5,42] 0,0006[2]	3,13 [1,65; 5,96] 0,0003[3]	6,0 [2,8; 9,2] 0,0003[3]
4-9	29/549 (5,3)	32/542 (5,9)	0,89 [0,55; 1,46] 0,6551[2]	0,89 [0,53; 1,49] 0,6549[3]	-0,6 [-3,3; 2,1] 0,6549[3]
≥ 10	22/307 (7,2)	15/304 (4,9)	1,45 [0,77; 2,75] 0,2508[2]	1,49 [0,76; 2,93] 0,2475[3]	2,2 [-1,5; 6,0] 0,2475[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 381.1.1: Interacting subgroups - adverse events according SOC Eye disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	29/156 (18,6)	9/169 (5,3)	3,49 [1,71; 7,14] 0,0006[2]	4,06 [1,85; 8,88] 0,0002[3]	13,3 [6,3; 20,2] 0,0002[3]
Positive	164/1089 (15,1)	56/1066 (5,3)	2,87 [2,14; 3,84] <,0001[2]	3,20 [2,33; 4,39] <,0001[3]	9,8 [7,3; 12,3] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 382.1.1: Interacting subgroups - adverse events according SOC Gastrointestinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,0005)					
North America / Europe	630/678 (92,9)	255/649 (39,3)	2,36 [2,14; 2,61] <,0001[2]	20,28 [14,53; 28,30] <,0001[3]	53,6 [49,4; 57,9] <,0001[3]
Asia	191/203 (94,1)	61/201 (30,3)	3,10 [2,51; 3,83] <,0001[2]	36,53 [18,95; 70,41] <,0001[3]	63,7 [56,6; 70,9] <,0001[3]
Other	321/402 (79,9)	96/414 (23,2)	3,44 [2,87; 4,13] <,0001[2]	13,13 [9,40; 18,33] <,0001[3]	56,7 [51,0; 62,3] <,0001[3]
Primary tumor size (Interaction p-value: 0,0491)					
< 20 mm	294/331 (88,8)	104/334 (31,1)	2,85 [2,42; 3,36] <,0001[2]	17,57 [11,63; 26,56] <,0001[3]	57,7 [51,7; 63,7] <,0001[3]
≥ 20 but < 50 mm	570/646 (88,2)	198/653 (30,3)	2,91 [2,58; 3,28] <,0001[2]	17,23 [12,87; 23,07] <,0001[3]	57,9 [53,6; 62,2] <,0001[3]
≥ 50 mm	264/289 (91,3)	105/265 (39,6)	2,31 [1,98; 2,69] <,0001[2]	16,09 [9,97; 25,96] <,0001[3]	51,7 [45,0; 58,4] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 383.1.1: Interacting subgroups - adverse events according SOC General disorders and administration site conditions from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,0324)					
North America / Europe	446/678 (65,8)	276/649 (42,5)	1,55 [1,39; 1,72] <,0001[2]	2,60 [2,08; 3,24] <,0001[3]	23,3 [18,0; 28,5] <,0001[3]
Asia	90/203 (44,3)	47/201 (23,4)	1,90 [1,41; 2,54] <,0001[2]	2,61 [1,70; 4,00] <,0001[3]	21,0 [12,0; 29,9] <,0001[3]
Other	180/402 (44,8)	89/414 (21,5)	2,08 [1,68; 2,58] <,0001[2]	2,96 [2,18; 4,02] <,0001[3]	23,3 [17,0; 29,5] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 385.1.1: Interacting subgroups - adverse events according SOC Investigations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,0484)					
North America / Europe	300/678 (44,2)	121/649 (18,6)	2,37 [1,98; 2,85] <,0001[2]	3,46 [2,70; 4,44] <,0001[3]	25,6 [20,8; 30,4] <,0001[3]
Asia	155/203 (76,4)	62/201 (30,8)	2,48 [1,99; 3,09] <,0001[2]	7,24 [4,66; 11,25] <,0001[3]	45,5 [36,9; 54,2] <,0001[3]
Other	168/402 (41,8)	98/414 (23,7)	1,77 [1,43; 2,17] <,0001[2]	2,32 [1,71; 3,13] <,0001[3]	18,1 [11,8; 24,4] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 386.1.1: Interacting subgroups - adverse events according SOC Metabolism and nutrition disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,0020)					
North America / Europe	200/678 (29,5)	104/649 (16,0)	1,84 [1,49; 2,27] <,0001[2]	2,19 [1,68; 2,86] <,0001[3]	13,5 [9,0; 17,9] <,0001[3]
Asia	56/203 (27,6)	18/201 (9,0)	3,08 [1,88; 5,05] <,0001[2]	3,87 [2,18; 6,87] <,0001[3]	18,6 [11,3; 25,9] <,0001[3]
Other	107/402 (26,6)	89/414 (21,5)	1,24 [0,97; 1,58] 0,0880[2]	1,32 [0,96; 1,83] 0,0870[3]	5,1 [-0,7; 11,0] 0,0870[3]
Primary tumor size (Interaction p-value: 0,0128)					
< 20 mm	78/331 (23,6)	64/334 (19,2)	1,23 [0,92; 1,65] 0,1672[2]	1,30 [0,90; 1,89] 0,1659[3]	4,4 [-1,8; 10,6] 0,1659[3]
≥ 20 but < 50 mm	181/646 (28,0)	104/653 (15,9)	1,76 [1,42; 2,18] <,0001[2]	2,05 [1,57; 2,69] <,0001[3]	12,1 [7,6; 16,5] <,0001[3]
≥ 50 mm	99/289 (34,3)	38/265 (14,3)	2,39 [1,71; 3,34] <,0001[2]	3,11 [2,04; 4,74] <,0001[3]	19,9 [13,0; 26,8] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 389.1.1: Interacting subgroups - adverse events according SOC Renal and urinary disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,0003)					
Negative	12/156 (7,7)	11/169 (6,5)	1,18 [0,54; 2,60] 0,6780[2]	1,20 [0,51; 2,80] 0,6777[3]	1,2 [-4,4; 6,8] 0,6777[3]
Positive	88/1089 (8,1)	57/1066 (5,3)	1,51 [1,09; 2,09] 0,0120[2]	1,56 [1,10; 2,20] 0,0113[3]	2,7 [0,6; 4,8] 0,0113[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,0220)					
White	83/958 (8,7)	45/943 (4,8)	1,82 [1,28; 2,58] 0,0009[2]	1,89 [1,30; 2,75] 0,0007[3]	3,9 [1,7; 6,1] 0,0007[3]
Asian	13/250 (5,2)	13/242 (5,4)	0,97 [0,46; 2,05] 0,9321[2]	0,97 [0,44; 2,13] 0,9321[3]	-0,2 [-4,1; 3,8] 0,9321[3]
Other	4/62 (6,5)	10/64 (15,6)	0,41 [0,14; 1,25] 0,1169[2]	0,37 [0,11; 1,26] 0,1014[3]	-9,2 [-20,0; 1,6] 0,1014[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 391.1.1: Interacting subgroups - adverse events according SOC Respiratory, thoracic and mediastinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	48/156 (30,8)	33/169 (19,5)	1,58 [1,07; 2,32] 0,0210[2]	1,83 [1,10; 3,05] 0,0192[3]	11,2 [1,9; 20,6] 0,0192[3]
Positive	316/1089 (29,0)	207/1066 (19,4)	1,49 [1,28; 1,74] <,0001[2]	1,70 [1,39; 2,07] <,0001[3]	9,6 [6,0; 13,2] <,0001[3]
Unknown	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 392.1.1: Interacting subgroups - adverse events according SOC Skin and subcutaneous tissue disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,0175)					
North America / Europe	298/678 (44,0)	177/649 (27,3)	1,61 [1,38; 1,88] <,0001[2]	2,09 [1,66; 2,63] <,0001[3]	16,7 [11,6; 21,7] <,0001[3]
Asia	90/203 (44,3)	58/201 (28,9)	1,54 [1,18; 2,01] 0,0016[2]	1,96 [1,30; 2,96] 0,0012[3]	15,5 [6,2; 24,7] 0,0012[3]
Other	120/402 (29,9)	48/414 (11,6)	2,57 [1,90; 3,49] <,0001[2]	3,24 [2,24; 4,69] <,0001[3]	18,3 [12,8; 23,7] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 393.1.1: Interacting subgroups - serious adverse events according SOC Gastrointestinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,0458)					
< 65 years	24/918 (2,6)	7/936 (0,7)	3,50 [1,51; 8,07] 0,0034[2]	3,56 [1,53; 8,31] 0,0017[3]	1,9 [0,7; 3,0] 0,0017[3]
≥ 65 years	7/365 (1,9)	7/328 (2,1)	0,90 [0,32; 2,53] 0,8399[2]	0,90 [0,31; 2,58] 0,8398[3]	-0,2 [-2,3; 1,9] 0,8398[3]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	3/156 (1,9)	3/169 (1,8)	1,08 [0,22; 5,29] 0,9212[2]	1,08 [0,22; 5,46] 1,0000[4]	0,1 [-2,8; 3,1] 1,0000[4]
Positive	26/1089 (2,4)	11/1066 (1,0)	2,31 [1,15; 4,66] 0,0188[2]	2,35 [1,15; 4,77] 0,0154[3]	1,4 [0,3; 2,4] 0,0154[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	4/114 (3,5)	0/132 (0,0)	10,41 [0,57; 191,27] 0,1147[2]	10,79 [0,57; 202,64] 0,0448[4]	3,5 [0,1; 6,9] 0,0448[4]
Aromatase inhibitor	27/1169 (2,3)	14/1132 (1,2)	1,87 [0,98; 3,54] 0,0559[2]	1,89 [0,98; 3,62] 0,0518[3]	1,1 [-0,0; 2,1] 0,0518[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 394.1.1: Interacting subgroups - serious adverse events according SOC Infections and infestations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Primary tumor size (Interaction p-value: 0,0218)					
< 20 mm	17/331 (5,1)	4/334 (1,2)	4,29 [1,46; 12,61] 0,0081[2]	4,47 [1,49; 13,42] 0,0037[3]	3,9 [1,3; 6,6] 0,0037[3]
≥ 20 but < 50 mm	31/646 (4,8)	25/653 (3,8)	1,25 [0,75; 2,10] 0,3904[2]	1,27 [0,74; 2,17] 0,3893[3]	1,0 [-1,2; 3,2] 0,3893[3]
≥ 50 mm	21/289 (7,3)	4/265 (1,5)	4,81 [1,67; 13,84] 0,0035[2]	5,11 [1,73; 15,10] 0,0011[3]	5,8 [2,4; 9,1] 0,0011[3]
Tumor grade (Interaction p-value: 0,0206)					
G1	4/91 (4,4)	5/93 (5,4)	0,82 [0,23; 2,95] 0,7583[2]	0,81 [0,21; 3,11] 1,0000[4]	-1,0 [-7,2; 5,2] 1,0000[4]
G2	38/612 (6,2)	8/602 (1,3)	4,67 [2,20; 9,93] <,0001[2]	4,92 [2,27; 10,63] <,0001[3]	4,9 [2,8; 7,0] <,0001[3]
G3	22/527 (4,2)	18/506 (3,6)	1,17 [0,64; 2,16] 0,6077[2]	1,18 [0,63; 2,23] 0,6072[3]	0,6 [-1,7; 3,0] 0,6072[3]
GX	5/51 (9,8)	2/59 (3,4)	2,89 [0,59; 14,27] 0,1923[2]	3,10 [0,57; 16,71] 0,2463[4]	6,4 [-3,0; 15,8] 0,2463[4]
Progesterone receptor status (Interaction p-value: 0,0132)					
Negative	7/156 (4,5)	7/169 (4,1)	1,08 [0,39; 3,02] 0,8783[2]	1,09 [0,37; 3,17] 0,8783[3]	0,3 [-4,1; 4,8] 0,8783[3]
Positive	61/1089 (5,6)	25/1066 (2,3)	2,39 [1,51; 3,77] 0,0002[2]	2,47 [1,54; 3,97] 0,0001[3]	3,3 [1,6; 4,9] 0,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	5/114 (4,4)	0/132 (0,0)	12,72 [0,71; 227,60] 0,0839[2]	13,31 [0,73; 243,39] 0,0204[4]	4,4 [0,6; 8,1] 0,0204[4]
Aromatase inhibitor	65/1169 (5,6)	33/1132 (2,9)	1,91 [1,26; 2,88] 0,0021[2]	1,96 [1,28; 3,01] 0,0017[3]	2,6 [1,0; 4,3] 0,0017[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 395.1.1: Interacting subgroups - serious adverse events according SOC Metabolism and nutrition disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	0/114 (0,0)	0/132 (0,0)	NE	NE	NE
Aromatase inhibitor	13/1169 (1,1)	4/1132 (0,4)	3,15 [1,03; 9,62] 0,0444[2]	3,17 [1,03; 9,76] 0,0336[3]	0,8 [0,1; 1,5] 0,0336[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 397.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Alanine aminotransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	1/114 (0,9)	0/132 (0,0)	3,47 [0,14; 84,34] 0,4448[2]	3,50 [0,14; 86,82] 0,4634[4]	0,9 [-0,8; 2,6] 0,4634[4]
Aromatase inhibitor	34/1169 (2,9)	7/1132 (0,6)	4,70 [2,09; 10,57] 0,0002[2]	4,81 [2,13; 10,91] <,0001[3]	2,3 [1,2; 3,4] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 398.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Anaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	0/114 (0,0)	0/132 (0,0)	NE	NE	NE
Aromatase inhibitor	39/1169 (3,3)	6/1132 (0,5)	6,29 [2,68; 14,81] <,0001[2]	6,48 [2,73; 15,36] <,0001[3]	2,8 [1,7; 3,9] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 399.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Aspartate aminotransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	1/114 (0,9)	0/132 (0,0)	3,47 [0,14; 84,34] 0,4448[2]	3,50 [0,14; 86,82] 0,4634[4]	0,9 [-0,8; 2,6] 0,4634[4]
Aromatase inhibitor	21/1169 (1,8)	4/1132 (0,4)	5,08 [1,75; 14,76] 0,0028[2]	5,16 [1,77; 15,08] 0,0008[3]	1,4 [0,6; 2,3] 0,0008[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 400.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Diarrhoea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor grade (Interaction p-value: <,0001)					
G1	8/91 (8,8)	0/93 (0,0)	17,37 [1,02; 296,59] 0,0486[2]	19,04 [1,08; 334,86] 0,0030[4]	8,8 [3,0; 14,6] 0,0030[4]
G2	52/612 (8,5)	1/602 (0,2)	51,15 [7,09; 368,81] <,0001[2]	55,81 [7,69; 405,03] <,0001[3]	8,3 [6,1; 10,6] <,0001[3]
G3	63/527 (12,0)	1/506 (0,2)	60,49 [8,42; 434,48] <,0001[2]	68,57 [9,47; 496,35] <,0001[3]	11,8 [9,0; 14,6] <,0001[3]
GX	2/51 (3,9)	0/59 (0,0)	5,77 [0,28; 117,46] 0,2544[2]	6,01 [0,28; 128,14] 0,2127[4]	3,9 [-1,4; 9,2] 0,2127[4]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	19/156 (12,2)	1/169 (0,6)	20,58 [2,79; 151,95] 0,0030[2]	23,30 [3,08; 176,25] <,0001[3]	11,6 [6,3; 16,8] <,0001[3]
Positive	102/1089 (9,4)	1/1066 (0,1)	99,85 [13,96; 714,34] <,0001[2]	110,06 [15,33; 790,36] <,0001[3]	9,3 [7,5; 11,0] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	7/114 (6,1)	0/132 (0,0)	17,35 [1,00; 300,45] 0,0499[2]	18,49 [1,04; 327,38] 0,0041[4]	6,1 [1,7; 10,5] 0,0041[4]
Aromatase inhibitor	118/1169 (10,1)	2/1132 (0,2)	57,13 [14,16; 230,58] <,0001[2]	63,43 [15,64; 257,27] <,0001[3]	9,9 [8,2; 11,7] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 401.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Fatigue from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	2/114 (1,8)	0/132 (0,0)	5,78 [0,28; 119,22] 0,2557[2]	5,89 [0,28; 123,94] 0,2137[4]	1,8 [-0,7; 4,2] 0,2137[4]
Aromatase inhibitor	32/1169 (2,7)	2/1132 (0,2)	15,49 [3,72; 64,50] 0,0002[2]	15,90 [3,80; 66,51] <,0001[3]	2,6 [1,6; 3,5] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 402.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Gamma-glutamyltransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: <,0001)					
< 65 years	14/918 (1,5)	5/936 (0,5)	2,85 [1,03; 7,89] 0,0432[2]	2,88 [1,03; 8,04] 0,0342[3]	1,0 [0,1; 1,9] 0,0342[3]
≥ 65 years	6/365 (1,6)	0/328 (0,0)	11,69 [0,66; 206,64] 0,0935[2]	11,88 [0,67; 211,69] 0,0319[4]	1,6 [0,3; 2,9] 0,0319[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	0/114 (0,0)	0/132 (0,0)	NE	NE	NE
Aromatase inhibitor	20/1169 (1,7)	5/1132 (0,4)	3,87 [1,46; 10,29] 0,0066[2]	3,92 [1,47; 10,49] 0,0033[3]	1,3 [0,4; 2,1] 0,0033[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 403.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Hypokalaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	1/114 (0,9)	0/132 (0,0)	3,47 [0,14; 84,34] 0,4448[2]	3,50 [0,14; 86,82] 0,4634[4]	0,9 [-0,8; 2,6] 0,4634[4]
Aromatase inhibitor	17/1169 (1,5)	4/1132 (0,4)	4,12 [1,39; 12,19] 0,0107[2]	4,16 [1,40; 12,41] 0,0055[3]	1,1 [0,3; 1,9] 0,0055[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 404.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Leukopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	4/114 (3,5)	0/132 (0,0)	10,41 [0,57; 191,27] 0,1147[2]	10,79 [0,57; 202,64] 0,0448[4]	3,5 [0,1; 6,9] 0,0448[4]
Aromatase inhibitor	44/1169 (3,8)	2/1132 (0,2)	21,30 [5,18; 87,67] <,0001[2]	22,10 [5,34; 91,37] <,0001[3]	3,6 [2,5; 4,7] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 405.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Lymphocyte count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	5/156 (3,2)	1/169 (0,6)	5,42 [0,64; 45,85] 0,1211[2]	5,56 [0,64; 48,15] 0,1086[4]	2,6 [-0,4; 5,6] 0,1086[4]
Positive	34/1089 (3,1)	4/1066 (0,4)	8,32 [2,96; 23,37] <,0001[2]	8,56 [3,03; 24,20] <,0001[3]	2,7 [1,7; 3,8] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	0/114 (0,0)	1/132 (0,8)	0,39 [0,02; 9,37] 0,5582[2]	0,38 [0,02; 9,49] 1,0000[4]	-0,8 [-2,2; 0,7] 1,0000[4]
Aromatase inhibitor	42/1169 (3,6)	4/1132 (0,4)	10,17 [3,66; 28,26] <,0001[2]	10,51 [3,76; 29,41] <,0001[3]	3,2 [2,1; 4,4] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 406.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Lymphopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	1/114 (0,9)	0/132 (0,0)	3,47 [0,14; 84,34] 0,4448[2]	3,50 [0,14; 86,82] 0,4634[4]	0,9 [-0,8; 2,6] 0,4634[4]
Aromatase inhibitor	21/1169 (1,8)	2/1132 (0,2)	10,17 [2,39; 43,26] 0,0017[2]	10,34 [2,42; 44,18] <,0001[3]	1,6 [0,8; 2,4] <,0001[3]
ECOG-PS (Interaction p-value: <,0001)					
ECOG-PS 0	17/1070 (1,6)	0/1019 (0,0)	33,33 [2,01; 553,56] 0,0144[2]	33,87 [2,03; 563,96] <,0001[3]	1,6 [0,8; 2,3] <,0001[3]
ECOG-PS 1	5/213 (2,3)	2/245 (0,8)	2,88 [0,56; 14,67] 0,2039[2]	2,92 [0,56; 15,21] 0,2586[4]	1,5 [-0,8; 3,9] 0,2586[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 407.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Neutropenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor grade (Interaction p-value: <,0001)					
G1	5/91 (5,5)	0/93 (0,0)	11,24 [0,63; 200,37] 0,0997[2]	11,89 [0,65; 218,22] 0,0280[4]	5,5 [0,8; 10,2] 0,0280[4]
G2	65/612 (10,6)	3/602 (0,5)	21,31 [6,74; 67,44] <,0001[2]	23,73 [7,41; 75,93] <,0001[3]	10,1 [7,6; 12,6] <,0001[3]
G3	65/527 (12,3)	1/506 (0,2)	62,41 [8,69; 448,06] <,0001[2]	71,05 [9,82; 514,09] <,0001[3]	12,1 [9,3; 15,0] <,0001[3]
GX	5/51 (9,8)	0/59 (0,0)	12,69 [0,72; 224,11] 0,0828[2]	14,08 [0,76; 261,07] 0,0192[4]	9,8 [1,6; 18,0] 0,0192[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	13/114 (11,4)	0/132 (0,0)	31,23 [1,88; 519,50] 0,0164[2]	35,25 [2,07; 599,95] <,0001[3]	11,4 [5,6; 17,2] <,0001[3]
Aromatase inhibitor	127/1169 (10,9)	4/1132 (0,4)	30,75 [11,40; 82,90] <,0001[2]	34,37 [12,66; 93,32] <,0001[3]	10,5 [8,7; 12,3] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 408.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Neutrophil count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	7/114 (6,1)	0/132 (0,0)	17,35 [1,00; 300,45] 0,0499[2]	18,49 [1,04; 327,38] 0,0041[4]	6,1 [1,7; 10,5] 0,0041[4]
Aromatase inhibitor	122/1169 (10,4)	4/1132 (0,4)	29,53 [10,95; 79,69] <,0001[2]	32,86 [12,09; 89,27] <,0001[3]	10,1 [8,3; 11,9] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 409.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT Platelet count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	1/114 (0,9)	0/132 (0,0)	3,47 [0,14; 84,34] 0,4448[2]	3,50 [0,14; 86,82] 0,4634[4]	0,9 [-0,8; 2,6] 0,4634[4]
Aromatase inhibitor	12/1169 (1,0)	0/1132 (0,0)	24,21 [1,44; 408,41] 0,0271[2]	24,46 [1,45; 413,61] 0,0006[3]	1,0 [0,4; 1,6] 0,0006[3]
ECOG-PS (Interaction p-value: <,0001)					
ECOG-PS 0	11/1070 (1,0)	0/1019 (0,0)	21,90 [1,29; 371,23] 0,0325[2]	22,13 [1,30; 376,06] 0,0012[3]	1,0 [0,4; 1,6] 0,0012[3]
ECOG-PS 1	2/213 (0,9)	0/245 (0,0)	5,75 [0,28; 119,06] 0,2581[2]	5,80 [0,28; 121,56] 0,2157[4]	0,9 [-0,4; 2,2] 0,2157[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 410.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according PT White blood cell count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	5/114 (4,4)	0/132 (0,0)	12,72 [0,71; 227,60] 0,0839[2]	13,31 [0,73; 243,39] 0,0204[4]	4,4 [0,6; 8,1] 0,0204[4]
Aromatase inhibitor	94/1169 (8,0)	3/1132 (0,3)	30,34 [9,64; 95,50] <,0001[2]	32,91 [10,39; 104,19] <,0001[3]	7,8 [6,2; 9,4] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 411.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC Blood and lymphatic system disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor grade (Interaction p-value: <,0001)					
G1	13/91 (14,3)	0/93 (0,0)	27,59 [1,66; 457,30] 0,0206[2]	32,16 [1,88; 549,64] 0,0002[3]	14,3 [7,1; 21,5] 0,0002[3]
G2	106/612 (17,3)	11/602 (1,8)	9,48 [5,15; 17,46] <,0001[2]	11,26 [5,98; 21,18] <,0001[3]	15,5 [12,3; 18,7] <,0001[3]
G3	82/527 (15,6)	4/506 (0,8)	19,68 [7,27; 53,30] <,0001[2]	23,13 [8,41; 63,60] <,0001[3]	14,8 [11,6; 18,0] <,0001[3]
GX	9/51 (17,6)	0/59 (0,0)	21,92 [1,31; 367,60] 0,0318[2]	26,60 [1,51; 469,58] 0,0007[4]	17,6 [7,2; 28,1] 0,0007[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	17/114 (14,9)	0/132 (0,0)	40,48 [2,46; 665,67] 0,0096[2]	47,56 [2,83; 800,58] <,0001[3]	14,9 [8,4; 21,5] <,0001[3]
Aromatase inhibitor	193/1169 (16,5)	15/1132 (1,3)	12,46 [7,42; 20,94] <,0001[2]	14,73 [8,65; 25,08] <,0001[3]	15,2 [13,0; 17,4] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 412.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC Gastrointestinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	21/156 (13,5)	5/169 (3,0)	4,55 [1,76; 11,77] 0,0018[2]	5,10 [1,87; 13,89] 0,0005[3]	10,5 [4,6; 16,4] 0,0005[3]
Positive	121/1089 (11,1)	13/1066 (1,2)	9,11 [5,17; 16,04] <,0001[2]	10,13 [5,68; 18,06] <,0001[3]	9,9 [7,9; 11,9] <,0001[3]
Unknown	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	8/114 (7,0)	0/132 (0,0)	19,66 [1,15; 336,92] 0,0399[2]	21,15 [1,21; 370,63] 0,0019[4]	7,0 [2,3; 11,7] 0,0019[4]
Aromatase inhibitor	140/1169 (12,0)	18/1132 (1,6)	7,53 [4,64; 12,22] <,0001[2]	8,42 [5,12; 13,86] <,0001[3]	10,4 [8,4; 12,4] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 413.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC General disorders and administration site conditions from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,0442)					
Negative	9/156 (5,8)	1/169 (0,6)	9,75 [1,25; 76,08] 0,0298[2]	10,29 [1,29; 82,15] 0,0082[4]	5,2 [1,3; 9,0] 0,0082[4]
Positive	44/1089 (4,0)	6/1066 (0,6)	7,18 [3,07; 16,77] <,0001[2]	7,44 [3,16; 17,53] <,0001[3]	3,5 [2,2; 4,7] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 414.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC Infections and infestations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Primary tumor size (Interaction p-value: 0,0489)					
< 20 mm	18/331 (5,4)	5/334 (1,5)	3,63 [1,36; 9,67] 0,0098[2]	3,78 [1,39; 10,32] 0,0054[3]	3,9 [1,2; 6,7] 0,0054[3]
≥ 20 but < 50 mm	34/646 (5,3)	26/653 (4,0)	1,32 [0,80; 2,18] 0,2730[2]	1,34 [0,79; 2,26] 0,2712[3]	1,3 [-1,0; 3,6] 0,2712[3]
≥ 50 mm	19/289 (6,6)	4/265 (1,5)	4,36 [1,50; 12,64] 0,0068[2]	4,59 [1,54; 13,68] 0,0028[3]	5,1 [1,9; 8,3] 0,0028[3]
Progesterone receptor status (Interaction p-value: 0,0145)					
Negative	6/156 (3,8)	7/169 (4,1)	0,93 [0,32; 2,70] 0,8919[2]	0,93 [0,30; 2,82] 0,8918[3]	-0,3 [-4,6; 4,0] 0,8918[3]
Positive	63/1089 (5,8)	27/1066 (2,5)	2,28 [1,47; 3,56] 0,0003[2]	2,36 [1,49; 3,74] 0,0002[3]	3,3 [1,6; 4,9] 0,0002[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	7/114 (6,1)	0/132 (0,0)	17,35 [1,00; 300,45] 0,0499[2]	18,49 [1,04; 327,38] 0,0041[4]	6,1 [1,7; 10,5] 0,0041[4]
Aromatase inhibitor	64/1169 (5,5)	35/1132 (3,1)	1,77 [1,18; 2,65] 0,0056[2]	1,82 [1,19; 2,76] 0,0049[3]	2,4 [0,7; 4,0] 0,0049[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 415.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC Investigations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Number of positive lymph nodes (Interaction p-value: 0,0360)					
0-3	80/427 (18,7)	4/418 (1,0)	19,58 [7,24; 52,96] <,0001[2]	23,86 [8,65; 65,79] <,0001[3]	17,8 [14,0; 21,6] <,0001[3]
4-9	95/549 (17,3)	11/542 (2,0)	8,53 [4,62; 15,74] <,0001[2]	10,10 [5,34; 19,09] <,0001[3]	15,3 [11,9; 18,7] <,0001[3]
≥ 10	71/307 (23,1)	15/304 (4,9)	4,69 [2,75; 7,99] <,0001[2]	5,80 [3,24; 10,38] <,0001[3]	18,2 [12,9; 23,5] <,0001[3]
Progesterone receptor status (Interaction p-value: <,0001)					
Negative	31/156 (19,9)	4/169 (2,4)	8,40 [3,03; 23,24] <,0001[2]	10,23 [3,52; 29,73] <,0001[3]	17,5 [10,8; 24,2] <,0001[3]
Positive	210/1089 (19,3)	25/1066 (2,3)	8,22 [5,48; 12,34] <,0001[2]	9,95 [6,51; 15,21] <,0001[3]	16,9 [14,4; 19,5] <,0001[3]
Unknown	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 416.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC Metabolism and nutrition disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor grade (Interaction p-value: <,0001)					
G1	7/91 (7,7)	1/93 (1,1)	7,15 [0,90; 56,99] 0,0631[2]	7,67 [0,92; 63,62] 0,0336[4]	6,6 [0,8; 12,5] 0,0336[4]
G2	30/612 (4,9)	18/602 (3,0)	1,64 [0,92; 2,91] 0,0911[2]	1,67 [0,92; 3,03] 0,0874[3]	1,9 [-0,3; 4,1] 0,0874[3]
G3	23/527 (4,4)	6/506 (1,2)	3,68 [1,51; 8,96] 0,0041[2]	3,80 [1,54; 9,42] 0,0020[3]	3,2 [1,2; 5,2] 0,0020[3]
GX	5/51 (9,8)	0/59 (0,0)	12,69 [0,72; 224,11] 0,0828[2]	14,08 [0,76; 261,07] 0,0192[4]	9,8 [1,6; 18,0] 0,0192[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 417.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC Renal and urinary disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor grade (Interaction p-value: <,0001)					
G1	0/91 (0,0)	0/93 (0,0)	NE	NE	NE
G2	6/612 (1,0)	1/602 (0,2)	5,90 [0,71; 48,88] 0,0998[2]	5,95 [0,71; 49,57] 0,1240[4]	0,8 [-0,0; 1,7] 0,1240[4]
G3	7/527 (1,3)	3/506 (0,6)	2,24 [0,58; 8,62] 0,2405[2]	2,26 [0,58; 8,78] 0,3424[4]	0,7 [-0,4; 1,9] 0,3424[4]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	0/114 (0,0)	0/132 (0,0)	NE	NE	NE
Aromatase inhibitor	13/1169 (1,1)	4/1132 (0,4)	3,15 [1,03; 9,62] 0,0444[2]	3,17 [1,03; 9,76] 0,0336[3]	0,8 [0,1; 1,5] 0,0336[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 418.1.1: Interacting subgroups - adverse events with CTCAE Grade ≥3 according SOC Respiratory, thoracic and mediastinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor grade (Interaction p-value: <,0001)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	9/612 (1,5)	5/602 (0,8)	1,77 [0,60; 5,25] 0,3031[2]	1,78 [0,59; 5,35] 0,2963[3]	0,6 [-0,6; 1,8] 0,2963[3]
G3	12/527 (2,3)	3/506 (0,6)	3,84 [1,09; 13,53] 0,0362[2]	3,91 [1,10; 13,93] 0,0237[3]	1,7 [0,2; 3,1] 0,0237[3]
GX	0/51 (0,0)	1/59 (1,7)	0,38 [0,02; 9,24] 0,5558[2]	0,38 [0,02; 9,50] 1,0000[4]	-1,7 [-5,0; 1,6] 1,0000[4]
First endocrine therapy (Interaction p-value: <,0001)					
Tamoxifen	2/114 (1,8)	0/132 (0,0)	5,78 [0,28; 119,22] 0,2557[2]	5,89 [0,28; 123,94] 0,2137[4]	1,8 [-0,7; 4,2] 0,2137[4]
Aromatase inhibitor	21/1169 (1,8)	9/1132 (0,8)	2,26 [1,04; 4,91] 0,0397[2]	2,28 [1,04; 5,01] 0,0343[3]	1,0 [0,1; 1,9] 0,0343[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Anhang 4-G2.4.11: Häufige unerwünschte Ereignisse nach Schweregrad und nach SOC und PT - Subgruppenanalyse nicht-interagierender Subgruppen (Prämenopausale Patientinnen)

Table 201.1.2: Subgroups - adverse events according PT Abdominal distension from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1576)					
Neoadjuvant chemotherapy	13/314 (4,1)	4/306 (1,3)	3,17 [1,04; 9,61] 0,0417[2]	3,26 [1,05; 10,11] 0,0308[3]	2,8 [0,3; 5,4] 0,0308[3]
Adjuvant chemotherapy	11/452 (2,4)	3/416 (0,7)	3,37 [0,95; 12,01] 0,0604[2]	3,43 [0,95; 12,40] 0,0454[3]	1,7 [0,1; 3,3] 0,0454[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,9991)					
North America / Europe	14/347 (4,0)	5/309 (1,6)	2,49 [0,91; 6,84] 0,0761[2]	2,56 [0,91; 7,18] 0,0655[3]	2,4 [-0,1; 4,9] 0,0655[3]
Asia	5/239 (2,1)	0/226 (0,0)	10,40 [0,58; 187,09] 0,1121[2]	10,62 [0,58; 193,25] 0,0616[4]	2,1 [0,3; 3,9] 0,0616[4]
Other	5/190 (2,6)	2/194 (1,0)	2,55 [0,50; 13,00] 0,2591[2]	2,59 [0,50; 13,54] 0,2802[4]	1,6 [-1,1; 4,3] 0,2802[4]
Primary tumor size (Interaction p-value: 0,7059)					
< 20 mm	10/204 (4,9)	3/189 (1,6)	3,09 [0,86; 11,05] 0,0830[2]	3,20 [0,87; 11,79] 0,0664[3]	3,3 [-0,1; 6,8] 0,0664[3]
≥ 20 but < 50 mm	6/360 (1,7)	4/346 (1,2)	1,44 [0,41; 5,06] 0,5683[2]	1,45 [0,41; 5,18] 0,7526[4]	0,5 [-1,2; 2,2] 0,7526[4]
≥ 50 mm	8/194 (4,1)	0/185 (0,0)	16,22 [0,94; 278,95] 0,0550[2]	16,91 [0,97; 295,08] 0,0074[4]	4,1 [1,3; 6,9] 0,0074[4]
Number of positive lymph nodes (Interaction p-value: 0,9952)					
0-3	7/269 (2,6)	3/269 (1,1)	2,33 [0,61; 8,93] 0,2159[2]	2,37 [0,61; 9,26] 0,2017[3]	1,5 [-0,8; 3,8] 0,2017[3]
4-9	11/353 (3,1)	4/326 (1,2)	2,54 [0,82; 7,90] 0,1073[2]	2,59 [0,82; 8,21] 0,0943[3]	1,9 [-0,3; 4,1] 0,0943[3]
≥ 10	6/154 (3,9)	0/134 (0,0)	11,32 [0,64; 199,13] 0,0971[2]	11,77 [0,66; 210,99] 0,0319[4]	3,9 [0,8; 7,0] 0,0319[4]
Tumor stage (Interaction p-value: 0,8141)					
IIA	3/79 (3,8)	2/77 (2,6)	1,46 [0,25; 8,51] 0,6726[2]	1,48 [0,24; 9,11] 1,0000[4]	1,2 [-4,3; 6,7] 1,0000[4]
IIB	1/73 (1,4)	0/93 (0,0)	3,81 [0,16; 92,20] 0,4105[2]	3,87 [0,16; 96,38] 0,4398[4]	1,4 [-1,3; 4,0] 0,4398[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	7/345 (2,0)	2/294 (0,7)	2,98 [0,62; 14,25] 0,1708[2]	3,02 [0,62; 14,67] 0,1892[4]	1,3 [-0,4; 3,1] 0,1892[4]
IIIB	0/22 (0,0)	1/19 (5,3)	0,29 [0,01; 6,72] 0,4401[2]	0,27 [0,01; 7,13] 0,4634[4]	-5,3 [-15,3; 4,8] 0,4634[4]
IIIC	13/253 (5,1)	2/245 (0,8)	6,29 [1,44; 27,60] 0,0147[2]	6,58 [1,47; 29,48] 0,0048[3]	4,3 [1,4; 7,3] 0,0048[3]
Tumor grade (Interaction p-value: 0,5047)					
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	9/349 (2,6)	3/323 (0,9)	2,78 [0,76; 10,17] 0,1230[2]	2,82 [0,76; 10,52] 0,1066[3]	1,7 [-0,3; 3,6] 0,1066[3]
G3	12/317 (3,8)	4/312 (1,3)	2,95 [0,96; 9,06] 0,0583[2]	3,03 [0,97; 9,50] 0,0462[3]	2,5 [0,1; 4,9] 0,0462[3]
GX	0/44 (0,0)	0/40 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9994)					
Negative	1/67 (1,5)	0/62 (0,0)	2,78 [0,12; 66,98] 0,5289[2]	2,82 [0,11; 70,51] 1,0000[4]	1,5 [-1,4; 4,4] 1,0000[4]
Positive	20/678 (2,9)	7/647 (1,1)	2,73 [1,16; 6,40] 0,0213[2]	2,78 [1,17; 6,62] 0,0161[3]	1,9 [0,4; 3,4] 0,0161[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,9993)					
White	17/461 (3,7)	6/440 (1,4)	2,70 [1,08; 6,80] 0,0343[2]	2,77 [1,08; 7,09] 0,0270[3]	2,3 [0,3; 4,4] 0,0270[3]
Asian	6/273 (2,2)	0/243 (0,0)	11,58 [0,66; 204,44] 0,0946[2]	11,83 [0,66; 211,16] 0,0319[4]	2,2 [0,5; 3,9] 0,0319[4]
Other	0/30 (0,0)	1/34 (2,9)	0,38 [0,02; 8,91] 0,5449[2]	0,37 [0,01; 9,33] 1,0000[4]	-2,9 [-8,6; 2,7] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,2994)					
Tamoxifen	15/553 (2,7)	3/534 (0,6)	4,83 [1,41; 16,58] 0,0124[2]	4,93 [1,42; 17,15] 0,0055[3]	2,2 [0,7; 3,6] 0,0055[3]
Aromatase inhibitor	9/223 (4,0)	4/195 (2,1)	1,97 [0,62; 6,29] 0,2537[2]	2,01 [0,61; 6,63] 0,2436[3]	2,0 [-1,3; 5,2] 0,2436[3]
ECOG-PS (Interaction p-value: 0,9749)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	21/685 (3,1)	7/649 (1,1)	2,84 [1,22; 6,64] 0,0158[2]	2,90 [1,22; 6,87] 0,0114[3]	2,0 [0,5; 3,5] 0,0114[3]
ECOG-PS 1	3/91 (3,3)	0/80 (0,0)	6,16 [0,32; 117,53] 0,2267[2]	6,37 [0,32; 125,17] 0,2487[4]	3,3 [-0,4; 7,0] 0,2487[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 202.1.2: Subgroups - adverse events according PT Abdominal pain from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,0828)					
North America / Europe	120/347 (34,6)	26/309 (8,4)	4,11 [2,77; 6,10] <,0001[2]	5,75 [3,64; 9,10] <,0001[3]	26,2 [20,3; 32,1] <,0001[3]
Asia	49/239 (20,5)	3/226 (1,3)	15,44 [4,88; 48,85] <,0001[2]	19,17 [5,88; 62,49] <,0001[3]	19,2 [13,8; 24,5] <,0001[3]
Other	38/190 (20,0)	6/194 (3,1)	6,47 [2,80; 14,94] <,0001[2]	7,83 [3,23; 19,02] <,0001[3]	16,9 [10,7; 23,1] <,0001[3]
Primary tumor size (Interaction p-value: 0,5429)					
< 20 mm	51/204 (25,0)	11/189 (5,8)	4,30 [2,31; 7,99] <,0001[2]	5,39 [2,72; 10,72] <,0001[3]	19,2 [12,4; 26,0] <,0001[3]
≥ 20 but < 50 mm	93/360 (25,8)	13/346 (3,8)	6,88 [3,92; 12,05] <,0001[2]	8,92 [4,89; 16,29] <,0001[3]	22,1 [17,1; 27,0] <,0001[3]
≥ 50 mm	62/194 (32,0)	11/185 (5,9)	5,37 [2,92; 9,88] <,0001[2]	7,43 [3,76; 14,67] <,0001[3]	26,0 [18,6; 33,4] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,5164)					
0-3	67/269 (24,9)	13/269 (4,8)	5,15 [2,92; 9,11] <,0001[2]	6,53 [3,51; 12,17] <,0001[3]	20,1 [14,3; 25,8] <,0001[3]
4-9	97/353 (27,5)	13/326 (4,0)	6,89 [3,94; 12,05] <,0001[2]	9,12 [5,00; 16,66] <,0001[3]	23,5 [18,4; 28,6] <,0001[3]
≥ 10	43/154 (27,9)	9/134 (6,7)	4,16 [2,11; 8,21] <,0001[2]	5,38 [2,51; 11,53] <,0001[3]	21,2 [12,9; 29,5] <,0001[3]
Tumor stage (Interaction p-value: 0,4569)					
IIA	18/79 (22,8)	2/77 (2,6)	8,77 [2,11; 36,54] 0,0029[2]	11,07 [2,47; 49,56] 0,0002[3]	20,2 [10,3; 30,1] 0,0002[3]
IIB	14/73 (19,2)	5/93 (5,4)	3,57 [1,35; 9,45] 0,0105[2]	4,18 [1,43; 12,21] 0,0056[3]	13,8 [3,7; 23,9] 0,0056[3]
IIIA	93/345 (27,0)	10/294 (3,4)	7,93 [4,21; 14,93] <,0001[2]	10,48 [5,34; 20,56] <,0001[3]	23,6 [18,4; 28,7] <,0001[3]
IIIB	8/22 (36,4)	1/19 (5,3)	6,91 [0,95; 50,35] 0,0565[2]	10,29 [1,15; 92,19] 0,0238[4]	31,1 [8,6; 53,6] 0,0238[4]
IIIC	73/253 (28,9)	17/245 (6,9)	4,16 [2,53; 6,84] <,0001[2]	5,44 [3,10; 9,55] <,0001[3]	21,9 [15,5; 28,3] <,0001[3]
Tumor grade (Interaction p-value: 0,8185)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	15/63 (23,8)	2/52 (3,8)	6,19 [1,48; 25,84] 0,0124[2]	7,81 [1,70; 35,99] 0,0027[3]	20,0 [8,2; 31,7] 0,0027[3]
G2	104/349 (29,8)	15/323 (4,6)	6,42 [3,82; 10,79] <,0001[2]	8,72 [4,95; 15,36] <,0001[3]	25,2 [19,8; 30,5] <,0001[3]
G3	78/317 (24,6)	16/312 (5,1)	4,80 [2,87; 8,03] <,0001[2]	6,04 [3,43; 10,62] <,0001[3]	19,5 [14,1; 24,8] <,0001[3]
GX	8/44 (18,2)	2/40 (5,0)	3,64 [0,82; 16,12] 0,0893[2]	4,22 [0,84; 21,23] 0,0923[4]	13,2 [-0,1; 26,4] 0,0923[4]
Progesterone receptor status (Interaction p-value: 0,9836)					
Negative	26/67 (38,8)	4/62 (6,5)	6,01 [2,23; 16,26] 0,0004[2]	9,20 [2,98; 28,35] <,0001[3]	32,4 [19,2; 45,5] <,0001[3]
Positive	164/678 (24,2)	28/647 (4,3)	5,59 [3,80; 8,22] <,0001[2]	7,05 [4,65; 10,71] <,0001[3]	19,9 [16,3; 23,4] <,0001[3]
Unknown	5/8 (62,5)	1/8 (12,5)	5,00 [0,74; 33,78] 0,0987[2]	11,67 [0,92; 147,56] 0,1189[4]	50,0 [9,4; 90,6] 0,1189[4]
First endocrine therapy (Interaction p-value: 0,7054)					
Tamoxifen	137/553 (24,8)	25/534 (4,7)	5,29 [3,51; 7,97] <,0001[2]	6,71 [4,29; 10,47] <,0001[3]	20,1 [16,1; 24,1] <,0001[3]
Aromatase inhibitor	70/223 (31,4)	10/195 (5,1)	6,12 [3,25; 11,54] <,0001[2]	8,46 [4,22; 16,98] <,0001[3]	26,3 [19,4; 33,1] <,0001[3]
ECOG-PS (Interaction p-value: 0,5689)					
ECOG-PS 0	188/685 (27,4)	31/649 (4,8)	5,75 [3,99; 8,27] <,0001[2]	7,54 [5,07; 11,23] <,0001[3]	22,7 [18,9; 26,4] <,0001[3]
ECOG-PS 1	19/91 (20,9)	4/80 (5,0)	4,18 [1,48; 11,76] 0,0068[2]	5,01 [1,63; 15,45] 0,0024[3]	15,9 [6,3; 25,5] 0,0024[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 203.1.2: Subgroups - adverse events according PT Abdominal pain upper from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9352)					
Neoadjuvant chemotherapy	37/314 (11,8)	9/306 (2,9)	4,01 [1,97; 8,16] 0,0001[2]	4,41 [2,09; 9,30] <,0001[3]	8,8 [4,8; 12,9] <,0001[3]
Adjuvant chemotherapy	59/452 (13,1)	16/416 (3,8)	3,39 [1,99; 5,80] <,0001[2]	3,75 [2,12; 6,63] <,0001[3]	9,2 [5,6; 12,8] <,0001[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,1560)					
North America / Europe	51/347 (14,7)	8/309 (2,6)	5,68 [2,74; 11,77] <,0001[2]	6,48 [3,02; 13,90] <,0001[3]	12,1 [8,0; 16,2] <,0001[3]
Asia	19/239 (7,9)	9/226 (4,0)	2,00 [0,92; 4,32] 0,0792[2]	2,08 [0,92; 4,70] 0,0723[3]	4,0 [-0,3; 8,2] 0,0723[3]
Other	27/190 (14,2)	8/194 (4,1)	3,45 [1,61; 7,39] 0,0015[2]	3,85 [1,70; 8,71] 0,0006[3]	10,1 [4,4; 15,8] 0,0006[3]
Primary tumor size (Interaction p-value: 0,2801)					
< 20 mm	32/204 (15,7)	8/189 (4,2)	3,71 [1,75; 7,84] 0,0006[2]	4,21 [1,89; 9,39] 0,0002[3]	11,5 [5,7; 17,2] 0,0002[3]
≥ 20 but < 50 mm	38/360 (10,6)	13/346 (3,8)	2,81 [1,52; 5,18] 0,0009[2]	3,02 [1,58; 5,78] 0,0005[3]	6,8 [3,0; 10,6] 0,0005[3]
≥ 50 mm	26/194 (13,4)	3/185 (1,6)	8,26 [2,54; 26,84] 0,0004[2]	9,39 [2,79; 31,59] <,0001[3]	11,8 [6,7; 16,9] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,2404)					
0-3	33/269 (12,3)	10/269 (3,7)	3,30 [1,66; 6,56] 0,0007[2]	3,62 [1,75; 7,51] 0,0003[3]	8,6 [4,0; 13,1] 0,0003[3]
4-9	44/353 (12,5)	14/326 (4,3)	2,90 [1,62; 5,20] 0,0003[2]	3,17 [1,70; 5,91] 0,0001[3]	8,2 [4,1; 12,3] 0,0001[3]
≥ 10	20/154 (13,0)	1/134 (0,7)	17,40 [2,37; 127,94] 0,0050[2]	19,85 [2,63; 150,04] <,0001[3]	12,2 [6,7; 17,7] <,0001[3]
Tumor stage (Interaction p-value: 0,3018)					
IIA	11/79 (13,9)	4/77 (5,2)	2,68 [0,89; 8,06] 0,0791[2]	2,95 [0,90; 9,71] 0,0645[3]	8,7 [-0,4; 17,8] 0,0645[3]
IIB	5/73 (6,8)	4/93 (4,3)	1,59 [0,44; 5,72] 0,4757[2]	1,64 [0,42; 6,32] 0,5085[4]	2,5 [-4,6; 9,7] 0,5085[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	44/345 (12,8)	11/294 (3,7)	3,41 [1,79; 6,48] 0,0002[2]	3,76 [1,90; 7,43] <,0001[3]	9,0 [4,9; 13,1] <,0001[3]
IIIB	1/22 (4,5)	1/19 (5,3)	0,86 [0,06; 12,89] 0,9153[2]	0,86 [0,05; 14,71] 1,0000[4]	-0,7 [-14,0; 12,6] 1,0000[4]
IIIC	36/253 (14,2)	5/245 (2,0)	6,97 [2,78; 17,47] <,0001[2]	7,96 [3,07; 20,66] <,0001[3]	12,2 [7,5; 16,8] <,0001[3]
Tumor grade (Interaction p-value: 0,8874)					
G1	9/63 (14,3)	1/52 (1,9)	7,43 [0,97; 56,74] 0,0532[2]	8,50 [1,04; 69,49] 0,0215[4]	12,4 [3,0; 21,8] 0,0215[4]
G2	36/349 (10,3)	8/323 (2,5)	4,16 [1,97; 8,83] 0,0002[2]	4,53 [2,07; 9,90] <,0001[3]	7,8 [4,2; 11,5] <,0001[3]
G3	48/317 (15,1)	14/312 (4,5)	3,37 [1,90; 5,99] <,0001[2]	3,80 [2,05; 7,04] <,0001[3]	10,7 [6,1; 15,2] <,0001[3]
GX	4/44 (9,1)	1/40 (2,5)	3,64 [0,42; 31,19] 0,2390[2]	3,90 [0,42; 36,46] 0,3626[4]	6,6 [-3,2; 16,4] 0,3626[4]
First endocrine therapy (Interaction p-value: 0,1244)					
Tamoxifen	69/553 (12,5)	22/534 (4,1)	3,03 [1,90; 4,82] <,0001[2]	3,32 [2,02; 5,45] <,0001[3]	8,4 [5,1; 11,6] <,0001[3]
Aromatase inhibitor	28/223 (12,6)	3/195 (1,5)	8,16 [2,52; 26,43] 0,0005[2]	9,19 [2,75; 30,73] <,0001[3]	11,0 [6,3; 15,7] <,0001[3]
ECOG-PS (Interaction p-value: 0,5989)					
ECOG-PS 0	88/685 (12,8)	22/649 (3,4)	3,79 [2,41; 5,97] <,0001[2]	4,20 [2,60; 6,79] <,0001[3]	9,5 [6,6; 12,3] <,0001[3]
ECOG-PS 1	9/91 (9,9)	3/80 (3,8)	2,64 [0,74; 9,41] 0,1350[2]	2,82 [0,74; 10,79] 0,1168[3]	6,1 [-1,3; 13,6] 0,1168[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 204.1.2: Subgroups - adverse events according PT Alanine aminotransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,5174)					
Neoadjuvant chemotherapy	32/314 (10,2)	11/306 (3,6)	2,83 [1,46; 5,52] 0,0022[2]	3,04 [1,50; 6,15] 0,0012[3]	6,6 [2,7; 10,5] 0,0012[3]
Adjuvant chemotherapy	52/452 (11,5)	27/416 (6,5)	1,77 [1,14; 2,77] 0,0118[2]	1,87 [1,15; 3,04] 0,0103[3]	5,0 [1,2; 8,8] 0,0103[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,2624)					
North America / Europe	21/347 (6,1)	4/309 (1,3)	4,68 [1,62; 13,47] 0,0043[2]	4,91 [1,67; 14,47] 0,0015[3]	4,8 [1,9; 7,6] 0,0015[3]
Asia	44/239 (18,4)	23/226 (10,2)	1,81 [1,13; 2,90] 0,0135[2]	1,99 [1,16; 3,42] 0,0115[3]	8,2 [1,9; 14,5] 0,0115[3]
Other	20/190 (10,5)	11/194 (5,7)	1,86 [0,91; 3,77] 0,0868[2]	1,96 [0,91; 4,21] 0,0807[3]	4,9 [-0,6; 10,3] 0,0807[3]
Primary tumor size (Interaction p-value: 0,5339)					
< 20 mm	28/204 (13,7)	9/189 (4,8)	2,88 [1,40; 5,95] 0,0042[2]	3,18 [1,46; 6,94] 0,0024[3]	9,0 [3,3; 14,6] 0,0024[3]
≥ 20 but < 50 mm	34/360 (9,4)	19/346 (5,5)	1,72 [1,00; 2,96] 0,0497[2]	1,79 [1,00; 3,21] 0,0463[3]	4,0 [0,1; 7,8] 0,0463[3]
≥ 50 mm	19/194 (9,8)	9/185 (4,9)	2,01 [0,93; 4,34] 0,0738[2]	2,12 [0,93; 4,82] 0,0667[3]	4,9 [-0,3; 10,1] 0,0667[3]
Number of positive lymph nodes (Interaction p-value: 0,2287)					
0-3	31/269 (11,5)	9/269 (3,3)	3,44 [1,67; 7,09] 0,0008[2]	3,76 [1,76; 8,07] 0,0003[3]	8,2 [3,8; 12,6] 0,0003[3]
4-9	36/353 (10,2)	21/326 (6,4)	1,58 [0,94; 2,65] 0,0814[2]	1,65 [0,94; 2,89] 0,0778[3]	3,8 [-0,4; 7,9] 0,0778[3]
≥ 10	18/154 (11,7)	8/134 (6,0)	1,96 [0,88; 4,36] 0,0998[2]	2,08 [0,88; 4,96] 0,0912[3]	5,7 [-0,8; 12,2] 0,0912[3]
Tumor stage (Interaction p-value: 0,5549)					
IIA	13/79 (16,5)	3/77 (3,9)	4,22 [1,25; 14,24] 0,0202[2]	4,86 [1,33; 17,80] 0,0097[3]	12,6 [3,3; 21,8] 0,0097[3]
IIB	6/73 (8,2)	5/93 (5,4)	1,53 [0,49; 4,81] 0,4681[2]	1,58 [0,46; 5,38] 0,5380[4]	2,8 [-4,9; 10,6] 0,5380[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	35/345 (10,1)	19/294 (6,5)	1,57 [0,92; 2,68] 0,0994[2]	1,63 [0,91; 2,92] 0,0953[3]	3,7 [-0,6; 7,9] 0,0953[3]
IIIB	2/22 (9,1)	1/19 (5,3)	1,73 [0,17; 17,59] 0,6444[2]	1,80 [0,15; 21,57] 1,0000[4]	3,8 [-11,8; 19,5] 1,0000[4]
IIIC	27/253 (10,7)	10/245 (4,1)	2,61 [1,29; 5,29] 0,0075[2]	2,81 [1,33; 5,93] 0,0051[3]	6,6 [2,1; 11,1] 0,0051[3]
Tumor grade (Interaction p-value: 0,8823)					
G1	11/63 (17,5)	0/52 (0,0)	19,05 [1,15; 315,71] 0,0397[2]	23,00 [1,32; 400,47] 0,0010[4]	17,5 [8,1; 26,8] 0,0010[4]
G2	28/349 (8,0)	17/323 (5,3)	1,52 [0,85; 2,73] 0,1566[2]	1,57 [0,84; 2,93] 0,1527[3]	2,8 [-1,0; 6,5] 0,1527[3]
G3	35/317 (11,0)	17/312 (5,4)	2,03 [1,16; 3,54] 0,0131[2]	2,15 [1,18; 3,93] 0,0109[3]	5,6 [1,3; 9,9] 0,0109[3]
GX	10/44 (22,7)	4/40 (10,0)	2,27 [0,77; 6,68] 0,1354[2]	2,65 [0,76; 9,25] 0,1180[3]	12,7 [-2,8; 28,2] 0,1180[3]
Progesterone receptor status (Interaction p-value: 0,9179)					
Negative	11/67 (16,4)	4/62 (6,5)	2,54 [0,85; 7,58] 0,0934[2]	2,85 [0,86; 9,47] 0,0777[3]	10,0 [-0,8; 20,7] 0,0777[3]
Positive	71/678 (10,5)	34/647 (5,3)	1,99 [1,34; 2,96] 0,0006[2]	2,11 [1,38; 3,22] 0,0004[3]	5,2 [2,3; 8,1] 0,0004[3]
Unknown	2/8 (25,0)	0/8 (0,0)	5,00 [0,28; 90,18] 0,2754[2]	6,54 [0,27; 160,97] 0,4667[4]	25,0 [-5,0; 55,0] 0,4667[4]
Race (Interaction p-value: 0,3734)					
White	36/461 (7,8)	12/440 (2,7)	2,86 [1,51; 5,43] 0,0013[2]	3,02 [1,55; 5,89] 0,0007[3]	5,1 [2,2; 8,0] 0,0007[3]
Asian	46/273 (16,8)	23/243 (9,5)	1,78 [1,11; 2,85] 0,0161[2]	1,94 [1,14; 3,31] 0,0139[3]	7,4 [1,6; 13,2] 0,0139[3]
Other	3/30 (10,0)	3/34 (8,8)	1,13 [0,25; 5,20] 0,8720[2]	1,15 [0,21; 6,17] 1,0000[4]	1,2 [-13,2; 15,5] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,0772)					
Tamoxifen	42/553 (7,6)	26/534 (4,9)	1,56 [0,97; 2,51] 0,0662[2]	1,61 [0,97; 2,66] 0,0635[3]	2,7 [-0,1; 5,6] 0,0635[3]
Aromatase inhibitor	43/223 (19,3)	12/195 (6,2)	3,13 [1,70; 5,77] 0,0002[2]	3,64 [1,86; 7,13] <,0001[3]	13,1 [6,9; 19,3] <,0001[3]
ECOG-PS (Interaction p-value: 0,7732)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	79/685 (11,5)	36/649 (5,5)	2,08 [1,42; 3,04] 0,0002[2]	2,22 [1,47; 3,34] <,0001[3]	6,0 [3,0; 9,0] <,0001[3]
ECOG-PS 1	6/91 (6,6)	2/80 (2,5)	2,64 [0,55; 12,70] 0,2266[2]	2,75 [0,54; 14,04] 0,2857[4]	4,1 [-2,0; 10,2] 0,2857[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 205.1.2: Subgroups - adverse events according PT Alopecia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,5273)					
Neoadjuvant chemotherapy	29/314 (9,2)	7/306 (2,3)	4,04 [1,80; 9,08] 0,0007[2]	4,35 [1,87; 10,08] 0,0002[3]	6,9 [3,3; 10,6] 0,0002[3]
Adjuvant chemotherapy	40/452 (8,8)	5/416 (1,2)	7,36 [2,93; 18,48] <,0001[2]	7,98 [3,12; 20,42] <,0001[3]	7,6 [4,8; 10,5] <,0001[3]
No chemotherapy	4/10 (40,0)	1/7 (14,3)	2,80 [0,39; 20,02] 0,3049[2]	4,00 [0,34; 47,11] 0,3382[4]	25,7 [-14,2; 65,6] 0,3382[4]
Region (Interaction p-value: 0,4911)					
North America / Europe	40/347 (11,5)	11/309 (3,6)	3,24 [1,69; 6,20] 0,0004[2]	3,53 [1,78; 7,01] 0,0001[3]	8,0 [4,0; 11,9] 0,0001[3]
Asia	18/239 (7,5)	2/226 (0,9)	8,51 [2,00; 36,26] 0,0038[2]	9,12 [2,09; 39,78] 0,0004[3]	6,6 [3,1; 10,2] 0,0004[3]
Other	15/190 (7,9)	0/194 (0,0)	31,65 [1,91; 525,21] 0,0159[2]	34,36 [2,04; 578,43] <,0001[3]	7,9 [4,1; 11,7] <,0001[3]
Primary tumor size (Interaction p-value: 0,3959)					
< 20 mm	23/204 (11,3)	5/189 (2,6)	4,26 [1,65; 10,98] 0,0027[2]	4,68 [1,74; 12,57] 0,0009[3]	8,6 [3,7; 13,5] 0,0009[3]
≥ 20 but < 50 mm	30/360 (8,3)	3/346 (0,9)	9,61 [2,96; 31,20] 0,0002[2]	10,39 [3,14; 34,39] <,0001[3]	7,5 [4,4; 10,5] <,0001[3]
≥ 50 mm	18/194 (9,3)	5/185 (2,7)	3,43 [1,30; 9,06] 0,0127[2]	3,68 [1,34; 10,13] 0,0074[3]	6,6 [1,9; 11,3] 0,0074[3]
Number of positive lymph nodes (Interaction p-value: 0,3544)					
0-3	30/269 (11,2)	3/269 (1,1)	10,00 [3,09; 32,37] 0,0001[2]	11,13 [3,35; 36,94] <,0001[3]	10,0 [6,1; 14,0] <,0001[3]
4-9	31/353 (8,8)	8/326 (2,5)	3,58 [1,67; 7,67] 0,0010[2]	3,83 [1,73; 8,45] 0,0004[3]	6,3 [2,9; 9,7] 0,0004[3]
≥ 10	12/154 (7,8)	2/134 (1,5)	5,22 [1,19; 22,91] 0,0285[2]	5,58 [1,23; 25,39] 0,0132[3]	6,3 [1,6; 11,0] 0,0132[3]
Tumor stage (Interaction p-value: 0,6597)					
IIA	9/79 (11,4)	0/77 (0,0)	18,53 [1,10; 312,87] 0,0430[2]	20,89 [1,19; 365,46] 0,0031[4]	11,4 [4,4; 18,4] 0,0031[4]
IIB	7/73 (9,6)	0/93 (0,0)	19,05 [1,11; 328,24] 0,0424[2]	21,09 [1,18; 375,68] 0,0027[4]	9,6 [2,8; 16,3] 0,0027[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	27/345 (7,8)	9/294 (3,1)	2,56 [1,22; 5,35] 0,0127[2]	2,69 [1,24; 5,81] 0,0092[3]	4,8 [1,3; 8,2] 0,0092[3]
IIIB	4/22 (18,2)	1/19 (5,3)	3,45 [0,42; 28,31] 0,2481[2]	4,00 [0,41; 39,37] 0,3499[4]	12,9 [-6,1; 31,9] 0,3499[4]
IIIC	24/253 (9,5)	3/245 (1,2)	7,75 [2,36; 25,40] 0,0007[2]	8,45 [2,51; 28,46] <,0001[3]	8,3 [4,4; 12,1] <,0001[3]
Race (Interaction p-value: 0,6034)					
White	48/461 (10,4)	11/440 (2,5)	4,16 [2,19; 7,91] <,0001[2]	4,53 [2,32; 8,85] <,0001[3]	7,9 [4,8; 11,1] <,0001[3]
Asian	21/273 (7,7)	2/243 (0,8)	9,35 [2,21; 39,45] 0,0024[2]	10,04 [2,33; 43,29] 0,0002[3]	6,9 [3,5; 10,2] 0,0002[3]
Other	2/30 (6,7)	0/34 (0,0)	5,65 [0,28; 113,12] 0,2578[2]	6,05 [0,28; 131,25] 0,2158[4]	6,7 [-2,3; 15,6] 0,2158[4]
First endocrine therapy (Interaction p-value: 0,3621)					
Tamoxifen	45/553 (8,1)	10/534 (1,9)	4,35 [2,21; 8,53] <,0001[2]	4,64 [2,31; 9,31] <,0001[3]	6,3 [3,7; 8,8] <,0001[3]
Aromatase inhibitor	28/223 (12,6)	3/195 (1,5)	8,16 [2,52; 26,43] 0,0005[2]	9,19 [2,75; 30,73] <,0001[3]	11,0 [6,3; 15,7] <,0001[3]
ECOG-PS (Interaction p-value: 0,4703)					
ECOG-PS 0	66/685 (9,6)	11/649 (1,7)	5,68 [3,03; 10,67] <,0001[2]	6,18 [3,24; 11,82] <,0001[3]	7,9 [5,5; 10,4] <,0001[3]
ECOG-PS 1	7/91 (7,7)	2/80 (2,5)	3,08 [0,66; 14,39] 0,1533[2]	3,25 [0,66; 16,12] 0,1763[4]	5,2 [-1,3; 11,6] 0,1763[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 206.1.2: Subgroups - adverse events according PT Anaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,3187)					
Neoadjuvant chemotherapy	62/314 (19,7)	8/306 (2,6)	7,55 [3,68; 15,50] <,0001[2]	9,16 [4,31; 19,50] <,0001[3]	17,1 [12,4; 21,9] <,0001[3]
Adjuvant chemotherapy	94/452 (20,8)	22/416 (5,3)	3,93 [2,52; 6,13] <,0001[2]	4,70 [2,89; 7,64] <,0001[3]	15,5 [11,2; 19,8] <,0001[3]
No chemotherapy	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]
Region (Interaction p-value: 0,1783)					
North America / Europe	51/347 (14,7)	14/309 (4,5)	3,24 [1,83; 5,74] <,0001[2]	3,63 [1,97; 6,70] <,0001[3]	10,2 [5,8; 14,6] <,0001[3]
Asia	54/239 (22,6)	7/226 (3,1)	7,29 [3,39; 15,69] <,0001[2]	9,13 [4,06; 20,55] <,0001[3]	19,5 [13,7; 25,3] <,0001[3]
Other	54/190 (28,4)	9/194 (4,6)	6,13 [3,11; 12,05] <,0001[2]	8,16 [3,90; 17,10] <,0001[3]	23,8 [16,7; 30,8] <,0001[3]
Primary tumor size (Interaction p-value: 0,6519)					
< 20 mm	34/204 (16,7)	8/189 (4,2)	3,94 [1,87; 8,29] 0,0003[2]	4,53 [2,04; 10,05] <,0001[3]	12,4 [6,6; 18,3] <,0001[3]
≥ 20 but < 50 mm	81/360 (22,5)	16/346 (4,6)	4,87 [2,91; 8,15] <,0001[2]	5,99 [3,42; 10,48] <,0001[3]	17,9 [13,0; 22,7] <,0001[3]
≥ 50 mm	36/194 (18,6)	5/185 (2,7)	6,87 [2,75; 17,12] <,0001[2]	8,20 [3,14; 21,41] <,0001[3]	15,9 [9,9; 21,8] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,1507)					
0-3	45/269 (16,7)	13/269 (4,8)	3,46 [1,91; 6,27] <,0001[2]	3,96 [2,08; 7,52] <,0001[3]	11,9 [6,8; 17,0] <,0001[3]
4-9	71/353 (20,1)	14/326 (4,3)	4,68 [2,69; 8,14] <,0001[2]	5,61 [3,09; 10,18] <,0001[3]	15,8 [11,1; 20,5] <,0001[3]
≥ 10	43/154 (27,9)	3/134 (2,2)	12,47 [3,96; 39,28] <,0001[2]	16,92 [5,11; 56,02] <,0001[3]	25,7 [18,2; 33,2] <,0001[3]
Tumor stage (Interaction p-value: 0,0557)					
IIA	9/79 (11,4)	3/77 (3,9)	2,92 [0,82; 10,40] 0,0973[2]	3,17 [0,82; 12,20] 0,0790[3]	7,5 [-0,7; 15,7] 0,0790[3]
IIB	18/73 (24,7)	10/93 (10,8)	2,29 [1,13; 4,66] 0,0219[2]	2,72 [1,17; 6,32] 0,0176[3]	13,9 [2,2; 25,6] 0,0176[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	67/345 (19,4)	13/294 (4,4)	4,39 [2,48; 7,79] <,0001[2]	5,21 [2,81; 9,65] <,0001[3]	15,0 [10,2; 19,8] <,0001[3]
IIIB	3/22 (13,6)	0/19 (0,0)	6,09 [0,33; 110,84] 0,2225[2]	7,00 [0,34; 144,73] 0,2354[4]	13,6 [-0,7; 28,0] 0,2354[4]
IIIC	61/253 (24,1)	4/245 (1,6)	14,77 [5,45; 39,99] <,0001[2]	19,14 [6,84; 53,58] <,0001[3]	22,5 [17,0; 28,0] <,0001[3]
Tumor grade (Interaction p-value: 0,1869)					
G1	13/63 (20,6)	2/52 (3,8)	5,37 [1,27; 22,71] 0,0225[2]	6,50 [1,39; 30,30] 0,0078[3]	16,8 [5,5; 28,1] 0,0078[3]
G2	75/349 (21,5)	8/323 (2,5)	8,68 [4,25; 17,70] <,0001[2]	10,78 [5,11; 22,74] <,0001[3]	19,0 [14,4; 23,6] <,0001[3]
G3	57/317 (18,0)	17/312 (5,4)	3,30 [1,96; 5,54] <,0001[2]	3,80 [2,16; 6,70] <,0001[3]	12,5 [7,6; 17,5] <,0001[3]
GX	12/44 (27,3)	3/40 (7,5)	3,64 [1,11; 11,96] 0,0336[2]	4,63 [1,20; 17,85] 0,0181[3]	19,8 [4,3; 35,3] 0,0181[3]
Race (Interaction p-value: 0,6346)					
White	90/461 (19,5)	20/440 (4,5)	4,30 [2,69; 6,85] <,0001[2]	5,09 [3,08; 8,43] <,0001[3]	15,0 [10,9; 19,1] <,0001[3]
Asian	58/273 (21,2)	8/243 (3,3)	6,45 [3,15; 13,24] <,0001[2]	7,92 [3,70; 16,98] <,0001[3]	18,0 [12,6; 23,3] <,0001[3]
Other	10/30 (33,3)	2/34 (5,9)	5,67 [1,35; 23,84] 0,0180[2]	8,00 [1,59; 40,33] 0,0050[3]	27,5 [8,8; 46,1] 0,0050[3]
First endocrine therapy (Interaction p-value: 0,2314)					
Tamoxifen	101/553 (18,3)	23/534 (4,3)	4,24 [2,74; 6,56] <,0001[2]	4,96 [3,10; 7,94] <,0001[3]	14,0 [10,3; 17,6] <,0001[3]
Aromatase inhibitor	58/223 (26,0)	7/195 (3,6)	7,25 [3,39; 15,50] <,0001[2]	9,44 [4,19; 21,26] <,0001[3]	22,4 [16,1; 28,7] <,0001[3]
ECOG-PS (Interaction p-value: 0,4061)					
ECOG-PS 0	139/685 (20,3)	28/649 (4,3)	4,70 [3,18; 6,96] <,0001[2]	5,65 [3,70; 8,61] <,0001[3]	16,0 [12,6; 19,4] <,0001[3]
ECOG-PS 1	20/91 (22,0)	2/80 (2,5)	8,79 [2,12; 36,45] 0,0027[2]	10,99 [2,48; 48,68] 0,0001[3]	19,5 [10,3; 28,6] 0,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 207.1.2: Subgroups - adverse events according PT Arthralgia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1995)					
Neoadjuvant chemotherapy	76/314 (24,2)	92/306 (30,1)	0,81 [0,62; 1,04] 0,1019[2]	0,74 [0,52; 1,06] 0,1006[3]	-5,9 [-12,9; 1,1] 0,1006[3]
Adjuvant chemotherapy	94/452 (20,8)	131/416 (31,5)	0,66 [0,53; 0,83] 0,0004[2]	0,57 [0,42; 0,78] 0,0003[3]	-10,7 [-16,5; -4,9] 0,0003[3]
No chemotherapy	1/10 (10,0)	4/7 (57,1)	0,18 [0,02; 1,25] 0,0824[2]	0,08 [0,01; 1,07] 0,1007[4]	-47,1 [-88,2; -6,0] 0,1007[4]
Region (Interaction p-value: 0,1151)					
North America / Europe	109/347 (31,4)	119/309 (38,5)	0,82 [0,66; 1,01] 0,0570[2]	0,73 [0,53; 1,01] 0,0567[3]	-7,1 [-14,4; 0,2] 0,0567[3]
Asia	35/239 (14,6)	58/226 (25,7)	0,57 [0,39; 0,83] 0,0036[2]	0,50 [0,31; 0,79] 0,0030[3]	-11,0 [-18,3; -3,8] 0,0030[3]
Other	27/190 (14,2)	50/194 (25,8)	0,55 [0,36; 0,84] 0,0058[2]	0,48 [0,28; 0,80] 0,0047[3]	-11,6 [-19,5; -3,7] 0,0047[3]
Primary tumor size (Interaction p-value: 0,1520)					
< 20 mm	45/204 (22,1)	65/189 (34,4)	0,64 [0,46; 0,89] 0,0073[2]	0,54 [0,35; 0,84] 0,0065[3]	-12,3 [-21,2; -3,5] 0,0065[3]
≥ 20 but < 50 mm	75/360 (20,8)	110/346 (31,8)	0,66 [0,51; 0,84] 0,0011[2]	0,56 [0,40; 0,79] 0,0009[3]	-11,0 [-17,4; -4,5] 0,0009[3]
≥ 50 mm	51/194 (26,3)	51/185 (27,6)	0,95 [0,68; 1,33] 0,7790[2]	0,94 [0,60; 1,48] 0,7790[3]	-1,3 [-10,2; 7,7] 0,7790[3]
Number of positive lymph nodes (Interaction p-value: 0,7824)					
0-3	64/269 (23,8)	89/269 (33,1)	0,72 [0,55; 0,94] 0,0180[2]	0,63 [0,43; 0,92] 0,0169[3]	-9,3 [-16,9; -1,7] 0,0169[3]
4-9	80/353 (22,7)	100/326 (30,7)	0,74 [0,57; 0,95] 0,0188[2]	0,66 [0,47; 0,93] 0,0181[3]	-8,0 [-14,7; -1,4] 0,0181[3]
≥ 10	27/154 (17,5)	38/134 (28,4)	0,62 [0,40; 0,96] 0,0305[2]	0,54 [0,31; 0,94] 0,0284[3]	-10,8 [-20,5; -1,1] 0,0284[3]
Tumor stage (Interaction p-value: 0,7827)					
IIA	17/79 (21,5)	30/77 (39,0)	0,55 [0,33; 0,92] 0,0213[2]	0,43 [0,21; 0,87] 0,0176[3]	-17,4 [-31,6; -3,3] 0,0176[3]
IIB	15/73 (20,5)	30/93 (32,3)	0,64 [0,37; 1,09] 0,1008[2]	0,54 [0,27; 1,11] 0,0920[3]	-11,7 [-25,0; 1,6] 0,0920[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	77/345 (22,3)	92/294 (31,3)	0,71 [0,55; 0,92] 0,0108[2]	0,63 [0,44; 0,90] 0,0104[3]	-9,0 [-15,9; -2,1] 0,0104[3]
IIIB	4/22 (18,2)	5/19 (26,3)	0,69 [0,22; 2,21] 0,5331[2]	0,62 [0,14; 2,76] 0,7087[4]	-8,1 [-33,7; 17,4] 0,7087[4]
IIIC	58/253 (22,9)	70/245 (28,6)	0,80 [0,59; 1,08] 0,1508[2]	0,74 [0,50; 1,11] 0,1494[3]	-5,6 [-13,3; 2,0] 0,1494[3]
Tumor grade (Interaction p-value: 0,6382)					
G1	12/63 (19,0)	20/52 (38,5)	0,50 [0,27; 0,92] 0,0250[2]	0,38 [0,16; 0,87] 0,0208[3]	-19,4 [-35,8; -3,0] 0,0208[3]
G2	85/349 (24,4)	103/323 (31,9)	0,76 [0,60; 0,97] 0,0305[2]	0,69 [0,49; 0,96] 0,0297[3]	-7,5 [-14,3; -0,7] 0,0297[3]
G3	68/317 (21,5)	96/312 (30,8)	0,70 [0,53; 0,91] 0,0084[2]	0,61 [0,43; 0,88] 0,0078[3]	-9,3 [-16,1; -2,5] 0,0078[3]
GX	5/44 (11,4)	6/40 (15,0)	0,76 [0,25; 2,29] 0,6230[2]	0,73 [0,20; 2,59] 0,6217[3]	-3,6 [-18,1; 10,9] 0,6217[3]
Progesterone receptor status (Interaction p-value: 0,2428)					
Negative	18/67 (26,9)	15/62 (24,2)	1,11 [0,61; 2,01] 0,7286[2]	1,15 [0,52; 2,55] 0,7282[3]	2,7 [-12,4; 17,7] 0,7282[3]
Positive	141/678 (20,8)	203/647 (31,4)	0,66 [0,55; 0,80] <,0001[2]	0,57 [0,45; 0,74] <,0001[3]	-10,6 [-15,3; -5,9] <,0001[3]
Unknown	2/8 (25,0)	2/8 (25,0)	1,00 [0,18; 5,46] 1,0000[2]	1,00 [0,10; 9,61] 1,0000[4]	0,0 [-42,4; 42,4] 1,0000[4]
Race (Interaction p-value: 0,3559)					
White	117/461 (25,4)	152/440 (34,5)	0,73 [0,60; 0,90] 0,0029[2]	0,64 [0,48; 0,86] 0,0027[3]	-9,2 [-15,1; -3,2] 0,0027[3]
Asian	41/273 (15,0)	62/243 (25,5)	0,59 [0,41; 0,84] 0,0034[2]	0,52 [0,33; 0,80] 0,0029[3]	-10,5 [-17,4; -3,6] 0,0029[3]
Other	9/30 (30,0)	10/34 (29,4)	1,02 [0,48; 2,17] 0,9590[2]	1,03 [0,35; 3,01] 0,9590[3]	0,6 [-21,8; 23,0] 0,9590[3]
First endocrine therapy (Interaction p-value: 0,6983)					
Tamoxifen	108/553 (19,5)	145/534 (27,2)	0,72 [0,58; 0,90] 0,0032[2]	0,65 [0,49; 0,86] 0,0029[3]	-7,6 [-12,6; -2,6] 0,0029[3]
Aromatase inhibitor	63/223 (28,3)	82/195 (42,1)	0,67 [0,51; 0,88] 0,0034[2]	0,54 [0,36; 0,82] 0,0031[3]	-13,8 [-22,9; -4,7] 0,0031[3]
ECOG-PS (Interaction p-value: 0,4130)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	151/685 (22,0)	197/649 (30,4)	0,73 [0,60; 0,87] 0,0006[2]	0,65 [0,51; 0,83] 0,0006[3]	-8,3 [-13,0; -3,6] 0,0006[3]
ECOG-PS 1	20/91 (22,0)	30/80 (37,5)	0,59 [0,36; 0,95] 0,0290[2]	0,47 [0,24; 0,92] 0,0260[3]	-15,5 [-29,1; -1,9] 0,0260[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 208.1.2: Subgroups - adverse events according PT Aspartate aminotransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,3444)					
Neoadjuvant chemotherapy	34/314 (10,8)	9/306 (2,9)	3,68 [1,80; 7,55] 0,0004[2]	4,01 [1,89; 8,51] 0,0001[3]	7,9 [4,0; 11,8] 0,0001[3]
Adjuvant chemotherapy	55/452 (12,2)	22/416 (5,3)	2,30 [1,43; 3,70] 0,0006[2]	2,48 [1,48; 4,15] 0,0004[3]	6,9 [3,2; 10,6] 0,0004[3]
No chemotherapy	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Region (Interaction p-value: 0,3837)					
North America / Europe	20/347 (5,8)	4/309 (1,3)	4,45 [1,54; 12,88] 0,0059[2]	4,66 [1,58; 13,80] 0,0023[3]	4,5 [1,7; 7,2] 0,0023[3]
Asia	50/239 (20,9)	17/226 (7,5)	2,78 [1,65; 4,68] 0,0001[2]	3,25 [1,81; 5,83] <,0001[3]	13,4 [7,2; 19,6] <,0001[3]
Other	20/190 (10,5)	11/194 (5,7)	1,86 [0,91; 3,77] 0,0868[2]	1,96 [0,91; 4,21] 0,0807[3]	4,9 [-0,6; 10,3] 0,0807[3]
Primary tumor size (Interaction p-value: 0,3502)					
< 20 mm	32/204 (15,7)	7/189 (3,7)	4,24 [1,92; 9,36] 0,0004[2]	4,84 [2,08; 11,25] <,0001[3]	12,0 [6,3; 17,7] <,0001[3]
≥ 20 but < 50 mm	37/360 (10,3)	16/346 (4,6)	2,22 [1,26; 3,92] 0,0058[2]	2,36 [1,29; 4,33] 0,0044[3]	5,7 [1,8; 9,5] 0,0044[3]
≥ 50 mm	17/194 (8,8)	8/185 (4,3)	2,03 [0,90; 4,58] 0,0897[2]	2,13 [0,89; 5,05] 0,0818[3]	4,4 [-0,5; 9,4] 0,0818[3]
Number of positive lymph nodes (Interaction p-value: 0,7950)					
0-3	28/269 (10,4)	9/269 (3,3)	3,11 [1,50; 6,47] 0,0024[2]	3,36 [1,55; 7,26] 0,0012[3]	7,1 [2,8; 11,3] 0,0012[3]
4-9	45/353 (12,7)	16/326 (4,9)	2,60 [1,50; 4,50] 0,0007[2]	2,83 [1,57; 5,12] 0,0004[3]	7,8 [3,6; 12,0] 0,0004[3]
≥ 10	17/154 (11,0)	7/134 (5,2)	2,11 [0,90; 4,94] 0,0842[2]	2,25 [0,90; 5,61] 0,0749[3]	5,8 [-0,4; 12,0] 0,0749[3]
Tumor stage (Interaction p-value: 0,8875)					
IIA	12/79 (15,2)	4/77 (5,2)	2,92 [0,99; 8,67] 0,0531[2]	3,27 [1,01; 10,63] 0,0397[3]	10,0 [0,7; 19,3] 0,0397[3]
IIB	7/73 (9,6)	4/93 (4,3)	2,23 [0,68; 7,33] 0,1865[2]	2,36 [0,66; 8,40] 0,2156[4]	5,3 [-2,6; 13,2] 0,2156[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	39/345 (11,3)	16/294 (5,4)	2,08 [1,19; 3,64] 0,0106[2]	2,21 [1,21; 4,05] 0,0085[3]	5,9 [1,6; 10,1] 0,0085[3]
IIIB	1/22 (4,5)	0/19 (0,0)	2,61 [0,11; 60,51] 0,5500[2]	2,72 [0,10; 70,79] 1,0000[4]	4,5 [-4,2; 13,2] 1,0000[4]
IIIC	28/253 (11,1)	8/245 (3,3)	3,39 [1,58; 7,29] 0,0018[2]	3,69 [1,65; 8,26] 0,0008[3]	7,8 [3,3; 12,3] 0,0008[3]
Tumor grade (Interaction p-value: 0,4162)					
G1	11/63 (17,5)	1/52 (1,9)	9,08 [1,21; 68,03] 0,0318[2]	10,79 [1,34; 86,64] 0,0067[3]	15,5 [5,4; 25,6] 0,0067[3]
G2	31/349 (8,9)	10/323 (3,1)	2,87 [1,43; 5,76] 0,0030[2]	3,05 [1,47; 6,33] 0,0017[3]	5,8 [2,3; 9,3] 0,0017[3]
G3	36/317 (11,4)	18/312 (5,8)	1,97 [1,14; 3,39] 0,0146[2]	2,09 [1,16; 3,77] 0,0124[3]	5,6 [1,2; 9,9] 0,0124[3]
GX	12/44 (27,3)	3/40 (7,5)	3,64 [1,11; 11,96] 0,0336[2]	4,63 [1,20; 17,85] 0,0181[3]	19,8 [4,3; 35,3] 0,0181[3]
Progesterone receptor status (Interaction p-value: 0,5494)					
Negative	12/67 (17,9)	2/62 (3,2)	5,55 [1,29; 23,83] 0,0211[2]	6,55 [1,40; 30,56] 0,0074[3]	14,7 [4,5; 24,9] 0,0074[3]
Positive	75/678 (11,1)	30/647 (4,6)	2,39 [1,58; 3,59] <,0001[2]	2,56 [1,65; 3,96] <,0001[3]	6,4 [3,6; 9,3] <,0001[3]
Unknown	2/8 (25,0)	0/8 (0,0)	5,00 [0,28; 90,18] 0,2754[2]	6,54 [0,27; 160,97] 0,4667[4]	25,0 [-5,0; 55,0] 0,4667[4]
Race (Interaction p-value: 0,6777)					
White	33/461 (7,2)	14/440 (3,2)	2,25 [1,22; 4,15] 0,0093[2]	2,35 [1,24; 4,45] 0,0073[3]	4,0 [1,1; 6,8] 0,0073[3]
Asian	52/273 (19,0)	17/243 (7,0)	2,72 [1,62; 4,58] 0,0002[2]	3,13 [1,75; 5,58] <,0001[3]	12,1 [6,4; 17,7] <,0001[3]
Other	5/30 (16,7)	1/34 (2,9)	5,67 [0,70; 45,82] 0,1038[2]	6,60 [0,72; 60,11] 0,0905[4]	13,7 [-0,8; 28,2] 0,0905[4]
First endocrine therapy (Interaction p-value: 0,0811)					
Tamoxifen	44/553 (8,0)	22/534 (4,1)	1,93 [1,17; 3,18] 0,0096[2]	2,01 [1,19; 3,41] 0,0081[3]	3,8 [1,0; 6,7] 0,0081[3]
Aromatase inhibitor	46/223 (20,6)	10/195 (5,1)	4,02 [2,09; 7,75] <,0001[2]	4,81 [2,35; 9,82] <,0001[3]	15,5 [9,4; 21,6] <,0001[3]
ECOG-PS (Interaction p-value: 0,3972)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	79/685 (11,5)	30/649 (4,6)	2,49 [1,66; 3,75] <,0001[2]	2,69 [1,74; 4,16] <,0001[3]	6,9 [4,0; 9,8] <,0001[3]
ECOG-PS 1	11/91 (12,1)	2/80 (2,5)	4,84 [1,10; 21,16] 0,0364[2]	5,36 [1,15; 24,98] 0,0183[3]	9,6 [2,1; 17,1] 0,0183[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 209.1.2: Subgroups - adverse events according PT Asthenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,3817)					
Neoadjuvant chemotherapy	29/314 (9,2)	17/306 (5,6)	1,66 [0,93; 2,96] 0,0846[2]	1,73 [0,93; 3,22] 0,0805[3]	3,7 [-0,4; 7,8] 0,0805[3]
Adjuvant chemotherapy	48/452 (10,6)	15/416 (3,6)	2,95 [1,68; 5,18] 0,0002[2]	3,18 [1,75; 5,76] <,0001[3]	7,0 [3,7; 10,4] <,0001[3]
No chemotherapy	0/10 (0,0)	1/7 (14,3)	0,24 [0,01; 5,21] 0,3654[2]	0,21 [0,01; 5,86] 0,4118[4]	-14,3 [-40,2; 11,6] 0,4118[4]
Region (Interaction p-value: 0,1029)					
North America / Europe	50/347 (14,4)	27/309 (8,7)	1,65 [1,06; 2,57] 0,0266[2]	1,76 [1,07; 2,89] 0,0243[3]	5,7 [0,8; 10,5] 0,0243[3]
Asia	2/239 (0,8)	1/226 (0,4)	1,89 [0,17; 20,71] 0,6018[2]	1,90 [0,17; 21,09] 1,0000[4]	0,4 [-1,0; 1,8] 1,0000[4]
Other	25/190 (13,2)	5/194 (2,6)	5,11 [2,00; 13,06] 0,0007[2]	5,73 [2,14; 15,30] 0,0001[3]	10,6 [5,3; 15,9] 0,0001[3]
Primary tumor size (Interaction p-value: 0,1398)					
< 20 mm	24/204 (11,8)	6/189 (3,2)	3,71 [1,55; 8,87] 0,0033[2]	4,07 [1,62; 10,18] 0,0014[3]	8,6 [3,5; 13,7] 0,0014[3]
≥ 20 but < 50 mm	40/360 (11,1)	16/346 (4,6)	2,40 [1,37; 4,21] 0,0022[2]	2,58 [1,42; 4,70] 0,0014[3]	6,5 [2,6; 10,4] 0,0014[3]
≥ 50 mm	12/194 (6,2)	10/185 (5,4)	1,14 [0,51; 2,58] 0,7457[2]	1,15 [0,49; 2,74] 0,7454[3]	0,8 [-3,9; 5,5] 0,7454[3]
Number of positive lymph nodes (Interaction p-value: 0,6436)					
0-3	30/269 (11,2)	13/269 (4,8)	2,31 [1,23; 4,33] 0,0091[2]	2,47 [1,26; 4,85] 0,0069[3]	6,3 [1,8; 10,9] 0,0069[3]
4-9	32/353 (9,1)	16/326 (4,9)	1,85 [1,03; 3,30] 0,0384[2]	1,93 [1,04; 3,59] 0,0347[3]	4,2 [0,4; 8,0] 0,0347[3]
≥ 10	15/154 (9,7)	4/134 (3,0)	3,26 [1,11; 9,59] 0,0316[2]	3,51 [1,13; 10,84] 0,0212[3]	6,8 [1,3; 12,3] 0,0212[3]
Tumor stage (Interaction p-value: 0,5461)					
IIA	9/79 (11,4)	4/77 (5,2)	2,19 [0,70; 6,82] 0,1752[2]	2,35 [0,69; 7,97] 0,1614[3]	6,2 [-2,4; 14,8] 0,1614[3]
IIB	8/73 (11,0)	3/93 (3,2)	3,40 [0,93; 12,35] 0,0634[2]	3,69 [0,94; 14,45] 0,0610[4]	7,7 [-0,3; 15,7] 0,0610[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	33/345 (9,6)	9/294 (3,1)	3,12 [1,52; 6,42] 0,0019[2]	3,35 [1,58; 7,12] 0,0009[3]	6,5 [2,8; 10,2] 0,0009[3]
IIIB	1/22 (4,5)	0/19 (0,0)	2,61 [0,11; 60,51] 0,5500[2]	2,72 [0,10; 70,79] 1,0000[4]	4,5 [-4,2; 13,2] 1,0000[4]
IIIC	26/253 (10,3)	17/245 (6,9)	1,48 [0,82; 2,66] 0,1886[2]	1,54 [0,81; 2,91] 0,1849[3]	3,3 [-1,6; 8,2] 0,1849[3]
Tumor grade (Interaction p-value: 0,5909)					
G1	8/63 (12,7)	2/52 (3,8)	3,30 [0,73; 14,88] 0,1199[2]	3,64 [0,74; 17,94] 0,1102[4]	8,9 [-0,9; 18,6] 0,1102[4]
G2	33/349 (9,5)	18/323 (5,6)	1,70 [0,98; 2,95] 0,0614[2]	1,77 [0,98; 3,21] 0,0576[3]	3,9 [-0,1; 7,8] 0,0576[3]
G3	33/317 (10,4)	11/312 (3,5)	2,95 [1,52; 5,74] 0,0014[2]	3,18 [1,58; 6,41] 0,0007[3]	6,9 [2,9; 10,8] 0,0007[3]
GX	3/44 (6,8)	1/40 (2,5)	2,73 [0,30; 25,17] 0,3762[2]	2,85 [0,28; 28,61] 0,6176[4]	4,3 [-4,6; 13,2] 0,6176[4]
Progesterone receptor status (Interaction p-value: 0,1469)					
Negative	7/67 (10,4)	2/62 (3,2)	3,24 [0,70; 15,00] 0,1330[2]	3,50 [0,70; 17,54] 0,1672[4]	7,2 [-1,3; 15,8] 0,1672[4]
Positive	68/678 (10,0)	31/647 (4,8)	2,09 [1,39; 3,16] 0,0004[2]	2,22 [1,43; 3,44] 0,0003[3]	5,2 [2,4; 8,0] 0,0003[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9312)					
White	67/461 (14,5)	29/440 (6,6)	2,21 [1,46; 3,34] 0,0002[2]	2,41 [1,53; 3,81] 0,0001[3]	7,9 [4,0; 11,9] 0,0001[3]
Asian	5/273 (1,8)	2/243 (0,8)	2,23 [0,44; 11,37] 0,3364[2]	2,25 [0,43; 11,69] 0,4555[4]	1,0 [-0,9; 3,0] 0,4555[4]
Other	3/30 (10,0)	1/34 (2,9)	3,40 [0,37; 30,97] 0,2776[2]	3,67 [0,36; 37,30] 0,3334[4]	7,1 [-5,1; 19,2] 0,3334[4]
First endocrine therapy (Interaction p-value: 0,1800)					
Tamoxifen	59/553 (10,7)	22/534 (4,1)	2,59 [1,61; 4,16] <,0001[2]	2,78 [1,68; 4,61] <,0001[3]	6,5 [3,5; 9,6] <,0001[3]
Aromatase inhibitor	18/223 (8,1)	11/195 (5,6)	1,43 [0,69; 2,95] 0,3328[2]	1,47 [0,68; 3,19] 0,3292[3]	2,4 [-2,4; 7,3] 0,3292[3]
ECOG-PS (Interaction p-value: 0,9403)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	65/685 (9,5)	28/649 (4,3)	2,20 [1,43; 3,38] 0,0003[2]	2,33 [1,47; 3,67] 0,0002[3]	5,2 [2,5; 7,9] 0,0002[3]
ECOG-PS 1	12/91 (13,2)	5/80 (6,3)	2,11 [0,78; 5,73] 0,1430[2]	2,28 [0,77; 6,78] 0,1304[3]	6,9 [-1,8; 15,7] 0,1304[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 210.1.2: Subgroups - adverse events according PT Blood creatinine increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9738)					
Neoadjuvant chemotherapy	31/314 (9,9)	0/306 (0,0)	61,40 [3,77; 998,95] 0,0038[2]	68,11 [4,15; 1118,25] <,0001[3]	9,9 [6,6; 13,2] <,0001[3]
Adjuvant chemotherapy	39/452 (8,6)	3/416 (0,7)	11,96 [3,73; 38,42] <,0001[2]	13,00 [3,99; 42,40] <,0001[3]	7,9 [5,2; 10,6] <,0001[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,8537)					
North America / Europe	31/347 (8,9)	1/309 (0,3)	27,61 [3,79; 201,02] 0,0011[2]	30,22 [4,10; 222,70] <,0001[3]	8,6 [5,5; 11,7] <,0001[3]
Asia	29/239 (12,1)	2/226 (0,9)	13,71 [3,31; 56,80] 0,0003[2]	15,47 [3,65; 65,62] <,0001[3]	11,2 [6,9; 15,6] <,0001[3]
Other	11/190 (5,8)	0/194 (0,0)	23,48 [1,39; 395,68] 0,0285[2]	24,92 [1,46; 426,00] 0,0007[3]	5,8 [2,5; 9,1] 0,0007[3]
Primary tumor size (Interaction p-value: 0,9996)					
< 20 mm	25/204 (12,3)	0/189 (0,0)	47,27 [2,90; 771,03] 0,0068[2]	53,84 [3,25; 890,98] <,0001[3]	12,3 [7,8; 16,8] <,0001[3]
≥ 20 but < 50 mm	27/360 (7,5)	3/346 (0,9)	8,65 [2,65; 28,25] 0,0004[2]	9,27 [2,79; 30,85] <,0001[3]	6,6 [3,7; 9,5] <,0001[3]
≥ 50 mm	17/194 (8,8)	0/185 (0,0)	33,38 [2,02; 551,17] 0,0142[2]	36,58 [2,18; 612,83] <,0001[3]	8,8 [4,8; 12,7] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,9996)					
0-3	31/269 (11,5)	0/269 (0,0)	63,00 [3,87; 1024,29] 0,0036[2]	71,19 [4,33; 1169,68] <,0001[3]	11,5 [7,7; 15,3] <,0001[3]
4-9	32/353 (9,1)	3/326 (0,9)	9,85 [3,05; 31,86] 0,0001[2]	10,73 [3,25; 35,40] <,0001[3]	8,1 [5,0; 11,3] <,0001[3]
≥ 10	8/154 (5,2)	0/134 (0,0)	14,81 [0,86; 254,14] 0,0632[2]	15,61 [0,89; 273,01] 0,0081[4]	5,2 [1,7; 8,7] 0,0081[4]
Tumor stage (Interaction p-value: 0,9999)					
IIA	9/79 (11,4)	0/77 (0,0)	18,53 [1,10; 312,87] 0,0430[2]	20,89 [1,19; 365,46] 0,0031[4]	11,4 [4,4; 18,4] 0,0031[4]
IIB	7/73 (9,6)	0/93 (0,0)	19,05 [1,11; 328,24] 0,0424[2]	21,09 [1,18; 375,68] 0,0027[4]	9,6 [2,8; 16,3] 0,0027[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	33/345 (9,6)	2/294 (0,7)	14,06 [3,40; 58,10] 0,0003[2]	15,44 [3,67; 64,93] <,0001[3]	8,9 [5,6; 12,1] <,0001[3]
IIIB	3/22 (13,6)	0/19 (0,0)	6,09 [0,33; 110,84] 0,2225[2]	7,00 [0,34; 144,73] 0,2354[4]	13,6 [-0,7; 28,0] 0,2354[4]
IIIC	18/253 (7,1)	1/245 (0,4)	17,43 [2,34; 129,57] 0,0052[2]	18,69 [2,48; 141,12] <,0001[3]	6,7 [3,4; 10,0] <,0001[3]
Tumor grade (Interaction p-value: 0,9628)					
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	31/349 (8,9)	1/323 (0,3)	28,69 [3,94; 208,96] 0,0009[2]	31,39 [4,26; 231,33] <,0001[3]	8,6 [5,5; 11,6] <,0001[3]
G3	30/317 (9,5)	2/312 (0,6)	14,76 [3,56; 61,25] 0,0002[2]	16,20 [3,84; 68,41] <,0001[3]	8,8 [5,5; 12,2] <,0001[3]
GX	8/44 (18,2)	0/40 (0,0)	15,49 [0,92; 260,01] 0,0569[2]	18,86 [1,05; 338,40] 0,0058[4]	18,2 [6,8; 29,6] 0,0058[4]
Progesterone receptor status (Interaction p-value: 0,9981)					
Negative	4/67 (6,0)	0/62 (0,0)	8,34 [0,46; 151,78] 0,1520[2]	8,86 [0,47; 167,99] 0,1203[4]	6,0 [0,3; 11,6] 0,1203[4]
Positive	61/678 (9,0)	3/647 (0,5)	19,40 [6,12; 61,53] <,0001[2]	21,22 [6,62; 67,99] <,0001[3]	8,5 [6,3; 10,7] <,0001[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,6836)					
White	40/461 (8,7)	1/440 (0,2)	38,18 [5,27; 276,51] 0,0003[2]	41,71 [5,71; 304,77] <,0001[3]	8,4 [5,8; 11,1] <,0001[3]
Asian	29/273 (10,6)	2/243 (0,8)	12,91 [3,11; 53,53] 0,0004[2]	14,32 [3,38; 60,68] <,0001[3]	9,8 [6,0; 13,6] <,0001[3]
Other	2/30 (6,7)	0/34 (0,0)	5,65 [0,28; 113,12] 0,2578[2]	6,05 [0,28; 131,25] 0,2158[4]	6,7 [-2,3; 15,6] 0,2158[4]
First endocrine therapy (Interaction p-value: 0,7839)					
Tamoxifen	51/553 (9,2)	2/534 (0,4)	24,62 [6,02; 100,64] <,0001[2]	27,02 [6,54; 111,59] <,0001[3]	8,8 [6,4; 11,3] <,0001[3]
Aromatase inhibitor	20/223 (9,0)	1/195 (0,5)	17,49 [2,37; 129,12] 0,0050[2]	19,11 [2,54; 143,79] <,0001[3]	8,5 [4,6; 12,3] <,0001[3]
ECOG-PS (Interaction p-value: 0,9764)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	61/685 (8,9)	3/649 (0,5)	19,26 [6,07; 61,09] <,0001[2]	21,05 [6,57; 67,44] <,0001[3]	8,4 [6,2; 10,6] <,0001[3]
ECOG-PS 1	10/91 (11,0)	0/80 (0,0)	18,49 [1,10; 310,59] 0,0427[2]	20,74 [1,20; 359,92] 0,0018[4]	11,0 [4,6; 17,4] 0,0018[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 211.1.2: Subgroups - adverse events according PT Cellulitis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8833)					
Neoadjuvant chemotherapy	12/314 (3,8)	3/306 (1,0)	3,90 [1,11; 13,68] 0,0337[2]	4,01 [1,12; 14,36] 0,0213[3]	2,8 [0,5; 5,2] 0,0213[3]
Adjuvant chemotherapy	8/452 (1,8)	3/416 (0,7)	2,45 [0,66; 9,19] 0,1826[2]	2,48 [0,65; 9,41] 0,1676[3]	1,0 [-0,4; 2,5] 0,1676[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,9845)					
North America / Europe	10/347 (2,9)	3/309 (1,0)	2,97 [0,82; 10,69] 0,0960[2]	3,03 [0,83; 11,10] 0,0796[3]	1,9 [-0,2; 4,0] 0,0796[3]
Asia	8/239 (3,3)	3/226 (1,3)	2,52 [0,68; 9,39] 0,1678[2]	2,57 [0,67; 9,83] 0,1520[3]	2,0 [-0,7; 4,7] 0,1520[3]
Other	3/190 (1,6)	0/194 (0,0)	7,15 [0,37; 137,43] 0,1923[2]	7,26 [0,37; 141,53] 0,1202[4]	1,6 [-0,2; 3,4] 0,1202[4]
Primary tumor size (Interaction p-value: 0,2022)					
< 20 mm	3/204 (1,5)	3/189 (1,6)	0,93 [0,19; 4,53] 0,9249[2]	0,93 [0,18; 4,64] 1,0000[4]	-0,1 [-2,5; 2,3] 1,0000[4]
≥ 20 but < 50 mm	12/360 (3,3)	2/346 (0,6)	5,77 [1,30; 25,58] 0,0212[2]	5,93 [1,32; 26,70] 0,0087[3]	2,8 [0,7; 4,8] 0,0087[3]
≥ 50 mm	6/194 (3,1)	1/185 (0,5)	5,72 [0,70; 47,07] 0,1048[2]	5,87 [0,70; 49,25] 0,1223[4]	2,6 [-0,1; 5,2] 0,1223[4]
Number of positive lymph nodes (Interaction p-value: 0,2327)					
0-3	8/269 (3,0)	3/269 (1,1)	2,67 [0,72; 9,94] 0,1441[2]	2,72 [0,71; 10,36] 0,1277[3]	1,9 [-0,5; 4,2] 0,1277[3]
4-9	11/353 (3,1)	1/326 (0,3)	10,16 [1,32; 78,25] 0,0260[2]	10,45 [1,34; 81,42] 0,0055[3]	2,8 [0,9; 4,7] 0,0055[3]
≥ 10	2/154 (1,3)	2/134 (1,5)	0,87 [0,12; 6,09] 0,8886[2]	0,87 [0,12; 6,25] 1,0000[4]	-0,2 [-2,9; 2,5] 1,0000[4]
Tumor stage (Interaction p-value: 0,6794)					
IIA	2/79 (2,5)	2/77 (2,6)	0,97 [0,14; 6,75] 0,9793[2]	0,97 [0,13; 7,09] 1,0000[4]	-0,1 [-5,0; 4,9] 1,0000[4]
IIB	1/73 (1,4)	0/93 (0,0)	3,81 [0,16; 92,20] 0,4105[2]	3,87 [0,16; 96,38] 0,4398[4]	1,4 [-1,3; 4,0] 0,4398[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	10/345 (2,9)	1/294 (0,3)	8,52 [1,10; 66,18] 0,0405[2]	8,75 [1,11; 68,73] 0,0132[3]	2,6 [0,7; 4,4] 0,0132[3]
IIIB	1/22 (4,5)	0/19 (0,0)	2,61 [0,11; 60,51] 0,5500[2]	2,72 [0,10; 70,79] 1,0000[4]	4,5 [-4,2; 13,2] 1,0000[4]
IIIC	7/253 (2,8)	3/245 (1,2)	2,26 [0,59; 8,64] 0,2335[2]	2,30 [0,59; 8,98] 0,3394[4]	1,5 [-0,9; 4,0] 0,3394[4]
Tumor grade (Interaction p-value: 0,6917)					
G1	0/63 (0,0)	1/52 (1,9)	0,28 [0,01; 6,64] 0,4275[2]	0,27 [0,01; 6,78] 0,4522[4]	-1,9 [-5,7; 1,8] 0,4522[4]
G2	10/349 (2,9)	4/323 (1,2)	2,31 [0,73; 7,30] 0,1527[2]	2,35 [0,73; 7,58] 0,1401[3]	1,6 [-0,5; 3,8] 0,1401[3]
G3	10/317 (3,2)	1/312 (0,3)	9,84 [1,27; 76,43] 0,0288[2]	10,13 [1,29; 79,61] 0,0067[3]	2,8 [0,8; 4,9] 0,0067[3]
GX	1/44 (2,3)	0/40 (0,0)	2,73 [0,11; 65,24] 0,5345[2]	2,79 [0,11; 70,54] 1,0000[4]	2,3 [-2,1; 6,7] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,9598)					
Negative	2/67 (3,0)	0/62 (0,0)	4,63 [0,23; 94,63] 0,3193[2]	4,77 [0,22; 101,36] 0,4969[4]	3,0 [-1,1; 7,1] 0,4969[4]
Positive	18/678 (2,7)	6/647 (0,9)	2,86 [1,14; 7,17] 0,0247[2]	2,91 [1,15; 7,39] 0,0184[3]	1,7 [0,3; 3,1] 0,0184[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,8353)					
White	13/461 (2,8)	3/440 (0,7)	4,14 [1,19; 14,42] 0,0258[2]	4,23 [1,20; 14,94] 0,0151[3]	2,1 [0,4; 3,8] 0,0151[3]
Asian	8/273 (2,9)	3/243 (1,2)	2,37 [0,64; 8,85] 0,1978[2]	2,42 [0,63; 9,21] 0,1831[3]	1,7 [-0,7; 4,1] 0,1831[3]
Other	0/30 (0,0)	0/34 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,6183)					
Tamoxifen	15/553 (2,7)	5/534 (0,9)	2,90 [1,06; 7,92] 0,0381[2]	2,95 [1,06; 8,17] 0,0294[3]	1,8 [0,2; 3,4] 0,0294[3]
Aromatase inhibitor	6/223 (2,7)	1/195 (0,5)	5,25 [0,64; 43,20] 0,1233[2]	5,36 [0,64; 44,95] 0,1278[4]	2,2 [-0,2; 4,5] 0,1278[4]
ECOG-PS (Interaction p-value: 0,8370)					
ECOG-PS 0	18/685 (2,6)	5/649 (0,8)	3,41 [1,27; 9,13] 0,0146[2]	3,48 [1,28; 9,42] 0,0092[3]	1,9 [0,5; 3,2] 0,0092[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	3/91 (3,3)	1/80 (1,3)	2,64 [0,28; 24,85] 0,3968[2]	2,69 [0,27; 26,42] 0,6237[4]	2,0 [-2,4; 6,4] 0,6237[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 212.1.2: Subgroups - adverse events according PT Chills from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1799)					
Neoadjuvant chemotherapy	10/314 (3,2)	1/306 (0,3)	9,75 [1,26; 75,67] 0,0295[2]	10,03 [1,28; 78,86] 0,0070[3]	2,9 [0,8; 4,9] 0,0070[3]
Adjuvant chemotherapy	8/452 (1,8)	1/416 (0,2)	7,36 [0,92; 58,62] 0,0593[2]	7,48 [0,93; 60,04] 0,0395[4]	1,5 [0,2; 2,8] 0,0395[4]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,7627)					
North America / Europe	13/347 (3,7)	1/309 (0,3)	11,58 [1,52; 87,98] 0,0180[2]	11,99 [1,56; 92,18] 0,0025[3]	3,4 [1,3; 5,5] 0,0025[3]
Asia	4/239 (1,7)	1/226 (0,4)	3,78 [0,43; 33,59] 0,2325[2]	3,83 [0,42; 34,53] 0,3733[4]	1,2 [-0,6; 3,1] 0,3733[4]
Other	1/190 (0,5)	0/194 (0,0)	3,06 [0,13; 74,72] 0,4922[2]	3,08 [0,12; 76,06] 0,4948[4]	0,5 [-0,5; 1,6] 0,4948[4]
Number of positive lymph nodes (Interaction p-value: 0,9995)					
0-3	10/269 (3,7)	0/269 (0,0)	21,00 [1,24; 356,57] 0,0351[2]	21,81 [1,27; 374,09] 0,0014[3]	3,7 [1,5; 6,0] 0,0014[3]
4-9	5/353 (1,4)	2/326 (0,6)	2,31 [0,45; 11,82] 0,3152[2]	2,33 [0,45; 12,08] 0,4533[4]	0,8 [-0,7; 2,3] 0,4533[4]
≥ 10	3/154 (1,9)	0/134 (0,0)	6,10 [0,32; 116,97] 0,2304[2]	6,21 [0,32; 121,41] 0,2510[4]	1,9 [-0,2; 4,1] 0,2510[4]
Tumor stage (Interaction p-value: 1,0000)					
IIA	4/79 (5,1)	0/77 (0,0)	8,78 [0,48; 160,29] 0,1428[2]	9,24 [0,49; 174,56] 0,1203[4]	5,1 [0,2; 9,9] 0,1203[4]
IIB	1/73 (1,4)	0/93 (0,0)	3,81 [0,16; 92,20] 0,4105[2]	3,87 [0,16; 96,38] 0,4398[4]	1,4 [-1,3; 4,0] 0,4398[4]
IIIA	8/345 (2,3)	2/294 (0,7)	3,41 [0,73; 15,93] 0,1190[2]	3,47 [0,73; 16,45] 0,1178[4]	1,6 [-0,2; 3,5] 0,1178[4]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	3/253 (1,2)	0/245 (0,0)	6,78 [0,35; 130,57] 0,2047[2]	6,86 [0,35; 133,51] 0,2487[4]	1,2 [-0,1; 2,5] 0,2487[4]
Progesterone receptor status (Interaction p-value: 0,9996)					
Negative	0/67 (0,0)	0/62 (0,0)	NE	NE	NE

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Positive	17/678 (2,5)	2/647 (0,3)	8,11 [1,88; 34,97] 0,0050[2]	8,29 [1,91; 36,04] 0,0008[3]	2,2 [0,9; 3,5] 0,0008[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,7777)					
White	11/461 (2,4)	1/440 (0,2)	10,50 [1,36; 80,98] 0,0241[2]	10,73 [1,38; 83,47] 0,0047[3]	2,2 [0,7; 3,6] 0,0047[3]
Asian	4/273 (1,5)	1/243 (0,4)	3,56 [0,40; 31,64] 0,2545[2]	3,60 [0,40; 32,42] 0,3768[4]	1,1 [-0,6; 2,7] 0,3768[4]
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
First endocrine therapy (Interaction p-value: 0,9772)					
Tamoxifen	14/553 (2,5)	2/534 (0,4)	6,76 [1,54; 29,60] 0,0112[2]	6,91 [1,56; 30,55] 0,0032[3]	2,2 [0,7; 3,6] 0,0032[3]
Aromatase inhibitor	4/223 (1,8)	0/195 (0,0)	7,88 [0,43; 145,35] 0,1653[2]	8,02 [0,43; 149,83] 0,1266[4]	1,8 [0,1; 3,5] 0,1266[4]
ECOG-PS (Interaction p-value: 0,9779)					
ECOG-PS 0	16/685 (2,3)	2/649 (0,3)	7,58 [1,75; 32,84] 0,0068[2]	7,74 [1,77; 33,78] 0,0013[3]	2,0 [0,8; 3,2] 0,0013[3]
ECOG-PS 1	2/91 (2,2)	0/80 (0,0)	4,40 [0,21; 90,35] 0,3364[2]	4,50 [0,21; 95,08] 0,4991[4]	2,2 [-0,8; 5,2] 0,4991[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 213.1.2: Subgroups - adverse events according PT Conjunctivitis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1756)					
Neoadjuvant chemotherapy	6/314 (1,9)	3/306 (1,0)	1,95 [0,49; 7,72] 0,3422[2]	1,97 [0,49; 7,94] 0,5049[4]	0,9 [-0,9; 2,8] 0,5049[4]
Adjuvant chemotherapy	9/452 (2,0)	2/416 (0,5)	4,14 [0,90; 19,06] 0,0680[2]	4,21 [0,90; 19,58] 0,0469[3]	1,5 [0,1; 3,0] 0,0469[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,8656)					
North America / Europe	5/347 (1,4)	2/309 (0,6)	2,23 [0,44; 11,39] 0,3367[2]	2,24 [0,43; 11,65] 0,4562[4]	0,8 [-0,7; 2,3] 0,4562[4]
Asia	8/239 (3,3)	2/226 (0,9)	3,78 [0,81; 17,62] 0,0902[2]	3,88 [0,81; 18,46] 0,1070[4]	2,5 [-0,1; 5,0] 0,1070[4]
Other	2/190 (1,1)	1/194 (0,5)	2,04 [0,19; 22,33] 0,5585[2]	2,05 [0,18; 22,83] 0,6201[4]	0,5 [-1,2; 2,3] 0,6201[4]
Tumor grade (Interaction p-value: 0,9506)					
G1	0/63 (0,0)	0/52 (0,0)	NE	NE	NE
G2	5/349 (1,4)	1/323 (0,3)	4,63 [0,54; 39,40] 0,1609[2]	4,68 [0,54; 40,28] 0,2188[4]	1,1 [-0,3; 2,5] 0,2188[4]
G3	8/317 (2,5)	3/312 (1,0)	2,62 [0,70; 9,80] 0,1512[2]	2,67 [0,70; 10,15] 0,1351[3]	1,6 [-0,5; 3,6] 0,1351[3]
GX	2/44 (4,5)	1/40 (2,5)	1,82 [0,17; 19,29] 0,6198[2]	1,86 [0,16; 21,30] 1,0000[4]	2,0 [-5,8; 9,9] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,9607)					
Negative	2/67 (3,0)	0/62 (0,0)	4,63 [0,23; 94,63] 0,3193[2]	4,77 [0,22; 101,36] 0,4969[4]	3,0 [-1,1; 7,1] 0,4969[4]
Positive	13/678 (1,9)	5/647 (0,8)	2,48 [0,89; 6,92] 0,0825[2]	2,51 [0,89; 7,08] 0,0720[3]	1,1 [-0,1; 2,4] 0,0720[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,8394)					
White	6/461 (1,3)	3/440 (0,7)	1,91 [0,48; 7,59] 0,3584[2]	1,92 [0,48; 7,73] 0,5067[4]	0,6 [-0,7; 1,9] 0,5067[4]
Asian	8/273 (2,9)	2/243 (0,8)	3,56 [0,76; 16,60] 0,1060[2]	3,64 [0,76; 17,30] 0,1119[4]	2,1 [-0,2; 4,4] 0,1119[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
First endocrine therapy (Interaction p-value: 0,9742)					
Tamoxifen	10/553 (1,8)	5/534 (0,9)	1,93 [0,66; 5,61] 0,2266[2]	1,95 [0,66; 5,74] 0,2179[3]	0,9 [-0,5; 2,3] 0,2179[3]
Aromatase inhibitor	5/223 (2,2)	0/195 (0,0)	9,63 [0,54; 172,96] 0,1245[2]	9,84 [0,54; 179,14] 0,0638[4]	2,2 [0,3; 4,2] 0,0638[4]
ECOG-PS (Interaction p-value: 0,9771)					
ECOG-PS 0	14/685 (2,0)	5/649 (0,8)	2,65 [0,96; 7,32] 0,0597[2]	2,69 [0,96; 7,50] 0,0498[3]	1,3 [0,0; 2,5] 0,0498[3]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 214.1.2: Subgroups - adverse events according PT Constipation from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9611)					
Neoadjuvant chemotherapy	44/314 (14,0)	20/306 (6,5)	2,14 [1,29; 3,55] 0,0031[2]	2,33 [1,34; 4,06] 0,0022[3]	7,5 [2,7; 12,2] 0,0022[3]
Adjuvant chemotherapy	55/452 (12,2)	26/416 (6,3)	1,95 [1,25; 3,04] 0,0035[2]	2,08 [1,28; 3,38] 0,0027[3]	5,9 [2,1; 9,7] 0,0027[3]
No chemotherapy	0/10 (0,0)	1/7 (14,3)	0,24 [0,01; 5,21] 0,3654[2]	0,21 [0,01; 5,86] 0,4118[4]	-14,3 [-40,2; 11,6] 0,4118[4]
Primary tumor size (Interaction p-value: 0,2117)					
< 20 mm	22/204 (10,8)	12/189 (6,3)	1,70 [0,86; 3,34] 0,1240[2]	1,78 [0,86; 3,71] 0,1181[3]	4,4 [-1,1; 9,9] 0,1181[3]
≥ 20 but < 50 mm	45/360 (12,5)	26/346 (7,5)	1,66 [1,05; 2,63] 0,0300[2]	1,76 [1,06; 2,92] 0,0277[3]	5,0 [0,6; 9,4] 0,0277[3]
≥ 50 mm	30/194 (15,5)	8/185 (4,3)	3,58 [1,68; 7,60] 0,0009[2]	4,05 [1,80; 9,08] 0,0003[3]	11,1 [5,3; 17,0] 0,0003[3]
Number of positive lymph nodes (Interaction p-value: 0,9100)					
0-3	39/269 (14,5)	21/269 (7,8)	1,86 [1,12; 3,07] 0,0158[2]	2,00 [1,14; 3,51] 0,0137[3]	6,7 [1,4; 12,0] 0,0137[3]
4-9	44/353 (12,5)	20/326 (6,1)	2,03 [1,22; 3,37] 0,0061[2]	2,18 [1,25; 3,78] 0,0048[3]	6,3 [2,0; 10,6] 0,0048[3]
≥ 10	16/154 (10,4)	6/134 (4,5)	2,32 [0,93; 5,76] 0,0696[2]	2,47 [0,94; 6,52] 0,0596[3]	5,9 [-0,0; 11,9] 0,0596[3]
Tumor stage (Interaction p-value: 0,9430)					
IIA	8/79 (10,1)	4/77 (5,2)	1,95 [0,61; 6,21] 0,2588[2]	2,06 [0,59; 7,13] 0,2478[3]	4,9 [-3,4; 13,2] 0,2478[3]
IIB	11/73 (15,1)	10/93 (10,8)	1,40 [0,63; 3,12] 0,4082[2]	1,47 [0,59; 3,69] 0,4064[3]	4,3 [-6,0; 14,7] 0,4064[3]
IIIA	43/345 (12,5)	18/294 (6,1)	2,04 [1,20; 3,45] 0,0083[2]	2,18 [1,23; 3,88] 0,0066[3]	6,3 [1,9; 10,8] 0,0066[3]
IIIB	3/22 (13,6)	0/19 (0,0)	6,09 [0,33; 110,84] 0,2225[2]	7,00 [0,34; 144,73] 0,2354[4]	13,6 [-0,7; 28,0] 0,2354[4]
IIIC	33/253 (13,0)	15/245 (6,1)	2,13 [1,19; 3,82] 0,0112[2]	2,30 [1,22; 4,35] 0,0089[3]	6,9 [1,8; 12,0] 0,0089[3]
Tumor grade (Interaction p-value: 0,1906)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	9/63 (14,3)	1/52 (1,9)	7,43 [0,97; 56,74] 0,0532[2]	8,50 [1,04; 69,49] 0,0215[4]	12,4 [3,0; 21,8] 0,0215[4]
G2	47/349 (13,5)	16/323 (5,0)	2,72 [1,57; 4,70] 0,0003[2]	2,99 [1,66; 5,38] 0,0002[3]	8,5 [4,2; 12,8] 0,0002[3]
G3	40/317 (12,6)	27/312 (8,7)	1,46 [0,92; 2,32] 0,1100[2]	1,52 [0,91; 2,55] 0,1071[3]	4,0 [-0,8; 8,8] 0,1071[3]
GX	3/44 (6,8)	2/40 (5,0)	1,36 [0,24; 7,75] 0,7264[2]	1,39 [0,22; 8,78] 1,0000[4]	1,8 [-8,2; 11,9] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,1125)					
Tamoxifen	79/553 (14,3)	43/534 (8,1)	1,77 [1,25; 2,52] 0,0014[2]	1,90 [1,29; 2,82] 0,0011[3]	6,2 [2,5; 10,0] 0,0011[3]
Aromatase inhibitor	20/223 (9,0)	4/195 (2,1)	4,37 [1,52; 12,57] 0,0062[2]	4,70 [1,58; 14,01] 0,0024[3]	6,9 [2,7; 11,2] 0,0024[3]
ECOG-PS (Interaction p-value: 0,8935)					
ECOG-PS 0	87/685 (12,7)	42/649 (6,5)	1,96 [1,38; 2,79] 0,0002[2]	2,10 [1,43; 3,09] 0,0001[3]	6,2 [3,1; 9,4] 0,0001[3]
ECOG-PS 1	12/91 (13,2)	5/80 (6,3)	2,11 [0,78; 5,73] 0,1430[2]	2,28 [0,77; 6,78] 0,1304[3]	6,9 [-1,8; 15,7] 0,1304[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 215.1.2: Subgroups - adverse events according PT Cough from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9313)					
Neoadjuvant chemotherapy	42/314 (13,4)	19/306 (6,2)	2,15 [1,28; 3,62] 0,0037[2]	2,33 [1,32; 4,11] 0,0027[3]	7,2 [2,5; 11,8] 0,0027[3]
Adjuvant chemotherapy	47/452 (10,4)	23/416 (5,5)	1,88 [1,16; 3,04] 0,0100[2]	1,98 [1,18; 3,33] 0,0085[3]	4,9 [1,3; 8,4] 0,0085[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,5611)					
North America / Europe	45/347 (13,0)	24/309 (7,8)	1,67 [1,04; 2,67] 0,0329[2]	1,77 [1,05; 2,98] 0,0302[3]	5,2 [0,6; 9,8] 0,0302[3]
Asia	30/239 (12,6)	11/226 (4,9)	2,58 [1,32; 5,02] 0,0053[2]	2,81 [1,37; 5,74] 0,0035[3]	7,7 [2,6; 12,7] 0,0035[3]
Other	15/190 (7,9)	7/194 (3,6)	2,19 [0,91; 5,25] 0,0793[2]	2,29 [0,91; 5,75] 0,0707[3]	4,3 [-0,4; 8,9] 0,0707[3]
Primary tumor size (Interaction p-value: 0,9392)					
< 20 mm	21/204 (10,3)	11/189 (5,8)	1,77 [0,88; 3,57] 0,1114[2]	1,86 [0,87; 3,96] 0,1052[3]	4,5 [-0,9; 9,8] 0,1052[3]
≥ 20 but < 50 mm	43/360 (11,9)	20/346 (5,8)	2,07 [1,24; 3,44] 0,0052[2]	2,21 [1,27; 3,84] 0,0041[3]	6,2 [2,0; 10,3] 0,0041[3]
≥ 50 mm	23/194 (11,9)	11/185 (5,9)	1,99 [1,00; 3,97] 0,0499[2]	2,13 [1,01; 4,50] 0,0442[3]	5,9 [0,2; 11,6] 0,0442[3]
Number of positive lymph nodes (Interaction p-value: 0,3563)					
0-3	37/269 (13,8)	16/269 (5,9)	2,31 [1,32; 4,05] 0,0034[2]	2,52 [1,37; 4,65] 0,0024[3]	7,8 [2,8; 12,8] 0,0024[3]
4-9	35/353 (9,9)	21/326 (6,4)	1,54 [0,92; 2,59] 0,1038[2]	1,60 [0,91; 2,81] 0,1002[3]	3,5 [-0,6; 7,6] 0,1002[3]
≥ 10	18/154 (11,7)	5/134 (3,7)	3,13 [1,20; 8,21] 0,0202[2]	3,41 [1,23; 9,47] 0,0130[3]	8,0 [2,0; 14,0] 0,0130[3]
Tumor stage (Interaction p-value: 0,2677)					
IIA	7/79 (8,9)	4/77 (5,2)	1,71 [0,52; 5,59] 0,3782[2]	1,77 [0,50; 6,32] 0,3712[3]	3,7 [-4,3; 11,7] 0,3712[3]
IIB	6/73 (8,2)	9/93 (9,7)	0,85 [0,32; 2,28] 0,7456[2]	0,84 [0,28; 2,47] 0,7450[3]	-1,5 [-10,2; 7,2] 0,7450[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	42/345 (12,2)	19/294 (6,5)	1,88 [1,12; 3,17] 0,0168[2]	2,01 [1,14; 3,53] 0,0143[3]	5,7 [1,3; 10,2] 0,0143[3]
IIIB	4/22 (18,2)	1/19 (5,3)	3,45 [0,42; 28,31] 0,2481[2]	4,00 [0,41; 39,37] 0,3499[4]	12,9 [-6,1; 31,9] 0,3499[4]
IIIC	31/253 (12,3)	9/245 (3,7)	3,34 [1,62; 6,86] 0,0011[2]	3,66 [1,70; 7,86] 0,0004[3]	8,6 [3,9; 13,3] 0,0004[3]
Tumor grade (Interaction p-value: 0,8244)					
G1	7/63 (11,1)	4/52 (7,7)	1,44 [0,45; 4,66] 0,5387[2]	1,50 [0,41; 5,44] 0,7518[4]	3,4 [-7,2; 14,0] 0,7518[4]
G2	36/349 (10,3)	16/323 (5,0)	2,08 [1,18; 3,68] 0,0115[2]	2,21 [1,20; 4,06] 0,0094[3]	5,4 [1,4; 9,3] 0,0094[3]
G3	42/317 (13,2)	21/312 (6,7)	1,97 [1,19; 3,25] 0,0079[2]	2,12 [1,22; 3,67] 0,0065[3]	6,5 [1,9; 11,2] 0,0065[3]
GX	5/44 (11,4)	1/40 (2,5)	4,55 [0,55; 37,26] 0,1584[2]	5,00 [0,56; 44,78] 0,2049[4]	8,9 [-1,7; 19,4] 0,2049[4]
Race (Interaction p-value: 0,3753)					
White	50/461 (10,8)	29/440 (6,6)	1,65 [1,06; 2,55] 0,0260[2]	1,72 [1,07; 2,78] 0,0240[3]	4,3 [0,6; 7,9] 0,0240[3]
Asian	35/273 (12,8)	12/243 (4,9)	2,60 [1,38; 4,89] 0,0031[2]	2,83 [1,43; 5,59] 0,0019[3]	7,9 [3,1; 12,7] 0,0019[3]
Other	4/30 (13,3)	1/34 (2,9)	4,53 [0,54; 38,36] 0,1654[2]	5,08 [0,53; 48,21] 0,1774[4]	10,4 [-3,0; 23,8] 0,1774[4]
First endocrine therapy (Interaction p-value: 0,2821)					
Tamoxifen	66/553 (11,9)	28/534 (5,2)	2,28 [1,49; 3,48] 0,0002[2]	2,45 [1,55; 3,88] <,0001[3]	6,7 [3,4; 10,0] <,0001[3]
Aromatase inhibitor	24/223 (10,8)	14/195 (7,2)	1,50 [0,80; 2,82] 0,2082[2]	1,56 [0,78; 3,11] 0,2037[3]	3,6 [-1,9; 9,0] 0,2037[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 216.1.2: Subgroups - adverse events according PT Decreased appetite from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,5139)					
North America / Europe	37/347 (10,7)	7/309 (2,3)	4,71 [2,13; 10,40] 0,0001[2]	5,15 [2,26; 11,73] <,0001[3]	8,4 [4,8; 12,0] <,0001[3]
Asia	20/239 (8,4)	2/226 (0,9)	9,46 [2,24; 40,00] 0,0023[2]	10,23 [2,36; 44,28] 0,0001[3]	7,5 [3,8; 11,2] 0,0001[3]
Other	13/190 (6,8)	1/194 (0,5)	13,27 [1,75; 100,47] 0,0123[2]	14,18 [1,84; 109,47] 0,0009[3]	6,3 [2,6; 10,1] 0,0009[3]
Primary tumor size (Interaction p-value: 0,7692)					
< 20 mm	16/204 (7,8)	2/189 (1,1)	7,41 [1,73; 31,81] 0,0070[2]	7,96 [1,80; 35,09] 0,0013[3]	6,8 [2,8; 10,8] 0,0013[3]
≥ 20 but < 50 mm	33/360 (9,2)	6/346 (1,7)	5,29 [2,24; 12,46] 0,0001[2]	5,72 [2,36; 13,83] <,0001[3]	7,4 [4,1; 10,7] <,0001[3]
≥ 50 mm	20/194 (10,3)	2/185 (1,1)	9,54 [2,26; 40,23] 0,0021[2]	10,52 [2,42; 45,66] 0,0001[3]	9,2 [4,7; 13,8] 0,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,4751)					
0-3	20/269 (7,4)	5/269 (1,9)	4,00 [1,52; 10,50] 0,0049[2]	4,24 [1,57; 11,47] 0,0021[3]	5,6 [2,1; 9,1] 0,0021[3]
4-9	32/353 (9,1)	3/326 (0,9)	9,85 [3,05; 31,86] 0,0001[2]	10,73 [3,25; 35,40] <,0001[3]	8,1 [5,0; 11,3] <,0001[3]
≥ 10	18/154 (11,7)	2/134 (1,5)	7,83 [1,85; 33,13] 0,0052[2]	8,74 [1,99; 38,39] 0,0007[3]	10,2 [4,7; 15,7] 0,0007[3]
Tumor stage (Interaction p-value: 0,4443)					
IIA	4/79 (5,1)	1/77 (1,3)	3,90 [0,45; 34,10] 0,2188[2]	4,05 [0,44; 37,11] 0,3671[4]	3,8 [-1,7; 9,2] 0,3671[4]
IIB	8/73 (11,0)	4/93 (4,3)	2,55 [0,80; 8,13] 0,1142[2]	2,74 [0,79; 9,48] 0,1001[3]	6,7 [-1,6; 14,9] 0,1001[3]
IIIA	24/345 (7,0)	1/294 (0,3)	20,45 [2,78; 150,27] 0,0030[2]	21,91 [2,95; 162,95] <,0001[3]	6,6 [3,9; 9,4] <,0001[3]
IIIB	4/22 (18,2)	0/19 (0,0)	7,83 [0,45; 136,60] 0,1585[2]	9,49 [0,48; 188,68] 0,1105[4]	18,2 [2,1; 34,3] 0,1105[4]
IIIC	30/253 (11,9)	4/245 (1,6)	7,26 [2,60; 20,31] 0,0002[2]	8,11 [2,81; 23,37] <,0001[3]	10,2 [5,9; 14,5] <,0001[3]
Tumor grade (Interaction p-value: 0,8186)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	4/63 (6,3)	0/52 (0,0)	7,45 [0,41; 135,32] 0,1745[2]	7,94 [0,42; 151,00] 0,1253[4]	6,3 [0,3; 12,4] 0,1253[4]
G2	37/349 (10,6)	4/323 (1,2)	8,56 [3,09; 23,75] <,0001[2]	9,46 [3,33; 26,85] <,0001[3]	9,4 [5,9; 12,8] <,0001[3]
G3	27/317 (8,5)	6/312 (1,9)	4,43 [1,85; 10,58] 0,0008[2]	4,75 [1,93; 11,67] 0,0002[3]	6,6 [3,2; 10,0] 0,0002[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,9749)					
Negative	7/67 (10,4)	0/62 (0,0)	13,90 [0,81; 238,36] 0,0695[2]	15,50 [0,87; 277,28] 0,0136[4]	10,4 [3,1; 17,8] 0,0136[4]
Positive	59/678 (8,7)	9/647 (1,4)	6,26 [3,13; 12,51] <,0001[2]	6,76 [3,32; 13,74] <,0001[3]	7,3 [5,0; 9,6] <,0001[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9961)					
White	43/461 (9,3)	7/440 (1,6)	5,86 [2,67; 12,89] <,0001[2]	6,36 [2,83; 14,30] <,0001[3]	7,7 [4,8; 10,6] <,0001[3]
Asian	21/273 (7,7)	3/243 (1,2)	6,23 [1,88; 20,63] 0,0027[2]	6,67 [1,96; 22,64] 0,0005[3]	6,5 [3,0; 9,9] 0,0005[3]
Other	2/30 (6,7)	0/34 (0,0)	5,65 [0,28; 113,12] 0,2578[2]	6,05 [0,28; 131,25] 0,2158[4]	6,7 [-2,3; 15,6] 0,2158[4]
First endocrine therapy (Interaction p-value: 0,8178)					
Tamoxifen	50/553 (9,0)	7/534 (1,3)	6,90 [3,16; 15,08] <,0001[2]	7,48 [3,36; 16,66] <,0001[3]	7,7 [5,2; 10,3] <,0001[3]
Aromatase inhibitor	20/223 (9,0)	3/195 (1,5)	5,83 [1,76; 19,32] 0,0039[2]	6,31 [1,84; 21,56] 0,0009[3]	7,4 [3,3; 11,6] 0,0009[3]
ECOG-PS (Interaction p-value: 0,0653)					
ECOG-PS 0	67/685 (9,8)	8/649 (1,2)	7,93 [3,84; 16,39] <,0001[2]	8,69 [4,14; 18,23] <,0001[3]	8,5 [6,2; 10,9] <,0001[3]
ECOG-PS 1	3/91 (3,3)	2/80 (2,5)	1,32 [0,23; 7,69] 0,7585[2]	1,33 [0,22; 8,16] 1,0000[4]	0,8 [-4,2; 5,8] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 217.1.2: Subgroups - adverse events according PT Diarrhoea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9299)					
Neoadjuvant chemotherapy	260/314 (82,8)	17/306 (5,6)	14,90 [9,36; 23,72] <,0001[2]	81,85 [46,28; 144,77] <,0001[3]	77,2 [72,3; 82,1] <,0001[3]
Adjuvant chemotherapy	375/452 (83,0)	26/416 (6,3)	13,27 [9,13; 19,30] <,0001[2]	73,05 [45,81; 116,49] <,0001[3]	76,7 [72,5; 80,9] <,0001[3]
No chemotherapy	7/10 (70,0)	0/7 (0,0)	10,91 [0,72; 164,61] 0,0844[2]	32,14 [1,40; 736,17] 0,0098[4]	70,0 [41,6; 98,4] 0,0098[4]
Region (Interaction p-value: 0,0732)					
North America / Europe	295/347 (85,0)	26/309 (8,4)	10,10 [6,98; 14,63] <,0001[2]	61,75 [37,52; 101,63] <,0001[3]	76,6 [71,7; 81,5] <,0001[3]
Asia	220/239 (92,1)	12/226 (5,3)	17,34 [9,98; 30,10] <,0001[2]	206,49 [97,85; 435,75] <,0001[3]	86,7 [82,2; 91,2] <,0001[3]
Other	127/190 (66,8)	5/194 (2,6)	25,93 [10,86; 61,96] <,0001[2]	76,20 [29,83; 194,68] <,0001[3]	64,3 [57,2; 71,3] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,9076)					
0-3	221/269 (82,2)	17/269 (6,3)	13,00 [8,18; 20,66] <,0001[2]	68,25 [38,14; 122,13] <,0001[3]	75,8 [70,4; 81,3] <,0001[3]
4-9	293/353 (83,0)	18/326 (5,5)	15,03 [9,57; 23,61] <,0001[2]	83,56 [48,19; 144,90] <,0001[3]	77,5 [72,8; 82,1] <,0001[3]
≥ 10	128/154 (83,1)	8/134 (6,0)	13,92 [7,08; 27,36] <,0001[2]	77,54 [33,82; 177,77] <,0001[3]	77,1 [70,0; 84,3] <,0001[3]
Tumor stage (Interaction p-value: 0,4576)					
IIA	66/79 (83,5)	5/77 (6,5)	12,87 [5,48; 30,20] <,0001[2]	73,11 [24,72; 216,17] <,0001[3]	77,1 [67,2; 86,9] <,0001[3]
IIB	56/73 (76,7)	9/93 (9,7)	7,93 [4,21; 14,94] <,0001[2]	30,75 [12,81; 73,82] <,0001[3]	67,0 [55,6; 78,4] <,0001[3]
IIIA	284/345 (82,3)	15/294 (5,1)	16,13 [9,83; 26,48] <,0001[2]	86,60 [48,07; 155,99] <,0001[3]	77,2 [72,5; 82,0] <,0001[3]
IIIB	19/22 (86,4)	1/19 (5,3)	16,41 [2,42; 111,36] 0,0042[2]	114,00 [10,84; 1199,18] <,0001[3]	81,1 [63,6; 98,6] <,0001[3]
IIIC	214/253 (84,6)	13/245 (5,3)	15,94 [9,37; 27,13] <,0001[2]	97,93 [50,89; 188,44] <,0001[3]	79,3 [74,0; 84,5] <,0001[3]
Tumor grade (Interaction p-value: 0,8964)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	52/63 (82,5)	2/52 (3,8)	21,46 [5,49; 83,93] <,0001[2]	118,18 [24,94; 560,07] <,0001[3]	78,7 [68,0; 89,4] <,0001[3]
G2	298/349 (85,4)	19/323 (5,9)	14,52 [9,36; 22,50] <,0001[2]	93,49 [53,91; 162,12] <,0001[3]	79,5 [75,0; 84,0] <,0001[3]
G3	258/317 (81,4)	20/312 (6,4)	12,70 [8,28; 19,46] <,0001[2]	63,84 [37,43; 108,91] <,0001[3]	75,0 [69,9; 80,1] <,0001[3]
GX	31/44 (70,5)	2/40 (5,0)	14,09 [3,60; 55,14] 0,0001[2]	45,31 [9,50; 216,14] <,0001[3]	65,5 [50,4; 80,5] <,0001[3]
Progesterone receptor status (Interaction p-value: 0,2314)					
Negative	57/67 (85,1)	6/62 (9,7)	8,79 [4,08; 18,93] <,0001[2]	53,20 [18,12; 156,22] <,0001[3]	75,4 [64,1; 86,7] <,0001[3]
Positive	562/678 (82,9)	33/647 (5,1)	16,25 [11,64; 22,70] <,0001[2]	90,14 [60,23; 134,92] <,0001[3]	77,8 [74,5; 81,1] <,0001[3]
Unknown	6/8 (75,0)	1/8 (12,5)	6,00 [0,92; 39,18] 0,0613[2]	21,00 [1,50; 293,25] 0,0406[4]	62,5 [24,7; 100,0] 0,0406[4]
Race (Interaction p-value: 0,4560)					
White	364/461 (79,0)	27/440 (6,1)	12,87 [8,90; 18,60] <,0001[2]	57,40 [36,63; 89,95] <,0001[3]	72,8 [68,5; 77,2] <,0001[3]
Asian	242/273 (88,6)	12/243 (4,9)	17,95 [10,32; 31,21] <,0001[2]	150,27 [75,35; 299,70] <,0001[3]	83,7 [79,1; 88,4] <,0001[3]
Other	24/30 (80,0)	3/34 (8,8)	9,07 [3,03; 27,11] <,0001[2]	41,33 [9,36; 182,45] <,0001[3]	71,2 [54,0; 88,4] <,0001[3]
First endocrine therapy (Interaction p-value: 0,6520)					
Tamoxifen	445/553 (80,5)	32/534 (6,0)	13,43 [9,57; 18,84] <,0001[2]	64,64 [42,70; 97,85] <,0001[3]	74,5 [70,6; 78,3] <,0001[3]
Aromatase inhibitor	197/223 (88,3)	11/195 (5,6)	15,66 [8,80; 27,86] <,0001[2]	126,74 [60,89; 263,80] <,0001[3]	82,7 [77,4; 88,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,1549)					
ECOG-PS 0	574/685 (83,8)	36/649 (5,5)	15,11 [10,98; 20,79] <,0001[2]	88,05 [59,45; 130,42] <,0001[3]	78,2 [75,0; 81,5] <,0001[3]
ECOG-PS 1	68/91 (74,7)	7/80 (8,8)	8,54 [4,17; 17,50] <,0001[2]	30,83 [12,43; 76,46] <,0001[3]	66,0 [55,1; 76,8] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 218.1.2: Subgroups - adverse events according PT Dizziness from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,3554)					
Neoadjuvant chemotherapy	23/314 (7,3)	22/306 (7,2)	1,02 [0,58; 1,79] 0,9482[2]	1,02 [0,56; 1,87] 0,9482[3]	0,1 [-3,9; 4,2] 0,9482[3]
Adjuvant chemotherapy	49/452 (10,8)	26/416 (6,3)	1,73 [1,10; 2,74] 0,0181[2]	1,82 [1,11; 2,99] 0,0162[3]	4,6 [0,9; 8,3] 0,0162[3]
No chemotherapy	2/10 (20,0)	1/7 (14,3)	1,40 [0,16; 12,60] 0,7641[2]	1,50 [0,11; 20,68] 1,0000[4]	5,7 [-30,2; 41,6] 1,0000[4]
Region (Interaction p-value: 0,8732)					
North America / Europe	39/347 (11,2)	23/309 (7,4)	1,51 [0,92; 2,47] 0,1006[2]	1,57 [0,92; 2,70] 0,0971[3]	3,8 [-0,6; 8,2] 0,0971[3]
Asia	26/239 (10,9)	18/226 (8,0)	1,37 [0,77; 2,42] 0,2860[2]	1,41 [0,75; 2,65] 0,2833[3]	2,9 [-2,4; 8,2] 0,2833[3]
Other	9/190 (4,7)	8/194 (4,1)	1,15 [0,45; 2,91] 0,7705[2]	1,16 [0,44; 3,06] 0,7703[3]	0,6 [-3,5; 4,7] 0,7703[3]
Primary tumor size (Interaction p-value: 0,3767)					
< 20 mm	18/204 (8,8)	15/189 (7,9)	1,11 [0,58; 2,14] 0,7516[2]	1,12 [0,55; 2,30] 0,7514[3]	0,9 [-4,6; 6,4] 0,7514[3]
≥ 20 but < 50 mm	35/360 (9,7)	26/346 (7,5)	1,29 [0,80; 2,10] 0,2984[2]	1,33 [0,78; 2,25] 0,2966[3]	2,2 [-1,9; 6,3] 0,2966[3]
≥ 50 mm	19/194 (9,8)	8/185 (4,3)	2,26 [1,02; 5,05] 0,0455[2]	2,40 [1,02; 5,63] 0,0385[3]	5,5 [0,4; 10,6] 0,0385[3]
Number of positive lymph nodes (Interaction p-value: 0,2504)					
0-3	24/269 (8,9)	24/269 (8,9)	1,00 [0,58; 1,72] 1,0000[2]	1,00 [0,55; 1,81] 1,0000[3]	0,0 [-4,8; 4,8] 1,0000[3]
4-9	35/353 (9,9)	17/326 (5,2)	1,90 [1,09; 3,33] 0,0244[2]	2,00 [1,10; 3,65] 0,0214[3]	4,7 [0,8; 8,6] 0,0214[3]
≥ 10	15/154 (9,7)	8/134 (6,0)	1,63 [0,71; 3,73] 0,2456[2]	1,70 [0,70; 4,14] 0,2391[3]	3,8 [-2,4; 9,9] 0,2391[3]
Tumor stage (Interaction p-value: 0,3739)					
IIA	6/79 (7,6)	8/77 (10,4)	0,73 [0,27; 2,01] 0,5435[2]	0,71 [0,23; 2,15] 0,5415[3]	-2,8 [-11,8; 6,2] 0,5415[3]
IIB	6/73 (8,2)	9/93 (9,7)	0,85 [0,32; 2,28] 0,7456[2]	0,84 [0,28; 2,47] 0,7450[3]	-1,5 [-10,2; 7,2] 0,7450[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	38/345 (11,0)	17/294 (5,8)	1,90 [1,10; 3,30] 0,0217[2]	2,02 [1,11; 3,65] 0,0188[3]	5,2 [1,0; 9,5] 0,0188[3]
IIIB	2/22 (9,1)	2/19 (10,5)	0,86 [0,13; 5,56] 0,8773[2]	0,85 [0,11; 6,69] 1,0000[4]	-1,4 [-19,7; 16,9] 1,0000[4]
IIIC	22/253 (8,7)	13/245 (5,3)	1,64 [0,84; 3,18] 0,1441[2]	1,70 [0,84; 3,46] 0,1390[3]	3,4 [-1,1; 7,9] 0,1390[3]
Tumor grade (Interaction p-value: 0,4603)					
G1	8/63 (12,7)	1/52 (1,9)	6,60 [0,85; 51,10] 0,0706[2]	7,42 [0,90; 61,40] 0,0393[4]	10,8 [1,7; 19,8] 0,0393[4]
G2	31/349 (8,9)	23/323 (7,1)	1,25 [0,74; 2,09] 0,4026[2]	1,27 [0,72; 2,23] 0,4013[3]	1,8 [-2,3; 5,9] 0,4013[3]
G3	33/317 (10,4)	23/312 (7,4)	1,41 [0,85; 2,35] 0,1838[2]	1,46 [0,84; 2,55] 0,1810[3]	3,0 [-1,4; 7,5] 0,1810[3]
GX	2/44 (4,5)	2/40 (5,0)	0,91 [0,13; 6,16] 0,9222[2]	0,90 [0,12; 6,74] 1,0000[4]	-0,5 [-9,6; 8,7] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,2695)					
Negative	7/67 (10,4)	9/62 (14,5)	0,72 [0,29; 1,82] 0,4861[2]	0,69 [0,24; 1,97] 0,4837[3]	-4,1 [-15,5; 7,4] 0,4837[3]
Positive	64/678 (9,4)	37/647 (5,7)	1,65 [1,12; 2,44] 0,0118[2]	1,72 [1,13; 2,62] 0,0107[3]	3,7 [0,9; 6,6] 0,0107[3]
Unknown	0/8 (0,0)	1/8 (12,5)	0,33 [0,02; 7,14] 0,4823[2]	0,29 [0,01; 8,37] 1,0000[4]	-12,5 [-35,4; 10,4] 1,0000[4]
Race (Interaction p-value: 0,7941)					
White	44/461 (9,5)	24/440 (5,5)	1,75 [1,08; 2,83] 0,0223[2]	1,83 [1,09; 3,06] 0,0202[3]	4,1 [0,7; 7,5] 0,0202[3]
Asian	29/273 (10,6)	19/243 (7,8)	1,36 [0,78; 2,36] 0,2766[2]	1,40 [0,76; 2,57] 0,2737[3]	2,8 [-2,2; 7,8] 0,2737[3]
Other	0/30 (0,0)	6/34 (17,6)	0,09 [0,01; 1,48] 0,0912[2]	0,07 [0,00; 1,33] 0,0259[4]	-17,6 [-30,5; -4,8] 0,0259[4]
First endocrine therapy (Interaction p-value: 0,7003)					
Tamoxifen	46/553 (8,3)	30/534 (5,6)	1,48 [0,95; 2,31] 0,0834[2]	1,52 [0,95; 2,45] 0,0809[3]	2,7 [-0,3; 5,7] 0,0809[3]
Aromatase inhibitor	28/223 (12,6)	19/195 (9,7)	1,29 [0,74; 2,23] 0,3661[2]	1,33 [0,72; 2,47] 0,3639[3]	2,8 [-3,2; 8,8] 0,3639[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 219.1.2: Subgroups - adverse events according PT Dry eye from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,4815)					
Neoadjuvant chemotherapy	11/314 (3,5)	8/306 (2,6)	1,34 [0,55; 3,29] 0,5225[2]	1,35 [0,54; 3,41] 0,5209[3]	0,9 [-1,8; 3,6] 0,5209[3]
Adjuvant chemotherapy	14/452 (3,1)	4/416 (1,0)	3,22 [1,07; 9,71] 0,0377[2]	3,29 [1,07; 10,08] 0,0274[3]	2,1 [0,3; 4,0] 0,0274[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,2978)					
North America / Europe	15/347 (4,3)	4/309 (1,3)	3,34 [1,12; 9,95] 0,0305[2]	3,45 [1,13; 10,49] 0,0210[3]	3,0 [0,5; 5,5] 0,0210[3]
Asia	8/239 (3,3)	7/226 (3,1)	1,08 [0,40; 2,93] 0,8789[2]	1,08 [0,39; 3,04] 0,8788[3]	0,2 [-3,0; 3,5] 0,8788[3]
Other	3/190 (1,6)	1/194 (0,5)	3,06 [0,32; 29,19] 0,3304[2]	3,10 [0,32; 30,03] 0,3679[4]	1,1 [-1,0; 3,1] 0,3679[4]
Primary tumor size (Interaction p-value: 0,0962)					
< 20 mm	7/204 (3,4)	7/189 (3,7)	0,93 [0,33; 2,59] 0,8843[2]	0,92 [0,32; 2,68] 0,8843[3]	-0,3 [-3,9; 3,4] 0,8843[3]
≥ 20 but < 50 mm	14/360 (3,9)	2/346 (0,6)	6,73 [1,54; 29,38] 0,0113[2]	6,96 [1,57; 30,85] 0,0031[3]	3,3 [1,2; 5,5] 0,0031[3]
≥ 50 mm	5/194 (2,6)	3/185 (1,6)	1,59 [0,39; 6,56] 0,5216[2]	1,60 [0,38; 6,81] 0,7243[4]	1,0 [-1,9; 3,8] 0,7243[4]
Number of positive lymph nodes (Interaction p-value: 0,1493)					
0-3	10/269 (3,7)	7/269 (2,6)	1,43 [0,55; 3,70] 0,4623[2]	1,45 [0,54; 3,85] 0,4597[3]	1,1 [-1,8; 4,1] 0,4597[3]
4-9	15/353 (4,2)	3/326 (0,9)	4,62 [1,35; 15,80] 0,0148[2]	4,78 [1,37; 16,66] 0,0070[3]	3,3 [1,0; 5,7] 0,0070[3]
≥ 10	1/154 (0,6)	2/134 (1,5)	0,44 [0,04; 4,74] 0,4948[2]	0,43 [0,04; 4,81] 0,5993[4]	-0,8 [-3,3; 1,6] 0,5993[4]
Tumor stage (Interaction p-value: 0,1088)					
IIA	3/79 (3,8)	2/77 (2,6)	1,46 [0,25; 8,51] 0,6726[2]	1,48 [0,24; 9,11] 1,0000[4]	1,2 [-4,3; 6,7] 1,0000[4]
IIB	3/73 (4,1)	0/93 (0,0)	8,89 [0,47; 169,46] 0,1462[2]	9,28 [0,47; 182,64] 0,0831[4]	4,1 [-0,4; 8,7] 0,0831[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	16/345 (4,6)	2/294 (0,7)	6,82 [1,58; 29,41] 0,0101[2]	7,10 [1,62; 31,14] 0,0026[3]	4,0 [1,5; 6,4] 0,0026[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	4/253 (1,6)	8/245 (3,3)	0,48 [0,15; 1,59] 0,2312[2]	0,48 [0,14; 1,60] 0,2204[3]	-1,7 [-4,4; 1,0] 0,2204[3]
Tumor grade (Interaction p-value: 0,3957)					
G1	1/63 (1,6)	0/52 (0,0)	2,48 [0,10; 59,73] 0,5749[2]	2,52 [0,10; 63,17] 1,0000[4]	1,6 [-1,5; 4,7] 1,0000[4]
G2	13/349 (3,7)	3/323 (0,9)	4,01 [1,15; 13,95] 0,0289[2]	4,13 [1,17; 14,62] 0,0175[3]	2,8 [0,6; 5,0] 0,0175[3]
G3	11/317 (3,5)	7/312 (2,2)	1,55 [0,61; 3,94] 0,3605[2]	1,57 [0,60; 4,09] 0,3563[3]	1,2 [-1,4; 3,8] 0,3563[3]
GX	1/44 (2,3)	2/40 (5,0)	0,45 [0,04; 4,82] 0,5129[2]	0,44 [0,04; 5,07] 0,6029[4]	-2,7 [-10,8; 5,3] 0,6029[4]
Progesterone receptor status (Interaction p-value: 0,9993)					
Negative	4/67 (6,0)	2/62 (3,2)	1,85 [0,35; 9,75] 0,4678[2]	1,90 [0,34; 10,79] 0,6815[4]	2,7 [-4,4; 9,9] 0,6815[4]
Positive	19/678 (2,8)	10/647 (1,5)	1,81 [0,85; 3,87] 0,1239[2]	1,84 [0,85; 3,98] 0,1181[3]	1,3 [-0,3; 2,8] 0,1181[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,2707)					
White	17/461 (3,7)	5/440 (1,1)	3,25 [1,21; 8,72] 0,0196[2]	3,33 [1,22; 9,11] 0,0131[3]	2,6 [0,6; 4,5] 0,0131[3]
Asian	8/273 (2,9)	7/243 (2,9)	1,02 [0,37; 2,76] 0,9732[2]	1,02 [0,36; 2,85] 0,9732[3]	0,0 [-2,9; 3,0] 0,9732[3]
Other	0/30 (0,0)	0/34 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,0636)					
Tamoxifen	22/553 (4,0)	7/534 (1,3)	3,03 [1,31; 7,05] 0,0098[2]	3,12 [1,32; 7,36] 0,0064[3]	2,7 [0,8; 4,6] 0,0064[3]
Aromatase inhibitor	4/223 (1,8)	5/195 (2,6)	0,70 [0,19; 2,57] 0,5903[2]	0,69 [0,18; 2,62] 0,7394[4]	-0,8 [-3,6; 2,1] 0,7394[4]
ECOG-PS (Interaction p-value: 0,4202)					
ECOG-PS 0	22/685 (3,2)	9/649 (1,4)	2,32 [1,07; 4,99] 0,0321[2]	2,36 [1,08; 5,16] 0,0270[3]	1,8 [0,2; 3,4] 0,0270[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	4/91 (4,4)	3/80 (3,8)	1,17 [0,27; 5,08] 0,8319[2]	1,18 [0,26; 5,44] 1,0000[4]	0,6 [-5,3; 6,6] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 220.1.2: Subgroups - adverse events according PT Dry mouth from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,2951)					
Neoadjuvant chemotherapy	7/314 (2,2)	1/306 (0,3)	6,82 [0,84; 55,12] 0,0717[2]	6,95 [0,85; 56,86] 0,0687[4]	1,9 [0,1; 3,7] 0,0687[4]
Adjuvant chemotherapy	12/452 (2,7)	3/416 (0,7)	3,68 [1,05; 12,95] 0,0423[2]	3,75 [1,05; 13,40] 0,0290[3]	1,9 [0,2; 3,6] 0,0290[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,9994)					
North America / Europe	10/347 (2,9)	4/309 (1,3)	2,23 [0,71; 7,03] 0,1723[2]	2,26 [0,70; 7,29] 0,1603[3]	1,6 [-0,6; 3,8] 0,1603[3]
Asia	4/239 (1,7)	0/226 (0,0)	8,51 [0,46; 157,22] 0,1500[2]	8,66 [0,46; 161,69] 0,1240[4]	1,7 [0,0; 3,3] 0,1240[4]
Other	5/190 (2,6)	0/194 (0,0)	11,23 [0,63; 201,70] 0,1007[2]	11,53 [0,63; 210,04] 0,0289[4]	2,6 [0,4; 4,9] 0,0289[4]
Primary tumor size (Interaction p-value: 0,3385)					
< 20 mm	3/204 (1,5)	2/189 (1,1)	1,39 [0,23; 8,23] 0,7168[2]	1,40 [0,23; 8,44] 1,0000[4]	0,4 [-1,8; 2,6] 1,0000[4]
≥ 20 but < 50 mm	11/360 (3,1)	1/346 (0,3)	10,57 [1,37; 81,45] 0,0236[2]	10,87 [1,40; 84,68] 0,0045[3]	2,8 [0,9; 4,6] 0,0045[3]
≥ 50 mm	4/194 (2,1)	1/185 (0,5)	3,81 [0,43; 33,81] 0,2292[2]	3,87 [0,43; 34,98] 0,3724[4]	1,5 [-0,7; 3,8] 0,3724[4]
Number of positive lymph nodes (Interaction p-value: 0,6145)					
0-3	5/269 (1,9)	2/269 (0,7)	2,50 [0,49; 12,77] 0,2709[2]	2,53 [0,49; 13,15] 0,4501[4]	1,1 [-0,8; 3,0] 0,4501[4]
4-9	10/353 (2,8)	1/326 (0,3)	9,24 [1,19; 71,75] 0,0336[2]	9,48 [1,21; 74,43] 0,0092[3]	2,5 [0,7; 4,4] 0,0092[3]
≥ 10	4/154 (2,6)	1/134 (0,7)	3,48 [0,39; 30,76] 0,2620[2]	3,55 [0,39; 32,13] 0,3767[4]	1,9 [-1,1; 4,8] 0,3767[4]
Tumor stage (Interaction p-value: 0,9751)					
IIA	2/79 (2,5)	1/77 (1,3)	1,95 [0,18; 21,06] 0,5825[2]	1,97 [0,18; 22,23] 1,0000[4]	1,2 [-3,1; 5,5] 1,0000[4]
IIB	1/73 (1,4)	0/93 (0,0)	3,81 [0,16; 92,20] 0,4105[2]	3,87 [0,16; 96,38] 0,4398[4]	1,4 [-1,3; 4,0] 0,4398[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	7/345 (2,0)	1/294 (0,3)	5,97 [0,74; 48,20] 0,0939[2]	6,07 [0,74; 49,61] 0,0756[4]	1,7 [0,1; 3,3] 0,0756[4]
IIIB	1/22 (4,5)	0/19 (0,0)	2,61 [0,11; 60,51] 0,5500[2]	2,72 [0,10; 70,79] 1,0000[4]	4,5 [-4,2; 13,2] 1,0000[4]
IIIC	8/253 (3,2)	2/245 (0,8)	3,87 [0,83; 18,06] 0,0847[2]	3,97 [0,83; 18,87] 0,1063[4]	2,3 [-0,1; 4,8] 0,1063[4]
Tumor grade (Interaction p-value: 0,6829)					
G1	1/63 (1,6)	1/52 (1,9)	0,83 [0,05; 12,88] 0,8911[2]	0,82 [0,05; 13,48] 1,0000[4]	-0,3 [-5,2; 4,5] 1,0000[4]
G2	11/349 (3,2)	2/323 (0,6)	5,09 [1,14; 22,79] 0,0334[2]	5,22 [1,15; 23,75] 0,0172[3]	2,5 [0,5; 4,6] 0,0172[3]
G3	6/317 (1,9)	1/312 (0,3)	5,91 [0,72; 48,77] 0,0992[2]	6,00 [0,72; 50,13] 0,1230[4]	1,6 [-0,1; 3,2] 0,1230[4]
GX	1/44 (2,3)	0/40 (0,0)	2,73 [0,11; 65,24] 0,5345[2]	2,79 [0,11; 70,54] 1,0000[4]	2,3 [-2,1; 6,7] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,4377)					
Negative	2/67 (3,0)	1/62 (1,6)	1,85 [0,17; 19,91] 0,6115[2]	1,88 [0,17; 21,23] 1,0000[4]	1,4 [-3,8; 6,5] 1,0000[4]
Positive	15/678 (2,2)	1/647 (0,2)	14,31 [1,90; 108,05] 0,0099[2]	14,62 [1,93; 110,96] 0,0006[3]	2,1 [0,9; 3,2] 0,0006[3]
Unknown	0/8 (0,0)	1/8 (12,5)	0,33 [0,02; 7,14] 0,4823[2]	0,29 [0,01; 8,37] 1,0000[4]	-12,5 [-35,4; 10,4] 1,0000[4]
Race (Interaction p-value: 0,9993)					
White	13/461 (2,8)	4/440 (0,9)	3,10 [1,02; 9,44] 0,0462[2]	3,16 [1,02; 9,78] 0,0351[3]	1,9 [0,2; 3,7] 0,0351[3]
Asian	5/273 (1,8)	0/243 (0,0)	9,80 [0,54; 176,24] 0,1217[2]	9,98 [0,55; 181,35] 0,0634[4]	1,8 [0,2; 3,4] 0,0634[4]
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
First endocrine therapy (Interaction p-value: 0,9749)					
Tamoxifen	13/553 (2,4)	4/534 (0,7)	3,14 [1,03; 9,56] 0,0443[2]	3,19 [1,03; 9,85] 0,0334[3]	1,6 [0,1; 3,1] 0,0334[3]
Aromatase inhibitor	6/223 (2,7)	0/195 (0,0)	11,38 [0,64; 200,63] 0,0968[2]	11,69 [0,65; 208,77] 0,0322[4]	2,7 [0,6; 4,8] 0,0322[4]
ECOG-PS (Interaction p-value: 0,9765)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	17/685 (2,5)	4/649 (0,6)	4,03 [1,36; 11,90] 0,0118[2]	4,10 [1,37; 12,26] 0,0062[3]	1,9 [0,6; 3,2] 0,0062[3]
ECOG-PS 1	2/91 (2,2)	0/80 (0,0)	4,40 [0,21; 90,35] 0,3364[2]	4,50 [0,21; 95,08] 0,4991[4]	2,2 [-0,8; 5,2] 0,4991[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 221.1.2: Subgroups - adverse events according PT Dry skin from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9892)					
Neoadjuvant chemotherapy	17/314 (5,4)	8/306 (2,6)	2,07 [0,91; 4,73] 0,0839[2]	2,13 [0,91; 5,02] 0,0764[3]	2,8 [-0,3; 5,9] 0,0764[3]
Adjuvant chemotherapy	22/452 (4,9)	9/416 (2,2)	2,25 [1,05; 4,83] 0,0375[2]	2,31 [1,05; 5,08] 0,0320[3]	2,7 [0,3; 5,1] 0,0320[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,9222)					
North America / Europe	20/347 (5,8)	9/309 (2,9)	1,98 [0,91; 4,28] 0,0830[2]	2,04 [0,91; 4,55] 0,0762[3]	2,9 [-0,2; 5,9] 0,0762[3]
Asia	16/239 (6,7)	6/226 (2,7)	2,52 [1,00; 6,33] 0,0489[2]	2,63 [1,01; 6,85] 0,0403[3]	4,0 [0,2; 7,8] 0,0403[3]
Other	4/190 (2,1)	2/194 (1,0)	2,04 [0,38; 11,02] 0,4064[2]	2,06 [0,37; 11,41] 0,4452[4]	1,1 [-1,4; 3,6] 0,4452[4]
Primary tumor size (Interaction p-value: 0,9948)					
< 20 mm	10/204 (4,9)	4/189 (2,1)	2,32 [0,74; 7,26] 0,1496[2]	2,38 [0,73; 7,73] 0,1366[3]	2,8 [-0,8; 6,4] 0,1366[3]
≥ 20 but < 50 mm	17/360 (4,7)	7/346 (2,0)	2,33 [0,98; 5,56] 0,0555[2]	2,40 [0,98; 5,86] 0,0479[3]	2,7 [0,1; 5,3] 0,0479[3]
≥ 50 mm	13/194 (6,7)	5/185 (2,7)	2,48 [0,90; 6,82] 0,0785[2]	2,59 [0,90; 7,40] 0,0673[3]	4,0 [-0,2; 8,2] 0,0673[3]
Number of positive lymph nodes (Interaction p-value: 0,7943)					
0-3	13/269 (4,8)	6/269 (2,2)	2,17 [0,84; 5,62] 0,1116[2]	2,23 [0,83; 5,95] 0,1020[3]	2,6 [-0,5; 5,7] 0,1020[3]
4-9	22/353 (6,2)	8/326 (2,5)	2,54 [1,15; 5,62] 0,0216[2]	2,64 [1,16; 6,02] 0,0167[3]	3,8 [0,7; 6,8] 0,0167[3]
≥ 10	5/154 (3,2)	3/134 (2,2)	1,45 [0,35; 5,95] 0,6060[2]	1,47 [0,34; 6,25] 0,7281[4]	1,0 [-2,7; 4,8] 0,7281[4]
Tumor stage (Interaction p-value: 0,7705)					
IIA	4/79 (5,1)	2/77 (2,6)	1,95 [0,37; 10,34] 0,4329[2]	2,00 [0,36; 11,25] 0,6815[4]	2,5 [-3,5; 8,5] 0,6815[4]
IIB	3/73 (4,1)	3/93 (3,2)	1,27 [0,26; 6,13] 0,7625[2]	1,29 [0,25; 6,57] 1,0000[4]	0,9 [-4,9; 6,7] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	20/345 (5,8)	5/294 (1,7)	3,41 [1,30; 8,97] 0,0130[2]	3,56 [1,32; 9,60] 0,0078[3]	4,1 [1,2; 7,0] 0,0078[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	11/253 (4,3)	7/245 (2,9)	1,52 [0,60; 3,86] 0,3769[2]	1,55 [0,59; 4,05] 0,3729[3]	1,5 [-1,8; 4,8] 0,3729[3]
Tumor grade (Interaction p-value: 0,9651)					
G1	5/63 (7,9)	0/52 (0,0)	9,11 [0,52; 161,00] 0,1316[2]	9,87 [0,53; 182,84] 0,0627[4]	7,9 [1,3; 14,6] 0,0627[4]
G2	17/349 (4,9)	7/323 (2,2)	2,25 [0,94; 5,35] 0,0672[2]	2,31 [0,95; 5,65] 0,0591[3]	2,7 [-0,1; 5,5] 0,0591[3]
G3	15/317 (4,7)	9/312 (2,9)	1,64 [0,73; 3,69] 0,2319[2]	1,67 [0,72; 3,88] 0,2266[3]	1,8 [-1,1; 4,8] 0,2266[3]
GX	2/44 (4,5)	1/40 (2,5)	1,82 [0,17; 19,29] 0,6198[2]	1,86 [0,16; 21,30] 1,0000[4]	2,0 [-5,8; 9,9] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,9208)					
Negative	5/67 (7,5)	0/62 (0,0)	10,19 [0,58; 180,59] 0,1135[2]	11,00 [0,60; 203,18] 0,0586[4]	7,5 [1,2; 13,8] 0,0586[4]
Positive	34/678 (5,0)	16/647 (2,5)	2,03 [1,13; 3,64] 0,0177[2]	2,08 [1,14; 3,81] 0,0152[3]	2,5 [0,5; 4,6] 0,0152[3]
Unknown	0/8 (0,0)	1/8 (12,5)	0,33 [0,02; 7,14] 0,4823[2]	0,29 [0,01; 8,37] 1,0000[4]	-12,5 [-35,4; 10,4] 1,0000[4]
Race (Interaction p-value: 0,8628)					
White	17/461 (3,7)	9/440 (2,0)	1,80 [0,81; 4,00] 0,1474[2]	1,83 [0,81; 4,16] 0,1411[3]	1,6 [-0,5; 3,8] 0,1411[3]
Asian	17/273 (6,2)	6/243 (2,5)	2,52 [1,01; 6,29] 0,0474[2]	2,62 [1,02; 6,76] 0,0389[3]	3,8 [0,3; 7,2] 0,0389[3]
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
First endocrine therapy (Interaction p-value: 0,2509)					
Tamoxifen	29/553 (5,2)	15/534 (2,8)	1,87 [1,01; 3,44] 0,0455[2]	1,91 [1,01; 3,61] 0,0417[3]	2,4 [0,1; 4,8] 0,0417[3]
Aromatase inhibitor	11/223 (4,9)	2/195 (1,0)	4,81 [1,08; 21,43] 0,0394[2]	5,01 [1,10; 22,88] 0,0217[3]	3,9 [0,7; 7,1] 0,0217[3]
ECOG-PS (Interaction p-value: 0,7762)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	36/685 (5,3)	15/649 (2,3)	2,27 [1,26; 4,11] 0,0066[2]	2,34 [1,27; 4,32] 0,0051[3]	2,9 [0,9; 5,0] 0,0051[3]
ECOG-PS 1	4/91 (4,4)	2/80 (2,5)	1,76 [0,33; 9,35] 0,5079[2]	1,79 [0,32; 10,06] 0,6859[4]	1,9 [-3,5; 7,3] 0,6859[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 222.1.2: Subgroups - adverse events according PT Dysgeusia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9890)					
Neoadjuvant chemotherapy	8/314 (2,5)	1/306 (0,3)	7,80 [0,98; 61,96] 0,0522[2]	7,97 [0,99; 64,14] 0,0378[4]	2,2 [0,4; 4,1] 0,0378[4]
Adjuvant chemotherapy	11/452 (2,4)	0/416 (0,0)	21,17 [1,25; 358,16] 0,0344[2]	21,70 [1,27; 369,37] 0,0014[3]	2,4 [1,0; 3,9] 0,0014[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Primary tumor size (Interaction p-value: 0,9998)					
< 20 mm	6/204 (2,9)	0/189 (0,0)	12,05 [0,68; 212,43] 0,0891[2]	12,41 [0,69; 221,82] 0,0307[4]	2,9 [0,6; 5,3] 0,0307[4]
≥ 20 but < 50 mm	9/360 (2,5)	1/346 (0,3)	8,65 [1,10; 67,92] 0,0402[2]	8,85 [1,11; 70,20] 0,0209[4]	2,2 [0,5; 3,9] 0,0209[4]
≥ 50 mm	5/194 (2,6)	0/185 (0,0)	10,49 [0,58; 188,43] 0,1107[2]	10,77 [0,59; 196,11] 0,0612[4]	2,6 [0,3; 4,8] 0,0612[4]
Tumor grade (Interaction p-value: 0,9997)					
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	8/349 (2,3)	1/323 (0,3)	7,40 [0,93; 58,87] 0,0584[2]	7,55 [0,94; 60,74] 0,0391[4]	2,0 [0,3; 3,7] 0,0391[4]
G3	10/317 (3,2)	0/312 (0,0)	20,67 [1,22; 351,22] 0,0361[2]	21,34 [1,25; 365,79] 0,0018[4]	3,2 [1,2; 5,1] 0,0018[4]
GX	0/44 (0,0)	0/40 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9582)					
Negative	2/67 (3,0)	0/62 (0,0)	4,63 [0,23; 94,63] 0,3193[2]	4,77 [0,22; 101,36] 0,4969[4]	3,0 [-1,1; 7,1] 0,4969[4]
Positive	17/678 (2,5)	1/647 (0,2)	16,22 [2,17; 121,55] 0,0067[2]	16,61 [2,20; 125,21] 0,0002[3]	2,4 [1,1; 3,6] 0,0002[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9995)					
White	13/461 (2,8)	1/440 (0,2)	12,41 [1,63; 94,45] 0,0150[2]	12,74 [1,66; 97,79] 0,0017[3]	2,6 [1,0; 4,2] 0,0017[3]
Asian	6/273 (2,2)	0/243 (0,0)	11,58 [0,66; 204,44] 0,0946[2]	11,83 [0,66; 211,16] 0,0319[4]	2,2 [0,5; 3,9] 0,0319[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
First endocrine therapy (Interaction p-value: 0,9783)					
Tamoxifen	15/553 (2,7)	1/534 (0,2)	14,48 [1,92; 109,27] 0,0095[2]	14,86 [1,96; 112,90] 0,0005[3]	2,5 [1,1; 3,9] 0,0005[3]
Aromatase inhibitor	5/223 (2,2)	0/195 (0,0)	9,63 [0,54; 172,96] 0,1245[2]	9,84 [0,54; 179,14] 0,0638[4]	2,2 [0,3; 4,2] 0,0638[4]
ECOG-PS (Interaction p-value: 0,9796)					
ECOG-PS 0	18/685 (2,6)	1/649 (0,2)	17,05 [2,28; 127,38] 0,0057[2]	17,49 [2,33; 131,37] 0,0001[3]	2,5 [1,2; 3,7] 0,0001[3]
ECOG-PS 1	2/91 (2,2)	0/80 (0,0)	4,40 [0,21; 90,35] 0,3364[2]	4,50 [0,21; 95,08] 0,4991[4]	2,2 [-0,8; 5,2] 0,4991[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 223.1.2: Subgroups - adverse events according PT Dyspepsia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,2431)					
Neoadjuvant chemotherapy	39/314 (12,4)	7/306 (2,3)	5,43 [2,47; 11,95] <,0001[2]	6,06 [2,67; 13,77] <,0001[3]	10,1 [6,1; 14,1] <,0001[3]
Adjuvant chemotherapy	29/452 (6,4)	9/416 (2,2)	2,97 [1,42; 6,19] 0,0038[2]	3,10 [1,45; 6,63] 0,0022[3]	4,3 [1,6; 6,9] 0,0022[3]
No chemotherapy	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Region (Interaction p-value: 0,3606)					
North America / Europe	30/347 (8,6)	10/309 (3,2)	2,67 [1,33; 5,37] 0,0059[2]	2,83 [1,36; 5,89] 0,0039[3]	5,4 [1,9; 9,0] 0,0039[3]
Asia	28/239 (11,7)	4/226 (1,8)	6,62 [2,36; 18,57] 0,0003[2]	7,36 [2,54; 21,35] <,0001[3]	9,9 [5,5; 14,4] <,0001[3]
Other	11/190 (5,8)	3/194 (1,5)	3,74 [1,06; 13,21] 0,0402[2]	3,91 [1,07; 14,25] 0,0266[3]	4,2 [0,5; 8,0] 0,0266[3]
Primary tumor size (Interaction p-value: 0,8623)					
< 20 mm	21/204 (10,3)	5/189 (2,6)	3,89 [1,50; 10,11] 0,0053[2]	4,22 [1,56; 11,44] 0,0023[3]	7,6 [2,9; 12,4] 0,0023[3]
≥ 20 but < 50 mm	28/360 (7,8)	6/346 (1,7)	4,49 [1,88; 10,70] 0,0007[2]	4,78 [1,95; 11,69] 0,0002[3]	6,0 [3,0; 9,1] 0,0002[3]
≥ 50 mm	20/194 (10,3)	6/185 (3,2)	3,18 [1,31; 7,74] 0,0109[2]	3,43 [1,35; 8,74] 0,0065[3]	7,1 [2,1; 12,0] 0,0065[3]
Number of positive lymph nodes (Interaction p-value: 0,8494)					
0-3	25/269 (9,3)	7/269 (2,6)	3,57 [1,57; 8,12] 0,0024[2]	3,83 [1,63; 9,03] 0,0010[3]	6,7 [2,7; 10,6] 0,0010[3]
4-9	31/353 (8,8)	8/326 (2,5)	3,58 [1,67; 7,67] 0,0010[2]	3,83 [1,73; 8,45] 0,0004[3]	6,3 [2,9; 9,7] 0,0004[3]
≥ 10	13/154 (8,4)	2/134 (1,5)	5,66 [1,30; 24,61] 0,0209[2]	6,09 [1,35; 27,48] 0,0081[3]	6,9 [2,1; 11,8] 0,0081[3]
Tumor stage (Interaction p-value: 0,3545)					
IIA	8/79 (10,1)	1/77 (1,3)	7,80 [1,00; 60,88] 0,0501[2]	8,56 [1,04; 70,20] 0,0339[4]	8,8 [1,7; 15,9] 0,0339[4]
IIB	6/73 (8,2)	2/93 (2,2)	3,82 [0,79; 18,38] 0,0943[2]	4,07 [0,80; 20,82] 0,1400[4]	6,1 [-0,9; 13,0] 0,1400[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	31/345 (9,0)	6/294 (2,0)	4,40 [1,86; 10,41] 0,0007[2]	4,74 [1,95; 11,52] 0,0002[3]	6,9 [3,5; 10,4] 0,0002[3]
IIIB	3/22 (13,6)	3/19 (15,8)	0,86 [0,20; 3,79] 0,8458[2]	0,84 [0,15; 4,76] 1,0000[4]	-2,2 [-23,9; 19,6] 1,0000[4]
IIIC	21/253 (8,3)	5/245 (2,0)	4,07 [1,56; 10,62] 0,0042[2]	4,34 [1,61; 11,71] 0,0017[3]	6,3 [2,4; 10,1] 0,0017[3]
Tumor grade (Interaction p-value: 0,9870)					
G1	3/63 (4,8)	1/52 (1,9)	2,48 [0,27; 23,10] 0,4262[2]	2,55 [0,26; 25,28] 0,6254[4]	2,8 [-3,6; 9,3] 0,6254[4]
G2	33/349 (9,5)	8/323 (2,5)	3,82 [1,79; 8,14] 0,0005[2]	4,11 [1,87; 9,04] 0,0002[3]	7,0 [3,5; 10,5] 0,0002[3]
G3	31/317 (9,8)	8/312 (2,6)	3,81 [1,78; 8,17] 0,0006[2]	4,12 [1,86; 9,11] 0,0002[3]	7,2 [3,5; 10,9] 0,0002[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,3084)					
Negative	13/67 (19,4)	1/62 (1,6)	12,03 [1,62; 89,28] 0,0150[2]	14,69 [1,86; 115,99] 0,0012[3]	17,8 [7,8; 27,8] 0,0012[3]
Positive	54/678 (8,0)	15/647 (2,3)	3,44 [1,96; 6,03] <,0001[2]	3,65 [2,04; 6,53] <,0001[3]	5,6 [3,3; 8,0] <,0001[3]
Unknown	1/8 (12,5)	1/8 (12,5)	1,00 [0,07; 13,37] 1,0000[2]	1,00 [0,05; 19,36] 1,0000[4]	0,0 [-32,4; 32,4] 1,0000[4]
Race (Interaction p-value: 0,3446)					
White	39/461 (8,5)	12/440 (2,7)	3,10 [1,65; 5,85] 0,0005[2]	3,30 [1,70; 6,38] 0,0002[3]	5,7 [2,8; 8,7] 0,0002[3]
Asian	29/273 (10,6)	4/243 (1,6)	6,45 [2,30; 18,09] 0,0004[2]	7,10 [2,46; 20,51] <,0001[3]	9,0 [5,0; 13,0] <,0001[3]
Other	1/30 (3,3)	1/34 (2,9)	1,13 [0,07; 17,34] 0,9283[2]	1,14 [0,07; 19,02] 1,0000[4]	0,4 [-8,2; 9,0] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,6493)					
Tamoxifen	55/553 (9,9)	13/534 (2,4)	4,09 [2,26; 7,39] <,0001[2]	4,43 [2,39; 8,20] <,0001[3]	7,5 [4,7; 10,3] <,0001[3]
Aromatase inhibitor	14/223 (6,3)	4/195 (2,1)	3,06 [1,02; 9,14] 0,0452[2]	3,20 [1,03; 9,89] 0,0337[3]	4,2 [0,5; 8,0] 0,0337[3]
ECOG-PS (Interaction p-value: 0,7731)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	62/685 (9,1)	15/649 (2,3)	3,92 [2,25; 6,81] <,0001[2]	4,21 [2,37; 7,47] <,0001[3]	6,7 [4,3; 9,2] <,0001[3]
ECOG-PS 1	7/91 (7,7)	2/80 (2,5)	3,08 [0,66; 14,39] 0,1533[2]	3,25 [0,66; 16,12] 0,1763[4]	5,2 [-1,3; 11,6] 0,1763[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 224.1.2: Subgroups - adverse events according PT Dyspnoea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8941)					
Neoadjuvant chemotherapy	17/314 (5,4)	6/306 (2,0)	2,76 [1,10; 6,91] 0,0300[2]	2,86 [1,11; 7,36] 0,0229[3]	3,5 [0,5; 6,4] 0,0229[3]
Adjuvant chemotherapy	25/452 (5,5)	11/416 (2,6)	2,09 [1,04; 4,20] 0,0378[2]	2,16 [1,05; 4,44] 0,0331[3]	2,9 [0,3; 5,5] 0,0331[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,7709)					
North America / Europe	34/347 (9,8)	12/309 (3,9)	2,52 [1,33; 4,78] 0,0046[2]	2,69 [1,37; 5,29] 0,0031[3]	5,9 [2,1; 9,7] 0,0031[3]
Asia	3/239 (1,3)	1/226 (0,4)	2,84 [0,30; 27,07] 0,3650[2]	2,86 [0,30; 27,70] 0,6240[4]	0,8 [-0,8; 2,5] 0,6240[4]
Other	6/190 (3,2)	4/194 (2,1)	1,53 [0,44; 5,34] 0,5036[2]	1,55 [0,43; 5,58] 0,5397[4]	1,1 [-2,1; 4,3] 0,5397[4]
Primary tumor size (Interaction p-value: 0,9198)					
< 20 mm	12/204 (5,9)	4/189 (2,1)	2,78 [0,91; 8,47] 0,0721[2]	2,89 [0,92; 9,12] 0,0591[3]	3,8 [-0,1; 7,6] 0,0591[3]
≥ 20 but < 50 mm	18/360 (5,0)	7/346 (2,0)	2,47 [1,05; 5,84] 0,0393[2]	2,55 [1,05; 6,18] 0,0324[3]	3,0 [0,3; 5,7] 0,0324[3]
≥ 50 mm	13/194 (6,7)	6/185 (3,2)	2,07 [0,80; 5,32] 0,1328[2]	2,14 [0,80; 5,76] 0,1231[3]	3,5 [-0,9; 7,8] 0,1231[3]
Number of positive lymph nodes (Interaction p-value: 0,8838)					
0-3	18/269 (6,7)	7/269 (2,6)	2,57 [1,09; 6,06] 0,0307[2]	2,68 [1,10; 6,54] 0,0243[3]	4,1 [0,5; 7,6] 0,0243[3]
4-9	19/353 (5,4)	7/326 (2,1)	2,51 [1,07; 5,88] 0,0348[2]	2,59 [1,08; 6,25] 0,0282[3]	3,2 [0,4; 6,1] 0,0282[3]
≥ 10	6/154 (3,9)	3/134 (2,2)	1,74 [0,44; 6,82] 0,4268[2]	1,77 [0,43; 7,22] 0,5106[4]	1,7 [-2,3; 5,6] 0,5106[4]
Tumor stage (Interaction p-value: 0,6791)					
IIA	5/79 (6,3)	2/77 (2,6)	2,44 [0,49; 12,18] 0,2781[2]	2,53 [0,48; 13,47] 0,4426[4]	3,7 [-2,7; 10,2] 0,4426[4]
IIB	2/73 (2,7)	3/93 (3,2)	0,85 [0,15; 4,95] 0,8559[2]	0,85 [0,14; 5,20] 1,0000[4]	-0,5 [-5,7; 4,7] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	21/345 (6,1)	5/294 (1,7)	3,58 [1,37; 9,37] 0,0094[2]	3,75 [1,39; 10,06] 0,0052[3]	4,4 [1,5; 7,3] 0,0052[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	13/253 (5,1)	7/245 (2,9)	1,80 [0,73; 4,43] 0,2022[2]	1,84 [0,72; 4,70] 0,1949[3]	2,3 [-1,1; 5,7] 0,1949[3]
Tumor grade (Interaction p-value: 0,2782)					
G1	7/63 (11,1)	1/52 (1,9)	5,78 [0,73; 45,46] 0,0956[2]	6,38 [0,76; 53,61] 0,0707[4]	9,2 [0,6; 17,8] 0,0707[4]
G2	16/349 (4,6)	9/323 (2,8)	1,65 [0,74; 3,67] 0,2239[2]	1,68 [0,73; 3,85] 0,2185[3]	1,8 [-1,0; 4,6] 0,2185[3]
G3	20/317 (6,3)	7/312 (2,2)	2,81 [1,21; 6,56] 0,0167[2]	2,93 [1,22; 7,04] 0,0119[3]	4,1 [0,9; 7,2] 0,0119[3]
GX	0/44 (0,0)	0/40 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9994)					
Negative	3/67 (4,5)	0/62 (0,0)	6,49 [0,34; 123,08] 0,2132[2]	6,78 [0,34; 134,01] 0,2453[4]	4,5 [-0,5; 9,4] 0,2453[4]
Positive	36/678 (5,3)	17/647 (2,6)	2,02 [1,15; 3,56] 0,0150[2]	2,08 [1,16; 3,74] 0,0128[3]	2,7 [0,6; 4,8] 0,0128[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,3714)					
White	32/461 (6,9)	13/440 (3,0)	2,35 [1,25; 4,42] 0,0080[2]	2,45 [1,27; 4,73] 0,0060[3]	4,0 [1,2; 6,8] 0,0060[3]
Asian	6/273 (2,2)	1/243 (0,4)	5,34 [0,65; 44,05] 0,1196[2]	5,44 [0,65; 45,49] 0,1269[4]	1,8 [-0,1; 3,7] 0,1269[4]
Other	1/30 (3,3)	2/34 (5,9)	0,57 [0,05; 5,94] 0,6357[2]	0,55 [0,05; 6,41] 1,0000[4]	-2,5 [-12,7; 7,6] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,1247)					
Tamoxifen	35/553 (6,3)	11/534 (2,1)	3,07 [1,58; 5,99] 0,0010[2]	3,21 [1,61; 6,39] 0,0005[3]	4,3 [1,9; 6,6] 0,0005[3]
Aromatase inhibitor	8/223 (3,6)	6/195 (3,1)	1,17 [0,41; 3,30] 0,7725[2]	1,17 [0,40; 3,44] 0,7723[3]	0,5 [-2,9; 4,0] 0,7723[3]
ECOG-PS (Interaction p-value: 0,6402)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	37/685 (5,4)	14/649 (2,2)	2,50 [1,37; 4,59] 0,0030[2]	2,59 [1,39; 4,84] 0,0020[3]	3,2 [1,2; 5,3] 0,0020[3]
ECOG-PS 1	6/91 (6,6)	3/80 (3,8)	1,76 [0,45; 6,80] 0,4136[2]	1,81 [0,44; 7,49] 0,5045[4]	2,8 [-3,7; 9,4] 0,5045[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 225.1.2: Subgroups - adverse events according PT Epistaxis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,9497)					
Negative	1/67 (1,5)	0/62 (0,0)	2,78 [0,12; 66,98] 0,5289[2]	2,82 [0,11; 70,51] 1,0000[4]	1,5 [-1,4; 4,4] 1,0000[4]
Positive	9/678 (1,3)	1/647 (0,2)	8,59 [1,09; 67,60] 0,0411[2]	8,69 [1,10; 68,79] 0,0214[4]	1,2 [0,3; 2,1] 0,0214[4]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,9796)					
ECOG-PS 0	9/685 (1,3)	1/649 (0,2)	8,53 [1,08; 67,12] 0,0417[2]	8,63 [1,09; 68,29] 0,0215[4]	1,2 [0,3; 2,1] 0,0215[4]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 226.1.2: Subgroups - adverse events according PT Erythema from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,9480)					
North America / Europe	10/347 (2,9)	2/309 (0,6)	4,45 [0,98; 20,16] 0,0526[2]	4,55 [0,99; 20,95] 0,0330[3]	2,2 [0,3; 4,2] 0,0330[3]
Asia	3/239 (1,3)	1/226 (0,4)	2,84 [0,30; 27,07] 0,3650[2]	2,86 [0,30; 27,70] 0,6240[4]	0,8 [-0,8; 2,5] 0,6240[4]
Other	3/190 (1,6)	0/194 (0,0)	7,15 [0,37; 137,43] 0,1923[2]	7,26 [0,37; 141,53] 0,1202[4]	1,6 [-0,2; 3,4] 0,1202[4]
Number of positive lymph nodes (Interaction p-value: 0,7499)					
0-3	4/269 (1,5)	1/269 (0,4)	4,00 [0,45; 35,55] 0,2136[2]	4,05 [0,45; 36,43] 0,3727[4]	1,1 [-0,5; 2,7] 0,3727[4]
4-9	9/353 (2,5)	1/326 (0,3)	8,31 [1,06; 65,24] 0,0440[2]	8,50 [1,07; 67,49] 0,0215[4]	2,2 [0,5; 4,0] 0,0215[4]
≥ 10	3/154 (1,9)	1/134 (0,7)	2,61 [0,27; 24,80] 0,4035[2]	2,64 [0,27; 25,71] 0,6260[4]	1,2 [-1,4; 3,8] 0,6260[4]
Tumor stage (Interaction p-value: 0,8030)					
IIA	1/79 (1,3)	0/77 (0,0)	2,93 [0,12; 70,72] 0,5090[2]	2,96 [0,12; 73,83] 1,0000[4]	1,3 [-1,2; 3,7] 1,0000[4]
IIB	1/73 (1,4)	0/93 (0,0)	3,81 [0,16; 92,20] 0,4105[2]	3,87 [0,16; 96,38] 0,4398[4]	1,4 [-1,3; 4,0] 0,4398[4]
IIIA	10/345 (2,9)	1/294 (0,3)	8,52 [1,10; 66,18] 0,0405[2]	8,75 [1,11; 68,73] 0,0132[3]	2,6 [0,7; 4,4] 0,0132[3]
IIIB	1/22 (4,5)	0/19 (0,0)	2,61 [0,11; 60,51] 0,5500[2]	2,72 [0,10; 70,79] 1,0000[4]	4,5 [-4,2; 13,2] 1,0000[4]
IIIC	3/253 (1,2)	2/245 (0,8)	1,45 [0,24; 8,62] 0,6811[2]	1,46 [0,24; 8,80] 1,0000[4]	0,4 [-1,4; 2,1] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,9516)					
Negative	3/67 (4,5)	0/62 (0,0)	6,49 [0,34; 123,08] 0,2132[2]	6,78 [0,34; 134,01] 0,2453[4]	4,5 [-0,5; 9,4] 0,2453[4]
Positive	13/678 (1,9)	3/647 (0,5)	4,14 [1,18; 14,44] 0,0261[2]	4,20 [1,19; 14,80] 0,0154[3]	1,5 [0,3; 2,6] 0,0154[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,8583)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
White	12/461 (2,6)	2/440 (0,5)	5,73 [1,29; 25,44] 0,0218[2]	5,85 [1,30; 26,30] 0,0091[3]	2,1 [0,6; 3,7] 0,0091[3]
Asian	3/273 (1,1)	1/243 (0,4)	2,67 [0,28; 25,50] 0,3936[2]	2,69 [0,28; 26,02] 0,6261[4]	0,7 [-0,8; 2,2] 0,6261[4]
Other	0/30 (0,0)	0/34 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,9768)					
Tamoxifen	13/553 (2,4)	3/534 (0,6)	4,18 [1,20; 14,60] 0,0248[2]	4,26 [1,21; 15,04] 0,0143[3]	1,8 [0,4; 3,2] 0,0143[3]
Aromatase inhibitor	3/223 (1,3)	0/195 (0,0)	6,13 [0,32; 117,84] 0,2296[2]	6,21 [0,32; 120,91] 0,2516[4]	1,3 [-0,2; 2,9] 0,2516[4]
ECOG-PS (Interaction p-value: 0,9784)					
ECOG-PS 0	15/685 (2,2)	3/649 (0,5)	4,74 [1,38; 16,29] 0,0136[2]	4,82 [1,39; 16,73] 0,0063[3]	1,7 [0,5; 2,9] 0,0063[3]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pre.sas
Output Location:
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 227.1.2: Subgroups - adverse events according PT Fatigue from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1913)					
Neoadjuvant chemotherapy	93/314 (29,6)	42/306 (13,7)	2,16 [1,55; 3,00] <,0001[2]	2,65 [1,76; 3,97] <,0001[3]	15,9 [9,5; 22,2] <,0001[3]
Adjuvant chemotherapy	106/452 (23,5)	41/416 (9,9)	2,38 [1,70; 3,33] <,0001[2]	2,80 [1,90; 4,13] <,0001[3]	13,6 [8,8; 18,4] <,0001[3]
No chemotherapy	3/10 (30,0)	3/7 (42,9)	0,70 [0,20; 2,51] 0,5838[2]	0,57 [0,08; 4,30] 0,6437[4]	-12,9 [-59,2; 33,5] 0,6437[4]
Region (Interaction p-value: 0,1195)					
North America / Europe	138/347 (39,8)	51/309 (16,5)	2,41 [1,82; 3,20] <,0001[2]	3,34 [2,31; 4,83] <,0001[3]	23,3 [16,7; 29,9] <,0001[3]
Asia	39/239 (16,3)	15/226 (6,6)	2,46 [1,39; 4,33] 0,0019[2]	2,74 [1,47; 5,13] 0,0011[3]	9,7 [4,0; 15,4] 0,0011[3]
Other	25/190 (13,2)	20/194 (10,3)	1,28 [0,73; 2,22] 0,3871[2]	1,32 [0,71; 2,46] 0,3856[3]	2,8 [-3,6; 9,3] 0,3856[3]
Primary tumor size (Interaction p-value: 0,0625)					
< 20 mm	56/204 (27,5)	34/189 (18,0)	1,53 [1,05; 2,23] 0,0282[2]	1,72 [1,07; 2,79] 0,0257[3]	9,5 [1,2; 17,7] 0,0257[3]
≥ 20 but < 50 mm	98/360 (27,2)	33/346 (9,5)	2,85 [1,98; 4,11] <,0001[2]	3,55 [2,31; 5,44] <,0001[3]	17,7 [12,1; 23,2] <,0001[3]
≥ 50 mm	46/194 (23,7)	19/185 (10,3)	2,31 [1,41; 3,79] 0,0009[2]	2,72 [1,52; 4,84] 0,0005[3]	13,4 [6,0; 20,9] 0,0005[3]
Number of positive lymph nodes (Interaction p-value: 0,8385)					
0-3	75/269 (27,9)	36/269 (13,4)	2,08 [1,45; 2,99] <,0001[2]	2,50 [1,61; 3,89] <,0001[3]	14,5 [7,8; 21,2] <,0001[3]
4-9	96/353 (27,2)	37/326 (11,3)	2,40 [1,69; 3,39] <,0001[2]	2,92 [1,93; 4,42] <,0001[3]	15,8 [10,1; 21,6] <,0001[3]
≥ 10	31/154 (20,1)	13/134 (9,7)	2,07 [1,13; 3,80] 0,0180[2]	2,35 [1,17; 4,70] 0,0141[3]	10,4 [2,4; 18,5] 0,0141[3]
Tumor grade (Interaction p-value: 0,3369)					
G1	16/63 (25,4)	2/52 (3,8)	6,60 [1,59; 27,41] 0,0093[2]	8,51 [1,86; 39,03] 0,0015[3]	21,6 [9,6; 33,5] 0,0015[3]
G2	103/349 (29,5)	41/323 (12,7)	2,33 [1,67; 3,23] <,0001[2]	2,88 [1,93; 4,30] <,0001[3]	16,8 [10,8; 22,8] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G3	77/317 (24,3)	41/312 (13,1)	1,85 [1,31; 2,61] 0,0005[2]	2,12 [1,40; 3,22] 0,0003[3]	11,1 [5,1; 17,2] 0,0003[3]
GX	4/44 (9,1)	2/40 (5,0)	1,82 [0,35; 9,40] 0,4756[2]	1,90 [0,33; 10,98] 0,6781[4]	4,1 [-6,8; 14,9] 0,6781[4]
Progesterone receptor status (Interaction p-value: 0,2382)					
Negative	23/67 (34,3)	6/62 (9,7)	3,55 [1,55; 8,13] 0,0028[2]	4,88 [1,83; 13,02] 0,0008[3]	24,7 [11,1; 38,2] 0,0008[3]
Positive	161/678 (23,7)	72/647 (11,1)	2,13 [1,65; 2,76] <,0001[2]	2,49 [1,84; 3,36] <,0001[3]	12,6 [8,6; 16,6] <,0001[3]
Unknown	5/8 (62,5)	4/8 (50,0)	1,25 [0,52; 3,00] 0,6178[2]	1,67 [0,23; 12,22] 1,0000[4]	12,5 [-35,7; 60,7] 1,0000[4]
Race (Interaction p-value: 0,0536)					
White	147/461 (31,9)	60/440 (13,6)	2,34 [1,78; 3,06] <,0001[2]	2,96 [2,12; 4,15] <,0001[3]	18,3 [12,9; 23,6] <,0001[3]
Asian	44/273 (16,1)	15/243 (6,2)	2,61 [1,49; 4,57] 0,0008[2]	2,92 [1,58; 5,40] 0,0004[3]	9,9 [4,6; 15,3] 0,0004[3]
Other	6/30 (20,0)	9/34 (26,5)	0,76 [0,30; 1,87] 0,5455[2]	0,69 [0,21; 2,25] 0,5420[3]	-6,5 [-27,1; 14,1] 0,5420[3]
First endocrine therapy (Interaction p-value: 0,7907)					
Tamoxifen	146/553 (26,4)	65/534 (12,2)	2,17 [1,66; 2,83] <,0001[2]	2,59 [1,88; 3,57] <,0001[3]	14,2 [9,6; 18,8] <,0001[3]
Aromatase inhibitor	56/223 (25,1)	21/195 (10,8)	2,33 [1,47; 3,71] 0,0003[2]	2,78 [1,61; 4,79] 0,0002[3]	14,3 [7,2; 21,5] 0,0002[3]
ECOG-PS (Interaction p-value: 0,4331)					
ECOG-PS 0	185/685 (27,0)	77/649 (11,9)	2,28 [1,78; 2,90] <,0001[2]	2,75 [2,05; 3,68] <,0001[3]	15,1 [11,0; 19,3] <,0001[3]
ECOG-PS 1	17/91 (18,7)	9/80 (11,3)	1,66 [0,78; 3,52] 0,1851[2]	1,81 [0,76; 4,33] 0,1769[3]	7,4 [-3,2; 18,0] 0,1769[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Output Location:
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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 228.1.2: Subgroups - adverse events according PT Flatulence from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,9497)					
Negative	1/67 (1,5)	0/62 (0,0)	2,78 [0,12; 66,98] 0,5289[2]	2,82 [0,11; 70,51] 1,0000[4]	1,5 [-1,4; 4,4] 1,0000[4]
Positive	12/678 (1,8)	2/647 (0,3)	5,73 [1,29; 25,48] 0,0220[2]	5,81 [1,30; 26,06] 0,0093[3]	1,5 [0,4; 2,5] 0,0093[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9824)					
White	8/461 (1,7)	2/440 (0,5)	3,82 [0,82; 17,88] 0,0890[2]	3,87 [0,82; 18,31] 0,1084[4]	1,3 [-0,1; 2,6] 0,1084[4]
Asian	5/273 (1,8)	0/243 (0,0)	9,80 [0,54; 176,24] 0,1217[2]	9,98 [0,55; 181,35] 0,0634[4]	1,8 [0,2; 3,4] 0,0634[4]
Other	0/30 (0,0)	0/34 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,9763)					
Tamoxifen	9/553 (1,6)	2/534 (0,4)	4,35 [0,94; 20,02] 0,0594[2]	4,40 [0,95; 20,46] 0,0391[3]	1,3 [0,1; 2,4] 0,0391[3]
Aromatase inhibitor	4/223 (1,8)	0/195 (0,0)	7,88 [0,43; 145,35] 0,1653[2]	8,02 [0,43; 149,83] 0,1266[4]	1,8 [0,1; 3,5] 0,1266[4]
ECOG-PS (Interaction p-value: 0,9771)					
ECOG-PS 0	11/685 (1,6)	2/649 (0,3)	5,21 [1,16; 23,42] 0,0313[2]	5,28 [1,17; 23,91] 0,0159[3]	1,3 [0,3; 2,3] 0,0159[3]
ECOG-PS 1	2/91 (2,2)	0/80 (0,0)	4,40 [0,21; 90,35] 0,3364[2]	4,50 [0,21; 95,08] 0,4991[4]	2,2 [-0,8; 5,2] 0,4991[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 229.1.2: Subgroups - adverse events according PT Gamma-glutamyltransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,2375)					
Neoadjuvant chemotherapy	9/314 (2,9)	2/306 (0,7)	4,39 [0,96; 20,13] 0,0573[2]	4,49 [0,96; 20,93] 0,0369[3]	2,2 [0,2; 4,3] 0,0369[3]
Adjuvant chemotherapy	19/452 (4,2)	6/416 (1,4)	2,91 [1,18; 7,23] 0,0210[2]	3,00 [1,19; 7,58] 0,0151[3]	2,8 [0,6; 4,9] 0,0151[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,7552)					
North America / Europe	5/347 (1,4)	2/309 (0,6)	2,23 [0,44; 11,39] 0,3367[2]	2,24 [0,43; 11,65] 0,4562[4]	0,8 [-0,7; 2,3] 0,4562[4]
Asia	13/239 (5,4)	4/226 (1,8)	3,07 [1,02; 9,29] 0,0466[2]	3,19 [1,03; 9,94] 0,0351[3]	3,7 [0,3; 7,0] 0,0351[3]
Other	10/190 (5,3)	2/194 (1,0)	5,11 [1,13; 22,99] 0,0337[2]	5,33 [1,15; 24,67] 0,0172[3]	4,2 [0,8; 7,7] 0,0172[3]
Primary tumor size (Interaction p-value: 0,5112)					
< 20 mm	7/204 (3,4)	2/189 (1,1)	3,24 [0,68; 15,42] 0,1391[2]	3,32 [0,68; 16,20] 0,1775[4]	2,4 [-0,5; 5,3] 0,1775[4]
≥ 20 but < 50 mm	15/360 (4,2)	3/346 (0,9)	4,81 [1,40; 16,45] 0,0124[2]	4,97 [1,43; 17,33] 0,0054[3]	3,3 [1,0; 5,6] 0,0054[3]
≥ 50 mm	5/194 (2,6)	3/185 (1,6)	1,59 [0,39; 6,56] 0,5216[2]	1,60 [0,38; 6,81] 0,7243[4]	1,0 [-1,9; 3,8] 0,7243[4]
Number of positive lymph nodes (Interaction p-value: 0,9941)					
0-3	10/269 (3,7)	3/269 (1,1)	3,33 [0,93; 11,98] 0,0651[2]	3,42 [0,93; 12,58] 0,0494[3]	2,6 [0,0; 5,2] 0,0494[3]
4-9	11/353 (3,1)	3/326 (0,9)	3,39 [0,95; 12,03] 0,0593[2]	3,46 [0,96; 12,53] 0,0442[3]	2,2 [0,1; 4,3] 0,0442[3]
≥ 10	7/154 (4,5)	2/134 (1,5)	3,05 [0,64; 14,41] 0,1602[2]	3,14 [0,64; 15,40] 0,1824[4]	3,1 [-0,8; 6,9] 0,1824[4]
Tumor stage (Interaction p-value: 0,9920)					
IIA	5/79 (6,3)	0/77 (0,0)	10,73 [0,60; 190,72] 0,1062[2]	11,44 [0,62; 210,58] 0,0586[4]	6,3 [1,0; 11,7] 0,0586[4]
IIB	2/73 (2,7)	1/93 (1,1)	2,55 [0,24; 27,55] 0,4413[2]	2,59 [0,23; 29,15] 0,5829[4]	1,7 [-2,6; 6,0] 0,5829[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	12/345 (3,5)	3/294 (1,0)	3,41 [0,97; 11,96] 0,0556[2]	3,50 [0,98; 12,51] 0,0408[3]	2,5 [0,2; 4,7] 0,0408[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	9/253 (3,6)	4/245 (1,6)	2,18 [0,68; 6,98] 0,1900[2]	2,22 [0,68; 7,31] 0,1781[3]	1,9 [-0,9; 4,7] 0,1781[3]
Tumor grade (Interaction p-value: 0,9970)					
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	15/349 (4,3)	5/323 (1,5)	2,78 [1,02; 7,55] 0,0455[2]	2,86 [1,03; 7,95] 0,0361[3]	2,8 [0,2; 5,3] 0,0361[3]
G3	7/317 (2,2)	3/312 (1,0)	2,30 [0,60; 8,80] 0,2252[2]	2,33 [0,60; 9,08] 0,3400[4]	1,2 [-0,7; 3,2] 0,3400[4]
GX	4/44 (9,1)	0/40 (0,0)	8,20 [0,46; 147,68] 0,1537[2]	9,00 [0,47; 172,65] 0,1177[4]	9,1 [0,6; 17,6] 0,1177[4]
Progesterone receptor status (Interaction p-value: 0,9993)					
Negative	3/67 (4,5)	0/62 (0,0)	6,49 [0,34; 123,08] 0,2132[2]	6,78 [0,34; 134,01] 0,2453[4]	4,5 [-0,5; 9,4] 0,2453[4]
Positive	24/678 (3,5)	8/647 (1,2)	2,86 [1,30; 6,33] 0,0093[2]	2,93 [1,31; 6,57] 0,0063[3]	2,3 [0,7; 3,9] 0,0063[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,9289)					
White	11/461 (2,4)	3/440 (0,7)	3,50 [0,98; 12,46] 0,0532[2]	3,56 [0,99; 12,85] 0,0387[3]	1,7 [0,1; 3,3] 0,0387[3]
Asian	13/273 (4,8)	4/243 (1,6)	2,89 [0,96; 8,75] 0,0601[2]	2,99 [0,96; 9,29] 0,0478[3]	3,1 [0,1; 6,1] 0,0478[3]
Other	4/30 (13,3)	1/34 (2,9)	4,53 [0,54; 38,36] 0,1654[2]	5,08 [0,53; 48,21] 0,1774[4]	10,4 [-3,0; 23,8] 0,1774[4]
First endocrine therapy (Interaction p-value: 0,7417)					
Tamoxifen	15/553 (2,7)	5/534 (0,9)	2,90 [1,06; 7,92] 0,0381[2]	2,95 [1,06; 8,17] 0,0294[3]	1,8 [0,2; 3,4] 0,0294[3]
Aromatase inhibitor	13/223 (5,8)	3/195 (1,5)	3,79 [1,10; 13,10] 0,0353[2]	3,96 [1,11; 14,12] 0,0225[3]	4,3 [0,8; 7,8] 0,0225[3]
ECOG-PS (Interaction p-value: 0,9775)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	27/685 (3,9)	8/649 (1,2)	3,20 [1,46; 6,99] 0,0036[2]	3,29 [1,48; 7,29] 0,0020[3]	2,7 [1,0; 4,4] 0,0020[3]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 230.1.2: Subgroups - adverse events according PT Gastritis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,3963)					
Neoadjuvant chemotherapy	10/314 (3,2)	2/306 (0,7)	4,87 [1,08; 22,06] 0,0398[2]	5,00 [1,09; 23,01] 0,0222[3]	2,5 [0,4; 4,7] 0,0222[3]
Adjuvant chemotherapy	12/452 (2,7)	5/416 (1,2)	2,21 [0,78; 6,22] 0,1333[2]	2,24 [0,78; 6,42] 0,1228[3]	1,5 [-0,4; 3,3] 0,1228[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,7991)					
North America / Europe	6/347 (1,7)	1/309 (0,3)	5,34 [0,65; 44,13] 0,1198[2]	5,42 [0,65; 45,27] 0,1274[4]	1,4 [-0,1; 2,9] 0,1274[4]
Asia	10/239 (4,2)	4/226 (1,8)	2,36 [0,75; 7,43] 0,1409[2]	2,42 [0,75; 7,84] 0,1278[3]	2,4 [-0,7; 5,5] 0,1278[3]
Other	6/190 (3,2)	2/194 (1,0)	3,06 [0,63; 14,99] 0,1670[2]	3,13 [0,62; 15,71] 0,1713[4]	2,1 [-0,7; 5,0] 0,1713[4]
Primary tumor size (Interaction p-value: 0,6214)					
< 20 mm	8/204 (3,9)	2/189 (1,1)	3,71 [0,80; 17,23] 0,0948[2]	3,82 [0,80; 18,20] 0,1075[4]	2,9 [-0,2; 5,9] 0,1075[4]
≥ 20 but < 50 mm	8/360 (2,2)	4/346 (1,2)	1,92 [0,58; 6,33] 0,2822[2]	1,94 [0,58; 6,51] 0,2733[3]	1,1 [-0,8; 3,0] 0,2733[3]
≥ 50 mm	6/194 (3,1)	1/185 (0,5)	5,72 [0,70; 47,07] 0,1048[2]	5,87 [0,70; 49,25] 0,1223[4]	2,6 [-0,1; 5,2] 0,1223[4]
Number of positive lymph nodes (Interaction p-value: 0,9370)					
0-3	6/269 (2,2)	3/269 (1,1)	2,00 [0,51; 7,91] 0,3233[2]	2,02 [0,50; 8,17] 0,5041[4]	1,1 [-1,1; 3,3] 0,5041[4]
4-9	12/353 (3,4)	4/326 (1,2)	2,77 [0,90; 8,50] 0,0749[2]	2,83 [0,90; 8,87] 0,0623[3]	2,2 [-0,1; 4,4] 0,0623[3]
≥ 10	4/154 (2,6)	0/134 (0,0)	7,84 [0,43; 144,27] 0,1659[2]	8,04 [0,43; 150,78] 0,1260[4]	2,6 [0,1; 5,1] 0,1260[4]
Tumor stage (Interaction p-value: 0,7615)					
IIA	3/79 (3,8)	0/77 (0,0)	6,83 [0,36; 129,97] 0,2014[2]	7,09 [0,36; 139,61] 0,2453[4]	3,8 [-0,4; 8,0] 0,2453[4]
IIB	2/73 (2,7)	1/93 (1,1)	2,55 [0,24; 27,55] 0,4413[2]	2,59 [0,23; 29,15] 0,5829[4]	1,7 [-2,6; 6,0] 0,5829[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	9/345 (2,6)	5/294 (1,7)	1,53 [0,52; 4,53] 0,4384[2]	1,55 [0,51; 4,67] 0,4345[3]	0,9 [-1,3; 3,1] 0,4345[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	8/253 (3,2)	1/245 (0,4)	7,75 [0,98; 61,48] 0,0527[2]	7,97 [0,99; 64,18] 0,0376[4]	2,8 [0,5; 5,1] 0,0376[4]
Tumor grade (Interaction p-value: 0,8078)					
G1	0/63 (0,0)	1/52 (1,9)	0,28 [0,01; 6,64] 0,4275[2]	0,27 [0,01; 6,78] 0,4522[4]	-1,9 [-5,7; 1,8] 0,4522[4]
G2	9/349 (2,6)	4/323 (1,2)	2,08 [0,65; 6,70] 0,2184[2]	2,11 [0,64; 6,92] 0,2075[3]	1,3 [-0,7; 3,4] 0,2075[3]
G3	11/317 (3,5)	2/312 (0,6)	5,41 [1,21; 24,22] 0,0272[2]	5,57 [1,22; 25,35] 0,0127[3]	2,8 [0,6; 5,0] 0,0127[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,0834)					
Negative	1/67 (1,5)	3/62 (4,8)	0,31 [0,03; 2,89] 0,3027[2]	0,30 [0,03; 2,94] 0,3505[4]	-3,3 [-9,4; 2,7] 0,3505[4]
Positive	21/678 (3,1)	4/647 (0,6)	5,01 [1,73; 14,52] 0,0030[2]	5,14 [1,75; 15,05] 0,0009[3]	2,5 [1,0; 3,9] 0,0009[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9554)					
White	10/461 (2,2)	3/440 (0,7)	3,18 [0,88; 11,48] 0,0772[2]	3,23 [0,88; 11,81] 0,0613[3]	1,5 [-0,0; 3,0] 0,0613[3]
Asian	11/273 (4,0)	4/243 (1,6)	2,45 [0,79; 7,59] 0,1209[2]	2,51 [0,79; 7,98] 0,1077[3]	2,4 [-0,4; 5,2] 0,1077[3]
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
First endocrine therapy (Interaction p-value: 0,5451)					
Tamoxifen	16/553 (2,9)	6/534 (1,1)	2,58 [1,02; 6,53] 0,0464[2]	2,62 [1,02; 6,75] 0,0383[3]	1,8 [0,1; 3,4] 0,0383[3]
Aromatase inhibitor	6/223 (2,7)	1/195 (0,5)	5,25 [0,64; 43,20] 0,1233[2]	5,36 [0,64; 44,95] 0,1278[4]	2,2 [-0,2; 4,5] 0,1278[4]
ECOG-PS (Interaction p-value: 0,9169)					
ECOG-PS 0	19/685 (2,8)	6/649 (0,9)	3,00 [1,21; 7,47] 0,0182[2]	3,06 [1,21; 7,70] 0,0128[3]	1,8 [0,4; 3,3] 0,0128[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	3/91 (3,3)	1/80 (1,3)	2,64 [0,28; 24,85] 0,3968[2]	2,69 [0,27; 26,42] 0,6237[4]	2,0 [-2,4; 6,4] 0,6237[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 231.1.2: Subgroups - adverse events according PT Haemorrhoids from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,7822)					
Neoadjuvant chemotherapy	11/314 (3,5)	6/306 (2,0)	1,79 [0,67; 4,77] 0,2468[2]	1,82 [0,66; 4,97] 0,2397[3]	1,5 [-1,0; 4,1] 0,2397[3]
Adjuvant chemotherapy	16/452 (3,5)	5/416 (1,2)	2,95 [1,09; 7,97] 0,0334[2]	3,02 [1,10; 8,31] 0,0251[3]	2,3 [0,3; 4,3] 0,0251[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,5559)					
North America / Europe	19/347 (5,5)	7/309 (2,3)	2,42 [1,03; 5,67] 0,0426[2]	2,50 [1,04; 6,03] 0,0354[3]	3,2 [0,3; 6,1] 0,0354[3]
Asia	4/239 (1,7)	3/226 (1,3)	1,26 [0,29; 5,57] 0,7598[2]	1,27 [0,28; 5,72] 1,0000[4]	0,3 [-1,9; 2,6] 1,0000[4]
Other	5/190 (2,6)	1/194 (0,5)	5,11 [0,60; 43,29] 0,1350[2]	5,22 [0,60; 45,07] 0,1187[4]	2,1 [-0,4; 4,6] 0,1187[4]
Primary tumor size (Interaction p-value: 0,0693)					
< 20 mm	12/204 (5,9)	2/189 (1,1)	5,56 [1,26; 24,51] 0,0235[2]	5,84 [1,29; 26,46] 0,0099[3]	4,8 [1,3; 8,4] 0,0099[3]
≥ 20 but < 50 mm	13/360 (3,6)	4/346 (1,2)	3,12 [1,03; 9,49] 0,0445[2]	3,20 [1,03; 9,92] 0,0334[3]	2,5 [0,2; 4,7] 0,0334[3]
≥ 50 mm	3/194 (1,5)	5/185 (2,7)	0,57 [0,14; 2,36] 0,4400[2]	0,57 [0,13; 2,40] 0,4940[4]	-1,2 [-4,1; 1,8] 0,4940[4]
Number of positive lymph nodes (Interaction p-value: 0,8540)					
0-3	12/269 (4,5)	4/269 (1,5)	3,00 [0,98; 9,18] 0,0543[2]	3,09 [0,98; 9,72] 0,0423[3]	3,0 [0,1; 5,8] 0,0423[3]
4-9	12/353 (3,4)	5/326 (1,5)	2,22 [0,79; 6,22] 0,1308[2]	2,26 [0,79; 6,48] 0,1200[3]	1,9 [-0,4; 4,2] 0,1200[3]
≥ 10	4/154 (2,6)	2/134 (1,5)	1,74 [0,32; 9,35] 0,5184[2]	1,76 [0,32; 9,76] 0,6888[4]	1,1 [-2,1; 4,3] 0,6888[4]
Tumor stage (Interaction p-value: 0,9124)					
IIA	5/79 (6,3)	0/77 (0,0)	10,73 [0,60; 190,72] 0,1062[2]	11,44 [0,62; 210,58] 0,0586[4]	6,3 [1,0; 11,7] 0,0586[4]
IIB	1/73 (1,4)	2/93 (2,2)	0,64 [0,06; 6,89] 0,7104[2]	0,63 [0,06; 7,11] 1,0000[4]	-0,8 [-4,8; 3,2] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	11/345 (3,2)	5/294 (1,7)	1,87 [0,66; 5,33] 0,2388[2]	1,90 [0,65; 5,54] 0,2303[3]	1,5 [-0,9; 3,9] 0,2303[3]
IIIB	1/22 (4,5)	0/19 (0,0)	2,61 [0,11; 60,51] 0,5500[2]	2,72 [0,10; 70,79] 1,0000[4]	4,5 [-4,2; 13,2] 1,0000[4]
IIIC	10/253 (4,0)	4/245 (1,6)	2,42 [0,77; 7,62] 0,1305[2]	2,48 [0,77; 8,01] 0,1174[3]	2,3 [-0,6; 5,2] 0,1174[3]
Tumor grade (Interaction p-value: 0,9997)					
G1	5/63 (7,9)	0/52 (0,0)	9,11 [0,52; 161,00] 0,1316[2]	9,87 [0,53; 182,84] 0,0627[4]	7,9 [1,3; 14,6] 0,0627[4]
G2	9/349 (2,6)	3/323 (0,9)	2,78 [0,76; 10,17] 0,1230[2]	2,82 [0,76; 10,52] 0,1066[3]	1,7 [-0,3; 3,6] 0,1066[3]
G3	13/317 (4,1)	5/312 (1,6)	2,56 [0,92; 7,09] 0,0709[2]	2,63 [0,92; 7,45] 0,0602[3]	2,5 [-0,1; 5,1] 0,0602[3]
GX	0/44 (0,0)	3/40 (7,5)	0,13 [0,01; 2,44] 0,1730[2]	0,12 [0,01; 2,41] 0,1037[4]	-7,5 [-15,7; 0,7] 0,1037[4]
Race (Interaction p-value: 0,6737)					
White	20/461 (4,3)	6/440 (1,4)	3,18 [1,29; 7,85] 0,0120[2]	3,28 [1,30; 8,25] 0,0077[3]	3,0 [0,8; 5,1] 0,0077[3]
Asian	5/273 (1,8)	3/243 (1,2)	1,48 [0,36; 6,14] 0,5864[2]	1,49 [0,35; 6,31] 0,7282[4]	0,6 [-1,5; 2,7] 0,7282[4]
Other	2/30 (6,7)	0/34 (0,0)	5,65 [0,28; 113,12] 0,2578[2]	6,05 [0,28; 131,25] 0,2158[4]	6,7 [-2,3; 15,6] 0,2158[4]
First endocrine therapy (Interaction p-value: 0,7302)					
Tamoxifen	21/553 (3,8)	9/534 (1,7)	2,25 [1,04; 4,87] 0,0391[2]	2,30 [1,04; 5,07] 0,0336[3]	2,1 [0,2; 4,0] 0,0336[3]
Aromatase inhibitor	7/223 (3,1)	2/195 (1,0)	3,06 [0,64; 14,56] 0,1598[2]	3,13 [0,64; 15,23] 0,1838[4]	2,1 [-0,6; 4,8] 0,1838[4]
ECOG-PS (Interaction p-value: 0,9768)					
ECOG-PS 0	27/685 (3,9)	11/649 (1,7)	2,33 [1,16; 4,65] 0,0170[2]	2,38 [1,17; 4,84] 0,0137[3]	2,2 [0,5; 4,0] 0,0137[3]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 232.1.2: Subgroups - adverse events according PT Hot flush from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8513)					
Neoadjuvant chemotherapy	56/314 (17,8)	75/306 (24,5)	0,73 [0,53; 0,99] 0,0432[2]	0,67 [0,45; 0,99] 0,0418[3]	-6,7 [-13,1; -0,3] 0,0418[3]
Adjuvant chemotherapy	74/452 (16,4)	96/416 (23,1)	0,71 [0,54; 0,93] 0,0135[2]	0,65 [0,47; 0,91] 0,0129[3]	-6,7 [-12,0; -1,4] 0,0129[3]
No chemotherapy	2/10 (20,0)	3/7 (42,9)	0,47 [0,10; 2,10] 0,3213[2]	0,33 [0,04; 2,87] 0,5928[4]	-22,9 [-67,1; 21,4] 0,5928[4]
Region (Interaction p-value: 0,1078)					
North America / Europe	81/347 (23,3)	114/309 (36,9)	0,63 [0,50; 0,80] 0,0002[2]	0,52 [0,37; 0,73] 0,0002[3]	-13,6 [-20,5; -6,6] 0,0002[3]
Asia	34/239 (14,2)	30/226 (13,3)	1,07 [0,68; 1,69] 0,7660[2]	1,08 [0,64; 1,84] 0,7659[3]	1,0 [-5,3; 7,2] 0,7659[3]
Other	17/190 (8,9)	30/194 (15,5)	0,58 [0,33; 1,01] 0,0556[2]	0,54 [0,29; 1,01] 0,0514[3]	-6,5 [-13,0; -0,0] 0,0514[3]
Primary tumor size (Interaction p-value: 0,3309)					
< 20 mm	38/204 (18,6)	47/189 (24,9)	0,75 [0,51; 1,09] 0,1352[2]	0,69 [0,43; 1,12] 0,1333[3]	-6,2 [-14,4; 1,9] 0,1333[3]
≥ 20 but < 50 mm	60/360 (16,7)	73/346 (21,1)	0,79 [0,58; 1,07] 0,1335[2]	0,75 [0,51; 1,09] 0,1322[3]	-4,4 [-10,2; 1,3] 0,1322[3]
≥ 50 mm	31/194 (16,0)	54/185 (29,2)	0,55 [0,37; 0,81] 0,0027[2]	0,46 [0,28; 0,76] 0,0021[3]	-13,2 [-21,5; -4,9] 0,0021[3]
Number of positive lymph nodes (Interaction p-value: 0,1592)					
0-3	56/269 (20,8)	66/269 (24,5)	0,85 [0,62; 1,16] 0,3042[2]	0,81 [0,54; 1,21] 0,3032[3]	-3,7 [-10,8; 3,4] 0,3032[3]
4-9	52/353 (14,7)	84/326 (25,8)	0,57 [0,42; 0,78] 0,0004[2]	0,50 [0,34; 0,73] 0,0003[3]	-11,0 [-17,1; -5,0] 0,0003[3]
≥ 10	24/154 (15,6)	24/134 (17,9)	0,87 [0,52; 1,46] 0,5974[2]	0,85 [0,46; 1,57] 0,5973[3]	-2,3 [-11,0; 6,3] 0,5973[3]
Tumor stage (Interaction p-value: 0,6537)					
IIA	14/79 (17,7)	20/77 (26,0)	0,68 [0,37; 1,25] 0,2167[2]	0,61 [0,28; 1,33] 0,2120[3]	-8,3 [-21,2; 4,7] 0,2120[3]
IIB	18/73 (24,7)	23/93 (24,7)	1,00 [0,58; 1,70] 0,9913[2]	1,00 [0,49; 2,03] 0,9913[3]	-0,1 [-13,3; 13,1] 0,9913[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	49/345 (14,2)	68/294 (23,1)	0,61 [0,44; 0,86] 0,0041[2]	0,55 [0,37; 0,83] 0,0036[3]	-8,9 [-15,0; -2,9] 0,0036[3]
IIIB	5/22 (22,7)	5/19 (26,3)	0,86 [0,29; 2,54] 0,7896[2]	0,82 [0,20; 3,43] 1,0000[4]	-3,6 [-30,0; 22,8] 1,0000[4]
IIIC	44/253 (17,4)	58/245 (23,7)	0,73 [0,52; 1,04] 0,0844[2]	0,68 [0,44; 1,05] 0,0824[3]	-6,3 [-13,4; 0,8] 0,0824[3]
Tumor grade (Interaction p-value: 0,1425)					
G1	11/63 (17,5)	16/52 (30,8)	0,57 [0,29; 1,11] 0,0995[2]	0,48 [0,20; 1,14] 0,0938[3]	-13,3 [-29,0; 2,4] 0,0938[3]
G2	53/349 (15,2)	86/323 (26,6)	0,57 [0,42; 0,78] 0,0003[2]	0,49 [0,34; 0,72] 0,0003[3]	-11,4 [-17,6; -5,3] 0,0003[3]
G3	59/317 (18,6)	69/312 (22,1)	0,84 [0,62; 1,15] 0,2762[2]	0,81 [0,55; 1,19] 0,2752[3]	-3,5 [-9,8; 2,8] 0,2752[3]
GX	6/44 (13,6)	3/40 (7,5)	1,82 [0,49; 6,79] 0,3740[2]	1,95 [0,45; 8,37] 0,4878[4]	6,1 [-6,9; 19,2] 0,4878[4]
Progesterone receptor status (Interaction p-value: 0,2188)					
Negative	14/67 (20,9)	10/62 (16,1)	1,30 [0,62; 2,70] 0,4895[2]	1,37 [0,56; 3,37] 0,4870[3]	4,8 [-8,6; 18,1] 0,4870[3]
Positive	111/678 (16,4)	160/647 (24,7)	0,66 [0,53; 0,82] 0,0002[2]	0,60 [0,45; 0,78] 0,0002[3]	-8,4 [-12,7; -4,0] 0,0002[3]
Unknown	1/8 (12,5)	2/8 (25,0)	0,50 [0,06; 4,47] 0,5353[2]	0,43 [0,03; 5,98] 1,0000[4]	-12,5 [-50,3; 25,3] 1,0000[4]
Race (Interaction p-value: 0,0765)					
White	84/461 (18,2)	128/440 (29,1)	0,63 [0,49; 0,80] 0,0002[2]	0,54 [0,40; 0,74] 0,0001[3]	-10,9 [-16,4; -5,4] 0,0001[3]
Asian	38/273 (13,9)	32/243 (13,2)	1,06 [0,68; 1,64] 0,8038[2]	1,07 [0,64; 1,77] 0,8037[3]	0,8 [-5,2; 6,7] 0,8037[3]
Other	7/30 (23,3)	7/34 (20,6)	1,13 [0,45; 2,86] 0,7910[2]	1,17 [0,36; 3,84] 0,7909[3]	2,7 [-17,6; 23,1] 0,7909[3]
First endocrine therapy (Interaction p-value: 0,2179)					
Tamoxifen	99/553 (17,9)	124/534 (23,2)	0,77 [0,61; 0,98] 0,0307[2]	0,72 [0,54; 0,97] 0,0299[3]	-5,3 [-10,1; -0,5] 0,0299[3]
Aromatase inhibitor	33/223 (14,8)	50/195 (25,6)	0,58 [0,39; 0,86] 0,0064[2]	0,50 [0,31; 0,82] 0,0056[3]	-10,8 [-18,5; -3,1] 0,0056[3]
ECOG-PS (Interaction p-value: 0,5462)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	119/685 (17,4)	161/649 (24,8)	0,70 [0,57; 0,86] 0,0009[2]	0,64 [0,49; 0,83] 0,0009[3]	-7,4 [-11,8; -3,1] 0,0009[3]
ECOG-PS 1	13/91 (14,3)	13/80 (16,3)	0,88 [0,43; 1,78] 0,7212[2]	0,86 [0,37; 1,98] 0,7211[3]	-2,0 [-12,8; 8,9] 0,7211[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 233.1.2: Subgroups - adverse events according PT Hypertriglyceridaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,5722)					
Neoadjuvant chemotherapy	15/314 (4,8)	4/306 (1,3)	3,65 [1,23; 10,89] 0,0200[2]	3,79 [1,24; 11,54] 0,0122[3]	3,5 [0,8; 6,2] 0,0122[3]
Adjuvant chemotherapy	13/452 (2,9)	8/416 (1,9)	1,50 [0,63; 3,57] 0,3648[2]	1,51 [0,62; 3,68] 0,3613[3]	1,0 [-1,1; 3,0] 0,3613[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,6736)					
North America / Europe	1/347 (0,3)	0/309 (0,0)	2,67 [0,11; 65,36] 0,5467[2]	2,68 [0,11; 66,02] 1,0000[4]	0,3 [-0,3; 0,9] 1,0000[4]
Asia	18/239 (7,5)	6/226 (2,7)	2,84 [1,15; 7,02] 0,0241[2]	2,99 [1,16; 7,67] 0,0175[3]	4,9 [0,9; 8,8] 0,0175[3]
Other	9/190 (4,7)	6/194 (3,1)	1,53 [0,56; 4,22] 0,4097[2]	1,56 [0,54; 4,47] 0,4058[3]	1,6 [-2,2; 5,5] 0,4058[3]
Primary tumor size (Interaction p-value: 0,5144)					
< 20 mm	10/204 (4,9)	2/189 (1,1)	4,63 [1,03; 20,87] 0,0459[2]	4,82 [1,04; 22,29] 0,0269[3]	3,8 [0,5; 7,1] 0,0269[3]
≥ 20 but < 50 mm	11/360 (3,1)	6/346 (1,7)	1,76 [0,66; 4,71] 0,2590[2]	1,79 [0,65; 4,88] 0,2522[3]	1,3 [-0,9; 3,6] 0,2522[3]
≥ 50 mm	5/194 (2,6)	3/185 (1,6)	1,59 [0,39; 6,56] 0,5216[2]	1,60 [0,38; 6,81] 0,7243[4]	1,0 [-1,9; 3,8] 0,7243[4]
Number of positive lymph nodes (Interaction p-value: 0,2230)					
0-3	7/269 (2,6)	1/269 (0,4)	7,00 [0,87; 56,51] 0,0678[2]	7,16 [0,87; 58,60] 0,0683[4]	2,2 [0,2; 4,3] 0,0683[4]
4-9	15/353 (4,2)	10/326 (3,1)	1,39 [0,63; 3,04] 0,4163[2]	1,40 [0,62; 3,17] 0,4139[3]	1,2 [-1,6; 4,0] 0,4139[3]
≥ 10	6/154 (3,9)	1/134 (0,7)	5,22 [0,64; 42,82] 0,1237[2]	5,39 [0,64; 45,37] 0,1268[4]	3,1 [-0,2; 6,5] 0,1268[4]
Tumor stage (Interaction p-value: 0,6328)					
IIA	3/79 (3,8)	0/77 (0,0)	6,83 [0,36; 129,97] 0,2014[2]	7,09 [0,36; 139,61] 0,2453[4]	3,8 [-0,4; 8,0] 0,2453[4]
IIB	1/73 (1,4)	1/93 (1,1)	1,27 [0,08; 20,02] 0,8632[2]	1,28 [0,08; 20,78] 1,0000[4]	0,3 [-3,1; 3,7] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	15/345 (4,3)	10/294 (3,4)	1,28 [0,58; 2,80] 0,5398[2]	1,29 [0,57; 2,92] 0,5385[3]	0,9 [-2,0; 3,9] 0,5385[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	8/253 (3,2)	1/245 (0,4)	7,75 [0,98; 61,48] 0,0527[2]	7,97 [0,99; 64,18] 0,0376[4]	2,8 [0,5; 5,1] 0,0376[4]
Tumor grade (Interaction p-value: 0,9989)					
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	15/349 (4,3)	7/323 (2,2)	1,98 [0,82; 4,80] 0,1291[2]	2,03 [0,82; 5,04] 0,1209[3]	2,1 [-0,5; 4,8] 0,1209[3]
G3	9/317 (2,8)	5/312 (1,6)	1,77 [0,60; 5,23] 0,3002[2]	1,79 [0,59; 5,41] 0,2932[3]	1,2 [-1,1; 3,5] 0,2932[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,6222)					
Negative	2/67 (3,0)	1/62 (1,6)	1,85 [0,17; 19,91] 0,6115[2]	1,88 [0,17; 21,23] 1,0000[4]	1,4 [-3,8; 6,5] 1,0000[4]
Positive	26/678 (3,8)	11/647 (1,7)	2,26 [1,12; 4,53] 0,0221[2]	2,31 [1,13; 4,71] 0,0184[3]	2,1 [0,4; 3,9] 0,0184[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,6460)					
White	7/461 (1,5)	5/440 (1,1)	1,34 [0,43; 4,18] 0,6183[2]	1,34 [0,42; 4,26] 0,6170[3]	0,4 [-1,1; 1,9] 0,6170[3]
Asian	18/273 (6,6)	6/243 (2,5)	2,67 [1,08; 6,62] 0,0339[2]	2,79 [1,09; 7,14] 0,0264[3]	4,1 [0,6; 7,7] 0,0264[3]
Other	2/30 (6,7)	1/34 (2,9)	2,27 [0,22; 23,76] 0,4949[2]	2,36 [0,20; 27,39] 0,5961[4]	3,7 [-6,9; 14,3] 0,5961[4]
First endocrine therapy (Interaction p-value: 0,5804)					
Tamoxifen	13/553 (2,4)	7/534 (1,3)	1,79 [0,72; 4,46] 0,2090[2]	1,81 [0,72; 4,58] 0,2021[3]	1,0 [-0,5; 2,6] 0,2021[3]
Aromatase inhibitor	15/223 (6,7)	5/195 (2,6)	2,62 [0,97; 7,09] 0,0571[2]	2,74 [0,98; 7,68] 0,0467[3]	4,2 [0,2; 8,1] 0,0467[3]
ECOG-PS (Interaction p-value: 0,9729)					
ECOG-PS 0	23/685 (3,4)	12/649 (1,8)	1,82 [0,91; 3,62] 0,0900[2]	1,84 [0,91; 3,74] 0,0849[3]	1,5 [-0,2; 3,2] 0,0849[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	5/91 (5,5)	0/80 (0,0)	9,68 [0,54; 172,46] 0,1222[2]	10,24 [0,56; 188,09] 0,0614[4]	5,5 [0,8; 10,2] 0,0614[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 234.1.2: Subgroups - adverse events according PT Hyperuricaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: 0,9796)					
ECOG-PS 0	9/685 (1,3)	1/649 (0,2)	8,53 [1,08; 67,12] 0,0417[2]	8,63 [1,09; 68,29] 0,0215[4]	1,2 [0,3; 2,1] 0,0215[4]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 235.1.2: Subgroups - adverse events according PT Hypokalaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,2843)					
Neoadjuvant chemotherapy	13/314 (4,1)	2/306 (0,7)	6,33 [1,44; 27,84] 0,0145[2]	6,56 [1,47; 29,34] 0,0047[3]	3,5 [1,1; 5,9] 0,0047[3]
Adjuvant chemotherapy	12/452 (2,7)	4/416 (1,0)	2,76 [0,90; 8,49] 0,0765[2]	2,81 [0,90; 8,78] 0,0639[3]	1,7 [-0,1; 3,4] 0,0639[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,5365)					
North America / Europe	7/347 (2,0)	3/309 (1,0)	2,08 [0,54; 7,97] 0,2861[2]	2,10 [0,54; 8,19] 0,3483[4]	1,0 [-0,8; 2,9] 0,3483[4]
Asia	12/239 (5,0)	2/226 (0,9)	5,67 [1,28; 25,07] 0,0220[2]	5,92 [1,31; 26,76] 0,0091[3]	4,1 [1,1; 7,2] 0,0091[3]
Other	6/190 (3,2)	1/194 (0,5)	6,13 [0,74; 50,41] 0,0919[2]	6,29 [0,75; 52,78] 0,0654[4]	2,6 [-0,0; 5,3] 0,0654[4]
Primary tumor size (Interaction p-value: 0,6993)					
< 20 mm	8/204 (3,9)	1/189 (0,5)	7,41 [0,94; 58,70] 0,0578[2]	7,67 [0,95; 61,94] 0,0381[4]	3,4 [0,5; 6,2] 0,0381[4]
≥ 20 but < 50 mm	12/360 (3,3)	3/346 (0,9)	3,84 [1,09; 13,51] 0,0357[2]	3,94 [1,10; 14,09] 0,0231[3]	2,5 [0,4; 4,6] 0,0231[3]
≥ 50 mm	5/194 (2,6)	2/185 (1,1)	2,38 [0,47; 12,14] 0,2954[2]	2,42 [0,46; 12,63] 0,4497[4]	1,5 [-1,2; 4,2] 0,4497[4]
Number of positive lymph nodes (Interaction p-value: 0,0514)					
0-3	3/269 (1,1)	4/269 (1,5)	0,75 [0,17; 3,32] 0,7046[2]	0,75 [0,17; 3,37] 1,0000[4]	-0,4 [-2,3; 1,5] 1,0000[4]
4-9	11/353 (3,1)	1/326 (0,3)	10,16 [1,32; 78,25] 0,0260[2]	10,45 [1,34; 81,42] 0,0055[3]	2,8 [0,9; 4,7] 0,0055[3]
≥ 10	11/154 (7,1)	1/134 (0,7)	9,57 [1,25; 73,17] 0,0295[2]	10,23 [1,30; 80,33] 0,0067[3]	6,4 [2,1; 10,7] 0,0067[3]
Tumor stage (Interaction p-value: 0,7786)					
IIA	1/79 (1,3)	1/77 (1,3)	0,97 [0,06; 15,31] 0,9854[2]	0,97 [0,06; 15,86] 1,0000[4]	-0,0 [-3,6; 3,5] 1,0000[4]
IIB	0/73 (0,0)	2/93 (2,2)	0,25 [0,01; 5,21] 0,3740[2]	0,25 [0,01; 5,27] 0,5043[4]	-2,2 [-5,1; 0,8] 0,5043[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	10/345 (2,9)	1/294 (0,3)	8,52 [1,10; 66,18] 0,0405[2]	8,75 [1,11; 68,73] 0,0132[3]	2,6 [0,7; 4,4] 0,0132[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	14/253 (5,5)	2/245 (0,8)	6,78 [1,56; 29,52] 0,0108[2]	7,12 [1,60; 31,65] 0,0028[3]	4,7 [1,7; 7,8] 0,0028[3]
Tumor grade (Interaction p-value: 0,7002)					
G1	4/63 (6,3)	0/52 (0,0)	7,45 [0,41; 135,32] 0,1745[2]	7,94 [0,42; 151,00] 0,1253[4]	6,3 [0,3; 12,4] 0,1253[4]
G2	12/349 (3,4)	2/323 (0,6)	5,55 [1,25; 24,62] 0,0241[2]	5,72 [1,27; 25,73] 0,0106[3]	2,8 [0,7; 4,9] 0,0106[3]
G3	7/317 (2,2)	4/312 (1,3)	1,72 [0,51; 5,83] 0,3818[2]	1,74 [0,50; 6,00] 0,3756[3]	0,9 [-1,1; 3,0] 0,3756[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,1138)					
Negative	1/67 (1,5)	1/62 (1,6)	0,93 [0,06; 14,48] 0,9559[2]	0,92 [0,06; 15,10] 1,0000[4]	-0,1 [-4,4; 4,2] 1,0000[4]
Positive	23/678 (3,4)	5/647 (0,8)	4,39 [1,68; 11,48] 0,0026[2]	4,51 [1,70; 11,93] 0,0009[3]	2,6 [1,1; 4,1] 0,0009[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,2377)					
White	7/461 (1,5)	1/440 (0,2)	6,68 [0,83; 54,08] 0,0751[2]	6,77 [0,83; 55,24] 0,0697[4]	1,3 [0,1; 2,5] 0,0697[4]
Asian	13/273 (4,8)	2/243 (0,8)	5,79 [1,32; 25,38] 0,0200[2]	6,03 [1,35; 26,97] 0,0079[3]	3,9 [1,2; 6,7] 0,0079[3]
Other	3/30 (10,0)	3/34 (8,8)	1,13 [0,25; 5,20] 0,8720[2]	1,15 [0,21; 6,17] 1,0000[4]	1,2 [-13,2; 15,5] 1,0000[4]
ECOG-PS (Interaction p-value: 0,9763)					
ECOG-PS 0	23/685 (3,4)	6/649 (0,9)	3,63 [1,49; 8,86] 0,0046[2]	3,72 [1,51; 9,20] 0,0023[3]	2,4 [0,9; 4,0] 0,0023[3]
ECOG-PS 1	2/91 (2,2)	0/80 (0,0)	4,40 [0,21; 90,35] 0,3364[2]	4,50 [0,21; 95,08] 0,4991[4]	2,2 [-0,8; 5,2] 0,4991[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 236.1.2: Subgroups - adverse events according PT Lacrimation increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9261)					
Neoadjuvant chemotherapy	16/314 (5,1)	0/306 (0,0)	32,16 [1,94; 533,72] 0,0155[2]	33,88 [2,02; 567,34] <,0001[3]	5,1 [2,7; 7,5] <,0001[3]
Adjuvant chemotherapy	19/452 (4,2)	2/416 (0,5)	8,74 [2,05; 37,31] 0,0034[2]	9,08 [2,10; 39,24] 0,0004[3]	3,7 [1,8; 5,7] 0,0004[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,8885)					
North America / Europe	21/347 (6,1)	1/309 (0,3)	18,70 [2,53; 138,21] 0,0041[2]	19,84 [2,65; 148,39] <,0001[3]	5,7 [3,1; 8,3] <,0001[3]
Asia	6/239 (2,5)	0/226 (0,0)	12,30 [0,70; 217,02] 0,0867[2]	12,61 [0,71; 225,15] 0,0306[4]	2,5 [0,5; 4,5] 0,0306[4]
Other	9/190 (4,7)	1/194 (0,5)	9,19 [1,18; 71,83] 0,0345[2]	9,60 [1,20; 76,50] 0,0101[4]	4,2 [1,0; 7,4] 0,0101[4]
Primary tumor size (Interaction p-value: 0,9729)					
< 20 mm	12/204 (5,9)	2/189 (1,1)	5,56 [1,26; 24,51] 0,0235[2]	5,84 [1,29; 26,46] 0,0099[3]	4,8 [1,3; 8,4] 0,0099[3]
≥ 20 but < 50 mm	13/360 (3,6)	0/346 (0,0)	25,95 [1,55; 434,90] 0,0236[2]	26,92 [1,59; 454,66] 0,0004[3]	3,6 [1,7; 5,5] 0,0004[3]
≥ 50 mm	9/194 (4,6)	0/185 (0,0)	18,12 [1,06; 309,17] 0,0453[2]	19,00 [1,10; 328,83] 0,0036[4]	4,6 [1,7; 7,6] 0,0036[4]
Number of positive lymph nodes (Interaction p-value: 0,9582)					
0-3	14/269 (5,2)	0/269 (0,0)	29,00 [1,74; 483,69] 0,0190[2]	30,59 [1,82; 515,44] 0,0001[3]	5,2 [2,6; 7,9] 0,0001[3]
4-9	13/353 (3,7)	1/326 (0,3)	12,01 [1,58; 91,26] 0,0163[2]	12,43 [1,62; 95,53] 0,0020[3]	3,4 [1,3; 5,4] 0,0020[3]
≥ 10	9/154 (5,8)	1/134 (0,7)	7,83 [1,01; 61,01] 0,0494[2]	8,26 [1,03; 66,03] 0,0223[4]	5,1 [1,1; 9,1] 0,0223[4]
Tumor stage (Interaction p-value: 0,9992)					
IIA	5/79 (6,3)	0/77 (0,0)	10,73 [0,60; 190,72] 0,1062[2]	11,44 [0,62; 210,58] 0,0586[4]	6,3 [1,0; 11,7] 0,0586[4]
IIB	1/73 (1,4)	0/93 (0,0)	3,81 [0,16; 92,20] 0,4105[2]	3,87 [0,16; 96,38] 0,4398[4]	1,4 [-1,3; 4,0] 0,4398[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	12/345 (3,5)	1/294 (0,3)	10,23 [1,34; 78,18] 0,0251[2]	10,56 [1,36; 81,69] 0,0051[3]	3,1 [1,1; 5,2] 0,0051[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	16/253 (6,3)	1/245 (0,4)	15,49 [2,07; 115,94] 0,0076[2]	16,47 [2,17; 125,20] 0,0003[3]	5,9 [2,8; 9,0] 0,0003[3]
Race (Interaction p-value: 0,9994)					
White	24/461 (5,2)	2/440 (0,5)	11,45 [2,72; 48,18] 0,0009[2]	12,03 [2,83; 51,20] <,0001[3]	4,8 [2,6; 6,9] <,0001[3]
Asian	8/273 (2,9)	0/243 (0,0)	15,14 [0,88; 260,92] 0,0614[2]	15,59 [0,90; 271,56] 0,0081[4]	2,9 [0,9; 4,9] 0,0081[4]
Other	4/30 (13,3)	0/34 (0,0)	10,16 [0,57; 181,28] 0,1148[2]	11,72 [0,60; 227,31] 0,0431[4]	13,3 [1,2; 25,5] 0,0431[4]
First endocrine therapy (Interaction p-value: 0,3015)					
Tamoxifen	29/553 (5,2)	1/534 (0,2)	28,00 [3,83; 204,85] 0,0010[2]	29,50 [4,00; 217,33] <,0001[3]	5,1 [3,2; 7,0] <,0001[3]
Aromatase inhibitor	7/223 (3,1)	1/195 (0,5)	6,12 [0,76; 49,31] 0,0888[2]	6,29 [0,77; 51,56] 0,0726[4]	2,6 [0,1; 5,1] 0,0726[4]
ECOG-PS (Interaction p-value: 0,9786)					
ECOG-PS 0	33/685 (4,8)	2/649 (0,3)	15,63 [3,77; 64,88] 0,0002[2]	16,37 [3,91; 68,52] <,0001[3]	4,5 [2,9; 6,2] <,0001[3]
ECOG-PS 1	3/91 (3,3)	0/80 (0,0)	6,16 [0,32; 117,53] 0,2267[2]	6,37 [0,32; 125,17] 0,2487[4]	3,3 [-0,4; 7,0] 0,2487[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 237.1.2: Subgroups - adverse events according PT Leukopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8114)					
Neoadjuvant chemotherapy	30/314 (9,6)	7/306 (2,3)	4,18 [1,86; 9,36] 0,0005[2]	4,51 [1,95; 10,44] 0,0001[3]	7,3 [3,6; 10,9] 0,0001[3]
Adjuvant chemotherapy	52/452 (11,5)	8/416 (1,9)	5,98 [2,88; 12,44] <,0001[2]	6,63 [3,11; 14,13] <,0001[3]	9,6 [6,4; 12,8] <,0001[3]
No chemotherapy	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Region (Interaction p-value: 0,7714)					
North America / Europe	24/347 (6,9)	3/309 (1,0)	7,12 [2,17; 23,43] 0,0012[2]	7,58 [2,26; 25,43] 0,0001[3]	5,9 [3,1; 8,8] 0,0001[3]
Asia	12/239 (5,0)	3/226 (1,3)	3,78 [1,08; 13,23] 0,0373[2]	3,93 [1,09; 14,11] 0,0243[3]	3,7 [0,5; 6,8] 0,0243[3]
Other	48/190 (25,3)	9/194 (4,6)	5,45 [2,75; 10,78] <,0001[2]	6,95 [3,30; 14,63] <,0001[3]	20,6 [13,8; 27,5] <,0001[3]
Primary tumor size (Interaction p-value: 0,1054)					
< 20 mm	22/204 (10,8)	8/189 (4,2)	2,55 [1,16; 5,58] 0,0195[2]	2,73 [1,19; 6,30] 0,0145[3]	6,6 [1,4; 11,7] 0,0145[3]
≥ 20 but < 50 mm	40/360 (11,1)	5/346 (1,4)	7,69 [3,07; 19,25] <,0001[2]	8,53 [3,32; 21,87] <,0001[3]	9,7 [6,2; 13,1] <,0001[3]
≥ 50 mm	21/194 (10,8)	2/185 (1,1)	10,01 [2,38; 42,11] 0,0017[2]	11,11 [2,57; 48,08] <,0001[3]	9,7 [5,1; 14,4] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,6584)					
0-3	25/269 (9,3)	6/269 (2,2)	4,17 [1,74; 9,99] 0,0014[2]	4,49 [1,81; 11,13] 0,0004[3]	7,1 [3,2; 11,0] 0,0004[3]
4-9	39/353 (11,0)	5/326 (1,5)	7,20 [2,87; 18,05] <,0001[2]	7,97 [3,10; 20,49] <,0001[3]	9,5 [6,0; 13,0] <,0001[3]
≥ 10	20/154 (13,0)	4/134 (3,0)	4,35 [1,53; 12,41] 0,0060[2]	4,85 [1,61; 14,58] 0,0022[3]	10,0 [4,0; 16,0] 0,0022[3]
Tumor stage (Interaction p-value: 0,9798)					
IIA	9/79 (11,4)	1/77 (1,3)	8,77 [1,14; 67,60] 0,0371[2]	9,77 [1,21; 79,11] 0,0178[4]	10,1 [2,6; 17,5] 0,0178[4]
IIB	5/73 (6,8)	1/93 (1,1)	6,37 [0,76; 53,34] 0,0877[2]	6,76 [0,77; 59,23] 0,0878[4]	5,8 [-0,4; 11,9] 0,0878[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	35/345 (10,1)	6/294 (2,0)	4,97 [2,12; 11,65] 0,0002[2]	5,42 [2,25; 13,08] <,0001[3]	8,1 [4,5; 11,7] <,0001[3]
IIIB	3/22 (13,6)	0/19 (0,0)	6,09 [0,33; 110,84] 0,2225[2]	7,00 [0,34; 144,73] 0,2354[4]	13,6 [-0,7; 28,0] 0,2354[4]
IIIC	32/253 (12,6)	7/245 (2,9)	4,43 [1,99; 9,84] 0,0003[2]	4,92 [2,13; 11,38] <,0001[3]	9,8 [5,2; 14,4] <,0001[3]
Tumor grade (Interaction p-value: 0,8748)					
G1	5/63 (7,9)	1/52 (1,9)	4,13 [0,50; 34,22] 0,1891[2]	4,40 [0,50; 38,88] 0,2195[4]	6,0 [-1,6; 13,7] 0,2195[4]
G2	41/349 (11,7)	6/323 (1,9)	6,32 [2,72; 14,70] <,0001[2]	7,03 [2,94; 16,80] <,0001[3]	9,9 [6,2; 13,6] <,0001[3]
G3	32/317 (10,1)	8/312 (2,6)	3,94 [1,84; 8,41] 0,0004[2]	4,27 [1,93; 9,41] 0,0001[3]	7,5 [3,8; 11,3] 0,0001[3]
GX	6/44 (13,6)	0/40 (0,0)	11,84 [0,69; 203,77] 0,0886[2]	13,68 [0,74; 251,05] 0,0268[4]	13,6 [3,5; 23,8] 0,0268[4]
Progesterone receptor status (Interaction p-value: 0,9577)					
Negative	5/67 (7,5)	0/62 (0,0)	10,19 [0,58; 180,59] 0,1135[2]	11,00 [0,60; 203,18] 0,0586[4]	7,5 [1,2; 13,8] 0,0586[4]
Positive	79/678 (11,7)	15/647 (2,3)	5,03 [2,92; 8,64] <,0001[2]	5,56 [3,16; 9,76] <,0001[3]	9,3 [6,7; 12,0] <,0001[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,8036)					
White	63/461 (13,7)	10/440 (2,3)	6,01 [3,13; 11,57] <,0001[2]	6,81 [3,44; 13,45] <,0001[3]	11,4 [8,0; 14,8] <,0001[3]
Asian	14/273 (5,1)	3/243 (1,2)	4,15 [1,21; 14,28] 0,0238[2]	4,32 [1,23; 15,23] 0,0134[3]	3,9 [0,9; 6,9] 0,0134[3]
Other	7/30 (23,3)	2/34 (5,9)	3,97 [0,89; 17,65] 0,0704[2]	4,87 [0,93; 25,62] 0,0709[4]	17,5 [0,4; 34,5] 0,0709[4]
First endocrine therapy (Interaction p-value: 0,3175)					
Tamoxifen	54/553 (9,8)	8/534 (1,5)	6,52 [3,13; 13,57] <,0001[2]	7,12 [3,35; 15,10] <,0001[3]	8,3 [5,6; 10,9] <,0001[3]
Aromatase inhibitor	30/223 (13,5)	7/195 (3,6)	3,75 [1,68; 8,34] 0,0012[2]	4,17 [1,79; 9,74] 0,0004[3]	9,9 [4,7; 15,0] 0,0004[3]
ECOG-PS (Interaction p-value: 0,4747)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	77/685 (11,2)	13/649 (2,0)	5,61 [3,15; 10,00] <,0001[2]	6,20 [3,41; 11,27] <,0001[3]	9,2 [6,6; 11,8] <,0001[3]
ECOG-PS 1	7/91 (7,7)	2/80 (2,5)	3,08 [0,66; 14,39] 0,1533[2]	3,25 [0,66; 16,12] 0,1763[4]	5,2 [-1,3; 11,6] 0,1763[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 238.1.2: Subgroups - adverse events according PT Lymphocyte count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,5242)					
Neoadjuvant chemotherapy	30/314 (9,6)	11/306 (3,6)	2,66 [1,36; 5,21] 0,0044[2]	2,83 [1,39; 5,76] 0,0028[3]	6,0 [2,1; 9,8] 0,0028[3]
Adjuvant chemotherapy	45/452 (10,0)	13/416 (3,1)	3,19 [1,74; 5,82] 0,0002[2]	3,43 [1,82; 6,45] <,0001[3]	6,8 [3,6; 10,1] <,0001[3]
No chemotherapy	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Region (Interaction p-value: 0,2482)					
North America / Europe	22/347 (6,3)	7/309 (2,3)	2,80 [1,21; 6,46] 0,0159[2]	2,92 [1,23; 6,93] 0,0113[3]	4,1 [1,0; 7,1] 0,0113[3]
Asia	34/239 (14,2)	7/226 (3,1)	4,59 [2,08; 10,15] 0,0002[2]	5,19 [2,25; 11,97] <,0001[3]	11,1 [6,2; 16,1] <,0001[3]
Other	20/190 (10,5)	11/194 (5,7)	1,86 [0,91; 3,77] 0,0868[2]	1,96 [0,91; 4,21] 0,0807[3]	4,9 [-0,6; 10,3] 0,0807[3]
Primary tumor size (Interaction p-value: 0,7277)					
< 20 mm	19/204 (9,3)	5/189 (2,6)	3,52 [1,34; 9,24] 0,0106[2]	3,78 [1,38; 10,34] 0,0058[3]	6,7 [2,1; 11,3] 0,0058[3]
≥ 20 but < 50 mm	34/360 (9,4)	14/346 (4,0)	2,33 [1,28; 4,27] 0,0060[2]	2,47 [1,30; 4,69] 0,0044[3]	5,4 [1,7; 9,1] 0,0044[3]
≥ 50 mm	20/194 (10,3)	6/185 (3,2)	3,18 [1,31; 7,74] 0,0109[2]	3,43 [1,35; 8,74] 0,0065[3]	7,1 [2,1; 12,0] 0,0065[3]
Number of positive lymph nodes (Interaction p-value: 0,1076)					
0-3	28/269 (10,4)	7/269 (2,6)	4,00 [1,78; 9,00] 0,0008[2]	4,35 [1,87; 10,14] 0,0002[3]	7,8 [3,7; 11,9] 0,0002[3]
4-9	39/353 (11,0)	11/326 (3,4)	3,27 [1,71; 6,28] 0,0004[2]	3,56 [1,79; 7,07] 0,0001[3]	7,7 [3,9; 11,5] 0,0001[3]
≥ 10	9/154 (5,8)	7/134 (5,2)	1,12 [0,43; 2,92] 0,8188[2]	1,13 [0,41; 3,11] 0,8187[3]	0,6 [-4,7; 5,9] 0,8187[3]
Tumor stage (Interaction p-value: 0,5623)					
IIA	9/79 (11,4)	0/77 (0,0)	18,53 [1,10; 312,87] 0,0430[2]	20,89 [1,19; 365,46] 0,0031[4]	11,4 [4,4; 18,4] 0,0031[4]
IIB	11/73 (15,1)	5/93 (5,4)	2,80 [1,02; 7,71] 0,0459[2]	3,12 [1,03; 9,44] 0,0357[3]	9,7 [0,3; 19,1] 0,0357[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	39/345 (11,3)	10/294 (3,4)	3,32 [1,69; 6,54] 0,0005[2]	3,62 [1,77; 7,39] 0,0002[3]	7,9 [4,0; 11,8] 0,0002[3]
IIIB	3/22 (13,6)	0/19 (0,0)	6,09 [0,33; 110,84] 0,2225[2]	7,00 [0,34; 144,73] 0,2354[4]	13,6 [-0,7; 28,0] 0,2354[4]
IIIC	14/253 (5,5)	10/245 (4,1)	1,36 [0,61; 2,99] 0,4515[2]	1,38 [0,60; 3,16] 0,4494[3]	1,5 [-2,3; 5,2] 0,4494[3]
Tumor grade (Interaction p-value: 0,1942)					
G1	8/63 (12,7)	1/52 (1,9)	6,60 [0,85; 51,10] 0,0706[2]	7,42 [0,90; 61,40] 0,0393[4]	10,8 [1,7; 19,8] 0,0393[4]
G2	39/349 (11,2)	10/323 (3,1)	3,61 [1,83; 7,11] 0,0002[2]	3,94 [1,93; 8,03] <,0001[3]	8,1 [4,3; 11,9] <,0001[3]
G3	21/317 (6,6)	13/312 (4,2)	1,59 [0,81; 3,12] 0,1774[2]	1,63 [0,80; 3,32] 0,1729[3]	2,5 [-1,1; 6,0] 0,1729[3]
GX	8/44 (18,2)	1/40 (2,5)	7,27 [0,95; 55,61] 0,0559[2]	8,67 [1,03; 72,76] 0,0311[4]	15,7 [3,3; 28,1] 0,0311[4]
Progesterone receptor status (Interaction p-value: 0,9994)					
Negative	9/67 (13,4)	3/62 (4,8)	2,78 [0,79; 9,79] 0,1123[2]	3,05 [0,79; 11,84] 0,0932[3]	8,6 [-1,2; 18,4] 0,0932[3]
Positive	62/678 (9,1)	21/647 (3,2)	2,82 [1,74; 4,57] <,0001[2]	3,00 [1,81; 4,98] <,0001[3]	5,9 [3,3; 8,5] <,0001[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,4094)					
White	40/461 (8,7)	17/440 (3,9)	2,25 [1,29; 3,90] 0,0041[2]	2,36 [1,32; 4,24] 0,0030[3]	4,8 [1,7; 8,0] 0,0030[3]
Asian	34/273 (12,5)	7/243 (2,9)	4,32 [1,95; 9,57] 0,0003[2]	4,80 [2,08; 11,03] <,0001[3]	9,6 [5,1; 14,0] <,0001[3]
Other	2/30 (6,7)	1/34 (2,9)	2,27 [0,22; 23,76] 0,4949[2]	2,36 [0,20; 27,39] 0,5961[4]	3,7 [-6,9; 14,3] 0,5961[4]
First endocrine therapy (Interaction p-value: 0,0940)					
Tamoxifen	57/553 (10,3)	15/534 (2,8)	3,67 [2,10; 6,40] <,0001[2]	3,98 [2,22; 7,12] <,0001[3]	7,5 [4,6; 10,4] <,0001[3]
Aromatase inhibitor	19/223 (8,5)	10/195 (5,1)	1,66 [0,79; 3,49] 0,1795[2]	1,72 [0,78; 3,80] 0,1733[3]	3,4 [-1,4; 8,2] 0,1733[3]
ECOG-PS (Interaction p-value: 0,8508)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	72/685 (10,5)	24/649 (3,7)	2,84 [1,81; 4,45] <,0001[2]	3,06 [1,90; 4,92] <,0001[3]	6,8 [4,1; 9,5] <,0001[3]
ECOG-PS 1	4/91 (4,4)	1/80 (1,3)	3,52 [0,40; 30,82] 0,2562[2]	3,63 [0,40; 33,19] 0,3729[4]	3,1 [-1,7; 8,0] 0,3729[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 239.1.2: Subgroups - adverse events according PT Lymphoedema from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,2865)					
Neoadjuvant chemotherapy	49/314 (15,6)	25/306 (8,2)	1,91 [1,21; 3,01] 0,0053[2]	2,08 [1,25; 3,46] 0,0043[3]	7,4 [2,4; 12,5] 0,0043[3]
Adjuvant chemotherapy	54/452 (11,9)	42/416 (10,1)	1,18 [0,81; 1,73] 0,3861[2]	1,21 [0,79; 1,85] 0,3851[3]	1,9 [-2,3; 6,0] 0,3851[3]
No chemotherapy	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Region (Interaction p-value: 0,4596)					
North America / Europe	49/347 (14,1)	34/309 (11,0)	1,28 [0,85; 1,93] 0,2327[2]	1,33 [0,83; 2,12] 0,2305[3]	3,1 [-1,9; 8,2] 0,2305[3]
Asia	33/239 (13,8)	22/226 (9,7)	1,42 [0,85; 2,36] 0,1774[2]	1,49 [0,84; 2,63] 0,1740[3]	4,1 [-1,8; 9,9] 0,1740[3]
Other	23/190 (12,1)	11/194 (5,7)	2,13 [1,07; 4,26] 0,0312[2]	2,29 [1,08; 4,84] 0,0265[3]	6,4 [0,8; 12,1] 0,0265[3]
Primary tumor size (Interaction p-value: 0,0697)					
< 20 mm	25/204 (12,3)	19/189 (10,1)	1,22 [0,69; 2,14] 0,4903[2]	1,25 [0,66; 2,35] 0,4891[3]	2,2 [-4,0; 8,4] 0,4891[3]
≥ 20 but < 50 mm	45/360 (12,5)	36/346 (10,4)	1,20 [0,80; 1,82] 0,3835[2]	1,23 [0,77; 1,96] 0,3825[3]	2,1 [-2,6; 6,8] 0,3825[3]
≥ 50 mm	33/194 (17,0)	11/185 (5,9)	2,86 [1,49; 5,49] 0,0016[2]	3,24 [1,59; 6,63] 0,0008[3]	11,1 [4,8; 17,4] 0,0008[3]
Number of positive lymph nodes (Interaction p-value: 0,3751)					
0-3	34/269 (12,6)	24/269 (8,9)	1,42 [0,86; 2,32] 0,1674[2]	1,48 [0,85; 2,57] 0,1645[3]	3,7 [-1,5; 8,9] 0,1645[3]
4-9	47/353 (13,3)	34/326 (10,4)	1,28 [0,84; 1,93] 0,2485[2]	1,32 [0,82; 2,11] 0,2466[3]	2,9 [-2,0; 7,7] 0,2466[3]
≥ 10	24/154 (15,6)	9/134 (6,7)	2,32 [1,12; 4,82] 0,0239[2]	2,56 [1,15; 5,73] 0,0184[3]	8,9 [1,7; 16,0] 0,0184[3]
Tumor stage (Interaction p-value: 0,8083)					
IIA	10/79 (12,7)	10/77 (13,0)	0,97 [0,43; 2,21] 0,9510[2]	0,97 [0,38; 2,48] 0,9510[3]	-0,3 [-10,8; 10,2] 0,9510[3]
IIB	10/73 (13,7)	9/93 (9,7)	1,42 [0,61; 3,30] 0,4212[2]	1,48 [0,57; 3,86] 0,4192[3]	4,0 [-5,9; 13,9] 0,4192[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	48/345 (13,9)	28/294 (9,5)	1,46 [0,94; 2,27] 0,0909[2]	1,54 [0,94; 2,52] 0,0876[3]	4,4 [-0,6; 9,3] 0,0876[3]
IIIB	3/22 (13,6)	1/19 (5,3)	2,59 [0,29; 22,88] 0,3917[2]	2,84 [0,27; 29,90] 0,6099[4]	8,4 [-9,1; 25,9] 0,6099[4]
IIIC	34/253 (13,4)	19/245 (7,8)	1,73 [1,02; 2,95] 0,0433[2]	1,85 [1,02; 3,34] 0,0398[3]	5,7 [0,3; 11,1] 0,0398[3]
Tumor grade (Interaction p-value: 0,3462)					
G1	12/63 (19,0)	4/52 (7,7)	2,48 [0,85; 7,22] 0,0968[2]	2,82 [0,85; 9,36] 0,0799[3]	11,4 [-0,7; 23,5] 0,0799[3]
G2	51/349 (14,6)	26/323 (8,0)	1,82 [1,16; 2,84] 0,0090[2]	1,95 [1,19; 3,22] 0,0076[3]	6,6 [1,8; 11,3] 0,0076[3]
G3	40/317 (12,6)	35/312 (11,2)	1,12 [0,73; 1,72] 0,5882[2]	1,14 [0,70; 1,85] 0,5879[3]	1,4 [-3,7; 6,5] 0,5879[3]
GX	2/44 (4,5)	1/40 (2,5)	1,82 [0,17; 19,29] 0,6198[2]	1,86 [0,16; 21,30] 1,0000[4]	2,0 [-5,8; 9,9] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,1615)					
Negative	12/67 (17,9)	2/62 (3,2)	5,55 [1,29; 23,83] 0,0211[2]	6,55 [1,40; 30,56] 0,0074[3]	14,7 [4,5; 24,9] 0,0074[3]
Positive	87/678 (12,8)	63/647 (9,7)	1,32 [0,97; 1,79] 0,0770[2]	1,36 [0,97; 1,92] 0,0755[3]	3,1 [-0,3; 6,5] 0,0755[3]
Unknown	1/8 (12,5)	1/8 (12,5)	1,00 [0,07; 13,37] 1,0000[2]	1,00 [0,05; 19,36] 1,0000[4]	0,0 [-32,4; 32,4] 1,0000[4]
Race (Interaction p-value: 0,7673)					
White	66/461 (14,3)	40/440 (9,1)	1,57 [1,09; 2,28] 0,0162[2]	1,67 [1,10; 2,53] 0,0149[3]	5,2 [1,0; 9,4] 0,0149[3]
Asian	34/273 (12,5)	24/243 (9,9)	1,26 [0,77; 2,06] 0,3567[2]	1,30 [0,75; 2,26] 0,3548[3]	2,6 [-2,8; 8,0] 0,3548[3]
Other	3/30 (10,0)	2/34 (5,9)	1,70 [0,30; 9,50] 0,5455[2]	1,78 [0,28; 11,43] 0,6586[4]	4,1 [-9,2; 17,5] 0,6586[4]
First endocrine therapy (Interaction p-value: 0,8123)					
Tamoxifen	78/553 (14,1)	52/534 (9,7)	1,45 [1,04; 2,02] 0,0278[2]	1,52 [1,05; 2,21] 0,0265[3]	4,4 [0,5; 8,2] 0,0265[3]
Aromatase inhibitor	27/223 (12,1)	15/195 (7,7)	1,57 [0,86; 2,87] 0,1392[2]	1,65 [0,85; 3,21] 0,1341[3]	4,4 [-1,3; 10,1] 0,1341[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 240.1.2: Subgroups - adverse events according PT Lymphopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,9527)					
North America / Europe	12/347 (3,5)	6/309 (1,9)	1,78 [0,68; 4,69] 0,2425[2]	1,81 [0,67; 4,88] 0,2353[3]	1,5 [-0,9; 4,0] 0,2353[3]
Asia	6/239 (2,5)	0/226 (0,0)	12,30 [0,70; 217,02] 0,0867[2]	12,61 [0,71; 225,15] 0,0306[4]	2,5 [0,5; 4,5] 0,0306[4]
Other	15/190 (7,9)	7/194 (3,6)	2,19 [0,91; 5,25] 0,0793[2]	2,29 [0,91; 5,75] 0,0707[3]	4,3 [-0,4; 8,9] 0,0707[3]
Primary tumor size (Interaction p-value: 0,8311)					
< 20 mm	8/204 (3,9)	4/189 (2,1)	1,85 [0,57; 6,05] 0,3072[2]	1,89 [0,56; 6,37] 0,2987[3]	1,8 [-1,6; 5,2] 0,2987[3]
≥ 20 but < 50 mm	15/360 (4,2)	6/346 (1,7)	2,40 [0,94; 6,12] 0,0662[2]	2,46 [0,94; 6,43] 0,0572[3]	2,4 [-0,0; 4,9] 0,0572[3]
≥ 50 mm	10/194 (5,2)	3/185 (1,6)	3,18 [0,89; 11,37] 0,0753[2]	3,30 [0,89; 12,18] 0,0589[3]	3,5 [-0,1; 7,1] 0,0589[3]
Number of positive lymph nodes (Interaction p-value: 0,7906)					
0-3	11/269 (4,1)	8/269 (3,0)	1,38 [0,56; 3,36] 0,4855[2]	1,39 [0,55; 3,51] 0,4835[3]	1,1 [-2,0; 4,2] 0,4835[3]
4-9	12/353 (3,4)	5/326 (1,5)	2,22 [0,79; 6,22] 0,1308[2]	2,26 [0,79; 6,48] 0,1200[3]	1,9 [-0,4; 4,2] 0,1200[3]
≥ 10	10/154 (6,5)	0/134 (0,0)	18,29 [1,08; 309,21] 0,0440[2]	19,55 [1,13; 336,82] 0,0021[4]	6,5 [2,6; 10,4] 0,0021[4]
Tumor stage (Interaction p-value: 0,1797)					
IIA	4/79 (5,1)	1/77 (1,3)	3,90 [0,45; 34,10] 0,2188[2]	4,05 [0,44; 37,11] 0,3671[4]	3,8 [-1,7; 9,2] 0,3671[4]
IIB	1/73 (1,4)	3/93 (3,2)	0,42 [0,05; 4,00] 0,4541[2]	0,42 [0,04; 4,09] 0,6315[4]	-1,9 [-6,3; 2,6] 0,6315[4]
IIIA	9/345 (2,6)	6/294 (2,0)	1,28 [0,46; 3,55] 0,6375[2]	1,29 [0,45; 3,66] 0,6365[3]	0,6 [-1,8; 2,9] 0,6365[3]
IIIB	3/22 (13,6)	1/19 (5,3)	2,59 [0,29; 22,88] 0,3917[2]	2,84 [0,27; 29,90] 0,6099[4]	8,4 [-9,1; 25,9] 0,6099[4]
IIIC	16/253 (6,3)	2/245 (0,8)	7,75 [1,80; 33,34] 0,0060[2]	8,20 [1,87; 36,06] 0,0010[3]	5,5 [2,3; 8,7] 0,0010[3]
Tumor grade (Interaction p-value: 0,8831)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	2/63 (3,2)	1/52 (1,9)	1,65 [0,15; 17,70] 0,6788[2]	1,67 [0,15; 18,98] 1,0000[4]	1,3 [-4,5; 7,0] 1,0000[4]
G2	12/349 (3,4)	7/323 (2,2)	1,59 [0,63; 3,98] 0,3253[2]	1,61 [0,62; 4,13] 0,3206[3]	1,3 [-1,2; 3,8] 0,3206[3]
G3	14/317 (4,4)	5/312 (1,6)	2,76 [1,00; 7,56] 0,0490[2]	2,84 [1,01; 7,97] 0,0393[3]	2,8 [0,2; 5,5] 0,0393[3]
GX	5/44 (11,4)	0/40 (0,0)	10,02 [0,57; 175,70] 0,1147[2]	11,28 [0,60; 210,81] 0,0565[4]	11,4 [2,0; 20,7] 0,0565[4]
Race (Interaction p-value: 0,9516)					
White	24/461 (5,2)	10/440 (2,3)	2,29 [1,11; 4,73] 0,0253[2]	2,36 [1,12; 5,00] 0,0209[3]	2,9 [0,5; 5,4] 0,0209[3]
Asian	6/273 (2,2)	0/243 (0,0)	11,58 [0,66; 204,44] 0,0946[2]	11,83 [0,66; 211,16] 0,0319[4]	2,2 [0,5; 3,9] 0,0319[4]
Other	3/30 (10,0)	2/34 (5,9)	1,70 [0,30; 9,50] 0,5455[2]	1,78 [0,28; 11,43] 0,6586[4]	4,1 [-9,2; 17,5] 0,6586[4]
First endocrine therapy (Interaction p-value: 0,3889)					
Tamoxifen	19/553 (3,4)	6/534 (1,1)	3,06 [1,23; 7,60] 0,0161[2]	3,13 [1,24; 7,90] 0,0110[3]	2,3 [0,6; 4,1] 0,0110[3]
Aromatase inhibitor	14/223 (6,3)	7/195 (3,6)	1,75 [0,72; 4,24] 0,2166[2]	1,80 [0,71; 4,55] 0,2094[3]	2,7 [-1,4; 6,8] 0,2094[3]
ECOG-PS (Interaction p-value: 0,9753)					
ECOG-PS 0	31/685 (4,5)	13/649 (2,0)	2,26 [1,19; 4,28] 0,0124[2]	2,32 [1,20; 4,47] 0,0099[3]	2,5 [0,6; 4,4] 0,0099[3]
ECOG-PS 1	2/91 (2,2)	0/80 (0,0)	4,40 [0,21; 90,35] 0,3364[2]	4,50 [0,21; 95,08] 0,4991[4]	2,2 [-0,8; 5,2] 0,4991[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 241.1.2: Subgroups - adverse events according PT Malaise from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9623)					
Neoadjuvant chemotherapy	14/314 (4,5)	6/306 (2,0)	2,27 [0,89; 5,84] 0,0879[2]	2,33 [0,88; 6,15] 0,0784[3]	2,5 [-0,3; 5,3] 0,0784[3]
Adjuvant chemotherapy	15/452 (3,3)	5/416 (1,2)	2,76 [1,01; 7,53] 0,0473[2]	2,82 [1,02; 7,83] 0,0379[3]	2,1 [0,2; 4,1] 0,0379[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,2323)					
North America / Europe	6/347 (1,7)	5/309 (1,6)	1,07 [0,33; 3,47] 0,9120[2]	1,07 [0,32; 3,54] 0,9120[3]	0,1 [-1,9; 2,1] 0,9120[3]
Asia	21/239 (8,8)	5/226 (2,2)	3,97 [1,52; 10,35] 0,0048[2]	4,26 [1,58; 11,49] 0,0020[3]	6,6 [2,5; 10,6] 0,0020[3]
Other	3/190 (1,6)	1/194 (0,5)	3,06 [0,32; 29,19] 0,3304[2]	3,10 [0,32; 30,03] 0,3679[4]	1,1 [-1,0; 3,1] 0,3679[4]
Primary tumor size (Interaction p-value: 0,7054)					
< 20 mm	7/204 (3,4)	4/189 (2,1)	1,62 [0,48; 5,45] 0,4347[2]	1,64 [0,47; 5,71] 0,4297[3]	1,3 [-1,9; 4,5] 0,4297[3]
≥ 20 but < 50 mm	15/360 (4,2)	5/346 (1,4)	2,88 [1,06; 7,85] 0,0382[2]	2,97 [1,07; 8,25] 0,0293[3]	2,7 [0,3; 5,1] 0,0293[3]
≥ 50 mm	7/194 (3,6)	2/185 (1,1)	3,34 [0,70; 15,86] 0,1296[2]	3,43 [0,70; 16,71] 0,1756[4]	2,5 [-0,5; 5,5] 0,1756[4]
Number of positive lymph nodes (Interaction p-value: 0,9800)					
0-3	10/269 (3,7)	5/269 (1,9)	2,00 [0,69; 5,77] 0,2000[2]	2,04 [0,69; 6,05] 0,1904[3]	1,9 [-0,9; 4,6] 0,1904[3]
4-9	15/353 (4,2)	6/326 (1,8)	2,31 [0,91; 5,88] 0,0793[2]	2,37 [0,91; 6,18] 0,0701[3]	2,4 [-0,2; 5,0] 0,0701[3]
≥ 10	5/154 (3,2)	0/134 (0,0)	9,58 [0,53; 171,67] 0,1248[2]	9,90 [0,54; 180,65] 0,0633[4]	3,2 [0,4; 6,0] 0,0633[4]
Tumor stage (Interaction p-value: 0,9849)					
IIA	3/79 (3,8)	1/77 (1,3)	2,92 [0,31; 27,50] 0,3481[2]	3,00 [0,31; 29,49] 0,6202[4]	2,5 [-2,4; 7,4] 0,6202[4]
IIB	3/73 (4,1)	2/93 (2,2)	1,91 [0,33; 11,14] 0,4715[2]	1,95 [0,32; 11,99] 0,6550[4]	2,0 [-3,5; 7,4] 0,6550[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	14/345 (4,1)	4/294 (1,4)	2,98 [0,99; 8,96] 0,0516[2]	3,07 [1,00; 9,42] 0,0400[3]	2,7 [0,2; 5,2] 0,0400[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	8/253 (3,2)	4/245 (1,6)	1,94 [0,59; 6,35] 0,2752[2]	1,97 [0,58; 6,62] 0,2658[3]	1,5 [-1,1; 4,2] 0,2658[3]
Tumor grade (Interaction p-value: 0,9901)					
G1	4/63 (6,3)	0/52 (0,0)	7,45 [0,41; 135,32] 0,1745[2]	7,94 [0,42; 151,00] 0,1253[4]	6,3 [0,3; 12,4] 0,1253[4]
G2	9/349 (2,6)	5/323 (1,5)	1,67 [0,56; 4,92] 0,3555[2]	1,68 [0,56; 5,08] 0,3499[3]	1,0 [-1,1; 3,2] 0,3499[3]
G3	13/317 (4,1)	6/312 (1,9)	2,13 [0,82; 5,54] 0,1200[2]	2,18 [0,82; 5,81] 0,1106[3]	2,2 [-0,5; 4,8] 0,1106[3]
GX	4/44 (9,1)	0/40 (0,0)	8,20 [0,46; 147,68] 0,1537[2]	9,00 [0,47; 172,65] 0,1177[4]	9,1 [0,6; 17,6] 0,1177[4]
Progesterone receptor status (Interaction p-value: 0,9998)					
Negative	0/67 (0,0)	0/62 (0,0)	NE	NE	NE
Positive	30/678 (4,4)	11/647 (1,7)	2,60 [1,32; 5,15] 0,0060[2]	2,68 [1,33; 5,39] 0,0042[3]	2,7 [0,9; 4,6] 0,0042[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,3324)					
White	8/461 (1,7)	6/440 (1,4)	1,27 [0,45; 3,64] 0,6529[2]	1,28 [0,44; 3,71] 0,6520[3]	0,4 [-1,2; 2,0] 0,6520[3]
Asian	21/273 (7,7)	5/243 (2,1)	3,74 [1,43; 9,76] 0,0071[2]	3,97 [1,47; 10,69] 0,0035[3]	5,6 [2,0; 9,3] 0,0035[3]
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
First endocrine therapy (Interaction p-value: 0,9835)					
Tamoxifen	24/553 (4,3)	9/534 (1,7)	2,58 [1,21; 5,49] 0,0143[2]	2,65 [1,22; 5,75] 0,0108[3]	2,7 [0,6; 4,7] 0,0108[3]
Aromatase inhibitor	6/223 (2,7)	2/195 (1,0)	2,62 [0,54; 12,85] 0,2341[2]	2,67 [0,53; 13,38] 0,2932[4]	1,7 [-0,9; 4,2] 0,2932[4]
ECOG-PS (Interaction p-value: 0,2532)					
ECOG-PS 0	28/685 (4,1)	9/649 (1,4)	2,95 [1,40; 6,20] 0,0044[2]	3,03 [1,42; 6,47] 0,0027[3]	2,7 [1,0; 4,4] 0,0027[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	2/91 (2,2)	2/80 (2,5)	0,88 [0,13; 6,10] 0,8963[2]	0,88 [0,12; 6,37] 1,0000[4]	-0,3 [-4,9; 4,3] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 242.1.2: Subgroups - adverse events according PT Mouth ulceration from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,9996)					
Negative	0/67 (0,0)	0/62 (0,0)	NE	NE	NE
Positive	13/678 (1,9)	1/647 (0,2)	12,41 [1,63; 94,56] 0,0151[2]	12,63 [1,65; 96,81] 0,0017[3]	1,8 [0,7; 2,8] 0,0017[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,9786)					
ECOG-PS 0	11/685 (1,6)	1/649 (0,2)	10,42 [1,35; 80,50] 0,0246[2]	10,58 [1,36; 82,15] 0,0050[3]	1,5 [0,5; 2,4] 0,0050[3]
ECOG-PS 1	2/91 (2,2)	0/80 (0,0)	4,40 [0,21; 90,35] 0,3364[2]	4,50 [0,21; 95,08] 0,4991[4]	2,2 [-0,8; 5,2] 0,4991[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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31OCT2025 / 03:54

Table 243.1.2: Subgroups - adverse events according PT Mucosal inflammation from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,3760)					
Neoadjuvant chemotherapy	8/314 (2,5)	5/306 (1,6)	1,56 [0,52; 4,71] 0,4313[2]	1,57 [0,51; 4,87] 0,4272[3]	0,9 [-1,3; 3,2] 0,4272[3]
Adjuvant chemotherapy	9/452 (2,0)	1/416 (0,2)	8,28 [1,05; 65,10] 0,0444[2]	8,43 [1,06; 66,84] 0,0218[4]	1,8 [0,4; 3,1] 0,0218[4]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,9994)					
North America / Europe	12/347 (3,5)	6/309 (1,9)	1,78 [0,68; 4,69] 0,2425[2]	1,81 [0,67; 4,88] 0,2353[3]	1,5 [-0,9; 4,0] 0,2353[3]
Asia	4/239 (1,7)	0/226 (0,0)	8,51 [0,46; 157,22] 0,1500[2]	8,66 [0,46; 161,69] 0,1240[4]	1,7 [0,0; 3,3] 0,1240[4]
Other	2/190 (1,1)	0/194 (0,0)	5,10 [0,25; 105,63] 0,2916[2]	5,16 [0,25; 108,17] 0,2442[4]	1,1 [-0,4; 2,5] 0,2442[4]
Primary tumor size (Interaction p-value: 0,5842)					
< 20 mm	5/204 (2,5)	1/189 (0,5)	4,63 [0,55; 39,29] 0,1599[2]	4,72 [0,55; 40,81] 0,2172[4]	1,9 [-0,4; 4,3] 0,2172[4]
≥ 20 but < 50 mm	7/360 (1,9)	4/346 (1,2)	1,68 [0,50; 5,69] 0,4034[2]	1,70 [0,49; 5,84] 0,3978[3]	0,8 [-1,0; 2,6] 0,3978[3]
≥ 50 mm	5/194 (2,6)	1/185 (0,5)	4,77 [0,56; 40,43] 0,1521[2]	4,87 [0,56; 42,07] 0,2158[4]	2,0 [-0,4; 4,5] 0,2158[4]
Number of positive lymph nodes (Interaction p-value: 0,7157)					
0-3	9/269 (3,3)	2/269 (0,7)	4,50 [0,98; 20,63] 0,0529[2]	4,62 [0,99; 21,59] 0,0330[3]	2,6 [0,2; 5,0] 0,0330[3]
4-9	7/353 (2,0)	3/326 (0,9)	2,15 [0,56; 8,26] 0,2629[2]	2,18 [0,56; 8,50] 0,3440[4]	1,1 [-0,7; 2,8] 0,3440[4]
≥ 10	2/154 (1,3)	1/134 (0,7)	1,74 [0,16; 18,98] 0,6495[2]	1,75 [0,16; 19,52] 1,0000[4]	0,6 [-1,8; 2,9] 1,0000[4]
Tumor stage (Interaction p-value: 0,8617)					
IIA	4/79 (5,1)	0/77 (0,0)	8,78 [0,48; 160,29] 0,1428[2]	9,24 [0,49; 174,56] 0,1203[4]	5,1 [0,2; 9,9] 0,1203[4]
IIB	2/73 (2,7)	1/93 (1,1)	2,55 [0,24; 27,55] 0,4413[2]	2,59 [0,23; 29,15] 0,5829[4]	1,7 [-2,6; 6,0] 0,5829[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	8/345 (2,3)	2/294 (0,7)	3,41 [0,73; 15,93] 0,1190[2]	3,47 [0,73; 16,45] 0,1178[4]	1,6 [-0,2; 3,5] 0,1178[4]
IIIB	1/22 (4,5)	0/19 (0,0)	2,61 [0,11; 60,51] 0,5500[2]	2,72 [0,10; 70,79] 1,0000[4]	4,5 [-4,2; 13,2] 1,0000[4]
IIIC	3/253 (1,2)	3/245 (1,2)	0,97 [0,20; 4,75] 0,9684[2]	0,97 [0,19; 4,84] 1,0000[4]	-0,0 [-2,0; 1,9] 1,0000[4]
Tumor grade (Interaction p-value: 0,2908)					
G1	0/63 (0,0)	0/52 (0,0)	NE	NE	NE
G2	10/349 (2,9)	2/323 (0,6)	4,63 [1,02; 20,96] 0,0468[2]	4,73 [1,03; 21,77] 0,0280[3]	2,2 [0,3; 4,2] 0,0280[3]
G3	8/317 (2,5)	4/312 (1,3)	1,97 [0,60; 6,47] 0,2647[2]	1,99 [0,59; 6,69] 0,2551[3]	1,2 [-0,9; 3,4] 0,2551[3]
GX	0/44 (0,0)	0/40 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9599)					
Negative	2/67 (3,0)	0/62 (0,0)	4,63 [0,23; 94,63] 0,3193[2]	4,77 [0,22; 101,36] 0,4969[4]	3,0 [-1,1; 7,1] 0,4969[4]
Positive	16/678 (2,4)	6/647 (0,9)	2,54 [1,00; 6,46] 0,0495[2]	2,58 [1,00; 6,64] 0,0414[3]	1,4 [0,1; 2,8] 0,0414[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9818)					
White	13/461 (2,8)	5/440 (1,1)	2,48 [0,89; 6,90] 0,0817[2]	2,52 [0,89; 7,14] 0,0710[3]	1,7 [-0,1; 3,5] 0,0710[3]
Asian	5/273 (1,8)	0/243 (0,0)	9,80 [0,54; 176,24] 0,1217[2]	9,98 [0,55; 181,35] 0,0634[4]	1,8 [0,2; 3,4] 0,0634[4]
Other	0/30 (0,0)	0/34 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,4046)					
Tamoxifen	12/553 (2,2)	3/534 (0,6)	3,86 [1,10; 13,61] 0,0355[2]	3,93 [1,10; 13,99] 0,0231[3]	1,6 [0,2; 3,0] 0,0231[3]
Aromatase inhibitor	6/223 (2,7)	3/195 (1,5)	1,75 [0,44; 6,90] 0,4247[2]	1,77 [0,44; 7,17] 0,5120[4]	1,2 [-1,6; 3,9] 0,5120[4]
ECOG-PS (Interaction p-value: 0,1978)					
ECOG-PS 0	16/685 (2,3)	4/649 (0,6)	3,79 [1,27; 11,28] 0,0166[2]	3,86 [1,28; 11,60] 0,0098[3]	1,7 [0,4; 3,0] 0,0098[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	2/91 (2,2)	2/80 (2,5)	0,88 [0,13; 6,10] 0,8963[2]	0,88 [0,12; 6,37] 1,0000[4]	-0,3 [-4,9; 4,3] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 244.1.2: Subgroups - adverse events according PT Nail disorder from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9116)					
Neoadjuvant chemotherapy	10/314 (3,2)	2/306 (0,7)	4,87 [1,08; 22,06] 0,0398[2]	5,00 [1,09; 23,01] 0,0222[3]	2,5 [0,4; 4,7] 0,0222[3]
Adjuvant chemotherapy	8/452 (1,8)	0/416 (0,0)	15,65 [0,91; 270,28] 0,0585[2]	15,93 [0,92; 276,84] 0,0079[4]	1,8 [0,6; 3,0] 0,0079[4]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,9979)					
North America / Europe	11/347 (3,2)	2/309 (0,6)	4,90 [1,09; 21,92] 0,0377[2]	5,03 [1,11; 22,85] 0,0207[3]	2,5 [0,5; 4,6] 0,0207[3]
Asia	6/239 (2,5)	0/226 (0,0)	12,30 [0,70; 217,02] 0,0867[2]	12,61 [0,71; 225,15] 0,0306[4]	2,5 [0,5; 4,5] 0,0306[4]
Other	1/190 (0,5)	0/194 (0,0)	3,06 [0,13; 74,72] 0,4922[2]	3,08 [0,12; 76,06] 0,4948[4]	0,5 [-0,5; 1,6] 0,4948[4]
Primary tumor size (Interaction p-value: 0,9690)					
< 20 mm	1/204 (0,5)	2/189 (1,1)	0,46 [0,04; 5,07] 0,5284[2]	0,46 [0,04; 5,12] 0,6102[4]	-0,6 [-2,3; 1,2] 0,6102[4]
≥ 20 but < 50 mm	10/360 (2,8)	0/346 (0,0)	20,19 [1,19; 343,15] 0,0376[2]	20,76 [1,21; 355,66] 0,0019[4]	2,8 [1,1; 4,5] 0,0019[4]
≥ 50 mm	5/194 (2,6)	0/185 (0,0)	10,49 [0,58; 188,43] 0,1107[2]	10,77 [0,59; 196,11] 0,0612[4]	2,6 [0,3; 4,8] 0,0612[4]
Number of positive lymph nodes (Interaction p-value: 0,9738)					
0-3	5/269 (1,9)	2/269 (0,7)	2,50 [0,49; 12,77] 0,2709[2]	2,53 [0,49; 13,15] 0,4501[4]	1,1 [-0,8; 3,0] 0,4501[4]
4-9	12/353 (3,4)	0/326 (0,0)	23,09 [1,37; 388,48] 0,0293[2]	23,90 [1,41; 405,34] 0,0008[3]	3,4 [1,5; 5,3] 0,0008[3]
≥ 10	1/154 (0,6)	0/134 (0,0)	2,61 [0,11; 63,61] 0,5554[2]	2,63 [0,11; 65,07] 1,0000[4]	0,6 [-0,6; 1,9] 1,0000[4]
Tumor grade (Interaction p-value: 0,9999)					
G1	0/63 (0,0)	0/52 (0,0)	NE	NE	NE
G2	10/349 (2,9)	0/323 (0,0)	19,44 [1,14; 330,41] 0,0401[2]	20,01 [1,17; 342,88] 0,0020[4]	2,9 [1,1; 4,6] 0,0020[4]
G3	6/317 (1,9)	2/312 (0,6)	2,95 [0,60; 14,52] 0,1827[2]	2,99 [0,60; 14,93] 0,2860[4]	1,3 [-0,5; 3,0] 0,2860[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,9971)					
Negative	0/67 (0,0)	0/62 (0,0)	NE	NE	NE
Positive	18/678 (2,7)	2/647 (0,3)	8,59 [2,00; 36,87] 0,0038[2]	8,80 [2,03; 38,06] 0,0005[3]	2,3 [1,1; 3,6] 0,0005[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9824)					
White	11/461 (2,4)	2/440 (0,5)	5,25 [1,17; 23,55] 0,0304[2]	5,35 [1,18; 24,29] 0,0151[3]	1,9 [0,4; 3,5] 0,0151[3]
Asian	7/273 (2,6)	0/243 (0,0)	13,36 [0,77; 232,66] 0,0754[2]	13,71 [0,78; 241,24] 0,0161[4]	2,6 [0,7; 4,4] 0,0161[4]
Other	0/30 (0,0)	0/34 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,9772)					
Tamoxifen	14/553 (2,5)	2/534 (0,4)	6,76 [1,54; 29,60] 0,0112[2]	6,91 [1,56; 30,55] 0,0032[3]	2,2 [0,7; 3,6] 0,0032[3]
Aromatase inhibitor	4/223 (1,8)	0/195 (0,0)	7,88 [0,43; 145,35] 0,1653[2]	8,02 [0,43; 149,83] 0,1266[4]	1,8 [0,1; 3,5] 0,1266[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 245.1.2: Subgroups - adverse events according PT Nasopharyngitis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,6918)					
Neoadjuvant chemotherapy	40/314 (12,7)	33/306 (10,8)	1,18 [0,77; 1,82] 0,4511[2]	1,21 [0,74; 1,97] 0,4503[3]	2,0 [-3,1; 7,0] 0,4503[3]
Adjuvant chemotherapy	55/452 (12,2)	33/416 (7,9)	1,53 [1,02; 2,31] 0,0411[2]	1,61 [1,02; 2,53] 0,0389[3]	4,2 [0,3; 8,2] 0,0389[3]
No chemotherapy	2/10 (20,0)	1/7 (14,3)	1,40 [0,16; 12,60] 0,7641[2]	1,50 [0,11; 20,68] 1,0000[4]	5,7 [-30,2; 41,6] 1,0000[4]
Region (Interaction p-value: 0,8162)					
North America / Europe	41/347 (11,8)	29/309 (9,4)	1,26 [0,80; 1,97] 0,3160[2]	1,29 [0,78; 2,14] 0,3142[3]	2,4 [-2,3; 7,1] 0,3142[3]
Asia	47/239 (19,7)	33/226 (14,6)	1,35 [0,90; 2,02] 0,1510[2]	1,43 [0,88; 2,33] 0,1482[3]	5,1 [-1,8; 11,9] 0,1482[3]
Other	9/190 (4,7)	5/194 (2,6)	1,84 [0,63; 5,38] 0,2670[2]	1,88 [0,62; 5,71] 0,2590[3]	2,2 [-1,6; 5,9] 0,2590[3]
Primary tumor size (Interaction p-value: 0,7601)					
< 20 mm	24/204 (11,8)	16/189 (8,5)	1,39 [0,76; 2,53] 0,2830[2]	1,44 [0,74; 2,81] 0,2798[3]	3,3 [-2,6; 9,2] 0,2798[3]
≥ 20 but < 50 mm	40/360 (11,1)	32/346 (9,2)	1,20 [0,77; 1,87] 0,4146[2]	1,23 [0,75; 2,00] 0,4136[3]	1,9 [-2,6; 6,3] 0,4136[3]
≥ 50 mm	31/194 (16,0)	19/185 (10,3)	1,56 [0,91; 2,65] 0,1049[2]	1,66 [0,90; 3,06] 0,1007[3]	5,7 [-1,1; 12,5] 0,1007[3]
Number of positive lymph nodes (Interaction p-value: 0,9899)					
0-3	34/269 (12,6)	25/269 (9,3)	1,36 [0,83; 2,22] 0,2168[2]	1,41 [0,82; 2,44] 0,2143[3]	3,3 [-1,9; 8,6] 0,2143[3]
4-9	45/353 (12,7)	30/326 (9,2)	1,39 [0,90; 2,14] 0,1436[2]	1,44 [0,88; 2,35] 0,1409[3]	3,5 [-1,1; 8,2] 0,1409[3]
≥ 10	18/154 (11,7)	12/134 (9,0)	1,31 [0,65; 2,61] 0,4511[2]	1,35 [0,62; 2,91] 0,4488[3]	2,7 [-4,3; 9,7] 0,4488[3]
Tumor stage (Interaction p-value: 0,8468)					
IIA	13/79 (16,5)	6/77 (7,8)	2,11 [0,85; 5,27] 0,1093[2]	2,33 [0,84; 6,49] 0,0981[3]	8,7 [-1,5; 18,8] 0,0981[3]
IIB	10/73 (13,7)	10/93 (10,8)	1,27 [0,56; 2,90] 0,5633[2]	1,32 [0,52; 3,36] 0,5628[3]	2,9 [-7,1; 13,0] 0,5628[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	39/345 (11,3)	24/294 (8,2)	1,38 [0,85; 2,25] 0,1875[2]	1,43 [0,84; 2,45] 0,1843[3]	3,1 [-1,4; 7,7] 0,1843[3]
IIIB	4/22 (18,2)	2/19 (10,5)	1,73 [0,35; 8,41] 0,4985[2]	1,89 [0,31; 11,68] 0,6681[4]	7,7 [-13,6; 28,9] 0,6681[4]
IIIC	30/253 (11,9)	25/245 (10,2)	1,16 [0,70; 1,92] 0,5567[2]	1,18 [0,67; 2,08] 0,5561[3]	1,7 [-3,8; 7,2] 0,5561[3]
Tumor grade (Interaction p-value: 0,5497)					
G1	12/63 (19,0)	4/52 (7,7)	2,48 [0,85; 7,22] 0,0968[2]	2,82 [0,85; 9,36] 0,0799[3]	11,4 [-0,7; 23,5] 0,0799[3]
G2	39/349 (11,2)	28/323 (8,7)	1,29 [0,81; 2,04] 0,2806[2]	1,33 [0,80; 2,21] 0,2786[3]	2,5 [-2,0; 7,0] 0,2786[3]
G3	38/317 (12,0)	26/312 (8,3)	1,44 [0,90; 2,31] 0,1325[2]	1,50 [0,89; 2,53] 0,1296[3]	3,7 [-1,1; 8,4] 0,1296[3]
GX	8/44 (18,2)	8/40 (20,0)	0,91 [0,38; 2,19] 0,8322[2]	0,89 [0,30; 2,64] 0,8322[3]	-1,8 [-18,7; 15,0] 0,8322[3]
Progesterone receptor status (Interaction p-value: 0,5961)					
Negative	6/67 (9,0)	5/62 (8,1)	1,11 [0,36; 3,46] 0,8565[2]	1,12 [0,32; 3,88] 0,8564[3]	0,9 [-8,7; 10,5] 0,8564[3]
Positive	89/678 (13,1)	59/647 (9,1)	1,44 [1,05; 1,96] 0,0216[2]	1,51 [1,06; 2,13] 0,0206[3]	4,0 [0,6; 7,4] 0,0206[3]
Unknown	1/8 (12,5)	2/8 (25,0)	0,50 [0,06; 4,47] 0,5353[2]	0,43 [0,03; 5,98] 1,0000[4]	-12,5 [-50,3; 25,3] 1,0000[4]
Race (Interaction p-value: 0,9406)					
White	43/461 (9,3)	33/440 (7,5)	1,24 [0,81; 1,92] 0,3251[2]	1,27 [0,79; 2,04] 0,3238[3]	1,8 [-1,8; 5,4] 0,3238[3]
Asian	51/273 (18,7)	33/243 (13,6)	1,38 [0,92; 2,06] 0,1203[2]	1,46 [0,91; 2,35] 0,1172[3]	5,1 [-1,2; 11,4] 0,1172[3]
Other	1/30 (3,3)	1/34 (2,9)	1,13 [0,07; 17,34] 0,9283[2]	1,14 [0,07; 19,02] 1,0000[4]	0,4 [-8,2; 9,0] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,2374)					
Tamoxifen	82/553 (14,8)	53/534 (9,9)	1,49 [1,08; 2,07] 0,0153[2]	1,58 [1,09; 2,28] 0,0143[3]	4,9 [1,0; 8,8] 0,0143[3]
Aromatase inhibitor	15/223 (6,7)	14/195 (7,2)	0,94 [0,46; 1,89] 0,8557[2]	0,93 [0,44; 1,98] 0,8557[3]	-0,5 [-5,3; 4,4] 0,8557[3]
ECOG-PS (Interaction p-value: 0,2878)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	90/685 (13,1)	65/649 (10,0)	1,31 [0,97; 1,77] 0,0766[2]	1,36 [0,97; 1,91] 0,0752[3]	3,1 [-0,3; 6,5] 0,0752[3]
ECOG-PS 1	7/91 (7,7)	2/80 (2,5)	3,08 [0,66; 14,39] 0,1533[2]	3,25 [0,66; 16,12] 0,1763[4]	5,2 [-1,3; 11,6] 0,1763[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 246.1.2: Subgroups - adverse events according PT Nausea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,6506)					
Neoadjuvant chemotherapy	93/314 (29,6)	29/306 (9,5)	3,13 [2,12; 4,60] <,0001[2]	4,02 [2,56; 6,32] <,0001[3]	20,1 [14,1; 26,2] <,0001[3]
Adjuvant chemotherapy	115/452 (25,4)	26/416 (6,3)	4,07 [2,72; 6,10] <,0001[2]	5,12 [3,26; 8,03] <,0001[3]	19,2 [14,6; 23,8] <,0001[3]
No chemotherapy	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]
Region (Interaction p-value: 0,5455)					
North America / Europe	108/347 (31,1)	31/309 (10,0)	3,10 [2,15; 4,49] <,0001[2]	4,05 [2,62; 6,26] <,0001[3]	21,1 [15,2; 27,0] <,0001[3]
Asia	57/239 (23,8)	12/226 (5,3)	4,49 [2,48; 8,15] <,0001[2]	5,59 [2,91; 10,73] <,0001[3]	18,5 [12,4; 24,7] <,0001[3]
Other	46/190 (24,2)	12/194 (6,2)	3,91 [2,14; 7,15] <,0001[2]	4,84 [2,47; 9,49] <,0001[3]	18,0 [11,1; 25,0] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,1591)					
0-3	85/269 (31,6)	21/269 (7,8)	4,05 [2,59; 6,33] <,0001[2]	5,46 [3,26; 9,12] <,0001[3]	23,8 [17,4; 30,2] <,0001[3]
4-9	79/353 (22,4)	27/326 (8,3)	2,70 [1,79; 4,07] <,0001[2]	3,19 [2,00; 5,09] <,0001[3]	14,1 [8,8; 19,4] <,0001[3]
≥ 10	47/154 (30,5)	7/134 (5,2)	5,84 [2,73; 12,49] <,0001[2]	7,97 [3,46; 18,36] <,0001[3]	25,3 [17,1; 33,5] <,0001[3]
Tumor stage (Interaction p-value: 0,3345)					
IIA	19/79 (24,1)	7/77 (9,1)	2,65 [1,18; 5,93] 0,0182[2]	3,17 [1,25; 8,05] 0,0122[3]	15,0 [3,6; 26,4] 0,0122[3]
IIB	21/73 (28,8)	9/93 (9,7)	2,97 [1,45; 6,10] 0,0029[2]	3,77 [1,60; 8,85] 0,0015[3]	19,1 [7,1; 31,1] 0,0015[3]
IIIA	80/345 (23,2)	21/294 (7,1)	3,25 [2,06; 5,12] <,0001[2]	3,92 [2,36; 6,53] <,0001[3]	16,0 [10,7; 21,4] <,0001[3]
IIIB	6/22 (27,3)	3/19 (15,8)	1,73 [0,50; 5,98] 0,3886[2]	2,00 [0,42; 9,42] 0,4659[4]	11,5 [-13,3; 36,3] 0,4659[4]
IIIC	83/253 (32,8)	15/245 (6,1)	5,36 [3,18; 9,02] <,0001[2]	7,49 [4,17; 13,43] <,0001[3]	26,7 [20,2; 33,2] <,0001[3]
Tumor grade (Interaction p-value: 0,9336)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	15/63 (23,8)	3/52 (5,8)	4,13 [1,26; 13,48] 0,0189[2]	5,10 [1,39; 18,76] 0,0080[3]	18,0 [5,8; 30,3] 0,0080[3]
G2	94/349 (26,9)	24/323 (7,4)	3,62 [2,38; 5,53] <,0001[2]	4,59 [2,85; 7,41] <,0001[3]	19,5 [14,0; 25,0] <,0001[3]
G3	92/317 (29,0)	25/312 (8,0)	3,62 [2,40; 5,48] <,0001[2]	4,69 [2,92; 7,55] <,0001[3]	21,0 [15,2; 26,8] <,0001[3]
GX	8/44 (18,2)	3/40 (7,5)	2,42 [0,69; 8,51] 0,1670[2]	2,74 [0,67; 11,16] 0,1472[3]	10,7 [-3,3; 24,7] 0,1472[3]
Progesterone receptor status (Interaction p-value: 0,8436)					
Negative	26/67 (38,8)	6/62 (9,7)	4,01 [1,77; 9,08] 0,0009[2]	5,92 [2,23; 15,69] 0,0001[3]	29,1 [15,3; 42,9] 0,0001[3]
Positive	176/678 (26,0)	46/647 (7,1)	3,65 [2,69; 4,96] <,0001[2]	4,58 [3,24; 6,47] <,0001[3]	18,8 [15,0; 22,7] <,0001[3]
Unknown	2/8 (25,0)	1/8 (12,5)	2,00 [0,22; 17,89] 0,5353[2]	2,33 [0,17; 32,58] 1,0000[4]	12,5 [-25,3; 50,3] 1,0000[4]
Race (Interaction p-value: 0,5776)					
White	137/461 (29,7)	35/440 (8,0)	3,74 [2,64; 5,29] <,0001[2]	4,89 [3,28; 7,29] <,0001[3]	21,8 [16,9; 26,6] <,0001[3]
Asian	64/273 (23,4)	13/243 (5,3)	4,38 [2,48; 7,75] <,0001[2]	5,42 [2,90; 10,12] <,0001[3]	18,1 [12,3; 23,9] <,0001[3]
Other	8/30 (26,7)	4/34 (11,8)	2,27 [0,76; 6,78] 0,1431[2]	2,73 [0,73; 10,21] 0,1275[3]	14,9 [-4,3; 34,1] 0,1275[3]
First endocrine therapy (Interaction p-value: 0,7822)					
Tamoxifen	153/553 (27,7)	40/534 (7,5)	3,69 [2,66; 5,12] <,0001[2]	4,72 [3,26; 6,85] <,0001[3]	20,2 [15,8; 24,5] <,0001[3]
Aromatase inhibitor	58/223 (26,0)	15/195 (7,7)	3,38 [1,98; 5,77] <,0001[2]	4,22 [2,30; 7,73] <,0001[3]	18,3 [11,5; 25,2] <,0001[3]
ECOG-PS (Interaction p-value: 0,5381)					
ECOG-PS 0	192/685 (28,0)	49/649 (7,6)	3,71 [2,76; 4,99] <,0001[2]	4,77 [3,41; 6,67] <,0001[3]	20,5 [16,5; 24,4] <,0001[3]
ECOG-PS 1	19/91 (20,9)	6/80 (7,5)	2,78 [1,17; 6,63] 0,0207[2]	3,25 [1,23; 8,62] 0,0135[3]	13,4 [3,2; 23,5] 0,0135[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 247.1.2: Subgroups - adverse events according PT Neutropenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1848)					
Neoadjuvant chemotherapy	60/314 (19,1)	15/306 (4,9)	3,90 [2,26; 6,71] <,0001[2]	4,58 [2,54; 8,27] <,0001[3]	14,2 [9,2; 19,2] <,0001[3]
Adjuvant chemotherapy	93/452 (20,6)	10/416 (2,4)	8,56 [4,52; 16,21] <,0001[2]	10,52 [5,40; 20,50] <,0001[3]	18,2 [14,2; 22,2] <,0001[3]
No chemotherapy	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Region (Interaction p-value: 0,2830)					
North America / Europe	67/347 (19,3)	8/309 (2,6)	7,46 [3,64; 15,27] <,0001[2]	9,00 [4,25; 19,08] <,0001[3]	16,7 [12,2; 21,2] <,0001[3]
Asia	24/239 (10,0)	7/226 (3,1)	3,24 [1,42; 7,38] 0,0050[2]	3,49 [1,47; 8,28] 0,0027[3]	6,9 [2,5; 11,4] 0,0027[3]
Other	64/190 (33,7)	10/194 (5,2)	6,53 [3,46; 12,34] <,0001[2]	9,35 [4,62; 18,89] <,0001[3]	28,5 [21,1; 35,9] <,0001[3]
Primary tumor size (Interaction p-value: 0,3030)					
< 20 mm	44/204 (21,6)	9/189 (4,8)	4,53 [2,27; 9,02] <,0001[2]	5,50 [2,60; 11,62] <,0001[3]	16,8 [10,4; 23,2] <,0001[3]
≥ 20 but < 50 mm	69/360 (19,2)	13/346 (3,8)	5,10 [2,87; 9,06] <,0001[2]	6,07 [3,29; 11,21] <,0001[3]	15,4 [10,9; 19,9] <,0001[3]
≥ 50 mm	40/194 (20,6)	3/185 (1,6)	12,71 [4,00; 40,39] <,0001[2]	15,76 [4,78; 51,94] <,0001[3]	19,0 [13,0; 25,0] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,7948)					
0-3	48/269 (17,8)	8/269 (3,0)	6,00 [2,89; 12,44] <,0001[2]	7,09 [3,28; 15,30] <,0001[3]	14,9 [9,9; 19,9] <,0001[3]
4-9	70/353 (19,8)	10/326 (3,1)	6,46 [3,39; 12,32] <,0001[2]	7,82 [3,95; 15,46] <,0001[3]	16,8 [12,2; 21,3] <,0001[3]
≥ 10	37/154 (24,0)	7/134 (5,2)	4,60 [2,12; 9,97] 0,0001[2]	5,74 [2,46; 13,37] <,0001[3]	18,8 [11,1; 26,5] <,0001[3]
Tumor stage (Interaction p-value: 0,7844)					
IIA	14/79 (17,7)	2/77 (2,6)	6,82 [1,60; 29,03] 0,0093[2]	8,08 [1,77; 36,87] 0,0019[3]	15,1 [6,0; 24,3] 0,0019[3]
IIB	11/73 (15,1)	2/93 (2,2)	7,01 [1,60; 30,63] 0,0097[2]	8,07 [1,73; 37,69] 0,0021[3]	12,9 [4,2; 21,6] 0,0021[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	59/345 (17,1)	6/294 (2,0)	8,38 [3,67; 19,13] <,0001[2]	9,90 [4,21; 23,30] <,0001[3]	15,1 [10,8; 19,3] <,0001[3]
IIIB	4/22 (18,2)	1/19 (5,3)	3,45 [0,42; 28,31] 0,2481[2]	4,00 [0,41; 39,37] 0,3499[4]	12,9 [-6,1; 31,9] 0,3499[4]
IIIC	67/253 (26,5)	14/245 (5,7)	4,63 [2,68; 8,02] <,0001[2]	5,94 [3,24; 10,91] <,0001[3]	20,8 [14,6; 26,9] <,0001[3]
Tumor grade (Interaction p-value: 0,9326)					
G1	7/63 (11,1)	1/52 (1,9)	5,78 [0,73; 45,46] 0,0956[2]	6,38 [0,76; 53,61] 0,0707[4]	9,2 [0,6; 17,8] 0,0707[4]
G2	75/349 (21,5)	14/323 (4,3)	4,96 [2,86; 8,60] <,0001[2]	6,04 [3,34; 10,94] <,0001[3]	17,2 [12,3; 22,0] <,0001[3]
G3	67/317 (21,1)	10/312 (3,2)	6,59 [3,46; 12,58] <,0001[2]	8,09 [4,08; 16,06] <,0001[3]	17,9 [13,0; 22,8] <,0001[3]
GX	6/44 (13,6)	0/40 (0,0)	11,84 [0,69; 203,77] 0,0886[2]	13,68 [0,74; 251,05] 0,0268[4]	13,6 [3,5; 23,8] 0,0268[4]
Progesterone receptor status (Interaction p-value: 0,7158)					
Negative	14/67 (20,9)	1/62 (1,6)	12,96 [1,75; 95,64] 0,0120[2]	16,11 [2,05; 126,66] 0,0006[3]	19,3 [9,1; 29,5] 0,0006[3]
Positive	139/678 (20,5)	24/647 (3,7)	5,53 [3,63; 8,41] <,0001[2]	6,69 [4,28; 10,48] <,0001[3]	16,8 [13,4; 20,2] <,0001[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,3015)					
White	118/461 (25,6)	16/440 (3,6)	7,04 [4,25; 11,67] <,0001[2]	9,12 [5,31; 15,66] <,0001[3]	22,0 [17,6; 26,3] <,0001[3]
Asian	26/273 (9,5)	7/243 (2,9)	3,31 [1,46; 7,48] 0,0041[2]	3,55 [1,51; 8,33] 0,0021[3]	6,6 [2,6; 10,7] 0,0021[3]
Other	9/30 (30,0)	2/34 (5,9)	5,10 [1,19; 21,77] 0,0278[2]	6,86 [1,35; 34,93] 0,0107[3]	24,1 [5,9; 42,3] 0,0107[3]
First endocrine therapy (Interaction p-value: 0,5420)					
Tamoxifen	105/553 (19,0)	16/534 (3,0)	6,34 [3,80; 10,58] <,0001[2]	7,59 [4,42; 13,03] <,0001[3]	16,0 [12,4; 19,6] <,0001[3]
Aromatase inhibitor	50/223 (22,4)	9/195 (4,6)	4,86 [2,45; 9,62] <,0001[2]	5,97 [2,85; 12,51] <,0001[3]	17,8 [11,6; 24,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,3793)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	138/685 (20,1)	21/649 (3,2)	6,23 [3,98; 9,73] <,0001[2]	7,54 [4,70; 12,11] <,0001[3]	16,9 [13,6; 20,2] <,0001[3]
ECOG-PS 1	17/91 (18,7)	4/80 (5,0)	3,74 [1,31; 10,64] 0,0136[2]	4,36 [1,40; 13,58] 0,0065[3]	13,7 [4,4; 23,0] 0,0065[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 248.1.2: Subgroups - adverse events according PT Neutrophil count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,6705)					
Neoadjuvant chemotherapy	76/314 (24,2)	18/306 (5,9)	4,11 [2,52; 6,71] <,0001[2]	5,11 [2,97; 8,78] <,0001[3]	18,3 [12,9; 23,7] <,0001[3]
Adjuvant chemotherapy	138/452 (30,5)	23/416 (5,5)	5,52 [3,63; 8,41] <,0001[2]	7,51 [4,71; 11,96] <,0001[3]	25,0 [20,2; 29,8] <,0001[3]
No chemotherapy	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Region (Interaction p-value: 0,7519)					
North America / Europe	55/347 (15,9)	9/309 (2,9)	5,44 [2,74; 10,83] <,0001[2]	6,28 [3,05; 12,94] <,0001[3]	12,9 [8,7; 17,2] <,0001[3]
Asia	135/239 (56,5)	28/226 (12,4)	4,56 [3,17; 6,56] <,0001[2]	9,18 [5,73; 14,70] <,0001[3]	44,1 [36,5; 51,7] <,0001[3]
Other	26/190 (13,7)	4/194 (2,1)	6,64 [2,36; 18,66] 0,0003[2]	7,53 [2,57; 22,02] <,0001[3]	11,6 [6,3; 16,9] <,0001[3]
Primary tumor size (Interaction p-value: 0,6542)					
< 20 mm	54/204 (26,5)	8/189 (4,2)	6,25 [3,06; 12,79] <,0001[2]	8,15 [3,76; 17,65] <,0001[3]	22,2 [15,5; 28,9] <,0001[3]
≥ 20 but < 50 mm	103/360 (28,6)	23/346 (6,6)	4,30 [2,81; 6,60] <,0001[2]	5,63 [3,48; 9,10] <,0001[3]	22,0 [16,6; 27,3] <,0001[3]
≥ 50 mm	50/194 (25,8)	9/185 (4,9)	5,30 [2,68; 10,46] <,0001[2]	6,79 [3,23; 14,28] <,0001[3]	20,9 [14,0; 27,8] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,1498)					
0-3	70/269 (26,0)	8/269 (3,0)	8,75 [4,29; 17,83] <,0001[2]	11,48 [5,40; 24,40] <,0001[3]	23,0 [17,4; 28,7] <,0001[3]
4-9	104/353 (29,5)	23/326 (7,1)	4,18 [2,73; 6,39] <,0001[2]	5,50 [3,40; 8,91] <,0001[3]	22,4 [16,9; 27,9] <,0001[3]
≥ 10	42/154 (27,3)	10/134 (7,5)	3,65 [1,91; 7,00] <,0001[2]	4,65 [2,23; 9,70] <,0001[3]	19,8 [11,5; 28,1] <,0001[3]
Tumor stage (Interaction p-value: 0,8258)					
IIA	17/79 (21,5)	4/77 (5,2)	4,14 [1,46; 11,75] 0,0076[2]	5,00 [1,60; 15,66] 0,0028[3]	16,3 [6,0; 26,7] 0,0028[3]
IIB	22/73 (30,1)	3/93 (3,2)	9,34 [2,91; 30,00] 0,0002[2]	12,94 [3,69; 45,36] <,0001[3]	26,9 [15,8; 38,0] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	111/345 (32,2)	21/294 (7,1)	4,50 [2,90; 6,99] <,0001[2]	6,17 [3,75; 10,15] <,0001[3]	25,0 [19,3; 30,8] <,0001[3]
IIIB	4/22 (18,2)	0/19 (0,0)	7,83 [0,45; 136,60] 0,1585[2]	9,49 [0,48; 188,68] 0,1105[4]	18,2 [2,1; 34,3] 0,1105[4]
IIIC	58/253 (22,9)	13/245 (5,3)	4,32 [2,43; 7,68] <,0001[2]	5,31 [2,82; 9,98] <,0001[3]	17,6 [11,7; 23,5] <,0001[3]
Tumor grade (Interaction p-value: 0,3274)					
G1	20/63 (31,7)	1/52 (1,9)	16,51 [2,29; 118,91] 0,0054[2]	23,72 [3,06; 184,07] <,0001[3]	29,8 [17,7; 41,9] <,0001[3]
G2	85/349 (24,4)	14/323 (4,3)	5,62 [3,26; 9,69] <,0001[2]	7,11 [3,94; 12,80] <,0001[3]	20,0 [15,0; 25,0] <,0001[3]
G3	85/317 (26,8)	18/312 (5,8)	4,65 [2,86; 7,54] <,0001[2]	5,98 [3,50; 10,24] <,0001[3]	21,0 [15,5; 26,6] <,0001[3]
GX	23/44 (52,3)	7/40 (17,5)	2,99 [1,44; 6,20] 0,0033[2]	5,16 [1,89; 14,14] 0,0009[3]	34,8 [15,9; 53,7] 0,0009[3]
Progesterone receptor status (Interaction p-value: 0,5220)					
Negative	20/67 (29,9)	6/62 (9,7)	3,08 [1,33; 7,18] 0,0089[2]	3,97 [1,47; 10,70] 0,0043[3]	20,2 [7,0; 33,4] 0,0043[3]
Positive	187/678 (27,6)	34/647 (5,3)	5,25 [3,70; 7,44] <,0001[2]	6,87 [4,68; 10,08] <,0001[3]	22,3 [18,5; 26,1] <,0001[3]
Unknown	3/8 (37,5)	0/8 (0,0)	7,00 [0,42; 116,91] 0,1755[2]	10,82 [0,46; 252,79] 0,2000[4]	37,5 [4,0; 71,0] 0,2000[4]
Race (Interaction p-value: 0,6283)					
White	73/461 (15,8)	12/440 (2,7)	5,81 [3,20; 10,54] <,0001[2]	6,71 [3,59; 12,55] <,0001[3]	13,1 [9,4; 16,8] <,0001[3]
Asian	136/273 (49,8)	28/243 (11,5)	4,32 [2,99; 6,25] <,0001[2]	7,62 [4,81; 12,07] <,0001[3]	38,3 [31,1; 45,5] <,0001[3]
Other	7/30 (23,3)	1/34 (2,9)	7,93 [1,03; 60,83] 0,0463[2]	10,04 [1,16; 87,25] 0,0211[4]	20,4 [4,2; 36,6] 0,0211[4]
First endocrine therapy (Interaction p-value: 0,1064)					
Tamoxifen	138/553 (25,0)	22/534 (4,1)	6,06 [3,92; 9,35] <,0001[2]	7,74 [4,85; 12,36] <,0001[3]	20,8 [16,9; 24,8] <,0001[3]
Aromatase inhibitor	78/223 (35,0)	19/195 (9,7)	3,59 [2,26; 5,70] <,0001[2]	4,98 [2,88; 8,62] <,0001[3]	25,2 [17,7; 32,8] <,0001[3]
ECOG-PS (Interaction p-value: 0,8864)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	195/685 (28,5)	37/649 (5,7)	4,99 [3,57; 6,98] <,0001[2]	6,58 [4,54; 9,54] <,0001[3]	22,8 [18,9; 26,6] <,0001[3]
ECOG-PS 1	21/91 (23,1)	4/80 (5,0)	4,62 [1,65; 12,88] 0,0035[2]	5,70 [1,86; 17,43] 0,0008[3]	18,1 [8,2; 28,0] 0,0008[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 249.1.2: Subgroups - adverse events according PT Oedema from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Number of positive lymph nodes (Interaction p-value: 0,9656)					
0-3	8/269 (3,0)	2/269 (0,7)	4,00 [0,86; 18,66] 0,0777[2]	4,09 [0,86; 19,45] 0,0555[3]	2,2 [-0,0; 4,5] 0,0555[3]
4-9	3/353 (0,8)	1/326 (0,3)	2,77 [0,29; 26,50] 0,3764[2]	2,79 [0,29; 26,92] 0,6251[4]	0,5 [-0,6; 1,7] 0,6251[4]
≥ 10	2/154 (1,3)	0/134 (0,0)	4,35 [0,21; 89,92] 0,3409[2]	4,41 [0,21; 92,67] 0,5007[4]	1,3 [-0,5; 3,1] 0,5007[4]
Progesterone receptor status (Interaction p-value: 0,9996)					
Negative	0/67 (0,0)	0/62 (0,0)	NE	NE	NE
Positive	13/678 (1,9)	3/647 (0,5)	4,14 [1,18; 14,44] 0,0261[2]	4,20 [1,19; 14,80] 0,0154[3]	1,5 [0,3; 2,6] 0,0154[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,6598)					
Tamoxifen	10/553 (1,8)	2/534 (0,4)	4,83 [1,06; 21,93] 0,0415[2]	4,90 [1,07; 22,46] 0,0237[3]	1,4 [0,2; 2,7] 0,0237[3]
Aromatase inhibitor	3/223 (1,3)	1/195 (0,5)	2,62 [0,28; 25,01] 0,4019[2]	2,65 [0,27; 25,64] 0,6266[4]	0,8 [-1,0; 2,6] 0,6266[4]
ECOG-PS (Interaction p-value: 0,9779)					
ECOG-PS 0	12/685 (1,8)	3/649 (0,5)	3,79 [1,07; 13,37] 0,0383[2]	3,84 [1,08; 13,67] 0,0256[3]	1,3 [0,2; 2,4] 0,0256[3]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 250.1.2: Subgroups - adverse events according PT Oedema peripheral from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,4247)					
Neoadjuvant chemotherapy	26/314 (8,3)	15/306 (4,9)	1,69 [0,91; 3,13] 0,0951[2]	1,75 [0,91; 3,38] 0,0906[3]	3,4 [-0,5; 7,3] 0,0906[3]
Adjuvant chemotherapy	29/452 (6,4)	19/416 (4,6)	1,40 [0,80; 2,47] 0,2367[2]	1,43 [0,79; 2,60] 0,2339[3]	1,8 [-1,2; 4,9] 0,2339[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,5508)					
North America / Europe	29/347 (8,4)	17/309 (5,5)	1,52 [0,85; 2,71] 0,1568[2]	1,57 [0,84; 2,91] 0,1528[3]	2,9 [-1,0; 6,7] 0,1528[3]
Asia	13/239 (5,4)	11/226 (4,9)	1,12 [0,51; 2,44] 0,7806[2]	1,12 [0,49; 2,56] 0,7805[3]	0,6 [-3,4; 4,6] 0,7805[3]
Other	13/190 (6,8)	6/194 (3,1)	2,21 [0,86; 5,70] 0,1001[2]	2,30 [0,86; 6,19] 0,0903[3]	3,7 [-0,6; 8,1] 0,0903[3]
Number of positive lymph nodes (Interaction p-value: 0,5547)					
0-3	13/269 (4,8)	12/269 (4,5)	1,08 [0,50; 2,33] 0,8378[2]	1,09 [0,49; 2,43] 0,8377[3]	0,4 [-3,2; 3,9] 0,8377[3]
4-9	30/353 (8,5)	17/326 (5,2)	1,63 [0,92; 2,90] 0,0963[2]	1,69 [0,91; 3,12] 0,0921[3]	3,3 [-0,5; 7,1] 0,0921[3]
≥ 10	12/154 (7,8)	5/134 (3,7)	2,09 [0,76; 5,78] 0,1560[2]	2,18 [0,75; 6,36] 0,1447[3]	4,1 [-1,3; 9,4] 0,1447[3]
Tumor stage (Interaction p-value: 0,5022)					
IIA	5/79 (6,3)	5/77 (6,5)	0,97 [0,29; 3,23] 0,9666[2]	0,97 [0,27; 3,50] 1,0000[4]	-0,2 [-7,9; 7,5] 1,0000[4]
IIB	2/73 (2,7)	5/93 (5,4)	0,51 [0,10; 2,55] 0,4121[2]	0,50 [0,09; 2,63] 0,4675[4]	-2,6 [-8,6; 3,3] 0,4675[4]
IIIA	25/345 (7,2)	13/294 (4,4)	1,64 [0,85; 3,15] 0,1375[2]	1,69 [0,85; 3,36] 0,1324[3]	2,8 [-0,8; 6,4] 0,1324[3]
IIIB	1/22 (4,5)	1/19 (5,3)	0,86 [0,06; 12,89] 0,9153[2]	0,86 [0,05; 14,71] 1,0000[4]	-0,7 [-14,0; 12,6] 1,0000[4]
IIIC	22/253 (8,7)	10/245 (4,1)	2,13 [1,03; 4,41] 0,0413[2]	2,24 [1,04; 4,83] 0,0358[3]	4,6 [0,3; 8,9] 0,0358[3]
Tumor grade (Interaction p-value: 0,8078)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	7/63 (11,1)	2/52 (3,8)	2,89 [0,63; 13,31] 0,1736[2]	3,13 [0,62; 15,74] 0,1808[4]	7,3 [-2,1; 16,6] 0,1808[4]
G2	24/349 (6,9)	14/323 (4,3)	1,59 [0,84; 3,01] 0,1585[2]	1,63 [0,83; 3,21] 0,1540[3]	2,5 [-0,9; 6,0] 0,1540[3]
G3	21/317 (6,6)	16/312 (5,1)	1,29 [0,69; 2,43] 0,4267[2]	1,31 [0,67; 2,57] 0,4252[3]	1,5 [-2,2; 5,2] 0,4252[3]
GX	2/44 (4,5)	1/40 (2,5)	1,82 [0,17; 19,29] 0,6198[2]	1,86 [0,16; 21,30] 1,0000[4]	2,0 [-5,8; 9,9] 1,0000[4]
Race (Interaction p-value: 0,3062)					
White	30/461 (6,5)	19/440 (4,3)	1,51 [0,86; 2,64] 0,1509[2]	1,54 [0,85; 2,78] 0,1474[3]	2,2 [-0,8; 5,1] 0,1474[3]
Asian	15/273 (5,5)	11/243 (4,5)	1,21 [0,57; 2,59] 0,6167[2]	1,23 [0,55; 2,72] 0,6159[3]	1,0 [-2,8; 4,7] 0,6159[3]
Other	6/30 (20,0)	1/34 (2,9)	6,80 [0,87; 53,31] 0,0681[2]	8,25 [0,93; 73,08] 0,0444[4]	17,1 [1,7; 32,5] 0,0444[4]
First endocrine therapy (Interaction p-value: 0,1815)					
Tamoxifen	43/553 (7,8)	23/534 (4,3)	1,81 [1,10; 2,95] 0,0186[2]	1,87 [1,11; 3,15] 0,0167[3]	3,5 [0,6; 6,3] 0,0167[3]
Aromatase inhibitor	12/223 (5,4)	11/195 (5,6)	0,95 [0,43; 2,11] 0,9075[2]	0,95 [0,41; 2,21] 0,9075[3]	-0,3 [-4,6; 4,1] 0,9075[3]
ECOG-PS (Interaction p-value: 0,2122)					
ECOG-PS 0	51/685 (7,4)	29/649 (4,5)	1,67 [1,07; 2,59] 0,0239[2]	1,72 [1,08; 2,75] 0,0221[3]	3,0 [0,4; 5,5] 0,0221[3]
ECOG-PS 1	4/91 (4,4)	5/80 (6,3)	0,70 [0,20; 2,53] 0,5899[2]	0,69 [0,18; 2,66] 0,7355[4]	-1,9 [-8,6; 4,9] 0,7355[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 251.1.2: Subgroups - adverse events according PT Onychoclasis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9965)					
Neoadjuvant chemotherapy	10/314 (3,2)	0/306 (0,0)	20,47 [1,20; 347,75] 0,0367[2]	21,14 [1,23; 362,32] 0,0018[4]	3,2 [1,2; 5,1] 0,0018[4]
Adjuvant chemotherapy	8/452 (1,8)	4/416 (1,0)	1,84 [0,56; 6,07] 0,3161[2]	1,86 [0,55; 6,21] 0,3082[3]	0,8 [-0,7; 2,3] 0,3082[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,5382)					
North America / Europe	16/347 (4,6)	3/309 (1,0)	4,75 [1,40; 16,14] 0,0126[2]	4,93 [1,42; 17,09] 0,0055[3]	3,6 [1,2; 6,1] 0,0055[3]
Asia	0/239 (0,0)	0/226 (0,0)	NE	NE	NE
Other	2/190 (1,1)	1/194 (0,5)	2,04 [0,19; 22,33] 0,5585[2]	2,05 [0,18; 22,83] 0,6201[4]	0,5 [-1,2; 2,3] 0,6201[4]
Number of positive lymph nodes (Interaction p-value: 0,5816)					
0-3	8/269 (3,0)	1/269 (0,4)	8,00 [1,01; 63,52] 0,0492[2]	8,21 [1,02; 66,14] 0,0375[4]	2,6 [0,4; 4,8] 0,0375[4]
4-9	7/353 (2,0)	3/326 (0,9)	2,15 [0,56; 8,26] 0,2629[2]	2,18 [0,56; 8,50] 0,3440[4]	1,1 [-0,7; 2,8] 0,3440[4]
≥ 10	3/154 (1,9)	0/134 (0,0)	6,10 [0,32; 116,97] 0,2304[2]	6,21 [0,32; 121,41] 0,2510[4]	1,9 [-0,2; 4,1] 0,2510[4]
Tumor grade (Interaction p-value: 0,3857)					
G1	2/63 (3,2)	2/52 (3,8)	0,83 [0,12; 5,66] 0,8451[2]	0,82 [0,11; 6,03] 1,0000[4]	-0,7 [-7,5; 6,1] 1,0000[4]
G2	10/349 (2,9)	2/323 (0,6)	4,63 [1,02; 20,96] 0,0468[2]	4,73 [1,03; 21,77] 0,0280[3]	2,2 [0,3; 4,2] 0,0280[3]
G3	6/317 (1,9)	0/312 (0,0)	12,80 [0,72; 226,17] 0,0820[2]	13,04 [0,73; 232,50] 0,0305[4]	1,9 [0,4; 3,4] 0,0305[4]
GX	0/44 (0,0)	0/40 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 1,0000)					
Negative	1/67 (1,5)	0/62 (0,0)	2,78 [0,12; 66,98] 0,5289[2]	2,82 [0,11; 70,51] 1,0000[4]	1,5 [-1,4; 4,4] 1,0000[4]
Positive	13/678 (1,9)	4/647 (0,6)	3,10 [1,02; 9,46] 0,0467[2]	3,14 [1,02; 9,69] 0,0357[3]	1,3 [0,1; 2,5] 0,0357[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,9995)					
White	15/461 (3,3)	4/440 (0,9)	3,58 [1,20; 10,70] 0,0225[2]	3,67 [1,21; 11,13] 0,0143[3]	2,3 [0,5; 4,2] 0,0143[3]
Asian	1/273 (0,4)	0/243 (0,0)	2,67 [0,11; 65,27] 0,5468[2]	2,68 [0,11; 66,11] 1,0000[4]	0,4 [-0,4; 1,1] 1,0000[4]
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
First endocrine therapy (Interaction p-value: 0,9758)					
Tamoxifen	14/553 (2,5)	4/534 (0,7)	3,38 [1,12; 10,20] 0,0307[2]	3,44 [1,13; 10,52] 0,0213[3]	1,8 [0,3; 3,3] 0,0213[3]
Aromatase inhibitor	4/223 (1,8)	0/195 (0,0)	7,88 [0,43; 145,35] 0,1653[2]	8,02 [0,43; 149,83] 0,1266[4]	1,8 [0,1; 3,5] 0,1266[4]
ECOG-PS (Interaction p-value: 0,9692)					
ECOG-PS 0	18/685 (2,6)	3/649 (0,5)	5,68 [1,68; 19,21] 0,0052[2]	5,81 [1,70; 19,82] 0,0015[3]	2,2 [0,9; 3,5] 0,0015[3]
ECOG-PS 1	0/91 (0,0)	1/80 (1,3)	0,29 [0,01; 7,10] 0,4508[2]	0,29 [0,01; 7,21] 0,4678[4]	-1,3 [-3,7; 1,2] 0,4678[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 252.1.2: Subgroups - adverse events according PT Palpitations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,9712)					
Negative	0/67 (0,0)	0/62 (0,0)	NE	NE	NE
Positive	9/678 (1,3)	1/647 (0,2)	8,59 [1,09; 67,60] 0,0411[2]	8,69 [1,10; 68,79] 0,0214[4]	1,2 [0,3; 2,1] 0,0214[4]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 253.1.2: Subgroups - adverse events according PT Platelet count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8195)					
Neoadjuvant chemotherapy	18/314 (5,7)	5/306 (1,6)	3,51 [1,32; 9,33] 0,0119[2]	3,66 [1,34; 9,99] 0,0069[3]	4,1 [1,2; 7,0] 0,0069[3]
Adjuvant chemotherapy	40/452 (8,8)	7/416 (1,7)	5,26 [2,38; 11,61] <,0001[2]	5,67 [2,51; 12,81] <,0001[3]	7,2 [4,3; 10,1] <,0001[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,6051)					
North America / Europe	13/347 (3,7)	2/309 (0,6)	5,79 [1,32; 25,45] 0,0201[2]	5,97 [1,34; 26,69] 0,0080[3]	3,1 [0,9; 5,3] 0,0080[3]
Asia	35/239 (14,6)	6/226 (2,7)	5,52 [2,37; 12,86] <,0001[2]	6,29 [2,59; 15,27] <,0001[3]	12,0 [7,0; 16,9] <,0001[3]
Other	11/190 (5,8)	4/194 (2,1)	2,81 [0,91; 8,66] 0,0725[2]	2,92 [0,91; 9,33] 0,0594[3]	3,7 [-0,1; 7,6] 0,0594[3]
Number of positive lymph nodes (Interaction p-value: 0,6633)					
0-3	16/269 (5,9)	2/269 (0,7)	8,00 [1,86; 34,46] 0,0053[2]	8,44 [1,92; 37,09] 0,0008[3]	5,2 [2,2; 8,2] 0,0008[3]
4-9	28/353 (7,9)	7/326 (2,1)	3,69 [1,64; 8,34] 0,0017[2]	3,93 [1,69; 9,12] 0,0007[3]	5,8 [2,6; 9,0] 0,0007[3]
≥ 10	15/154 (9,7)	3/134 (2,2)	4,35 [1,29; 14,70] 0,0180[2]	4,71 [1,33; 16,65] 0,0087[3]	7,5 [2,2; 12,8] 0,0087[3]
Tumor stage (Interaction p-value: 0,9502)					
IIA	2/79 (2,5)	1/77 (1,3)	1,95 [0,18; 21,06] 0,5825[2]	1,97 [0,18; 22,23] 1,0000[4]	1,2 [-3,1; 5,5] 1,0000[4]
IIB	7/73 (9,6)	0/93 (0,0)	19,05 [1,11; 328,24] 0,0424[2]	21,09 [1,18; 375,68] 0,0027[4]	9,6 [2,8; 16,3] 0,0027[4]
IIIA	27/345 (7,8)	7/294 (2,4)	3,29 [1,45; 7,44] 0,0043[2]	3,48 [1,49; 8,12] 0,0022[3]	5,4 [2,1; 8,8] 0,0022[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	21/253 (8,3)	4/245 (1,6)	5,08 [1,77; 14,60] 0,0025[2]	5,45 [1,84; 16,13] 0,0007[3]	6,7 [2,9; 10,4] 0,0007[3]
Tumor grade (Interaction p-value: 0,9447)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	27/349 (7,7)	5/323 (1,5)	5,00 [1,95; 12,82] 0,0008[2]	5,33 [2,03; 14,02] 0,0002[3]	6,2 [3,1; 9,3] 0,0002[3]
G3	24/317 (7,6)	7/312 (2,2)	3,37 [1,48; 7,72] 0,0040[2]	3,57 [1,51; 8,41] 0,0020[3]	5,3 [2,0; 8,7] 0,0020[3]
GX	6/44 (13,6)	0/40 (0,0)	11,84 [0,69; 203,77] 0,0886[2]	13,68 [0,74; 251,05] 0,0268[4]	13,6 [3,5; 23,8] 0,0268[4]
Progesterone receptor status (Interaction p-value: 0,9295)					
Negative	7/67 (10,4)	1/62 (1,6)	6,48 [0,82; 51,16] 0,0764[2]	7,12 [0,85; 59,61] 0,0635[4]	8,8 [0,9; 16,8] 0,0635[4]
Positive	49/678 (7,2)	11/647 (1,7)	4,25 [2,23; 8,10] <,0001[2]	4,50 [2,32; 8,74] <,0001[3]	5,5 [3,3; 7,7] <,0001[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,8334)					
White	23/461 (5,0)	6/440 (1,4)	3,66 [1,50; 8,90] 0,0042[2]	3,80 [1,53; 9,42] 0,0021[3]	3,6 [1,4; 5,9] 0,0021[3]
Asian	36/273 (13,2)	6/243 (2,5)	5,34 [2,29; 12,46] 0,0001[2]	6,00 [2,48; 14,51] <,0001[3]	10,7 [6,3; 15,2] <,0001[3]
Other	0/30 (0,0)	0/34 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,9989)					
Tamoxifen	38/553 (6,9)	8/534 (1,5)	4,59 [2,16; 9,74] <,0001[2]	4,85 [2,24; 10,50] <,0001[3]	5,4 [3,0; 7,7] <,0001[3]
Aromatase inhibitor	21/223 (9,4)	4/195 (2,1)	4,59 [1,60; 13,14] 0,0045[2]	4,96 [1,67; 14,73] 0,0015[3]	7,4 [3,0; 11,7] 0,0015[3]
ECOG-PS (Interaction p-value: 0,0791)					
ECOG-PS 0	51/685 (7,4)	8/649 (1,2)	6,04 [2,89; 12,63] <,0001[2]	6,45 [3,03; 13,69] <,0001[3]	6,2 [4,1; 8,4] <,0001[3]
ECOG-PS 1	8/91 (8,8)	4/80 (5,0)	1,76 [0,55; 5,62] 0,3412[2]	1,83 [0,53; 6,33] 0,3328[3]	3,8 [-3,7; 11,3] 0,3328[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 254.1.2: Subgroups - adverse events according PT Pneumonia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,4432)					
Neoadjuvant chemotherapy	4/314 (1,3)	4/306 (1,3)	0,97 [0,25; 3,86] 0,9707[2]	0,97 [0,24; 3,93] 1,0000[4]	-0,0 [-1,8; 1,7] 1,0000[4]
Adjuvant chemotherapy	16/452 (3,5)	5/416 (1,2)	2,95 [1,09; 7,97] 0,0334[2]	3,02 [1,10; 8,31] 0,0251[3]	2,3 [0,3; 4,3] 0,0251[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,7736)					
North America / Europe	10/347 (2,9)	4/309 (1,3)	2,23 [0,71; 7,03] 0,1723[2]	2,26 [0,70; 7,29] 0,1603[3]	1,6 [-0,6; 3,8] 0,1603[3]
Asia	7/239 (2,9)	4/226 (1,8)	1,65 [0,49; 5,58] 0,4165[2]	1,67 [0,48; 5,80] 0,4111[3]	1,2 [-1,6; 3,9] 0,4111[3]
Other	4/190 (2,1)	1/194 (0,5)	4,08 [0,46; 36,21] 0,2063[2]	4,15 [0,46; 37,48] 0,2115[4]	1,6 [-0,7; 3,9] 0,2115[4]
Primary tumor size (Interaction p-value: 0,8494)					
< 20 mm	5/204 (2,5)	3/189 (1,6)	1,54 [0,37; 6,37] 0,5481[2]	1,56 [0,37; 6,61] 0,7254[4]	0,9 [-1,9; 3,6] 0,7254[4]
≥ 20 but < 50 mm	5/360 (1,4)	3/346 (0,9)	1,60 [0,39; 6,65] 0,5166[2]	1,61 [0,38; 6,79] 0,7254[4]	0,5 [-1,0; 2,1] 0,7254[4]
≥ 50 mm	8/194 (4,1)	3/185 (1,6)	2,54 [0,69; 9,44] 0,1631[2]	2,61 [0,68; 9,99] 0,1469[3]	2,5 [-0,8; 5,8] 0,1469[3]
Number of positive lymph nodes (Interaction p-value: 0,3319)					
0-3	6/269 (2,2)	4/269 (1,5)	1,50 [0,43; 5,26] 0,5262[2]	1,51 [0,42; 5,42] 0,5232[3]	0,7 [-1,5; 3,0] 0,5232[3]
4-9	11/353 (3,1)	2/326 (0,6)	5,08 [1,13; 22,74] 0,0336[2]	5,21 [1,15; 23,69] 0,0174[3]	2,5 [0,5; 4,5] 0,0174[3]
≥ 10	4/154 (2,6)	3/134 (2,2)	1,16 [0,26; 5,09] 0,8439[2]	1,16 [0,26; 5,30] 1,0000[4]	0,4 [-3,2; 3,9] 1,0000[4]
Tumor stage (Interaction p-value: 0,2715)					
IIA	0/79 (0,0)	2/77 (2,6)	0,20 [0,01; 4,00] 0,2888[2]	0,19 [0,01; 4,02] 0,2420[4]	-2,6 [-6,2; 1,0] 0,2420[4]
IIB	0/73 (0,0)	0/93 (0,0)	NE	NE	NE

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	14/345 (4,1)	1/294 (0,3)	11,93 [1,58; 90,19] 0,0163[2]	12,39 [1,62; 94,82] 0,0020[3]	3,7 [1,5; 5,9] 0,0020[3]
IIIB	1/22 (4,5)	2/19 (10,5)	0,43 [0,04; 4,40] 0,4782[2]	0,40 [0,03; 4,85] 0,5883[4]	-6,0 [-22,3; 10,3] 0,5883[4]
IIIC	5/253 (2,0)	4/245 (1,6)	1,21 [0,33; 4,45] 0,7739[2]	1,21 [0,32; 4,58] 1,0000[4]	0,3 [-2,0; 2,7] 1,0000[4]
Tumor grade (Interaction p-value: 0,9735)					
G1	1/63 (1,6)	0/52 (0,0)	2,48 [0,10; 59,73] 0,5749[2]	2,52 [0,10; 63,17] 1,0000[4]	1,6 [-1,5; 4,7] 1,0000[4]
G2	10/349 (2,9)	4/323 (1,2)	2,31 [0,73; 7,30] 0,1527[2]	2,35 [0,73; 7,58] 0,1401[3]	1,6 [-0,5; 3,8] 0,1401[3]
G3	8/317 (2,5)	5/312 (1,6)	1,57 [0,52; 4,76] 0,4211[2]	1,59 [0,51; 4,91] 0,4169[3]	0,9 [-1,3; 3,1] 0,4169[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,1409)					
Negative	1/67 (1,5)	2/62 (3,2)	0,46 [0,04; 4,98] 0,5248[2]	0,45 [0,04; 5,14] 0,6078[4]	-1,7 [-7,0; 3,5] 0,6078[4]
Positive	19/678 (2,8)	7/647 (1,1)	2,59 [1,10; 6,12] 0,0301[2]	2,64 [1,10; 6,31] 0,0240[3]	1,7 [0,2; 3,2] 0,0240[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,6384)					
White	13/461 (2,8)	4/440 (0,9)	3,10 [1,02; 9,44] 0,0462[2]	3,16 [1,02; 9,78] 0,0351[3]	1,9 [0,2; 3,7] 0,0351[3]
Asian	7/273 (2,6)	4/243 (1,6)	1,56 [0,46; 5,26] 0,4751[2]	1,57 [0,45; 5,44] 0,4711[3]	0,9 [-1,5; 3,4] 0,4711[3]
Other	1/30 (3,3)	1/34 (2,9)	1,13 [0,07; 17,34] 0,9283[2]	1,14 [0,07; 19,02] 1,0000[4]	0,4 [-8,2; 9,0] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,9712)					
Tamoxifen	11/553 (2,0)	5/534 (0,9)	2,12 [0,74; 6,07] 0,1597[2]	2,15 [0,74; 6,22] 0,1496[3]	1,1 [-0,4; 2,5] 0,1496[3]
Aromatase inhibitor	10/223 (4,5)	4/195 (2,1)	2,19 [0,70; 6,86] 0,1801[2]	2,24 [0,69; 7,27] 0,1678[3]	2,4 [-0,9; 5,8] 0,1678[3]
ECOG-PS (Interaction p-value: 0,0543)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	20/685 (2,9)	6/649 (0,9)	3,16 [1,28; 7,81] 0,0129[2]	3,22 [1,29; 8,08] 0,0084[3]	2,0 [0,5; 3,5] 0,0084[3]
ECOG-PS 1	1/91 (1,1)	3/80 (3,8)	0,29 [0,03; 2,76] 0,2835[2]	0,29 [0,03; 2,80] 0,3411[4]	-2,7 [-7,3; 2,0] 0,3411[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 255.1.2: Subgroups - adverse events according PT Pneumonitis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,0719)					
Neoadjuvant chemotherapy	3/314 (1,0)	2/306 (0,7)	1,46 [0,25; 8,69] 0,6763[2]	1,47 [0,24; 8,84] 1,0000[4]	0,3 [-1,1; 1,7] 1,0000[4]
Adjuvant chemotherapy	13/452 (2,9)	1/416 (0,2)	11,96 [1,57; 91,06] 0,0165[2]	12,29 [1,60; 94,36] 0,0021[3]	2,6 [1,0; 4,2] 0,0021[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,8612)					
North America / Europe	3/347 (0,9)	1/309 (0,3)	2,67 [0,28; 25,55] 0,3937[2]	2,69 [0,28; 25,96] 0,6264[4]	0,5 [-0,6; 1,7] 0,6264[4]
Asia	12/239 (5,0)	2/226 (0,9)	5,67 [1,28; 25,07] 0,0220[2]	5,92 [1,31; 26,76] 0,0091[3]	4,1 [1,1; 7,2] 0,0091[3]
Other	1/190 (0,5)	0/194 (0,0)	3,06 [0,13; 74,72] 0,4922[2]	3,08 [0,12; 76,06] 0,4948[4]	0,5 [-0,5; 1,6] 0,4948[4]
Number of positive lymph nodes (Interaction p-value: 0,3840)					
0-3	3/269 (1,1)	2/269 (0,7)	1,50 [0,25; 8,91] 0,6555[2]	1,51 [0,25; 9,08] 1,0000[4]	0,4 [-1,2; 2,0] 1,0000[4]
4-9	11/353 (3,1)	1/326 (0,3)	10,16 [1,32; 78,25] 0,0260[2]	10,45 [1,34; 81,42] 0,0055[3]	2,8 [0,9; 4,7] 0,0055[3]
≥ 10	2/154 (1,3)	0/134 (0,0)	4,35 [0,21; 89,92] 0,3409[2]	4,41 [0,21; 92,67] 0,5007[4]	1,3 [-0,5; 3,1] 0,5007[4]
Tumor grade (Interaction p-value: 0,2448)					
G1	1/63 (1,6)	0/52 (0,0)	2,48 [0,10; 59,73] 0,5749[2]	2,52 [0,10; 63,17] 1,0000[4]	1,6 [-1,5; 4,7] 1,0000[4]
G2	11/349 (3,2)	1/323 (0,3)	10,18 [1,32; 78,41] 0,0259[2]	10,48 [1,35; 81,63] 0,0054[3]	2,8 [0,9; 4,8] 0,0054[3]
G3	3/317 (0,9)	2/312 (0,6)	1,48 [0,25; 8,78] 0,6684[2]	1,48 [0,25; 8,92] 1,0000[4]	0,3 [-1,1; 1,7] 1,0000[4]
GX	0/44 (0,0)	0/40 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9533)					
Negative	2/67 (3,0)	0/62 (0,0)	4,63 [0,23; 94,63] 0,3193[2]	4,77 [0,22; 101,36] 0,4969[4]	3,0 [-1,1; 7,1] 0,4969[4]
Positive	13/678 (1,9)	3/647 (0,5)	4,14 [1,18; 14,44] 0,0261[2]	4,20 [1,19; 14,80] 0,0154[3]	1,5 [0,3; 2,6] 0,0154[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9026)					
White	3/461 (0,7)	1/440 (0,2)	2,86 [0,30; 27,42] 0,3615[2]	2,88 [0,30; 27,75] 0,6246[4]	0,4 [-0,4; 1,3] 0,6246[4]
Asian	12/273 (4,4)	2/243 (0,8)	5,34 [1,21; 23,62] 0,0272[2]	5,54 [1,23; 25,01] 0,0127[3]	3,6 [0,9; 6,3] 0,0127[3]
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
First endocrine therapy (Interaction p-value: 0,8317)					
Tamoxifen	6/553 (1,1)	1/534 (0,2)	5,79 [0,70; 47,96] 0,1033[2]	5,85 [0,70; 48,73] 0,1242[4]	0,9 [-0,0; 1,8] 0,1242[4]
Aromatase inhibitor	10/223 (4,5)	2/195 (1,0)	4,37 [0,97; 19,71] 0,0549[2]	4,53 [0,98; 20,94] 0,0346[3]	3,5 [0,4; 6,5] 0,0346[3]
ECOG-PS (Interaction p-value: 0,4381)					
ECOG-PS 0	9/685 (1,3)	1/649 (0,2)	8,53 [1,08; 67,12] 0,0417[2]	8,63 [1,09; 68,29] 0,0215[4]	1,2 [0,3; 2,1] 0,0215[4]
ECOG-PS 1	7/91 (7,7)	2/80 (2,5)	3,08 [0,66; 14,39] 0,1533[2]	3,25 [0,66; 16,12] 0,1763[4]	5,2 [-1,3; 11,6] 0,1763[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 256.1.2: Subgroups - adverse events according PT Productive cough from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,6297)					
Neoadjuvant chemotherapy	3/314 (1,0)	2/306 (0,7)	1,46 [0,25; 8,69] 0,6763[2]	1,47 [0,24; 8,84] 1,0000[4]	0,3 [-1,1; 1,7] 1,0000[4]
Adjuvant chemotherapy	10/452 (2,2)	2/416 (0,5)	4,60 [1,01; 20,88] 0,0479[2]	4,68 [1,02; 21,50] 0,0291[3]	1,7 [0,2; 3,2] 0,0291[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,9533)					
Negative	2/67 (3,0)	0/62 (0,0)	4,63 [0,23; 94,63] 0,3193[2]	4,77 [0,22; 101,36] 0,4969[4]	3,0 [-1,1; 7,1] 0,4969[4]
Positive	12/678 (1,8)	4/647 (0,6)	2,86 [0,93; 8,83] 0,0672[2]	2,90 [0,93; 9,03] 0,0550[3]	1,2 [-0,0; 2,3] 0,0550[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,8204)					
Tamoxifen	11/553 (2,0)	3/534 (0,6)	3,54 [0,99; 12,62] 0,0512[2]	3,59 [1,00; 12,95] 0,0369[3]	1,4 [0,1; 2,8] 0,0369[3]
Aromatase inhibitor	3/223 (1,3)	1/195 (0,5)	2,62 [0,28; 25,01] 0,4019[2]	2,65 [0,27; 25,64] 0,6266[4]	0,8 [-1,0; 2,6] 0,6266[4]
ECOG-PS (Interaction p-value: 0,9747)					
ECOG-PS 0	11/685 (1,6)	4/649 (0,6)	2,61 [0,83; 8,14] 0,0995[2]	2,63 [0,83; 8,31] 0,0867[3]	1,0 [-0,1; 2,1] 0,0867[3]
ECOG-PS 1	3/91 (3,3)	0/80 (0,0)	6,16 [0,32; 117,53] 0,2267[2]	6,37 [0,32; 125,17] 0,2487[4]	3,3 [-0,4; 7,0] 0,2487[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 257.1.2: Subgroups - adverse events according PT Pruritus from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,2953)					
Neoadjuvant chemotherapy	30/314 (9,6)	9/306 (2,9)	3,25 [1,57; 6,73] 0,0015[2]	3,49 [1,63; 7,47] 0,0007[3]	6,6 [2,9; 10,4] 0,0007[3]
Adjuvant chemotherapy	40/452 (8,8)	23/416 (5,5)	1,60 [0,98; 2,63] 0,0627[2]	1,66 [0,98; 2,82] 0,0596[3]	3,3 [-0,1; 6,7] 0,0596[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,7085)					
North America / Europe	21/347 (6,1)	11/309 (3,6)	1,70 [0,83; 3,47] 0,1448[2]	1,75 [0,83; 3,68] 0,1391[3]	2,5 [-0,8; 5,7] 0,1391[3]
Asia	35/239 (14,6)	16/226 (7,1)	2,07 [1,18; 3,63] 0,0114[2]	2,25 [1,21; 4,19] 0,0091[3]	7,6 [2,0; 13,2] 0,0091[3]
Other	14/190 (7,4)	5/194 (2,6)	2,86 [1,05; 7,78] 0,0398[2]	3,01 [1,06; 8,52] 0,0304[3]	4,8 [0,5; 9,1] 0,0304[3]
Primary tumor size (Interaction p-value: 0,9851)					
< 20 mm	20/204 (9,8)	9/189 (4,8)	2,06 [0,96; 4,41] 0,0630[2]	2,17 [0,96; 4,90] 0,0561[3]	5,0 [-0,0; 10,1] 0,0561[3]
≥ 20 but < 50 mm	31/360 (8,6)	15/346 (4,3)	1,99 [1,09; 3,61] 0,0246[2]	2,08 [1,10; 3,92] 0,0214[3]	4,3 [0,7; 7,9] 0,0214[3]
≥ 50 mm	16/194 (8,2)	7/185 (3,8)	2,18 [0,92; 5,18] 0,0775[2]	2,29 [0,92; 5,69] 0,0689[3]	4,5 [-0,3; 9,2] 0,0689[3]
Number of positive lymph nodes (Interaction p-value: 0,8483)					
0-3	23/269 (8,6)	13/269 (4,8)	1,77 [0,92; 3,42] 0,0896[2]	1,84 [0,91; 3,72] 0,0845[3]	3,7 [-0,5; 7,9] 0,0845[3]
4-9	37/353 (10,5)	15/326 (4,6)	2,28 [1,27; 4,07] 0,0055[2]	2,43 [1,31; 4,51] 0,0040[3]	5,9 [2,0; 9,8] 0,0040[3]
≥ 10	10/154 (6,5)	4/134 (3,0)	2,18 [0,70; 6,78] 0,1800[2]	2,26 [0,69; 7,37] 0,1673[3]	3,5 [-1,3; 8,4] 0,1673[3]
Tumor stage (Interaction p-value: 0,9823)					
IIA	5/79 (6,3)	3/77 (3,9)	1,62 [0,40; 6,56] 0,4959[2]	1,67 [0,38; 7,23] 0,7195[4]	2,4 [-4,5; 9,3] 0,7195[4]
IIB	7/73 (9,6)	4/93 (4,3)	2,23 [0,68; 7,33] 0,1865[2]	2,36 [0,66; 8,40] 0,2156[4]	5,3 [-2,6; 13,2] 0,2156[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	36/345 (10,4)	16/294 (5,4)	1,92 [1,09; 3,38] 0,0247[2]	2,02 [1,10; 3,73] 0,0214[3]	5,0 [0,9; 9,1] 0,0214[3]
IIIB	4/22 (18,2)	1/19 (5,3)	3,45 [0,42; 28,31] 0,2481[2]	4,00 [0,41; 39,37] 0,3499[4]	12,9 [-6,1; 31,9] 0,3499[4]
IIIC	17/253 (6,7)	8/245 (3,3)	2,06 [0,90; 4,68] 0,0852[2]	2,13 [0,90; 5,04] 0,0776[3]	3,5 [-0,3; 7,3] 0,0776[3]
Tumor grade (Interaction p-value: 0,8711)					
G1	9/63 (14,3)	0/52 (0,0)	15,73 [0,94; 264,08] 0,0555[2]	18,30 [1,04; 322,47] 0,0039[4]	14,3 [5,6; 22,9] 0,0039[4]
G2	24/349 (6,9)	13/323 (4,0)	1,71 [0,89; 3,30] 0,1104[2]	1,76 [0,88; 3,52] 0,1054[3]	2,9 [-0,6; 6,3] 0,1054[3]
G3	31/317 (9,8)	15/312 (4,8)	2,03 [1,12; 3,69] 0,0196[2]	2,15 [1,13; 4,06] 0,0166[3]	5,0 [0,9; 9,0] 0,0166[3]
GX	5/44 (11,4)	4/40 (10,0)	1,14 [0,33; 3,94] 0,8403[2]	1,15 [0,29; 4,64] 1,0000[4]	1,4 [-11,8; 14,6] 1,0000[4]
Race (Interaction p-value: 0,8082)					
White	27/461 (5,9)	14/440 (3,2)	1,84 [0,98; 3,46] 0,0585[2]	1,89 [0,98; 3,66] 0,0541[3]	2,7 [-0,0; 5,4] 0,0541[3]
Asian	38/273 (13,9)	16/243 (6,6)	2,11 [1,21; 3,69] 0,0085[2]	2,29 [1,24; 4,23] 0,0066[3]	7,3 [2,2; 12,5] 0,0066[3]
Other	2/30 (6,7)	2/34 (5,9)	1,13 [0,17; 7,56] 0,8971[2]	1,14 [0,15; 8,65] 1,0000[4]	0,8 [-11,1; 12,7] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,1894)					
Tamoxifen	51/553 (9,2)	20/534 (3,7)	2,46 [1,49; 4,07] 0,0004[2]	2,61 [1,53; 4,44] 0,0003[3]	5,5 [2,6; 8,4] 0,0003[3]
Aromatase inhibitor	19/223 (8,5)	12/195 (6,2)	1,38 [0,69; 2,78] 0,3600[2]	1,42 [0,67; 3,01] 0,3570[3]	2,4 [-2,6; 7,3] 0,3570[3]
ECOG-PS (Interaction p-value: 0,9360)					
ECOG-PS 0	65/685 (9,5)	30/649 (4,6)	2,05 [1,35; 3,12] 0,0008[2]	2,16 [1,38; 3,38] 0,0006[3]	4,9 [2,1; 7,6] 0,0006[3]
ECOG-PS 1	5/91 (5,5)	2/80 (2,5)	2,20 [0,44; 11,02] 0,3384[2]	2,27 [0,43; 12,02] 0,4503[4]	3,0 [-2,8; 8,8] 0,4503[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 258.1.2: Subgroups - adverse events according PT Pyrexia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8650)					
Neoadjuvant chemotherapy	40/314 (12,7)	16/306 (5,2)	2,44 [1,39; 4,26] 0,0018[2]	2,65 [1,45; 4,83] 0,0011[3]	7,5 [3,1; 12,0] 0,0011[3]
Adjuvant chemotherapy	43/452 (9,5)	20/416 (4,8)	1,98 [1,18; 3,31] 0,0092[2]	2,08 [1,20; 3,60] 0,0076[3]	4,7 [1,3; 8,1] 0,0076[3]
No chemotherapy	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]
Region (Interaction p-value: 0,5562)					
North America / Europe	38/347 (11,0)	16/309 (5,2)	2,11 [1,20; 3,72] 0,0092[2]	2,25 [1,23; 4,13] 0,0072[3]	5,8 [1,7; 9,9] 0,0072[3]
Asia	28/239 (11,7)	14/226 (6,2)	1,89 [1,02; 3,50] 0,0424[2]	2,01 [1,03; 3,92] 0,0379[3]	5,5 [0,4; 10,7] 0,0379[3]
Other	20/190 (10,5)	6/194 (3,1)	3,40 [1,40; 8,29] 0,0070[2]	3,69 [1,45; 9,40] 0,0037[3]	7,4 [2,4; 12,4] 0,0037[3]
Primary tumor size (Interaction p-value: 0,4917)					
< 20 mm	18/204 (8,8)	10/189 (5,3)	1,67 [0,79; 3,52] 0,1798[2]	1,73 [0,78; 3,85] 0,1738[3]	3,5 [-1,5; 8,6] 0,1738[3]
≥ 20 but < 50 mm	43/360 (11,9)	18/346 (5,2)	2,30 [1,35; 3,90] 0,0021[2]	2,47 [1,40; 4,38] 0,0014[3]	6,7 [2,7; 10,8] 0,0014[3]
≥ 50 mm	24/194 (12,4)	7/185 (3,8)	3,27 [1,44; 7,40] 0,0045[2]	3,59 [1,51; 8,55] 0,0023[3]	8,6 [3,2; 14,0] 0,0023[3]
Number of positive lymph nodes (Interaction p-value: 0,6060)					
0-3	26/269 (9,7)	11/269 (4,1)	2,36 [1,19; 4,69] 0,0138[2]	2,51 [1,21; 5,19] 0,0106[3]	5,6 [1,3; 9,8] 0,0106[3]
4-9	44/353 (12,5)	21/326 (6,4)	1,93 [1,18; 3,18] 0,0093[2]	2,07 [1,20; 3,56] 0,0077[3]	6,0 [1,7; 10,4] 0,0077[3]
≥ 10	16/154 (10,4)	4/134 (3,0)	3,48 [1,19; 10,16] 0,0225[2]	3,77 [1,23; 11,57] 0,0137[3]	7,4 [1,8; 13,0] 0,0137[3]
Tumor stage (Interaction p-value: 0,3615)					
IIA	8/79 (10,1)	2/77 (2,6)	3,90 [0,85; 17,78] 0,0788[2]	4,23 [0,87; 20,58] 0,0983[4]	7,5 [-0,0; 15,1] 0,0983[4]
IIB	7/73 (9,6)	5/93 (5,4)	1,78 [0,59; 5,39] 0,3052[2]	1,87 [0,57; 6,14] 0,2982[3]	4,2 [-4,0; 12,4] 0,2982[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	40/345 (11,6)	22/294 (7,5)	1,55 [0,94; 2,55] 0,0839[2]	1,62 [0,94; 2,80] 0,0801[3]	4,1 [-0,4; 8,6] 0,0801[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	28/253 (11,1)	7/245 (2,9)	3,87 [1,72; 8,70] 0,0010[2]	4,23 [1,81; 9,88] 0,0003[3]	8,2 [3,8; 12,6] 0,0003[3]
Tumor grade (Interaction p-value: 0,4158)					
G1	10/63 (15,9)	1/52 (1,9)	8,25 [1,09; 62,38] 0,0408[2]	9,62 [1,19; 77,90] 0,0117[4]	13,9 [4,2; 23,7] 0,0117[4]
G2	43/349 (12,3)	22/323 (6,8)	1,81 [1,11; 2,96] 0,0180[2]	1,92 [1,12; 3,29] 0,0158[3]	5,5 [1,1; 9,9] 0,0158[3]
G3	28/317 (8,8)	11/312 (3,5)	2,51 [1,27; 4,94] 0,0081[2]	2,65 [1,30; 5,42] 0,0058[3]	5,3 [1,6; 9,0] 0,0058[3]
GX	5/44 (11,4)	1/40 (2,5)	4,55 [0,55; 37,26] 0,1584[2]	5,00 [0,56; 44,78] 0,2049[4]	8,9 [-1,7; 19,4] 0,2049[4]
Progesterone receptor status (Interaction p-value: 0,8815)					
Negative	7/67 (10,4)	2/62 (3,2)	3,24 [0,70; 15,00] 0,1330[2]	3,50 [0,70; 17,54] 0,1672[4]	7,2 [-1,3; 15,8] 0,1672[4]
Positive	77/678 (11,4)	34/647 (5,3)	2,16 [1,46; 3,19] 0,0001[2]	2,31 [1,52; 3,51] <,0001[3]	6,1 [3,2; 9,0] <,0001[3]
Unknown	2/8 (25,0)	0/8 (0,0)	5,00 [0,28; 90,18] 0,2754[2]	6,54 [0,27; 160,97] 0,4667[4]	25,0 [-5,0; 55,0] 0,4667[4]
Race (Interaction p-value: 0,3164)					
White	50/461 (10,8)	18/440 (4,1)	2,65 [1,57; 4,47] 0,0003[2]	2,85 [1,64; 4,97] 0,0001[3]	6,8 [3,4; 10,1] 0,0001[3]
Asian	31/273 (11,4)	15/243 (6,2)	1,84 [1,02; 3,32] 0,0435[2]	1,95 [1,02; 3,70] 0,0392[3]	5,2 [0,4; 10,0] 0,0392[3]
Other	2/30 (6,7)	3/34 (8,8)	0,76 [0,14; 4,22] 0,7495[2]	0,74 [0,11; 4,74] 1,0000[4]	-2,2 [-15,2; 10,9] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,9875)					
Tamoxifen	58/553 (10,5)	25/534 (4,7)	2,24 [1,42; 3,53] 0,0005[2]	2,39 [1,47; 3,87] 0,0003[3]	5,8 [2,7; 8,9] 0,0003[3]
Aromatase inhibitor	28/223 (12,6)	11/195 (5,6)	2,23 [1,14; 4,35] 0,0193[2]	2,40 [1,16; 4,96] 0,0153[3]	6,9 [1,5; 12,3] 0,0153[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 259.1.2: Subgroups - adverse events according PT Rash from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9786)					
Neoadjuvant chemotherapy	21/314 (6,7)	9/306 (2,9)	2,27 [1,06; 4,89] 0,0353[2]	2,37 [1,07; 5,25] 0,0297[3]	3,7 [0,4; 7,1] 0,0297[3]
Adjuvant chemotherapy	41/452 (9,1)	15/416 (3,6)	2,52 [1,41; 4,48] 0,0017[2]	2,67 [1,45; 4,89] 0,0011[3]	5,5 [2,3; 8,7] 0,0011[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,1353)					
North America / Europe	32/347 (9,2)	7/309 (2,3)	4,07 [1,82; 9,09] 0,0006[2]	4,38 [1,91; 10,08] 0,0002[3]	7,0 [3,5; 10,4] 0,0002[3]
Asia	24/239 (10,0)	15/226 (6,6)	1,51 [0,81; 2,81] 0,1898[2]	1,57 [0,80; 3,08] 0,1856[3]	3,4 [-1,6; 8,4] 0,1856[3]
Other	7/190 (3,7)	2/194 (1,0)	3,57 [0,75; 16,98] 0,1093[2]	3,67 [0,75; 17,91] 0,1022[4]	2,7 [-0,4; 5,7] 0,1022[4]
Number of positive lymph nodes (Interaction p-value: 0,9990)					
0-3	22/269 (8,2)	9/269 (3,3)	2,44 [1,15; 5,21] 0,0206[2]	2,57 [1,16; 5,70] 0,0162[3]	4,8 [0,9; 8,7] 0,0162[3]
4-9	27/353 (7,6)	10/326 (3,1)	2,49 [1,23; 5,07] 0,0116[2]	2,62 [1,25; 5,50] 0,0086[3]	4,6 [1,2; 7,9] 0,0086[3]
≥ 10	14/154 (9,1)	5/134 (3,7)	2,44 [0,90; 6,59] 0,0793[2]	2,58 [0,90; 7,36] 0,0676[3]	5,4 [-0,2; 10,9] 0,0676[3]
Tumor stage (Interaction p-value: 0,8085)					
IIA	6/79 (7,6)	2/77 (2,6)	2,92 [0,61; 14,04] 0,1802[2]	3,08 [0,60; 15,77] 0,2765[4]	5,0 [-1,8; 11,8] 0,2765[4]
IIB	5/73 (6,8)	5/93 (5,4)	1,27 [0,38; 4,23] 0,6928[2]	1,29 [0,36; 4,65] 0,7502[4]	1,5 [-5,9; 8,9] 0,7502[4]
IIIA	26/345 (7,5)	7/294 (2,4)	3,17 [1,39; 7,19] 0,0059[2]	3,34 [1,43; 7,82] 0,0033[3]	5,2 [1,9; 8,4] 0,0033[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	23/253 (9,1)	10/245 (4,1)	2,23 [1,08; 4,58] 0,0296[2]	2,35 [1,09; 5,05] 0,0247[3]	5,0 [0,7; 9,3] 0,0247[3]
Tumor grade (Interaction p-value: 0,9977)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	7/63 (11,1)	0/52 (0,0)	12,42 [0,73; 212,50] 0,0820[2]	13,94 [0,78; 250,11] 0,0157[4]	11,1 [3,4; 18,9] 0,0157[4]
G2	27/349 (7,7)	12/323 (3,7)	2,08 [1,07; 4,04] 0,0301[2]	2,17 [1,08; 4,37] 0,0259[3]	4,0 [0,5; 7,5] 0,0259[3]
G3	23/317 (7,3)	12/312 (3,8)	1,89 [0,96; 3,72] 0,0674[2]	1,96 [0,96; 4,00] 0,0622[3]	3,4 [-0,2; 7,0] 0,0622[3]
GX	5/44 (11,4)	0/40 (0,0)	10,02 [0,57; 175,70] 0,1147[2]	11,28 [0,60; 210,81] 0,0565[4]	11,4 [2,0; 20,7] 0,0565[4]
Progesterone receptor status (Interaction p-value: 0,9753)					
Negative	3/67 (4,5)	1/62 (1,6)	2,78 [0,30; 25,99] 0,3709[2]	2,86 [0,29; 28,24] 0,6202[4]	2,9 [-3,0; 8,7] 0,6202[4]
Positive	56/678 (8,3)	22/647 (3,4)	2,43 [1,50; 3,93] 0,0003[2]	2,56 [1,54; 4,24] 0,0002[3]	4,9 [2,4; 7,4] 0,0002[3]
Unknown	3/8 (37,5)	1/8 (12,5)	3,00 [0,39; 23,07] 0,2912[2]	4,20 [0,33; 53,12] 0,5692[4]	25,0 [-15,6; 65,6] 0,5692[4]
Race (Interaction p-value: 0,3565)					
White	32/461 (6,9)	9/440 (2,0)	3,39 [1,64; 7,03] 0,0010[2]	3,57 [1,68; 7,57] 0,0004[3]	4,9 [2,2; 7,6] 0,0004[3]
Asian	27/273 (9,9)	14/243 (5,8)	1,72 [0,92; 3,20] 0,0886[2]	1,80 [0,92; 3,51] 0,0835[3]	4,1 [-0,5; 8,7] 0,0835[3]
Other	3/30 (10,0)	1/34 (2,9)	3,40 [0,37; 30,97] 0,2776[2]	3,67 [0,36; 37,30] 0,3334[4]	7,1 [-5,1; 19,2] 0,3334[4]
First endocrine therapy (Interaction p-value: 0,8038)					
Tamoxifen	45/553 (8,1)	17/534 (3,2)	2,56 [1,48; 4,41] 0,0007[2]	2,69 [1,52; 4,77] 0,0004[3]	5,0 [2,2; 7,7] 0,0004[3]
Aromatase inhibitor	18/223 (8,1)	7/195 (3,6)	2,25 [0,96; 5,27] 0,0622[2]	2,36 [0,96; 5,77] 0,0539[3]	4,5 [0,1; 8,9] 0,0539[3]
ECOG-PS (Interaction p-value: 0,7731)					
ECOG-PS 0	61/685 (8,9)	23/649 (3,5)	2,51 [1,57; 4,01] 0,0001[2]	2,66 [1,63; 4,35] <,0001[3]	5,4 [2,8; 7,9] <,0001[3]
ECOG-PS 1	2/91 (2,2)	1/80 (1,3)	1,76 [0,16; 19,03] 0,6424[2]	1,78 [0,16; 19,95] 1,0000[4]	0,9 [-2,9; 4,8] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 260.1.2: Subgroups - adverse events according PT Rectal haemorrhage from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9903)					
Neoadjuvant chemotherapy	5/314 (1,6)	0/306 (0,0)	10,72 [0,60; 193,05] 0,1078[2]	10,89 [0,60; 197,85] 0,0616[4]	1,6 [0,2; 3,0] 0,0616[4]
Adjuvant chemotherapy	9/452 (2,0)	2/416 (0,5)	4,14 [0,90; 19,06] 0,0680[2]	4,21 [0,90; 19,58] 0,0469[3]	1,5 [0,1; 3,0] 0,0469[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,3018)					
North America / Europe	12/347 (3,5)	1/309 (0,3)	10,69 [1,40; 81,71] 0,0225[2]	11,03 [1,43; 85,35] 0,0040[3]	3,1 [1,1; 5,2] 0,0040[3]
Asia	0/239 (0,0)	0/226 (0,0)	NE	NE	NE
Other	2/190 (1,1)	1/194 (0,5)	2,04 [0,19; 22,33] 0,5585[2]	2,05 [0,18; 22,83] 0,6201[4]	0,5 [-1,2; 2,3] 0,6201[4]
Progesterone receptor status (Interaction p-value: 0,9494)					
Negative	5/67 (7,5)	0/62 (0,0)	10,19 [0,58; 180,59] 0,1135[2]	11,00 [0,60; 203,18] 0,0586[4]	7,5 [1,2; 13,8] 0,0586[4]
Positive	8/678 (1,2)	2/647 (0,3)	3,82 [0,81; 17,91] 0,0894[2]	3,85 [0,81; 18,20] 0,1090[4]	0,9 [-0,0; 1,8] 0,1090[4]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9937)					
White	13/461 (2,8)	1/440 (0,2)	12,41 [1,63; 94,45] 0,0150[2]	12,74 [1,66; 97,79] 0,0017[3]	2,6 [1,0; 4,2] 0,0017[3]
Asian	0/273 (0,0)	0/243 (0,0)	NE	NE	NE
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
First endocrine therapy (Interaction p-value: 0,9773)					
Tamoxifen	11/553 (2,0)	2/534 (0,4)	5,31 [1,18; 23,85] 0,0293[2]	5,40 [1,19; 24,47] 0,0144[3]	1,6 [0,3; 2,9] 0,0144[3]
Aromatase inhibitor	3/223 (1,3)	0/195 (0,0)	6,13 [0,32; 117,84] 0,2296[2]	6,21 [0,32; 120,91] 0,2516[4]	1,3 [-0,2; 2,9] 0,2516[4]
ECOG-PS (Interaction p-value: 0,1309)					
ECOG-PS 0	13/685 (1,9)	1/649 (0,2)	12,32 [1,62; 93,89] 0,0154[2]	12,54 [1,64; 96,10] 0,0018[3]	1,7 [0,7; 2,8] 0,0018[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	1/91 (1,1)	1/80 (1,3)	0,88 [0,06; 13,83] 0,9270[2]	0,88 [0,05; 14,27] 1,0000[4]	-0,2 [-3,4; 3,1] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 261.1.2: Subgroups - adverse events according PT Sinusitis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1176)					
Neoadjuvant chemotherapy	11/314 (3,5)	4/306 (1,3)	2,68 [0,86; 8,33] 0,0883[2]	2,74 [0,86; 8,70] 0,0752[3]	2,2 [-0,2; 4,6] 0,0752[3]
Adjuvant chemotherapy	18/452 (4,0)	5/416 (1,2)	3,31 [1,24; 8,84] 0,0168[2]	3,41 [1,25; 9,27] 0,0108[3]	2,8 [0,7; 4,9] 0,0108[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,9979)					
North America / Europe	19/347 (5,5)	9/309 (2,9)	1,88 [0,86; 4,09] 0,1119[2]	1,93 [0,86; 4,33] 0,1050[3]	2,6 [-0,5; 5,6] 0,1050[3]
Asia	2/239 (0,8)	0/226 (0,0)	4,73 [0,23; 97,97] 0,3150[2]	4,77 [0,23; 99,87] 0,4993[4]	0,8 [-0,3; 2,0] 0,4993[4]
Other	8/190 (4,2)	0/194 (0,0)	17,36 [1,01; 298,60] 0,0493[2]	18,12 [1,04; 316,15] 0,0033[4]	4,2 [1,4; 7,1] 0,0033[4]
Primary tumor size (Interaction p-value: 0,3540)					
< 20 mm	5/204 (2,5)	5/189 (2,6)	0,93 [0,27; 3,15] 0,9026[2]	0,92 [0,26; 3,25] 1,0000[4]	-0,2 [-3,3; 2,9] 1,0000[4]
≥ 20 but < 50 mm	13/360 (3,6)	4/346 (1,2)	3,12 [1,03; 9,49] 0,0445[2]	3,20 [1,03; 9,92] 0,0334[3]	2,5 [0,2; 4,7] 0,0334[3]
≥ 50 mm	11/194 (5,7)	0/185 (0,0)	21,94 [1,30; 369,64] 0,0321[2]	23,25 [1,36; 397,46] 0,0010[3]	5,7 [2,4; 8,9] 0,0010[3]
Number of positive lymph nodes (Interaction p-value: 0,6822)					
0-3	14/269 (5,2)	6/269 (2,2)	2,33 [0,91; 5,98] 0,0777[2]	2,41 [0,91; 6,36] 0,0683[3]	3,0 [-0,2; 6,2] 0,0683[3]
4-9	11/353 (3,1)	2/326 (0,6)	5,08 [1,13; 22,74] 0,0336[2]	5,21 [1,15; 23,69] 0,0174[3]	2,5 [0,5; 4,5] 0,0174[3]
≥ 10	4/154 (2,6)	1/134 (0,7)	3,48 [0,39; 30,76] 0,2620[2]	3,55 [0,39; 32,13] 0,3767[4]	1,9 [-1,1; 4,8] 0,3767[4]
Tumor stage (Interaction p-value: 0,2886)					
IIA	2/79 (2,5)	3/77 (3,9)	0,65 [0,11; 3,78] 0,6314[2]	0,64 [0,10; 3,94] 0,6794[4]	-1,4 [-6,9; 4,2] 0,6794[4]
IIB	4/73 (5,5)	3/93 (3,2)	1,70 [0,39; 7,35] 0,4785[2]	1,74 [0,38; 8,03] 0,7005[4]	2,3 [-4,1; 8,6] 0,7005[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	14/345 (4,1)	2/294 (0,7)	5,97 [1,37; 26,03] 0,0175[2]	6,18 [1,39; 27,40] 0,0065[3]	3,4 [1,1; 5,7] 0,0065[3]
IIIB	1/22 (4,5)	0/19 (0,0)	2,61 [0,11; 60,51] 0,5500[2]	2,72 [0,10; 70,79] 1,0000[4]	4,5 [-4,2; 13,2] 1,0000[4]
IIIC	8/253 (3,2)	1/245 (0,4)	7,75 [0,98; 61,48] 0,0527[2]	7,97 [0,99; 64,18] 0,0376[4]	2,8 [0,5; 5,1] 0,0376[4]
Tumor grade (Interaction p-value: 0,4467)					
G1	5/63 (7,9)	1/52 (1,9)	4,13 [0,50; 34,22] 0,1891[2]	4,40 [0,50; 38,88] 0,2195[4]	6,0 [-1,6; 13,7] 0,2195[4]
G2	6/349 (1,7)	3/323 (0,9)	1,85 [0,47; 7,34] 0,3810[2]	1,87 [0,46; 7,52] 0,5078[4]	0,8 [-0,9; 2,5] 0,5078[4]
G3	18/317 (5,7)	5/312 (1,6)	3,54 [1,33; 9,43] 0,0113[2]	3,70 [1,36; 10,08] 0,0065[3]	4,1 [1,2; 7,0] 0,0065[3]
GX	0/44 (0,0)	0/40 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9236)					
Negative	2/67 (3,0)	0/62 (0,0)	4,63 [0,23; 94,63] 0,3193[2]	4,77 [0,22; 101,36] 0,4969[4]	3,0 [-1,1; 7,1] 0,4969[4]
Positive	26/678 (3,8)	8/647 (1,2)	3,10 [1,41; 6,80] 0,0047[2]	3,19 [1,43; 7,09] 0,0028[3]	2,6 [0,9; 4,3] 0,0028[3]
Unknown	0/8 (0,0)	1/8 (12,5)	0,33 [0,02; 7,14] 0,4823[2]	0,29 [0,01; 8,37] 1,0000[4]	-12,5 [-35,4; 10,4] 1,0000[4]
Race (Interaction p-value: 0,7848)					
White	26/461 (5,6)	8/440 (1,8)	3,10 [1,42; 6,78] 0,0045[2]	3,23 [1,45; 7,21] 0,0026[3]	3,8 [1,4; 6,3] 0,0026[3]
Asian	2/273 (0,7)	0/243 (0,0)	4,45 [0,21; 92,29] 0,3342[2]	4,48 [0,21; 93,87] 0,5007[4]	0,7 [-0,3; 1,7] 0,5007[4]
Other	1/30 (3,3)	1/34 (2,9)	1,13 [0,07; 17,34] 0,9283[2]	1,14 [0,07; 19,02] 1,0000[4]	0,4 [-8,2; 9,0] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,6897)					
Tamoxifen	20/553 (3,6)	7/534 (1,3)	2,76 [1,18; 6,47] 0,0196[2]	2,82 [1,18; 6,74] 0,0146[3]	2,3 [0,5; 4,1] 0,0146[3]
Aromatase inhibitor	9/223 (4,0)	2/195 (1,0)	3,93 [0,86; 17,99] 0,0773[2]	4,06 [0,87; 19,02] 0,0551[3]	3,0 [0,1; 6,0] 0,0551[3]
ECOG-PS (Interaction p-value: 0,9773)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	28/685 (4,1)	9/649 (1,4)	2,95 [1,40; 6,20] 0,0044[2]	3,03 [1,42; 6,47] 0,0027[3]	2,7 [1,0; 4,4] 0,0027[3]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 262.1.2: Subgroups - adverse events according PT Stomatitis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9995)					
Neoadjuvant chemotherapy	25/314 (8,0)	6/306 (2,0)	4,06 [1,69; 9,76] 0,0017[2]	4,33 [1,75; 10,70] 0,0006[3]	6,0 [2,6; 9,4] 0,0006[3]
Adjuvant chemotherapy	31/452 (6,9)	7/416 (1,7)	4,08 [1,81; 9,16] 0,0007[2]	4,30 [1,87; 9,88] 0,0002[3]	5,2 [2,5; 7,8] 0,0002[3]
No chemotherapy	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Region (Interaction p-value: 0,6495)					
North America / Europe	25/347 (7,2)	4/309 (1,3)	5,57 [1,96; 15,81] 0,0013[2]	5,92 [2,04; 17,21] 0,0002[3]	5,9 [2,9; 8,9] 0,0002[3]
Asia	29/239 (12,1)	9/226 (4,0)	3,05 [1,48; 6,29] 0,0026[2]	3,33 [1,54; 7,20] 0,0013[3]	8,2 [3,3; 13,0] 0,0013[3]
Other	4/190 (2,1)	0/194 (0,0)	9,19 [0,50; 169,50] 0,1359[2]	9,39 [0,50; 175,54] 0,0590[4]	2,1 [0,1; 4,1] 0,0590[4]
Primary tumor size (Interaction p-value: 0,4412)					
< 20 mm	16/204 (7,8)	3/189 (1,6)	4,94 [1,46; 16,69] 0,0101[2]	5,28 [1,51; 18,41] 0,0039[3]	6,3 [2,2; 10,4] 0,0039[3]
≥ 20 but < 50 mm	28/360 (7,8)	5/346 (1,4)	5,38 [2,10; 13,78] 0,0004[2]	5,75 [2,19; 15,07] <,0001[3]	6,3 [3,3; 9,4] <,0001[3]
≥ 50 mm	12/194 (6,2)	5/185 (2,7)	2,29 [0,82; 6,37] 0,1129[2]	2,37 [0,82; 6,87] 0,1015[3]	3,5 [-0,6; 7,6] 0,1015[3]
Number of positive lymph nodes (Interaction p-value: 0,6742)					
0-3	20/269 (7,4)	5/269 (1,9)	4,00 [1,52; 10,50] 0,0049[2]	4,24 [1,57; 11,47] 0,0021[3]	5,6 [2,1; 9,1] 0,0021[3]
4-9	29/353 (8,2)	5/326 (1,5)	5,36 [2,10; 13,67] 0,0004[2]	5,75 [2,20; 15,03] <,0001[3]	6,7 [3,5; 9,8] <,0001[3]
≥ 10	9/154 (5,8)	3/134 (2,2)	2,61 [0,72; 9,44] 0,1436[2]	2,71 [0,72; 10,23] 0,1267[3]	3,6 [-0,9; 8,1] 0,1267[3]
Tumor stage (Interaction p-value: 0,4564)					
IIA	7/79 (8,9)	2/77 (2,6)	3,41 [0,73; 15,91] 0,1183[2]	3,65 [0,73; 18,14] 0,1672[4]	6,3 [-0,9; 13,5] 0,1672[4]
IIB	2/73 (2,7)	2/93 (2,2)	1,27 [0,18; 8,83] 0,8063[2]	1,28 [0,18; 9,32] 1,0000[4]	0,6 [-4,2; 5,4] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	32/345 (9,3)	4/294 (1,4)	6,82 [2,44; 19,05] 0,0003[2]	7,41 [2,59; 21,22] <,0001[3]	7,9 [4,6; 11,2] <,0001[3]
IIIB	1/22 (4,5)	1/19 (5,3)	0,86 [0,06; 12,89] 0,9153[2]	0,86 [0,05; 14,71] 1,0000[4]	-0,7 [-14,0; 12,6] 1,0000[4]
IIIC	15/253 (5,9)	4/245 (1,6)	3,63 [1,22; 10,79] 0,0203[2]	3,80 [1,24; 11,61] 0,0123[3]	4,3 [1,0; 7,6] 0,0123[3]
Tumor grade (Interaction p-value: 0,9283)					
G1	8/63 (12,7)	2/52 (3,8)	3,30 [0,73; 14,88] 0,1199[2]	3,64 [0,74; 17,94] 0,1102[4]	8,9 [-0,9; 18,6] 0,1102[4]
G2	27/349 (7,7)	5/323 (1,5)	5,00 [1,95; 12,82] 0,0008[2]	5,33 [2,03; 14,02] 0,0002[3]	6,2 [3,1; 9,3] 0,0002[3]
G3	20/317 (6,3)	6/312 (1,9)	3,28 [1,34; 8,06] 0,0096[2]	3,43 [1,36; 8,67] 0,0057[3]	4,4 [1,3; 7,5] 0,0057[3]
GX	3/44 (6,8)	0/40 (0,0)	6,38 [0,34; 119,78] 0,2156[2]	6,83 [0,34; 136,48] 0,2427[4]	6,8 [-0,6; 14,3] 0,2427[4]
Progesterone receptor status (Interaction p-value: 0,0888)					
Negative	7/67 (10,4)	1/62 (1,6)	6,48 [0,82; 51,16] 0,0764[2]	7,12 [0,85; 59,61] 0,0635[4]	8,8 [0,9; 16,8] 0,0635[4]
Positive	50/678 (7,4)	12/647 (1,9)	3,98 [2,14; 7,40] <,0001[2]	4,21 [2,22; 7,99] <,0001[3]	5,5 [3,3; 7,7] <,0001[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,4493)					
White	23/461 (5,0)	3/440 (0,7)	7,32 [2,21; 24,20] 0,0011[2]	7,65 [2,28; 25,66] 0,0001[3]	4,3 [2,2; 6,4] 0,0001[3]
Asian	30/273 (11,0)	9/243 (3,7)	2,97 [1,44; 6,12] 0,0033[2]	3,21 [1,49; 6,91] 0,0018[3]	7,3 [2,9; 11,7] 0,0018[3]
Other	0/30 (0,0)	0/34 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,9648)					
Tamoxifen	48/553 (8,7)	11/534 (2,1)	4,21 [2,21; 8,03] <,0001[2]	4,52 [2,32; 8,80] <,0001[3]	6,6 [4,0; 9,3] <,0001[3]
Aromatase inhibitor	10/223 (4,5)	2/195 (1,0)	4,37 [0,97; 19,71] 0,0549[2]	4,53 [0,98; 20,94] 0,0346[3]	3,5 [0,4; 6,5] 0,0346[3]
ECOG-PS (Interaction p-value: 0,9741)					
ECOG-PS 0	52/685 (7,6)	13/649 (2,0)	3,79 [2,08; 6,89] <,0001[2]	4,02 [2,17; 7,45] <,0001[3]	5,6 [3,3; 7,8] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	6/91 (6,6)	0/80 (0,0)	11,45 [0,65; 200,04] 0,0949[2]	12,24 [0,68; 220,79] 0,0304[4]	6,6 [1,5; 11,7] 0,0304[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 263.1.2: Subgroups - adverse events according PT Thrombocytopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8685)					
Neoadjuvant chemotherapy	9/314 (2,9)	4/306 (1,3)	2,19 [0,68; 7,05] 0,1874[2]	2,23 [0,68; 7,31] 0,1755[3]	1,6 [-0,7; 3,8] 0,1755[3]
Adjuvant chemotherapy	18/452 (4,0)	5/416 (1,2)	3,31 [1,24; 8,84] 0,0168[2]	3,41 [1,25; 9,27] 0,0108[3]	2,8 [0,7; 4,9] 0,0108[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,5227)					
North America / Europe	8/347 (2,3)	4/309 (1,3)	1,78 [0,54; 5,86] 0,3420[2]	1,80 [0,54; 6,04] 0,3348[3]	1,0 [-1,0; 3,0] 0,3348[3]
Asia	7/239 (2,9)	1/226 (0,4)	6,62 [0,82; 53,38] 0,0760[2]	6,79 [0,83; 55,62] 0,0688[4]	2,5 [0,2; 4,8] 0,0688[4]
Other	13/190 (6,8)	4/194 (2,1)	3,32 [1,10; 10,00] 0,0330[2]	3,49 [1,12; 10,90] 0,0228[3]	4,8 [0,7; 8,9] 0,0228[3]
Primary tumor size (Interaction p-value: 0,5343)					
< 20 mm	6/204 (2,9)	3/189 (1,6)	1,85 [0,47; 7,30] 0,3782[2]	1,88 [0,46; 7,62] 0,5057[4]	1,4 [-1,6; 4,3] 0,5057[4]
≥ 20 but < 50 mm	14/360 (3,9)	5/346 (1,4)	2,69 [0,98; 7,39] 0,0548[2]	2,76 [0,98; 7,75] 0,0449[3]	2,4 [0,1; 4,8] 0,0449[3]
≥ 50 mm	8/194 (4,1)	1/185 (0,5)	7,63 [0,96; 60,40] 0,0543[2]	7,91 [0,98; 63,91] 0,0373[4]	3,6 [0,6; 6,6] 0,0373[4]
Number of positive lymph nodes (Interaction p-value: 0,5955)					
0-3	12/269 (4,5)	4/269 (1,5)	3,00 [0,98; 9,18] 0,0543[2]	3,09 [0,98; 9,72] 0,0423[3]	3,0 [0,1; 5,8] 0,0423[3]
4-9	13/353 (3,7)	3/326 (0,9)	4,00 [1,15; 13,92] 0,0292[2]	4,12 [1,16; 14,58] 0,0177[3]	2,8 [0,5; 5,0] 0,0177[3]
≥ 10	3/154 (1,9)	2/134 (1,5)	1,31 [0,22; 7,69] 0,7686[2]	1,31 [0,22; 7,97] 1,0000[4]	0,5 [-2,5; 3,5] 1,0000[4]
Tumor stage (Interaction p-value: 0,7102)					
IIA	5/79 (6,3)	3/77 (3,9)	1,62 [0,40; 6,56] 0,4959[2]	1,67 [0,38; 7,23] 0,7195[4]	2,4 [-4,5; 9,3] 0,7195[4]
IIB	2/73 (2,7)	1/93 (1,1)	2,55 [0,24; 27,55] 0,4413[2]	2,59 [0,23; 29,15] 0,5829[4]	1,7 [-2,6; 6,0] 0,5829[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	11/345 (3,2)	1/294 (0,3)	9,37 [1,22; 72,18] 0,0316[2]	9,65 [1,24; 75,19] 0,0082[3]	2,8 [0,9; 4,8] 0,0082[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	8/253 (3,2)	4/245 (1,6)	1,94 [0,59; 6,35] 0,2752[2]	1,97 [0,58; 6,62] 0,2658[3]	1,5 [-1,1; 4,2] 0,2658[3]
Tumor grade (Interaction p-value: 0,6009)					
G1	4/63 (6,3)	0/52 (0,0)	7,45 [0,41; 135,32] 0,1745[2]	7,94 [0,42; 151,00] 0,1253[4]	6,3 [0,3; 12,4] 0,1253[4]
G2	9/349 (2,6)	6/323 (1,9)	1,39 [0,50; 3,86] 0,5292[2]	1,40 [0,49; 3,97] 0,5272[3]	0,7 [-1,5; 2,9] 0,5272[3]
G3	13/317 (4,1)	3/312 (1,0)	4,26 [1,23; 14,82] 0,0225[2]	4,40 [1,24; 15,61] 0,0124[3]	3,1 [0,7; 5,6] 0,0124[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,9602)					
Negative	2/67 (3,0)	0/62 (0,0)	4,63 [0,23; 94,63] 0,3193[2]	4,77 [0,22; 101,36] 0,4969[4]	3,0 [-1,1; 7,1] 0,4969[4]
Positive	26/678 (3,8)	9/647 (1,4)	2,76 [1,30; 5,84] 0,0081[2]	2,83 [1,31; 6,08] 0,0056[3]	2,4 [0,7; 4,1] 0,0056[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,6096)					
White	17/461 (3,7)	7/440 (1,6)	2,32 [0,97; 5,54] 0,0584[2]	2,37 [0,97; 5,77] 0,0507[3]	2,1 [0,0; 4,2] 0,0507[3]
Asian	8/273 (2,9)	1/243 (0,4)	7,12 [0,90; 56,53] 0,0633[2]	7,31 [0,91; 58,84] 0,0403[4]	2,5 [0,4; 4,7] 0,0403[4]
Other	3/30 (10,0)	1/34 (2,9)	3,40 [0,37; 30,97] 0,2776[2]	3,67 [0,36; 37,30] 0,3334[4]	7,1 [-5,1; 19,2] 0,3334[4]
First endocrine therapy (Interaction p-value: 0,5232)					
Tamoxifen	18/553 (3,3)	7/534 (1,3)	2,48 [1,05; 5,90] 0,0393[2]	2,53 [1,05; 6,11] 0,0325[3]	1,9 [0,2; 3,7] 0,0325[3]
Aromatase inhibitor	10/223 (4,5)	2/195 (1,0)	4,37 [0,97; 19,71] 0,0549[2]	4,53 [0,98; 20,94] 0,0346[3]	3,5 [0,4; 6,5] 0,0346[3]
ECOG-PS (Interaction p-value: 0,8568)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	24/685 (3,5)	8/649 (1,2)	2,84 [1,29; 6,28] 0,0098[2]	2,91 [1,30; 6,52] 0,0067[3]	2,3 [0,7; 3,9] 0,0067[3]
ECOG-PS 1	4/91 (4,4)	1/80 (1,3)	3,52 [0,40; 30,82] 0,2562[2]	3,63 [0,40; 33,19] 0,3729[4]	3,1 [-1,7; 8,0] 0,3729[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 264.1.2: Subgroups - adverse events according PT Urinary tract infection from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9968)					
Neoadjuvant chemotherapy	28/314 (8,9)	14/306 (4,6)	1,95 [1,05; 3,63] 0,0355[2]	2,04 [1,05; 3,96] 0,0315[3]	4,3 [0,4; 8,3] 0,0315[3]
Adjuvant chemotherapy	39/452 (8,6)	19/416 (4,6)	1,89 [1,11; 3,22] 0,0191[2]	1,97 [1,12; 3,47] 0,0167[3]	4,1 [0,8; 7,3] 0,0167[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,5449)					
North America / Europe	46/347 (13,3)	18/309 (5,8)	2,28 [1,35; 3,84] 0,0021[2]	2,47 [1,40; 4,36] 0,0014[3]	7,4 [3,0; 11,9] 0,0014[3]
Asia	5/239 (2,1)	4/226 (1,8)	1,18 [0,32; 4,35] 0,8013[2]	1,19 [0,31; 4,47] 1,0000[4]	0,3 [-2,2; 2,8] 1,0000[4]
Other	17/190 (8,9)	11/194 (5,7)	1,58 [0,76; 3,28] 0,2217[2]	1,63 [0,74; 3,59] 0,2168[3]	3,3 [-1,9; 8,5] 0,2168[3]
Primary tumor size (Interaction p-value: 0,4052)					
< 20 mm	23/204 (11,3)	8/189 (4,2)	2,66 [1,22; 5,81] 0,0138[2]	2,88 [1,25; 6,60] 0,0097[3]	7,0 [1,8; 12,2] 0,0097[3]
≥ 20 but < 50 mm	23/360 (6,4)	16/346 (4,6)	1,38 [0,74; 2,57] 0,3074[2]	1,41 [0,73; 2,71] 0,3049[3]	1,8 [-1,6; 5,1] 0,3049[3]
≥ 50 mm	20/194 (10,3)	9/185 (4,9)	2,12 [0,99; 4,53] 0,0529[2]	2,25 [1,00; 5,07] 0,0463[3]	5,4 [0,2; 10,7] 0,0463[3]
Number of positive lymph nodes (Interaction p-value: 0,7998)					
0-3	22/269 (8,2)	12/269 (4,5)	1,83 [0,93; 3,63] 0,0819[2]	1,91 [0,92; 3,94] 0,0764[3]	3,7 [-0,4; 7,8] 0,0764[3]
4-9	31/353 (8,8)	16/326 (4,9)	1,79 [1,00; 3,21] 0,0510[2]	1,87 [1,00; 3,48] 0,0469[3]	3,9 [0,1; 7,6] 0,0469[3]
≥ 10	15/154 (9,7)	5/134 (3,7)	2,61 [0,97; 6,99] 0,0563[2]	2,78 [0,98; 7,88] 0,0454[3]	6,0 [0,3; 11,7] 0,0454[3]
Tumor stage (Interaction p-value: 0,6759)					
IIA	7/79 (8,9)	2/77 (2,6)	3,41 [0,73; 15,91] 0,1183[2]	3,65 [0,73; 18,14] 0,1672[4]	6,3 [-0,9; 13,5] 0,1672[4]
IIB	3/73 (4,1)	4/93 (4,3)	0,96 [0,22; 4,14] 0,9514[2]	0,95 [0,21; 4,40] 1,0000[4]	-0,2 [-6,3; 6,0] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	27/345 (7,8)	14/294 (4,8)	1,64 [0,88; 3,07] 0,1201[2]	1,70 [0,87; 3,30] 0,1152[3]	3,1 [-0,7; 6,8] 0,1152[3]
IIIB	1/22 (4,5)	1/19 (5,3)	0,86 [0,06; 12,89] 0,9153[2]	0,86 [0,05; 14,71] 1,0000[4]	-0,7 [-14,0; 12,6] 1,0000[4]
IIIC	29/253 (11,5)	12/245 (4,9)	2,34 [1,22; 4,48] 0,0103[2]	2,51 [1,25; 5,05] 0,0077[3]	6,6 [1,8; 11,3] 0,0077[3]
Tumor grade (Interaction p-value: 0,9781)					
G1	5/63 (7,9)	0/52 (0,0)	9,11 [0,52; 161,00] 0,1316[2]	9,87 [0,53; 182,84] 0,0627[4]	7,9 [1,3; 14,6] 0,0627[4]
G2	35/349 (10,0)	19/323 (5,9)	1,70 [1,00; 2,92] 0,0518[2]	1,78 [1,00; 3,19] 0,0482[3]	4,1 [0,1; 8,2] 0,0482[3]
G3	25/317 (7,9)	13/312 (4,2)	1,89 [0,99; 3,63] 0,0550[2]	1,97 [0,99; 3,92] 0,0503[3]	3,7 [0,0; 7,4] 0,0503[3]
GX	3/44 (6,8)	1/40 (2,5)	2,73 [0,30; 25,17] 0,3762[2]	2,85 [0,28; 28,61] 0,6176[4]	4,3 [-4,6; 13,2] 0,6176[4]
Progesterone receptor status (Interaction p-value: 0,1501)					
Negative	1/67 (1,5)	4/62 (6,5)	0,23 [0,03; 2,01] 0,1849[2]	0,22 [0,02; 2,02] 0,1944[4]	-5,0 [-11,7; 1,8] 0,1944[4]
Positive	63/678 (9,3)	29/647 (4,5)	2,07 [1,35; 3,18] 0,0008[2]	2,18 [1,39; 3,44] 0,0006[3]	4,8 [2,1; 7,5] 0,0006[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,3600)					
White	51/461 (11,1)	27/440 (6,1)	1,80 [1,15; 2,82] 0,0099[2]	1,90 [1,17; 3,09] 0,0086[3]	4,9 [1,3; 8,6] 0,0086[3]
Asian	7/273 (2,6)	4/243 (1,6)	1,56 [0,46; 5,26] 0,4751[2]	1,57 [0,45; 5,44] 0,4711[3]	0,9 [-1,5; 3,4] 0,4711[3]
Other	7/30 (23,3)	1/34 (2,9)	7,93 [1,03; 60,83] 0,0463[2]	10,04 [1,16; 87,25] 0,0211[4]	20,4 [4,2; 36,6] 0,0211[4]
First endocrine therapy (Interaction p-value: 0,5227)					
Tamoxifen	48/553 (8,7)	22/534 (4,1)	2,11 [1,29; 3,44] 0,0029[2]	2,21 [1,32; 3,72] 0,0022[3]	4,6 [1,7; 7,4] 0,0022[3]
Aromatase inhibitor	20/223 (9,0)	11/195 (5,6)	1,59 [0,78; 3,23] 0,2007[2]	1,65 [0,77; 3,53] 0,1952[3]	3,3 [-1,6; 8,3] 0,1952[3]
ECOG-PS (Interaction p-value: 0,0981)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	61/685 (8,9)	26/649 (4,0)	2,22 [1,42; 3,47] 0,0005[2]	2,34 [1,46; 3,76] 0,0003[3]	4,9 [2,3; 7,5] 0,0003[3]
ECOG-PS 1	7/91 (7,7)	7/80 (8,8)	0,88 [0,32; 2,40] 0,8014[2]	0,87 [0,29; 2,59] 0,8013[3]	-1,1 [-9,3; 7,2] 0,8013[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 265.1.2: Subgroups - adverse events according PT Vaginal discharge from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,3204)					
Neoadjuvant chemotherapy	3/314 (1,0)	10/306 (3,3)	0,29 [0,08; 1,05] 0,0598[2]	0,29 [0,08; 1,05] 0,0445[3]	-2,3 [-4,6; -0,0] 0,0445[3]
Adjuvant chemotherapy	8/452 (1,8)	16/416 (3,8)	0,46 [0,20; 1,06] 0,0695[2]	0,45 [0,19; 1,06] 0,0624[3]	-2,1 [-4,3; 0,1] 0,0624[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,4351)					
North America / Europe	7/347 (2,0)	10/309 (3,2)	0,62 [0,24; 1,62] 0,3313[2]	0,62 [0,23; 1,64] 0,3267[3]	-1,2 [-3,7; 1,2] 0,3267[3]
Asia	3/239 (1,3)	12/226 (5,3)	0,24 [0,07; 0,83] 0,0240[2]	0,23 [0,06; 0,81] 0,0134[3]	-4,1 [-7,3; -0,8] 0,0134[3]
Other	1/190 (0,5)	4/194 (2,1)	0,26 [0,03; 2,26] 0,2200[2]	0,25 [0,03; 2,27] 0,3719[4]	-1,5 [-3,8; 0,7] 0,3719[4]
Primary tumor size (Interaction p-value: 0,4243)					
< 20 mm	3/204 (1,5)	9/189 (4,8)	0,31 [0,08; 1,12] 0,0746[2]	0,30 [0,08; 1,12] 0,0581[3]	-3,3 [-6,7; 0,2] 0,0581[3]
≥ 20 but < 50 mm	3/360 (0,8)	12/346 (3,5)	0,24 [0,07; 0,84] 0,0261[2]	0,23 [0,07; 0,84] 0,0152[3]	-2,6 [-4,8; -0,5] 0,0152[3]
≥ 50 mm	4/194 (2,1)	5/185 (2,7)	0,76 [0,21; 2,80] 0,6831[2]	0,76 [0,20; 2,87] 0,7458[4]	-0,6 [-3,7; 2,4] 0,7458[4]
Number of positive lymph nodes (Interaction p-value: 0,9922)					
0-3	5/269 (1,9)	12/269 (4,5)	0,42 [0,15; 1,17] 0,0956[2]	0,41 [0,14; 1,17] 0,0845[3]	-2,6 [-5,6; 0,3] 0,0845[3]
4-9	5/353 (1,4)	12/326 (3,7)	0,38 [0,14; 1,08] 0,0698[2]	0,38 [0,13; 1,08] 0,0592[3]	-2,3 [-4,7; 0,1] 0,0592[3]
≥ 10	1/154 (0,6)	2/134 (1,5)	0,44 [0,04; 4,74] 0,4948[2]	0,43 [0,04; 4,81] 0,5993[4]	-0,8 [-3,3; 1,6] 0,5993[4]
Tumor stage (Interaction p-value: 0,8051)					
IIA	2/79 (2,5)	5/77 (6,5)	0,39 [0,08; 1,95] 0,2514[2]	0,37 [0,07; 1,99] 0,2732[4]	-4,0 [-10,5; 2,5] 0,2732[4]
IIB	1/73 (1,4)	5/93 (5,4)	0,25 [0,03; 2,13] 0,2073[2]	0,24 [0,03; 2,14] 0,2309[4]	-4,0 [-9,3; 1,3] 0,2309[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	6/345 (1,7)	9/294 (3,1)	0,57 [0,20; 1,58] 0,2778[2]	0,56 [0,20; 1,59] 0,2713[3]	-1,3 [-3,7; 1,1] 0,2713[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	1/253 (0,4)	7/245 (2,9)	0,14 [0,02; 1,12] 0,0633[2]	0,13 [0,02; 1,10] 0,0349[4]	-2,5 [-4,7; -0,2] 0,0349[4]
Tumor grade (Interaction p-value: 0,7358)					
G1	1/63 (1,6)	1/52 (1,9)	0,83 [0,05; 12,88] 0,8911[2]	0,82 [0,05; 13,48] 1,0000[4]	-0,3 [-5,2; 4,5] 1,0000[4]
G2	6/349 (1,7)	10/323 (3,1)	0,56 [0,20; 1,51] 0,2493[2]	0,55 [0,20; 1,52] 0,2421[3]	-1,4 [-3,7; 1,0] 0,2421[3]
G3	4/317 (1,3)	15/312 (4,8)	0,26 [0,09; 0,78] 0,0163[2]	0,25 [0,08; 0,77] 0,0094[3]	-3,5 [-6,2; -0,9] 0,0094[3]
GX	0/44 (0,0)	0/40 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9967)					
Negative	0/67 (0,0)	0/62 (0,0)	NE	NE	NE
Positive	9/678 (1,3)	26/647 (4,0)	0,33 [0,16; 0,70] 0,0038[2]	0,32 [0,15; 0,69] 0,0023[3]	-2,7 [-4,4; -0,9] 0,0023[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,5835)					
White	8/461 (1,7)	14/440 (3,2)	0,55 [0,23; 1,29] 0,1665[2]	0,54 [0,22; 1,29] 0,1597[3]	-1,4 [-3,5; 0,6] 0,1597[3]
Asian	3/273 (1,1)	11/243 (4,5)	0,24 [0,07; 0,86] 0,0283[2]	0,23 [0,06; 0,85] 0,0167[3]	-3,4 [-6,3; -0,5] 0,0167[3]
Other	0/30 (0,0)	1/34 (2,9)	0,38 [0,02; 8,91] 0,5449[2]	0,37 [0,01; 9,33] 1,0000[4]	-2,9 [-8,6; 2,7] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,3272)					
Tamoxifen	7/553 (1,3)	21/534 (3,9)	0,32 [0,14; 0,75] 0,0087[2]	0,31 [0,13; 0,74] 0,0055[3]	-2,7 [-4,6; -0,8] 0,0055[3]
Aromatase inhibitor	4/223 (1,8)	5/195 (2,6)	0,70 [0,19; 2,57] 0,5903[2]	0,69 [0,18; 2,62] 0,7394[4]	-0,8 [-3,6; 2,1] 0,7394[4]
ECOG-PS (Interaction p-value: 0,9734)					
ECOG-PS 0	11/685 (1,6)	24/649 (3,7)	0,43 [0,21; 0,88] 0,0205[2]	0,43 [0,21; 0,87] 0,0169[3]	-2,1 [-3,8; -0,4] 0,0169[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	0/91 (0,0)	2/80 (2,5)	0,18 [0,01; 3,61] 0,2599[2]	0,17 [0,01; 3,63] 0,2174[4]	-2,5 [-5,9; 0,9] 0,2174[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 266.1.2: Subgroups - adverse events according PT Vomiting from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,4678)					
Neoadjuvant chemotherapy	57/314 (18,2)	8/306 (2,6)	6,94 [3,37; 14,31] <,0001[2]	8,26 [3,87; 17,64] <,0001[3]	15,5 [10,9; 20,2] <,0001[3]
Adjuvant chemotherapy	64/452 (14,2)	15/416 (3,6)	3,93 [2,27; 6,78] <,0001[2]	4,41 [2,47; 7,87] <,0001[3]	10,6 [6,9; 14,2] <,0001[3]
No chemotherapy	4/10 (40,0)	0/7 (0,0)	6,55 [0,41; 105,10] 0,1847[2]	10,38 [0,47; 231,63] 0,1029[4]	40,0 [9,6; 70,4] 0,1029[4]
Region (Interaction p-value: 0,6485)					
North America / Europe	73/347 (21,0)	11/309 (3,6)	5,91 [3,19; 10,93] <,0001[2]	7,22 [3,75; 13,89] <,0001[3]	17,5 [12,7; 22,2] <,0001[3]
Asia	27/239 (11,3)	7/226 (3,1)	3,65 [1,62; 8,21] 0,0018[2]	3,98 [1,70; 9,35] 0,0007[3]	8,2 [3,6; 12,8] 0,0007[3]
Other	25/190 (13,2)	5/194 (2,6)	5,11 [2,00; 13,06] 0,0007[2]	5,73 [2,14; 15,30] 0,0001[3]	10,6 [5,3; 15,9] 0,0001[3]
Primary tumor size (Interaction p-value: 0,0503)					
< 20 mm	34/204 (16,7)	6/189 (3,2)	5,25 [2,26; 12,22] 0,0001[2]	6,10 [2,50; 14,89] <,0001[3]	13,5 [7,8; 19,2] <,0001[3]
≥ 20 but < 50 mm	51/360 (14,2)	16/346 (4,6)	3,06 [1,78; 5,27] <,0001[2]	3,40 [1,90; 6,10] <,0001[3]	9,5 [5,3; 13,8] <,0001[3]
≥ 50 mm	37/194 (19,1)	1/185 (0,5)	35,28 [4,89; 254,54] 0,0004[2]	43,36 [5,88; 319,66] <,0001[3]	18,5 [12,9; 24,2] <,0001[3]
Tumor stage (Interaction p-value: 0,5092)					
IIA	14/79 (17,7)	4/77 (5,2)	3,41 [1,17; 9,91] 0,0241[2]	3,93 [1,23; 12,54] 0,0143[3]	12,5 [2,8; 22,3] 0,0143[3]
IIB	15/73 (20,5)	1/93 (1,1)	19,11 [2,58; 141,33] 0,0039[2]	23,79 [3,06; 184,96] <,0001[3]	19,5 [10,0; 29,0] <,0001[3]
IIIA	52/345 (15,1)	11/294 (3,7)	4,03 [2,14; 7,58] <,0001[2]	4,57 [2,33; 8,93] <,0001[3]	11,3 [7,0; 15,7] <,0001[3]
IIIB	3/22 (13,6)	1/19 (5,3)	2,59 [0,29; 22,88] 0,3917[2]	2,84 [0,27; 29,90] 0,6099[4]	8,4 [-9,1; 25,9] 0,6099[4]
IIIC	40/253 (15,8)	6/245 (2,4)	6,46 [2,79; 14,95] <,0001[2]	7,48 [3,11; 17,99] <,0001[3]	13,4 [8,5; 18,3] <,0001[3]
Tumor grade (Interaction p-value: 0,7245)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	9/63 (14,3)	1/52 (1,9)	7,43 [0,97; 56,74] 0,0532[2]	8,50 [1,04; 69,49] 0,0215[4]	12,4 [3,0; 21,8] 0,0215[4]
G2	58/349 (16,6)	8/323 (2,5)	6,71 [3,25; 13,83] <,0001[2]	7,85 [3,68; 16,72] <,0001[3]	14,1 [9,9; 18,4] <,0001[3]
G3	54/317 (17,0)	13/312 (4,2)	4,09 [2,28; 7,34] <,0001[2]	4,72 [2,52; 8,85] <,0001[3]	12,9 [8,2; 17,6] <,0001[3]
GX	4/44 (9,1)	1/40 (2,5)	3,64 [0,42; 31,19] 0,2390[2]	3,90 [0,42; 36,46] 0,3626[4]	6,6 [-3,2; 16,4] 0,3626[4]
Progesterone receptor status (Interaction p-value: 0,9749)					
Negative	13/67 (19,4)	2/62 (3,2)	6,01 [1,41; 25,59] 0,0152[2]	7,22 [1,56; 33,47] 0,0042[3]	16,2 [5,7; 26,6] 0,0042[3]
Positive	106/678 (15,6)	20/647 (3,1)	5,06 [3,18; 8,06] <,0001[2]	5,81 [3,56; 9,49] <,0001[3]	12,5 [9,5; 15,6] <,0001[3]
Unknown	2/8 (25,0)	0/8 (0,0)	5,00 [0,28; 90,18] 0,2754[2]	6,54 [0,27; 160,97] 0,4667[4]	25,0 [-5,0; 55,0] 0,4667[4]
Race (Interaction p-value: 0,7398)					
White	86/461 (18,7)	14/440 (3,2)	5,86 [3,38; 10,16] <,0001[2]	6,98 [3,90; 12,48] <,0001[3]	15,5 [11,6; 19,4] <,0001[3]
Asian	33/273 (12,1)	7/243 (2,9)	4,20 [1,89; 9,31] 0,0004[2]	4,64 [2,01; 10,69] <,0001[3]	9,2 [4,8; 13,6] <,0001[3]
Other	3/30 (10,0)	1/34 (2,9)	3,40 [0,37; 30,97] 0,2776[2]	3,67 [0,36; 37,30] 0,3334[4]	7,1 [-5,1; 19,2] 0,3334[4]
First endocrine therapy (Interaction p-value: 0,8018)					
Tamoxifen	82/553 (14,8)	15/534 (2,8)	5,28 [3,08; 9,04] <,0001[2]	6,02 [3,43; 10,59] <,0001[3]	12,0 [8,7; 15,3] <,0001[3]
Aromatase inhibitor	43/223 (19,3)	8/195 (4,1)	4,70 [2,27; 9,75] <,0001[2]	5,58 [2,55; 12,20] <,0001[3]	15,2 [9,3; 21,1] <,0001[3]
ECOG-PS (Interaction p-value: 0,9653)					
ECOG-PS 0	113/685 (16,5)	21/649 (3,2)	5,10 [3,24; 8,02] <,0001[2]	5,91 [3,66; 9,54] <,0001[3]	13,3 [10,2; 16,4] <,0001[3]
ECOG-PS 1	12/91 (13,2)	2/80 (2,5)	5,27 [1,22; 22,86] 0,0263[2]	5,92 [1,28; 27,34] 0,0110[3]	10,7 [2,9; 18,4] 0,0110[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 267.1.2: Subgroups - adverse events according PT White blood cell count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8275)					
Neoadjuvant chemotherapy	79/314 (25,2)	24/306 (7,8)	3,21 [2,09; 4,93] <,0001[2]	3,95 [2,42; 6,44] <,0001[3]	17,3 [11,6; 23,0] <,0001[3]
Adjuvant chemotherapy	133/452 (29,4)	32/416 (7,7)	3,83 [2,66; 5,49] <,0001[2]	5,00 [3,31; 7,57] <,0001[3]	21,7 [16,8; 26,7] <,0001[3]
No chemotherapy	3/10 (30,0)	0/7 (0,0)	5,09 [0,30; 85,39] 0,2580[2]	7,00 [0,31; 160,32] 0,2279[4]	30,0 [1,6; 58,4] 0,2279[4]
Region (Interaction p-value: 0,5759)					
North America / Europe	55/347 (15,9)	12/309 (3,9)	4,08 [2,23; 7,48] <,0001[2]	4,66 [2,45; 8,89] <,0001[3]	12,0 [7,6; 16,4] <,0001[3]
Asia	123/239 (51,5)	36/226 (15,9)	3,23 [2,34; 4,47] <,0001[2]	5,60 [3,61; 8,67] <,0001[3]	35,5 [27,6; 43,5] <,0001[3]
Other	37/190 (19,5)	8/194 (4,1)	4,72 [2,26; 9,87] <,0001[2]	5,62 [2,54; 12,43] <,0001[3]	15,3 [9,1; 21,6] <,0001[3]
Primary tumor size (Interaction p-value: 0,6729)					
< 20 mm	55/204 (27,0)	12/189 (6,3)	4,25 [2,35; 7,68] <,0001[2]	5,44 [2,81; 10,55] <,0001[3]	20,6 [13,6; 27,6] <,0001[3]
≥ 20 but < 50 mm	108/360 (30,0)	29/346 (8,4)	3,58 [2,44; 5,25] <,0001[2]	4,68 [3,01; 7,29] <,0001[3]	21,6 [16,1; 27,2] <,0001[3]
≥ 50 mm	43/194 (22,2)	14/185 (7,6)	2,93 [1,66; 5,17] 0,0002[2]	3,48 [1,83; 6,61] <,0001[3]	14,6 [7,6; 21,6] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,2887)					
0-3	64/269 (23,8)	12/269 (4,5)	5,33 [2,95; 9,65] <,0001[2]	6,69 [3,51; 12,72] <,0001[3]	19,3 [13,7; 25,0] <,0001[3]
4-9	104/353 (29,5)	31/326 (9,5)	3,10 [2,14; 4,49] <,0001[2]	3,97 [2,57; 6,14] <,0001[3]	20,0 [14,2; 25,7] <,0001[3]
≥ 10	47/154 (30,5)	13/134 (9,7)	3,15 [1,78; 5,56] <,0001[2]	4,09 [2,10; 7,97] <,0001[3]	20,8 [12,0; 29,7] <,0001[3]
Tumor stage (Interaction p-value: 0,3305)					
IIA	15/79 (19,0)	4/77 (5,2)	3,66 [1,27; 10,52] 0,0163[2]	4,28 [1,35; 13,55] 0,0085[3]	13,8 [3,8; 23,8] 0,0085[3]
IIB	23/73 (31,5)	2/93 (2,2)	14,65 [3,57; 60,13] 0,0002[2]	20,93 [4,74; 92,45] <,0001[3]	29,4 [18,3; 40,4] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	107/345 (31,0)	30/294 (10,2)	3,04 [2,09; 4,42] <,0001[2]	3,96 [2,54; 6,15] <,0001[3]	20,8 [14,8; 26,8] <,0001[3]
IIIB	3/22 (13,6)	0/19 (0,0)	6,09 [0,33; 110,84] 0,2225[2]	7,00 [0,34; 144,73] 0,2354[4]	13,6 [-0,7; 28,0] 0,2354[4]
IIIC	63/253 (24,9)	20/245 (8,2)	3,05 [1,90; 4,89] <,0001[2]	3,73 [2,18; 6,39] <,0001[3]	16,7 [10,4; 23,1] <,0001[3]
Tumor grade (Interaction p-value: 0,2817)					
G1	23/63 (36,5)	1/52 (1,9)	18,98 [2,65; 135,88] 0,0034[2]	29,33 [3,80; 226,54] <,0001[3]	34,6 [22,1; 47,0] <,0001[3]
G2	94/349 (26,9)	24/323 (7,4)	3,62 [2,38; 5,53] <,0001[2]	4,59 [2,85; 7,41] <,0001[3]	19,5 [14,0; 25,0] <,0001[3]
G3	73/317 (23,0)	22/312 (7,1)	3,27 [2,08; 5,12] <,0001[2]	3,94 [2,38; 6,54] <,0001[3]	16,0 [10,5; 21,4] <,0001[3]
GX	22/44 (50,0)	8/40 (20,0)	2,50 [1,26; 4,97] 0,0089[2]	4,00 [1,51; 10,60] 0,0042[3]	30,0 [10,7; 49,3] 0,0042[3]
Progesterone receptor status (Interaction p-value: 0,8590)					
Negative	16/67 (23,9)	3/62 (4,8)	4,94 [1,51; 16,12] 0,0082[2]	6,17 [1,70; 22,39] 0,0023[3]	19,0 [7,5; 30,6] 0,0023[3]
Positive	191/678 (28,2)	52/647 (8,0)	3,51 [2,63; 4,67] <,0001[2]	4,49 [3,23; 6,24] <,0001[3]	20,1 [16,2; 24,1] <,0001[3]
Unknown	2/8 (25,0)	0/8 (0,0)	5,00 [0,28; 90,18] 0,2754[2]	6,54 [0,27; 160,97] 0,4667[4]	25,0 [-5,0; 55,0] 0,4667[4]
Race (Interaction p-value: 0,3412)					
White	82/461 (17,8)	17/440 (3,9)	4,60 [2,78; 7,63] <,0001[2]	5,38 [3,14; 9,24] <,0001[3]	13,9 [10,0; 17,9] <,0001[3]
Asian	124/273 (45,4)	37/243 (15,2)	2,98 [2,16; 4,12] <,0001[2]	4,63 [3,03; 7,08] <,0001[3]	30,2 [22,8; 37,6] <,0001[3]
Other	8/30 (26,7)	2/34 (5,9)	4,53 [1,04; 19,71] 0,0438[2]	5,82 [1,13; 30,05] 0,0363[4]	20,8 [3,1; 38,5] 0,0363[4]
First endocrine therapy (Interaction p-value: 0,1239)					
Tamoxifen	140/553 (25,3)	32/534 (6,0)	4,22 [2,93; 6,09] <,0001[2]	5,32 [3,55; 7,98] <,0001[3]	19,3 [15,2; 23,5] <,0001[3]
Aromatase inhibitor	75/223 (33,6)	24/195 (12,3)	2,73 [1,80; 4,15] <,0001[2]	3,61 [2,17; 6,01] <,0001[3]	21,3 [13,6; 29,1] <,0001[3]
ECOG-PS (Interaction p-value: 0,3539)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	195/685 (28,5)	49/649 (7,6)	3,77 [2,81; 5,06] <,0001[2]	4,87 [3,49; 6,81] <,0001[3]	20,9 [17,0; 24,9] <,0001[3]
ECOG-PS 1	20/91 (22,0)	7/80 (8,8)	2,51 [1,12; 5,63] 0,0252[2]	2,94 [1,17; 7,38] 0,0179[3]	13,2 [2,7; 23,8] 0,0179[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 268.1.2: Subgroups - adverse events according SOC Blood and lymphatic system disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8061)					
Neoadjuvant chemotherapy	109/314 (34,7)	35/306 (11,4)	3,03 [2,15; 4,29] <,0001[2]	4,12 [2,70; 6,28] <,0001[3]	23,3 [16,9; 29,6] <,0001[3]
Adjuvant chemotherapy	173/452 (38,3)	45/416 (10,8)	3,54 [2,62; 4,77] <,0001[2]	5,11 [3,56; 7,35] <,0001[3]	27,5 [22,1; 32,8] <,0001[3]
No chemotherapy	4/10 (40,0)	0/7 (0,0)	6,55 [0,41; 105,10] 0,1847[2]	10,38 [0,47; 231,63] 0,1029[4]	40,0 [9,6; 70,4] 0,1029[4]
Region (Interaction p-value: 0,1999)					
North America / Europe	107/347 (30,8)	34/309 (11,0)	2,80 [1,97; 3,99] <,0001[2]	3,61 [2,36; 5,50] <,0001[3]	19,8 [13,9; 25,8] <,0001[3]
Asia	75/239 (31,4)	14/226 (6,2)	5,07 [2,95; 8,70] <,0001[2]	6,93 [3,78; 12,69] <,0001[3]	25,2 [18,5; 31,9] <,0001[3]
Other	104/190 (54,7)	32/194 (16,5)	3,32 [2,36; 4,67] <,0001[2]	6,12 [3,81; 9,84] <,0001[3]	38,2 [29,4; 47,0] <,0001[3]
Primary tumor size (Interaction p-value: 0,3344)					
< 20 mm	72/204 (35,3)	25/189 (13,2)	2,67 [1,77; 4,02] <,0001[2]	3,58 [2,15; 5,96] <,0001[3]	22,1 [13,9; 30,2] <,0001[3]
≥ 20 but < 50 mm	141/360 (39,2)	40/346 (11,6)	3,39 [2,46; 4,66] <,0001[2]	4,93 [3,33; 7,29] <,0001[3]	27,6 [21,5; 33,7] <,0001[3]
≥ 50 mm	65/194 (33,5)	14/185 (7,6)	4,43 [2,58; 7,61] <,0001[2]	6,15 [3,31; 11,45] <,0001[3]	25,9 [18,3; 33,6] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,1104)					
0-3	87/269 (32,3)	35/269 (13,0)	2,49 [1,74; 3,54] <,0001[2]	3,20 [2,06; 4,95] <,0001[3]	19,3 [12,4; 26,2] <,0001[3]
4-9	130/353 (36,8)	32/326 (9,8)	3,75 [2,63; 5,36] <,0001[2]	5,36 [3,50; 8,19] <,0001[3]	27,0 [21,0; 33,0] <,0001[3]
≥ 10	69/154 (44,8)	13/134 (9,7)	4,62 [2,68; 7,97] <,0001[2]	7,56 [3,93; 14,54] <,0001[3]	35,1 [25,8; 44,4] <,0001[3]
Tumor stage (Interaction p-value: 0,2052)					
IIA	24/79 (30,4)	9/77 (11,7)	2,60 [1,29; 5,23] 0,0074[2]	3,30 [1,42; 7,67] 0,0043[3]	18,7 [6,3; 31,1] 0,0043[3]
IIB	28/73 (38,4)	17/93 (18,3)	2,10 [1,25; 3,53] 0,0051[2]	2,78 [1,37; 5,64] 0,0039[3]	20,1 [6,4; 33,7] 0,0039[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	115/345 (33,3)	29/294 (9,9)	3,38 [2,32; 4,92] <,0001[2]	4,57 [2,93; 7,12] <,0001[3]	23,5 [17,4; 29,5] <,0001[3]
IIIB	7/22 (31,8)	1/19 (5,3)	6,05 [0,82; 44,82] 0,0784[2]	8,40 [0,93; 76,15] 0,0497[4]	26,6 [4,7; 48,5] 0,0497[4]
IIIC	111/253 (43,9)	24/245 (9,8)	4,48 [2,99; 6,71] <,0001[2]	7,20 [4,41; 11,74] <,0001[3]	34,1 [26,9; 41,2] <,0001[3]
Tumor grade (Interaction p-value: 0,4940)					
G1	19/63 (30,2)	3/52 (5,8)	5,23 [1,64; 16,69] 0,0052[2]	7,05 [1,95; 25,47] 0,0009[3]	24,4 [11,4; 37,4] 0,0009[3]
G2	135/349 (38,7)	35/323 (10,8)	3,57 [2,54; 5,01] <,0001[2]	5,19 [3,44; 7,84] <,0001[3]	27,8 [21,7; 34,0] <,0001[3]
G3	112/317 (35,3)	39/312 (12,5)	2,83 [2,03; 3,93] <,0001[2]	3,82 [2,55; 5,75] <,0001[3]	22,8 [16,4; 29,2] <,0001[3]
GX	18/44 (40,9)	3/40 (7,5)	5,45 [1,74; 17,14] 0,0037[2]	8,54 [2,28; 32,00] 0,0004[3]	33,4 [16,7; 50,1] 0,0004[3]
Progesterone receptor status (Interaction p-value: 0,9724)					
Negative	28/67 (41,8)	7/62 (11,3)	3,70 [1,74; 7,86] 0,0007[2]	5,64 [2,24; 14,22] <,0001[3]	30,5 [16,3; 44,7] <,0001[3]
Positive	254/678 (37,5)	72/647 (11,1)	3,37 [2,65; 4,27] <,0001[2]	4,78 [3,58; 6,39] <,0001[3]	26,3 [22,0; 30,7] <,0001[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,4330)					
White	185/461 (40,1)	55/440 (12,5)	3,21 [2,45; 4,21] <,0001[2]	4,69 [3,35; 6,58] <,0001[3]	27,6 [22,2; 33,1] <,0001[3]
Asian	81/273 (29,7)	16/243 (6,6)	4,51 [2,71; 7,49] <,0001[2]	5,99 [3,39; 10,58] <,0001[3]	23,1 [16,8; 29,3] <,0001[3]
Other	17/30 (56,7)	7/34 (20,6)	2,75 [1,33; 5,71] 0,0066[2]	5,04 [1,68; 15,17] 0,0029[3]	36,1 [13,7; 58,4] 0,0029[3]
First endocrine therapy (Interaction p-value: 0,6856)					
Tamoxifen	184/553 (33,3)	55/534 (10,3)	3,23 [2,45; 4,26] <,0001[2]	4,34 [3,12; 6,04] <,0001[3]	23,0 [18,3; 27,7] <,0001[3]
Aromatase inhibitor	102/223 (45,7)	25/195 (12,8)	3,57 [2,41; 5,28] <,0001[2]	5,73 [3,49; 9,41] <,0001[3]	32,9 [24,9; 41,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,8949)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	254/685 (37,1)	72/649 (11,1)	3,34 [2,63; 4,24] <,0001[2]	4,72 [3,53; 6,31] <,0001[3]	26,0 [21,6; 30,3] <,0001[3]
ECOG-PS 1	32/91 (35,2)	8/80 (10,0)	3,52 [1,72; 7,18] 0,0006[2]	4,88 [2,09; 11,40] 0,0001[3]	25,2 [13,4; 37,0] 0,0001[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 269.1.2: Subgroups - adverse events according SOC Endocrine disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8018)					
Neoadjuvant chemotherapy	6/314 (1,9)	15/306 (4,9)	0,39 [0,15; 0,99] 0,0479[2]	0,38 [0,14; 0,99] 0,0395[3]	-3,0 [-5,8; -0,1] 0,0395[3]
Adjuvant chemotherapy	7/452 (1,5)	11/416 (2,6)	0,59 [0,23; 1,50] 0,2637[2]	0,58 [0,22; 1,51] 0,2578[3]	-1,1 [-3,0; 0,8] 0,2578[3]
No chemotherapy	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Region (Interaction p-value: 0,0976)					
North America / Europe	4/347 (1,2)	15/309 (4,9)	0,24 [0,08; 0,71] 0,0099[2]	0,23 [0,08; 0,70] 0,0048[3]	-3,7 [-6,3; -1,1] 0,0048[3]
Asia	5/239 (2,1)	9/226 (4,0)	0,53 [0,18; 1,54] 0,2418[2]	0,52 [0,17; 1,56] 0,2332[3]	-1,9 [-5,0; 1,2] 0,2332[3]
Other	5/190 (2,6)	3/194 (1,5)	1,70 [0,41; 7,02] 0,4622[2]	1,72 [0,41; 7,30] 0,4993[4]	1,1 [-1,8; 3,9] 0,4993[4]
Primary tumor size (Interaction p-value: 0,7845)					
< 20 mm	6/204 (2,9)	9/189 (4,8)	0,62 [0,22; 1,70] 0,3516[2]	0,61 [0,21; 1,74] 0,3466[3]	-1,8 [-5,6; 2,0] 0,3466[3]
≥ 20 but < 50 mm	6/360 (1,7)	12/346 (3,5)	0,48 [0,18; 1,27] 0,1382[2]	0,47 [0,18; 1,27] 0,1290[3]	-1,8 [-4,1; 0,5] 0,1290[3]
≥ 50 mm	2/194 (1,0)	6/185 (3,2)	0,32 [0,06; 1,55] 0,1571[2]	0,31 [0,06; 1,56] 0,1660[4]	-2,2 [-5,1; 0,7] 0,1660[4]
Number of positive lymph nodes (Interaction p-value: 0,4514)					
0-3	6/269 (2,2)	7/269 (2,6)	0,86 [0,29; 2,52] 0,7791[2]	0,85 [0,28; 2,57] 0,7789[3]	-0,4 [-3,0; 2,2] 0,7789[3]
4-9	6/353 (1,7)	16/326 (4,9)	0,35 [0,14; 0,87] 0,0248[2]	0,34 [0,13; 0,87] 0,0183[3]	-3,2 [-5,9; -0,5] 0,0183[3]
≥ 10	2/154 (1,3)	4/134 (3,0)	0,44 [0,08; 2,34] 0,3320[2]	0,43 [0,08; 2,37] 0,4218[4]	-1,7 [-5,1; 1,7] 0,4218[4]
Tumor stage (Interaction p-value: 0,6166)					
IIA	4/79 (5,1)	3/77 (3,9)	1,30 [0,30; 5,62] 0,7257[2]	1,32 [0,28; 6,08] 1,0000[4]	1,2 [-5,3; 7,7] 1,0000[4]
IIB	0/73 (0,0)	2/93 (2,2)	0,25 [0,01; 5,21] 0,3740[2]	0,25 [0,01; 5,27] 0,5043[4]	-2,2 [-5,1; 0,8] 0,5043[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	5/345 (1,4)	14/294 (4,8)	0,30 [0,11; 0,83] 0,0209[2]	0,29 [0,10; 0,83] 0,0140[3]	-3,3 [-6,1; -0,6] 0,0140[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	5/253 (2,0)	8/245 (3,3)	0,61 [0,20; 1,82] 0,3724[2]	0,60 [0,19; 1,85] 0,3671[3]	-1,3 [-4,1; 1,5] 0,3671[3]
Tumor grade (Interaction p-value: 0,8602)					
G1	1/63 (1,6)	0/52 (0,0)	2,48 [0,10; 59,73] 0,5749[2]	2,52 [0,10; 63,17] 1,0000[4]	1,6 [-1,5; 4,7] 1,0000[4]
G2	5/349 (1,4)	16/323 (5,0)	0,29 [0,11; 0,78] 0,0143[2]	0,28 [0,10; 0,77] 0,0088[3]	-3,5 [-6,2; -0,8] 0,0088[3]
G3	6/317 (1,9)	11/312 (3,5)	0,54 [0,20; 1,43] 0,2146[2]	0,53 [0,19; 1,45] 0,2067[3]	-1,6 [-4,2; 0,9] 0,2067[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,0998)					
Negative	1/67 (1,5)	3/62 (4,8)	0,31 [0,03; 2,89] 0,3027[2]	0,30 [0,03; 2,94] 0,3505[4]	-3,3 [-9,4; 2,7] 0,3505[4]
Positive	13/678 (1,9)	24/647 (3,7)	0,52 [0,27; 1,01] 0,0522[2]	0,51 [0,26; 1,01] 0,0478[3]	-1,8 [-3,6; -0,0] 0,0478[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,6967)					
White	7/461 (1,5)	17/440 (3,9)	0,39 [0,16; 0,94] 0,0355[2]	0,38 [0,16; 0,93] 0,0289[3]	-2,3 [-4,5; -0,2] 0,0289[3]
Asian	7/273 (2,6)	9/243 (3,7)	0,69 [0,26; 1,83] 0,4586[2]	0,68 [0,25; 1,87] 0,4560[3]	-1,1 [-4,2; 1,9] 0,4560[3]
Other	0/30 (0,0)	0/34 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,3343)					
Tamoxifen	8/553 (1,4)	20/534 (3,7)	0,39 [0,17; 0,87] 0,0215[2]	0,38 [0,16; 0,86] 0,0168[3]	-2,3 [-4,2; -0,4] 0,0168[3]
Aromatase inhibitor	6/223 (2,7)	7/195 (3,6)	0,75 [0,26; 2,19] 0,5986[2]	0,74 [0,25; 2,25] 0,5973[3]	-0,9 [-4,3; 2,5] 0,5973[3]
ECOG-PS (Interaction p-value: 0,1162)					
ECOG-PS 0	11/685 (1,6)	26/649 (4,0)	0,40 [0,20; 0,80] 0,0101[2]	0,39 [0,19; 0,80] 0,0076[3]	-2,4 [-4,2; -0,6] 0,0076[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	3/91 (3,3)	1/80 (1,3)	2,64 [0,28; 24,85] 0,3968[2]	2,69 [0,27; 26,42] 0,6237[4]	2,0 [-2,4; 6,4] 0,6237[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 270.1.2: Subgroups - adverse events according SOC Eye disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,4248)					
Neoadjuvant chemotherapy	41/314 (13,1)	25/306 (8,2)	1,60 [1,00; 2,56] 0,0514[2]	1,69 [1,00; 2,85] 0,0485[3]	4,9 [0,1; 9,7] 0,0485[3]
Adjuvant chemotherapy	62/452 (13,7)	23/416 (5,5)	2,48 [1,57; 3,93] 0,0001[2]	2,72 [1,65; 4,47] <,0001[3]	8,2 [4,3; 12,0] <,0001[3]
No chemotherapy	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Region (Interaction p-value: 0,8575)					
North America / Europe	57/347 (16,4)	25/309 (8,1)	2,03 [1,30; 3,17] 0,0018[2]	2,23 [1,36; 3,67] 0,0013[3]	8,3 [3,4; 13,3] 0,0013[3]
Asia	29/239 (12,1)	15/226 (6,6)	1,83 [1,01; 3,32] 0,0473[2]	1,94 [1,01; 3,73] 0,0430[3]	5,5 [0,2; 10,8] 0,0430[3]
Other	19/190 (10,0)	8/194 (4,1)	2,43 [1,09; 5,40] 0,0303[2]	2,58 [1,10; 6,05] 0,0243[3]	5,9 [0,8; 11,0] 0,0243[3]
Primary tumor size (Interaction p-value: 0,4950)					
< 20 mm	34/204 (16,7)	19/189 (10,1)	1,66 [0,98; 2,80] 0,0593[2]	1,79 [0,98; 3,26] 0,0551[3]	6,6 [-0,1; 13,3] 0,0551[3]
≥ 20 but < 50 mm	45/360 (12,5)	17/346 (4,9)	2,54 [1,49; 4,36] 0,0007[2]	2,76 [1,55; 4,93] 0,0004[3]	7,6 [3,5; 11,7] 0,0004[3]
≥ 50 mm	20/194 (10,3)	11/185 (5,9)	1,73 [0,85; 3,52] 0,1274[2]	1,82 [0,85; 3,91] 0,1213[3]	4,4 [-1,1; 9,8] 0,1213[3]
Number of positive lymph nodes (Interaction p-value: 0,6226)					
0-3	37/269 (13,8)	21/269 (7,8)	1,76 [1,06; 2,93] 0,0289[2]	1,88 [1,07; 3,31] 0,0261[3]	5,9 [0,7; 11,2] 0,0261[3]
4-9	51/353 (14,4)	19/326 (5,8)	2,48 [1,50; 4,11] 0,0004[2]	2,73 [1,57; 4,73] 0,0002[3]	8,6 [4,2; 13,1] 0,0002[3]
≥ 10	17/154 (11,0)	8/134 (6,0)	1,85 [0,82; 4,15] 0,1359[2]	1,95 [0,82; 4,69] 0,1275[3]	5,1 [-1,3; 11,4] 0,1275[3]
Tumor stage (Interaction p-value: 0,8315)					
IIA	15/79 (19,0)	7/77 (9,1)	2,09 [0,90; 4,84] 0,0859[2]	2,34 [0,90; 6,12] 0,0758[3]	9,9 [-0,9; 20,7] 0,0758[3]
IIB	6/73 (8,2)	5/93 (5,4)	1,53 [0,49; 4,81] 0,4681[2]	1,58 [0,46; 5,38] 0,5380[4]	2,8 [-4,9; 10,6] 0,5380[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	50/345 (14,5)	17/294 (5,8)	2,51 [1,48; 4,25] 0,0006[2]	2,76 [1,56; 4,90] 0,0003[3]	8,7 [4,1; 13,3] 0,0003[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	32/253 (12,6)	19/245 (7,8)	1,63 [0,95; 2,80] 0,0757[2]	1,72 [0,95; 3,13] 0,0718[3]	4,9 [-0,4; 10,2] 0,0718[3]
Tumor grade (Interaction p-value: 0,2197)					
G1	13/63 (20,6)	1/52 (1,9)	10,73 [1,45; 79,33] 0,0201[2]	13,26 [1,67; 105,19] 0,0023[3]	18,7 [8,0; 29,4] 0,0023[3]
G2	41/349 (11,7)	16/323 (5,0)	2,37 [1,36; 4,14] 0,0024[2]	2,55 [1,40; 4,65] 0,0016[3]	6,8 [2,7; 10,9] 0,0016[3]
G3	46/317 (14,5)	27/312 (8,7)	1,68 [1,07; 2,63] 0,0240[2]	1,79 [1,08; 2,96] 0,0218[3]	5,9 [0,9; 10,8] 0,0218[3]
GX	5/44 (11,4)	4/40 (10,0)	1,14 [0,33; 3,94] 0,8403[2]	1,15 [0,29; 4,64] 1,0000[4]	1,4 [-11,8; 14,6] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,7952)					
Negative	14/67 (20,9)	5/62 (8,1)	2,59 [0,99; 6,77] 0,0522[2]	3,01 [1,02; 8,93] 0,0399[3]	12,8 [1,0; 24,7] 0,0399[3]
Positive	82/678 (12,1)	43/647 (6,6)	1,82 [1,28; 2,59] 0,0009[2]	1,93 [1,31; 2,84] 0,0007[3]	5,4 [2,3; 8,6] 0,0007[3]
Unknown	2/8 (25,0)	0/8 (0,0)	5,00 [0,28; 90,18] 0,2754[2]	6,54 [0,27; 160,97] 0,4667[4]	25,0 [-5,0; 55,0] 0,4667[4]
Race (Interaction p-value: 0,9805)					
White	62/461 (13,4)	28/440 (6,4)	2,11 [1,38; 3,24] 0,0006[2]	2,29 [1,43; 3,65] 0,0004[3]	7,1 [3,2; 10,9] 0,0004[3]
Asian	36/273 (13,2)	16/243 (6,6)	2,00 [1,14; 3,52] 0,0156[2]	2,16 [1,16; 3,99] 0,0129[3]	6,6 [1,5; 11,7] 0,0129[3]
Other	5/30 (16,7)	3/34 (8,8)	1,89 [0,49; 7,25] 0,3539[2]	2,07 [0,45; 9,50] 0,4576[4]	7,8 [-8,6; 24,2] 0,4576[4]
First endocrine therapy (Interaction p-value: 0,1187)					
Tamoxifen	80/553 (14,5)	32/534 (6,0)	2,41 [1,63; 3,57] <,0001[2]	2,65 [1,73; 4,07] <,0001[3]	8,5 [4,9; 12,0] <,0001[3]
Aromatase inhibitor	25/223 (11,2)	16/195 (8,2)	1,37 [0,75; 2,48] 0,3058[2]	1,41 [0,73; 2,73] 0,3027[3]	3,0 [-2,6; 8,7] 0,3027[3]
ECOG-PS (Interaction p-value: 0,4575)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	91/685 (13,3)	40/649 (6,2)	2,16 [1,51; 3,08] <,0001[2]	2,33 [1,58; 3,44] <,0001[3]	7,1 [4,0; 10,3] <,0001[3]
ECOG-PS 1	14/91 (15,4)	8/80 (10,0)	1,54 [0,68; 3,48] 0,3003[2]	1,64 [0,65; 4,13] 0,2940[3]	5,4 [-4,5; 15,3] 0,2940[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 271.1.2: Subgroups - adverse events according SOC Gastrointestinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1266)					
Neoadjuvant chemotherapy	282/314 (89,8)	104/306 (34,0)	2,64 [2,25; 3,10] <,0001[2]	17,12 [11,07; 26,46] <,0001[3]	55,8 [49,5; 62,1] <,0001[3]
Adjuvant chemotherapy	409/452 (90,5)	118/416 (28,4)	3,19 [2,73; 3,73] <,0001[2]	24,02 [16,43; 35,11] <,0001[3]	62,1 [57,0; 67,2] <,0001[3]
No chemotherapy	7/10 (70,0)	3/7 (42,9)	1,63 [0,63; 4,21] 0,3098[2]	3,11 [0,41; 23,39] 0,3500[4]	27,1 [-19,2; 73,5] 0,3500[4]
Region (Interaction p-value: 0,2866)					
North America / Europe	319/347 (91,9)	105/309 (34,0)	2,71 [2,31; 3,17] <,0001[2]	22,13 [14,08; 34,80] <,0001[3]	58,0 [51,9; 64,0] <,0001[3]
Asia	229/239 (95,8)	76/226 (33,6)	2,85 [2,37; 3,43] <,0001[2]	45,20 [22,65; 90,17] <,0001[3]	62,2 [55,5; 68,8] <,0001[3]
Other	150/190 (78,9)	44/194 (22,7)	3,48 [2,66; 4,56] <,0001[2]	12,78 [7,88; 20,75] <,0001[3]	56,3 [48,0; 64,5] <,0001[3]
Primary tumor size (Interaction p-value: 0,2085)					
< 20 mm	183/204 (89,7)	60/189 (31,7)	2,83 [2,28; 3,50] <,0001[2]	18,74 [10,86; 32,33] <,0001[3]	58,0 [50,1; 65,8] <,0001[3]
≥ 20 but < 50 mm	318/360 (88,3)	113/346 (32,7)	2,70 [2,31; 3,16] <,0001[2]	15,61 [10,54; 23,12] <,0001[3]	55,7 [49,7; 61,6] <,0001[3]
≥ 50 mm	180/194 (92,8)	49/185 (26,5)	3,50 [2,75; 4,47] <,0001[2]	35,69 [18,92; 67,29] <,0001[3]	66,3 [59,0; 73,6] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,7715)					
0-3	244/269 (90,7)	85/269 (31,6)	2,87 [2,40; 3,44] <,0001[2]	21,13 [13,00; 34,32] <,0001[3]	59,1 [52,6; 65,7] <,0001[3]
4-9	318/353 (90,1)	103/326 (31,6)	2,85 [2,42; 3,36] <,0001[2]	19,67 [12,93; 29,94] <,0001[3]	58,5 [52,6; 64,4] <,0001[3]
≥ 10	136/154 (88,3)	37/134 (27,6)	3,20 [2,42; 4,23] <,0001[2]	19,81 [10,65; 36,84] <,0001[3]	60,7 [51,6; 69,8] <,0001[3]
Tumor grade (Interaction p-value: 0,1374)					
G1	56/63 (88,9)	13/52 (25,0)	3,56 [2,20; 5,74] <,0001[2]	24,00 [8,78; 65,61] <,0001[3]	63,9 [49,8; 78,0] <,0001[3]
G2	318/349 (91,1)	92/323 (28,5)	3,20 [2,68; 3,81] <,0001[2]	25,76 [16,57; 40,03] <,0001[3]	62,6 [56,9; 68,4] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G3	286/317 (90,2)	102/312 (32,7)	2,76 [2,34; 3,25] <,0001[2]	18,99 [12,24; 29,48] <,0001[3]	57,5 [51,4; 63,7] <,0001[3]
GX	35/44 (79,5)	16/40 (40,0)	1,99 [1,32; 2,99] 0,0010[2]	5,83 [2,22; 15,35] 0,0002[3]	39,5 [20,2; 58,8] 0,0002[3]
Progesterone receptor status (Interaction p-value: 0,2773)					
Negative	64/67 (95,5)	23/62 (37,1)	2,57 [1,85; 3,58] <,0001[2]	36,17 [10,19; 128,46] <,0001[3]	58,4 [45,4; 71,4] <,0001[3]
Positive	606/678 (89,4)	193/647 (29,8)	3,00 [2,65; 3,38] <,0001[2]	19,80 [14,72; 26,64] <,0001[3]	59,6 [55,3; 63,8] <,0001[3]
Unknown	7/8 (87,5)	4/8 (50,0)	1,75 [0,83; 3,67] 0,1387[2]	7,00 [0,57; 86,32] 0,2821[4]	37,5 [-4,0; 79,0] 0,2821[4]
Race (Interaction p-value: 0,9342)					
White	406/461 (88,1)	131/440 (29,8)	2,96 [2,55; 3,43] <,0001[2]	17,41 [12,30; 24,66] <,0001[3]	58,3 [53,1; 63,5] <,0001[3]
Asian	254/273 (93,0)	77/243 (31,7)	2,94 [2,43; 3,54] <,0001[2]	28,82 [16,81; 49,40] <,0001[3]	61,4 [54,8; 67,9] <,0001[3]
Other	26/30 (86,7)	11/34 (32,4)	2,68 [1,62; 4,44] 0,0001[2]	13,59 [3,80; 48,61] <,0001[3]	54,3 [34,4; 74,2] <,0001[3]
ECOG-PS (Interaction p-value: 0,6866)					
ECOG-PS 0	623/685 (90,9)	204/649 (31,4)	2,89 [2,58; 3,25] <,0001[2]	21,92 [16,09; 29,86] <,0001[3]	59,5 [55,3; 63,7] <,0001[3]
ECOG-PS 1	75/91 (82,4)	21/80 (26,3)	3,14 [2,15; 4,59] <,0001[2]	13,17 [6,32; 27,45] <,0001[3]	56,2 [43,8; 68,6] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 272.1.2: Subgroups - adverse events according SOC General disorders and administration site conditions from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,2811)					
Neoadjuvant chemotherapy	180/314 (57,3)	106/306 (34,6)	1,65 [1,38; 1,98] <,0001[2]	2,53 [1,83; 3,51] <,0001[3]	22,7 [15,0; 30,3] <,0001[3]
Adjuvant chemotherapy	237/452 (52,4)	122/416 (29,3)	1,79 [1,50; 2,13] <,0001[2]	2,66 [2,01; 3,52] <,0001[3]	23,1 [16,8; 29,5] <,0001[3]
No chemotherapy	5/10 (50,0)	4/7 (57,1)	0,88 [0,36; 2,14] 0,7692[2]	0,75 [0,11; 5,24] 1,0000[4]	-7,1 [-55,1; 40,9] 1,0000[4]
Region (Interaction p-value: 0,8668)					
North America / Europe	237/347 (68,3)	129/309 (41,7)	1,64 [1,41; 1,90] <,0001[2]	3,01 [2,18; 4,14] <,0001[3]	26,6 [19,2; 33,9] <,0001[3]
Asia	113/239 (47,3)	61/226 (27,0)	1,75 [1,36; 2,26] <,0001[2]	2,43 [1,65; 3,58] <,0001[3]	20,3 [11,7; 28,9] <,0001[3]
Other	72/190 (37,9)	42/194 (21,6)	1,75 [1,27; 2,42] 0,0007[2]	2,21 [1,41; 3,46] 0,0005[3]	16,2 [7,2; 25,3] 0,0005[3]
Primary tumor size (Interaction p-value: 0,8575)					
< 20 mm	121/204 (59,3)	68/189 (36,0)	1,65 [1,32; 2,06] <,0001[2]	2,59 [1,73; 3,90] <,0001[3]	23,3 [13,7; 32,9] <,0001[3]
≥ 20 but < 50 mm	197/360 (54,7)	106/346 (30,6)	1,79 [1,49; 2,15] <,0001[2]	2,74 [2,01; 3,73] <,0001[3]	24,1 [17,0; 31,2] <,0001[3]
≥ 50 mm	100/194 (51,5)	56/185 (30,3)	1,70 [1,32; 2,20] <,0001[2]	2,45 [1,61; 3,74] <,0001[3]	21,3 [11,6; 30,9] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,4045)					
0-3	154/269 (57,2)	96/269 (35,7)	1,60 [1,33; 1,94] <,0001[2]	2,41 [1,71; 3,42] <,0001[3]	21,6 [13,3; 29,8] <,0001[3]
4-9	195/353 (55,2)	106/326 (32,5)	1,70 [1,42; 2,04] <,0001[2]	2,56 [1,87; 3,50] <,0001[3]	22,7 [15,5; 30,0] <,0001[3]
≥ 10	73/154 (47,4)	30/134 (22,4)	2,12 [1,48; 3,02] <,0001[2]	3,12 [1,87; 5,23] <,0001[3]	25,0 [14,4; 35,6] <,0001[3]
Tumor stage (Interaction p-value: 0,5269)					
IIA	47/79 (59,5)	34/77 (44,2)	1,35 [0,99; 1,84] 0,0596[2]	1,86 [0,98; 3,51] 0,0552[3]	15,3 [-0,2; 30,8] 0,0552[3]
IIB	39/73 (53,4)	31/93 (33,3)	1,60 [1,12; 2,29] 0,0099[2]	2,29 [1,22; 4,31] 0,0093[3]	20,1 [5,2; 35,0] 0,0093[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	186/345 (53,9)	91/294 (31,0)	1,74 [1,43; 2,12] <,0001[2]	2,61 [1,88; 3,61] <,0001[3]	23,0 [15,5; 30,4] <,0001[3]
IIIB	13/22 (59,1)	7/19 (36,8)	1,60 [0,81; 3,18] 0,1756[2]	2,48 [0,70; 8,74] 0,1553[3]	22,2 [-7,6; 52,1] 0,1553[3]
IIIC	135/253 (53,4)	69/245 (28,2)	1,89 [1,50; 2,39] <,0001[2]	2,92 [2,01; 4,23] <,0001[3]	25,2 [16,9; 33,5] <,0001[3]
Tumor grade (Interaction p-value: 0,4348)					
G1	36/63 (57,1)	12/52 (23,1)	2,48 [1,44; 4,25] 0,0010[2]	4,44 [1,97; 10,05] 0,0002[3]	34,1 [17,3; 50,8] 0,0002[3]
G2	192/349 (55,0)	112/323 (34,7)	1,59 [1,33; 1,89] <,0001[2]	2,30 [1,69; 3,15] <,0001[3]	20,3 [13,0; 27,7] <,0001[3]
G3	174/317 (54,9)	99/312 (31,7)	1,73 [1,43; 2,09] <,0001[2]	2,62 [1,89; 3,62] <,0001[3]	23,2 [15,6; 30,7] <,0001[3]
GX	18/44 (40,9)	8/40 (20,0)	2,05 [1,00; 4,18] 0,0496[2]	2,77 [1,04; 7,38] 0,0384[3]	20,9 [1,8; 40,0] 0,0384[3]
Progesterone receptor status (Interaction p-value: 0,7168)					
Negative	39/67 (58,2)	19/62 (30,6)	1,90 [1,24; 2,91] 0,0032[2]	3,15 [1,53; 6,52] 0,0017[3]	27,6 [11,1; 44,0] 0,0017[3]
Positive	360/678 (53,1)	202/647 (31,2)	1,70 [1,49; 1,95] <,0001[2]	2,49 [1,99; 3,12] <,0001[3]	21,9 [16,7; 27,1] <,0001[3]
Unknown	7/8 (87,5)	5/8 (62,5)	1,40 [0,77; 2,54] 0,2695[2]	4,20 [0,33; 53,12] 0,5692[4]	25,0 [-15,6; 65,6] 0,5692[4]
Race (Interaction p-value: 0,7624)					
White	268/461 (58,1)	148/440 (33,6)	1,73 [1,48; 2,01] <,0001[2]	2,74 [2,09; 3,59] <,0001[3]	24,5 [18,2; 30,8] <,0001[3]
Asian	129/273 (47,3)	64/243 (26,3)	1,79 [1,40; 2,29] <,0001[2]	2,51 [1,73; 3,63] <,0001[3]	20,9 [12,8; 29,0] <,0001[3]
Other	15/30 (50,0)	12/34 (35,3)	1,42 [0,79; 2,53] 0,2383[2]	1,83 [0,67; 5,00] 0,2345[3]	14,7 [-9,3; 38,8] 0,2345[3]
First endocrine therapy (Interaction p-value: 0,1923)					
Tamoxifen	311/553 (56,2)	167/534 (31,3)	1,80 [1,55; 2,08] <,0001[2]	2,82 [2,20; 3,62] <,0001[3]	25,0 [19,3; 30,7] <,0001[3]
Aromatase inhibitor	111/223 (49,8)	65/195 (33,3)	1,49 [1,18; 1,90] 0,0010[2]	1,98 [1,33; 2,95] 0,0007[3]	16,4 [7,1; 25,8] 0,0007[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.					

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Table 273.1.2: Subgroups - adverse events according SOC Infections and infestations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,3097)					
Neoadjuvant chemotherapy	164/314 (52,2)	133/306 (43,5)	1,20 [1,02; 1,42] 0,0300[2]	1,42 [1,04; 1,95] 0,0289[3]	8,8 [0,9; 16,6] 0,0289[3]
Adjuvant chemotherapy	255/452 (56,4)	168/416 (40,4)	1,40 [1,21; 1,61] <,0001[2]	1,91 [1,46; 2,50] <,0001[3]	16,0 [9,5; 22,6] <,0001[3]
No chemotherapy	6/10 (60,0)	2/7 (28,6)	2,10 [0,59; 7,52] 0,2544[2]	3,75 [0,47; 29,75] 0,3348[4]	31,4 [-13,8; 76,6] 0,3348[4]
Region (Interaction p-value: 0,7806)					
North America / Europe	190/347 (54,8)	132/309 (42,7)	1,28 [1,09; 1,51] 0,0025[2]	1,62 [1,19; 2,21] 0,0021[3]	12,0 [4,4; 19,6] 0,0021[3]
Asia	146/239 (61,1)	107/226 (47,3)	1,29 [1,09; 1,53] 0,0034[2]	1,75 [1,21; 2,52] 0,0029[3]	13,7 [4,8; 22,7] 0,0029[3]
Other	89/190 (46,8)	64/194 (33,0)	1,42 [1,10; 1,83] 0,0063[2]	1,79 [1,18; 2,71] 0,0056[3]	13,9 [4,2; 23,6] 0,0056[3]
Primary tumor size (Interaction p-value: 0,2848)					
< 20 mm	117/204 (57,4)	77/189 (40,7)	1,41 [1,14; 1,73] 0,0013[2]	1,96 [1,31; 2,92] 0,0010[3]	16,6 [6,9; 26,4] 0,0010[3]
≥ 20 but < 50 mm	187/360 (51,9)	149/346 (43,1)	1,21 [1,03; 1,41] 0,0190[2]	1,43 [1,06; 1,92] 0,0182[3]	8,9 [1,5; 16,2] 0,0182[3]
≥ 50 mm	112/194 (57,7)	73/185 (39,5)	1,46 [1,18; 1,81] 0,0005[2]	2,10 [1,39; 3,16] 0,0004[3]	18,3 [8,4; 28,2] 0,0004[3]
Number of positive lymph nodes (Interaction p-value: 0,7057)					
0-3	148/269 (55,0)	113/269 (42,0)	1,31 [1,10; 1,56] 0,0028[2]	1,69 [1,20; 2,37] 0,0025[3]	13,0 [4,6; 21,4] 0,0025[3]
4-9	186/353 (52,7)	135/326 (41,4)	1,27 [1,08; 1,50] 0,0037[2]	1,58 [1,16; 2,13] 0,0033[3]	11,3 [3,8; 18,7] 0,0033[3]
≥ 10	91/154 (59,1)	55/134 (41,0)	1,44 [1,13; 1,83] 0,0031[2]	2,07 [1,30; 3,32] 0,0022[3]	18,0 [6,7; 29,4] 0,0022[3]
Tumor stage (Interaction p-value: 0,7993)					
IIA	45/79 (57,0)	28/77 (36,4)	1,57 [1,10; 2,23] 0,0125[2]	2,32 [1,22; 4,41] 0,0099[3]	20,6 [5,3; 35,9] 0,0099[3]
IIB	39/73 (53,4)	43/93 (46,2)	1,16 [0,85; 1,57] 0,3554[2]	1,33 [0,72; 2,47] 0,3579[3]	7,2 [-8,1; 22,5] 0,3579[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	182/345 (52,8)	117/294 (39,8)	1,33 [1,12; 1,58] 0,0014[2]	1,69 [1,23; 2,31] 0,0011[3]	13,0 [5,3; 20,6] 0,0011[3]
IIIB	12/22 (54,5)	8/19 (42,1)	1,30 [0,68; 2,48] 0,4356[2]	1,65 [0,48; 5,69] 0,4268[3]	12,4 [-18,0; 42,9] 0,4268[3]
IIIC	144/253 (56,9)	107/245 (43,7)	1,30 [1,09; 1,56] 0,0036[2]	1,70 [1,20; 2,43] 0,0031[3]	13,2 [4,5; 22,0] 0,0031[3]
Tumor grade (Interaction p-value: 0,5439)					
G1	34/63 (54,0)	17/52 (32,7)	1,65 [1,05; 2,59] 0,0297[2]	2,41 [1,13; 5,17] 0,0223[3]	21,3 [3,6; 39,0] 0,0223[3]
G2	189/349 (54,2)	131/323 (40,6)	1,34 [1,13; 1,57] 0,0005[2]	1,73 [1,27; 2,35] 0,0004[3]	13,6 [6,1; 21,1] 0,0004[3]
G3	174/317 (54,9)	131/312 (42,0)	1,31 [1,11; 1,54] 0,0014[2]	1,68 [1,23; 2,30] 0,0012[3]	12,9 [5,2; 20,6] 0,0012[3]
GX	26/44 (59,1)	22/40 (55,0)	1,07 [0,74; 1,56] 0,7061[2]	1,18 [0,50; 2,81] 0,7051[3]	4,1 [-17,1; 25,3] 0,7051[3]
Progesterone receptor status (Interaction p-value: 0,0634)					
Negative	30/67 (44,8)	30/62 (48,4)	0,93 [0,64; 1,34] 0,6811[2]	0,86 [0,43; 1,73] 0,6812[3]	-3,6 [-20,8; 13,6] 0,6812[3]
Positive	377/678 (55,6)	259/647 (40,0)	1,39 [1,24; 1,56] <,0001[2]	1,88 [1,51; 2,33] <,0001[3]	15,6 [10,3; 20,9] <,0001[3]
Unknown	4/8 (50,0)	5/8 (62,5)	0,80 [0,33; 1,92] 0,6178[2]	0,60 [0,08; 4,40] 1,0000[4]	-12,5 [-60,7; 35,7] 1,0000[4]
Race (Interaction p-value: 0,6211)					
White	243/461 (52,7)	172/440 (39,1)	1,35 [1,17; 1,56] <,0001[2]	1,74 [1,33; 2,26] <,0001[3]	13,6 [7,2; 20,1] <,0001[3]
Asian	159/273 (58,2)	109/243 (44,9)	1,30 [1,09; 1,54] 0,0029[2]	1,71 [1,21; 2,43] 0,0024[3]	13,4 [4,8; 21,9] 0,0024[3]
Other	17/30 (56,7)	18/34 (52,9)	1,07 [0,69; 1,67] 0,7647[2]	1,16 [0,43; 3,12] 0,7651[3]	3,7 [-20,7; 28,1] 0,7651[3]
First endocrine therapy (Interaction p-value: 0,9299)					
Tamoxifen	302/553 (54,6)	222/534 (41,6)	1,31 [1,16; 1,49] <,0001[2]	1,69 [1,33; 2,15] <,0001[3]	13,0 [7,1; 18,9] <,0001[3]
Aromatase inhibitor	123/223 (55,2)	81/195 (41,5)	1,33 [1,08; 1,63] 0,0065[2]	1,73 [1,17; 2,55] 0,0055[3]	13,6 [4,1; 23,1] 0,0055[3]
ECOG-PS (Interaction p-value: 0,0635)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	385/685 (56,2)	267/649 (41,1)	1,37 [1,22; 1,53] <,0001[2]	1,84 [1,48; 2,28] <,0001[3]	15,1 [9,8; 20,4] <,0001[3]
ECOG-PS 1	40/91 (44,0)	36/80 (45,0)	0,98 [0,70; 1,37] 0,8909[2]	0,96 [0,52; 1,75] 0,8910[3]	-1,0 [-16,0; 13,9] 0,8910[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 274.1.2: Subgroups - adverse events according SOC Investigations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,6591)					
Neoadjuvant chemotherapy	158/314 (50,3)	69/306 (22,5)	2,23 [1,76; 2,82] <,0001[2]	3,48 [2,46; 4,92] <,0001[3]	27,8 [20,5; 35,0] <,0001[3]
Adjuvant chemotherapy	241/452 (53,3)	89/416 (21,4)	2,49 [2,03; 3,05] <,0001[2]	4,20 [3,11; 5,66] <,0001[3]	31,9 [25,9; 38,0] <,0001[3]
No chemotherapy	6/10 (60,0)	1/7 (14,3)	4,20 [0,64; 27,63] 0,1354[2]	9,00 [0,76; 106,00] 0,1340[4]	45,7 [5,8; 85,6] 0,1340[4]
Region (Interaction p-value: 0,0763)					
North America / Europe	148/347 (42,7)	43/309 (13,9)	3,06 [2,26; 4,15] <,0001[2]	4,60 [3,13; 6,77] <,0001[3]	28,7 [22,3; 35,2] <,0001[3]
Asia	181/239 (75,7)	74/226 (32,7)	2,31 [1,89; 2,83] <,0001[2]	6,41 [4,27; 9,62] <,0001[3]	43,0 [34,8; 51,2] <,0001[3]
Other	76/190 (40,0)	42/194 (21,6)	1,85 [1,34; 2,54] 0,0002[2]	2,41 [1,54; 3,78] <,0001[3]	18,4 [9,3; 27,4] <,0001[3]
Primary tumor size (Interaction p-value: 0,5241)					
< 20 mm	110/204 (53,9)	37/189 (19,6)	2,75 [2,01; 3,78] <,0001[2]	4,81 [3,06; 7,56] <,0001[3]	34,3 [25,5; 43,2] <,0001[3]
≥ 20 but < 50 mm	186/360 (51,7)	81/346 (23,4)	2,21 [1,78; 2,74] <,0001[2]	3,50 [2,53; 4,83] <,0001[3]	28,3 [21,4; 35,1] <,0001[3]
≥ 50 mm	97/194 (50,0)	39/185 (21,1)	2,37 [1,74; 3,24] <,0001[2]	3,74 [2,38; 5,88] <,0001[3]	28,9 [19,8; 38,1] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,1083)					
0-3	143/269 (53,2)	47/269 (17,5)	3,04 [2,29; 4,04] <,0001[2]	5,36 [3,61; 7,96] <,0001[3]	35,7 [28,2; 43,2] <,0001[3]
4-9	178/353 (50,4)	77/326 (23,6)	2,13 [1,71; 2,66] <,0001[2]	3,29 [2,36; 4,57] <,0001[3]	26,8 [19,8; 33,8] <,0001[3]
≥ 10	84/154 (54,5)	35/134 (26,1)	2,09 [1,52; 2,87] <,0001[2]	3,39 [2,06; 5,59] <,0001[3]	28,4 [17,6; 39,3] <,0001[3]
Tumor stage (Interaction p-value: 0,6185)					
IIA	37/79 (46,8)	11/77 (14,3)	3,28 [1,81; 5,95] <,0001[2]	5,29 [2,43; 11,49] <,0001[3]	32,5 [19,1; 46,0] <,0001[3]
IIB	44/73 (60,3)	20/93 (21,5)	2,80 [1,82; 4,31] <,0001[2]	5,54 [2,80; 10,95] <,0001[3]	38,8 [24,8; 52,8] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	185/345 (53,6)	74/294 (25,2)	2,13 [1,71; 2,66] <,0001[2]	3,44 [2,45; 4,82] <,0001[3]	28,5 [21,2; 35,7] <,0001[3]
IIIB	9/22 (40,9)	3/19 (15,8)	2,59 [0,82; 8,21] 0,1057[2]	3,69 [0,83; 16,51] 0,0779[3]	25,1 [-1,2; 51,4] 0,0779[3]
IIIC	126/253 (49,8)	51/245 (20,8)	2,39 [1,82; 3,15] <,0001[2]	3,77 [2,54; 5,60] <,0001[3]	29,0 [21,0; 37,0] <,0001[3]
Tumor grade (Interaction p-value: 0,3705)					
G1	39/63 (61,9)	9/52 (17,3)	3,58 [1,91; 6,68] <,0001[2]	7,76 [3,22; 18,72] <,0001[3]	44,6 [28,8; 60,4] <,0001[3]
G2	170/349 (48,7)	75/323 (23,2)	2,10 [1,67; 2,63] <,0001[2]	3,14 [2,25; 4,38] <,0001[3]	25,5 [18,5; 32,5] <,0001[3]
G3	159/317 (50,2)	62/312 (19,9)	2,52 [1,97; 3,24] <,0001[2]	4,06 [2,85; 5,79] <,0001[3]	30,3 [23,2; 37,3] <,0001[3]
GX	34/44 (77,3)	12/40 (30,0)	2,58 [1,56; 4,25] 0,0002[2]	7,93 [2,99; 21,07] <,0001[3]	47,3 [28,4; 66,1] <,0001[3]
Progesterone receptor status (Interaction p-value: 0,8930)					
Negative	37/67 (55,2)	13/62 (21,0)	2,63 [1,55; 4,47] 0,0003[2]	4,65 [2,13; 10,12] <,0001[3]	34,3 [18,6; 49,9] <,0001[3]
Positive	350/678 (51,6)	145/647 (22,4)	2,30 [1,96; 2,71] <,0001[2]	3,69 [2,91; 4,69] <,0001[3]	29,2 [24,3; 34,2] <,0001[3]
Unknown	4/8 (50,0)	0/8 (0,0)	9,00 [0,56; 143,89] 0,1203[2]	17,00 [0,74; 391,68] 0,0769[4]	50,0 [15,4; 84,6] 0,0769[4]
Race (Interaction p-value: 0,5376)					
White	202/461 (43,8)	75/440 (17,0)	2,57 [2,04; 3,24] <,0001[2]	3,80 [2,79; 5,17] <,0001[3]	26,8 [21,0; 32,5] <,0001[3]
Asian	187/273 (68,5)	77/243 (31,7)	2,16 [1,77; 2,64] <,0001[2]	4,69 [3,23; 6,80] <,0001[3]	36,8 [28,8; 44,8] <,0001[3]
Other	15/30 (50,0)	7/34 (20,6)	2,43 [1,15; 5,15] 0,0206[2]	3,86 [1,29; 11,55] 0,0134[3]	29,4 [6,9; 51,9] 0,0134[3]
First endocrine therapy (Interaction p-value: 0,0854)					
Tamoxifen	268/553 (48,5)	99/534 (18,5)	2,61 [2,15; 3,18] <,0001[2]	4,13 [3,14; 5,44] <,0001[3]	29,9 [24,6; 35,2] <,0001[3]
Aromatase inhibitor	137/223 (61,4)	60/195 (30,8)	2,00 [1,58; 2,53] <,0001[2]	3,58 [2,39; 5,38] <,0001[3]	30,7 [21,6; 39,8] <,0001[3]
ECOG-PS (Interaction p-value: 0,8223)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	369/685 (53,9)	145/649 (22,3)	2,41 [2,06; 2,83] <,0001[2]	4,06 [3,20; 5,15] <,0001[3]	31,5 [26,6; 36,4] <,0001[3]
ECOG-PS 1	36/91 (39,6)	14/80 (17,5)	2,26 [1,32; 3,88] 0,0030[2]	3,09 [1,51; 6,30] 0,0016[3]	22,1 [9,0; 35,1] 0,0016[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 275.1.2: Subgroups - adverse events according SOC Metabolism and nutrition disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,5275)					
Neoadjuvant chemotherapy	77/314 (24,5)	33/306 (10,8)	2,27 [1,56; 3,31] <,0001[2]	2,69 [1,73; 4,19] <,0001[3]	13,7 [7,8; 19,6] <,0001[3]
Adjuvant chemotherapy	97/452 (21,5)	52/416 (12,5)	1,72 [1,26; 2,34] 0,0006[2]	1,91 [1,32; 2,76] 0,0005[3]	9,0 [4,0; 13,9] 0,0005[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,5152)					
North America / Europe	71/347 (20,5)	31/309 (10,0)	2,04 [1,38; 3,02] 0,0004[2]	2,31 [1,47; 3,63] 0,0002[3]	10,4 [5,0; 15,8] 0,0002[3]
Asia	57/239 (23,8)	24/226 (10,6)	2,25 [1,45; 3,49] 0,0003[2]	2,64 [1,57; 4,42] 0,0002[3]	13,2 [6,5; 20,0] 0,0002[3]
Other	47/190 (24,7)	30/194 (15,5)	1,60 [1,06; 2,42] 0,0254[2]	1,80 [1,08; 2,99] 0,0233[3]	9,3 [1,3; 17,2] 0,0233[3]
Primary tumor size (Interaction p-value: 0,8106)					
< 20 mm	41/204 (20,1)	18/189 (9,5)	2,11 [1,26; 3,54] 0,0047[2]	2,39 [1,32; 4,33] 0,0034[3]	10,6 [3,7; 17,5] 0,0034[3]
≥ 20 but < 50 mm	87/360 (24,2)	42/346 (12,1)	1,99 [1,42; 2,79] <,0001[2]	2,31 [1,54; 3,45] <,0001[3]	12,0 [6,4; 17,6] <,0001[3]
≥ 50 mm	43/194 (22,2)	24/185 (13,0)	1,71 [1,08; 2,70] 0,0216[2]	1,91 [1,11; 3,30] 0,0190[3]	9,2 [1,6; 16,8] 0,0190[3]
Number of positive lymph nodes (Interaction p-value: 0,4420)					
0-3	51/269 (19,0)	29/269 (10,8)	1,76 [1,15; 2,69] 0,0090[2]	1,94 [1,18; 3,16] 0,0077[3]	8,2 [2,2; 14,2] 0,0077[3]
4-9	86/353 (24,4)	35/326 (10,7)	2,27 [1,58; 3,26] <,0001[2]	2,68 [1,75; 4,10] <,0001[3]	13,6 [8,0; 19,2] <,0001[3]
≥ 10	38/154 (24,7)	21/134 (15,7)	1,57 [0,97; 2,54] 0,0638[2]	1,76 [0,97; 3,19] 0,0590[3]	9,0 [-0,2; 18,2] 0,0590[3]
Tumor stage (Interaction p-value: 0,8384)					
IIA	13/79 (16,5)	5/77 (6,5)	2,53 [0,95; 6,77] 0,0636[2]	2,84 [0,96; 8,39] 0,0515[3]	10,0 [0,1; 19,8] 0,0515[3]
IIB	16/73 (21,9)	15/93 (16,1)	1,36 [0,72; 2,56] 0,3433[2]	1,46 [0,67; 3,19] 0,3421[3]	5,8 [-6,3; 17,9] 0,3421[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	77/345 (22,3)	34/294 (11,6)	1,93 [1,33; 2,80] 0,0005[2]	2,20 [1,42; 3,41] 0,0003[3]	10,8 [5,0; 16,5] 0,0003[3]
IIIB	5/22 (22,7)	0/19 (0,0)	9,57 [0,56; 162,47] 0,1181[2]	12,26 [0,63; 237,99] 0,0507[4]	22,7 [5,2; 40,2] 0,0507[4]
IIIC	63/253 (24,9)	31/245 (12,7)	1,97 [1,33; 2,91] 0,0007[2]	2,29 [1,43; 3,67] 0,0005[3]	12,2 [5,5; 19,0] 0,0005[3]
Tumor grade (Interaction p-value: 0,3735)					
G1	16/63 (25,4)	5/52 (9,6)	2,64 [1,04; 6,73] 0,0417[2]	3,20 [1,08; 9,45] 0,0292[3]	15,8 [2,4; 29,2] 0,0292[3]
G2	83/349 (23,8)	39/323 (12,1)	1,97 [1,39; 2,79] 0,0001[2]	2,27 [1,50; 3,44] <,0001[3]	11,7 [6,0; 17,4] <,0001[3]
G3	67/317 (21,1)	40/312 (12,8)	1,65 [1,15; 2,36] 0,0064[2]	1,82 [1,19; 2,79] 0,0055[3]	8,3 [2,5; 14,1] 0,0055[3]
GX	9/44 (20,5)	1/40 (2,5)	8,18 [1,08; 61,75] 0,0415[2]	10,03 [1,21; 83,20] 0,0158[4]	18,0 [5,1; 30,8] 0,0158[4]
Progesterone receptor status (Interaction p-value: 0,4543)					
Negative	11/67 (16,4)	6/62 (9,7)	1,70 [0,67; 4,31] 0,2667[2]	1,83 [0,63; 5,30] 0,2581[3]	6,7 [-4,8; 18,3] 0,2581[3]
Positive	158/678 (23,3)	76/647 (11,7)	1,98 [1,54; 2,55] <,0001[2]	2,28 [1,69; 3,08] <,0001[3]	11,6 [7,5; 15,6] <,0001[3]
Unknown	1/8 (12,5)	2/8 (25,0)	0,50 [0,06; 4,47] 0,5353[2]	0,43 [0,03; 5,98] 1,0000[4]	-12,5 [-50,3; 25,3] 1,0000[4]
Race (Interaction p-value: 0,3021)					
White	96/461 (20,8)	49/440 (11,1)	1,87 [1,36; 2,57] 0,0001[2]	2,10 [1,45; 3,05] <,0001[3]	9,7 [5,0; 14,4] <,0001[3]
Asian	62/273 (22,7)	25/243 (10,3)	2,21 [1,43; 3,40] 0,0003[2]	2,56 [1,55; 4,23] 0,0002[3]	12,4 [6,2; 18,7] 0,0002[3]
Other	10/30 (33,3)	10/34 (29,4)	1,13 [0,55; 2,34] 0,7355[2]	1,20 [0,42; 3,46] 0,7355[3]	3,9 [-18,9; 26,7] 0,7355[3]
First endocrine therapy (Interaction p-value: 0,3256)					
Tamoxifen	115/553 (20,8)	53/534 (9,9)	2,10 [1,55; 2,84] <,0001[2]	2,38 [1,68; 3,38] <,0001[3]	10,9 [6,6; 15,1] <,0001[3]
Aromatase inhibitor	60/223 (26,9)	32/195 (16,4)	1,64 [1,12; 2,41] 0,0115[2]	1,88 [1,16; 3,03] 0,0098[3]	10,5 [2,7; 18,3] 0,0098[3]
ECOG-PS (Interaction p-value: 0,8014)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	159/685 (23,2)	77/649 (11,9)	1,96 [1,52; 2,51] <,0001[2]	2,25 [1,67; 3,02] <,0001[3]	11,3 [7,3; 15,4] <,0001[3]
ECOG-PS 1	16/91 (17,6)	8/80 (10,0)	1,76 [0,79; 3,89] 0,1635[2]	1,92 [0,77; 4,76] 0,1544[3]	7,6 [-2,6; 17,8] 0,1544[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 276.1.2: Subgroups - adverse events according SOC Musculoskeletal and connective tissue disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8768)					
Neoadjuvant chemotherapy	157/314 (50,0)	171/306 (55,9)	0,89 [0,77; 1,04] 0,1429[2]	0,79 [0,58; 1,08] 0,1424[3]	-5,9 [-13,7; 2,0] 0,1424[3]
Adjuvant chemotherapy	204/452 (45,1)	215/416 (51,7)	0,87 [0,76; 1,00] 0,0538[2]	0,77 [0,59; 1,00] 0,0537[3]	-6,5 [-13,2; 0,1] 0,0537[3]
No chemotherapy	4/10 (40,0)	4/7 (57,1)	0,70 [0,26; 1,89] 0,4818[2]	0,50 [0,07; 3,55] 0,6372[4]	-17,1 [-64,7; 30,5] 0,6372[4]
Primary tumor size (Interaction p-value: 0,0901)					
< 20 mm	98/204 (48,0)	108/189 (57,1)	0,84 [0,70; 1,02] 0,0715[2]	0,69 [0,47; 1,03] 0,0710[3]	-9,1 [-18,9; 0,7] 0,0710[3]
≥ 20 but < 50 mm	158/360 (43,9)	185/346 (53,5)	0,82 [0,70; 0,96] 0,0113[2]	0,68 [0,51; 0,92] 0,0109[3]	-9,6 [-16,9; -2,2] 0,0109[3]
≥ 50 mm	106/194 (54,6)	95/185 (51,4)	1,06 [0,88; 1,29] 0,5221[2]	1,14 [0,76; 1,71] 0,5215[3]	3,3 [-6,8; 13,3] 0,5215[3]
Number of positive lymph nodes (Interaction p-value: 0,1914)					
0-3	142/269 (52,8)	147/269 (54,6)	0,97 [0,83; 1,13] 0,6656[2]	0,93 [0,66; 1,30] 0,6655[3]	-1,9 [-10,3; 6,6] 0,6655[3]
4-9	151/353 (42,8)	176/326 (54,0)	0,79 [0,68; 0,93] 0,0036[2]	0,64 [0,47; 0,86] 0,0035[3]	-11,2 [-18,7; -3,7] 0,0035[3]
≥ 10	72/154 (46,8)	67/134 (50,0)	0,94 [0,74; 1,19] 0,5818[2]	0,88 [0,55; 1,40] 0,5823[3]	-3,2 [-14,8; 8,3] 0,5823[3]
Tumor stage (Interaction p-value: 0,5886)					
IIA	41/79 (51,9)	46/77 (59,7)	0,87 [0,66; 1,15] 0,3255[2]	0,73 [0,39; 1,37] 0,3242[3]	-7,8 [-23,4; 7,7] 0,3242[3]
IIB	34/73 (46,6)	48/93 (51,6)	0,90 [0,66; 1,24] 0,5225[2]	0,82 [0,44; 1,51] 0,5193[3]	-5,0 [-20,3; 10,3] 0,5193[3]
IIIA	156/345 (45,2)	166/294 (56,5)	0,80 [0,69; 0,93] 0,0046[2]	0,64 [0,47; 0,87] 0,0046[3]	-11,2 [-19,0; -3,5] 0,0046[3]
IIIB	10/22 (45,5)	9/19 (47,4)	0,96 [0,50; 1,85] 0,9024[2]	0,93 [0,27; 3,17] 0,9025[3]	-1,9 [-32,5; 28,7] 0,9025[3]
IIIC	122/253 (48,2)	121/245 (49,4)	0,98 [0,82; 1,17] 0,7946[2]	0,95 [0,67; 1,36] 0,7946[3]	-1,2 [-9,9; 7,6] 0,7946[3]
Tumor grade (Interaction p-value: 0,0742)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	25/63 (39,7)	34/52 (65,4)	0,61 [0,42; 0,87] 0,0070[2]	0,35 [0,16; 0,75] 0,0061[3]	-25,7 [-43,4; -8,0] 0,0061[3]
G2	168/349 (48,1)	180/323 (55,7)	0,86 [0,75; 1,00] 0,0493[2]	0,74 [0,54; 1,00] 0,0491[3]	-7,6 [-15,1; -0,1] 0,0491[3]
G3	161/317 (50,8)	161/312 (51,6)	0,98 [0,84; 1,15] 0,8382[2]	0,97 [0,71; 1,32] 0,8382[3]	-0,8 [-8,6; 7,0] 0,8382[3]
GX	9/44 (20,5)	13/40 (32,5)	0,63 [0,30; 1,31] 0,2164[2]	0,53 [0,20; 1,43] 0,2098[3]	-12,0 [-30,8; 6,7] 0,2098[3]
Progesterone receptor status (Interaction p-value: 0,8972)					
Negative	32/67 (47,8)	32/62 (51,6)	0,93 [0,65; 1,31] 0,6618[2]	0,86 [0,43; 1,71] 0,6620[3]	-3,9 [-21,1; 13,4] 0,6620[3]
Positive	314/678 (46,3)	347/647 (53,6)	0,86 [0,77; 0,96] 0,0078[2]	0,75 [0,60; 0,93] 0,0077[3]	-7,3 [-12,7; -1,9] 0,0077[3]
Unknown	4/8 (50,0)	4/8 (50,0)	1,00 [0,38; 2,66] 1,0000[2]	1,00 [0,14; 7,10] 1,0000[4]	0,0 [-49,0; 49,0] 1,0000[4]
Race (Interaction p-value: 0,7908)					
White	233/461 (50,5)	248/440 (56,4)	0,90 [0,79; 1,01] 0,0802[2]	0,79 [0,61; 1,03] 0,0800[3]	-5,8 [-12,3; 0,7] 0,0800[3]
Asian	106/273 (38,8)	114/243 (46,9)	0,83 [0,68; 1,01] 0,0640[2]	0,72 [0,51; 1,02] 0,0638[3]	-8,1 [-16,6; 0,4] 0,0638[3]
Other	16/30 (53,3)	20/34 (58,8)	0,91 [0,59; 1,40] 0,6605[2]	0,80 [0,30; 2,15] 0,6586[3]	-5,5 [-29,8; 18,8] 0,6586[3]
First endocrine therapy (Interaction p-value: 0,6228)					
Tamoxifen	250/553 (45,2)	271/534 (50,7)	0,89 [0,79; 1,01] 0,0678[2]	0,80 [0,63; 1,02] 0,0675[3]	-5,5 [-11,5; 0,4] 0,0675[3]
Aromatase inhibitor	115/223 (51,6)	119/195 (61,0)	0,85 [0,71; 1,00] 0,0517[2]	0,68 [0,46; 1,00] 0,0520[3]	-9,5 [-18,9; 0,0] 0,0520[3]
ECOG-PS (Interaction p-value: 0,6239)					
ECOG-PS 0	325/685 (47,4)	347/649 (53,5)	0,89 [0,80; 0,99] 0,0280[2]	0,79 [0,63; 0,97] 0,0279[3]	-6,0 [-11,4; -0,7] 0,0279[3]
ECOG-PS 1	40/91 (44,0)	43/80 (53,8)	0,82 [0,60; 1,11] 0,2012[2]	0,67 [0,37; 1,23] 0,2010[3]	-9,8 [-24,7; 5,2] 0,2010[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.					

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Table 277.1.2: Subgroups - adverse events according SOC Nervous system disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,0696)					
Neoadjuvant chemotherapy	108/314 (34,4)	104/306 (34,0)	1,01 [0,81; 1,26] 0,9147[2]	1,02 [0,73; 1,42] 0,9147[3]	0,4 [-7,1; 7,9] 0,9147[3]
Adjuvant chemotherapy	168/452 (37,2)	109/416 (26,2)	1,42 [1,16; 1,73] 0,0006[2]	1,67 [1,25; 2,23] 0,0005[3]	11,0 [4,8; 17,1] 0,0005[3]
No chemotherapy	7/10 (70,0)	3/7 (42,9)	1,63 [0,63; 4,21] 0,3098[2]	3,11 [0,41; 23,39] 0,3500[4]	27,1 [-19,2; 73,5] 0,3500[4]
Region (Interaction p-value: 0,0799)					
North America / Europe	141/347 (40,6)	116/309 (37,5)	1,08 [0,89; 1,31] 0,4189[2]	1,14 [0,83; 1,56] 0,4178[3]	3,1 [-4,4; 10,6] 0,4178[3]
Asia	91/239 (38,1)	54/226 (23,9)	1,59 [1,20; 2,12] 0,0013[2]	1,96 [1,31; 2,93] 0,0010[3]	14,2 [5,9; 22,5] 0,0010[3]
Other	51/190 (26,8)	46/194 (23,7)	1,13 [0,80; 1,60] 0,4807[2]	1,18 [0,74; 1,87] 0,4802[3]	3,1 [-5,6; 11,8] 0,4802[3]
Primary tumor size (Interaction p-value: 0,1566)					
< 20 mm	76/204 (37,3)	62/189 (32,8)	1,14 [0,87; 1,49] 0,3572[2]	1,22 [0,80; 1,84] 0,3557[3]	4,5 [-5,0; 13,9] 0,3557[3]
≥ 20 but < 50 mm	123/360 (34,2)	106/346 (30,6)	1,12 [0,90; 1,38] 0,3173[2]	1,18 [0,86; 1,61] 0,3164[3]	3,5 [-3,4; 10,4] 0,3164[3]
≥ 50 mm	79/194 (40,7)	48/185 (25,9)	1,57 [1,17; 2,11] 0,0029[2]	1,96 [1,27; 3,03] 0,0023[3]	14,8 [5,4; 24,1] 0,0023[3]
Number of positive lymph nodes (Interaction p-value: 0,4873)					
0-3	102/269 (37,9)	86/269 (32,0)	1,19 [0,94; 1,50] 0,1492[2]	1,30 [0,91; 1,85] 0,1480[3]	5,9 [-2,1; 14,0] 0,1480[3]
4-9	121/353 (34,3)	95/326 (29,1)	1,18 [0,94; 1,47] 0,1528[2]	1,27 [0,92; 1,75] 0,1511[3]	5,1 [-1,9; 12,1] 0,1511[3]
≥ 10	60/154 (39,0)	35/134 (26,1)	1,49 [1,05; 2,11] 0,0238[2]	1,81 [1,09; 2,99] 0,0208[3]	12,8 [2,1; 23,5] 0,0208[3]
Tumor stage (Interaction p-value: 0,5773)					
IIA	29/79 (36,7)	26/77 (33,8)	1,09 [0,71; 1,66] 0,7008[2]	1,14 [0,59; 2,20] 0,7005[3]	2,9 [-12,0; 17,9] 0,7005[3]
IIB	25/73 (34,2)	30/93 (32,3)	1,06 [0,69; 1,64] 0,7867[2]	1,09 [0,57; 2,10] 0,7870[3]	2,0 [-12,5; 16,4] 0,7870[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	125/345 (36,2)	84/294 (28,6)	1,27 [1,01; 1,59] 0,0417[2]	1,42 [1,02; 1,99] 0,0397[3]	7,7 [0,4; 14,9] 0,0397[3]
IIIB	7/22 (31,8)	8/19 (42,1)	0,76 [0,34; 1,69] 0,4966[2]	0,64 [0,18; 2,30] 0,4953[3]	-10,3 [-39,8; 19,2] 0,4953[3]
IIIC	96/253 (37,9)	68/245 (27,8)	1,37 [1,06; 1,77] 0,0167[2]	1,59 [1,09; 2,32] 0,0156[3]	10,2 [2,0; 18,4] 0,0156[3]
Tumor grade (Interaction p-value: 0,5928)					
G1	31/63 (49,2)	15/52 (28,8)	1,71 [1,04; 2,80] 0,0345[2]	2,39 [1,10; 5,20] 0,0265[3]	20,4 [2,9; 37,8] 0,0265[3]
G2	124/349 (35,5)	93/323 (28,8)	1,23 [0,99; 1,54] 0,0637[2]	1,36 [0,98; 1,89] 0,0620[3]	6,7 [-0,3; 13,8] 0,0620[3]
G3	121/317 (38,2)	101/312 (32,4)	1,18 [0,95; 1,46] 0,1294[2]	1,29 [0,93; 1,79] 0,1281[3]	5,8 [-1,7; 13,3] 0,1281[3]
GX	7/44 (15,9)	6/40 (15,0)	1,06 [0,39; 2,89] 0,9084[2]	1,07 [0,33; 3,51] 0,9084[3]	0,9 [-14,6; 16,4] 0,9084[3]
Progesterone receptor status (Interaction p-value: 0,4146)					
Negative	32/67 (47,8)	18/62 (29,0)	1,65 [1,04; 2,61] 0,0350[2]	2,23 [1,08; 4,63] 0,0292[3]	18,7 [2,3; 35,2] 0,0292[3]
Positive	238/678 (35,1)	191/647 (29,5)	1,19 [1,02; 1,39] 0,0306[2]	1,29 [1,02; 1,63] 0,0299[3]	5,6 [0,6; 10,6] 0,0299[3]
Unknown	3/8 (37,5)	2/8 (25,0)	1,50 [0,34; 6,70] 0,5955[2]	1,80 [0,21; 15,41] 1,0000[4]	12,5 [-32,5; 57,5] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,4805)					
Tamoxifen	200/553 (36,2)	152/534 (28,5)	1,27 [1,07; 1,51] 0,0070[2]	1,42 [1,10; 1,84] 0,0067[3]	7,7 [2,2; 13,2] 0,0067[3]
Aromatase inhibitor	83/223 (37,2)	64/195 (32,8)	1,13 [0,87; 1,48] 0,3493[2]	1,21 [0,81; 1,82] 0,3474[3]	4,4 [-4,7; 13,5] 0,3474[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 278.1.2: Subgroups - adverse events according SOC Renal and urinary disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9993)					
Neoadjuvant chemotherapy	22/314 (7,0)	14/306 (4,6)	1,53 [0,80; 2,94] 0,1997[2]	1,57 [0,79; 3,13] 0,1956[3]	2,4 [-1,2; 6,1] 0,1956[3]
Adjuvant chemotherapy	32/452 (7,1)	19/416 (4,6)	1,55 [0,89; 2,69] 0,1195[2]	1,59 [0,89; 2,85] 0,1159[3]	2,5 [-0,6; 5,6] 0,1159[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,4208)					
North America / Europe	30/347 (8,6)	13/309 (4,2)	2,05 [1,09; 3,87] 0,0256[2]	2,15 [1,10; 4,21] 0,0219[3]	4,4 [0,7; 8,1] 0,0219[3]
Asia	15/239 (6,3)	10/226 (4,4)	1,42 [0,65; 3,09] 0,3793[2]	1,45 [0,64; 3,29] 0,3763[3]	1,9 [-2,2; 5,9] 0,3763[3]
Other	10/190 (5,3)	10/194 (5,2)	1,02 [0,43; 2,40] 0,9618[2]	1,02 [0,42; 2,51] 0,9618[3]	0,1 [-4,3; 4,6] 0,9618[3]
Primary tumor size (Interaction p-value: 0,2633)					
< 20 mm	17/204 (8,3)	9/189 (4,8)	1,75 [0,80; 3,83] 0,1615[2]	1,82 [0,79; 4,18] 0,1547[3]	3,6 [-1,3; 8,4] 0,1547[3]
≥ 20 but < 50 mm	21/360 (5,8)	19/346 (5,5)	1,06 [0,58; 1,94] 0,8443[2]	1,07 [0,56; 2,02] 0,8442[3]	0,3 [-3,1; 3,8] 0,8442[3]
≥ 50 mm	14/194 (7,2)	5/185 (2,7)	2,67 [0,98; 7,27] 0,0545[2]	2,80 [0,99; 7,94] 0,0441[3]	4,5 [0,2; 8,8] 0,0441[3]
Number of positive lymph nodes (Interaction p-value: 0,9222)					
0-3	23/269 (8,6)	16/269 (5,9)	1,44 [0,78; 2,66] 0,2477[2]	1,48 [0,76; 2,87] 0,2445[3]	2,6 [-1,8; 7,0] 0,2445[3]
4-9	22/353 (6,2)	12/326 (3,7)	1,69 [0,85; 3,37] 0,1331[2]	1,74 [0,85; 3,57] 0,1278[3]	2,6 [-0,7; 5,8] 0,1278[3]
≥ 10	10/154 (6,5)	5/134 (3,7)	1,74 [0,61; 4,96] 0,3002[2]	1,79 [0,60; 5,38] 0,2927[3]	2,8 [-2,3; 7,8] 0,2927[3]
Tumor stage (Interaction p-value: 0,1686)					
IIA	9/79 (11,4)	4/77 (5,2)	2,19 [0,70; 6,82] 0,1752[2]	2,35 [0,69; 7,97] 0,1614[3]	6,2 [-2,4; 14,8] 0,1614[3]
IIB	2/73 (2,7)	8/93 (8,6)	0,32 [0,07; 1,45] 0,1398[2]	0,30 [0,06; 1,45] 0,1880[4]	-5,9 [-12,7; 1,0] 0,1880[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	29/345 (8,4)	10/294 (3,4)	2,47 [1,23; 4,99] 0,0115[2]	2,61 [1,25; 5,44] 0,0084[3]	5,0 [1,4; 8,6] 0,0084[3]
IIIB	2/22 (9,1)	1/19 (5,3)	1,73 [0,17; 17,59] 0,6444[2]	1,80 [0,15; 21,57] 1,0000[4]	3,8 [-11,8; 19,5] 1,0000[4]
IIIC	13/253 (5,1)	10/245 (4,1)	1,26 [0,56; 2,82] 0,5753[2]	1,27 [0,55; 2,96] 0,5743[3]	1,1 [-2,6; 4,7] 0,5743[3]
Tumor grade (Interaction p-value: 0,8218)					
G1	7/63 (11,1)	3/52 (5,8)	1,93 [0,52; 7,08] 0,3237[2]	2,04 [0,50; 8,33] 0,5082[4]	5,3 [-4,7; 15,4] 0,5082[4]
G2	26/349 (7,4)	13/323 (4,0)	1,85 [0,97; 3,54] 0,0627[2]	1,92 [0,97; 3,80] 0,0578[3]	3,4 [-0,1; 6,9] 0,0578[3]
G3	20/317 (6,3)	16/312 (5,1)	1,23 [0,65; 2,33] 0,5247[2]	1,25 [0,63; 2,45] 0,5238[3]	1,2 [-2,4; 4,8] 0,5238[3]
GX	2/44 (4,5)	1/40 (2,5)	1,82 [0,17; 19,29] 0,6198[2]	1,86 [0,16; 21,30] 1,0000[4]	2,0 [-5,8; 9,9] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,6341)					
Negative	5/67 (7,5)	1/62 (1,6)	4,63 [0,56; 38,51] 0,1565[2]	4,92 [0,56; 43,34] 0,2098[4]	5,8 [-1,2; 12,9] 0,2098[4]
Positive	49/678 (7,2)	29/647 (4,5)	1,61 [1,03; 2,52] 0,0359[2]	1,66 [1,04; 2,66] 0,0338[3]	2,7 [0,2; 5,3] 0,0338[3]
Unknown	0/8 (0,0)	3/8 (37,5)	0,14 [0,01; 2,39] 0,1755[2]	0,09 [0,00; 2,16] 0,2000[4]	-37,5 [-71,0; -4,0] 0,2000[4]
Race (Interaction p-value: 0,8749)					
White	35/461 (7,6)	20/440 (4,5)	1,67 [0,98; 2,85] 0,0595[2]	1,73 [0,98; 3,04] 0,0562[3]	3,0 [-0,1; 6,2] 0,0562[3]
Asian	17/273 (6,2)	11/243 (4,5)	1,38 [0,66; 2,88] 0,3973[2]	1,40 [0,64; 3,05] 0,3947[3]	1,7 [-2,2; 5,6] 0,3947[3]
Other	2/30 (6,7)	1/34 (2,9)	2,27 [0,22; 23,76] 0,4949[2]	2,36 [0,20; 27,39] 0,5961[4]	3,7 [-6,9; 14,3] 0,5961[4]
First endocrine therapy (Interaction p-value: 0,3254)					
Tamoxifen	37/553 (6,7)	26/534 (4,9)	1,37 [0,84; 2,24] 0,2011[2]	1,40 [0,84; 2,35] 0,1988[3]	1,8 [-0,9; 4,6] 0,1988[3]
Aromatase inhibitor	18/223 (8,1)	7/195 (3,6)	2,25 [0,96; 5,27] 0,0622[2]	2,36 [0,96; 5,77] 0,0539[3]	4,5 [0,1; 8,9] 0,0539[3]
ECOG-PS (Interaction p-value: 0,5483)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	47/685 (6,9)	27/649 (4,2)	1,65 [1,04; 2,62] 0,0334[2]	1,70 [1,04; 2,76] 0,0312[3]	2,7 [0,3; 5,1] 0,0312[3]
ECOG-PS 1	8/91 (8,8)	6/80 (7,5)	1,17 [0,42; 3,23] 0,7590[2]	1,19 [0,39; 3,59] 0,7586[3]	1,3 [-6,9; 9,5] 0,7586[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 279.1.2: Subgroups - adverse events according SOC Respiratory, thoracic and mediastinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9279)					
Neoadjuvant chemotherapy	87/314 (27,7)	46/306 (15,0)	1,84 [1,34; 2,54] 0,0002[2]	2,17 [1,45; 3,23] 0,0001[3]	12,7 [6,3; 19,0] 0,0001[3]
Adjuvant chemotherapy	126/452 (27,9)	65/416 (15,6)	1,78 [1,36; 2,33] <,0001[2]	2,09 [1,49; 2,92] <,0001[3]	12,3 [6,8; 17,7] <,0001[3]
No chemotherapy	4/10 (40,0)	2/7 (28,6)	1,40 [0,35; 5,65] 0,6366[2]	1,67 [0,21; 13,22] 1,0000[4]	11,4 [-33,8; 56,6] 1,0000[4]
Region (Interaction p-value: 0,2013)					
North America / Europe	110/347 (31,7)	48/309 (15,5)	2,04 [1,51; 2,76] <,0001[2]	2,52 [1,72; 3,70] <,0001[3]	16,2 [9,8; 22,5] <,0001[3]
Asia	79/239 (33,1)	41/226 (18,1)	1,82 [1,31; 2,54] 0,0004[2]	2,23 [1,45; 3,43] 0,0002[3]	14,9 [7,1; 22,7] 0,0002[3]
Other	28/190 (14,7)	24/194 (12,4)	1,19 [0,72; 1,98] 0,4989[2]	1,22 [0,68; 2,20] 0,4982[3]	2,4 [-4,5; 9,2] 0,4982[3]
Primary tumor size (Interaction p-value: 0,9283)					
< 20 mm	57/204 (27,9)	30/189 (15,9)	1,76 [1,19; 2,61] 0,0051[2]	2,06 [1,25; 3,37] 0,0040[3]	12,1 [4,0; 20,1] 0,0040[3]
≥ 20 but < 50 mm	102/360 (28,3)	53/346 (15,3)	1,85 [1,37; 2,49] <,0001[2]	2,19 [1,51; 3,17] <,0001[3]	13,0 [7,0; 19,0] <,0001[3]
≥ 50 mm	51/194 (26,3)	29/185 (15,7)	1,68 [1,11; 2,52] 0,0132[2]	1,92 [1,15; 3,19] 0,0114[3]	10,6 [2,5; 18,7] 0,0114[3]
Number of positive lymph nodes (Interaction p-value: 0,4074)					
0-3	76/269 (28,3)	37/269 (13,8)	2,05 [1,44; 2,93] <,0001[2]	2,47 [1,60; 3,82] <,0001[3]	14,5 [7,7; 21,3] <,0001[3]
4-9	98/353 (27,8)	58/326 (17,8)	1,56 [1,17; 2,08] 0,0024[2]	1,78 [1,23; 2,56] 0,0020[3]	10,0 [3,7; 16,2] 0,0020[3]
≥ 10	43/154 (27,9)	18/134 (13,4)	2,08 [1,26; 3,42] 0,0041[2]	2,50 [1,36; 4,59] 0,0027[3]	14,5 [5,3; 23,6] 0,0027[3]
Tumor stage (Interaction p-value: 0,2393)					
IIA	20/79 (25,3)	8/77 (10,4)	2,44 [1,14; 5,20] 0,0212[2]	2,92 [1,20; 7,12] 0,0151[3]	14,9 [3,2; 26,7] 0,0151[3]
IIB	13/73 (17,8)	16/93 (17,2)	1,04 [0,53; 2,01] 0,9190[2]	1,04 [0,47; 2,33] 0,9190[3]	0,6 [-11,1; 12,3] 0,9190[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	99/345 (28,7)	51/294 (17,3)	1,65 [1,23; 2,23] 0,0010[2]	1,92 [1,31; 2,81] 0,0007[3]	11,3 [4,9; 17,8] 0,0007[3]
IIIB	8/22 (36,4)	1/19 (5,3)	6,91 [0,95; 50,35] 0,0565[2]	10,29 [1,15; 92,19] 0,0238[4]	31,1 [8,6; 53,6] 0,0238[4]
IIIC	75/253 (29,6)	37/245 (15,1)	1,96 [1,38; 2,79] 0,0002[2]	2,37 [1,52; 3,68] 0,0001[3]	14,5 [7,3; 21,7] 0,0001[3]
Tumor grade (Interaction p-value: 0,6186)					
G1	21/63 (33,3)	6/52 (11,5)	2,89 [1,26; 6,62] 0,0122[2]	3,83 [1,41; 10,41] 0,0061[3]	21,8 [7,3; 36,3] 0,0061[3]
G2	93/349 (26,6)	53/323 (16,4)	1,62 [1,20; 2,20] 0,0016[2]	1,85 [1,27; 2,70] 0,0013[3]	10,2 [4,1; 16,4] 0,0013[3]
G3	92/317 (29,0)	48/312 (15,4)	1,89 [1,38; 2,58] <,0001[2]	2,25 [1,52; 3,33] <,0001[3]	13,6 [7,2; 20,0] <,0001[3]
GX	10/44 (22,7)	5/40 (12,5)	1,82 [0,68; 4,87] 0,2339[2]	2,06 [0,64; 6,65] 0,2216[3]	10,2 [-5,8; 26,3] 0,2216[3]
Progesterone receptor status (Interaction p-value: 0,8312)					
Negative	19/67 (28,4)	9/62 (14,5)	1,95 [0,96; 3,99] 0,0660[2]	2,33 [0,96; 5,64] 0,0567[3]	13,8 [-0,1; 27,7] 0,0567[3]
Positive	183/678 (27,0)	101/647 (15,6)	1,73 [1,39; 2,15] <,0001[2]	2,00 [1,52; 2,62] <,0001[3]	11,4 [7,0; 15,7] <,0001[3]
Unknown	3/8 (37,5)	1/8 (12,5)	3,00 [0,39; 23,07] 0,2912[2]	4,20 [0,33; 53,12] 0,5692[4]	25,0 [-15,6; 65,6] 0,5692[4]
Race (Interaction p-value: 0,8350)					
White	118/461 (25,6)	63/440 (14,3)	1,79 [1,36; 2,36] <,0001[2]	2,06 [1,47; 2,89] <,0001[3]	11,3 [6,1; 16,4] <,0001[3]
Asian	85/273 (31,1)	42/243 (17,3)	1,80 [1,30; 2,50] 0,0004[2]	2,16 [1,42; 3,29] 0,0003[3]	13,9 [6,6; 21,1] 0,0003[3]
Other	7/30 (23,3)	6/34 (17,6)	1,32 [0,50; 3,50] 0,5739[2]	1,42 [0,42; 4,82] 0,5726[3]	5,7 [-14,1; 25,5] 0,5726[3]
First endocrine therapy (Interaction p-value: 0,1269)					
Tamoxifen	157/553 (28,4)	76/534 (14,2)	1,99 [1,56; 2,55] <,0001[2]	2,39 [1,76; 3,24] <,0001[3]	14,2 [9,4; 18,9] <,0001[3]
Aromatase inhibitor	60/223 (26,9)	37/195 (19,0)	1,42 [0,99; 2,04] 0,0585[2]	1,57 [0,99; 2,50] 0,0553[3]	7,9 [-0,1; 15,9] 0,0553[3]
ECOG-PS (Interaction p-value: 0,1031)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	189/685 (27,6)	93/649 (14,3)	1,93 [1,54; 2,41] <,0001[2]	2,28 [1,73; 3,00] <,0001[3]	13,3 [9,0; 17,6] <,0001[3]
ECOG-PS 1	28/91 (30,8)	20/80 (25,0)	1,23 [0,75; 2,01] 0,4052[2]	1,33 [0,68; 2,62] 0,4022[3]	5,8 [-7,6; 19,2] 0,4022[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 280.1.2: Subgroups - adverse events according SOC Skin and subcutaneous tissue disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,4069)					
Neoadjuvant chemotherapy	123/314 (39,2)	53/306 (17,3)	2,26 [1,71; 3,00] <,0001[2]	3,07 [2,12; 4,46] <,0001[3]	21,9 [15,0; 28,7] <,0001[3]
Adjuvant chemotherapy	175/452 (38,7)	90/416 (21,6)	1,79 [1,44; 2,22] <,0001[2]	2,29 [1,69; 3,09] <,0001[3]	17,1 [11,1; 23,1] <,0001[3]
No chemotherapy	7/10 (70,0)	2/7 (28,6)	2,45 [0,71; 8,46] 0,1565[2]	5,83 [0,70; 48,87] 0,1534[4]	41,4 [-2,5; 85,3] 0,1534[4]
Region (Interaction p-value: 0,6462)					
North America / Europe	154/347 (44,4)	73/309 (23,6)	1,88 [1,49; 2,37] <,0001[2]	2,58 [1,84; 3,61] <,0001[3]	20,8 [13,7; 27,8] <,0001[3]
Asia	108/239 (45,2)	54/226 (23,9)	1,89 [1,44; 2,48] <,0001[2]	2,63 [1,76; 3,91] <,0001[3]	21,3 [12,9; 29,7] <,0001[3]
Other	43/190 (22,6)	18/194 (9,3)	2,44 [1,46; 4,07] 0,0007[2]	2,86 [1,58; 5,17] 0,0003[3]	13,4 [6,1; 20,6] 0,0003[3]
Primary tumor size (Interaction p-value: 0,3529)					
< 20 mm	82/204 (40,2)	31/189 (16,4)	2,45 [1,71; 3,52] <,0001[2]	3,43 [2,13; 5,51] <,0001[3]	23,8 [15,2; 32,3] <,0001[3]
≥ 20 but < 50 mm	132/360 (36,7)	69/346 (19,9)	1,84 [1,43; 2,36] <,0001[2]	2,32 [1,65; 3,26] <,0001[3]	16,7 [10,2; 23,2] <,0001[3]
≥ 50 mm	82/194 (42,3)	44/185 (23,8)	1,78 [1,31; 2,41] 0,0002[2]	2,35 [1,51; 3,65] 0,0001[3]	18,5 [9,2; 27,8] 0,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,9599)					
0-3	115/269 (42,8)	58/269 (21,6)	1,98 [1,52; 2,59] <,0001[2]	2,72 [1,86; 3,96] <,0001[3]	21,2 [13,5; 28,9] <,0001[3]
4-9	137/353 (38,8)	65/326 (19,9)	1,95 [1,51; 2,51] <,0001[2]	2,55 [1,80; 3,60] <,0001[3]	18,9 [12,2; 25,6] <,0001[3]
≥ 10	53/154 (34,4)	22/134 (16,4)	2,10 [1,35; 3,25] 0,0010[2]	2,67 [1,52; 4,70] 0,0005[3]	18,0 [8,2; 27,8] 0,0005[3]
Tumor stage (Interaction p-value: 0,4647)					
IIA	31/79 (39,2)	13/77 (16,9)	2,32 [1,32; 4,10] 0,0035[2]	3,18 [1,50; 6,72] 0,0019[3]	22,4 [8,7; 36,0] 0,0019[3]
IIB	29/73 (39,7)	24/93 (25,8)	1,54 [0,99; 2,40] 0,0578[2]	1,89 [0,98; 3,67] 0,0562[3]	13,9 [-0,4; 28,2] 0,0562[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	133/345 (38,6)	56/294 (19,0)	2,02 [1,54; 2,65] <,0001[2]	2,67 [1,85; 3,83] <,0001[3]	19,5 [12,7; 26,3] <,0001[3]
IIIB	12/22 (54,5)	2/19 (10,5)	5,18 [1,32; 20,30] 0,0182[2]	10,20 [1,88; 55,19] 0,0030[3]	44,0 [19,1; 69,0] 0,0030[3]
IIIC	96/253 (37,9)	50/245 (20,4)	1,86 [1,39; 2,49] <,0001[2]	2,38 [1,60; 3,56] <,0001[3]	17,5 [9,7; 25,4] <,0001[3]
Tumor grade (Interaction p-value: 0,3465)					
G1	28/63 (44,4)	9/52 (17,3)	2,57 [1,33; 4,94] 0,0048[2]	3,82 [1,60; 9,16] 0,0019[3]	27,1 [11,1; 43,1] 0,0019[3]
G2	146/349 (41,8)	61/323 (18,9)	2,22 [1,71; 2,87] <,0001[2]	3,09 [2,18; 4,39] <,0001[3]	22,9 [16,2; 29,7] <,0001[3]
G3	115/317 (36,3)	67/312 (21,5)	1,69 [1,31; 2,19] <,0001[2]	2,08 [1,46; 2,97] <,0001[3]	14,8 [7,8; 21,8] <,0001[3]
GX	13/44 (29,5)	8/40 (20,0)	1,48 [0,68; 3,19] 0,3204[2]	1,68 [0,61; 4,60] 0,3130[3]	9,5 [-8,8; 27,9] 0,3130[3]
Progesterone receptor status (Interaction p-value: 0,6519)					
Negative	23/67 (34,3)	9/62 (14,5)	2,36 [1,19; 4,71] 0,0143[2]	3,08 [1,29; 7,33] 0,0092[3]	19,8 [5,5; 34,2] 0,0092[3]
Positive	269/678 (39,7)	134/647 (20,7)	1,92 [1,60; 2,29] <,0001[2]	2,52 [1,97; 3,22] <,0001[3]	19,0 [14,1; 23,8] <,0001[3]
Unknown	4/8 (50,0)	1/8 (12,5)	4,00 [0,56; 28,40] 0,1657[2]	7,00 [0,57; 86,32] 0,2821[4]	37,5 [-4,0; 79,0] 0,2821[4]
Race (Interaction p-value: 0,5605)					
White	163/461 (35,4)	81/440 (18,4)	1,92 [1,52; 2,42] <,0001[2]	2,42 [1,78; 3,30] <,0001[3]	16,9 [11,3; 22,6] <,0001[3]
Asian	119/273 (43,6)	55/243 (22,6)	1,93 [1,47; 2,52] <,0001[2]	2,64 [1,80; 3,88] <,0001[3]	21,0 [13,1; 28,8] <,0001[3]
Other	14/30 (46,7)	5/34 (14,7)	3,17 [1,30; 7,77] 0,0115[2]	5,08 [1,54; 16,68] 0,0052[3]	32,0 [10,5; 53,4] 0,0052[3]
First endocrine therapy (Interaction p-value: 0,8086)					
Tamoxifen	222/553 (40,1)	107/534 (20,0)	2,00 [1,64; 2,44] <,0001[2]	2,68 [2,04; 3,51] <,0001[3]	20,1 [14,8; 25,4] <,0001[3]
Aromatase inhibitor	83/223 (37,2)	38/195 (19,5)	1,91 [1,37; 2,66] 0,0001[2]	2,45 [1,57; 3,83] <,0001[3]	17,7 [9,3; 26,2] <,0001[3]
ECOG-PS (Interaction p-value: 0,6325)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	274/685 (40,0)	133/649 (20,5)	1,95 [1,64; 2,33] <,0001[2]	2,59 [2,03; 3,30] <,0001[3]	19,5 [14,7; 24,3] <,0001[3]
ECOG-PS 1	31/91 (34,1)	12/80 (15,0)	2,27 [1,25; 4,12] 0,0069[2]	2,93 [1,38; 6,21] 0,0041[3]	19,1 [6,6; 31,6] 0,0041[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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31OCT2025 / 03:54

Table 281.1.2: Subgroups - serious adverse events according SOC Hepatobiliary disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,9497)					
Negative	1/67 (1,5)	0/62 (0,0)	2,78 [0,12; 66,98] 0,5289[2]	2,82 [0,11; 70,51] 1,0000[4]	1,5 [-1,4; 4,4] 1,0000[4]
Positive	9/678 (1,3)	1/647 (0,2)	8,59 [1,09; 67,60] 0,0411[2]	8,69 [1,10; 68,79] 0,0214[4]	1,2 [0,3; 2,1] 0,0214[4]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
31OCT2025 / 03:54

Table 282.1.2: Subgroups - adverse events with CTCAE Grade ≥ 3 according PT Alanine aminotransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,0565)					
Neoadjuvant chemotherapy	8/314 (2,5)	2/306 (0,7)	3,90 [0,83; 18,21] 0,0837[2]	3,97 [0,84; 18,87] 0,1068[4]	1,9 [-0,1; 3,9] 0,1068[4]
Adjuvant chemotherapy	13/452 (2,9)	1/416 (0,2)	11,96 [1,57; 91,06] 0,0165[2]	12,29 [1,60; 94,36] 0,0021[3]	2,6 [1,0; 4,2] 0,0021[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,9966)					
North America / Europe	4/347 (1,2)	0/309 (0,0)	8,02 [0,43; 148,31] 0,1620[2]	8,11 [0,43; 151,23] 0,1264[4]	1,2 [0,0; 2,3] 0,1264[4]
Asia	12/239 (5,0)	2/226 (0,9)	5,67 [1,28; 25,07] 0,0220[2]	5,92 [1,31; 26,76] 0,0091[3]	4,1 [1,1; 7,2] 0,0091[3]
Other	5/190 (2,6)	1/194 (0,5)	5,11 [0,60; 43,29] 0,1350[2]	5,22 [0,60; 45,07] 0,1187[4]	2,1 [-0,4; 4,6] 0,1187[4]
Primary tumor size (Interaction p-value: 0,9935)					
< 20 mm	6/204 (2,9)	1/189 (0,5)	5,56 [0,68; 45,75] 0,1107[2]	5,70 [0,68; 47,77] 0,1236[4]	2,4 [-0,1; 5,0] 0,1236[4]
≥ 20 but < 50 mm	10/360 (2,8)	2/346 (0,6)	4,81 [1,06; 21,78] 0,0417[2]	4,91 [1,07; 22,59] 0,0238[3]	2,2 [0,3; 4,1] 0,0238[3]
≥ 50 mm	4/194 (2,1)	0/185 (0,0)	8,58 [0,47; 158,35] 0,1483[2]	8,76 [0,47; 163,92] 0,1234[4]	2,1 [0,1; 4,1] 0,1234[4]
Number of positive lymph nodes (Interaction p-value: 0,6825)					
0-3	6/269 (2,2)	0/269 (0,0)	13,00 [0,74; 229,62] 0,0800[2]	13,30 [0,75; 237,20] 0,0304[4]	2,2 [0,5; 4,0] 0,0304[4]
4-9	9/353 (2,5)	1/326 (0,3)	8,31 [1,06; 65,24] 0,0440[2]	8,50 [1,07; 67,49] 0,0215[4]	2,2 [0,5; 4,0] 0,0215[4]
≥ 10	6/154 (3,9)	2/134 (1,5)	2,61 [0,54; 12,72] 0,2350[2]	2,68 [0,53; 13,49] 0,2918[4]	2,4 [-1,3; 6,1] 0,2918[4]
Tumor stage (Interaction p-value: 0,9960)					
IIA	3/79 (3,8)	0/77 (0,0)	6,83 [0,36; 129,97] 0,2014[2]	7,09 [0,36; 139,61] 0,2453[4]	3,8 [-0,4; 8,0] 0,2453[4]
IIB	1/73 (1,4)	0/93 (0,0)	3,81 [0,16; 92,20] 0,4105[2]	3,87 [0,16; 96,38] 0,4398[4]	1,4 [-1,3; 4,0] 0,4398[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	8/345 (2,3)	1/294 (0,3)	6,82 [0,86; 54,19] 0,0696[2]	6,96 [0,86; 55,94] 0,0431[4]	2,0 [0,3; 3,7] 0,0431[4]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	8/253 (3,2)	2/245 (0,8)	3,87 [0,83; 18,06] 0,0847[2]	3,97 [0,83; 18,87] 0,1063[4]	2,3 [-0,1; 4,8] 0,1063[4]
Tumor grade (Interaction p-value: 0,9988)					
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	5/349 (1,4)	2/323 (0,6)	2,31 [0,45; 11,84] 0,3140[2]	2,33 [0,45; 12,11] 0,4531[4]	0,8 [-0,7; 2,3] 0,4531[4]
G3	11/317 (3,5)	0/312 (0,0)	22,64 [1,34; 382,51] 0,0306[2]	23,45 [1,38; 399,69] 0,0009[3]	3,5 [1,5; 5,5] 0,0009[3]
GX	2/44 (4,5)	1/40 (2,5)	1,82 [0,17; 19,29] 0,6198[2]	1,86 [0,16; 21,30] 1,0000[4]	2,0 [-5,8; 9,9] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,3738)					
Negative	1/67 (1,5)	1/62 (1,6)	0,93 [0,06; 14,48] 0,9559[2]	0,92 [0,06; 15,10] 1,0000[4]	-0,1 [-4,4; 4,2] 1,0000[4]
Positive	18/678 (2,7)	2/647 (0,3)	8,59 [2,00; 36,87] 0,0038[2]	8,80 [2,03; 38,06] 0,0005[3]	2,3 [1,1; 3,6] 0,0005[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,5884)					
White	7/461 (1,5)	0/440 (0,0)	14,32 [0,82; 249,95] 0,0681[2]	14,54 [0,83; 255,31] 0,0154[4]	1,5 [0,4; 2,6] 0,0154[4]
Asian	13/273 (4,8)	2/243 (0,8)	5,79 [1,32; 25,38] 0,0200[2]	6,03 [1,35; 26,97] 0,0079[3]	3,9 [1,2; 6,7] 0,0079[3]
Other	1/30 (3,3)	1/34 (2,9)	1,13 [0,07; 17,34] 0,9283[2]	1,14 [0,07; 19,02] 1,0000[4]	0,4 [-8,2; 9,0] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,4932)					
Tamoxifen	11/553 (2,0)	1/534 (0,2)	10,62 [1,38; 81,99] 0,0234[2]	10,82 [1,39; 84,08] 0,0045[3]	1,8 [0,6; 3,0] 0,0045[3]
Aromatase inhibitor	10/223 (4,5)	2/195 (1,0)	4,37 [0,97; 19,71] 0,0549[2]	4,53 [0,98; 20,94] 0,0346[3]	3,5 [0,4; 6,5] 0,0346[3]
ECOG-PS (Interaction p-value: 0,2515)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	19/685 (2,8)	2/649 (0,3)	9,00 [2,10; 38,49] 0,0030[2]	9,23 [2,14; 39,78] 0,0003[3]	2,5 [1,2; 3,8] 0,0003[3]
ECOG-PS 1	2/91 (2,2)	1/80 (1,3)	1,76 [0,16; 19,03] 0,6424[2]	1,78 [0,16; 19,95] 1,0000[4]	0,9 [-2,9; 4,8] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 283.1.2: Subgroups - adverse events with CTCAE Grade ≥ 3 according PT Aspartate aminotransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,9742)					
North America / Europe	2/347 (0,6)	0/309 (0,0)	4,45 [0,21; 92,42] 0,3343[2]	4,48 [0,21; 93,66] 0,5009[4]	0,6 [-0,2; 1,4] 0,5009[4]
Asia	9/239 (3,8)	2/226 (0,9)	4,26 [0,93; 19,48] 0,0621[2]	4,38 [0,94; 20,51] 0,0411[3]	2,9 [0,2; 5,6] 0,0411[3]
Other	5/190 (2,6)	0/194 (0,0)	11,23 [0,63; 201,70] 0,1007[2]	11,53 [0,63; 210,04] 0,0289[4]	2,6 [0,4; 4,9] 0,0289[4]
Primary tumor size (Interaction p-value: 0,9999)					
< 20 mm	3/204 (1,5)	0/189 (0,0)	6,49 [0,34; 124,78] 0,2151[2]	6,58 [0,34; 128,29] 0,2492[4]	1,5 [-0,2; 3,1] 0,2492[4]
≥ 20 but < 50 mm	9/360 (2,5)	2/346 (0,6)	4,33 [0,94; 19,88] 0,0598[2]	4,41 [0,95; 20,56] 0,0393[3]	1,9 [0,1; 3,7] 0,0393[3]
≥ 50 mm	3/194 (1,5)	0/185 (0,0)	6,68 [0,35; 128,38] 0,2081[2]	6,78 [0,35; 132,18] 0,2484[4]	1,5 [-0,2; 3,3] 0,2484[4]
Number of positive lymph nodes (Interaction p-value: 0,7580)					
0-3	4/269 (1,5)	0/269 (0,0)	9,00 [0,49; 166,35] 0,1398[2]	9,14 [0,49; 170,52] 0,1236[4]	1,5 [0,0; 2,9] 0,1236[4]
4-9	9/353 (2,5)	1/326 (0,3)	8,31 [1,06; 65,24] 0,0440[2]	8,50 [1,07; 67,49] 0,0215[4]	2,2 [0,5; 4,0] 0,0215[4]
≥ 10	3/154 (1,9)	1/134 (0,7)	2,61 [0,27; 24,80] 0,4035[2]	2,64 [0,27; 25,71] 0,6260[4]	1,2 [-1,4; 3,8] 0,6260[4]
Progesterone receptor status (Interaction p-value: 0,9533)					
Negative	2/67 (3,0)	0/62 (0,0)	4,63 [0,23; 94,63] 0,3193[2]	4,77 [0,22; 101,36] 0,4969[4]	3,0 [-1,1; 7,1] 0,4969[4]
Positive	13/678 (1,9)	2/647 (0,3)	6,20 [1,41; 27,38] 0,0160[2]	6,30 [1,42; 28,05] 0,0057[3]	1,6 [0,5; 2,7] 0,0057[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9996)					
White	4/461 (0,9)	0/440 (0,0)	8,59 [0,46; 159,10] 0,1487[2]	8,67 [0,47; 161,42] 0,1246[4]	0,9 [0,0; 1,7] 0,1246[4]
Asian	10/273 (3,7)	2/243 (0,8)	4,45 [0,98; 20,11] 0,0524[2]	4,58 [0,99; 21,12] 0,0326[3]	2,8 [0,3; 5,3] 0,0326[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Other	2/30 (6,7)	0/34 (0,0)	5,65 [0,28; 113,12] 0,2578[2]	6,05 [0,28; 131,25] 0,2158[4]	6,7 [-2,3; 15,6] 0,2158[4]
First endocrine therapy (Interaction p-value: 0,6845)					
Tamoxifen	10/553 (1,8)	1/534 (0,2)	9,66 [1,24; 75,17] 0,0303[2]	9,82 [1,25; 76,95] 0,0076[3]	1,6 [0,5; 2,8] 0,0076[3]
Aromatase inhibitor	6/223 (2,7)	1/195 (0,5)	5,25 [0,64; 43,20] 0,1233[2]	5,36 [0,64; 44,95] 0,1278[4]	2,2 [-0,2; 4,5] 0,1278[4]
ECOG-PS (Interaction p-value: 0,1107)					
ECOG-PS 0	15/685 (2,2)	1/649 (0,2)	14,21 [1,88; 107,28] 0,0101[2]	14,51 [1,91; 110,14] 0,0006[3]	2,0 [0,9; 3,2] 0,0006[3]
ECOG-PS 1	1/91 (1,1)	1/80 (1,3)	0,88 [0,06; 13,83] 0,9270[2]	0,88 [0,05; 14,27] 1,0000[4]	-0,2 [-3,4; 3,1] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 284.1.2: Subgroups - adverse events with CTCAE Grade ≥ 3 according PT Diarrhoea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9028)					
Neoadjuvant chemotherapy	20/314 (6,4)	1/306 (0,3)	19,49 [2,63; 144,33] 0,0036[2]	20,75 [2,77; 155,59] <,0001[3]	6,0 [3,3; 8,8] <,0001[3]
Adjuvant chemotherapy	24/452 (5,3)	2/416 (0,5)	11,04 [2,63; 46,44] 0,0010[2]	11,61 [2,73; 49,43] <,0001[3]	4,8 [2,7; 7,0] <,0001[3]
No chemotherapy	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Region (Interaction p-value: 0,8410)					
North America / Europe	24/347 (6,9)	1/309 (0,3)	21,37 [2,91; 157,05] 0,0026[2]	22,89 [3,08; 170,20] <,0001[3]	6,6 [3,8; 9,3] <,0001[3]
Asia	13/239 (5,4)	1/226 (0,4)	12,29 [1,62; 93,21] 0,0152[2]	12,94 [1,68; 99,77] 0,0016[3]	5,0 [2,0; 8,0] 0,0016[3]
Other	9/190 (4,7)	1/194 (0,5)	9,19 [1,18; 71,83] 0,0345[2]	9,60 [1,20; 76,50] 0,0101[4]	4,2 [1,0; 7,4] 0,0101[4]
Primary tumor size (Interaction p-value: 0,9261)					
< 20 mm	15/204 (7,4)	2/189 (1,1)	6,95 [1,61; 29,98] 0,0094[2]	7,42 [1,67; 32,90] 0,0022[3]	6,3 [2,4; 10,2] 0,0022[3]
≥ 20 but < 50 mm	17/360 (4,7)	0/346 (0,0)	33,64 [2,03; 557,27] 0,0141[2]	35,31 [2,11; 589,41] <,0001[3]	4,7 [2,5; 6,9] <,0001[3]
≥ 50 mm	12/194 (6,2)	1/185 (0,5)	11,44 [1,50; 87,13] 0,0186[2]	12,13 [1,56; 94,26] 0,0025[3]	5,6 [2,1; 9,2] 0,0025[3]
Number of positive lymph nodes (Interaction p-value: 0,7486)					
0-3	16/269 (5,9)	1/269 (0,4)	16,00 [2,14; 119,80] 0,0069[2]	16,95 [2,23; 128,74] 0,0002[3]	5,6 [2,7; 8,5] 0,0002[3]
4-9	16/353 (4,5)	0/326 (0,0)	30,48 [1,84; 506,05] 0,0171[2]	31,92 [1,91; 534,31] 0,0001[3]	4,5 [2,4; 6,7] 0,0001[3]
≥ 10	14/154 (9,1)	2/134 (1,5)	6,09 [1,41; 26,32] 0,0155[2]	6,60 [1,47; 29,60] 0,0050[3]	7,6 [2,6; 12,6] 0,0050[3]
Tumor stage (Interaction p-value: 0,9947)					
IIA	7/79 (8,9)	1/77 (1,3)	6,82 [0,86; 54,16] 0,0693[2]	7,39 [0,89; 61,55] 0,0635[4]	7,6 [0,8; 14,3] 0,0635[4]
IIB	2/73 (2,7)	0/93 (0,0)	6,35 [0,31; 130,28] 0,2304[2]	6,54 [0,31; 138,33] 0,1919[4]	2,7 [-1,0; 6,5] 0,1919[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	15/345 (4,3)	0/294 (0,0)	26,43 [1,59; 439,83] 0,0225[2]	27,62 [1,65; 463,68] 0,0003[3]	4,3 [2,2; 6,5] 0,0003[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	20/253 (7,9)	2/245 (0,8)	9,68 [2,29; 40,99] 0,0020[2]	10,43 [2,41; 45,12] 0,0001[3]	7,1 [3,6; 10,6] 0,0001[3]
Tumor grade (Interaction p-value: 0,9385)					
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	20/349 (5,7)	2/323 (0,6)	9,26 [2,18; 39,28] 0,0026[2]	9,76 [2,26; 42,08] 0,0002[3]	5,1 [2,5; 7,7] 0,0002[3]
G3	21/317 (6,6)	1/312 (0,3)	20,67 [2,80; 152,72] 0,0030[2]	22,06 [2,95; 165,07] <,0001[3]	6,3 [3,5; 9,1] <,0001[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,9981)					
Negative	4/67 (6,0)	0/62 (0,0)	8,34 [0,46; 151,78] 0,1520[2]	8,86 [0,47; 167,99] 0,1203[4]	6,0 [0,3; 11,6] 0,1203[4]
Positive	40/678 (5,9)	2/647 (0,3)	19,09 [4,63; 78,65] <,0001[2]	20,22 [4,87; 84,01] <,0001[3]	5,6 [3,8; 7,4] <,0001[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,1705)					
White	30/461 (6,5)	1/440 (0,2)	28,63 [3,92; 209,07] 0,0009[2]	30,56 [4,15; 225,06] <,0001[3]	6,3 [4,0; 8,6] <,0001[3]
Asian	13/273 (4,8)	1/243 (0,4)	11,57 [1,52; 87,81] 0,0179[2]	12,10 [1,57; 93,19] 0,0024[3]	4,4 [1,7; 7,0] 0,0024[3]
Other	1/30 (3,3)	1/34 (2,9)	1,13 [0,07; 17,34] 0,9283[2]	1,14 [0,07; 19,02] 1,0000[4]	0,4 [-8,2; 9,0] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,9780)					
Tamoxifen	30/553 (5,4)	2/534 (0,4)	14,48 [3,48; 60,31] 0,0002[2]	15,26 [3,63; 64,17] <,0001[3]	5,1 [3,1; 7,0] <,0001[3]
Aromatase inhibitor	16/223 (7,2)	1/195 (0,5)	13,99 [1,87; 104,54] 0,0101[2]	15,00 [1,97; 114,15] 0,0006[3]	6,7 [3,1; 10,2] 0,0006[3]
ECOG-PS (Interaction p-value: 0,9807)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	45/685 (6,6)	3/649 (0,5)	14,21 [4,44; 45,50] <,0001[2]	15,14 [4,68; 48,97] <,0001[3]	6,1 [4,2; 8,0] <,0001[3]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 288.1.2: Subgroups - adverse events with CTCAE Grade ≥ 3 according PT Lymphocyte count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1799)					
Neoadjuvant chemotherapy	16/314 (5,1)	0/306 (0,0)	32,16 [1,94; 533,72] 0,0155[2]	33,88 [2,02; 567,34] <,0001[3]	5,1 [2,7; 7,5] <,0001[3]
Adjuvant chemotherapy	17/452 (3,8)	1/416 (0,2)	15,65 [2,09; 117,05] 0,0074[2]	16,22 [2,15; 122,41] 0,0003[3]	3,5 [1,7; 5,3] 0,0003[3]
No chemotherapy	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Region (Interaction p-value: 0,6084)					
North America / Europe	16/347 (4,6)	1/309 (0,3)	14,25 [1,90; 106,81] 0,0097[2]	14,89 [1,96; 112,93] 0,0006[3]	4,3 [2,0; 6,6] 0,0006[3]
Asia	15/239 (6,3)	0/226 (0,0)	29,32 [1,76; 487,17] 0,0185[2]	31,28 [1,86; 525,87] 0,0001[3]	6,3 [3,2; 9,4] 0,0001[3]
Other	3/190 (1,6)	1/194 (0,5)	3,06 [0,32; 29,19] 0,3304[2]	3,10 [0,32; 30,03] 0,3679[4]	1,1 [-1,0; 3,1] 0,3679[4]
Primary tumor size (Interaction p-value: 0,9979)					
< 20 mm	9/204 (4,4)	1/189 (0,5)	8,34 [1,07; 65,19] 0,0432[2]	8,68 [1,09; 69,15] 0,0208[4]	3,9 [0,9; 6,9] 0,0208[4]
≥ 20 but < 50 mm	16/360 (4,4)	0/346 (0,0)	31,72 [1,91; 526,68] 0,0159[2]	33,19 [1,98; 555,43] <,0001[3]	4,4 [2,3; 6,6] <,0001[3]
≥ 50 mm	8/194 (4,1)	1/185 (0,5)	7,63 [0,96; 60,40] 0,0543[2]	7,91 [0,98; 63,91] 0,0373[4]	3,6 [0,6; 6,6] 0,0373[4]
Number of positive lymph nodes (Interaction p-value: 0,9992)					
0-3	14/269 (5,2)	0/269 (0,0)	29,00 [1,74; 483,69] 0,0190[2]	30,59 [1,82; 515,44] 0,0001[3]	5,2 [2,6; 7,9] 0,0001[3]
4-9	17/353 (4,8)	0/326 (0,0)	32,33 [1,95; 535,45] 0,0152[2]	33,96 [2,03; 567,04] <,0001[3]	4,8 [2,6; 7,0] <,0001[3]
≥ 10	3/154 (1,9)	2/134 (1,5)	1,31 [0,22; 7,69] 0,7686[2]	1,31 [0,22; 7,97] 1,0000[4]	0,5 [-2,5; 3,5] 1,0000[4]
Tumor stage (Interaction p-value: 1,0000)					
IIA	6/79 (7,6)	0/77 (0,0)	12,68 [0,73; 221,21] 0,0817[2]	13,71 [0,76; 247,65] 0,0284[4]	7,6 [1,8; 13,4] 0,0284[4]
IIB	5/73 (6,8)	0/93 (0,0)	13,97 [0,79; 248,67] 0,0726[2]	15,01 [0,82; 276,11] 0,0152[4]	6,8 [1,1; 12,6] 0,0152[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	18/345 (5,2)	0/294 (0,0)	31,55 [1,91; 521,22] 0,0159[2]	33,27 [2,00; 554,53] <,0001[3]	5,2 [2,9; 7,6] <,0001[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	3/253 (1,2)	2/245 (0,8)	1,45 [0,24; 8,62] 0,6811[2]	1,46 [0,24; 8,80] 1,0000[4]	0,4 [-1,4; 2,1] 1,0000[4]
Tumor grade (Interaction p-value: 0,5067)					
G1	3/63 (4,8)	1/52 (1,9)	2,48 [0,27; 23,10] 0,4262[2]	2,55 [0,26; 25,28] 0,6254[4]	2,8 [-3,6; 9,3] 0,6254[4]
G2	16/349 (4,6)	1/323 (0,3)	14,81 [1,97; 111,03] 0,0087[2]	15,47 [2,04; 117,34] 0,0004[3]	4,3 [2,0; 6,6] 0,0004[3]
G3	10/317 (3,2)	0/312 (0,0)	20,67 [1,22; 351,22] 0,0361[2]	21,34 [1,25; 365,79] 0,0018[4]	3,2 [1,2; 5,1] 0,0018[4]
GX	5/44 (11,4)	0/40 (0,0)	10,02 [0,57; 175,70] 0,1147[2]	11,28 [0,60; 210,81] 0,0565[4]	11,4 [2,0; 20,7] 0,0565[4]
Progesterone receptor status (Interaction p-value: 0,0510)					
Negative	2/67 (3,0)	1/62 (1,6)	1,85 [0,17; 19,91] 0,6115[2]	1,88 [0,17; 21,23] 1,0000[4]	1,4 [-3,8; 6,5] 1,0000[4]
Positive	29/678 (4,3)	1/647 (0,2)	27,67 [3,78; 202,56] 0,0011[2]	28,87 [3,92; 212,53] <,0001[3]	4,1 [2,6; 5,7] <,0001[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9993)					
White	19/461 (4,1)	1/440 (0,2)	18,13 [2,44; 134,89] 0,0046[2]	18,87 [2,52; 141,58] <,0001[3]	3,9 [2,0; 5,8] <,0001[3]
Asian	15/273 (5,5)	0/243 (0,0)	27,61 [1,66; 458,93] 0,0207[2]	29,20 [1,74; 490,68] 0,0002[3]	5,5 [2,8; 8,2] 0,0002[3]
Other	0/30 (0,0)	1/34 (2,9)	0,38 [0,02; 8,91] 0,5449[2]	0,37 [0,01; 9,33] 1,0000[4]	-2,9 [-8,6; 2,7] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,9724)					
Tamoxifen	24/553 (4,3)	0/534 (0,0)	47,32 [2,88; 776,15] 0,0069[2]	49,46 [3,00; 815,45] <,0001[3]	4,3 [2,6; 6,0] <,0001[3]
Aromatase inhibitor	10/223 (4,5)	2/195 (1,0)	4,37 [0,97; 19,71] 0,0549[2]	4,53 [0,98; 20,94] 0,0346[3]	3,5 [0,4; 6,5] 0,0346[3]
ECOG-PS (Interaction p-value: 0,9784)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	31/685 (4,5)	2/649 (0,3)	14,69 [3,53; 61,11] 0,0002[2]	15,33 [3,65; 64,34] <,0001[3]	4,2 [2,6; 5,8] <,0001[3]
ECOG-PS 1	3/91 (3,3)	0/80 (0,0)	6,16 [0,32; 117,53] 0,2267[2]	6,37 [0,32; 125,17] 0,2487[4]	3,3 [-0,4; 7,0] 0,2487[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 288.1.2: Subgroups - adverse events with CTCAE Grade ≥ 3 according PT Lymphocyte count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1799)					
Neoadjuvant chemotherapy	16/314 (5,1)	0/306 (0,0)	32,16 [1,94; 533,72] 0,0155[2]	33,88 [2,02; 567,34] <,0001[3]	5,1 [2,7; 7,5] <,0001[3]
Adjuvant chemotherapy	17/452 (3,8)	1/416 (0,2)	15,65 [2,09; 117,05] 0,0074[2]	16,22 [2,15; 122,41] 0,0003[3]	3,5 [1,7; 5,3] 0,0003[3]
No chemotherapy	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Region (Interaction p-value: 0,6084)					
North America / Europe	16/347 (4,6)	1/309 (0,3)	14,25 [1,90; 106,81] 0,0097[2]	14,89 [1,96; 112,93] 0,0006[3]	4,3 [2,0; 6,6] 0,0006[3]
Asia	15/239 (6,3)	0/226 (0,0)	29,32 [1,76; 487,17] 0,0185[2]	31,28 [1,86; 525,87] 0,0001[3]	6,3 [3,2; 9,4] 0,0001[3]
Other	3/190 (1,6)	1/194 (0,5)	3,06 [0,32; 29,19] 0,3304[2]	3,10 [0,32; 30,03] 0,3679[4]	1,1 [-1,0; 3,1] 0,3679[4]
Primary tumor size (Interaction p-value: 0,9979)					
< 20 mm	9/204 (4,4)	1/189 (0,5)	8,34 [1,07; 65,19] 0,0432[2]	8,68 [1,09; 69,15] 0,0208[4]	3,9 [0,9; 6,9] 0,0208[4]
≥ 20 but < 50 mm	16/360 (4,4)	0/346 (0,0)	31,72 [1,91; 526,68] 0,0159[2]	33,19 [1,98; 555,43] <,0001[3]	4,4 [2,3; 6,6] <,0001[3]
≥ 50 mm	8/194 (4,1)	1/185 (0,5)	7,63 [0,96; 60,40] 0,0543[2]	7,91 [0,98; 63,91] 0,0373[4]	3,6 [0,6; 6,6] 0,0373[4]
Number of positive lymph nodes (Interaction p-value: 0,9992)					
0-3	14/269 (5,2)	0/269 (0,0)	29,00 [1,74; 483,69] 0,0190[2]	30,59 [1,82; 515,44] 0,0001[3]	5,2 [2,6; 7,9] 0,0001[3]
4-9	17/353 (4,8)	0/326 (0,0)	32,33 [1,95; 535,45] 0,0152[2]	33,96 [2,03; 567,04] <,0001[3]	4,8 [2,6; 7,0] <,0001[3]
≥ 10	3/154 (1,9)	2/134 (1,5)	1,31 [0,22; 7,69] 0,7686[2]	1,31 [0,22; 7,97] 1,0000[4]	0,5 [-2,5; 3,5] 1,0000[4]
Tumor stage (Interaction p-value: 1,0000)					
IIA	6/79 (7,6)	0/77 (0,0)	12,68 [0,73; 221,21] 0,0817[2]	13,71 [0,76; 247,65] 0,0284[4]	7,6 [1,8; 13,4] 0,0284[4]
IIB	5/73 (6,8)	0/93 (0,0)	13,97 [0,79; 248,67] 0,0726[2]	15,01 [0,82; 276,11] 0,0152[4]	6,8 [1,1; 12,6] 0,0152[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	18/345 (5,2)	0/294 (0,0)	31,55 [1,91; 521,22] 0,0159[2]	33,27 [2,00; 554,53] <,0001[3]	5,2 [2,9; 7,6] <,0001[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	3/253 (1,2)	2/245 (0,8)	1,45 [0,24; 8,62] 0,6811[2]	1,46 [0,24; 8,80] 1,0000[4]	0,4 [-1,4; 2,1] 1,0000[4]
Tumor grade (Interaction p-value: 0,5067)					
G1	3/63 (4,8)	1/52 (1,9)	2,48 [0,27; 23,10] 0,4262[2]	2,55 [0,26; 25,28] 0,6254[4]	2,8 [-3,6; 9,3] 0,6254[4]
G2	16/349 (4,6)	1/323 (0,3)	14,81 [1,97; 111,03] 0,0087[2]	15,47 [2,04; 117,34] 0,0004[3]	4,3 [2,0; 6,6] 0,0004[3]
G3	10/317 (3,2)	0/312 (0,0)	20,67 [1,22; 351,22] 0,0361[2]	21,34 [1,25; 365,79] 0,0018[4]	3,2 [1,2; 5,1] 0,0018[4]
GX	5/44 (11,4)	0/40 (0,0)	10,02 [0,57; 175,70] 0,1147[2]	11,28 [0,60; 210,81] 0,0565[4]	11,4 [2,0; 20,7] 0,0565[4]
Progesterone receptor status (Interaction p-value: 0,0510)					
Negative	2/67 (3,0)	1/62 (1,6)	1,85 [0,17; 19,91] 0,6115[2]	1,88 [0,17; 21,23] 1,0000[4]	1,4 [-3,8; 6,5] 1,0000[4]
Positive	29/678 (4,3)	1/647 (0,2)	27,67 [3,78; 202,56] 0,0011[2]	28,87 [3,92; 212,53] <,0001[3]	4,1 [2,6; 5,7] <,0001[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9993)					
White	19/461 (4,1)	1/440 (0,2)	18,13 [2,44; 134,89] 0,0046[2]	18,87 [2,52; 141,58] <,0001[3]	3,9 [2,0; 5,8] <,0001[3]
Asian	15/273 (5,5)	0/243 (0,0)	27,61 [1,66; 458,93] 0,0207[2]	29,20 [1,74; 490,68] 0,0002[3]	5,5 [2,8; 8,2] 0,0002[3]
Other	0/30 (0,0)	1/34 (2,9)	0,38 [0,02; 8,91] 0,5449[2]	0,37 [0,01; 9,33] 1,0000[4]	-2,9 [-8,6; 2,7] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,9724)					
Tamoxifen	24/553 (4,3)	0/534 (0,0)	47,32 [2,88; 776,15] 0,0069[2]	49,46 [3,00; 815,45] <,0001[3]	4,3 [2,6; 6,0] <,0001[3]
Aromatase inhibitor	10/223 (4,5)	2/195 (1,0)	4,37 [0,97; 19,71] 0,0549[2]	4,53 [0,98; 20,94] 0,0346[3]	3,5 [0,4; 6,5] 0,0346[3]
ECOG-PS (Interaction p-value: 0,9784)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	31/685 (4,5)	2/649 (0,3)	14,69 [3,53; 61,11] 0,0002[2]	15,33 [3,65; 64,34] <,0001[3]	4,2 [2,6; 5,8] <,0001[3]
ECOG-PS 1	3/91 (3,3)	0/80 (0,0)	6,16 [0,32; 117,53] 0,2267[2]	6,37 [0,32; 125,17] 0,2487[4]	3,3 [-0,4; 7,0] 0,2487[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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31OCT2025 / 03:54

Table 289.1.2: Subgroups - adverse events with CTCAE Grade ≥ 3 according PT Lymphopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,9562)					
Negative	1/67 (1,5)	0/62 (0,0)	2,78 [0,12; 66,98] 0,5289[2]	2,82 [0,11; 70,51] 1,0000[4]	1,5 [-1,4; 4,4] 1,0000[4]
Positive	11/678 (1,6)	3/647 (0,5)	3,50 [0,98; 12,49] 0,0536[2]	3,54 [0,98; 12,75] 0,0392[3]	1,2 [0,1; 2,2] 0,0392[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9994)					
White	9/461 (2,0)	2/440 (0,5)	4,30 [0,93; 19,77] 0,0613[2]	4,36 [0,94; 20,30] 0,0407[3]	1,5 [0,1; 2,9] 0,0407[3]
Asian	2/273 (0,7)	0/243 (0,0)	4,45 [0,21; 92,29] 0,3342[2]	4,48 [0,21; 93,87] 0,5007[4]	0,7 [-0,3; 1,7] 0,5007[4]
Other	1/30 (3,3)	0/34 (0,0)	3,39 [0,14; 80,15] 0,4498[2]	3,51 [0,14; 89,42] 0,4688[4]	3,3 [-3,1; 9,8] 0,4688[4]
ECOG-PS (Interaction p-value: 0,9777)					
ECOG-PS 0	11/685 (1,6)	3/649 (0,5)	3,47 [0,97; 12,40] 0,0550[2]	3,51 [0,98; 12,65] 0,0405[3]	1,1 [0,1; 2,2] 0,0405[3]
ECOG-PS 1	1/91 (1,1)	0/80 (0,0)	2,64 [0,11; 63,94] 0,5502[2]	2,67 [0,11; 66,43] 1,0000[4]	1,1 [-1,0; 3,2] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 290.1.2: Subgroups - adverse events with CTCAE Grade ≥ 3 according PT Neutropenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,6027)					
North America / Europe	26/347 (7,5)	2/309 (0,6)	11,58 [2,77; 48,38] 0,0008[2]	12,43 [2,93; 52,83] <,0001[3]	6,8 [3,9; 9,8] <,0001[3]
Asia	13/239 (5,4)	2/226 (0,9)	6,15 [1,40; 26,93] 0,0160[2]	6,44 [1,44; 28,88] 0,0055[3]	4,6 [1,4; 7,7] 0,0055[3]
Other	21/190 (11,1)	1/194 (0,5)	21,44 [2,91; 157,82] 0,0026[2]	23,98 [3,19; 180,19] <,0001[3]	10,5 [6,0; 15,1] <,0001[3]
Primary tumor size (Interaction p-value: 0,4467)					
< 20 mm	15/204 (7,4)	4/189 (2,1)	3,47 [1,17; 10,28] 0,0245[2]	3,67 [1,20; 11,27] 0,0156[3]	5,2 [1,1; 9,4] 0,0156[3]
≥ 20 but < 50 mm	29/360 (8,1)	0/346 (0,0)	56,71 [3,48; 924,54] 0,0046[2]	61,67 [3,75; 1013,38] <,0001[3]	8,1 [5,2; 10,9] <,0001[3]
≥ 50 mm	16/194 (8,2)	1/185 (0,5)	15,26 [2,04; 113,90] 0,0079[2]	16,54 [2,17; 126,03] 0,0003[3]	7,7 [3,7; 11,7] 0,0003[3]
Number of positive lymph nodes (Interaction p-value: 0,5722)					
0-3	23/269 (8,6)	1/269 (0,4)	23,00 [3,13; 169,10] 0,0021[2]	25,06 [3,36; 186,93] <,0001[3]	8,2 [4,8; 11,6] <,0001[3]
4-9	23/353 (6,5)	2/326 (0,6)	10,62 [2,52; 44,69] 0,0013[2]	11,29 [2,64; 48,28] <,0001[3]	5,9 [3,2; 8,6] <,0001[3]
≥ 10	14/154 (9,1)	2/134 (1,5)	6,09 [1,41; 26,32] 0,0155[2]	6,60 [1,47; 29,60] 0,0050[3]	7,6 [2,6; 12,6] 0,0050[3]
Tumor stage (Interaction p-value: 0,9907)					
IIA	7/79 (8,9)	1/77 (1,3)	6,82 [0,86; 54,16] 0,0693[2]	7,39 [0,89; 61,55] 0,0635[4]	7,6 [0,8; 14,3] 0,0635[4]
IIB	6/73 (8,2)	0/93 (0,0)	16,51 [0,95; 288,43] 0,0547[2]	18,01 [1,00; 325,12] 0,0064[4]	8,2 [1,9; 14,5] 0,0064[4]
IIIA	17/345 (4,9)	1/294 (0,3)	14,49 [1,94; 108,20] 0,0092[2]	15,19 [2,01; 114,81] 0,0005[3]	4,6 [2,2; 7,0] 0,0005[3]
IIIB	3/22 (13,6)	0/19 (0,0)	6,09 [0,33; 110,84] 0,2225[2]	7,00 [0,34; 144,73] 0,2354[4]	13,6 [-0,7; 28,0] 0,2354[4]
IIIC	27/253 (10,7)	3/245 (1,2)	8,72 [2,68; 28,36] 0,0003[2]	9,64 [2,88; 32,21] <,0001[3]	9,4 [5,4; 13,5] <,0001[3]
Tumor grade (Interaction p-value: 0,7321)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	4/63 (6,3)	0/52 (0,0)	7,45 [0,41; 135,32] 0,1745[2]	7,94 [0,42; 151,00] 0,1253[4]	6,3 [0,3; 12,4] 0,1253[4]
G2	29/349 (8,3)	4/323 (1,2)	6,71 [2,39; 18,88] 0,0003[2]	7,23 [2,51; 20,79] <,0001[3]	7,1 [3,9; 10,2] <,0001[3]
G3	25/317 (7,9)	1/312 (0,3)	24,61 [3,35; 180,48] 0,0016[2]	26,63 [3,59; 197,76] <,0001[3]	7,6 [4,5; 10,6] <,0001[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,9996)					
Negative	6/67 (9,0)	0/62 (0,0)	12,04 [0,69; 209,46] 0,0877[2]	13,21 [0,73; 239,60] 0,0284[4]	9,0 [2,1; 15,8] 0,0284[4]
Positive	53/678 (7,8)	5/647 (0,8)	10,12 [4,07; 25,14] <,0001[2]	10,89 [4,32; 27,42] <,0001[3]	7,0 [4,9; 9,2] <,0001[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,3304)					
White	42/461 (9,1)	2/440 (0,5)	20,04 [4,88; 82,30] <,0001[2]	21,95 [5,28; 91,26] <,0001[3]	8,7 [6,0; 11,4] <,0001[3]
Asian	14/273 (5,1)	2/243 (0,8)	6,23 [1,43; 27,14] 0,0148[2]	6,51 [1,47; 28,96] 0,0049[3]	4,3 [1,5; 7,2] 0,0049[3]
Other	3/30 (10,0)	1/34 (2,9)	3,40 [0,37; 30,97] 0,2776[2]	3,67 [0,36; 37,30] 0,3334[4]	7,1 [-5,1; 19,2] 0,3334[4]
First endocrine therapy (Interaction p-value: 0,9746)					
Tamoxifen	42/553 (7,6)	5/534 (0,9)	8,11 [3,23; 20,35] <,0001[2]	8,70 [3,41; 22,15] <,0001[3]	6,7 [4,3; 9,0] <,0001[3]
Aromatase inhibitor	18/223 (8,1)	0/195 (0,0)	32,38 [1,96; 533,71] 0,0150[2]	35,20 [2,11; 588,08] <,0001[3]	8,1 [4,5; 11,6] <,0001[3]
ECOG-PS (Interaction p-value: 0,0855)					
ECOG-PS 0	53/685 (7,7)	3/649 (0,5)	16,74 [5,26; 53,30] <,0001[2]	18,06 [5,61; 58,09] <,0001[3]	7,3 [5,2; 9,3] <,0001[3]
ECOG-PS 1	7/91 (7,7)	2/80 (2,5)	3,08 [0,66; 14,39] 0,1533[2]	3,25 [0,66; 16,12] 0,1763[4]	5,2 [-1,3; 11,6] 0,1763[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 291.1.2: Subgroups - adverse events with CTCAE Grade ≥ 3 according PT Neutrophil count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,4579)					
Neoadjuvant chemotherapy	33/314 (10,5)	4/306 (1,3)	8,04 [2,88; 22,42] <,0001[2]	8,87 [3,10; 25,35] <,0001[3]	9,2 [5,6; 12,8] <,0001[3]
Adjuvant chemotherapy	53/452 (11,7)	2/416 (0,5)	24,39 [5,98; 99,45] <,0001[2]	27,50 [6,66; 113,58] <,0001[3]	11,2 [8,2; 14,3] <,0001[3]
No chemotherapy	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Region (Interaction p-value: 0,6983)					
North America / Europe	26/347 (7,5)	3/309 (1,0)	7,72 [2,36; 25,25] 0,0007[2]	8,26 [2,48; 27,58] <,0001[3]	6,5 [3,5; 9,5] <,0001[3]
Asia	50/239 (20,9)	3/226 (1,3)	15,76 [4,99; 49,81] <,0001[2]	19,66 [6,04; 64,06] <,0001[3]	19,6 [14,2; 25,0] <,0001[3]
Other	11/190 (5,8)	0/194 (0,0)	23,48 [1,39; 395,68] 0,0285[2]	24,92 [1,46; 426,00] 0,0007[3]	5,8 [2,5; 9,1] 0,0007[3]
Primary tumor size (Interaction p-value: 0,5329)					
< 20 mm	23/204 (11,3)	1/189 (0,5)	21,31 [2,91; 156,25] 0,0026[2]	23,89 [3,19; 178,74] <,0001[3]	10,7 [6,3; 15,2] <,0001[3]
≥ 20 but < 50 mm	39/360 (10,8)	2/346 (0,6)	18,74 [4,56; 77,02] <,0001[2]	20,90 [5,01; 87,25] <,0001[3]	10,3 [6,9; 13,6] <,0001[3]
≥ 50 mm	24/194 (12,4)	3/185 (1,6)	7,63 [2,34; 24,91] 0,0008[2]	8,56 [2,53; 28,96] <,0001[3]	10,7 [5,8; 15,7] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,4958)					
0-3	31/269 (11,5)	1/269 (0,4)	31,00 [4,26; 225,46] 0,0007[2]	34,91 [4,73; 257,67] <,0001[3]	11,2 [7,3; 15,0] <,0001[3]
4-9	37/353 (10,5)	4/326 (1,2)	8,54 [3,08; 23,70] <,0001[2]	9,43 [3,32; 26,75] <,0001[3]	9,3 [5,8; 12,7] <,0001[3]
≥ 10	19/154 (12,3)	1/134 (0,7)	16,53 [2,24; 121,85] 0,0059[2]	18,72 [2,47; 141,83] 0,0001[3]	11,6 [6,2; 17,0] 0,0001[3]
Tumor stage (Interaction p-value: 0,9644)					
IIA	5/79 (6,3)	1/77 (1,3)	4,87 [0,58; 40,76] 0,1439[2]	5,14 [0,59; 45,01] 0,2099[4]	5,0 [-0,9; 11,0] 0,2099[4]
IIB	11/73 (15,1)	0/93 (0,0)	29,22 [1,75; 487,71] 0,0188[2]	34,41 [1,99; 594,53] <,0001[4]	15,1 [6,9; 23,3] <,0001[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	42/345 (12,2)	3/294 (1,0)	11,93 [3,74; 38,09] <,0001[2]	13,45 [4,12; 43,86] <,0001[3]	11,2 [7,5; 14,8] <,0001[3]
IIIB	3/22 (13,6)	0/19 (0,0)	6,09 [0,33; 110,84] 0,2225[2]	7,00 [0,34; 144,73] 0,2354[4]	13,6 [-0,7; 28,0] 0,2354[4]
IIIC	25/253 (9,9)	2/245 (0,8)	12,10 [2,90; 50,56] 0,0006[2]	13,32 [3,12; 56,88] <,0001[3]	9,1 [5,2; 12,9] <,0001[3]
Tumor grade (Interaction p-value: 0,7373)					
G1	13/63 (20,6)	0/52 (0,0)	22,36 [1,36; 367,36] 0,0296[2]	28,07 [1,63; 484,76] 0,0005[3]	20,6 [10,6; 30,6] 0,0005[3]
G2	37/349 (10,6)	3/323 (0,9)	11,41 [3,55; 36,66] <,0001[2]	12,65 [3,86; 41,45] <,0001[3]	9,7 [6,3; 13,1] <,0001[3]
G3	32/317 (10,1)	2/312 (0,6)	15,75 [3,81; 65,15] 0,0001[2]	17,40 [4,13; 73,28] <,0001[3]	9,5 [6,0; 12,9] <,0001[3]
GX	4/44 (9,1)	1/40 (2,5)	3,64 [0,42; 31,19] 0,2390[2]	3,90 [0,42; 36,46] 0,3626[4]	6,6 [-3,2; 16,4] 0,3626[4]
Progesterone receptor status (Interaction p-value: 0,8348)					
Negative	8/67 (11,9)	1/62 (1,6)	7,40 [0,95; 57,50] 0,0556[2]	8,27 [1,00; 68,18] 0,0339[4]	10,3 [2,0; 18,7] 0,0339[4]
Positive	77/678 (11,4)	5/647 (0,8)	14,70 [5,99; 36,08] <,0001[2]	16,45 [6,61; 40,92] <,0001[3]	10,6 [8,1; 13,1] <,0001[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,8779)					
White	31/461 (6,7)	3/440 (0,7)	9,86 [3,04; 32,03] 0,0001[2]	10,50 [3,19; 34,61] <,0001[3]	6,0 [3,6; 8,5] <,0001[3]
Asian	51/273 (18,7)	3/243 (1,2)	15,13 [4,78; 47,86] <,0001[2]	18,38 [5,66; 59,73] <,0001[3]	17,4 [12,6; 22,3] <,0001[3]
Other	5/30 (16,7)	0/34 (0,0)	12,42 [0,72; 215,65] 0,0837[2]	14,88 [0,79; 281,50] 0,0187[4]	16,7 [3,3; 30,0] 0,0187[4]
First endocrine therapy (Interaction p-value: 0,4352)					
Tamoxifen	57/553 (10,3)	5/534 (0,9)	11,01 [4,45; 27,25] <,0001[2]	12,16 [4,83; 30,58] <,0001[3]	9,4 [6,7; 12,0] <,0001[3]
Aromatase inhibitor	30/223 (13,5)	1/195 (0,5)	26,23 [3,61; 190,59] 0,0012[2]	30,16 [4,07; 223,33] <,0001[3]	12,9 [8,4; 17,5] <,0001[3]
ECOG-PS (Interaction p-value: 0,9763)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	80/685 (11,7)	6/649 (0,9)	12,63 [5,55; 28,76] <,0001[2]	14,17 [6,14; 32,73] <,0001[3]	10,8 [8,2; 13,3] <,0001[3]
ECOG-PS 1	7/91 (7,7)	0/80 (0,0)	13,21 [0,77; 227,65] 0,0756[2]	14,29 [0,80; 254,30] 0,0150[4]	7,7 [2,2; 13,2] 0,0150[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 292.1.2: Subgroups - adverse events with CTCAE Grade ≥ 3 according PT White blood cell count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,7274)					
North America / Europe	21/347 (6,1)	3/309 (1,0)	6,23 [1,88; 20,69] 0,0028[2]	6,57 [1,94; 22,25] 0,0005[3]	5,1 [2,3; 7,8] 0,0005[3]
Asia	39/239 (16,3)	3/226 (1,3)	12,29 [3,85; 39,22] <,0001[2]	14,50 [4,41; 47,63] <,0001[3]	15,0 [10,1; 19,9] <,0001[3]
Other	8/190 (4,2)	0/194 (0,0)	17,36 [1,01; 298,60] 0,0493[2]	18,12 [1,04; 316,15] 0,0033[4]	4,2 [1,4; 7,1] 0,0033[4]
Primary tumor size (Interaction p-value: 0,4587)					
< 20 mm	17/204 (8,3)	2/189 (1,1)	7,88 [1,84; 33,63] 0,0053[2]	8,50 [1,94; 37,31] 0,0008[3]	7,3 [3,2; 11,3] 0,0008[3]
≥ 20 but < 50 mm	39/360 (10,8)	2/346 (0,6)	18,74 [4,56; 77,02] <,0001[2]	20,90 [5,01; 87,25] <,0001[3]	10,3 [6,9; 13,6] <,0001[3]
≥ 50 mm	11/194 (5,7)	2/185 (1,1)	5,24 [1,18; 23,34] 0,0296[2]	5,50 [1,20; 25,16] 0,0141[3]	4,6 [1,0; 8,2] 0,0141[3]
Number of positive lymph nodes (Interaction p-value: 0,7492)					
0-3	20/269 (7,4)	0/269 (0,0)	41,00 [2,49; 674,45] 0,0093[2]	44,29 [2,66; 736,10] <,0001[3]	7,4 [4,3; 10,6] <,0001[3]
4-9	32/353 (9,1)	5/326 (1,5)	5,91 [2,33; 14,99] 0,0002[2]	6,40 [2,46; 16,63] <,0001[3]	7,5 [4,3; 10,8] <,0001[3]
≥ 10	16/154 (10,4)	1/134 (0,7)	13,92 [1,87; 103,59] 0,0101[2]	15,42 [2,02; 117,91] 0,0005[3]	9,6 [4,6; 14,7] 0,0005[3]
Tumor stage (Interaction p-value: 0,9979)					
IIA	4/79 (5,1)	0/77 (0,0)	8,78 [0,48; 160,29] 0,1428[2]	9,24 [0,49; 174,56] 0,1203[4]	5,1 [0,2; 9,9] 0,1203[4]
IIB	10/73 (13,7)	0/93 (0,0)	26,68 [1,59; 447,82] 0,0225[2]	30,92 [1,78; 537,18] 0,0002[4]	13,7 [5,8; 21,6] 0,0002[4]
IIIA	31/345 (9,0)	3/294 (1,0)	8,81 [2,72; 28,51] 0,0003[2]	9,58 [2,90; 31,66] <,0001[3]	8,0 [4,7; 11,2] <,0001[3]
IIIB	2/22 (9,1)	0/19 (0,0)	4,35 [0,22; 85,31] 0,3332[2]	4,76 [0,21; 105,47] 0,4902[4]	9,1 [-2,9; 21,1] 0,4902[4]
IIIC	20/253 (7,9)	3/245 (1,2)	6,46 [1,94; 21,45] 0,0023[2]	6,92 [2,03; 23,61] 0,0004[3]	6,7 [3,1; 10,3] 0,0004[3]
Tumor grade (Interaction p-value: 0,7215)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	10/63 (15,9)	0/52 (0,0)	17,39 [1,04; 289,89] 0,0467[2]	20,61 [1,18; 360,73] 0,0019[4]	15,9 [6,8; 24,9] 0,0019[4]
G2	28/349 (8,0)	4/323 (1,2)	6,48 [2,30; 18,27] 0,0004[2]	6,96 [2,41; 20,06] <,0001[3]	6,8 [3,7; 9,9] <,0001[3]
G3	23/317 (7,3)	1/312 (0,3)	22,64 [3,08; 166,60] 0,0022[2]	24,33 [3,26; 181,30] <,0001[3]	6,9 [4,0; 9,9] <,0001[3]
GX	6/44 (13,6)	1/40 (2,5)	5,45 [0,69; 43,37] 0,1088[2]	6,16 [0,71; 53,59] 0,1122[4]	11,1 [-0,1; 22,4] 0,1122[4]
Progesterone receptor status (Interaction p-value: 0,9516)					
Negative	3/67 (4,5)	0/62 (0,0)	6,49 [0,34; 123,08] 0,2132[2]	6,78 [0,34; 134,01] 0,2453[4]	4,5 [-0,5; 9,4] 0,2453[4]
Positive	61/678 (9,0)	6/647 (0,9)	9,70 [4,22; 22,29] <,0001[2]	10,56 [4,53; 24,61] <,0001[3]	8,1 [5,8; 10,3] <,0001[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9242)					
White	26/461 (5,6)	3/440 (0,7)	8,27 [2,52; 27,13] 0,0005[2]	8,71 [2,62; 28,98] <,0001[3]	5,0 [2,7; 7,2] <,0001[3]
Asian	39/273 (14,3)	3/243 (1,2)	11,57 [3,62; 36,97] <,0001[2]	13,33 [4,06; 43,74] <,0001[3]	13,1 [8,7; 17,4] <,0001[3]
Other	3/30 (10,0)	0/34 (0,0)	7,90 [0,42; 147,05] 0,1658[2]	8,78 [0,43; 177,32] 0,0974[4]	10,0 [-0,7; 20,7] 0,0974[4]
First endocrine therapy (Interaction p-value: 0,4191)					
Tamoxifen	44/553 (8,0)	5/534 (0,9)	8,50 [3,40; 21,27] <,0001[2]	9,15 [3,60; 23,25] <,0001[3]	7,0 [4,6; 9,4] <,0001[3]
Aromatase inhibitor	24/223 (10,8)	1/195 (0,5)	20,99 [2,87; 153,70] 0,0027[2]	23,40 [3,13; 174,64] <,0001[3]	10,2 [6,1; 14,4] <,0001[3]
ECOG-PS (Interaction p-value: 0,6754)					
ECOG-PS 0	60/685 (8,8)	5/649 (0,8)	11,37 [4,59; 28,13] <,0001[2]	12,36 [4,93; 30,99] <,0001[3]	8,0 [5,8; 10,2] <,0001[3]
ECOG-PS 1	8/91 (8,8)	1/80 (1,3)	7,03 [0,90; 55,02] 0,0631[2]	7,61 [0,93; 62,28] 0,0376[4]	7,5 [1,2; 13,8] 0,0376[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 293.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Blood and lymphatic system disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,1640)					
North America / Europe	36/347 (10,4)	9/309 (2,9)	3,56 [1,74; 7,28] 0,0005[2]	3,86 [1,83; 8,15] 0,0002[3]	7,5 [3,7; 11,2] 0,0002[3]
Asia	22/239 (9,2)	2/226 (0,9)	10,40 [2,47; 43,73] 0,0014[2]	11,35 [2,64; 48,87] <,0001[3]	8,3 [4,5; 12,2] <,0001[3]
Other	33/190 (17,4)	3/194 (1,5)	11,23 [3,50; 36,00] <,0001[2]	13,38 [4,03; 44,46] <,0001[3]	15,8 [10,2; 21,5] <,0001[3]
Primary tumor size (Interaction p-value: 0,9249)					
< 20 mm	24/204 (11,8)	4/189 (2,1)	5,56 [1,97; 15,72] 0,0012[2]	6,17 [2,10; 18,13] 0,0002[3]	9,6 [4,8; 14,5] 0,0002[3]
≥ 20 but < 50 mm	45/360 (12,5)	6/346 (1,7)	7,21 [3,12; 16,68] <,0001[2]	8,10 [3,41; 19,24] <,0001[3]	10,8 [7,1; 14,4] <,0001[3]
≥ 50 mm	22/194 (11,3)	3/185 (1,6)	6,99 [2,13; 22,97] 0,0014[2]	7,76 [2,28; 26,39] 0,0001[3]	9,7 [4,9; 14,5] 0,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,9600)					
0-3	30/269 (11,2)	5/269 (1,9)	6,00 [2,36; 15,23] 0,0002[2]	6,63 [2,53; 17,36] <,0001[3]	9,3 [5,2; 13,4] <,0001[3]
4-9	36/353 (10,2)	5/326 (1,5)	6,65 [2,64; 16,74] <,0001[2]	7,29 [2,82; 18,82] <,0001[3]	8,7 [5,2; 12,1] <,0001[3]
≥ 10	25/154 (16,2)	4/134 (3,0)	5,44 [1,94; 15,23] 0,0013[2]	6,30 [2,13; 18,61] 0,0002[3]	13,2 [6,8; 19,7] 0,0002[3]
Tumor stage (Interaction p-value: 0,4964)					
IIA	12/79 (15,2)	1/77 (1,3)	11,70 [1,56; 87,79] 0,0168[2]	13,61 [1,72; 107,47] 0,0017[3]	13,9 [5,6; 22,2] 0,0017[3]
IIB	7/73 (9,6)	4/93 (4,3)	2,23 [0,68; 7,33] 0,1865[2]	2,36 [0,66; 8,40] 0,2156[4]	5,3 [-2,6; 13,2] 0,2156[4]
IIIA	27/345 (7,8)	4/294 (1,4)	5,75 [2,04; 16,25] 0,0010[2]	6,16 [2,13; 17,80] 0,0001[3]	6,5 [3,3; 9,6] 0,0001[3]
IIIB	4/22 (18,2)	0/19 (0,0)	7,83 [0,45; 136,60] 0,1585[2]	9,49 [0,48; 188,68] 0,1105[4]	18,2 [2,1; 34,3] 0,1105[4]
IIIC	41/253 (16,2)	5/245 (2,0)	7,94 [3,19; 19,76] <,0001[2]	9,28 [3,60; 23,92] <,0001[3]	14,2 [9,3; 19,0] <,0001[3]
Tumor grade (Interaction p-value: 0,9930)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	8/63 (12,7)	0/52 (0,0)	14,08 [0,83; 238,28] 0,0669[2]	16,08 [0,91; 285,62] 0,0078[4]	12,7 [4,5; 20,9] 0,0078[4]
G2	43/349 (12,3)	8/323 (2,5)	4,97 [2,38; 10,42] <,0001[2]	5,53 [2,56; 11,96] <,0001[3]	9,8 [6,0; 13,7] <,0001[3]
G3	36/317 (11,4)	6/312 (1,9)	5,91 [2,52; 13,82] <,0001[2]	6,53 [2,71; 15,74] <,0001[3]	9,4 [5,6; 13,2] <,0001[3]
GX	4/44 (9,1)	0/40 (0,0)	8,20 [0,46; 147,68] 0,1537[2]	9,00 [0,47; 172,65] 0,1177[4]	9,1 [0,6; 17,6] 0,1177[4]
Progesterone receptor status (Interaction p-value: 0,9140)					
Negative	10/67 (14,9)	1/62 (1,6)	9,25 [1,22; 70,21] 0,0314[2]	10,70 [1,33; 86,27] 0,0068[3]	13,3 [4,2; 22,4] 0,0068[3]
Positive	80/678 (11,8)	13/647 (2,0)	5,87 [3,30; 10,45] <,0001[2]	6,52 [3,59; 11,85] <,0001[3]	9,8 [7,1; 12,4] <,0001[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,1885)					
White	60/461 (13,0)	7/440 (1,6)	8,18 [3,78; 17,70] <,0001[2]	9,26 [4,18; 20,49] <,0001[3]	11,4 [8,1; 14,7] <,0001[3]
Asian	24/273 (8,8)	2/243 (0,8)	10,68 [2,55; 44,73] 0,0012[2]	11,61 [2,72; 49,68] <,0001[3]	8,0 [4,4; 11,5] <,0001[3]
Other	6/30 (20,0)	3/34 (8,8)	2,27 [0,62; 8,28] 0,2159[2]	2,58 [0,59; 11,40] 0,2849[4]	11,2 [-6,0; 28,4] 0,2849[4]
First endocrine therapy (Interaction p-value: 0,3193)					
Tamoxifen	62/553 (11,2)	8/534 (1,5)	7,48 [3,62; 15,48] <,0001[2]	8,30 [3,94; 17,51] <,0001[3]	9,7 [6,9; 12,5] <,0001[3]
Aromatase inhibitor	29/223 (13,0)	6/195 (3,1)	4,23 [1,79; 9,97] 0,0010[2]	4,71 [1,91; 11,60] 0,0003[3]	9,9 [4,9; 15,0] 0,0003[3]
ECOG-PS (Interaction p-value: 0,6468)					
ECOG-PS 0	81/685 (11,8)	12/649 (1,8)	6,40 [3,52; 11,61] <,0001[2]	7,12 [3,84; 13,19] <,0001[3]	10,0 [7,3; 12,6] <,0001[3]
ECOG-PS 1	10/91 (11,0)	2/80 (2,5)	4,40 [0,99; 19,47] 0,0512[2]	4,81 [1,02; 22,68] 0,0301[3]	8,5 [1,2; 15,8] 0,0301[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.					

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Table 294.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Gastrointestinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,5011)					
Neoadjuvant chemotherapy	22/314 (7,0)	1/306 (0,3)	21,44 [2,91; 158,07] 0,0026[2]	22,98 [3,08; 171,58] <,0001[3]	6,7 [3,8; 9,6] <,0001[3]
Adjuvant chemotherapy	38/452 (8,4)	6/416 (1,4)	5,83 [2,49; 13,65] <,0001[2]	6,27 [2,62; 15,00] <,0001[3]	7,0 [4,2; 9,8] <,0001[3]
No chemotherapy	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Region (Interaction p-value: 0,4955)					
North America / Europe	32/347 (9,2)	3/309 (1,0)	9,50 [2,94; 30,71] 0,0002[2]	10,36 [3,14; 34,19] <,0001[3]	8,3 [5,0; 11,5] <,0001[3]
Asia	17/239 (7,1)	1/226 (0,4)	16,08 [2,16; 119,80] 0,0067[2]	17,23 [2,27; 130,57] 0,0002[3]	6,7 [3,3; 10,0] 0,0002[3]
Other	13/190 (6,8)	3/194 (1,5)	4,42 [1,28; 15,28] 0,0187[2]	4,68 [1,31; 16,68] 0,0094[3]	5,3 [1,3; 9,3] 0,0094[3]
Primary tumor size (Interaction p-value: 0,9716)					
< 20 mm	20/204 (9,8)	2/189 (1,1)	9,26 [2,20; 39,10] 0,0024[2]	10,16 [2,34; 44,10] 0,0002[3]	8,7 [4,4; 13,1] 0,0002[3]
≥ 20 but < 50 mm	23/360 (6,4)	3/346 (0,9)	7,37 [2,23; 24,32] 0,0010[2]	7,80 [2,32; 26,23] <,0001[3]	5,5 [2,8; 8,2] <,0001[3]
≥ 50 mm	17/194 (8,8)	2/185 (1,1)	8,11 [1,90; 34,60] 0,0047[2]	8,79 [2,00; 38,59] 0,0006[3]	7,7 [3,4; 11,9] 0,0006[3]
Number of positive lymph nodes (Interaction p-value: 0,5621)					
0-3	22/269 (8,2)	4/269 (1,5)	5,50 [1,92; 15,75] 0,0015[2]	5,90 [2,01; 17,36] 0,0003[3]	6,7 [3,1; 10,3] 0,0003[3]
4-9	20/353 (5,7)	1/326 (0,3)	18,47 [2,49; 136,85] 0,0043[2]	19,52 [2,60; 146,29] <,0001[3]	5,4 [2,9; 7,8] <,0001[3]
≥ 10	20/154 (13,0)	2/134 (1,5)	8,70 [2,07; 36,54] 0,0031[2]	9,85 [2,26; 42,98] 0,0002[3]	11,5 [5,8; 17,2] 0,0002[3]
Tumor stage (Interaction p-value: 0,3591)					
IIA	7/79 (8,9)	1/77 (1,3)	6,82 [0,86; 54,16] 0,0693[2]	7,39 [0,89; 61,55] 0,0635[4]	7,6 [0,8; 14,3] 0,0635[4]
IIB	5/73 (6,8)	3/93 (3,2)	2,12 [0,52; 8,59] 0,2912[2]	2,21 [0,51; 9,55] 0,3017[4]	3,6 [-3,2; 10,4] 0,3017[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	21/345 (6,1)	1/294 (0,3)	17,90 [2,42; 132,24] 0,0047[2]	18,99 [2,54; 142,06] <,0001[3]	5,7 [3,1; 8,4] <,0001[3]
IIIB	0/22 (0,0)	0/19 (0,0)	NE	NE	NE
IIIC	27/253 (10,7)	2/245 (0,8)	13,07 [3,14; 54,39] 0,0004[2]	14,52 [3,41; 61,74] <,0001[3]	9,9 [5,9; 13,8] <,0001[3]
Tumor grade (Interaction p-value: 0,9593)					
G1	3/63 (4,8)	0/52 (0,0)	5,80 [0,31; 109,73] 0,2415[2]	6,07 [0,31; 120,33] 0,2503[4]	4,8 [-0,5; 10,0] 0,2503[4]
G2	31/349 (8,9)	3/323 (0,9)	9,56 [2,95; 30,98] 0,0002[2]	10,40 [3,15; 34,36] <,0001[3]	8,0 [4,8; 11,1] <,0001[3]
G3	25/317 (7,9)	4/312 (1,3)	6,15 [2,17; 17,47] 0,0006[2]	6,59 [2,27; 19,17] <,0001[3]	6,6 [3,4; 9,8] <,0001[3]
GX	2/44 (4,5)	0/40 (0,0)	4,56 [0,23; 92,12] 0,3229[2]	4,76 [0,22; 102,30] 0,4951[4]	4,5 [-1,6; 10,7] 0,4951[4]
Progesterone receptor status (Interaction p-value: 0,9715)					
Negative	8/67 (11,9)	1/62 (1,6)	7,40 [0,95; 57,50] 0,0556[2]	8,27 [1,00; 68,18] 0,0339[4]	10,3 [2,0; 18,7] 0,0339[4]
Positive	51/678 (7,5)	5/647 (0,8)	9,73 [3,91; 24,23] <,0001[2]	10,44 [4,14; 26,34] <,0001[3]	6,7 [4,7; 8,8] <,0001[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,6091)					
Tamoxifen	40/553 (7,2)	4/534 (0,7)	9,66 [3,48; 26,80] <,0001[2]	10,33 [3,67; 29,08] <,0001[3]	6,5 [4,2; 8,8] <,0001[3]
Aromatase inhibitor	22/223 (9,9)	3/195 (1,5)	6,41 [1,95; 21,10] 0,0022[2]	7,00 [2,06; 23,78] 0,0003[3]	8,3 [4,0; 12,6] 0,0003[3]
ECOG-PS (Interaction p-value: 0,9780)					
ECOG-PS 0	60/685 (8,8)	7/649 (1,1)	8,12 [3,74; 17,63] <,0001[2]	8,80 [3,99; 19,41] <,0001[3]	7,7 [5,4; 9,9] <,0001[3]
ECOG-PS 1	2/91 (2,2)	0/80 (0,0)	4,40 [0,21; 90,35] 0,3364[2]	4,50 [0,21; 95,08] 0,4991[4]	2,2 [-0,8; 5,2] 0,4991[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.					

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 295.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC General disorders and administration site conditions from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,6171)					
Neoadjuvant chemotherapy	8/314 (2,5)	1/306 (0,3)	7,80 [0,98; 61,96] 0,0522[2]	7,97 [0,99; 64,14] 0,0378[4]	2,2 [0,4; 4,1] 0,0378[4]
Adjuvant chemotherapy	8/452 (1,8)	4/416 (1,0)	1,84 [0,56; 6,07] 0,3161[2]	1,86 [0,55; 6,21] 0,3082[3]	0,8 [-0,7; 2,3] 0,3082[3]
No chemotherapy	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,9632)					
North America / Europe	12/347 (3,5)	4/309 (1,3)	2,67 [0,87; 8,20] 0,0858[2]	2,73 [0,87; 8,56] 0,0729[3]	2,2 [-0,1; 4,5] 0,0729[3]
Asia	0/239 (0,0)	1/226 (0,4)	0,32 [0,01; 7,70] 0,4789[2]	0,31 [0,01; 7,74] 0,4860[4]	-0,4 [-1,3; 0,4] 0,4860[4]
Other	4/190 (2,1)	0/194 (0,0)	9,19 [0,50; 169,50] 0,1359[2]	9,39 [0,50; 175,54] 0,0590[4]	2,1 [0,1; 4,1] 0,0590[4]
Primary tumor size (Interaction p-value: 0,6593)					
< 20 mm	3/204 (1,5)	2/189 (1,1)	1,39 [0,23; 8,23] 0,7168[2]	1,40 [0,23; 8,44] 1,0000[4]	0,4 [-1,8; 2,6] 1,0000[4]
≥ 20 but < 50 mm	8/360 (2,2)	2/346 (0,6)	3,84 [0,82; 17,98] 0,0871[2]	3,91 [0,82; 18,54] 0,1076[4]	1,6 [-0,1; 3,4] 0,1076[4]
≥ 50 mm	4/194 (2,1)	1/185 (0,5)	3,81 [0,43; 33,81] 0,2292[2]	3,87 [0,43; 34,98] 0,3724[4]	1,5 [-0,7; 3,8] 0,3724[4]
Number of positive lymph nodes (Interaction p-value: 0,6713)					
0-3	8/269 (3,0)	2/269 (0,7)	4,00 [0,86; 18,66] 0,0777[2]	4,09 [0,86; 19,45] 0,0555[3]	2,2 [-0,0; 4,5] 0,0555[3]
4-9	5/353 (1,4)	3/326 (0,9)	1,54 [0,37; 6,39] 0,5526[2]	1,55 [0,37; 6,52] 0,7267[4]	0,5 [-1,1; 2,1] 0,7267[4]
≥ 10	3/154 (1,9)	0/134 (0,0)	6,10 [0,32; 116,97] 0,2304[2]	6,21 [0,32; 121,41] 0,2510[4]	1,9 [-0,2; 4,1] 0,2510[4]
Tumor grade (Interaction p-value: 0,9647)					
G1	2/63 (3,2)	0/52 (0,0)	4,14 [0,20; 84,38] 0,3556[2]	4,27 [0,20; 90,91] 0,5002[4]	3,2 [-1,2; 7,5] 0,5002[4]
G2	6/349 (1,7)	4/323 (1,2)	1,39 [0,40; 4,87] 0,6087[2]	1,40 [0,39; 4,99] 0,7539[4]	0,5 [-1,3; 2,3] 0,7539[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G3	8/317 (2,5)	1/312 (0,3)	7,87 [0,99; 62,58] 0,0511[2]	8,05 [1,00; 64,76] 0,0378[4]	2,2 [0,4; 4,0] 0,0378[4]
GX	0/44 (0,0)	0/40 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9618)					
Negative	1/67 (1,5)	0/62 (0,0)	2,78 [0,12; 66,98] 0,5289[2]	2,82 [0,11; 70,51] 1,0000[4]	1,5 [-1,4; 4,4] 1,0000[4]
Positive	15/678 (2,2)	4/647 (0,6)	3,58 [1,19; 10,73] 0,0228[2]	3,64 [1,20; 11,02] 0,0147[3]	1,6 [0,3; 2,9] 0,0147[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9996)					
White	13/461 (2,8)	4/440 (0,9)	3,10 [1,02; 9,44] 0,0462[2]	3,16 [1,02; 9,78] 0,0351[3]	1,9 [0,2; 3,7] 0,0351[3]
Asian	0/273 (0,0)	1/243 (0,4)	0,30 [0,01; 7,25] 0,4564[2]	0,30 [0,01; 7,29] 0,4709[4]	-0,4 [-1,2; 0,4] 0,4709[4]
Other	2/30 (6,7)	0/34 (0,0)	5,65 [0,28; 113,12] 0,2578[2]	6,05 [0,28; 131,25] 0,2158[4]	6,7 [-2,3; 15,6] 0,2158[4]
First endocrine therapy (Interaction p-value: 0,3964)					
Tamoxifen	9/553 (1,6)	4/534 (0,7)	2,17 [0,67; 7,01] 0,1943[2]	2,19 [0,67; 7,16] 0,1829[3]	0,9 [-0,4; 2,2] 0,1829[3]
Aromatase inhibitor	7/223 (3,1)	1/195 (0,5)	6,12 [0,76; 49,31] 0,0888[2]	6,29 [0,77; 51,56] 0,0726[4]	2,6 [0,1; 5,1] 0,0726[4]
ECOG-PS (Interaction p-value: 0,9756)					
ECOG-PS 0	14/685 (2,0)	5/649 (0,8)	2,65 [0,96; 7,32] 0,0597[2]	2,69 [0,96; 7,50] 0,0498[3]	1,3 [0,0; 2,5] 0,0498[3]
ECOG-PS 1	2/91 (2,2)	0/80 (0,0)	4,40 [0,21; 90,35] 0,3364[2]	4,50 [0,21; 95,08] 0,4991[4]	2,2 [-0,8; 5,2] 0,4991[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 296.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Hepatobiliary disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,9497)					
Negative	1/67 (1,5)	0/62 (0,0)	2,78 [0,12; 66,98] 0,5289[2]	2,82 [0,11; 70,51] 1,0000[4]	1,5 [-1,4; 4,4] 1,0000[4]
Positive	10/678 (1,5)	2/647 (0,3)	4,77 [1,05; 21,69] 0,0431[2]	4,83 [1,05; 22,12] 0,0251[3]	1,2 [0,2; 2,2] 0,0251[3]
Unknown	0/8 (0,0)	0/8 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,3200)					
Tamoxifen	9/553 (1,6)	1/534 (0,2)	8,69 [1,10; 68,36] 0,0399[2]	8,82 [1,11; 69,84] 0,0211[4]	1,4 [0,3; 2,6] 0,0211[4]
Aromatase inhibitor	2/223 (0,9)	1/195 (0,5)	1,75 [0,16; 19,14] 0,6470[2]	1,76 [0,16; 19,51] 1,0000[4]	0,4 [-1,2; 2,0] 1,0000[4]
ECOG-PS (Interaction p-value: 0,9767)					
ECOG-PS 0	9/685 (1,3)	2/649 (0,3)	4,26 [0,92; 19,66] 0,0630[2]	4,31 [0,93; 20,01] 0,0423[3]	1,0 [0,1; 2,0] 0,0423[3]
ECOG-PS 1	2/91 (2,2)	0/80 (0,0)	4,40 [0,21; 90,35] 0,3364[2]	4,50 [0,21; 95,08] 0,4991[4]	2,2 [-0,8; 5,2] 0,4991[4]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 297.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Infections and infestations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,3145)					
North America / Europe	23/347 (6,6)	8/309 (2,6)	2,56 [1,16; 5,64] 0,0196[2]	2,67 [1,18; 6,06] 0,0149[3]	4,0 [0,9; 7,2] 0,0149[3]
Asia	6/239 (2,5)	6/226 (2,7)	0,95 [0,31; 2,89] 0,9218[2]	0,94 [0,30; 2,97] 0,9218[3]	-0,1 [-3,0; 2,7] 0,9218[3]
Other	8/190 (4,2)	3/194 (1,5)	2,72 [0,73; 10,11] 0,1345[2]	2,80 [0,73; 10,71] 0,1176[3]	2,7 [-0,7; 6,0] 0,1176[3]
Primary tumor size (Interaction p-value: 0,3893)					
< 20 mm	7/204 (3,4)	6/189 (3,2)	1,08 [0,37; 3,16] 0,8870[2]	1,08 [0,36; 3,28] 0,8869[3]	0,3 [-3,3; 3,8] 0,8869[3]
≥ 20 but < 50 mm	18/360 (5,0)	6/346 (1,7)	2,88 [1,16; 7,18] 0,0229[2]	2,98 [1,17; 7,60] 0,0167[3]	3,3 [0,6; 5,9] 0,0167[3]
≥ 50 mm	11/194 (5,7)	5/185 (2,7)	2,10 [0,74; 5,92] 0,1617[2]	2,16 [0,74; 6,35] 0,1510[3]	3,0 [-1,0; 7,0] 0,1510[3]
Number of positive lymph nodes (Interaction p-value: 0,4249)					
0-3	10/269 (3,7)	7/269 (2,6)	1,43 [0,55; 3,70] 0,4623[2]	1,45 [0,54; 3,85] 0,4597[3]	1,1 [-1,8; 4,1] 0,4597[3]
4-9	18/353 (5,1)	5/326 (1,5)	3,32 [1,25; 8,85] 0,0162[2]	3,45 [1,27; 9,40] 0,0103[3]	3,6 [0,9; 6,2] 0,0103[3]
≥ 10	9/154 (5,8)	5/134 (3,7)	1,57 [0,54; 4,56] 0,4105[2]	1,60 [0,52; 4,90] 0,4056[3]	2,1 [-2,8; 7,0] 0,4056[3]
Tumor stage (Interaction p-value: 0,2541)					
IIA	1/79 (1,3)	4/77 (5,2)	0,24 [0,03; 2,13] 0,2019[2]	0,23 [0,03; 2,14] 0,2068[4]	-3,9 [-9,5; 1,6] 0,2068[4]
IIB	2/73 (2,7)	0/93 (0,0)	6,35 [0,31; 130,28] 0,2304[2]	6,54 [0,31; 138,33] 0,1919[4]	2,7 [-1,0; 6,5] 0,1919[4]
IIIA	19/345 (5,5)	4/294 (1,4)	4,05 [1,39; 11,76] 0,0102[2]	4,23 [1,42; 12,56] 0,0050[3]	4,1 [1,4; 6,9] 0,0050[3]
IIIB	0/22 (0,0)	1/19 (5,3)	0,29 [0,01; 6,72] 0,4401[2]	0,27 [0,01; 7,13] 0,4634[4]	-5,3 [-15,3; 4,8] 0,4634[4]
IIIC	15/253 (5,9)	8/245 (3,3)	1,82 [0,78; 4,21] 0,1639[2]	1,87 [0,78; 4,49] 0,1568[3]	2,7 [-1,0; 6,3] 0,1568[3]
Tumor grade (Interaction p-value: 0,6332)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	4/63 (6,3)	1/52 (1,9)	3,30 [0,38; 28,64] 0,2785[2]	3,46 [0,37; 31,93] 0,3757[4]	4,4 [-2,7; 11,5] 0,3757[4]
G2	19/349 (5,4)	7/323 (2,2)	2,51 [1,07; 5,90] 0,0344[2]	2,60 [1,08; 6,27] 0,0278[3]	3,3 [0,4; 6,1] 0,0278[3]
G3	11/317 (3,5)	9/312 (2,9)	1,20 [0,51; 2,86] 0,6762[2]	1,21 [0,49; 2,96] 0,6757[3]	0,6 [-2,2; 3,3] 0,6757[3]
GX	3/44 (6,8)	0/40 (0,0)	6,38 [0,34; 119,78] 0,2156[2]	6,83 [0,34; 136,48] 0,2427[4]	6,8 [-0,6; 14,3] 0,2427[4]
Progesterone receptor status (Interaction p-value: 0,5496)					
Negative	3/67 (4,5)	3/62 (4,8)	0,93 [0,19; 4,42] 0,9225[2]	0,92 [0,18; 4,75] 1,0000[4]	-0,4 [-7,6; 6,9] 1,0000[4]
Positive	30/678 (4,4)	12/647 (1,9)	2,39 [1,23; 4,62] 0,0099[2]	2,45 [1,24; 4,83] 0,0076[3]	2,6 [0,7; 4,4] 0,0076[3]
Unknown	1/8 (12,5)	0/8 (0,0)	3,00 [0,14; 64,26] 0,4823[2]	3,40 [0,12; 96,70] 1,0000[4]	12,5 [-10,4; 35,4] 1,0000[4]
Race (Interaction p-value: 0,2647)					
White	28/461 (6,1)	10/440 (2,3)	2,67 [1,31; 5,44] 0,0067[2]	2,78 [1,33; 5,79] 0,0045[3]	3,8 [1,2; 6,4] 0,0045[3]
Asian	6/273 (2,2)	6/243 (2,5)	0,89 [0,29; 2,72] 0,8383[2]	0,89 [0,28; 2,79] 0,8383[3]	-0,3 [-2,9; 2,3] 0,8383[3]
Other	2/30 (6,7)	1/34 (2,9)	2,27 [0,22; 23,76] 0,4949[2]	2,36 [0,20; 27,39] 0,5961[4]	3,7 [-6,9; 14,3] 0,5961[4]
First endocrine therapy (Interaction p-value: 0,9802)					
Tamoxifen	21/553 (3,8)	10/534 (1,9)	2,03 [0,96; 4,27] 0,0624[2]	2,07 [0,96; 4,43] 0,0567[3]	1,9 [-0,0; 3,9] 0,0567[3]
Aromatase inhibitor	16/223 (7,2)	7/195 (3,6)	2,00 [0,84; 4,76] 0,1175[2]	2,08 [0,84; 5,16] 0,1088[3]	3,6 [-0,7; 7,9] 0,1088[3]
ECOG-PS (Interaction p-value: 0,3725)					
ECOG-PS 0	35/685 (5,1)	15/649 (2,3)	2,21 [1,22; 4,01] 0,0090[2]	2,28 [1,23; 4,21] 0,0072[3]	2,8 [0,8; 4,8] 0,0072[3]
ECOG-PS 1	2/91 (2,2)	2/80 (2,5)	0,88 [0,13; 6,10] 0,8963[2]	0,88 [0,12; 6,37] 1,0000[4]	-0,3 [-4,9; 4,3] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Premenopausal 1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.					

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Table 298.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Investigations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,0586)					
Neoadjuvant chemotherapy	68/314 (21,7)	8/306 (2,6)	8,28 [4,05; 16,94] <,0001[2]	10,30 [4,86; 21,84] <,0001[3]	19,0 [14,1; 23,9] <,0001[3]
Adjuvant chemotherapy	93/452 (20,6)	5/416 (1,2)	17,12 [7,03; 41,68] <,0001[2]	21,29 [8,56; 52,95] <,0001[3]	19,4 [15,5; 23,2] <,0001[3]
No chemotherapy	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Region (Interaction p-value: 0,7353)					
North America / Europe	53/347 (15,3)	5/309 (1,6)	9,44 [3,82; 23,31] <,0001[2]	10,96 [4,32; 27,80] <,0001[3]	13,7 [9,6; 17,7] <,0001[3]
Asia	87/239 (36,4)	8/226 (3,5)	10,28 [5,10; 20,73] <,0001[2]	15,60 [7,34; 33,12] <,0001[3]	32,9 [26,3; 39,4] <,0001[3]
Other	22/190 (11,6)	1/194 (0,5)	22,46 [3,06; 164,99] 0,0022[2]	25,27 [3,37; 189,51] <,0001[3]	11,1 [6,4; 15,7] <,0001[3]
Primary tumor size (Interaction p-value: 0,3239)					
< 20 mm	43/204 (21,1)	5/189 (2,6)	7,97 [3,22; 19,69] <,0001[2]	9,83 [3,80; 25,41] <,0001[3]	18,4 [12,4; 24,5] <,0001[3]
≥ 20 but < 50 mm	78/360 (21,7)	4/346 (1,2)	18,74 [6,94; 50,64] <,0001[2]	23,65 [8,55; 65,39] <,0001[3]	20,5 [16,1; 24,9] <,0001[3]
≥ 50 mm	38/194 (19,6)	5/185 (2,7)	7,25 [2,92; 18,01] <,0001[2]	8,77 [3,37; 22,83] <,0001[3]	16,9 [10,8; 22,9] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,1009)					
0-3	58/269 (21,6)	1/269 (0,4)	58,00 [8,09; 415,71] <,0001[2]	73,67 [10,12; 536,24] <,0001[3]	21,2 [16,2; 26,2] <,0001[3]
4-9	73/353 (20,7)	8/326 (2,5)	8,43 [4,13; 17,21] <,0001[2]	10,36 [4,91; 21,88] <,0001[3]	18,2 [13,7; 22,8] <,0001[3]
≥ 10	31/154 (20,1)	5/134 (3,7)	5,39 [2,16; 13,48] 0,0003[2]	6,50 [2,45; 17,26] <,0001[3]	16,4 [9,3; 23,5] <,0001[3]
Tumor stage (Interaction p-value: 0,7781)					
IIA	17/79 (21,5)	1/77 (1,3)	16,57 [2,26; 121,48] 0,0057[2]	20,84 [2,70; 160,98] <,0001[3]	20,2 [10,8; 29,6] <,0001[3]
IIB	21/73 (28,8)	0/93 (0,0)	54,62 [3,36; 886,86] 0,0049[2]	76,58 [4,55; 1290,14] <,0001[3]	28,8 [18,4; 39,2] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	76/345 (22,0)	6/294 (2,0)	10,79 [4,77; 24,42] <,0001[2]	13,56 [5,81; 31,65] <,0001[3]	20,0 [15,3; 24,7] <,0001[3]
IIIB	5/22 (22,7)	0/19 (0,0)	9,57 [0,56; 162,47] 0,1181[2]	12,26 [0,63; 237,99] 0,0507[4]	22,7 [5,2; 40,2] 0,0507[4]
IIIC	41/253 (16,2)	7/245 (2,9)	5,67 [2,59; 12,40] <,0001[2]	6,58 [2,89; 14,97] <,0001[3]	13,3 [8,4; 18,3] <,0001[3]
Tumor grade (Interaction p-value: 0,3787)					
G1	18/63 (28,6)	1/52 (1,9)	14,86 [2,05; 107,60] 0,0076[2]	20,40 [2,62; 158,97] 0,0001[3]	26,6 [14,9; 38,4] 0,0001[3]
G2	65/349 (18,6)	8/323 (2,5)	7,52 [3,67; 15,43] <,0001[2]	9,01 [4,25; 19,11] <,0001[3]	16,1 [11,7; 20,6] <,0001[3]
G3	65/317 (20,5)	3/312 (1,0)	21,32 [6,77; 67,13] <,0001[2]	26,57 [8,25; 85,54] <,0001[3]	19,5 [15,0; 24,1] <,0001[3]
GX	12/44 (27,3)	2/40 (5,0)	5,45 [1,30; 22,89] 0,0204[2]	7,13 [1,48; 34,22] 0,0062[3]	22,3 [7,5; 37,1] 0,0062[3]
Progesterone receptor status (Interaction p-value: 0,7962)					
Negative	14/67 (20,9)	2/62 (3,2)	6,48 [1,53; 27,36] 0,0110[2]	7,92 [1,72; 36,49] 0,0024[3]	17,7 [7,0; 28,4] 0,0024[3]
Positive	139/678 (20,5)	12/647 (1,9)	11,05 [6,19; 19,74] <,0001[2]	13,65 [7,48; 24,88] <,0001[3]	18,6 [15,4; 21,9] <,0001[3]
Unknown	2/8 (25,0)	0/8 (0,0)	5,00 [0,28; 90,18] 0,2754[2]	6,54 [0,27; 160,97] 0,4667[4]	25,0 [-5,0; 55,0] 0,4667[4]
Race (Interaction p-value: 0,8801)					
White	66/461 (14,3)	5/440 (1,1)	12,60 [5,12; 30,98] <,0001[2]	14,54 [5,80; 36,45] <,0001[3]	13,2 [9,8; 16,5] <,0001[3]
Asian	89/273 (32,6)	8/243 (3,3)	9,90 [4,91; 19,99] <,0001[2]	14,21 [6,72; 30,04] <,0001[3]	29,3 [23,3; 35,3] <,0001[3]
Other	7/30 (23,3)	1/34 (2,9)	7,93 [1,03; 60,83] 0,0463[2]	10,04 [1,16; 87,25] 0,0211[4]	20,4 [4,2; 36,6] 0,0211[4]
First endocrine therapy (Interaction p-value: 0,8671)					
Tamoxifen	104/553 (18,8)	9/534 (1,7)	11,16 [5,71; 21,82] <,0001[2]	13,51 [6,76; 27,01] <,0001[3]	17,1 [13,7; 20,6] <,0001[3]
Aromatase inhibitor	58/223 (26,0)	5/195 (2,6)	10,14 [4,15; 24,78] <,0001[2]	13,36 [5,23; 34,09] <,0001[3]	23,4 [17,3; 29,6] <,0001[3]
ECOG-PS (Interaction p-value: 0,4764)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	147/685 (21,5)	12/649 (1,8)	11,61 [6,51; 20,70] <,0001[2]	14,50 [7,96; 26,42] <,0001[3]	19,6 [16,4; 22,9] <,0001[3]
ECOG-PS 1	15/91 (16,5)	2/80 (2,5)	6,59 [1,56; 27,95] 0,0105[2]	7,70 [1,70; 34,80] 0,0023[3]	14,0 [5,6; 22,3] 0,0023[3]

Data cut-off: 15.07.2025
Safety Population - Premenopausal
1: According to appropriate comparator by GBA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Anhang 4-G2.4.12: Häufige unerwünschte Ereignisse nach Schweregrad und nach SOC und PT - Subgruppenanalyse nicht-interagierender Subgruppen (Postmenopausale Patientinnen); Teil 1

Table 300.1.2: Subgroups - adverse events according PT Abdominal discomfort from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,4105)					
< 65 years	18/918 (2,0)	6/936 (0,6)	3,06 [1,22; 7,67] 0,0172[2]	3,10 [1,22; 7,84] 0,0120[3]	1,3 [0,3; 2,4] 0,0120[3]
≥ 65 years	1/365 (0,3)	1/328 (0,3)	0,90 [0,06; 14,31] 0,9397[2]	0,90 [0,06; 14,42] 1,0000[4]	-0,0 [-0,8; 0,8] 1,0000[4]
Region (Interaction p-value: 0,9968)					
North America / Europe	12/678 (1,8)	5/649 (0,8)	2,30 [0,81; 6,48] 0,1162[2]	2,32 [0,81; 6,62] 0,1056[3]	1,0 [-0,2; 2,2] 0,1056[3]
Asia	5/203 (2,5)	2/201 (1,0)	2,48 [0,49; 12,61] 0,2752[2]	2,51 [0,48; 13,10] 0,4491[4]	1,5 [-1,1; 4,0] 0,4491[4]
Other	2/402 (0,5)	0/414 (0,0)	5,15 [0,25; 106,92] 0,2896[2]	5,17 [0,25; 108,12] 0,2424[4]	0,5 [-0,2; 1,2] 0,2424[4]
Primary tumor size (Interaction p-value: 0,1587)					
< 20 mm	5/331 (1,5)	3/334 (0,9)	1,68 [0,41; 6,98] 0,4741[2]	1,69 [0,40; 7,14] 0,5035[4]	0,6 [-1,0; 2,3] 0,5035[4]
≥ 20 but < 50 mm	11/646 (1,7)	1/653 (0,2)	11,12 [1,44; 85,88] 0,0209[2]	11,29 [1,45; 87,74] 0,0035[3]	1,5 [0,5; 2,6] 0,0035[3]
≥ 50 mm	3/289 (1,0)	3/265 (1,1)	0,92 [0,19; 4,50] 0,9150[2]	0,92 [0,18; 4,58] 1,0000[4]	-0,1 [-1,8; 1,6] 1,0000[4]
Tumor stage (Interaction p-value: 0,8921)					
IIA	1/113 (0,9)	0/114 (0,0)	3,03 [0,12; 73,51] 0,4963[2]	3,05 [0,12; 75,75] 0,4978[4]	0,9 [-0,8; 2,6] 0,4978[4]
IIB	4/151 (2,6)	0/136 (0,0)	8,11 [0,44; 149,30] 0,1589[2]	8,33 [0,44; 156,14] 0,1244[4]	2,6 [0,1; 5,2] 0,1244[4]
IIIA	6/495 (1,2)	1/488 (0,2)	5,92 [0,71; 48,95] 0,0992[2]	5,98 [0,72; 49,82] 0,1237[4]	1,0 [-0,0; 2,1] 0,1237[4]
IIIB	0/54 (0,0)	1/45 (2,2)	0,28 [0,01; 6,68] 0,4306[2]	0,27 [0,01; 6,85] 0,4545[4]	-2,2 [-6,5; 2,1] 0,4545[4]
IIIC	8/468 (1,7)	5/479 (1,0)	1,64 [0,54; 4,97] 0,3838[2]	1,65 [0,54; 5,08] 0,3788[3]	0,7 [-0,8; 2,2] 0,3788[3]
Progesterone receptor status (Interaction p-value: 0,3408)					
Negative	3/156 (1,9)	1/169 (0,6)	3,25 [0,34; 30,92] 0,3051[2]	3,29 [0,34; 32,00] 0,3537[4]	1,3 [-1,1; 3,8] 0,3537[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Positive	16/1089 (1,5)	6/1066 (0,6)	2,61 [1,03; 6,65] 0,0442[2]	2,63 [1,03; 6,76] 0,0364[3]	0,9 [0,1; 1,8] 0,0364[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9772)					
White	12/958 (1,3)	5/943 (0,5)	2,36 [0,84; 6,68] 0,1050[2]	2,38 [0,84; 6,78] 0,0944[3]	0,7 [-0,1; 1,6] 0,0944[3]
Asian	6/250 (2,4)	2/242 (0,8)	2,90 [0,59; 14,25] 0,1889[2]	2,95 [0,59; 14,77] 0,2856[4]	1,6 [-0,6; 3,8] 0,2856[4]
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
First endocrine therapy (Interaction p-value: 0,8968)					
Tamoxifen	2/114 (1,8)	1/132 (0,8)	2,32 [0,21; 25,21] 0,4906[2]	2,34 [0,21; 26,14] 0,5979[4]	1,0 [-1,8; 3,8] 0,5979[4]
Aromatase inhibitor	17/1169 (1,5)	6/1132 (0,5)	2,74 [1,09; 6,93] 0,0329[2]	2,77 [1,09; 7,05] 0,0259[3]	0,9 [0,1; 1,7] 0,0259[3]
ECOG-PS (Interaction p-value: 0,1766)					
ECOG-PS 0	18/1070 (1,7)	5/1019 (0,5)	3,43 [1,28; 9,20] 0,0144[2]	3,47 [1,28; 9,38] 0,0091[3]	1,2 [0,3; 2,1] 0,0091[3]
ECOG-PS 1	1/213 (0,5)	2/245 (0,8)	0,58 [0,05; 6,30] 0,6506[2]	0,57 [0,05; 6,37] 1,0000[4]	-0,3 [-1,8; 1,1] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 301.1.2: Subgroups - adverse events according PT Abdominal distension from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9487)					
< 65 years	28/918 (3,1)	10/936 (1,1)	2,85 [1,39; 5,84] 0,0041[2]	2,91 [1,41; 6,03] 0,0026[3]	2,0 [0,7; 3,3] 0,0026[3]
≥ 65 years	6/365 (1,6)	2/328 (0,6)	2,70 [0,55; 13,26] 0,2225[2]	2,72 [0,55; 13,59] 0,2919[4]	1,0 [-0,5; 2,6] 0,2919[4]
Prior treatment (Interaction p-value: 0,6706)					
Neoadjuvant chemotherapy	12/430 (2,8)	3/415 (0,7)	3,86 [1,10; 13,58] 0,0353[2]	3,94 [1,10; 14,07] 0,0229[3]	2,1 [0,3; 3,8] 0,0229[3]
Adjuvant chemotherapy	18/784 (2,3)	9/768 (1,2)	1,96 [0,89; 4,33] 0,0969[2]	1,98 [0,88; 4,44] 0,0904[3]	1,1 [-0,2; 2,4] 0,0904[3]
No chemotherapy	4/69 (5,8)	0/81 (0,0)	10,54 [0,58; 192,43] 0,1119[2]	11,20 [0,59; 211,78] 0,0427[4]	5,8 [0,3; 11,3] 0,0427[4]
Region (Interaction p-value: 0,7139)					
North America / Europe	21/678 (3,1)	10/649 (1,5)	2,01 [0,95; 4,24] 0,0663[2]	2,04 [0,95; 4,37] 0,0606[3]	1,6 [-0,1; 3,2] 0,0606[3]
Asia	5/203 (2,5)	0/201 (0,0)	10,89 [0,61; 195,70] 0,1052[2]	11,17 [0,61; 203,28] 0,0610[4]	2,5 [0,3; 4,6] 0,0610[4]
Other	8/402 (2,0)	2/414 (0,5)	4,12 [0,88; 19,28] 0,0722[2]	4,18 [0,88; 19,82] 0,0604[4]	1,5 [-0,0; 3,0] 0,0604[4]
Primary tumor size (Interaction p-value: 0,6950)					
< 20 mm	7/331 (2,1)	4/334 (1,2)	1,77 [0,52; 5,98] 0,3606[2]	1,78 [0,52; 6,15] 0,3538[3]	0,9 [-1,0; 2,9] 0,3538[3]
≥ 20 but < 50 mm	17/646 (2,6)	5/653 (0,8)	3,44 [1,28; 9,26] 0,0146[2]	3,50 [1,28; 9,55] 0,0092[3]	1,9 [0,5; 3,3] 0,0092[3]
≥ 50 mm	10/289 (3,5)	3/265 (1,1)	3,06 [0,85; 10,99] 0,0870[2]	3,13 [0,85; 11,50] 0,0706[3]	2,3 [-0,1; 4,8] 0,0706[3]
Tumor stage (Interaction p-value: 0,3805)					
IIA	2/113 (1,8)	2/114 (1,8)	1,01 [0,14; 7,04] 0,9929[2]	1,01 [0,14; 7,29] 1,0000[4]	0,0 [-3,4; 3,4] 1,0000[4]
IIB	4/151 (2,6)	3/136 (2,2)	1,20 [0,27; 5,27] 0,8083[2]	1,21 [0,27; 5,49] 1,0000[4]	0,4 [-3,1; 4,0] 1,0000[4]
IIIA	16/495 (3,2)	2/488 (0,4)	7,89 [1,82; 34,12] 0,0057[2]	8,12 [1,86; 35,49] 0,0010[3]	2,8 [1,2; 4,5] 0,0010[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	10/468 (2,1)	5/479 (1,0)	2,05 [0,71; 5,94] 0,1878[2]	2,07 [0,70; 6,10] 0,1781[3]	1,1 [-0,5; 2,7] 0,1781[3]
Tumor grade (Interaction p-value: 0,1449)					
G1	1/91 (1,1)	2/93 (2,2)	0,51 [0,05; 5,54] 0,5808[2]	0,51 [0,05; 5,67] 1,0000[4]	-1,1 [-4,7; 2,6] 1,0000[4]
G2	16/612 (2,6)	1/602 (0,2)	15,74 [2,09; 118,30] 0,0074[2]	16,13 [2,13; 122,05] 0,0003[3]	2,4 [1,1; 3,8] 0,0003[3]
G3	16/527 (3,0)	8/506 (1,6)	1,92 [0,83; 4,45] 0,1278[2]	1,95 [0,83; 4,60] 0,1207[3]	1,5 [-0,4; 3,3] 0,1207[3]
GX	1/51 (2,0)	1/59 (1,7)	1,16 [0,07; 18,03] 0,9172[2]	1,16 [0,07; 19,03] 1,0000[4]	0,3 [-4,8; 5,3] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,0896)					
Negative	8/156 (5,1)	2/169 (1,2)	4,33 [0,93; 20,09] 0,0610[2]	4,51 [0,94; 21,59] 0,0532[4]	3,9 [0,1; 7,8] 0,0532[4]
Positive	25/1089 (2,3)	10/1066 (0,9)	2,45 [1,18; 5,07] 0,0160[2]	2,48 [1,19; 5,19] 0,0127[3]	1,4 [0,3; 2,4] 0,0127[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,5662)					
White	26/958 (2,7)	8/943 (0,8)	3,20 [1,46; 7,03] 0,0038[2]	3,26 [1,47; 7,24] 0,0022[3]	1,9 [0,7; 3,0] 0,0022[3]
Asian	6/250 (2,4)	2/242 (0,8)	2,90 [0,59; 14,25] 0,1889[2]	2,95 [0,59; 14,77] 0,2856[4]	1,6 [-0,6; 3,8] 0,2856[4]
Other	2/62 (3,2)	2/64 (3,1)	1,03 [0,15; 7,10] 0,9743[2]	1,03 [0,14; 7,57] 1,0000[4]	0,1 [-6,0; 6,2] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,6296)					
Tamoxifen	4/114 (3,5)	1/132 (0,8)	4,63 [0,53; 40,85] 0,1675[2]	4,76 [0,52; 43,25] 0,1855[4]	2,8 [-0,9; 6,4] 0,1855[4]
Aromatase inhibitor	30/1169 (2,6)	11/1132 (1,0)	2,64 [1,33; 5,24] 0,0055[2]	2,68 [1,34; 5,38] 0,0038[3]	1,6 [0,5; 2,7] 0,0038[3]
ECOG-PS (Interaction p-value: 0,5259)					
ECOG-PS 0	27/1070 (2,5)	8/1019 (0,8)	3,21 [1,47; 7,04] 0,0035[2]	3,27 [1,48; 7,23] 0,0020[3]	1,7 [0,7; 2,8] 0,0020[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	7/213 (3,3)	4/245 (1,6)	2,01 [0,60; 6,78] 0,2590[2]	2,05 [0,59; 7,09] 0,2489[3]	1,7 [-1,2; 4,5] 0,2489[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 302.1.2: Subgroups - adverse events according PT Abdominal pain from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5588)					
< 65 years	237/918 (25,8)	48/936 (5,1)	5,03 [3,74; 6,77] <,0001[2]	6,44 [4,65; 8,92] <,0001[3]	20,7 [17,5; 23,9] <,0001[3]
≥ 65 years	75/365 (20,5)	16/328 (4,9)	4,21 [2,51; 7,08] <,0001[2]	5,04 [2,87; 8,85] <,0001[3]	15,7 [10,9; 20,4] <,0001[3]
Prior treatment (Interaction p-value: 0,9400)					
Neoadjuvant chemotherapy	106/430 (24,7)	20/415 (4,8)	5,12 [3,23; 8,09] <,0001[2]	6,46 [3,92; 10,65] <,0001[3]	19,8 [15,3; 24,4] <,0001[3]
Adjuvant chemotherapy	191/784 (24,4)	40/768 (5,2)	4,68 [3,38; 6,48] <,0001[2]	5,86 [4,10; 8,38] <,0001[3]	19,2 [15,8; 22,5] <,0001[3]
No chemotherapy	15/69 (21,7)	4/81 (4,9)	4,40 [1,53; 12,64] 0,0059[2]	5,35 [1,68; 17,00] 0,0020[3]	16,8 [6,0; 27,6] 0,0020[3]
Region (Interaction p-value: 0,6716)					
North America / Europe	198/678 (29,2)	36/649 (5,5)	5,26 [3,75; 7,38] <,0001[2]	7,02 [4,83; 10,22] <,0001[3]	23,7 [19,8; 27,5] <,0001[3]
Asia	22/203 (10,8)	5/201 (2,5)	4,36 [1,68; 11,28] 0,0024[2]	4,76 [1,77; 12,85] 0,0008[3]	8,3 [3,6; 13,1] 0,0008[3]
Other	92/402 (22,9)	23/414 (5,6)	4,12 [2,66; 6,37] <,0001[2]	5,05 [3,12; 8,16] <,0001[3]	17,3 [12,7; 22,0] <,0001[3]
Primary tumor size (Interaction p-value: 0,1568)					
< 20 mm	80/331 (24,2)	18/334 (5,4)	4,48 [2,75; 7,31] <,0001[2]	5,60 [3,27; 9,58] <,0001[3]	18,8 [13,6; 24,0] <,0001[3]
≥ 20 but < 50 mm	157/646 (24,3)	26/653 (4,0)	6,10 [4,09; 9,11] <,0001[2]	7,74 [5,03; 11,92] <,0001[3]	20,3 [16,7; 24,0] <,0001[3]
≥ 50 mm	73/289 (25,3)	20/265 (7,5)	3,35 [2,10; 5,33] <,0001[2]	4,14 [2,44; 7,02] <,0001[3]	17,7 [11,8; 23,6] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,7770)					
0-3	109/427 (25,5)	24/418 (5,7)	4,45 [2,92; 6,77] <,0001[2]	5,63 [3,53; 8,97] <,0001[3]	19,8 [15,1; 24,5] <,0001[3]
4-9	136/549 (24,8)	25/542 (4,6)	5,37 [3,57; 8,09] <,0001[2]	6,81 [4,36; 10,63] <,0001[3]	20,2 [16,1; 24,2] <,0001[3]
≥ 10	67/307 (21,8)	15/304 (4,9)	4,42 [2,59; 7,57] <,0001[2]	5,38 [3,00; 9,66] <,0001[3]	16,9 [11,7; 22,1] <,0001[3]
Tumor stage (Interaction p-value: 0,7670)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	25/113 (22,1)	4/114 (3,5)	6,31 [2,27; 17,54] 0,0004[2]	7,81 [2,62; 23,28] <,0001[3]	18,6 [10,2; 27,0] <,0001[3]
IIB	36/151 (23,8)	7/136 (5,1)	4,63 [2,13; 10,06] 0,0001[2]	5,77 [2,47; 13,47] <,0001[3]	18,7 [10,9; 26,4] <,0001[3]
IIIA	127/495 (25,7)	22/488 (4,5)	5,69 [3,68; 8,79] <,0001[2]	7,31 [4,56; 11,73] <,0001[3]	21,1 [16,9; 25,4] <,0001[3]
IIIB	14/54 (25,9)	3/45 (6,7)	3,89 [1,19; 12,69] 0,0244[2]	4,90 [1,31; 18,34] 0,0114[3]	19,3 [5,5; 33,0] 0,0114[3]
IIIC	109/468 (23,3)	28/479 (5,8)	3,98 [2,68; 5,92] <,0001[2]	4,89 [3,16; 7,58] <,0001[3]	17,4 [13,1; 21,8] <,0001[3]
Tumor grade (Interaction p-value: 0,8821)					
G1	22/91 (24,2)	5/93 (5,4)	4,50 [1,78; 11,36] 0,0015[2]	5,61 [2,02; 15,58] 0,0003[3]	18,8 [8,9; 28,7] 0,0003[3]
G2	146/612 (23,9)	28/602 (4,7)	5,13 [3,48; 7,56] <,0001[2]	6,42 [4,21; 9,80] <,0001[3]	19,2 [15,4; 23,0] <,0001[3]
G3	128/527 (24,3)	30/506 (5,9)	4,10 [2,81; 5,98] <,0001[2]	5,09 [3,35; 7,74] <,0001[3]	18,4 [14,2; 22,6] <,0001[3]
GX	16/51 (31,4)	0/59 (0,0)	38,08 [2,34; 619,24] 0,0105[2]	55,31 [3,22; 950,49] <,0001[3]	31,4 [18,6; 44,1] <,0001[3]
Race (Interaction p-value: 0,9490)					
White	257/958 (26,8)	53/943 (5,6)	4,77 [3,60; 6,33] <,0001[2]	6,16 [4,51; 8,41] <,0001[3]	21,2 [18,0; 24,4] <,0001[3]
Asian	31/250 (12,4)	6/242 (2,5)	5,00 [2,12; 11,77] 0,0002[2]	5,57 [2,28; 13,60] <,0001[3]	9,9 [5,4; 14,5] <,0001[3]
Other	20/62 (32,3)	5/64 (7,8)	4,13 [1,65; 10,32] 0,0024[2]	5,62 [1,95; 16,17] 0,0006[3]	24,4 [11,1; 37,8] 0,0006[3]
First endocrine therapy (Interaction p-value: 0,1945)					
Tamoxifen	26/114 (22,8)	3/132 (2,3)	10,04 [3,12; 32,29] 0,0001[2]	12,70 [3,73; 43,27] <,0001[3]	20,5 [12,4; 28,6] <,0001[3]
Aromatase inhibitor	286/1169 (24,5)	61/1132 (5,4)	4,54 [3,49; 5,91] <,0001[2]	5,69 [4,25; 7,60] <,0001[3]	19,1 [16,3; 21,9] <,0001[3]
ECOG-PS (Interaction p-value: 0,7874)					
ECOG-PS 0	258/1070 (24,1)	52/1019 (5,1)	4,73 [3,55; 6,29] <,0001[2]	5,91 [4,32; 8,07] <,0001[3]	19,0 [16,1; 21,9] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	54/213 (25,4)	12/245 (4,9)	5,18 [2,85; 9,41] <,0001[2]	6,59 [3,42; 12,72] <,0001[3]	20,5 [14,0; 26,9] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 303.1.2: Subgroups - adverse events according PT Abdominal pain upper from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8999)					
< 65 years	89/918 (9,7)	33/936 (3,5)	2,75 [1,86; 4,06] <,0001[2]	2,94 [1,95; 4,43] <,0001[3]	6,2 [3,9; 8,4] <,0001[3]
≥ 65 years	35/365 (9,6)	12/328 (3,7)	2,62 [1,38; 4,96] 0,0031[2]	2,79 [1,42; 5,48] 0,0019[3]	5,9 [2,3; 9,6] 0,0019[3]
Prior treatment (Interaction p-value: 0,3012)					
Neoadjuvant chemotherapy	45/430 (10,5)	11/415 (2,7)	3,95 [2,07; 7,53] <,0001[2]	4,29 [2,19; 8,42] <,0001[3]	7,8 [4,5; 11,1] <,0001[3]
Adjuvant chemotherapy	70/784 (8,9)	31/768 (4,0)	2,21 [1,47; 3,34] 0,0002[2]	2,33 [1,51; 3,60] <,0001[3]	4,9 [2,5; 7,3] <,0001[3]
No chemotherapy	9/69 (13,0)	3/81 (3,7)	3,52 [0,99; 12,50] 0,0514[2]	3,90 [1,01; 15,03] 0,0356[3]	9,3 [0,4; 18,3] 0,0356[3]
Region (Interaction p-value: 0,0584)					
North America / Europe	69/678 (10,2)	16/649 (2,5)	4,13 [2,42; 7,03] <,0001[2]	4,48 [2,57; 7,81] <,0001[3]	7,7 [5,1; 10,3] <,0001[3]
Asia	17/203 (8,4)	6/201 (3,0)	2,81 [1,13; 6,97] 0,0263[2]	2,97 [1,15; 7,70] 0,0194[3]	5,4 [0,9; 9,9] 0,0194[3]
Other	38/402 (9,5)	23/414 (5,6)	1,70 [1,03; 2,80] 0,0369[2]	1,77 [1,04; 3,04] 0,0343[3]	3,9 [0,3; 7,5] 0,0343[3]
Primary tumor size (Interaction p-value: 0,8707)					
< 20 mm	32/331 (9,7)	10/334 (3,0)	3,23 [1,61; 6,46] 0,0009[2]	3,47 [1,68; 7,18] 0,0004[3]	6,7 [3,0; 10,3] 0,0004[3]
≥ 20 but < 50 mm	53/646 (8,2)	20/653 (3,1)	2,68 [1,62; 4,43] 0,0001[2]	2,83 [1,67; 4,79] <,0001[3]	5,1 [2,6; 7,6] <,0001[3]
≥ 50 mm	39/289 (13,5)	14/265 (5,3)	2,55 [1,42; 4,60] 0,0018[2]	2,80 [1,48; 5,28] 0,0010[3]	8,2 [3,4; 13,0] 0,0010[3]
Number of positive lymph nodes (Interaction p-value: 0,4527)					
0-3	47/427 (11,0)	15/418 (3,6)	3,07 [1,74; 5,40] 0,0001[2]	3,32 [1,83; 6,04] <,0001[3]	7,4 [4,0; 10,9] <,0001[3]
4-9	45/549 (8,2)	14/542 (2,6)	3,17 [1,76; 5,71] 0,0001[2]	3,37 [1,83; 6,21] <,0001[3]	5,6 [3,0; 8,3] <,0001[3]
≥ 10	32/307 (10,4)	16/304 (5,3)	1,98 [1,11; 3,53] 0,0207[2]	2,09 [1,12; 3,90] 0,0178[3]	5,2 [0,9; 9,4] 0,0178[3]
Tumor stage (Interaction p-value: 0,2805)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	10/113 (8,8)	2/114 (1,8)	5,04 [1,13; 22,51] 0,0340[2]	5,44 [1,16; 25,40] 0,0169[3]	7,1 [1,3; 12,9] 0,0169[3]
IIB	13/151 (8,6)	6/136 (4,4)	1,95 [0,76; 4,99] 0,1629[2]	2,04 [0,75; 5,53] 0,1533[3]	4,2 [-1,5; 9,8] 0,1533[3]
IIIA	55/495 (11,1)	13/488 (2,7)	4,17 [2,31; 7,53] <,0001[2]	4,57 [2,46; 8,47] <,0001[3]	8,4 [5,3; 11,6] <,0001[3]
IIIB	3/54 (5,6)	0/45 (0,0)	5,85 [0,31; 110,43] 0,2383[2]	6,18 [0,31; 122,97] 0,2486[4]	5,6 [-0,6; 11,7] 0,2486[4]
IIIC	43/468 (9,2)	23/479 (4,8)	1,91 [1,17; 3,12] 0,0094[2]	2,01 [1,19; 3,39] 0,0080[3]	4,4 [1,1; 7,6] 0,0080[3]
Tumor grade (Interaction p-value: 0,9324)					
G1	10/91 (11,0)	5/93 (5,4)	2,04 [0,73; 5,75] 0,1753[2]	2,17 [0,71; 6,63] 0,1642[3]	5,6 [-2,3; 13,5] 0,1642[3]
G2	61/612 (10,0)	21/602 (3,5)	2,86 [1,76; 4,63] <,0001[2]	3,06 [1,84; 5,10] <,0001[3]	6,5 [3,7; 9,3] <,0001[3]
G3	45/527 (8,5)	18/506 (3,6)	2,40 [1,41; 4,09] 0,0013[2]	2,53 [1,44; 4,44] 0,0008[3]	5,0 [2,1; 7,9] 0,0008[3]
GX	8/51 (15,7)	0/59 (0,0)	19,62 [1,16; 331,69] 0,0391[2]	23,25 [1,31; 413,75] 0,0016[4]	15,7 [5,7; 25,7] 0,0016[4]
Progesterone receptor status (Interaction p-value: 0,9898)					
Negative	19/156 (12,2)	2/169 (1,2)	10,29 [2,44; 43,47] 0,0015[2]	11,58 [2,65; 50,59] <,0001[3]	11,0 [5,6; 16,4] <,0001[3]
Positive	102/1089 (9,4)	43/1066 (4,0)	2,32 [1,64; 3,28] <,0001[2]	2,46 [1,70; 3,55] <,0001[3]	5,3 [3,2; 7,4] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9550)					
White	96/958 (10,0)	36/943 (3,8)	2,62 [1,81; 3,81] <,0001[2]	2,81 [1,89; 4,16] <,0001[3]	6,2 [3,9; 8,5] <,0001[3]
Asian	18/250 (7,2)	6/242 (2,5)	2,90 [1,17; 7,19] 0,0212[2]	3,05 [1,19; 7,82] 0,0151[3]	4,7 [1,0; 8,5] 0,0151[3]
Other	9/62 (14,5)	3/64 (4,7)	3,10 [0,88; 10,91] 0,0785[2]	3,45 [0,89; 13,42] 0,0602[3]	9,8 [-0,4; 20,0] 0,0602[3]
First endocrine therapy (Interaction p-value: 0,1037)					
Tamoxifen	11/114 (9,6)	9/132 (6,8)	1,42 [0,61; 3,29] 0,4203[2]	1,46 [0,58; 3,66] 0,4179[3]	2,8 [-4,1; 9,7] 0,4179[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	113/1169 (9,7)	36/1132 (3,2)	3,04 [2,11; 4,38] <,0001[2]	3,26 [2,22; 4,79] <,0001[3]	6,5 [4,5; 8,5] <,0001[3]
ECOG-PS (Interaction p-value: 0,9810)					
ECOG-PS 0	105/1070 (9,8)	37/1019 (3,6)	2,70 [1,88; 3,89] <,0001[2]	2,89 [1,96; 4,24] <,0001[3]	6,2 [4,1; 8,3] <,0001[3]
ECOG-PS 1	19/213 (8,9)	8/245 (3,3)	2,73 [1,22; 6,11] 0,0145[2]	2,90 [1,24; 6,77] 0,0104[3]	5,7 [1,2; 10,1] 0,0104[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 304.1.2: Subgroups - adverse events according PT Alanine aminotransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9544)					
< 65 years	120/918 (13,1)	54/936 (5,8)	2,27 [1,67; 3,08] <,0001[2]	2,46 [1,76; 3,43] <,0001[3]	7,3 [4,7; 9,9] <,0001[3]
≥ 65 years	36/365 (9,9)	14/328 (4,3)	2,31 [1,27; 4,21] 0,0061[2]	2,45 [1,30; 4,64] 0,0045[3]	5,6 [1,8; 9,4] 0,0045[3]
Prior treatment (Interaction p-value: 0,5797)					
Neoadjuvant chemotherapy	65/430 (15,1)	27/415 (6,5)	2,32 [1,51; 3,56] 0,0001[2]	2,56 [1,60; 4,10] <,0001[3]	8,6 [4,5; 12,7] <,0001[3]
Adjuvant chemotherapy	83/784 (10,6)	39/768 (5,1)	2,08 [1,44; 3,01] <,0001[2]	2,21 [1,49; 3,28] <,0001[3]	5,5 [2,9; 8,2] <,0001[3]
No chemotherapy	8/69 (11,6)	2/81 (2,5)	4,70 [1,03; 21,38] 0,0455[2]	5,18 [1,06; 25,28] 0,0444[4]	9,1 [0,8; 17,4] 0,0444[4]
Region (Interaction p-value: 0,6835)					
North America / Europe	53/678 (7,8)	26/649 (4,0)	1,95 [1,24; 3,08] 0,0041[2]	2,03 [1,25; 3,29] 0,0034[3]	3,8 [1,3; 6,3] 0,0034[3]
Asia	45/203 (22,2)	17/201 (8,5)	2,62 [1,55; 4,42] 0,0003[2]	3,08 [1,70; 5,60] 0,0001[3]	13,7 [6,8; 20,6] 0,0001[3]
Other	58/402 (14,4)	25/414 (6,0)	2,39 [1,53; 3,74] 0,0001[2]	2,62 [1,61; 4,29] <,0001[3]	8,4 [4,3; 12,5] <,0001[3]
Primary tumor size (Interaction p-value: 0,5544)					
< 20 mm	48/331 (14,5)	18/334 (5,4)	2,69 [1,60; 4,53] 0,0002[2]	2,98 [1,69; 5,24] <,0001[3]	9,1 [4,6; 13,6] <,0001[3]
≥ 20 but < 50 mm	72/646 (11,1)	37/653 (5,7)	1,97 [1,34; 2,88] 0,0005[2]	2,09 [1,38; 3,15] 0,0004[3]	5,5 [2,5; 8,5] 0,0004[3]
≥ 50 mm	32/289 (11,1)	11/265 (4,2)	2,67 [1,37; 5,18] 0,0038[2]	2,88 [1,42; 5,83] 0,0024[3]	6,9 [2,6; 11,3] 0,0024[3]
Number of positive lymph nodes (Interaction p-value: 0,2158)					
0-3	54/427 (12,6)	19/418 (4,5)	2,78 [1,68; 4,61] <,0001[2]	3,04 [1,77; 5,22] <,0001[3]	8,1 [4,4; 11,8] <,0001[3]
4-9	70/549 (12,8)	28/542 (5,2)	2,47 [1,62; 3,76] <,0001[2]	2,68 [1,70; 4,23] <,0001[3]	7,6 [4,2; 10,9] <,0001[3]
≥ 10	32/307 (10,4)	21/304 (6,9)	1,51 [0,89; 2,56] 0,1261[2]	1,57 [0,88; 2,79] 0,1227[3]	3,5 [-0,9; 8,0] 0,1227[3]
Tumor stage (Interaction p-value: 0,3399)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	21/113 (18,6)	7/114 (6,1)	3,03 [1,34; 6,84] 0,0077[2]	3,49 [1,42; 8,58] 0,0044[3]	12,4 [4,0; 20,9] 0,0044[3]
IIB	12/151 (7,9)	9/136 (6,6)	1,20 [0,52; 2,76] 0,6665[2]	1,22 [0,50; 2,99] 0,6659[3]	1,3 [-4,7; 7,3] 0,6659[3]
IIIA	65/495 (13,1)	25/488 (5,1)	2,56 [1,64; 4,00] <,0001[2]	2,80 [1,73; 4,52] <,0001[3]	8,0 [4,4; 11,6] <,0001[3]
IIIB	8/54 (14,8)	1/45 (2,2)	6,67 [0,87; 51,32] 0,0685[2]	7,65 [0,92; 63,72] 0,0374[4]	12,6 [2,2; 23,0] 0,0374[4]
IIIC	49/468 (10,5)	26/479 (5,4)	1,93 [1,22; 3,05] 0,0049[2]	2,04 [1,24; 3,34] 0,0041[3]	5,0 [1,6; 8,5] 0,0041[3]
Tumor grade (Interaction p-value: 0,1531)					
G1	7/91 (7,7)	1/93 (1,1)	7,15 [0,90; 56,99] 0,0631[2]	7,67 [0,92; 63,62] 0,0336[4]	6,6 [0,8; 12,5] 0,0336[4]
G2	67/612 (10,9)	37/602 (6,1)	1,78 [1,21; 2,62] 0,0033[2]	1,88 [1,24; 2,85] 0,0028[3]	4,8 [1,7; 7,9] 0,0028[3]
G3	72/527 (13,7)	28/506 (5,5)	2,47 [1,62; 3,75] <,0001[2]	2,70 [1,71; 4,26] <,0001[3]	8,1 [4,6; 11,7] <,0001[3]
GX	10/51 (19,6)	1/59 (1,7)	11,57 [1,53; 87,31] 0,0176[2]	14,15 [1,74; 114,85] 0,0018[3]	17,9 [6,5; 29,3] 0,0018[3]
Progesterone receptor status (Interaction p-value: 0,6586)					
Negative	18/156 (11,5)	9/169 (5,3)	2,17 [1,00; 4,68] 0,0491[2]	2,32 [1,01; 5,33] 0,0426[3]	6,2 [0,2; 12,3] 0,0426[3]
Positive	136/1089 (12,5)	57/1066 (5,3)	2,34 [1,73; 3,14] <,0001[2]	2,53 [1,83; 3,48] <,0001[3]	7,1 [4,8; 9,5] <,0001[3]
Unknown	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Race (Interaction p-value: 0,4004)					
White	100/958 (10,4)	48/943 (5,1)	2,05 [1,47; 2,86] <,0001[2]	2,17 [1,52; 3,10] <,0001[3]	5,3 [3,0; 7,7] <,0001[3]
Asian	46/250 (18,4)	19/242 (7,9)	2,34 [1,42; 3,88] 0,0009[2]	2,65 [1,50; 4,67] 0,0006[3]	10,5 [4,7; 16,4] 0,0006[3]
Other	8/62 (12,9)	1/64 (1,6)	8,26 [1,06; 64,10] 0,0435[2]	9,33 [1,13; 77,01] 0,0160[4]	11,3 [2,5; 20,2] 0,0160[4]
First endocrine therapy (Interaction p-value: 0,8343)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	5/114 (4,4)	3/132 (2,3)	1,93 [0,47; 7,90] 0,3605[2]	1,97 [0,46; 8,44] 0,4772[4]	2,1 [-2,4; 6,7] 0,4772[4]
Aromatase inhibitor	151/1169 (12,9)	65/1132 (5,7)	2,25 [1,70; 2,97] <,0001[2]	2,43 [1,80; 3,30] <,0001[3]	7,2 [4,8; 9,5] <,0001[3]
ECOG-PS (Interaction p-value: 0,8265)					
ECOG-PS 0	138/1070 (12,9)	58/1019 (5,7)	2,27 [1,69; 3,04] <,0001[2]	2,45 [1,78; 3,38] <,0001[3]	7,2 [4,7; 9,7] <,0001[3]
ECOG-PS 1	18/213 (8,5)	10/245 (4,1)	2,07 [0,98; 4,39] 0,0575[2]	2,17 [0,98; 4,81] 0,0516[3]	4,4 [-0,1; 8,9] 0,0516[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 305.1.2: Subgroups - adverse events according PT Alopecia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1301)					
< 65 years	94/918 (10,2)	28/936 (3,0)	3,42 [2,27; 5,17] <,0001[2]	3,70 [2,40; 5,70] <,0001[3]	7,2 [5,0; 9,5] <,0001[3]
≥ 65 years	58/365 (15,9)	8/328 (2,4)	6,52 [3,16; 13,44] <,0001[2]	7,56 [3,55; 16,09] <,0001[3]	13,5 [9,3; 17,6] <,0001[3]
Prior treatment (Interaction p-value: 0,3704)					
Neoadjuvant chemotherapy	53/430 (12,3)	8/415 (1,9)	6,39 [3,08; 13,28] <,0001[2]	7,15 [3,36; 15,24] <,0001[3]	10,4 [7,0; 13,8] <,0001[3]
Adjuvant chemotherapy	91/784 (11,6)	25/768 (3,3)	3,57 [2,32; 5,49] <,0001[2]	3,90 [2,48; 6,15] <,0001[3]	8,4 [5,8; 10,9] <,0001[3]
No chemotherapy	8/69 (11,6)	3/81 (3,7)	3,13 [0,86; 11,34] 0,0823[2]	3,41 [0,87; 13,40] 0,0647[3]	7,9 [-0,7; 16,5] 0,0647[3]
Region (Interaction p-value: 0,2488)					
North America / Europe	111/678 (16,4)	33/649 (5,1)	3,22 [2,22; 4,68] <,0001[2]	3,65 [2,44; 5,48] <,0001[3]	11,3 [8,0; 14,5] <,0001[3]
Asia	14/203 (6,9)	0/201 (0,0)	28,72 [1,72; 478,15] 0,0193[2]	30,84 [1,83; 520,53] 0,0002[3]	6,9 [3,4; 10,4] 0,0002[3]
Other	27/402 (6,7)	3/414 (0,7)	9,27 [2,83; 30,31] 0,0002[2]	9,86 [2,97; 32,78] <,0001[3]	6,0 [3,4; 8,6] <,0001[3]
Primary tumor size (Interaction p-value: 0,1084)					
< 20 mm	37/331 (11,2)	3/334 (0,9)	12,45 [3,88; 39,97] <,0001[2]	13,89 [4,24; 45,51] <,0001[3]	10,3 [6,7; 13,8] <,0001[3]
≥ 20 but < 50 mm	68/646 (10,5)	19/653 (2,9)	3,62 [2,20; 5,95] <,0001[2]	3,93 [2,33; 6,61] <,0001[3]	7,6 [4,9; 10,3] <,0001[3]
≥ 50 mm	44/289 (15,2)	13/265 (4,9)	3,10 [1,71; 5,63] 0,0002[2]	3,48 [1,83; 6,62] <,0001[3]	10,3 [5,4; 15,2] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,0816)					
0-3	49/427 (11,5)	6/418 (1,4)	7,99 [3,46; 18,46] <,0001[2]	8,90 [3,77; 21,02] <,0001[3]	10,0 [6,8; 13,3] <,0001[3]
4-9	63/549 (11,5)	22/542 (4,1)	2,83 [1,77; 4,53] <,0001[2]	3,06 [1,86; 5,06] <,0001[3]	7,4 [4,3; 10,6] <,0001[3]
≥ 10	40/307 (13,0)	8/304 (2,6)	4,95 [2,36; 10,40] <,0001[2]	5,54 [2,55; 12,05] <,0001[3]	10,4 [6,2; 14,6] <,0001[3]
Tumor stage (Interaction p-value: 0,5394)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	9/113 (8,0)	1/114 (0,9)	9,08 [1,17; 70,50] 0,0349[2]	9,78 [1,22; 78,52] 0,0099[4]	7,1 [1,8; 12,4] 0,0099[4]
IIB	19/151 (12,6)	2/136 (1,5)	8,56 [2,03; 36,06] 0,0034[2]	9,64 [2,20; 42,23] 0,0003[3]	11,1 [5,4; 16,8] 0,0003[3]
IIIA	57/495 (11,5)	19/488 (3,9)	2,96 [1,79; 4,90] <,0001[2]	3,21 [1,88; 5,49] <,0001[3]	7,6 [4,3; 10,9] <,0001[3]
IIIB	7/54 (13,0)	0/45 (0,0)	12,55 [0,74; 213,82] 0,0804[2]	14,37 [0,80; 258,91] 0,0149[4]	13,0 [4,0; 21,9] 0,0149[4]
IIIC	60/468 (12,8)	14/479 (2,9)	4,39 [2,49; 7,74] <,0001[2]	4,88 [2,69; 8,87] <,0001[3]	9,9 [6,5; 13,3] <,0001[3]
Tumor grade (Interaction p-value: 0,6649)					
G1	11/91 (12,1)	4/93 (4,3)	2,81 [0,93; 8,50] 0,0674[2]	3,06 [0,94; 9,99] 0,0536[3]	7,8 [-0,1; 15,7] 0,0536[3]
G2	86/612 (14,1)	18/602 (3,0)	4,70 [2,86; 7,71] <,0001[2]	5,30 [3,15; 8,94] <,0001[3]	11,1 [8,0; 14,1] <,0001[3]
G3	53/527 (10,1)	13/506 (2,6)	3,91 [2,16; 7,09] <,0001[2]	4,24 [2,28; 7,88] <,0001[3]	7,5 [4,6; 10,4] <,0001[3]
GX	1/51 (2,0)	1/59 (1,7)	1,16 [0,07; 18,03] 0,9172[2]	1,16 [0,07; 19,03] 1,0000[4]	0,3 [-4,8; 5,3] 1,0000[4]
Race (Interaction p-value: 0,3632)					
White	129/958 (13,5)	34/943 (3,6)	3,73 [2,59; 5,39] <,0001[2]	4,16 [2,82; 6,14] <,0001[3]	9,9 [7,4; 12,3] <,0001[3]
Asian	17/250 (6,8)	1/242 (0,4)	16,46 [2,21; 122,70] 0,0063[2]	17,58 [2,32; 133,19] 0,0002[3]	6,4 [3,2; 9,6] 0,0002[3]
Other	3/62 (4,8)	0/64 (0,0)	7,22 [0,38; 137,01] 0,1879[2]	7,59 [0,38; 150,00] 0,1162[4]	4,8 [-0,5; 10,2] 0,1162[4]
ECOG-PS (Interaction p-value: 0,5286)					
ECOG-PS 0	129/1070 (12,1)	28/1019 (2,7)	4,39 [2,94; 6,54] <,0001[2]	4,85 [3,19; 7,37] <,0001[3]	9,3 [7,1; 11,5] <,0001[3]
ECOG-PS 1	23/213 (10,8)	8/245 (3,3)	3,31 [1,51; 7,24] 0,0028[2]	3,59 [1,57; 8,20] 0,0014[3]	7,5 [2,8; 12,3] 0,0014[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 306.1.2: Subgroups - adverse events according PT Anaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9107)					
< 65 years	217/918 (23,6)	33/936 (3,5)	6,70 [4,70; 9,56] <,0001[2]	8,47 [5,80; 12,38] <,0001[3]	20,1 [17,1; 23,1] <,0001[3]
≥ 65 years	116/365 (31,8)	15/328 (4,6)	6,95 [4,15; 11,65] <,0001[2]	9,72 [5,54; 17,07] <,0001[3]	27,2 [21,9; 32,5] <,0001[3]
Prior treatment (Interaction p-value: 0,9646)					
Neoadjuvant chemotherapy	107/430 (24,9)	16/415 (3,9)	6,45 [3,88; 10,72] <,0001[2]	8,26 [4,79; 14,25] <,0001[3]	21,0 [16,5; 25,5] <,0001[3]
Adjuvant chemotherapy	208/784 (26,5)	29/768 (3,8)	7,03 [4,83; 10,23] <,0001[2]	9,20 [6,15; 13,78] <,0001[3]	22,8 [19,4; 26,1] <,0001[3]
No chemotherapy	18/69 (26,1)	3/81 (3,7)	7,04 [2,17; 22,91] 0,0012[2]	9,18 [2,57; 32,75] <,0001[3]	22,4 [11,2; 33,5] <,0001[3]
Region (Interaction p-value: 0,2981)					
North America / Europe	147/678 (21,7)	19/649 (2,9)	7,41 [4,65; 11,80] <,0001[2]	9,18 [5,61; 15,01] <,0001[3]	18,8 [15,4; 22,1] <,0001[3]
Asia	72/203 (35,5)	7/201 (3,5)	10,18 [4,81; 21,58] <,0001[2]	15,23 [6,80; 34,14] <,0001[3]	32,0 [24,9; 39,0] <,0001[3]
Other	114/402 (28,4)	22/414 (5,3)	5,34 [3,45; 8,25] <,0001[2]	7,05 [4,36; 11,41] <,0001[3]	23,0 [18,1; 28,0] <,0001[3]
Primary tumor size (Interaction p-value: 0,7665)					
< 20 mm	80/331 (24,2)	12/334 (3,6)	6,73 [3,74; 12,10] <,0001[2]	8,55 [4,56; 16,04] <,0001[3]	20,6 [15,6; 25,6] <,0001[3]
≥ 20 but < 50 mm	188/646 (29,1)	30/653 (4,6)	6,33 [4,38; 9,17] <,0001[2]	8,52 [5,69; 12,76] <,0001[3]	24,5 [20,7; 28,4] <,0001[3]
≥ 50 mm	58/289 (20,1)	6/265 (2,3)	8,86 [3,89; 20,20] <,0001[2]	10,84 [4,59; 25,59] <,0001[3]	17,8 [12,9; 22,8] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,5811)					
0-3	89/427 (20,8)	13/418 (3,1)	6,70 [3,80; 11,80] <,0001[2]	8,20 [4,50; 14,94] <,0001[3]	17,7 [13,5; 21,9] <,0001[3]
4-9	153/549 (27,9)	25/542 (4,6)	6,04 [4,03; 9,07] <,0001[2]	7,99 [5,13; 12,44] <,0001[3]	23,3 [19,1; 27,4] <,0001[3]
≥ 10	91/307 (29,6)	10/304 (3,3)	9,01 [4,78; 16,98] <,0001[2]	12,39 [6,30; 24,36] <,0001[3]	26,4 [20,9; 31,8] <,0001[3]
Tumor stage (Interaction p-value: 0,3013)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	21/113 (18,6)	6/114 (5,3)	3,53 [1,48; 8,42] 0,0044[2]	4,11 [1,59; 10,61] 0,0019[3]	13,3 [5,1; 21,6] 0,0019[3]
IIB	40/151 (26,5)	3/136 (2,2)	12,01 [3,80; 37,93] <,0001[2]	15,98 [4,81; 53,04] <,0001[3]	24,3 [16,8; 31,7] <,0001[3]
IIIA	129/495 (26,1)	24/488 (4,9)	5,30 [3,49; 8,04] <,0001[2]	6,81 [4,32; 10,76] <,0001[3]	21,1 [16,8; 25,5] <,0001[3]
IIIB	17/54 (31,5)	0/45 (0,0)	29,27 [1,81; 473,60] 0,0174[2]	42,47 [2,47; 729,89] <,0001[3]	31,5 [19,1; 43,9] <,0001[3]
IIIC	125/468 (26,7)	15/479 (3,1)	8,53 [5,07; 14,35] <,0001[2]	11,27 [6,48; 19,61] <,0001[3]	23,6 [19,3; 27,9] <,0001[3]
Tumor grade (Interaction p-value: 0,6706)					
G1	23/91 (25,3)	2/93 (2,2)	11,75 [2,85; 48,41] 0,0006[2]	15,39 [3,51; 67,52] <,0001[3]	23,1 [13,7; 32,5] <,0001[3]
G2	164/612 (26,8)	21/602 (3,5)	7,68 [4,95; 11,93] <,0001[2]	10,13 [6,33; 16,22] <,0001[3]	23,3 [19,5; 27,1] <,0001[3]
G3	124/527 (23,5)	21/506 (4,2)	5,67 [3,63; 8,86] <,0001[2]	7,11 [4,39; 11,50] <,0001[3]	19,4 [15,4; 23,4] <,0001[3]
GX	21/51 (41,2)	4/59 (6,8)	6,07 [2,23; 16,53] 0,0004[2]	9,63 [3,02; 30,64] <,0001[3]	34,4 [19,4; 49,3] <,0001[3]
Race (Interaction p-value: 0,3669)					
White	226/958 (23,6)	35/943 (3,7)	6,36 [4,50; 8,97] <,0001[2]	8,01 [5,54; 11,59] <,0001[3]	19,9 [16,9; 22,8] <,0001[3]
Asian	85/250 (34,0)	8/242 (3,3)	10,29 [5,09; 20,77] <,0001[2]	15,07 [7,11; 31,95] <,0001[3]	30,7 [24,4; 37,0] <,0001[3]
Other	18/62 (29,0)	4/64 (6,3)	4,65 [1,67; 12,95] 0,0033[2]	6,14 [1,94; 19,40] 0,0008[3]	22,8 [10,0; 35,5] 0,0008[3]
First endocrine therapy (Interaction p-value: 0,2577)					
Tamoxifen	18/114 (15,8)	1/132 (0,8)	20,84 [2,83; 153,70] 0,0029[2]	24,56 [3,22; 187,17] <,0001[3]	15,0 [8,2; 21,9] <,0001[3]
Aromatase inhibitor	315/1169 (26,9)	47/1132 (4,2)	6,49 [4,83; 8,72] <,0001[2]	8,51 [6,19; 11,72] <,0001[3]	22,8 [20,0; 25,6] <,0001[3]
ECOG-PS (Interaction p-value: 0,2517)					
ECOG-PS 0	271/1070 (25,3)	41/1019 (4,0)	6,29 [4,58; 8,64] <,0001[2]	8,09 [5,75; 11,38] <,0001[3]	21,3 [18,4; 24,2] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	62/213 (29,1)	7/245 (2,9)	10,19 [4,77; 21,78] <,0001[2]	13,96 [6,22; 31,31] <,0001[3]	26,3 [19,8; 32,7] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 307.1.2: Subgroups - adverse events according PT Anxiety from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,4022)					
Neoadjuvant chemotherapy	13/430 (3,0)	16/415 (3,9)	0,78 [0,38; 1,61] 0,5076[2]	0,78 [0,37; 1,64] 0,5065[3]	-0,8 [-3,3; 1,6] 0,5065[3]
Adjuvant chemotherapy	21/784 (2,7)	37/768 (4,8)	0,56 [0,33; 0,94] 0,0288[2]	0,54 [0,32; 0,94] 0,0263[3]	-2,1 [-4,0; -0,2] 0,0263[3]
No chemotherapy	3/69 (4,3)	2/81 (2,5)	1,76 [0,30; 10,24] 0,5287[2]	1,80 [0,29; 11,07] 0,6617[4]	1,9 [-4,0; 7,8] 0,6617[4]
Region (Interaction p-value: 0,9637)					
North America / Europe	26/678 (3,8)	33/649 (5,1)	0,75 [0,46; 1,25] 0,2712[2]	0,74 [0,44; 1,26] 0,2695[3]	-1,2 [-3,5; 1,0] 0,2695[3]
Asia	0/203 (0,0)	5/201 (2,5)	0,09 [0,01; 1,62] 0,1023[2]	0,09 [0,00; 1,60] 0,0297[4]	-2,5 [-4,6; -0,3] 0,0297[4]
Other	11/402 (2,7)	17/414 (4,1)	0,67 [0,32; 1,40] 0,2862[2]	0,66 [0,30; 1,42] 0,2825[3]	-1,4 [-3,9; 1,1] 0,2825[3]
Primary tumor size (Interaction p-value: 0,9666)					
< 20 mm	11/331 (3,3)	16/334 (4,8)	0,69 [0,33; 1,47] 0,3409[2]	0,68 [0,31; 1,50] 0,3378[3]	-1,5 [-4,5; 1,5] 0,3378[3]
≥ 20 but < 50 mm	18/646 (2,8)	26/653 (4,0)	0,70 [0,39; 1,26] 0,2365[2]	0,69 [0,38; 1,27] 0,2338[3]	-1,2 [-3,2; 0,8] 0,2338[3]
≥ 50 mm	8/289 (2,8)	12/265 (4,5)	0,61 [0,25; 1,47] 0,2724[2]	0,60 [0,24; 1,49] 0,2673[3]	-1,8 [-4,9; 1,4] 0,2673[3]
Number of positive lymph nodes (Interaction p-value: 0,2018)					
0-3	16/427 (3,7)	15/418 (3,6)	1,04 [0,52; 2,08] 0,9024[2]	1,05 [0,51; 2,14] 0,9024[3]	0,2 [-2,4; 2,7] 0,9024[3]
4-9	13/549 (2,4)	29/542 (5,4)	0,44 [0,23; 0,84] 0,0130[2]	0,43 [0,22; 0,83] 0,0105[3]	-3,0 [-5,3; -0,7] 0,0105[3]
≥ 10	8/307 (2,6)	11/304 (3,6)	0,72 [0,29; 1,77] 0,4731[2]	0,71 [0,28; 1,80] 0,4709[3]	-1,0 [-3,8; 1,7] 0,4709[3]
Tumor stage (Interaction p-value: 0,6017)					
IIA	4/113 (3,5)	4/114 (3,5)	1,01 [0,26; 3,94] 0,9899[2]	1,01 [0,25; 4,14] 1,0000[4]	0,0 [-4,8; 4,8] 1,0000[4]
IIB	5/151 (3,3)	3/136 (2,2)	1,50 [0,37; 6,16] 0,5730[2]	1,52 [0,36; 6,48] 0,7258[4]	1,1 [-2,7; 4,9] 0,7258[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	13/495 (2,6)	27/488 (5,5)	0,47 [0,25; 0,91] 0,0246[2]	0,46 [0,23; 0,90] 0,0211[3]	-2,9 [-5,4; -0,4] 0,0211[3]
IIIB	1/54 (1,9)	1/45 (2,2)	0,83 [0,05; 12,95] 0,8964[2]	0,83 [0,05; 13,66] 1,0000[4]	-0,4 [-6,0; 5,2] 1,0000[4]
IIIC	14/468 (3,0)	20/479 (4,2)	0,72 [0,37; 1,40] 0,3301[2]	0,71 [0,35; 1,42] 0,3275[3]	-1,2 [-3,5; 1,2] 0,3275[3]
Race (Interaction p-value: 0,3935)					
White	35/958 (3,7)	46/943 (4,9)	0,75 [0,49; 1,15] 0,1880[2]	0,74 [0,47; 1,16] 0,1863[3]	-1,2 [-3,0; 0,6] 0,1863[3]
Asian	1/250 (0,4)	5/242 (2,1)	0,19 [0,02; 1,65] 0,1326[2]	0,19 [0,02; 1,64] 0,1172[4]	-1,7 [-3,6; 0,3] 0,1172[4]
Other	1/62 (1,6)	3/64 (4,7)	0,34 [0,04; 3,22] 0,3497[2]	0,33 [0,03; 3,29] 0,6191[4]	-3,1 [-9,1; 3,0] 0,6191[4]
First endocrine therapy (Interaction p-value: 0,2940)					
Tamoxifen	6/114 (5,3)	6/132 (4,5)	1,16 [0,38; 3,49] 0,7946[2]	1,17 [0,37; 3,72] 0,7944[3]	0,7 [-4,7; 6,1] 0,7944[3]
Aromatase inhibitor	31/1169 (2,7)	49/1132 (4,3)	0,61 [0,39; 0,95] 0,0299[2]	0,60 [0,38; 0,95] 0,0282[3]	-1,7 [-3,2; -0,2] 0,0282[3]
ECOG-PS (Interaction p-value: 0,3875)					
ECOG-PS 0	33/1070 (3,1)	44/1019 (4,3)	0,71 [0,46; 1,11] 0,1366[2]	0,71 [0,45; 1,12] 0,1346[3]	-1,2 [-2,9; 0,4] 0,1346[3]
ECOG-PS 1	4/213 (1,9)	11/245 (4,5)	0,42 [0,14; 1,29] 0,1304[2]	0,41 [0,13; 1,30] 0,1173[3]	-2,6 [-5,8; 0,6] 0,1173[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 308.1.2: Subgroups - adverse events according PT Arthralgia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7570)					
< 65 years	246/918 (26,8)	364/936 (38,9)	0,69 [0,60; 0,79] <,0001[2]	0,58 [0,47; 0,70] <,0001[3]	-12,1 [-16,3; -7,9] <,0001[3]
≥ 65 years	98/365 (26,8)	133/328 (40,5)	0,66 [0,53; 0,82] 0,0002[2]	0,54 [0,39; 0,74] 0,0001[3]	-13,7 [-20,7; -6,7] 0,0001[3]
Prior treatment (Interaction p-value: 0,6455)					
Neoadjuvant chemotherapy	121/430 (28,1)	161/415 (38,8)	0,73 [0,60; 0,88] 0,0011[2]	0,62 [0,46; 0,82] 0,0010[3]	-10,7 [-17,0; -4,3] 0,0010[3]
Adjuvant chemotherapy	213/784 (27,2)	315/768 (41,0)	0,66 [0,57; 0,76] <,0001[2]	0,54 [0,43; 0,66] <,0001[3]	-13,8 [-18,5; -9,2] <,0001[3]
No chemotherapy	10/69 (14,5)	21/81 (25,9)	0,56 [0,28; 1,10] 0,0942[2]	0,48 [0,21; 1,12] 0,0848[3]	-11,4 [-24,1; 1,2] 0,0848[3]
Region (Interaction p-value: 0,7911)					
North America / Europe	232/678 (34,2)	319/649 (49,2)	0,70 [0,61; 0,79] <,0001[2]	0,54 [0,43; 0,67] <,0001[3]	-14,9 [-20,2; -9,7] <,0001[3]
Asia	39/203 (19,2)	61/201 (30,3)	0,63 [0,45; 0,90] 0,0108[2]	0,55 [0,34; 0,87] 0,0095[3]	-11,1 [-19,5; -2,8] 0,0095[3]
Other	73/402 (18,2)	117/414 (28,3)	0,64 [0,50; 0,83] 0,0008[2]	0,56 [0,40; 0,78] 0,0006[3]	-10,1 [-15,8; -4,4] 0,0006[3]
Primary tumor size (Interaction p-value: 0,9249)					
< 20 mm	91/331 (27,5)	134/334 (40,1)	0,69 [0,55; 0,85] 0,0007[2]	0,57 [0,41; 0,78] 0,0006[3]	-12,6 [-19,8; -5,5] 0,0006[3]
≥ 20 but < 50 mm	163/646 (25,2)	241/653 (36,9)	0,68 [0,58; 0,81] <,0001[2]	0,58 [0,45; 0,73] <,0001[3]	-11,7 [-16,7; -6,7] <,0001[3]
≥ 50 mm	85/289 (29,4)	120/265 (45,3)	0,65 [0,52; 0,81] 0,0001[2]	0,50 [0,35; 0,71] 0,0001[3]	-15,9 [-23,8; -7,9] 0,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,2323)					
0-3	130/427 (30,4)	175/418 (41,9)	0,73 [0,61; 0,87] 0,0006[2]	0,61 [0,46; 0,81] 0,0005[3]	-11,4 [-17,9; -5,0] 0,0005[3]
4-9	151/549 (27,5)	210/542 (38,7)	0,71 [0,60; 0,84] <,0001[2]	0,60 [0,46; 0,77] <,0001[3]	-11,2 [-16,8; -5,7] <,0001[3]
≥ 10	63/307 (20,5)	112/304 (36,8)	0,56 [0,43; 0,73] <,0001[2]	0,44 [0,31; 0,64] <,0001[3]	-16,3 [-23,4; -9,3] <,0001[3]
Tumor stage (Interaction p-value: 0,7008)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	35/113 (31,0)	46/114 (40,4)	0,77 [0,54; 1,09] 0,1435[2]	0,66 [0,38; 1,15] 0,1403[3]	-9,4 [-21,8; 3,0] 0,1403[3]
IIB	44/151 (29,1)	57/136 (41,9)	0,70 [0,51; 0,96] 0,0250[2]	0,57 [0,35; 0,93] 0,0237[3]	-12,8 [-23,8; -1,8] 0,0237[3]
IIIA	138/495 (27,9)	188/488 (38,5)	0,72 [0,60; 0,87] 0,0004[2]	0,62 [0,47; 0,81] 0,0004[3]	-10,6 [-16,5; -4,8] 0,0004[3]
IIIB	15/54 (27,8)	19/45 (42,2)	0,66 [0,38; 1,14] 0,1352[2]	0,53 [0,23; 1,22] 0,1318[3]	-14,4 [-33,2; 4,3] 0,1318[3]
IIIC	111/468 (23,7)	187/479 (39,0)	0,61 [0,50; 0,74] <,0001[2]	0,49 [0,37; 0,64] <,0001[3]	-15,3 [-21,1; -9,5] <,0001[3]
Tumor grade (Interaction p-value: 0,3195)					
G1	27/91 (29,7)	32/93 (34,4)	0,86 [0,56; 1,32] 0,4922[2]	0,80 [0,43; 1,50] 0,4911[3]	-4,7 [-18,2; 8,7] 0,4911[3]
G2	161/612 (26,3)	244/602 (40,5)	0,65 [0,55; 0,76] <,0001[2]	0,52 [0,41; 0,67] <,0001[3]	-14,2 [-19,5; -9,0] <,0001[3]
G3	142/527 (26,9)	207/506 (40,9)	0,66 [0,55; 0,78] <,0001[2]	0,53 [0,41; 0,69] <,0001[3]	-14,0 [-19,7; -8,2] <,0001[3]
GX	13/51 (25,5)	14/59 (23,7)	1,07 [0,56; 2,07] 0,8304[2]	1,10 [0,46; 2,62] 0,8305[3]	1,8 [-14,4; 17,9] 0,8305[3]
Progesterone receptor status (Interaction p-value: 0,4111)					
Negative	44/156 (28,2)	61/169 (36,1)	0,78 [0,57; 1,08] 0,1319[2]	0,70 [0,44; 1,11] 0,1286[3]	-7,9 [-18,0; 2,2] 0,1286[3]
Positive	286/1089 (26,3)	418/1066 (39,2)	0,67 [0,59; 0,76] <,0001[2]	0,55 [0,46; 0,66] <,0001[3]	-12,9 [-16,9; -9,0] <,0001[3]
Unknown	4/10 (40,0)	2/7 (28,6)	1,40 [0,35; 5,65] 0,6366[2]	1,67 [0,21; 13,22] 1,0000[4]	11,4 [-33,8; 56,6] 1,0000[4]
Race (Interaction p-value: 0,9736)					
White	278/958 (29,0)	397/943 (42,1)	0,69 [0,61; 0,78] <,0001[2]	0,56 [0,46; 0,68] <,0001[3]	-13,1 [-17,3; -8,8] <,0001[3]
Asian	47/250 (18,8)	68/242 (28,1)	0,67 [0,48; 0,93] 0,0160[2]	0,59 [0,39; 0,90] 0,0148[3]	-9,3 [-16,8; -1,8] 0,0148[3]
Other	16/62 (25,8)	23/64 (35,9)	0,72 [0,42; 1,22] 0,2242[2]	0,62 [0,29; 1,33] 0,2188[3]	-10,1 [-26,2; 5,9] 0,2188[3]
First endocrine therapy (Interaction p-value: 0,2590)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	21/114 (18,4)	27/132 (20,5)	0,90 [0,54; 1,50] 0,6887[2]	0,88 [0,47; 1,66] 0,6882[3]	-2,0 [-11,9; 7,9] 0,6882[3]
Aromatase inhibitor	323/1169 (27,6)	470/1132 (41,5)	0,67 [0,59; 0,75] <,0001[2]	0,54 [0,45; 0,64] <,0001[3]	-13,9 [-17,7; -10,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,8579)					
ECOG-PS 0	289/1070 (27,0)	402/1019 (39,5)	0,68 [0,60; 0,78] <,0001[2]	0,57 [0,47; 0,68] <,0001[3]	-12,4 [-16,5; -8,4] <,0001[3]
ECOG-PS 1	55/213 (25,8)	95/245 (38,8)	0,67 [0,50; 0,88] 0,0040[2]	0,55 [0,37; 0,82] 0,0032[3]	-13,0 [-21,4; -4,5] 0,0032[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 309.1.2: Subgroups - adverse events according PT Aspartate aminotransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,6289)					
< 65 years	110/918 (12,0)	52/936 (5,6)	2,16 [1,57; 2,96] <,0001[2]	2,31 [1,64; 3,26] <,0001[3]	6,4 [3,9; 9,0] <,0001[3]
≥ 65 years	37/365 (10,1)	13/328 (4,0)	2,56 [1,38; 4,73] 0,0027[2]	2,73 [1,43; 5,24] 0,0017[3]	6,2 [2,4; 9,9] 0,0017[3]
Prior treatment (Interaction p-value: 0,2937)					
Neoadjuvant chemotherapy	59/430 (13,7)	22/415 (5,3)	2,59 [1,62; 4,14] <,0001[2]	2,84 [1,71; 4,73] <,0001[3]	8,4 [4,5; 12,3] <,0001[3]
Adjuvant chemotherapy	79/784 (10,1)	41/768 (5,3)	1,89 [1,31; 2,72] 0,0006[2]	1,99 [1,34; 2,94] 0,0005[3]	4,7 [2,1; 7,4] 0,0005[3]
No chemotherapy	9/69 (13,0)	2/81 (2,5)	5,28 [1,18; 23,63] 0,0294[2]	5,93 [1,23; 28,44] 0,0133[3]	10,6 [1,9; 19,2] 0,0133[3]
Region (Interaction p-value: 0,3038)					
North America / Europe	51/678 (7,5)	21/649 (3,2)	2,32 [1,41; 3,82] 0,0009[2]	2,43 [1,45; 4,09] 0,0006[3]	4,3 [1,9; 6,7] 0,0006[3]
Asia	44/203 (21,7)	14/201 (7,0)	3,11 [1,76; 5,50] <,0001[2]	3,70 [1,95; 6,99] <,0001[3]	14,7 [8,0; 21,4] <,0001[3]
Other	52/402 (12,9)	30/414 (7,2)	1,79 [1,16; 2,74] 0,0079[2]	1,90 [1,19; 3,05] 0,0069[3]	5,7 [1,6; 9,8] 0,0069[3]
Primary tumor size (Interaction p-value: 0,6069)					
< 20 mm	40/331 (12,1)	18/334 (5,4)	2,24 [1,31; 3,83] 0,0031[2]	2,41 [1,35; 4,30] 0,0022[3]	6,7 [2,4; 11,0] 0,0022[3]
≥ 20 but < 50 mm	70/646 (10,8)	35/653 (5,4)	2,02 [1,37; 2,99] 0,0004[2]	2,15 [1,41; 3,27] 0,0003[3]	5,5 [2,5; 8,4] 0,0003[3]
≥ 50 mm	33/289 (11,4)	10/265 (3,8)	3,03 [1,52; 6,02] 0,0016[2]	3,29 [1,59; 6,81] 0,0008[3]	7,6 [3,3; 12,0] 0,0008[3]
Number of positive lymph nodes (Interaction p-value: 0,3268)					
0-3	48/427 (11,2)	17/418 (4,1)	2,76 [1,62; 4,73] 0,0002[2]	2,99 [1,69; 5,29] <,0001[3]	7,2 [3,6; 10,7] <,0001[3]
4-9	65/549 (11,8)	27/542 (5,0)	2,38 [1,54; 3,66] <,0001[2]	2,56 [1,61; 4,08] <,0001[3]	6,9 [3,6; 10,1] <,0001[3]
≥ 10	34/307 (11,1)	21/304 (6,9)	1,60 [0,95; 2,70] 0,0754[2]	1,68 [0,95; 2,96] 0,0720[3]	4,2 [-0,4; 8,7] 0,0720[3]
Tumor stage (Interaction p-value: 0,9973)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	17/113 (15,0)	8/114 (7,0)	2,14 [0,96; 4,77] 0,0614[2]	2,35 [0,97; 5,68] 0,0534[3]	8,0 [-0,1; 16,1] 0,0534[3]
IIB	11/151 (7,3)	5/136 (3,7)	1,98 [0,71; 5,56] 0,1938[2]	2,06 [0,70; 6,08] 0,1834[3]	3,6 [-1,6; 8,8] 0,1834[3]
IIIA	64/495 (12,9)	28/488 (5,7)	2,25 [1,47; 3,45] 0,0002[2]	2,44 [1,54; 3,88] 0,0001[3]	7,2 [3,6; 10,8] 0,0001[3]
IIIB	7/54 (13,0)	0/45 (0,0)	12,55 [0,74; 213,82] 0,0804[2]	14,37 [0,80; 258,91] 0,0149[4]	13,0 [4,0; 21,9] 0,0149[4]
IIIC	47/468 (10,0)	24/479 (5,0)	2,00 [1,25; 3,22] 0,0041[2]	2,12 [1,27; 3,52] 0,0033[3]	5,0 [1,7; 8,4] 0,0033[3]
Tumor grade (Interaction p-value: 0,2171)					
G1	9/91 (9,9)	1/93 (1,1)	9,20 [1,19; 71,14] 0,0335[2]	10,10 [1,25; 81,42] 0,0091[4]	8,8 [2,3; 15,3] 0,0091[4]
G2	63/612 (10,3)	36/602 (6,0)	1,72 [1,16; 2,55] 0,0069[2]	1,80 [1,18; 2,76] 0,0060[3]	4,3 [1,3; 7,4] 0,0060[3]
G3	64/527 (12,1)	22/506 (4,3)	2,79 [1,75; 4,46] <,0001[2]	3,04 [1,84; 5,02] <,0001[3]	7,8 [4,5; 11,1] <,0001[3]
GX	11/51 (21,6)	5/59 (8,5)	2,55 [0,95; 6,84] 0,0640[2]	2,97 [0,96; 9,23] 0,0521[3]	13,1 [-0,2; 26,4] 0,0521[3]
Progesterone receptor status (Interaction p-value: 0,5767)					
Negative	19/156 (12,2)	11/169 (6,5)	1,87 [0,92; 3,81] 0,0837[2]	1,99 [0,92; 4,33] 0,0777[3]	5,7 [-0,7; 12,0] 0,0777[3]
Positive	127/1089 (11,7)	53/1066 (5,0)	2,35 [1,72; 3,20] <,0001[2]	2,52 [1,81; 3,52] <,0001[3]	6,7 [4,4; 9,0] <,0001[3]
Unknown	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Race (Interaction p-value: 0,5151)					
White	94/958 (9,8)	46/943 (4,9)	2,01 [1,43; 2,83] <,0001[2]	2,12 [1,47; 3,06] <,0001[3]	4,9 [2,6; 7,3] <,0001[3]
Asian	45/250 (18,0)	15/242 (6,2)	2,90 [1,66; 5,07] 0,0002[2]	3,32 [1,80; 6,14] <,0001[3]	11,8 [6,2; 17,5] <,0001[3]
Other	7/62 (11,3)	4/64 (6,3)	1,81 [0,56; 5,87] 0,3251[2]	1,91 [0,53; 6,88] 0,3163[3]	5,0 [-4,8; 14,9] 0,3163[3]
First endocrine therapy (Interaction p-value: 0,9436)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	6/114 (5,3)	3/132 (2,3)	2,32 [0,59; 9,05] 0,2272[2]	2,39 [0,58; 9,78] 0,3097[4]	3,0 [-1,8; 7,8] 0,3097[4]
Aromatase inhibitor	141/1169 (12,1)	62/1132 (5,5)	2,20 [1,65; 2,94] <,0001[2]	2,37 [1,73; 3,23] <,0001[3]	6,6 [4,3; 8,9] <,0001[3]
ECOG-PS (Interaction p-value: 0,5640)					
ECOG-PS 0	126/1070 (11,8)	52/1019 (5,1)	2,31 [1,69; 3,15] <,0001[2]	2,48 [1,78; 3,47] <,0001[3]	6,7 [4,3; 9,0] <,0001[3]
ECOG-PS 1	21/213 (9,9)	13/245 (5,3)	1,86 [0,95; 3,62] 0,0686[2]	1,95 [0,95; 4,00] 0,0638[3]	4,6 [-0,3; 9,4] 0,0638[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 310.1.2: Subgroups - adverse events according PT Asthenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5200)					
< 65 years	101/918 (11,0)	52/936 (5,6)	1,98 [1,44; 2,73] <,0001[2]	2,10 [1,48; 2,98] <,0001[3]	5,4 [2,9; 7,9] <,0001[3]
≥ 65 years	46/365 (12,6)	17/328 (5,2)	2,43 [1,42; 4,16] 0,0012[2]	2,64 [1,48; 4,70] 0,0007[3]	7,4 [3,3; 11,6] 0,0007[3]
Prior treatment (Interaction p-value: 0,4313)					
Neoadjuvant chemotherapy	54/430 (12,6)	19/415 (4,6)	2,74 [1,66; 4,55] <,0001[2]	2,99 [1,74; 5,14] <,0001[3]	8,0 [4,3; 11,7] <,0001[3]
Adjuvant chemotherapy	86/784 (11,0)	45/768 (5,9)	1,87 [1,32; 2,65] 0,0004[2]	1,98 [1,36; 2,88] 0,0003[3]	5,1 [2,4; 7,9] 0,0003[3]
No chemotherapy	7/69 (10,1)	5/81 (6,2)	1,64 [0,55; 4,95] 0,3768[2]	1,72 [0,52; 5,67] 0,3715[3]	4,0 [-4,9; 12,8] 0,3715[3]
Region (Interaction p-value: 0,5850)					
North America / Europe	82/678 (12,1)	43/649 (6,6)	1,83 [1,28; 2,60] 0,0008[2]	1,94 [1,32; 2,85] 0,0007[3]	5,5 [2,4; 8,6] 0,0007[3]
Asia	3/203 (1,5)	0/201 (0,0)	6,93 [0,36; 133,33] 0,1994[2]	7,03 [0,36; 137,07] 0,2482[4]	1,5 [-0,2; 3,1] 0,2482[4]
Other	62/402 (15,4)	26/414 (6,3)	2,46 [1,59; 3,80] <,0001[2]	2,72 [1,68; 4,40] <,0001[3]	9,1 [4,9; 13,4] <,0001[3]
Primary tumor size (Interaction p-value: 0,3605)					
< 20 mm	39/331 (11,8)	13/334 (3,9)	3,03 [1,65; 5,57] 0,0004[2]	3,30 [1,73; 6,30] 0,0002[3]	7,9 [3,8; 11,9] 0,0002[3]
≥ 20 but < 50 mm	79/646 (12,2)	44/653 (6,7)	1,81 [1,28; 2,58] 0,0009[2]	1,93 [1,31; 2,84] 0,0007[3]	5,5 [2,3; 8,7] 0,0007[3]
≥ 50 mm	26/289 (9,0)	12/265 (4,5)	1,99 [1,02; 3,86] 0,0425[2]	2,08 [1,03; 4,22] 0,0377[3]	4,5 [0,3; 8,6] 0,0377[3]
Number of positive lymph nodes (Interaction p-value: 0,7582)					
0-3	50/427 (11,7)	26/418 (6,2)	1,88 [1,20; 2,97] 0,0063[2]	2,00 [1,22; 3,28] 0,0053[3]	5,5 [1,7; 9,3] 0,0053[3]
4-9	67/549 (12,2)	28/542 (5,2)	2,36 [1,54; 3,61] <,0001[2]	2,55 [1,61; 4,03] <,0001[3]	7,0 [3,7; 10,3] <,0001[3]
≥ 10	30/307 (9,8)	15/304 (4,9)	1,98 [1,09; 3,61] 0,0254[2]	2,09 [1,10; 3,96] 0,0221[3]	4,8 [0,7; 9,0] 0,0221[3]
Tumor stage (Interaction p-value: 0,7770)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	13/113 (11,5)	6/114 (5,3)	2,19 [0,86; 5,55] 0,1000[2]	2,34 [0,86; 6,39] 0,0896[3]	6,2 [-0,9; 13,4] 0,0896[3]
IIB	16/151 (10,6)	8/136 (5,9)	1,80 [0,80; 4,08] 0,1577[2]	1,90 [0,78; 4,58] 0,1498[3]	4,7 [-1,6; 11,0] 0,1498[3]
IIIA	65/495 (13,1)	25/488 (5,1)	2,56 [1,64; 4,00] <,0001[2]	2,80 [1,73; 4,52] <,0001[3]	8,0 [4,4; 11,6] <,0001[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	50/468 (10,7)	30/479 (6,3)	1,71 [1,10; 2,63] 0,0160[2]	1,79 [1,12; 2,87] 0,0145[3]	4,4 [0,9; 8,0] 0,0145[3]
Tumor grade (Interaction p-value: 0,6557)					
G1	10/91 (11,0)	7/93 (7,5)	1,46 [0,58; 3,67] 0,4210[2]	1,52 [0,55; 4,17] 0,4175[3]	3,5 [-4,9; 11,8] 0,4175[3]
G2	73/612 (11,9)	30/602 (5,0)	2,39 [1,59; 3,61] <,0001[2]	2,58 [1,66; 4,01] <,0001[3]	6,9 [3,8; 10,0] <,0001[3]
G3	58/527 (11,0)	32/506 (6,3)	1,74 [1,15; 2,63] 0,0087[2]	1,83 [1,17; 2,87] 0,0076[3]	4,7 [1,3; 8,1] 0,0076[3]
GX	5/51 (9,8)	0/59 (0,0)	12,69 [0,72; 224,11] 0,0828[2]	14,08 [0,76; 261,07] 0,0192[4]	9,8 [1,6; 18,0] 0,0192[4]
Race (Interaction p-value: 0,7393)					
White	136/958 (14,2)	62/943 (6,6)	2,16 [1,62; 2,88] <,0001[2]	2,35 [1,72; 3,22] <,0001[3]	7,6 [4,9; 10,3] <,0001[3]
Asian	5/250 (2,0)	0/242 (0,0)	10,65 [0,59; 191,56] 0,1086[2]	10,87 [0,60; 197,57] 0,0614[4]	2,0 [0,3; 3,7] 0,0614[4]
Other	5/62 (8,1)	4/64 (6,3)	1,29 [0,36; 4,58] 0,6935[2]	1,32 [0,34; 5,15] 0,7417[4]	1,8 [-7,2; 10,8] 0,7417[4]
First endocrine therapy (Interaction p-value: 0,6054)					
Tamoxifen	10/114 (8,8)	7/132 (5,3)	1,65 [0,65; 4,20] 0,2903[2]	1,72 [0,63; 4,67] 0,2848[3]	3,5 [-3,0; 9,9] 0,2848[3]
Aromatase inhibitor	137/1169 (11,7)	62/1132 (5,5)	2,14 [1,60; 2,86] <,0001[2]	2,29 [1,68; 3,13] <,0001[3]	6,2 [4,0; 8,5] <,0001[3]
ECOG-PS (Interaction p-value: 0,8689)					
ECOG-PS 0	124/1070 (11,6)	57/1019 (5,6)	2,07 [1,53; 2,80] <,0001[2]	2,21 [1,60; 3,07] <,0001[3]	6,0 [3,6; 8,4] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	23/213 (10,8)	12/245 (4,9)	2,20 [1,12; 4,32] 0,0214[2]	2,35 [1,14; 4,85] 0,0178[3]	5,9 [0,9; 10,9] 0,0178[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 311.1.2: Subgroups - adverse events according PT Back pain from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,3546)					
< 65 years	89/918 (9,7)	111/936 (11,9)	0,82 [0,63; 1,06] 0,1341[2]	0,80 [0,59; 1,07] 0,1332[3]	-2,2 [-5,0; 0,7] 0,1332[3]
≥ 65 years	26/365 (7,1)	37/328 (11,3)	0,63 [0,39; 1,02] 0,0599[2]	0,60 [0,36; 1,02] 0,0573[3]	-4,2 [-8,5; 0,2] 0,0573[3]
Prior treatment (Interaction p-value: 0,6229)					
Neoadjuvant chemotherapy	40/430 (9,3)	44/415 (10,6)	0,88 [0,58; 1,32] 0,5281[2]	0,86 [0,55; 1,36] 0,5278[3]	-1,3 [-5,3; 2,7] 0,5278[3]
Adjuvant chemotherapy	72/784 (9,2)	97/768 (12,6)	0,73 [0,55; 0,97] 0,0302[2]	0,70 [0,51; 0,97] 0,0293[3]	-3,4 [-6,5; -0,3] 0,0293[3]
No chemotherapy	3/69 (4,3)	7/81 (8,6)	0,50 [0,14; 1,87] 0,3055[2]	0,48 [0,12; 1,93] 0,3434[4]	-4,3 [-12,1; 3,5] 0,3434[4]
Region (Interaction p-value: 0,5465)					
North America / Europe	82/678 (12,1)	97/649 (14,9)	0,81 [0,62; 1,06] 0,1294[2]	0,78 [0,57; 1,07] 0,1285[3]	-2,9 [-6,5; 0,8] 0,1285[3]
Asia	10/203 (4,9)	19/201 (9,5)	0,52 [0,25; 1,09] 0,0845[2]	0,50 [0,22; 1,10] 0,0780[3]	-4,5 [-9,5; 0,5] 0,0780[3]
Other	23/402 (5,7)	32/414 (7,7)	0,74 [0,44; 1,24] 0,2549[2]	0,72 [0,42; 1,26] 0,2527[3]	-2,0 [-5,4; 1,4] 0,2527[3]
Primary tumor size (Interaction p-value: 0,8443)					
< 20 mm	28/331 (8,5)	34/334 (10,2)	0,83 [0,52; 1,34] 0,4464[2]	0,82 [0,48; 1,38] 0,4455[3]	-1,7 [-6,1; 2,7] 0,4455[3]
≥ 20 but < 50 mm	56/646 (8,7)	79/653 (12,1)	0,72 [0,52; 0,99] 0,0442[2]	0,69 [0,48; 0,99] 0,0429[3]	-3,4 [-6,7; -0,1] 0,0429[3]
≥ 50 mm	31/289 (10,7)	35/265 (13,2)	0,81 [0,52; 1,28] 0,3688[2]	0,79 [0,47; 1,32] 0,3679[3]	-2,5 [-7,9; 2,9] 0,3679[3]
Number of positive lymph nodes (Interaction p-value: 0,0847)					
0-3	52/427 (12,2)	48/418 (11,5)	1,06 [0,73; 1,53] 0,7547[2]	1,07 [0,70; 1,62] 0,7546[3]	0,7 [-3,7; 5,0] 0,7546[3]
4-9	38/549 (6,9)	63/542 (11,6)	0,60 [0,41; 0,87] 0,0083[2]	0,57 [0,37; 0,86] 0,0074[3]	-4,7 [-8,1; -1,3] 0,0074[3]
≥ 10	25/307 (8,1)	37/304 (12,2)	0,67 [0,41; 1,08] 0,1022[2]	0,64 [0,37; 1,09] 0,0992[3]	-4,0 [-8,8; 0,8] 0,0992[3]
Tumor stage (Interaction p-value: 0,1205)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	18/113 (15,9)	9/114 (7,9)	2,02 [0,95; 4,30] 0,0690[2]	2,21 [0,95; 5,16] 0,0615[3]	8,0 [-0,3; 16,4] 0,0615[3]
IIB	16/151 (10,6)	19/136 (14,0)	0,76 [0,41; 1,41] 0,3847[2]	0,73 [0,36; 1,48] 0,3830[3]	-3,4 [-11,0; 4,2] 0,3830[3]
IIIA	40/495 (8,1)	58/488 (11,9)	0,68 [0,46; 1,00] 0,0483[2]	0,65 [0,43; 1,00] 0,0465[3]	-3,8 [-7,5; -0,1] 0,0465[3]
IIIB	4/54 (7,4)	4/45 (8,9)	0,83 [0,22; 3,15] 0,7879[2]	0,82 [0,19; 3,48] 1,0000[4]	-1,5 [-12,3; 9,4] 1,0000[4]
IIIC	37/468 (7,9)	58/479 (12,1)	0,65 [0,44; 0,97] 0,0331[2]	0,62 [0,40; 0,96] 0,0314[3]	-4,2 [-8,0; -0,4] 0,0314[3]
Tumor grade (Interaction p-value: 0,4024)					
G1	5/91 (5,5)	14/93 (15,1)	0,36 [0,14; 0,97] 0,0437[2]	0,33 [0,11; 0,95] 0,0331[3]	-9,6 [-18,2; -0,9] 0,0331[3]
G2	52/612 (8,5)	65/602 (10,8)	0,79 [0,56; 1,11] 0,1757[2]	0,77 [0,52; 1,13] 0,1744[3]	-2,3 [-5,6; 1,0] 0,1744[3]
G3	51/527 (9,7)	62/506 (12,3)	0,79 [0,56; 1,12] 0,1862[2]	0,77 [0,52; 1,14] 0,1849[3]	-2,6 [-6,4; 1,2] 0,1849[3]
GX	7/51 (13,7)	7/59 (11,9)	1,16 [0,43; 3,08] 0,7704[2]	1,18 [0,38; 3,63] 0,7702[3]	1,9 [-10,7; 14,4] 0,7702[3]
Progesterone receptor status (Interaction p-value: 0,7913)					
Negative	19/156 (12,2)	22/169 (13,0)	0,94 [0,53; 1,66] 0,8202[2]	0,93 [0,48; 1,79] 0,8201[3]	-0,8 [-8,1; 6,4] 0,8201[3]
Positive	93/1089 (8,5)	121/1066 (11,4)	0,75 [0,58; 0,97] 0,0299[2]	0,73 [0,55; 0,97] 0,0292[3]	-2,8 [-5,3; -0,3] 0,0292[3]
Unknown	1/10 (10,0)	1/7 (14,3)	0,70 [0,05; 9,41] 0,7879[2]	0,67 [0,03; 12,84] 1,0000[4]	-4,3 [-36,2; 27,6] 1,0000[4]
Race (Interaction p-value: 0,8310)					
White	95/958 (9,9)	124/943 (13,1)	0,75 [0,59; 0,97] 0,0280[2]	0,73 [0,55; 0,97] 0,0273[3]	-3,2 [-6,1; -0,4] 0,0273[3]
Asian	13/250 (5,2)	18/242 (7,4)	0,70 [0,35; 1,40] 0,3101[2]	0,68 [0,33; 1,43] 0,3071[3]	-2,2 [-6,5; 2,1] 0,3071[3]
Other	6/62 (9,7)	6/64 (9,4)	1,03 [0,35; 3,03] 0,9539[2]	1,04 [0,32; 3,40] 0,9539[3]	0,3 [-10,0; 10,6] 0,9539[3]
First endocrine therapy (Interaction p-value: 0,9770)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	8/114 (7,0)	12/132 (9,1)	0,77 [0,33; 1,82] 0,5547[2]	0,75 [0,30; 1,92] 0,5529[3]	-2,1 [-8,9; 4,7] 0,5529[3]
Aromatase inhibitor	107/1169 (9,2)	136/1132 (12,0)	0,76 [0,60; 0,97] 0,0262[2]	0,74 [0,56; 0,96] 0,0256[3]	-2,9 [-5,4; -0,3] 0,0256[3]
ECOG-PS (Interaction p-value: 0,2169)					
ECOG-PS 0	97/1070 (9,1)	129/1019 (12,7)	0,72 [0,56; 0,92] 0,0086[2]	0,69 [0,52; 0,91] 0,0082[3]	-3,6 [-6,3; -0,9] 0,0082[3]
ECOG-PS 1	18/213 (8,5)	19/245 (7,8)	1,09 [0,59; 2,02] 0,7853[2]	1,10 [0,56; 2,15] 0,7853[3]	0,7 [-4,3; 5,7] 0,7853[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 312.1.2: Subgroups - adverse events according PT Blood alkaline phosphatase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5976)					
< 65 years	42/918 (4,6)	26/936 (2,8)	1,65 [1,02; 2,66] 0,0418[2]	1,68 [1,02; 2,76] 0,0395[3]	1,8 [0,1; 3,5] 0,0395[3]
≥ 65 years	19/365 (5,2)	13/328 (4,0)	1,31 [0,66; 2,62] 0,4384[2]	1,33 [0,65; 2,74] 0,4366[3]	1,2 [-1,9; 4,3] 0,4366[3]
Prior treatment (Interaction p-value: 0,8767)					
Neoadjuvant chemotherapy	25/430 (5,8)	16/415 (3,9)	1,51 [0,82; 2,78] 0,1889[2]	1,54 [0,81; 2,93] 0,1853[3]	2,0 [-0,9; 4,8] 0,1853[3]
Adjuvant chemotherapy	32/784 (4,1)	21/768 (2,7)	1,49 [0,87; 2,56] 0,1470[2]	1,51 [0,86; 2,65] 0,1440[3]	1,3 [-0,5; 3,1] 0,1440[3]
No chemotherapy	4/69 (5,8)	2/81 (2,5)	2,35 [0,44; 12,43] 0,3155[2]	2,43 [0,43; 13,69] 0,4143[4]	3,3 [-3,1; 9,8] 0,4143[4]
Region (Interaction p-value: 0,5048)					
North America / Europe	17/678 (2,5)	14/649 (2,2)	1,16 [0,58; 2,34] 0,6732[2]	1,17 [0,57; 2,39] 0,6729[3]	0,4 [-1,3; 2,0] 0,6729[3]
Asia	12/203 (5,9)	5/201 (2,5)	2,38 [0,85; 6,62] 0,0979[2]	2,46 [0,85; 7,12] 0,0866[3]	3,4 [-0,5; 7,3] 0,0866[3]
Other	32/402 (8,0)	20/414 (4,8)	1,65 [0,96; 2,83] 0,0707[2]	1,70 [0,96; 3,03] 0,0673[3]	3,1 [-0,2; 6,5] 0,0673[3]
Primary tumor size (Interaction p-value: 0,5358)					
< 20 mm	11/331 (3,3)	10/334 (3,0)	1,11 [0,48; 2,58] 0,8083[2]	1,11 [0,47; 2,66] 0,8082[3]	0,3 [-2,3; 3,0] 0,8082[3]
≥ 20 but < 50 mm	36/646 (5,6)	19/653 (2,9)	1,92 [1,11; 3,30] 0,0194[2]	1,97 [1,12; 3,47] 0,0172[3]	2,7 [0,5; 4,9] 0,0172[3]
≥ 50 mm	12/289 (4,2)	8/265 (3,0)	1,38 [0,57; 3,31] 0,4772[2]	1,39 [0,56; 3,46] 0,4750[3]	1,1 [-2,0; 4,2] 0,4750[3]
Number of positive lymph nodes (Interaction p-value: 0,5587)					
0-3	21/427 (4,9)	10/418 (2,4)	2,06 [0,98; 4,31] 0,0566[2]	2,11 [0,98; 4,54] 0,0509[3]	2,5 [0,0; 5,0] 0,0509[3]
4-9	22/549 (4,0)	14/542 (2,6)	1,55 [0,80; 3,00] 0,1918[2]	1,57 [0,80; 3,11] 0,1879[3]	1,4 [-0,7; 3,5] 0,1879[3]
≥ 10	18/307 (5,9)	15/304 (4,9)	1,19 [0,61; 2,31] 0,6120[2]	1,20 [0,59; 2,43] 0,6115[3]	0,9 [-2,7; 4,5] 0,6115[3]
Tumor stage (Interaction p-value: 0,9806)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	5/113 (4,4)	3/114 (2,6)	1,68 [0,41; 6,87] 0,4693[2]	1,71 [0,40; 7,34] 0,4990[4]	1,8 [-3,0; 6,6] 0,4990[4]
IIB	9/151 (6,0)	4/136 (2,9)	2,03 [0,64; 6,43] 0,2306[2]	2,09 [0,63; 6,95] 0,2194[3]	3,0 [-1,7; 7,7] 0,2194[3]
IIIA	19/495 (3,8)	13/488 (2,7)	1,44 [0,72; 2,89] 0,3025[2]	1,46 [0,71; 2,99] 0,2995[3]	1,2 [-1,0; 3,4] 0,2995[3]
IIIB	3/54 (5,6)	0/45 (0,0)	5,85 [0,31; 110,43] 0,2383[2]	6,18 [0,31; 122,97] 0,2486[4]	5,6 [-0,6; 11,7] 0,2486[4]
IIIC	25/468 (5,3)	19/479 (4,0)	1,35 [0,75; 2,41] 0,3168[2]	1,37 [0,74; 2,52] 0,3148[3]	1,4 [-1,3; 4,1] 0,3148[3]
Tumor grade (Interaction p-value: 0,2420)					
G1	3/91 (3,3)	5/93 (5,4)	0,61 [0,15; 2,49] 0,4941[2]	0,60 [0,14; 2,59] 0,7206[4]	-2,1 [-8,0; 3,8] 0,7206[4]
G2	20/612 (3,3)	17/602 (2,8)	1,16 [0,61; 2,19] 0,6530[2]	1,16 [0,60; 2,24] 0,6527[3]	0,4 [-1,5; 2,4] 0,6527[3]
G3	31/527 (5,9)	14/506 (2,8)	2,13 [1,14; 3,95] 0,0170[2]	2,20 [1,15; 4,18] 0,0142[3]	3,1 [0,7; 5,6] 0,0142[3]
GX	7/51 (13,7)	3/59 (5,1)	2,70 [0,74; 9,90] 0,1342[2]	2,97 [0,73; 12,15] 0,1829[4]	8,6 [-2,3; 19,6] 0,1829[4]
Race (Interaction p-value: 0,6060)					
White	48/958 (5,0)	33/943 (3,5)	1,43 [0,93; 2,21] 0,1050[2]	1,45 [0,93; 2,29] 0,1029[3]	1,5 [-0,3; 3,3] 0,1029[3]
Asian	13/250 (5,2)	5/242 (2,1)	2,52 [0,91; 6,95] 0,0750[2]	2,60 [0,91; 7,41] 0,0642[3]	3,1 [-0,2; 6,4] 0,0642[3]
Other	0/62 (0,0)	1/64 (1,6)	0,34 [0,01; 8,28] 0,5109[2]	0,34 [0,01; 8,47] 1,0000[4]	-1,6 [-4,6; 1,5] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,4193)					
Tamoxifen	1/114 (0,9)	2/132 (1,5)	0,58 [0,05; 6,30] 0,6536[2]	0,58 [0,05; 6,43] 1,0000[4]	-0,6 [-3,3; 2,1] 1,0000[4]
Aromatase inhibitor	60/1169 (5,1)	37/1132 (3,3)	1,57 [1,05; 2,35] 0,0276[2]	1,60 [1,05; 2,43] 0,0261[3]	1,9 [0,2; 3,5] 0,0261[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 313.1.2: Subgroups - adverse events according PT Blood creatinine increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5103)					
< 65 years	93/918 (10,1)	11/936 (1,2)	8,62 [4,65; 16,00] <,0001[2]	9,48 [5,04; 17,83] <,0001[3]	9,0 [6,9; 11,0] <,0001[3]
≥ 65 years	57/365 (15,6)	4/328 (1,2)	12,81 [4,70; 34,91] <,0001[2]	14,99 [5,37; 41,81] <,0001[3]	14,4 [10,5; 18,3] <,0001[3]
Prior treatment (Interaction p-value: 0,3624)					
Neoadjuvant chemotherapy	50/430 (11,6)	8/415 (1,9)	6,03 [2,90; 12,57] <,0001[2]	6,69 [3,13; 14,30] <,0001[3]	9,7 [6,4; 13,0] <,0001[3]
Adjuvant chemotherapy	93/784 (11,9)	7/768 (0,9)	13,01 [6,08; 27,88] <,0001[2]	14,63 [6,74; 31,76] <,0001[3]	11,0 [8,6; 13,3] <,0001[3]
No chemotherapy	7/69 (10,1)	0/81 (0,0)	17,57 [1,02; 302,22] 0,0483[2]	19,56 [1,10; 349,01] 0,0037[4]	10,1 [3,0; 17,3] 0,0037[4]
Region (Interaction p-value: 0,3151)					
North America / Europe	81/678 (11,9)	7/649 (1,1)	11,08 [5,16; 23,79] <,0001[2]	12,44 [5,70; 27,15] <,0001[3]	10,9 [8,3; 13,4] <,0001[3]
Asia	27/203 (13,3)	1/201 (0,5)	26,73 [3,67; 194,87] 0,0012[2]	30,68 [4,13; 228,12] <,0001[3]	12,8 [8,0; 17,6] <,0001[3]
Other	42/402 (10,4)	7/414 (1,7)	6,18 [2,81; 13,59] <,0001[2]	6,78 [3,01; 15,29] <,0001[3]	8,8 [5,5; 12,0] <,0001[3]
Primary tumor size (Interaction p-value: 0,7755)					
< 20 mm	37/331 (11,2)	3/334 (0,9)	12,45 [3,88; 39,97] <,0001[2]	13,89 [4,24; 45,51] <,0001[3]	10,3 [6,7; 13,8] <,0001[3]
≥ 20 but < 50 mm	82/646 (12,7)	10/653 (1,5)	8,29 [4,34; 15,84] <,0001[2]	9,35 [4,80; 18,20] <,0001[3]	11,2 [8,4; 13,9] <,0001[3]
≥ 50 mm	27/289 (9,3)	2/265 (0,8)	12,38 [2,97; 51,55] 0,0005[2]	13,55 [3,19; 57,57] <,0001[3]	8,6 [5,1; 12,1] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,8624)					
0-3	49/427 (11,5)	4/418 (1,0)	11,99 [4,37; 32,93] <,0001[2]	13,42 [4,80; 37,53] <,0001[3]	10,5 [7,4; 13,7] <,0001[3]
4-9	60/549 (10,9)	7/542 (1,3)	8,46 [3,90; 18,35] <,0001[2]	9,38 [4,25; 20,71] <,0001[3]	9,6 [6,9; 12,4] <,0001[3]
≥ 10	41/307 (13,4)	4/304 (1,3)	10,15 [3,68; 27,99] <,0001[2]	11,56 [4,09; 32,70] <,0001[3]	12,0 [8,0; 16,1] <,0001[3]
Tumor stage (Interaction p-value: 0,5171)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	13/113 (11,5)	0/114 (0,0)	27,24 [1,64; 452,75] 0,0212[2]	30,76 [1,81; 524,06] 0,0002[3]	11,5 [5,6; 17,4] 0,0002[3]
IIB	16/151 (10,6)	4/136 (2,9)	3,60 [1,23; 10,51] 0,0190[2]	3,91 [1,27; 12,01] 0,0110[3]	7,7 [2,0; 13,3] 0,0110[3]
IIIA	53/495 (10,7)	6/488 (1,2)	8,71 [3,78; 20,07] <,0001[2]	9,63 [4,10; 22,63] <,0001[3]	9,5 [6,6; 12,4] <,0001[3]
IIIB	4/54 (7,4)	0/45 (0,0)	7,53 [0,42; 136,17] 0,1718[2]	8,11 [0,42; 154,79] 0,1236[4]	7,4 [0,4; 14,4] 0,1236[4]
IIIC	63/468 (13,5)	5/479 (1,0)	12,90 [5,23; 31,77] <,0001[2]	14,75 [5,88; 37,01] <,0001[3]	12,4 [9,2; 15,6] <,0001[3]
Tumor grade (Interaction p-value: 0,9969)					
G1	6/91 (6,6)	0/93 (0,0)	13,28 [0,76; 232,41] 0,0765[2]	14,22 [0,79; 256,15] 0,0134[4]	6,6 [1,5; 11,7] 0,0134[4]
G2	74/612 (12,1)	8/602 (1,3)	9,10 [4,43; 18,71] <,0001[2]	10,21 [4,88; 21,38] <,0001[3]	10,8 [8,0; 13,5] <,0001[3]
G3	60/527 (11,4)	6/506 (1,2)	9,60 [4,19; 22,03] <,0001[2]	10,71 [4,58; 25,02] <,0001[3]	10,2 [7,3; 13,1] <,0001[3]
GX	10/51 (19,6)	1/59 (1,7)	11,57 [1,53; 87,31] 0,0176[2]	14,15 [1,74; 114,85] 0,0018[3]	17,9 [6,5; 29,3] 0,0018[3]
Race (Interaction p-value: 0,4758)					
White	107/958 (11,2)	14/943 (1,5)	7,52 [4,34; 13,04] <,0001[2]	8,34 [4,74; 14,68] <,0001[3]	9,7 [7,5; 11,8] <,0001[3]
Asian	28/250 (11,2)	1/242 (0,4)	27,10 [3,72; 197,65] 0,0011[2]	30,40 [4,10; 225,27] <,0001[3]	10,8 [6,8; 14,8] <,0001[3]
Other	10/62 (16,1)	0/64 (0,0)	21,67 [1,30; 361,97] 0,0323[2]	25,80 [1,48; 450,66] 0,0006[4]	16,1 [7,0; 25,3] 0,0006[4]
ECOG-PS (Interaction p-value: 0,8776)					
ECOG-PS 0	122/1070 (11,4)	12/1019 (1,2)	9,68 [5,38; 17,41] <,0001[2]	10,80 [5,93; 19,67] <,0001[3]	10,2 [8,2; 12,2] <,0001[3]
ECOG-PS 1	28/213 (13,1)	3/245 (1,2)	10,74 [3,31; 34,81] <,0001[2]	12,21 [3,66; 40,78] <,0001[3]	11,9 [7,2; 16,7] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 314.1.2: Subgroups - adverse events according PT COVID-19 from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7504)					
< 65 years	30/918 (3,3)	7/936 (0,7)	4,37 [1,93; 9,90] 0,0004[2]	4,48 [1,96; 10,26] 0,0001[3]	2,5 [1,2; 3,8] 0,0001[3]
≥ 65 years	7/365 (1,9)	1/328 (0,3)	6,29 [0,78; 50,86] 0,0846[2]	6,39 [0,78; 52,25] 0,0718[4]	1,6 [0,1; 3,1] 0,0718[4]
Region (Interaction p-value: 0,3691)					
North America / Europe	22/678 (3,2)	6/649 (0,9)	3,51 [1,43; 8,60] 0,0060[2]	3,59 [1,45; 8,92] 0,0033[3]	2,3 [0,8; 3,8] 0,0033[3]
Asia	0/203 (0,0)	0/201 (0,0)	NE	NE	NE
Other	15/402 (3,7)	2/414 (0,5)	7,72 [1,78; 33,56] 0,0064[2]	7,98 [1,81; 35,14] 0,0012[3]	3,2 [1,3; 5,2] 0,0012[3]
Primary tumor size (Interaction p-value: 0,8811)					
< 20 mm	12/331 (3,6)	2/334 (0,6)	6,05 [1,37; 26,84] 0,0178[2]	6,24 [1,39; 28,12] 0,0066[3]	3,0 [0,8; 5,2] 0,0066[3]
≥ 20 but < 50 mm	16/646 (2,5)	4/653 (0,6)	4,04 [1,36; 12,03] 0,0120[2]	4,12 [1,37; 12,39] 0,0064[3]	1,9 [0,5; 3,2] 0,0064[3]
≥ 50 mm	8/289 (2,8)	2/265 (0,8)	3,67 [0,79; 17,12] 0,0982[2]	3,74 [0,79; 17,79] 0,1095[4]	2,0 [-0,1; 4,2] 0,1095[4]
Number of positive lymph nodes (Interaction p-value: 0,4720)					
0-3	10/427 (2,3)	1/418 (0,2)	9,79 [1,26; 76,13] 0,0293[2]	10,00 [1,27; 78,47] 0,0070[3]	2,1 [0,6; 3,6] 0,0070[3]
4-9	20/549 (3,6)	4/542 (0,7)	4,94 [1,70; 14,35] 0,0034[2]	5,09 [1,73; 14,98] 0,0011[3]	2,9 [1,2; 4,6] 0,0011[3]
≥ 10	7/307 (2,3)	3/304 (1,0)	2,31 [0,60; 8,85] 0,2217[2]	2,34 [0,60; 9,14] 0,3397[4]	1,3 [-0,7; 3,3] 0,3397[4]
Tumor stage (Interaction p-value: 1,0000)					
IIA	5/113 (4,4)	0/114 (0,0)	11,10 [0,62; 198,36] 0,1019[2]	11,61 [0,63; 212,44] 0,0292[4]	4,4 [0,6; 8,2] 0,0292[4]
IIB	3/151 (2,0)	0/136 (0,0)	6,31 [0,33; 121,05] 0,2217[2]	6,43 [0,33; 125,70] 0,2494[4]	2,0 [-0,2; 4,2] 0,2494[4]
IIIA	14/495 (2,8)	4/488 (0,8)	3,45 [1,14; 10,41] 0,0279[2]	3,52 [1,15; 10,78] 0,0189[3]	2,0 [0,3; 3,7] 0,0189[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	13/468 (2,8)	4/479 (0,8)	3,33 [1,09; 10,13] 0,0344[2]	3,39 [1,10; 10,48] 0,0244[3]	1,9 [0,2; 3,6] 0,0244[3]
Tumor grade (Interaction p-value: 0,1362)					
G1	2/91 (2,2)	3/93 (3,2)	0,68 [0,12; 3,98] 0,6701[2]	0,67 [0,11; 4,13] 1,0000[4]	-1,0 [-5,7; 3,7] 1,0000[4]
G2	18/612 (2,9)	4/602 (0,7)	4,43 [1,51; 13,00] 0,0068[2]	4,53 [1,52; 13,47] 0,0029[3]	2,3 [0,8; 3,8] 0,0029[3]
G3	16/527 (3,0)	1/506 (0,2)	15,36 [2,04; 115,41] 0,0079[2]	15,81 [2,09; 119,68] 0,0003[3]	2,8 [1,3; 4,4] 0,0003[3]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,3322)					
Negative	3/156 (1,9)	1/169 (0,6)	3,25 [0,34; 30,92] 0,3051[2]	3,29 [0,34; 32,00] 0,3537[4]	1,3 [-1,1; 3,8] 0,3537[4]
Positive	34/1089 (3,1)	7/1066 (0,7)	4,75 [2,12; 10,68] 0,0002[2]	4,88 [2,15; 11,05] <,0001[3]	2,5 [1,3; 3,6] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9997)					
White	29/958 (3,0)	8/943 (0,8)	3,57 [1,64; 7,76] 0,0013[2]	3,65 [1,66; 8,02] 0,0006[3]	2,2 [0,9; 3,4] 0,0006[3]
Asian	3/250 (1,2)	0/242 (0,0)	6,78 [0,35; 130,51] 0,2048[2]	6,86 [0,35; 133,48] 0,2487[4]	1,2 [-0,1; 2,5] 0,2487[4]
Other	5/62 (8,1)	0/64 (0,0)	11,35 [0,64; 201,02] 0,0976[2]	12,34 [0,67; 228,05] 0,0265[4]	8,1 [1,3; 14,8] 0,0265[4]
First endocrine therapy (Interaction p-value: 0,9903)					
Tamoxifen	4/114 (3,5)	1/132 (0,8)	4,63 [0,53; 40,85] 0,1675[2]	4,76 [0,52; 43,25] 0,1855[4]	2,8 [-0,9; 6,4] 0,1855[4]
Aromatase inhibitor	33/1169 (2,8)	7/1132 (0,6)	4,57 [2,03; 10,28] 0,0002[2]	4,67 [2,06; 10,60] <,0001[3]	2,2 [1,2; 3,3] <,0001[3]
ECOG-PS (Interaction p-value: 0,9713)					
ECOG-PS 0	29/1070 (2,7)	8/1019 (0,8)	3,45 [1,59; 7,52] 0,0018[2]	3,52 [1,60; 7,74] 0,0009[3]	1,9 [0,8; 3,0] 0,0009[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	8/213 (3,8)	0/245 (0,0)	19,54 [1,13; 336,58] 0,0407[2]	20,31 [1,17; 353,98] 0,0020[4]	3,8 [1,2; 6,3] 0,0020[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 315.1.2: Subgroups - adverse events according PT Cataract from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9434)					
< 65 years	13/918 (1,4)	5/936 (0,5)	2,65 [0,95; 7,41] 0,0629[2]	2,67 [0,95; 7,53] 0,0528[3]	0,9 [-0,0; 1,8] 0,0528[3]
≥ 65 years	14/365 (3,8)	5/328 (1,5)	2,52 [0,92; 6,91] 0,0734[2]	2,58 [0,92; 7,23] 0,0628[3]	2,3 [-0,1; 4,7] 0,0628[3]
Prior treatment (Interaction p-value: 0,5732)					
Neoadjuvant chemotherapy	13/430 (3,0)	3/415 (0,7)	4,18 [1,20; 14,57] 0,0246[2]	4,28 [1,21; 15,14] 0,0142[3]	2,3 [0,5; 4,1] 0,0142[3]
Adjuvant chemotherapy	13/784 (1,7)	7/768 (0,9)	1,82 [0,73; 4,54] 0,1991[2]	1,83 [0,73; 4,62] 0,1922[3]	0,7 [-0,4; 1,9] 0,1922[3]
No chemotherapy	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Region (Interaction p-value: 0,5419)					
North America / Europe	10/678 (1,5)	5/649 (0,8)	1,91 [0,66; 5,57] 0,2334[2]	1,93 [0,66; 5,67] 0,2249[3]	0,7 [-0,4; 1,8] 0,2249[3]
Asia	10/203 (4,9)	4/201 (2,0)	2,48 [0,79; 7,76] 0,1201[2]	2,55 [0,79; 8,27] 0,1067[3]	2,9 [-0,6; 6,5] 0,1067[3]
Other	7/402 (1,7)	1/414 (0,2)	7,21 [0,89; 58,33] 0,0641[2]	7,32 [0,90; 59,76] 0,0357[4]	1,5 [0,1; 2,9] 0,0357[4]
Primary tumor size (Interaction p-value: 0,6804)					
< 20 mm	9/331 (2,7)	4/334 (1,2)	2,27 [0,71; 7,30] 0,1688[2]	2,31 [0,70; 7,56] 0,1565[3]	1,5 [-0,6; 3,6] 0,1565[3]
≥ 20 but < 50 mm	12/646 (1,9)	3/653 (0,5)	4,04 [1,15; 14,26] 0,0298[2]	4,10 [1,15; 14,60] 0,0184[3]	1,4 [0,2; 2,6] 0,0184[3]
≥ 50 mm	6/289 (2,1)	3/265 (1,1)	1,83 [0,46; 7,26] 0,3876[2]	1,85 [0,46; 7,48] 0,5080[4]	0,9 [-1,1; 3,0] 0,5080[4]
Number of positive lymph nodes (Interaction p-value: 0,5206)					
0-3	11/427 (2,6)	3/418 (0,7)	3,59 [1,01; 12,77] 0,0485[2]	3,66 [1,01; 13,21] 0,0343[3]	1,9 [0,2; 3,6] 0,0343[3]
4-9	8/549 (1,5)	5/542 (0,9)	1,58 [0,52; 4,80] 0,4200[2]	1,59 [0,52; 4,89] 0,4158[3]	0,5 [-0,8; 1,8] 0,4158[3]
≥ 10	8/307 (2,6)	2/304 (0,7)	3,96 [0,85; 18,50] 0,0801[2]	4,04 [0,85; 19,18] 0,1065[4]	1,9 [-0,1; 3,9] 0,1065[4]
Tumor stage (Interaction p-value: 0,7289)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	2/113 (1,8)	2/114 (1,8)	1,01 [0,14; 7,04] 0,9929[2]	1,01 [0,14; 7,29] 1,0000[4]	0,0 [-3,4; 3,4] 1,0000[4]
IIB	3/151 (2,0)	0/136 (0,0)	6,31 [0,33; 121,05] 0,2217[2]	6,43 [0,33; 125,70] 0,2494[4]	2,0 [-0,2; 4,2] 0,2494[4]
IIIA	8/495 (1,6)	4/488 (0,8)	1,97 [0,60; 6,51] 0,2650[2]	1,99 [0,59; 6,64] 0,2555[3]	0,8 [-0,6; 2,2] 0,2555[3]
IIIB	0/54 (0,0)	1/45 (2,2)	0,28 [0,01; 6,68] 0,4306[2]	0,27 [0,01; 6,85] 0,4545[4]	-2,2 [-6,5; 2,1] 0,4545[4]
IIIC	14/468 (3,0)	3/479 (0,6)	4,78 [1,38; 16,51] 0,0135[2]	4,89 [1,40; 17,14] 0,0061[3]	2,4 [0,7; 4,1] 0,0061[3]
Tumor grade (Interaction p-value: 0,0630)					
G1	1/91 (1,1)	2/93 (2,2)	0,51 [0,05; 5,54] 0,5808[2]	0,51 [0,05; 5,67] 1,0000[4]	-1,1 [-4,7; 2,6] 1,0000[4]
G2	14/612 (2,3)	2/602 (0,3)	6,89 [1,57; 30,17] 0,0105[2]	7,02 [1,59; 31,04] 0,0028[3]	2,0 [0,7; 3,2] 0,0028[3]
G3	12/527 (2,3)	6/506 (1,2)	1,92 [0,73; 5,08] 0,1884[2]	1,94 [0,72; 5,21] 0,1803[3]	1,1 [-0,5; 2,7] 0,1803[3]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9155)					
White	17/958 (1,8)	5/943 (0,5)	3,35 [1,24; 9,03] 0,0171[2]	3,39 [1,25; 9,22] 0,0112[3]	1,2 [0,3; 2,2] 0,0112[3]
Asian	10/250 (4,0)	4/242 (1,7)	2,42 [0,77; 7,61] 0,1307[2]	2,48 [0,77; 8,01] 0,1175[3]	2,3 [-0,6; 5,3] 0,1175[3]
Other	0/62 (0,0)	1/64 (1,6)	0,34 [0,01; 8,28] 0,5109[2]	0,34 [0,01; 8,47] 1,0000[4]	-1,6 [-4,6; 1,5] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,1870)					
Tamoxifen	1/114 (0,9)	2/132 (1,5)	0,58 [0,05; 6,30] 0,6536[2]	0,58 [0,05; 6,43] 1,0000[4]	-0,6 [-3,3; 2,1] 1,0000[4]
Aromatase inhibitor	26/1169 (2,2)	8/1132 (0,7)	3,15 [1,43; 6,92] 0,0044[2]	3,20 [1,44; 7,09] 0,0026[3]	1,5 [0,5; 2,5] 0,0026[3]
ECOG-PS (Interaction p-value: 0,4131)					
ECOG-PS 0	23/1070 (2,1)	7/1019 (0,7)	3,13 [1,35; 7,26] 0,0079[2]	3,18 [1,36; 7,43] 0,0050[3]	1,5 [0,5; 2,5] 0,0050[3]
ECOG-PS 1	4/213 (1,9)	3/245 (1,2)	1,53 [0,35; 6,78] 0,5726[2]	1,54 [0,34; 6,98] 0,7096[4]	0,7 [-1,6; 2,9] 0,7096[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 316.1.2: Subgroups - adverse events according PT Constipation from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1854)					
Neoadjuvant chemotherapy	53/430 (12,3)	16/415 (3,9)	3,20 [1,86; 5,50] <,0001[2]	3,51 [1,97; 6,24] <,0001[3]	8,5 [4,9; 12,1] <,0001[3]
Adjuvant chemotherapy	90/784 (11,5)	50/768 (6,5)	1,76 [1,27; 2,46] 0,0008[2]	1,86 [1,30; 2,67] 0,0006[3]	5,0 [2,1; 7,8] 0,0006[3]
No chemotherapy	11/69 (15,9)	6/81 (7,4)	2,15 [0,84; 5,52] 0,1106[2]	2,37 [0,83; 6,79] 0,1003[3]	8,5 [-1,8; 18,9] 0,1003[3]
Region (Interaction p-value: 0,9930)					
North America / Europe	114/678 (16,8)	53/649 (8,2)	2,06 [1,51; 2,80] <,0001[2]	2,27 [1,61; 3,21] <,0001[3]	8,6 [5,1; 12,2] <,0001[3]
Asia	17/203 (8,4)	8/201 (4,0)	2,10 [0,93; 4,76] 0,0745[2]	2,20 [0,93; 5,23] 0,0668[3]	4,4 [-0,3; 9,1] 0,0668[3]
Other	23/402 (5,7)	11/414 (2,7)	2,15 [1,06; 4,36] 0,0330[2]	2,22 [1,07; 4,62] 0,0285[3]	3,1 [0,3; 5,8] 0,0285[3]
Primary tumor size (Interaction p-value: 0,1221)					
< 20 mm	45/331 (13,6)	20/334 (6,0)	2,27 [1,37; 3,76] 0,0014[2]	2,47 [1,42; 4,28] 0,0010[3]	7,6 [3,1; 12,1] 0,0010[3]
≥ 20 but < 50 mm	63/646 (9,8)	39/653 (6,0)	1,63 [1,11; 2,40] 0,0124[2]	1,70 [1,12; 2,58] 0,0113[3]	3,8 [0,9; 6,7] 0,0113[3]
≥ 50 mm	45/289 (15,6)	12/265 (4,5)	3,44 [1,86; 6,36] <,0001[2]	3,89 [2,01; 7,53] <,0001[3]	11,0 [6,2; 15,9] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,0866)					
0-3	58/427 (13,6)	22/418 (5,3)	2,58 [1,61; 4,14] <,0001[2]	2,83 [1,70; 4,72] <,0001[3]	8,3 [4,4; 12,2] <,0001[3]
4-9	50/549 (9,1)	34/542 (6,3)	1,45 [0,95; 2,21] 0,0813[2]	1,50 [0,95; 2,35] 0,0791[3]	2,8 [-0,3; 6,0] 0,0791[3]
≥ 10	46/307 (15,0)	16/304 (5,3)	2,85 [1,65; 4,92] 0,0002[2]	3,17 [1,75; 5,74] <,0001[3]	9,7 [5,0; 14,4] <,0001[3]
Tumor stage (Interaction p-value: 0,3622)					
IIA	17/113 (15,0)	4/114 (3,5)	4,29 [1,49; 12,35] 0,0070[2]	4,87 [1,58; 14,97] 0,0027[3]	11,5 [4,1; 18,9] 0,0027[3]
IIB	20/151 (13,2)	9/136 (6,6)	2,00 [0,94; 4,24] 0,0705[2]	2,15 [0,95; 4,91] 0,0629[3]	6,6 [-0,2; 13,5] 0,0629[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	47/495 (9,5)	30/488 (6,1)	1,54 [0,99; 2,40] 0,0532[2]	1,60 [0,99; 2,58] 0,0508[3]	3,3 [-0,0; 6,7] 0,0508[3]
IIIB	4/54 (7,4)	2/45 (4,4)	1,67 [0,32; 8,68] 0,5441[2]	1,72 [0,30; 9,85] 0,6859[4]	3,0 [-6,3; 12,2] 0,6859[4]
IIIC	66/468 (14,1)	27/479 (5,6)	2,50 [1,63; 3,84] <,0001[2]	2,75 [1,72; 4,39] <,0001[3]	8,5 [4,7; 12,2] <,0001[3]
Tumor grade (Interaction p-value: 0,8049)					
G1	10/91 (11,0)	4/93 (4,3)	2,55 [0,83; 7,85] 0,1016[2]	2,75 [0,83; 9,10] 0,0871[3]	6,7 [-0,9; 14,3] 0,0871[3]
G2	71/612 (11,6)	38/602 (6,3)	1,84 [1,26; 2,68] 0,0016[2]	1,95 [1,29; 2,94] 0,0013[3]	5,3 [2,1; 8,5] 0,0013[3]
G3	68/527 (12,9)	28/506 (5,5)	2,33 [1,53; 3,56] <,0001[2]	2,53 [1,60; 4,00] <,0001[3]	7,4 [3,9; 10,9] <,0001[3]
GX	5/51 (9,8)	2/59 (3,4)	2,89 [0,59; 14,27] 0,1923[2]	3,10 [0,57; 16,71] 0,2463[4]	6,4 [-3,0; 15,8] 0,2463[4]
Race (Interaction p-value: 0,5995)					
White	128/958 (13,4)	57/943 (6,0)	2,21 [1,64; 2,98] <,0001[2]	2,40 [1,73; 3,32] <,0001[3]	7,3 [4,7; 10,0] <,0001[3]
Asian	20/250 (8,0)	8/242 (3,3)	2,42 [1,09; 5,39] 0,0305[2]	2,54 [1,10; 5,89] 0,0246[3]	4,7 [0,6; 8,7] 0,0246[3]
Other	6/62 (9,7)	5/64 (7,8)	1,24 [0,40; 3,85] 0,7115[2]	1,26 [0,37; 4,38] 0,7108[3]	1,9 [-8,0; 11,7] 0,7108[3]
First endocrine therapy (Interaction p-value: 0,3408)					
Tamoxifen	8/114 (7,0)	7/132 (5,3)	1,32 [0,50; 3,54] 0,5764[2]	1,35 [0,47; 3,84] 0,5752[3]	1,7 [-4,3; 7,8] 0,5752[3]
Aromatase inhibitor	146/1169 (12,5)	65/1132 (5,7)	2,18 [1,64; 2,88] <,0001[2]	2,34 [1,73; 3,18] <,0001[3]	6,7 [4,4; 9,1] <,0001[3]
ECOG-PS (Interaction p-value: 0,1650)					
ECOG-PS 0	128/1070 (12,0)	52/1019 (5,1)	2,34 [1,72; 3,20] <,0001[2]	2,53 [1,81; 3,53] <,0001[3]	6,9 [4,5; 9,2] <,0001[3]
ECOG-PS 1	26/213 (12,2)	20/245 (8,2)	1,50 [0,86; 2,60] 0,1541[2]	1,56 [0,85; 2,89] 0,1510[3]	4,0 [-1,5; 9,6] 0,1510[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 317.1.2: Subgroups - adverse events according PT Cough from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7182)					
< 65 years	132/918 (14,4)	80/936 (8,5)	1,68 [1,29; 2,19] 0,0001[2]	1,80 [1,34; 2,41] <,0001[3]	5,8 [2,9; 8,7] <,0001[3]
≥ 65 years	53/365 (14,5)	31/328 (9,5)	1,54 [1,01; 2,33] 0,0437[2]	1,63 [1,02; 2,61] 0,0412[3]	5,1 [0,3; 9,9] 0,0412[3]
Prior treatment (Interaction p-value: 0,2570)					
Neoadjuvant chemotherapy	60/430 (14,0)	29/415 (7,0)	2,00 [1,31; 3,05] 0,0013[2]	2,16 [1,35; 3,44] 0,0010[3]	7,0 [2,9; 11,1] 0,0010[3]
Adjuvant chemotherapy	110/784 (14,0)	75/768 (9,8)	1,44 [1,09; 1,89] 0,0101[2]	1,51 [1,10; 2,06] 0,0095[3]	4,3 [1,1; 7,5] 0,0095[3]
No chemotherapy	15/69 (21,7)	7/81 (8,6)	2,52 [1,09; 5,81] 0,0309[2]	2,94 [1,12; 7,69] 0,0238[3]	13,1 [1,6; 24,6] 0,0238[3]
Region (Interaction p-value: 0,5785)					
North America / Europe	113/678 (16,7)	66/649 (10,2)	1,64 [1,23; 2,18] 0,0006[2]	1,77 [1,28; 2,44] 0,0005[3]	6,5 [2,9; 10,1] 0,0005[3]
Asia	33/203 (16,3)	16/201 (8,0)	2,04 [1,16; 3,59] 0,0131[2]	2,24 [1,19; 4,22] 0,0107[3]	8,3 [2,0; 14,6] 0,0107[3]
Other	39/402 (9,7)	29/414 (7,0)	1,38 [0,87; 2,20] 0,1658[2]	1,43 [0,86; 2,36] 0,1635[3]	2,7 [-1,1; 6,5] 0,1635[3]
Primary tumor size (Interaction p-value: 0,3798)					
< 20 mm	42/331 (12,7)	20/334 (6,0)	2,12 [1,27; 3,53] 0,0039[2]	2,28 [1,31; 3,98] 0,0030[3]	6,7 [2,3; 11,1] 0,0030[3]
≥ 20 but < 50 mm	96/646 (14,9)	57/653 (8,7)	1,70 [1,25; 2,32] 0,0007[2]	1,83 [1,29; 2,58] 0,0006[3]	6,1 [2,6; 9,6] 0,0006[3]
≥ 50 mm	45/289 (15,6)	31/265 (11,7)	1,33 [0,87; 2,04] 0,1883[2]	1,39 [0,85; 2,28] 0,1857[3]	3,9 [-1,8; 9,6] 0,1857[3]
Number of positive lymph nodes (Interaction p-value: 0,8143)					
0-3	63/427 (14,8)	36/418 (8,6)	1,71 [1,16; 2,52] 0,0064[2]	1,84 [1,19; 2,83] 0,0055[3]	6,1 [1,8; 10,4] 0,0055[3]
4-9	70/549 (12,8)	40/542 (7,4)	1,73 [1,19; 2,50] 0,0038[2]	1,83 [1,22; 2,76] 0,0032[3]	5,4 [1,8; 8,9] 0,0032[3]
≥ 10	52/307 (16,9)	35/304 (11,5)	1,47 [0,99; 2,19] 0,0573[2]	1,57 [0,99; 2,49] 0,0550[3]	5,4 [-0,1; 10,9] 0,0550[3]
Tumor stage (Interaction p-value: 0,2307)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	14/113 (12,4)	6/114 (5,3)	2,35 [0,94; 5,91] 0,0683[2]	2,55 [0,94; 6,88] 0,0582[3]	7,1 [-0,2; 14,5] 0,0582[3]
IIB	18/151 (11,9)	16/136 (11,8)	1,01 [0,54; 1,91] 0,9675[2]	1,02 [0,50; 2,08] 0,9675[3]	0,2 [-7,3; 7,6] 0,9675[3]
IIIA	71/495 (14,3)	36/488 (7,4)	1,94 [1,33; 2,85] 0,0006[2]	2,10 [1,38; 3,21] 0,0005[3]	7,0 [3,1; 10,8] 0,0005[3]
IIIB	7/54 (13,0)	1/45 (2,2)	5,83 [0,75; 45,66] 0,0930[2]	6,55 [0,77; 55,43] 0,0682[4]	10,7 [0,8; 20,7] 0,0682[4]
IIIC	73/468 (15,6)	52/479 (10,9)	1,44 [1,03; 2,00] 0,0324[2]	1,52 [1,04; 2,22] 0,0311[3]	4,7 [0,4; 9,1] 0,0311[3]
Tumor grade (Interaction p-value: 0,7171)					
G1	14/91 (15,4)	6/93 (6,5)	2,38 [0,96; 5,93] 0,0617[2]	2,64 [0,97; 7,20] 0,0516[3]	8,9 [-0,0; 17,9] 0,0516[3]
G2	88/612 (14,4)	56/602 (9,3)	1,55 [1,13; 2,12] 0,0068[2]	1,64 [1,15; 2,34] 0,0062[3]	5,1 [1,5; 8,7] 0,0062[3]
G3	76/527 (14,4)	45/506 (8,9)	1,62 [1,15; 2,30] 0,0065[2]	1,73 [1,17; 2,55] 0,0057[3]	5,5 [1,6; 9,4] 0,0057[3]
GX	7/51 (13,7)	3/59 (5,1)	2,70 [0,74; 9,90] 0,1342[2]	2,97 [0,73; 12,15] 0,1829[4]	8,6 [-2,3; 19,6] 0,1829[4]
Race (Interaction p-value: 0,7752)					
White	138/958 (14,4)	86/943 (9,1)	1,58 [1,23; 2,04] 0,0004[2]	1,68 [1,26; 2,23] 0,0004[3]	5,3 [2,4; 8,2] 0,0004[3]
Asian	41/250 (16,4)	21/242 (8,7)	1,89 [1,15; 3,10] 0,0118[2]	2,06 [1,18; 3,61] 0,0099[3]	7,7 [1,9; 13,5] 0,0099[3]
Other	6/62 (9,7)	3/64 (4,7)	2,06 [0,54; 7,89] 0,2894[2]	2,18 [0,52; 9,13] 0,3198[4]	5,0 [-4,0; 14,0] 0,3198[4]
First endocrine therapy (Interaction p-value: 0,6772)					
Tamoxifen	12/114 (10,5)	10/132 (7,6)	1,39 [0,62; 3,10] 0,4209[2]	1,44 [0,60; 3,46] 0,4187[3]	3,0 [-4,3; 10,2] 0,4187[3]
Aromatase inhibitor	173/1169 (14,8)	101/1132 (8,9)	1,66 [1,32; 2,09] <,0001[2]	1,77 [1,37; 2,30] <,0001[3]	5,9 [3,2; 8,5] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 318.1.2: Subgroups - adverse events according PT Decreased appetite from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1491)					
< 65 years	90/918 (9,8)	30/936 (3,2)	3,06 [2,04; 4,58] <,0001[2]	3,28 [2,15; 5,02] <,0001[3]	6,6 [4,4; 8,8] <,0001[3]
≥ 65 years	74/365 (20,3)	13/328 (4,0)	5,12 [2,89; 9,05] <,0001[2]	6,16 [3,35; 11,35] <,0001[3]	16,3 [11,7; 20,9] <,0001[3]
Prior treatment (Interaction p-value: 0,7519)					
Neoadjuvant chemotherapy	55/430 (12,8)	15/415 (3,6)	3,54 [2,03; 6,16] <,0001[2]	3,91 [2,17; 7,04] <,0001[3]	9,2 [5,5; 12,8] <,0001[3]
Adjuvant chemotherapy	98/784 (12,5)	26/768 (3,4)	3,69 [2,42; 5,62] <,0001[2]	4,08 [2,61; 6,36] <,0001[3]	9,1 [6,5; 11,8] <,0001[3]
No chemotherapy	11/69 (15,9)	2/81 (2,5)	6,46 [1,48; 28,14] 0,0130[2]	7,49 [1,60; 35,09] 0,0035[3]	13,5 [4,2; 22,7] 0,0035[3]
Region (Interaction p-value: 0,4443)					
North America / Europe	92/678 (13,6)	28/649 (4,3)	3,15 [2,09; 4,73] <,0001[2]	3,48 [2,25; 5,39] <,0001[3]	9,3 [6,2; 12,3] <,0001[3]
Asia	21/203 (10,3)	4/201 (2,0)	5,20 [1,82; 14,87] 0,0021[2]	5,68 [1,91; 16,87] 0,0005[3]	8,4 [3,7; 13,0] 0,0005[3]
Other	51/402 (12,7)	11/414 (2,7)	4,77 [2,53; 9,03] <,0001[2]	5,32 [2,73; 10,37] <,0001[3]	10,0 [6,4; 13,6] <,0001[3]
Primary tumor size (Interaction p-value: 0,1413)					
< 20 mm	31/331 (9,4)	14/334 (4,2)	2,23 [1,21; 4,12] 0,0101[2]	2,36 [1,23; 4,53] 0,0079[3]	5,2 [1,4; 9,0] 0,0079[3]
≥ 20 but < 50 mm	84/646 (13,0)	17/653 (2,6)	4,99 [3,00; 8,32] <,0001[2]	5,59 [3,28; 9,53] <,0001[3]	10,4 [7,5; 13,3] <,0001[3]
≥ 50 mm	48/289 (16,6)	12/265 (4,5)	3,67 [1,99; 6,75] <,0001[2]	4,20 [2,18; 8,10] <,0001[3]	12,1 [7,1; 17,0] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,3645)					
0-3	48/427 (11,2)	12/418 (2,9)	3,92 [2,11; 7,26] <,0001[2]	4,28 [2,24; 8,19] <,0001[3]	8,4 [5,0; 11,8] <,0001[3]
4-9	79/549 (14,4)	17/542 (3,1)	4,59 [2,75; 7,64] <,0001[2]	5,19 [3,03; 8,90] <,0001[3]	11,3 [8,0; 14,5] <,0001[3]
≥ 10	37/307 (12,1)	14/304 (4,6)	2,62 [1,44; 4,74] 0,0015[2]	2,84 [1,50; 5,37] 0,0009[3]	7,4 [3,1; 11,8] 0,0009[3]
Tumor grade (Interaction p-value: 0,8069)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	13/91 (14,3)	2/93 (2,2)	6,64 [1,54; 28,61] 0,0110[2]	7,58 [1,66; 34,64] 0,0026[3]	12,1 [4,4; 19,9] 0,0026[3]
G2	83/612 (13,6)	26/602 (4,3)	3,14 [2,05; 4,81] <,0001[2]	3,48 [2,20; 5,48] <,0001[3]	9,2 [6,1; 12,4] <,0001[3]
G3	56/527 (10,6)	15/506 (3,0)	3,58 [2,05; 6,25] <,0001[2]	3,89 [2,17; 6,98] <,0001[3]	7,7 [4,6; 10,7] <,0001[3]
GX	12/51 (23,5)	0/59 (0,0)	28,85 [1,75; 475,41] 0,0187[2]	37,66 [2,17; 654,41] <,0001[3]	23,5 [11,9; 35,2] <,0001[3]
Race (Interaction p-value: 0,1493)					
White	128/958 (13,4)	32/943 (3,4)	3,94 [2,70; 5,74] <,0001[2]	4,39 [2,95; 6,54] <,0001[3]	10,0 [7,5; 12,4] <,0001[3]
Asian	23/250 (9,2)	5/242 (2,1)	4,45 [1,72; 11,52] 0,0021[2]	4,80 [1,80; 12,85] 0,0006[3]	7,1 [3,1; 11,1] 0,0006[3]
Other	6/62 (9,7)	5/64 (7,8)	1,24 [0,40; 3,85] 0,7115[2]	1,26 [0,37; 4,38] 0,7108[3]	1,9 [-8,0; 11,7] 0,7108[3]
First endocrine therapy (Interaction p-value: 0,7694)					
Tamoxifen	8/114 (7,0)	3/132 (2,3)	3,09 [0,84; 11,36] 0,0899[2]	3,25 [0,84; 12,54] 0,0726[3]	4,7 [-0,6; 10,1] 0,0726[3]
Aromatase inhibitor	156/1169 (13,3)	40/1132 (3,5)	3,78 [2,69; 5,29] <,0001[2]	4,20 [2,94; 6,01] <,0001[3]	9,8 [7,6; 12,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,3949)					
ECOG-PS 0	129/1070 (12,1)	35/1019 (3,4)	3,51 [2,44; 5,05] <,0001[2]	3,85 [2,62; 5,66] <,0001[3]	8,6 [6,4; 10,9] <,0001[3]
ECOG-PS 1	35/213 (16,4)	8/245 (3,3)	5,03 [2,39; 10,61] <,0001[2]	5,83 [2,64; 12,86] <,0001[3]	13,2 [7,7; 18,6] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 319.1.2: Subgroups - adverse events according PT Deep vein thrombosis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9411)					
Neoadjuvant chemotherapy	8/430 (1,9)	1/415 (0,2)	7,72 [0,97; 61,46] 0,0535[2]	7,85 [0,98; 63,03] 0,0383[4]	1,6 [0,3; 3,0] 0,0383[4]
Adjuvant chemotherapy	10/784 (1,3)	2/768 (0,3)	4,90 [1,08; 22,28] 0,0398[2]	4,95 [1,08; 22,66] 0,0225[3]	1,0 [0,2; 1,9] 0,0225[3]
No chemotherapy	3/69 (4,3)	0/81 (0,0)	8,20 [0,43; 156,04] 0,1615[2]	8,58 [0,44; 169,04] 0,0950[4]	4,3 [-0,5; 9,2] 0,0950[4]
Region (Interaction p-value: 0,9091)					
North America / Europe	15/678 (2,2)	2/649 (0,3)	7,18 [1,65; 31,27] 0,0087[2]	7,32 [1,67; 32,13] 0,0020[3]	1,9 [0,7; 3,1] 0,0020[3]
Asia	0/203 (0,0)	0/201 (0,0)	NE	NE	NE
Other	6/402 (1,5)	1/414 (0,2)	6,18 [0,75; 51,10] 0,0911[2]	6,26 [0,75; 52,21] 0,0655[4]	1,3 [-0,0; 2,5] 0,0655[4]
Primary tumor size (Interaction p-value: 0,9550)					
< 20 mm	4/331 (1,2)	1/334 (0,3)	4,04 [0,45; 35,92] 0,2109[2]	4,07 [0,45; 36,64] 0,2152[4]	0,9 [-0,4; 2,2] 0,2152[4]
≥ 20 but < 50 mm	12/646 (1,9)	2/653 (0,3)	6,07 [1,36; 26,99] 0,0180[2]	6,16 [1,37; 27,64] 0,0068[3]	1,6 [0,4; 2,7] 0,0068[3]
≥ 50 mm	5/289 (1,7)	0/265 (0,0)	10,09 [0,56; 181,60] 0,1170[2]	10,27 [0,56; 186,54] 0,0625[4]	1,7 [0,2; 3,2] 0,0625[4]
Tumor stage (Interaction p-value: 0,9877)					
IIA	2/113 (1,8)	0/114 (0,0)	5,04 [0,24; 103,90] 0,2945[2]	5,13 [0,24; 108,15] 0,2467[4]	1,8 [-0,7; 4,2] 0,2467[4]
IIB	3/151 (2,0)	0/136 (0,0)	6,31 [0,33; 121,05] 0,2217[2]	6,43 [0,33; 125,70] 0,2494[4]	2,0 [-0,2; 4,2] 0,2494[4]
IIIA	9/495 (1,8)	2/488 (0,4)	4,44 [0,96; 20,43] 0,0559[2]	4,50 [0,97; 20,93] 0,0358[3]	1,4 [0,1; 2,7] 0,0358[3]
IIIB	0/54 (0,0)	0/45 (0,0)	NE	NE	NE
IIIC	7/468 (1,5)	1/479 (0,2)	7,16 [0,88; 58,01] 0,0650[2]	7,26 [0,89; 59,22] 0,0363[4]	1,3 [0,1; 2,5] 0,0363[4]
Tumor grade (Interaction p-value: 0,1855)					
G1	1/91 (1,1)	1/93 (1,1)	1,02 [0,06; 16,09] 0,9877[2]	1,02 [0,06; 16,59] 1,0000[4]	0,0 [-3,0; 3,0] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G2	12/612 (2,0)	1/602 (0,2)	11,80 [1,54; 90,50] 0,0175[2]	12,02 [1,56; 92,73] 0,0024[3]	1,8 [0,6; 2,9] 0,0024[3]
G3	8/527 (1,5)	1/506 (0,2)	7,68 [0,96; 61,19] 0,0542[2]	7,78 [0,97; 62,46] 0,0386[4]	1,3 [0,2; 2,4] 0,0386[4]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9633)					
Negative	3/156 (1,9)	0/169 (0,0)	7,58 [0,39; 145,58] 0,1792[2]	7,73 [0,40; 150,85] 0,1095[4]	1,9 [-0,2; 4,1] 0,1095[4]
Positive	17/1089 (1,6)	3/1066 (0,3)	5,55 [1,63; 18,87] 0,0061[2]	5,62 [1,64; 19,23] 0,0020[3]	1,3 [0,5; 2,1] 0,0020[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,2492)					
White	19/958 (2,0)	1/943 (0,1)	18,70 [2,51; 139,43] 0,0043[2]	19,06 [2,55; 142,67] <,0001[3]	1,9 [1,0; 2,8] <,0001[3]
Asian	1/250 (0,4)	0/242 (0,0)	2,90 [0,12; 70,95] 0,5132[2]	2,92 [0,12; 71,93] 1,0000[4]	0,4 [-0,4; 1,2] 1,0000[4]
Other	1/62 (1,6)	1/64 (1,6)	1,03 [0,07; 16,14] 0,9819[2]	1,03 [0,06; 16,88] 1,0000[4]	0,1 [-4,3; 4,4] 1,0000[4]
ECOG-PS (Interaction p-value: 0,2792)					
ECOG-PS 0	15/1070 (1,4)	1/1019 (0,1)	14,29 [1,89; 107,95] 0,0100[2]	14,47 [1,91; 109,77] 0,0006[3]	1,3 [0,6; 2,0] 0,0006[3]
ECOG-PS 1	6/213 (2,8)	2/245 (0,8)	3,45 [0,70; 16,92] 0,1268[2]	3,52 [0,70; 17,64] 0,1532[4]	2,0 [-0,5; 4,5] 0,1532[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 320.1.2: Subgroups - adverse events according PT Dehydration from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8270)					
Neoadjuvant chemotherapy	11/430 (2,6)	2/415 (0,5)	5,31 [1,18; 23,80] 0,0292[2]	5,42 [1,19; 24,61] 0,0142[3]	2,1 [0,4; 3,7] 0,0142[3]
Adjuvant chemotherapy	12/784 (1,5)	1/768 (0,1)	11,76 [1,53; 90,18] 0,0178[2]	11,92 [1,55; 91,91] 0,0025[3]	1,4 [0,5; 2,3] 0,0025[3]
No chemotherapy	3/69 (4,3)	0/81 (0,0)	8,20 [0,43; 156,04] 0,1615[2]	8,58 [0,44; 169,04] 0,0950[4]	4,3 [-0,5; 9,2] 0,0950[4]
Region (Interaction p-value: 0,9111)					
North America / Europe	19/678 (2,8)	2/649 (0,3)	9,09 [2,13; 38,89] 0,0029[2]	9,33 [2,16; 40,20] 0,0003[3]	2,5 [1,2; 3,8] 0,0003[3]
Asia	2/203 (1,0)	0/201 (0,0)	4,95 [0,24; 102,48] 0,3008[2]	5,00 [0,24; 104,80] 0,4988[4]	1,0 [-0,4; 2,3] 0,4988[4]
Other	5/402 (1,2)	1/414 (0,2)	5,15 [0,60; 43,88] 0,1338[2]	5,20 [0,61; 44,72] 0,1185[4]	1,0 [-0,2; 2,2] 0,1185[4]
Primary tumor size (Interaction p-value: 0,4448)					
< 20 mm	2/331 (0,6)	1/334 (0,3)	2,02 [0,18; 22,15] 0,5656[2]	2,02 [0,18; 22,43] 0,6227[4]	0,3 [-0,7; 1,3] 0,6227[4]
≥ 20 but < 50 mm	15/646 (2,3)	1/653 (0,2)	15,16 [2,01; 114,45] 0,0084[2]	15,50 [2,04; 117,68] 0,0004[3]	2,2 [1,0; 3,4] 0,0004[3]
≥ 50 mm	9/289 (3,1)	1/265 (0,4)	8,25 [1,05; 64,70] 0,0446[2]	8,49 [1,07; 67,44] 0,0215[4]	2,7 [0,6; 4,9] 0,0215[4]
Number of positive lymph nodes (Interaction p-value: 0,8241)					
0-3	9/427 (2,1)	2/418 (0,5)	4,41 [0,96; 20,27] 0,0569[2]	4,48 [0,96; 20,85] 0,0367[3]	1,6 [0,1; 3,1] 0,0367[3]
4-9	7/549 (1,3)	0/542 (0,0)	14,81 [0,85; 258,66] 0,0648[2]	15,00 [0,85; 263,28] 0,0153[4]	1,3 [0,3; 2,2] 0,0153[4]
≥ 10	10/307 (3,3)	1/304 (0,3)	9,90 [1,28; 76,88] 0,0283[2]	10,20 [1,30; 80,19] 0,0065[3]	2,9 [0,8; 5,0] 0,0065[3]
Tumor stage (Interaction p-value: 0,9799)					
IIA	1/113 (0,9)	0/114 (0,0)	3,03 [0,12; 73,51] 0,4963[2]	3,05 [0,12; 75,75] 0,4978[4]	0,9 [-0,8; 2,6] 0,4978[4]
IIB	3/151 (2,0)	1/136 (0,7)	2,70 [0,28; 25,67] 0,3868[2]	2,74 [0,28; 26,62] 0,6244[4]	1,3 [-1,4; 3,9] 0,6244[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	8/495 (1,6)	0/488 (0,0)	16,76 [0,97; 289,58] 0,0525[2]	17,03 [0,98; 295,95] 0,0076[4]	1,6 [0,5; 2,7] 0,0076[4]
IIIB	1/54 (1,9)	0/45 (0,0)	2,51 [0,10; 60,13] 0,5703[2]	2,55 [0,10; 64,17] 1,0000[4]	1,9 [-1,7; 5,4] 1,0000[4]
IIIC	13/468 (2,8)	2/479 (0,4)	6,65 [1,51; 29,32] 0,0123[2]	6,81 [1,53; 30,36] 0,0036[3]	2,4 [0,8; 4,0] 0,0036[3]
Tumor grade (Interaction p-value: 0,8960)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	12/612 (2,0)	1/602 (0,2)	11,80 [1,54; 90,50] 0,0175[2]	12,02 [1,56; 92,73] 0,0024[3]	1,8 [0,6; 2,9] 0,0024[3]
G3	9/527 (1,7)	2/506 (0,4)	4,32 [0,94; 19,90] 0,0604[2]	4,38 [0,94; 20,36] 0,0399[3]	1,3 [0,1; 2,5] 0,0399[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesterone receptor status (Interaction p-value: 0,2718)					
Negative	4/156 (2,6)	1/169 (0,6)	4,33 [0,49; 38,35] 0,1875[2]	4,42 [0,49; 39,99] 0,1985[4]	2,0 [-0,8; 4,7] 0,1985[4]
Positive	22/1089 (2,0)	2/1066 (0,2)	10,77 [2,54; 45,68] 0,0013[2]	10,97 [2,57; 46,76] <,0001[3]	1,8 [1,0; 2,7] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9997)					
White	18/958 (1,9)	3/943 (0,3)	5,91 [1,75; 19,98] 0,0043[2]	6,00 [1,76; 20,44] 0,0011[3]	1,6 [0,6; 2,5] 0,0011[3]
Asian	2/250 (0,8)	0/242 (0,0)	4,84 [0,23; 100,31] 0,3079[2]	4,88 [0,23; 102,16] 0,4991[4]	0,8 [-0,3; 1,9] 0,4991[4]
Other	6/62 (9,7)	0/64 (0,0)	13,41 [0,77; 233,15] 0,0748[2]	14,84 [0,82; 269,32] 0,0125[4]	9,7 [2,3; 17,0] 0,0125[4]
ECOG-PS (Interaction p-value: 0,9744)					
ECOG-PS 0	22/1070 (2,1)	3/1019 (0,3)	6,98 [2,10; 23,26] 0,0015[2]	7,11 [2,12; 23,83] 0,0002[3]	1,8 [0,8; 2,7] 0,0002[3]
ECOG-PS 1	4/213 (1,9)	0/245 (0,0)	10,35 [0,56; 191,06] 0,1163[2]	10,55 [0,56; 197,03] 0,0461[4]	1,9 [0,1; 3,7] 0,0461[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 321.1.2: Subgroups - adverse events according PT Dermatitis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8072)					
< 65 years	14/918 (1,5)	5/936 (0,5)	2,85 [1,03; 7,89] 0,0432[2]	2,88 [1,03; 8,04] 0,0342[3]	1,0 [0,1; 1,9] 0,0342[3]
≥ 65 years	5/365 (1,4)	2/328 (0,6)	2,25 [0,44; 11,50] 0,3313[2]	2,26 [0,44; 11,75] 0,4555[4]	0,8 [-0,7; 2,2] 0,4555[4]
Prior treatment (Interaction p-value: 0,8069)					
Neoadjuvant chemotherapy	7/430 (1,6)	2/415 (0,5)	3,38 [0,71; 16,17] 0,1276[2]	3,42 [0,71; 16,55] 0,1780[4]	1,1 [-0,2; 2,5] 0,1780[4]
Adjuvant chemotherapy	11/784 (1,4)	4/768 (0,5)	2,69 [0,86; 8,42] 0,0884[2]	2,72 [0,86; 8,57] 0,0757[3]	0,9 [-0,1; 1,9] 0,0757[3]
No chemotherapy	1/69 (1,4)	1/81 (1,2)	1,17 [0,07; 18,42] 0,9091[2]	1,18 [0,07; 19,17] 1,0000[4]	0,2 [-3,5; 3,9] 1,0000[4]
Region (Interaction p-value: 0,3321)					
North America / Europe	5/678 (0,7)	4/649 (0,6)	1,20 [0,32; 4,44] 0,7884[2]	1,20 [0,32; 4,48] 1,0000[4]	0,1 [-0,8; 1,0] 1,0000[4]
Asia	9/203 (4,4)	2/201 (1,0)	4,46 [0,97; 20,37] 0,0540[2]	4,62 [0,98; 21,64] 0,0337[3]	3,4 [0,3; 6,6] 0,0337[3]
Other	5/402 (1,2)	1/414 (0,2)	5,15 [0,60; 43,88] 0,1338[2]	5,20 [0,61; 44,72] 0,1185[4]	1,0 [-0,2; 2,2] 0,1185[4]
Primary tumor size (Interaction p-value: 0,2891)					
< 20 mm	3/331 (0,9)	1/334 (0,3)	3,03 [0,32; 28,95] 0,3363[2]	3,05 [0,32; 29,43] 0,3716[4]	0,6 [-0,6; 1,8] 0,3716[4]
≥ 20 but < 50 mm	15/646 (2,3)	4/653 (0,6)	3,79 [1,26; 11,36] 0,0173[2]	3,86 [1,27; 11,68] 0,0103[3]	1,7 [0,4; 3,0] 0,0103[3]
≥ 50 mm	1/289 (0,3)	2/265 (0,8)	0,46 [0,04; 5,03] 0,5233[2]	0,46 [0,04; 5,06] 0,6087[4]	-0,4 [-1,7; 0,8] 0,6087[4]
Number of positive lymph nodes (Interaction p-value: 0,5331)					
0-3	5/427 (1,2)	1/418 (0,2)	4,89 [0,57; 41,72] 0,1463[2]	4,94 [0,57; 42,47] 0,2172[4]	0,9 [-0,2; 2,1] 0,2172[4]
4-9	10/549 (1,8)	3/542 (0,6)	3,29 [0,91; 11,89] 0,0692[2]	3,33 [0,91; 12,18] 0,0536[3]	1,3 [-0,0; 2,5] 0,0536[3]
≥ 10	4/307 (1,3)	3/304 (1,0)	1,32 [0,30; 5,85] 0,7145[2]	1,32 [0,29; 5,97] 1,0000[4]	0,3 [-1,4; 2,0] 1,0000[4]
Tumor stage (Interaction p-value: 0,8994)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	1/113 (0,9)	0/114 (0,0)	3,03 [0,12; 73,51] 0,4963[2]	3,05 [0,12; 75,75] 0,4978[4]	0,9 [-0,8; 2,6] 0,4978[4]
IIB	4/151 (2,6)	0/136 (0,0)	8,11 [0,44; 149,30] 0,1589[2]	8,33 [0,44; 156,14] 0,1244[4]	2,6 [0,1; 5,2] 0,1244[4]
IIIA	7/495 (1,4)	2/488 (0,4)	3,45 [0,72; 16,53] 0,1212[2]	3,49 [0,72; 16,86] 0,1778[4]	1,0 [-0,2; 2,2] 0,1778[4]
IIIB	1/54 (1,9)	0/45 (0,0)	2,51 [0,10; 60,13] 0,5703[2]	2,55 [0,10; 64,17] 1,0000[4]	1,9 [-1,7; 5,4] 1,0000[4]
IIIC	6/468 (1,3)	5/479 (1,0)	1,23 [0,38; 4,00] 0,7328[2]	1,23 [0,37; 4,06] 0,7323[3]	0,2 [-1,1; 1,6] 0,7323[3]
Tumor grade (Interaction p-value: 0,7827)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	10/612 (1,6)	5/602 (0,8)	1,97 [0,68; 5,72] 0,2141[2]	1,98 [0,67; 5,84] 0,2052[3]	0,8 [-0,4; 2,0] 0,2052[3]
G3	7/527 (1,3)	2/506 (0,4)	3,36 [0,70; 16,10] 0,1294[2]	3,39 [0,70; 16,41] 0,1786[4]	0,9 [-0,2; 2,1] 0,1786[4]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9998)					
Negative	0/156 (0,0)	0/169 (0,0)	NE	NE	NE
Positive	19/1089 (1,7)	7/1066 (0,7)	2,66 [1,12; 6,29] 0,0264[2]	2,69 [1,12; 6,42] 0,0207[3]	1,1 [0,2; 2,0] 0,0207[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,6415)					
White	9/958 (0,9)	5/943 (0,5)	1,77 [0,60; 5,27] 0,3035[2]	1,78 [0,59; 5,33] 0,2968[3]	0,4 [-0,4; 1,2] 0,2968[3]
Asian	9/250 (3,6)	2/242 (0,8)	4,36 [0,95; 19,96] 0,0581[2]	4,48 [0,96; 20,96] 0,0375[3]	2,8 [0,2; 5,3] 0,0375[3]
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
First endocrine therapy (Interaction p-value: 0,3482)					
Tamoxifen	2/114 (1,8)	2/132 (1,5)	1,16 [0,17; 8,09] 0,8825[2]	1,16 [0,16; 8,37] 1,0000[4]	0,2 [-2,9; 3,4] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	17/1169 (1,5)	5/1132 (0,4)	3,29 [1,22; 8,89] 0,0188[2]	3,33 [1,22; 9,05] 0,0126[3]	1,0 [0,2; 1,8] 0,0126[3]
ECOG-PS (Interaction p-value: 0,2238)					
ECOG-PS 0	16/1070 (1,5)	4/1019 (0,4)	3,81 [1,28; 11,36] 0,0164[2]	3,85 [1,28; 11,56] 0,0097[3]	1,1 [0,3; 1,9] 0,0097[3]
ECOG-PS 1	3/213 (1,4)	3/245 (1,2)	1,15 [0,23; 5,64] 0,8630[2]	1,15 [0,23; 5,77] 1,0000[4]	0,2 [-1,9; 2,3] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 322.1.2: Subgroups - adverse events according PT Diarrhoea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,7077)					
Neoadjuvant chemotherapy	352/430 (81,9)	38/415 (9,2)	8,94 [6,58; 12,14] <,0001[2]	44,77 [29,59; 67,74] <,0001[3]	72,7 [68,1; 77,3] <,0001[3]
Adjuvant chemotherapy	652/784 (83,2)	68/768 (8,9)	9,39 [7,47; 11,81] <,0001[2]	50,85 [37,24; 69,42] <,0001[3]	74,3 [71,0; 77,6] <,0001[3]
No chemotherapy	56/69 (81,2)	5/81 (6,2)	13,15 [5,58; 30,97] <,0001[2]	65,48 [22,07; 194,28] <,0001[3]	75,0 [64,4; 85,6] <,0001[3]
Primary tumor size (Interaction p-value: 0,4738)					
< 20 mm	272/331 (82,2)	27/334 (8,1)	10,17 [7,06; 14,64] <,0001[2]	52,42 [32,31; 85,03] <,0001[3]	74,1 [69,0; 79,1] <,0001[3]
≥ 20 but < 50 mm	528/646 (81,7)	53/653 (8,1)	10,07 [7,76; 13,07] <,0001[2]	50,66 [35,89; 71,49] <,0001[3]	73,6 [70,0; 77,3] <,0001[3]
≥ 50 mm	248/289 (85,8)	29/265 (10,9)	7,84 [5,54; 11,09] <,0001[2]	49,22 [29,62; 81,80] <,0001[3]	74,9 [69,4; 80,4] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,7530)					
0-3	347/427 (81,3)	33/418 (7,9)	10,29 [7,40; 14,33] <,0001[2]	50,60 [32,90; 77,84] <,0001[3]	73,4 [68,9; 77,9] <,0001[3]
4-9	462/549 (84,2)	52/542 (9,6)	8,77 [6,76; 11,39] <,0001[2]	50,04 [34,69; 72,18] <,0001[3]	74,6 [70,6; 78,5] <,0001[3]
≥ 10	251/307 (81,8)	26/304 (8,6)	9,56 [6,59; 13,86] <,0001[2]	47,92 [29,20; 78,66] <,0001[3]	73,2 [67,9; 78,5] <,0001[3]
Tumor stage (Interaction p-value: 0,3755)					
IIA	87/113 (77,0)	11/114 (9,6)	7,98 [4,51; 14,12] <,0001[2]	31,33 [14,65; 67,03] <,0001[3]	67,3 [57,9; 76,8] <,0001[3]
IIB	122/151 (80,8)	8/136 (5,9)	13,74 [6,98; 27,02] <,0001[2]	67,31 [29,61; 152,99] <,0001[3]	74,9 [67,5; 82,3] <,0001[3]
IIIA	422/495 (85,3)	39/488 (8,0)	10,67 [7,88; 14,45] <,0001[2]	66,55 [44,13; 100,37] <,0001[3]	77,3 [73,3; 81,2] <,0001[3]
IIIB	41/54 (75,9)	6/45 (13,3)	5,69 [2,66; 12,17] <,0001[2]	20,50 [7,09; 59,29] <,0001[3]	62,6 [47,5; 77,7] <,0001[3]
IIIC	387/468 (82,7)	46/479 (9,6)	8,61 [6,52; 11,37] <,0001[2]	44,97 [30,54; 66,22] <,0001[3]	73,1 [68,8; 77,4] <,0001[3]
Tumor grade (Interaction p-value: 0,4036)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	78/91 (85,7)	8/93 (8,6)	9,96 [5,11; 19,43] <,0001[2]	63,75 [25,08; 162,03] <,0001[3]	77,1 [67,9; 86,3] <,0001[3]
G2	516/612 (84,3)	57/602 (9,5)	8,90 [6,94; 11,43] <,0001[2]	51,39 [36,25; 72,87] <,0001[3]	74,8 [71,1; 78,6] <,0001[3]
G3	422/527 (80,1)	44/506 (8,7)	9,21 [6,92; 12,25] <,0001[2]	42,20 [28,98; 61,46] <,0001[3]	71,4 [67,2; 75,6] <,0001[3]
GX	42/51 (82,4)	1/59 (1,7)	48,59 [6,93; 340,64] <,0001[2]	270,67 [33,02; 2218,73] <,0001[3]	80,7 [69,7; 91,6] <,0001[3]
Race (Interaction p-value: 0,0514)					
White	792/958 (82,7)	93/943 (9,9)	8,38 [6,90; 10,19] <,0001[2]	43,61 [33,23; 57,22] <,0001[3]	72,8 [69,7; 75,9] <,0001[3]
Asian	204/250 (81,6)	11/242 (4,5)	17,95 [10,05; 32,07] <,0001[2]	93,13 [46,98; 184,61] <,0001[3]	77,1 [71,6; 82,5] <,0001[3]
Other	52/62 (83,9)	6/64 (9,4)	8,95 [4,14; 19,31] <,0001[2]	50,27 [17,09; 147,89] <,0001[3]	74,5 [62,9; 86,1] <,0001[3]
First endocrine therapy (Interaction p-value: 0,3933)					
Tamoxifen	86/114 (75,4)	8/132 (6,1)	12,45 [6,31; 24,56] <,0001[2]	47,61 [20,71; 109,45] <,0001[3]	69,4 [60,5; 78,3] <,0001[3]
Aromatase inhibitor	974/1169 (83,3)	103/1132 (9,1)	9,16 [7,60; 11,03] <,0001[2]	49,90 [38,70; 64,35] <,0001[3]	74,2 [71,5; 76,9] <,0001[3]
ECOG-PS (Interaction p-value: 0,5566)					
ECOG-PS 0	894/1070 (83,6)	93/1019 (9,1)	9,15 [7,53; 11,13] <,0001[2]	50,58 [38,70; 66,09] <,0001[3]	74,4 [71,6; 77,3] <,0001[3]
ECOG-PS 1	166/213 (77,9)	18/245 (7,3)	10,61 [6,76; 16,64] <,0001[2]	44,54 [24,96; 79,47] <,0001[3]	70,6 [64,1; 77,0] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 323.1.2: Subgroups - adverse events according PT Dizziness from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7591)					
< 65 years	98/918 (10,7)	61/936 (6,5)	1,64 [1,21; 2,23] 0,0016[2]	1,71 [1,23; 2,39] 0,0014[3]	4,2 [1,6; 6,7] 0,0014[3]
≥ 65 years	40/365 (11,0)	24/328 (7,3)	1,50 [0,92; 2,43] 0,1016[2]	1,56 [0,92; 2,65] 0,0983[3]	3,6 [-0,6; 7,9] 0,0983[3]
Prior treatment (Interaction p-value: 0,3869)					
Neoadjuvant chemotherapy	45/430 (10,5)	26/415 (6,3)	1,67 [1,05; 2,66] 0,0301[2]	1,75 [1,06; 2,89] 0,0278[3]	4,2 [0,5; 7,9] 0,0278[3]
Adjuvant chemotherapy	82/784 (10,5)	55/768 (7,2)	1,46 [1,05; 2,02] 0,0231[2]	1,51 [1,06; 2,16] 0,0220[3]	3,3 [0,5; 6,1] 0,0220[3]
No chemotherapy	11/69 (15,9)	4/81 (4,9)	3,23 [1,08; 9,68] 0,0365[2]	3,65 [1,11; 12,05] 0,0252[3]	11,0 [1,2; 20,8] 0,0252[3]
Region (Interaction p-value: 0,6923)					
North America / Europe	83/678 (12,2)	48/649 (7,4)	1,66 [1,18; 2,32] 0,0035[2]	1,75 [1,20; 2,54] 0,0031[3]	4,8 [1,7; 8,0] 0,0031[3]
Asia	23/203 (11,3)	18/201 (9,0)	1,27 [0,70; 2,27] 0,4308[2]	1,30 [0,68; 2,49] 0,4293[3]	2,4 [-3,5; 8,3] 0,4293[3]
Other	32/402 (8,0)	19/414 (4,6)	1,73 [1,00; 3,01] 0,0500[2]	1,80 [1,00; 3,23] 0,0467[3]	3,4 [0,0; 6,7] 0,0467[3]
Primary tumor size (Interaction p-value: 0,4405)					
< 20 mm	27/331 (8,2)	20/334 (6,0)	1,36 [0,78; 2,38] 0,2775[2]	1,39 [0,77; 2,54] 0,2752[3]	2,2 [-1,7; 6,1] 0,2752[3]
≥ 20 but < 50 mm	79/646 (12,2)	43/653 (6,6)	1,86 [1,30; 2,65] 0,0006[2]	1,98 [1,34; 2,92] 0,0005[3]	5,6 [2,5; 8,8] 0,0005[3]
≥ 50 mm	31/289 (10,7)	22/265 (8,3)	1,29 [0,77; 2,17] 0,3344[2]	1,33 [0,75; 2,36] 0,3324[3]	2,4 [-2,5; 7,3] 0,3324[3]
Number of positive lymph nodes (Interaction p-value: 0,5556)					
0-3	46/427 (10,8)	27/418 (6,5)	1,67 [1,06; 2,63] 0,0278[2]	1,75 [1,07; 2,87] 0,0257[3]	4,3 [0,5; 8,1] 0,0257[3]
4-9	60/549 (10,9)	33/542 (6,1)	1,79 [1,19; 2,70] 0,0049[2]	1,89 [1,22; 2,95] 0,0042[3]	4,8 [1,5; 8,1] 0,0042[3]
≥ 10	32/307 (10,4)	25/304 (8,2)	1,27 [0,77; 2,09] 0,3514[2]	1,30 [0,75; 2,25] 0,3499[3]	2,2 [-2,4; 6,8] 0,3499[3]
Tumor stage (Interaction p-value: 0,7881)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	10/113 (8,8)	8/114 (7,0)	1,26 [0,52; 3,08] 0,6105[2]	1,29 [0,49; 3,39] 0,6095[3]	1,8 [-5,2; 8,9] 0,6095[3]
IIB	17/151 (11,3)	9/136 (6,6)	1,70 [0,78; 3,69] 0,1785[2]	1,79 [0,77; 4,16] 0,1714[3]	4,6 [-1,9; 11,2] 0,1714[3]
IIIA	56/495 (11,3)	28/488 (5,7)	1,97 [1,27; 3,05] 0,0023[2]	2,10 [1,31; 3,36] 0,0018[3]	5,6 [2,1; 9,0] 0,0018[3]
IIIB	5/54 (9,3)	3/45 (6,7)	1,39 [0,35; 5,50] 0,6397[2]	1,43 [0,32; 6,34] 0,7248[4]	2,6 [-8,0; 13,2] 0,7248[4]
IIIC	50/468 (10,7)	37/479 (7,7)	1,38 [0,92; 2,07] 0,1170[2]	1,43 [0,92; 2,23] 0,1149[3]	3,0 [-0,7; 6,6] 0,1149[3]
Tumor grade (Interaction p-value: 0,9502)					
G1	7/91 (7,7)	6/93 (6,5)	1,19 [0,42; 3,41] 0,7430[2]	1,21 [0,39; 3,74] 0,7426[3]	1,2 [-6,2; 8,7] 0,7426[3]
G2	79/612 (12,9)	47/602 (7,8)	1,65 [1,17; 2,33] 0,0041[2]	1,75 [1,20; 2,56] 0,0036[3]	5,1 [1,7; 8,5] 0,0036[3]
G3	49/527 (9,3)	30/506 (5,9)	1,57 [1,01; 2,43] 0,0439[2]	1,63 [1,01; 2,61] 0,0417[3]	3,4 [0,1; 6,6] 0,0417[3]
GX	3/51 (5,9)	2/59 (3,4)	1,74 [0,30; 9,98] 0,5369[2]	1,78 [0,29; 11,10] 0,6613[4]	2,5 [-5,4; 10,4] 0,6613[4]
Race (Interaction p-value: 0,8984)					
White	100/958 (10,4)	60/943 (6,4)	1,64 [1,21; 2,23] 0,0016[2]	1,72 [1,23; 2,39] 0,0014[3]	4,1 [1,6; 6,6] 0,0014[3]
Asian	27/250 (10,8)	18/242 (7,4)	1,45 [0,82; 2,57] 0,1994[2]	1,51 [0,81; 2,81] 0,1959[3]	3,4 [-1,7; 8,4] 0,1959[3]
Other	9/62 (14,5)	5/64 (7,8)	1,86 [0,66; 5,24] 0,2411[2]	2,00 [0,63; 6,36] 0,2313[3]	6,7 [-4,3; 17,7] 0,2313[3]
First endocrine therapy (Interaction p-value: 0,3204)					
Tamoxifen	13/114 (11,4)	6/132 (4,5)	2,51 [0,99; 6,39] 0,0537[2]	2,70 [0,99; 7,36] 0,0445[3]	6,9 [0,0; 13,7] 0,0445[3]
Aromatase inhibitor	125/1169 (10,7)	79/1132 (7,0)	1,53 [1,17; 2,01] 0,0019[2]	1,60 [1,19; 2,14] 0,0017[3]	3,7 [1,4; 6,0] 0,0017[3]
ECOG-PS (Interaction p-value: 0,8368)					
ECOG-PS 0	110/1070 (10,3)	66/1019 (6,5)	1,59 [1,18; 2,13] 0,0020[2]	1,65 [1,20; 2,27] 0,0018[3]	3,8 [1,4; 6,2] 0,0018[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	28/213 (13,1)	19/245 (7,8)	1,70 [0,98; 2,95] 0,0614[2]	1,80 [0,97; 3,33] 0,0579[3]	5,4 [-0,2; 11,0] 0,0579[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 324.1.2: Subgroups - adverse events according PT Dry eye from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5410)					
< 65 years	31/918 (3,4)	10/936 (1,1)	3,16 [1,56; 6,41] 0,0014[2]	3,24 [1,58; 6,64] 0,0007[3]	2,3 [1,0; 3,6] 0,0007[3]
≥ 65 years	7/365 (1,9)	1/328 (0,3)	6,29 [0,78; 50,86] 0,0846[2]	6,39 [0,78; 52,25] 0,0718[4]	1,6 [0,1; 3,1] 0,0718[4]
Prior treatment (Interaction p-value: 0,9901)					
Neoadjuvant chemotherapy	11/430 (2,6)	3/415 (0,7)	3,54 [0,99; 12,59] 0,0510[2]	3,61 [1,00; 13,02] 0,0367[3]	1,8 [0,1; 3,5] 0,0367[3]
Adjuvant chemotherapy	26/784 (3,3)	8/768 (1,0)	3,18 [1,45; 6,99] 0,0039[2]	3,26 [1,47; 7,24] 0,0022[3]	2,3 [0,8; 3,7] 0,0022[3]
No chemotherapy	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Region (Interaction p-value: 0,6962)					
North America / Europe	26/678 (3,8)	6/649 (0,9)	4,15 [1,72; 10,01] 0,0016[2]	4,27 [1,75; 10,45] 0,0006[3]	2,9 [1,3; 4,5] 0,0006[3]
Asia	6/203 (3,0)	2/201 (1,0)	2,97 [0,61; 14,54] 0,1791[2]	3,03 [0,60; 15,20] 0,2842[4]	2,0 [-0,7; 4,7] 0,2842[4]
Other	6/402 (1,5)	3/414 (0,7)	2,06 [0,52; 8,18] 0,3045[2]	2,08 [0,52; 8,36] 0,3344[4]	0,8 [-0,7; 2,2] 0,3344[4]
Primary tumor size (Interaction p-value: 0,8832)					
< 20 mm	9/331 (2,7)	2/334 (0,6)	4,54 [0,99; 20,86] 0,0518[2]	4,64 [0,99; 21,64] 0,0321[3]	2,1 [0,2; 4,1] 0,0321[3]
≥ 20 but < 50 mm	19/646 (2,9)	6/653 (0,9)	3,20 [1,29; 7,96] 0,0123[2]	3,27 [1,30; 8,24] 0,0080[3]	2,0 [0,5; 3,5] 0,0080[3]
≥ 50 mm	9/289 (3,1)	3/265 (1,1)	2,75 [0,75; 10,05] 0,1259[2]	2,81 [0,75; 10,48] 0,1094[3]	2,0 [-0,4; 4,4] 0,1094[3]
Number of positive lymph nodes (Interaction p-value: 0,5057)					
0-3	18/427 (4,2)	3/418 (0,7)	5,87 [1,74; 19,79] 0,0043[2]	6,09 [1,78; 20,83] 0,0011[3]	3,5 [1,4; 5,6] 0,0011[3]
4-9	12/549 (2,2)	5/542 (0,9)	2,37 [0,84; 6,68] 0,1028[2]	2,40 [0,84; 6,86] 0,0921[3]	1,3 [-0,2; 2,7] 0,0921[3]
≥ 10	8/307 (2,6)	3/304 (1,0)	2,64 [0,71; 9,86] 0,1486[2]	2,68 [0,71; 10,22] 0,1324[3]	1,6 [-0,5; 3,7] 0,1324[3]
Tumor stage (Interaction p-value: 0,5145)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	3/113 (2,7)	0/114 (0,0)	7,06 [0,37; 135,16] 0,1943[2]	7,25 [0,37; 142,05] 0,1217[4]	2,7 [-0,3; 5,6] 0,1217[4]
IIB	5/151 (3,3)	1/136 (0,7)	4,50 [0,53; 38,07] 0,1670[2]	4,62 [0,53; 40,08] 0,2177[4]	2,6 [-0,6; 5,8] 0,2177[4]
IIIA	14/495 (2,8)	3/488 (0,6)	4,60 [1,33; 15,91] 0,0159[2]	4,71 [1,34; 16,48] 0,0078[3]	2,2 [0,6; 3,8] 0,0078[3]
IIIB	1/54 (1,9)	2/45 (4,4)	0,42 [0,04; 4,45] 0,4686[2]	0,41 [0,04; 4,63] 0,5894[4]	-2,6 [-9,6; 4,4] 0,5894[4]
IIIC	15/468 (3,2)	5/479 (1,0)	3,07 [1,12; 8,38] 0,0285[2]	3,14 [1,13; 8,71] 0,0207[3]	2,2 [0,3; 4,0] 0,0207[3]
Tumor grade (Interaction p-value: 0,4789)					
G1	3/91 (3,3)	2/93 (2,2)	1,53 [0,26; 8,96] 0,6354[2]	1,55 [0,25; 9,51] 0,6806[4]	1,1 [-3,6; 5,9] 0,6806[4]
G2	16/612 (2,6)	6/602 (1,0)	2,62 [1,03; 6,66] 0,0424[2]	2,67 [1,04; 6,86] 0,0346[3]	1,6 [0,1; 3,1] 0,0346[3]
G3	17/527 (3,2)	2/506 (0,4)	8,16 [1,90; 35,14] 0,0048[2]	8,40 [1,93; 36,55] 0,0007[3]	2,8 [1,2; 4,4] 0,0007[3]
GX	2/51 (3,9)	1/59 (1,7)	2,31 [0,22; 24,78] 0,4880[2]	2,37 [0,21; 26,90] 0,5957[4]	2,2 [-4,0; 8,5] 0,5957[4]
Progesterone receptor status (Interaction p-value: 0,2710)					
Negative	5/156 (3,2)	2/169 (1,2)	2,71 [0,53; 13,76] 0,2296[2]	2,76 [0,53; 14,46] 0,2669[4]	2,0 [-1,2; 5,2] 0,2669[4]
Positive	32/1089 (2,9)	9/1066 (0,8)	3,48 [1,67; 7,26] 0,0009[2]	3,56 [1,69; 7,49] 0,0004[3]	2,1 [1,0; 3,2] 0,0004[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9642)					
White	28/958 (2,9)	9/943 (1,0)	3,06 [1,45; 6,45] 0,0033[2]	3,12 [1,47; 6,66] 0,0019[3]	2,0 [0,7; 3,2] 0,0019[3]
Asian	8/250 (3,2)	2/242 (0,8)	3,87 [0,83; 18,05] 0,0848[2]	3,97 [0,83; 18,87] 0,1063[4]	2,4 [-0,1; 4,8] 0,1063[4]
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
First endocrine therapy (Interaction p-value: 0,6245)					
Tamoxifen	4/114 (3,5)	2/132 (1,5)	2,32 [0,43; 12,41] 0,3269[2]	2,36 [0,42; 13,15] 0,4199[4]	2,0 [-2,0; 6,0] 0,4199[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	34/1169 (2,9)	9/1132 (0,8)	3,66 [1,76; 7,59] 0,0005[2]	3,74 [1,78; 7,83] 0,0002[3]	2,1 [1,0; 3,2] 0,0002[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 325.1.2: Subgroups - adverse events according PT Dry mouth from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,4649)					
< 65 years	27/918 (2,9)	9/936 (1,0)	3,06 [1,45; 6,47] 0,0034[2]	3,12 [1,46; 6,67] 0,0020[3]	2,0 [0,7; 3,2] 0,0020[3]
≥ 65 years	18/365 (4,9)	8/328 (2,4)	2,02 [0,89; 4,59] 0,0922[2]	2,07 [0,89; 4,84] 0,0847[3]	2,5 [-0,3; 5,3] 0,0847[3]
Prior treatment (Interaction p-value: 0,5442)					
Neoadjuvant chemotherapy	11/430 (2,6)	7/415 (1,7)	1,52 [0,59; 3,87] 0,3842[2]	1,53 [0,59; 3,99] 0,3805[3]	0,9 [-1,1; 2,8] 0,3805[3]
Adjuvant chemotherapy	30/784 (3,8)	10/768 (1,3)	2,94 [1,45; 5,97] 0,0029[2]	3,02 [1,46; 6,21] 0,0017[3]	2,5 [1,0; 4,1] 0,0017[3]
No chemotherapy	4/69 (5,8)	0/81 (0,0)	10,54 [0,58; 192,43] 0,1119[2]	11,20 [0,59; 211,78] 0,0427[4]	5,8 [0,3; 11,3] 0,0427[4]
Region (Interaction p-value: 0,4423)					
North America / Europe	38/678 (5,6)	13/649 (2,0)	2,80 [1,50; 5,20] 0,0012[2]	2,90 [1,53; 5,50] 0,0006[3]	3,6 [1,6; 5,6] 0,0006[3]
Asia	3/203 (1,5)	3/201 (1,5)	0,99 [0,20; 4,85] 0,9903[2]	0,99 [0,20; 4,96] 1,0000[4]	-0,0 [-2,4; 2,3] 1,0000[4]
Other	4/402 (1,0)	1/414 (0,2)	4,12 [0,46; 36,70] 0,2045[2]	4,15 [0,46; 37,30] 0,2109[4]	0,8 [-0,3; 1,8] 0,2109[4]
Primary tumor size (Interaction p-value: 0,1122)					
< 20 mm	16/331 (4,8)	1/334 (0,3)	16,15 [2,15; 121,05] 0,0068[2]	16,91 [2,23; 128,29] 0,0002[3]	4,5 [2,2; 6,9] 0,0002[3]
≥ 20 but < 50 mm	16/646 (2,5)	10/653 (1,5)	1,62 [0,74; 3,54] 0,2285[2]	1,63 [0,74; 3,63] 0,2238[3]	0,9 [-0,6; 2,5] 0,2238[3]
≥ 50 mm	13/289 (4,5)	6/265 (2,3)	1,99 [0,77; 5,15] 0,1579[2]	2,03 [0,76; 5,43] 0,1489[3]	2,2 [-0,8; 5,2] 0,1489[3]
Number of positive lymph nodes (Interaction p-value: 0,2561)					
0-3	18/427 (4,2)	4/418 (1,0)	4,41 [1,50; 12,91] 0,0069[2]	4,56 [1,53; 13,57] 0,0029[3]	3,3 [1,1; 5,4] 0,0029[3]
4-9	16/549 (2,9)	10/542 (1,8)	1,58 [0,72; 3,45] 0,2513[2]	1,60 [0,72; 3,55] 0,2469[3]	1,1 [-0,7; 2,9] 0,2469[3]
≥ 10	11/307 (3,6)	3/304 (1,0)	3,63 [1,02; 12,89] 0,0460[2]	3,73 [1,03; 13,50] 0,0320[3]	2,6 [0,2; 5,0] 0,0320[3]
Tumor stage (Interaction p-value: 0,6980)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	8/113 (7,1)	0/114 (0,0)	17,15 [1,00; 293,63] 0,0499[2]	18,45 [1,05; 323,59] 0,0033[4]	7,1 [2,4; 11,8] 0,0033[4]
IIB	2/151 (1,3)	2/136 (1,5)	0,90 [0,13; 6,31] 0,9161[2]	0,90 [0,12; 6,47] 1,0000[4]	-0,1 [-2,9; 2,6] 1,0000[4]
IIIA	16/495 (3,2)	10/488 (2,0)	1,58 [0,72; 3,44] 0,2522[2]	1,60 [0,72; 3,55] 0,2478[3]	1,2 [-0,8; 3,2] 0,2478[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	17/468 (3,6)	5/479 (1,0)	3,48 [1,29; 9,36] 0,0135[2]	3,57 [1,31; 9,77] 0,0082[3]	2,6 [0,7; 4,5] 0,0082[3]
Tumor grade (Interaction p-value: 0,3093)					
G1	7/91 (7,7)	2/93 (2,2)	3,58 [0,76; 16,76] 0,1058[2]	3,79 [0,77; 18,77] 0,0980[4]	5,5 [-0,7; 11,8] 0,0980[4]
G2	22/612 (3,6)	10/602 (1,7)	2,16 [1,03; 4,53] 0,0406[2]	2,21 [1,04; 4,70] 0,0355[3]	1,9 [0,1; 3,7] 0,0355[3]
G3	16/527 (3,0)	5/506 (1,0)	3,07 [1,13; 8,32] 0,0273[2]	3,14 [1,14; 8,63] 0,0197[3]	2,0 [0,3; 3,7] 0,0197[3]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9617)					
Negative	5/156 (3,2)	0/169 (0,0)	11,91 [0,66; 213,66] 0,0926[2]	12,31 [0,67; 224,42] 0,0246[4]	3,2 [0,4; 6,0] 0,0246[4]
Positive	39/1089 (3,6)	16/1066 (1,5)	2,39 [1,34; 4,24] 0,0031[2]	2,44 [1,35; 4,39] 0,0022[3]	2,1 [0,8; 3,4] 0,0022[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,6216)					
White	38/958 (4,0)	13/943 (1,4)	2,88 [1,54; 5,37] 0,0009[2]	2,95 [1,56; 5,58] 0,0005[3]	2,6 [1,1; 4,0] 0,0005[3]
Asian	4/250 (1,6)	3/242 (1,2)	1,29 [0,29; 5,71] 0,7365[2]	1,30 [0,29; 5,85] 1,0000[4]	0,4 [-1,7; 2,4] 1,0000[4]
Other	2/62 (3,2)	0/64 (0,0)	5,16 [0,25; 105,34] 0,2864[2]	5,33 [0,25; 113,30] 0,2401[4]	3,2 [-1,2; 7,6] 0,2401[4]
First endocrine therapy (Interaction p-value: 0,5869)					
Tamoxifen	4/114 (3,5)	1/132 (0,8)	4,63 [0,53; 40,85] 0,1675[2]	4,76 [0,52; 43,25] 0,1855[4]	2,8 [-0,9; 6,4] 0,1855[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	41/1169 (3,5)	16/1132 (1,4)	2,48 [1,40; 4,40] 0,0018[2]	2,54 [1,41; 4,54] 0,0012[3]	2,1 [0,8; 3,4] 0,0012[3]
ECOG-PS (Interaction p-value: 0,5821)					
ECOG-PS 0	34/1070 (3,2)	11/1019 (1,1)	2,94 [1,50; 5,78] 0,0017[2]	3,01 [1,52; 5,97] 0,0010[3]	2,1 [0,9; 3,3] 0,0010[3]
ECOG-PS 1	11/213 (5,2)	6/245 (2,4)	2,11 [0,79; 5,61] 0,1347[2]	2,17 [0,79; 5,97] 0,1252[3]	2,7 [-0,8; 6,3] 0,1252[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 326.1.2: Subgroups - adverse events according PT Dry skin from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5109)					
< 65 years	37/918 (4,0)	17/936 (1,8)	2,22 [1,26; 3,91] 0,0059[2]	2,27 [1,27; 4,06] 0,0046[3]	2,2 [0,7; 3,7] 0,0046[3]
≥ 65 years	14/365 (3,8)	8/328 (2,4)	1,57 [0,67; 3,70] 0,2998[2]	1,60 [0,66; 3,85] 0,2951[3]	1,4 [-1,2; 4,0] 0,2951[3]
Prior treatment (Interaction p-value: 0,7983)					
Neoadjuvant chemotherapy	15/430 (3,5)	6/415 (1,4)	2,41 [0,95; 6,16] 0,0654[2]	2,46 [0,95; 6,41] 0,0566[3]	2,0 [-0,0; 4,1] 0,0566[3]
Adjuvant chemotherapy	34/784 (4,3)	17/768 (2,2)	1,96 [1,10; 3,48] 0,0216[2]	2,00 [1,11; 3,62] 0,0190[3]	2,1 [0,4; 3,9] 0,0190[3]
No chemotherapy	2/69 (2,9)	2/81 (2,5)	1,17 [0,17; 8,12] 0,8709[2]	1,18 [0,16; 8,60] 1,0000[4]	0,4 [-4,8; 5,6] 1,0000[4]
Region (Interaction p-value: 0,4606)					
North America / Europe	32/678 (4,7)	15/649 (2,3)	2,04 [1,12; 3,74] 0,0205[2]	2,09 [1,12; 3,90] 0,0177[3]	2,4 [0,4; 4,4] 0,0177[3]
Asia	11/203 (5,4)	8/201 (4,0)	1,36 [0,56; 3,31] 0,4966[2]	1,38 [0,54; 3,51] 0,4947[3]	1,4 [-2,7; 5,6] 0,4947[3]
Other	8/402 (2,0)	2/414 (0,5)	4,12 [0,88; 19,28] 0,0722[2]	4,18 [0,88; 19,82] 0,0604[4]	1,5 [-0,0; 3,0] 0,0604[4]
Primary tumor size (Interaction p-value: 0,4331)					
< 20 mm	12/331 (3,6)	3/334 (0,9)	4,04 [1,15; 14,17] 0,0295[2]	4,15 [1,16; 14,85] 0,0179[3]	2,7 [0,5; 5,0] 0,0179[3]
≥ 20 but < 50 mm	26/646 (4,0)	14/653 (2,1)	1,88 [0,99; 3,56] 0,0540[2]	1,91 [0,99; 3,70] 0,0498[3]	1,9 [0,0; 3,8] 0,0498[3]
≥ 50 mm	13/289 (4,5)	8/265 (3,0)	1,49 [0,63; 3,54] 0,3661[2]	1,51 [0,62; 3,71] 0,3624[3]	1,5 [-1,7; 4,6] 0,3624[3]
Tumor stage (Interaction p-value: 0,1579)					
IIA	3/113 (2,7)	4/114 (3,5)	0,76 [0,17; 3,30] 0,7108[2]	0,75 [0,16; 3,43] 1,0000[4]	-0,9 [-5,3; 3,6] 1,0000[4]
IIB	3/151 (2,0)	5/136 (3,7)	0,54 [0,13; 2,22] 0,3931[2]	0,53 [0,12; 2,27] 0,4833[4]	-1,7 [-5,6; 2,2] 0,4833[4]
IIIA	21/495 (4,2)	6/488 (1,2)	3,45 [1,40; 8,48] 0,0069[2]	3,56 [1,42; 8,90] 0,0039[3]	3,0 [1,0; 5,0] 0,0039[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	3/54 (5,6)	1/45 (2,2)	2,50 [0,27; 23,21] 0,4203[2]	2,59 [0,26; 25,79] 0,6237[4]	3,3 [-4,1; 10,8] 0,6237[4]
IIIC	21/468 (4,5)	9/479 (1,9)	2,39 [1,11; 5,16] 0,0268[2]	2,45 [1,11; 5,41] 0,0219[3]	2,6 [0,4; 4,8] 0,0219[3]
Tumor grade (Interaction p-value: 0,2920)					
G1	4/91 (4,4)	1/93 (1,1)	4,09 [0,47; 35,88] 0,2039[2]	4,23 [0,46; 38,59] 0,2086[4]	3,3 [-1,4; 8,0] 0,2086[4]
G2	26/612 (4,2)	9/602 (1,5)	2,84 [1,34; 6,01] 0,0063[2]	2,92 [1,36; 6,29] 0,0042[3]	2,8 [0,9; 4,6] 0,0042[3]
G3	20/527 (3,8)	12/506 (2,4)	1,60 [0,79; 3,24] 0,1913[2]	1,62 [0,79; 3,36] 0,1868[3]	1,4 [-0,7; 3,5] 0,1868[3]
GX	1/51 (2,0)	3/59 (5,1)	0,39 [0,04; 3,59] 0,4027[2]	0,37 [0,04; 3,71] 0,6221[4]	-3,1 [-9,9; 3,7] 0,6221[4]
Progesterone receptor status (Interaction p-value: 0,1223)					
Negative	13/156 (8,3)	6/169 (3,6)	2,35 [0,91; 6,02] 0,0760[2]	2,47 [0,91; 6,67] 0,0663[3]	4,8 [-0,4; 9,9] 0,0663[3]
Positive	38/1089 (3,5)	19/1066 (1,8)	1,96 [1,14; 3,37] 0,0155[2]	1,99 [1,14; 3,48] 0,0135[3]	1,7 [0,4; 3,1] 0,0135[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,5629)					
White	36/958 (3,8)	14/943 (1,5)	2,53 [1,37; 4,66] 0,0029[2]	2,59 [1,39; 4,84] 0,0020[3]	2,3 [0,8; 3,7] 0,0020[3]
Asian	12/250 (4,8)	8/242 (3,3)	1,45 [0,60; 3,49] 0,4046[2]	1,47 [0,59; 3,67] 0,4014[3]	1,5 [-2,0; 5,0] 0,4014[3]
Other	3/62 (4,8)	2/64 (3,1)	1,55 [0,27; 8,95] 0,6253[2]	1,58 [0,25; 9,77] 0,6774[4]	1,7 [-5,1; 8,5] 0,6774[4]
First endocrine therapy (Interaction p-value: 0,6420)					
Tamoxifen	5/114 (4,4)	2/132 (1,5)	2,89 [0,57; 14,64] 0,1986[2]	2,98 [0,57; 15,67] 0,2546[4]	2,9 [-1,4; 7,2] 0,2546[4]
Aromatase inhibitor	46/1169 (3,9)	23/1132 (2,0)	1,94 [1,18; 3,17] 0,0087[2]	1,98 [1,19; 3,28] 0,0074[3]	1,9 [0,5; 3,3] 0,0074[3]
ECOG-PS (Interaction p-value: 0,3664)					
ECOG-PS 0	42/1070 (3,9)	22/1019 (2,2)	1,82 [1,09; 3,02] 0,0213[2]	1,85 [1,10; 3,12] 0,0192[3]	1,8 [0,3; 3,2] 0,0192[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	9/213 (4,2)	3/245 (1,2)	3,45 [0,95; 12,58] 0,0606[2]	3,56 [0,95; 13,32] 0,0449[3]	3,0 [-0,0; 6,0] 0,0449[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 327.1.2: Subgroups - adverse events according PT Dysgeusia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,3072)					
< 65 years	35/918 (3,8)	5/936 (0,5)	7,14 [2,81; 18,14] <,0001[2]	7,38 [2,88; 18,92] <,0001[3]	3,3 [2,0; 4,6] <,0001[3]
≥ 65 years	25/365 (6,8)	1/328 (0,3)	22,47 [3,06; 164,88] 0,0022[2]	24,04 [3,24; 178,47] <,0001[3]	6,5 [3,9; 9,2] <,0001[3]
Prior treatment (Interaction p-value: 0,5816)					
Neoadjuvant chemotherapy	21/430 (4,9)	1/415 (0,2)	20,27 [2,74; 149,99] 0,0032[2]	21,26 [2,85; 158,76] <,0001[3]	4,6 [2,6; 6,7] <,0001[3]
Adjuvant chemotherapy	32/784 (4,1)	5/768 (0,7)	6,27 [2,46; 16,01] 0,0001[2]	6,49 [2,52; 16,76] <,0001[3]	3,4 [1,9; 4,9] <,0001[3]
No chemotherapy	7/69 (10,1)	0/81 (0,0)	17,57 [1,02; 302,22] 0,0483[2]	19,56 [1,10; 349,01] 0,0037[4]	10,1 [3,0; 17,3] 0,0037[4]
Region (Interaction p-value: 0,7785)					
North America / Europe	33/678 (4,9)	4/649 (0,6)	7,90 [2,81; 22,17] <,0001[2]	8,25 [2,91; 23,42] <,0001[3]	4,3 [2,5; 6,0] <,0001[3]
Asia	18/203 (8,9)	1/201 (0,5)	17,82 [2,40; 132,25] 0,0048[2]	19,46 [2,57; 147,22] <,0001[3]	8,4 [4,3; 12,4] <,0001[3]
Other	9/402 (2,2)	1/414 (0,2)	9,27 [1,18; 72,82] 0,0343[2]	9,46 [1,19; 75,00] 0,0102[4]	2,0 [0,5; 3,5] 0,0102[4]
Primary tumor size (Interaction p-value: 0,6822)					
< 20 mm	17/331 (5,1)	1/334 (0,3)	17,15 [2,30; 128,16] 0,0056[2]	18,03 [2,39; 136,27] 0,0001[3]	4,8 [2,4; 7,3] 0,0001[3]
≥ 20 but < 50 mm	28/646 (4,3)	4/653 (0,6)	7,08 [2,50; 20,06] 0,0002[2]	7,35 [2,56; 21,08] <,0001[3]	3,7 [2,0; 5,4] <,0001[3]
≥ 50 mm	15/289 (5,2)	1/265 (0,4)	13,75 [1,83; 103,41] 0,0109[2]	14,45 [1,90; 110,18] 0,0007[3]	4,8 [2,2; 7,5] 0,0007[3]
Number of positive lymph nodes (Interaction p-value: 0,3471)					
0-3	24/427 (5,6)	1/418 (0,2)	23,49 [3,19; 172,88] 0,0019[2]	24,83 [3,34; 184,43] <,0001[3]	5,4 [3,1; 7,6] <,0001[3]
4-9	23/549 (4,2)	5/542 (0,9)	4,54 [1,74; 11,86] 0,0020[2]	4,70 [1,77; 12,44] 0,0006[3]	3,3 [1,4; 5,1] 0,0006[3]
≥ 10	13/307 (4,2)	0/304 (0,0)	26,74 [1,60; 447,77] 0,0223[2]	27,92 [1,65; 471,75] 0,0003[3]	4,2 [2,0; 6,5] 0,0003[3]
Tumor stage (Interaction p-value: 0,9908)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	5/113 (4,4)	0/114 (0,0)	11,10 [0,62; 198,36] 0,1019[2]	11,61 [0,63; 212,44] 0,0292[4]	4,4 [0,6; 8,2] 0,0292[4]
IIB	10/151 (6,6)	1/136 (0,7)	9,01 [1,17; 69,44] 0,0349[2]	9,57 [1,21; 75,81] 0,0095[3]	5,9 [1,7; 10,1] 0,0095[3]
IIIA	19/495 (3,8)	3/488 (0,6)	6,24 [1,86; 20,96] 0,0030[2]	6,45 [1,90; 21,95] 0,0006[3]	3,2 [1,4; 5,1] 0,0006[3]
IIIB	6/54 (11,1)	0/45 (0,0)	10,87 [0,63; 187,90] 0,1007[2]	12,20 [0,67; 222,70] 0,0303[4]	11,1 [2,7; 19,5] 0,0303[4]
IIIC	20/468 (4,3)	2/479 (0,4)	10,24 [2,41; 43,54] 0,0016[2]	10,65 [2,47; 45,81] <,0001[3]	3,9 [1,9; 5,8] <,0001[3]
Tumor grade (Interaction p-value: 0,9986)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	27/612 (4,4)	3/602 (0,5)	8,85 [2,70; 29,03] 0,0003[2]	9,22 [2,78; 30,54] <,0001[3]	3,9 [2,2; 5,6] <,0001[3]
G3	24/527 (4,6)	3/506 (0,6)	7,68 [2,33; 25,35] 0,0008[2]	8,00 [2,39; 26,74] <,0001[3]	4,0 [2,1; 5,9] <,0001[3]
GX	7/51 (13,7)	0/59 (0,0)	17,31 [1,01; 295,80] 0,0490[2]	20,06 [1,12; 360,50] 0,0036[4]	13,7 [4,3; 23,2] 0,0036[4]
Progesterone receptor status (Interaction p-value: 0,9979)					
Negative	7/156 (4,5)	0/169 (0,0)	16,24 [0,94; 282,05] 0,0556[2]	17,01 [0,96; 300,29] 0,0055[4]	4,5 [1,2; 7,7] 0,0055[4]
Positive	52/1089 (4,8)	5/1066 (0,5)	10,18 [4,08; 25,39] <,0001[2]	10,64 [4,23; 26,75] <,0001[3]	4,3 [3,0; 5,6] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Race (Interaction p-value: 0,6370)					
White	32/958 (3,3)	5/943 (0,5)	6,30 [2,47; 16,10] 0,0001[2]	6,48 [2,52; 16,71] <,0001[3]	2,8 [1,6; 4,0] <,0001[3]
Asian	19/250 (7,6)	1/242 (0,4)	18,39 [2,48; 136,32] 0,0044[2]	19,82 [2,63; 149,27] <,0001[3]	7,2 [3,8; 10,6] <,0001[3]
Other	7/62 (11,3)	0/64 (0,0)	15,48 [0,90; 265,33] 0,0588[2]	17,43 [0,97; 312,14] 0,0058[4]	11,3 [3,4; 19,2] 0,0058[4]
ECOG-PS (Interaction p-value: 0,9729)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	51/1070 (4,8)	6/1019 (0,6)	8,09 [3,49; 18,78] <,0001[2]	8,45 [3,61; 19,78] <,0001[3]	4,2 [2,8; 5,5] <,0001[3]
ECOG-PS 1	9/213 (4,2)	0/245 (0,0)	21,84 [1,28; 373,05] 0,0332[2]	22,81 [1,32; 394,27] 0,0009[4]	4,2 [1,5; 6,9] 0,0009[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 328.1.2: Subgroups - adverse events according PT Dyspepsia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,1740)					
Neoadjuvant chemotherapy	36/430 (8,4)	6/415 (1,4)	5,79 [2,47; 13,60] <,0001[2]	6,23 [2,60; 14,95] <,0001[3]	6,9 [4,1; 9,8] <,0001[3]
Adjuvant chemotherapy	54/784 (6,9)	23/768 (3,0)	2,30 [1,43; 3,71] 0,0006[2]	2,40 [1,46; 3,94] 0,0004[3]	3,9 [1,7; 6,0] 0,0004[3]
No chemotherapy	6/69 (8,7)	3/81 (3,7)	2,35 [0,61; 9,04] 0,2147[2]	2,48 [0,60; 10,30] 0,3025[4]	5,0 [-2,8; 12,8] 0,3025[4]
Primary tumor size (Interaction p-value: 0,2058)					
< 20 mm	24/331 (7,3)	9/334 (2,7)	2,69 [1,27; 5,70] 0,0098[2]	2,82 [1,29; 6,17] 0,0068[3]	4,6 [1,3; 7,8] 0,0068[3]
≥ 20 but < 50 mm	46/646 (7,1)	10/653 (1,5)	4,65 [2,37; 9,13] <,0001[2]	4,93 [2,47; 9,86] <,0001[3]	5,6 [3,4; 7,8] <,0001[3]
≥ 50 mm	26/289 (9,0)	12/265 (4,5)	1,99 [1,02; 3,86] 0,0425[2]	2,08 [1,03; 4,22] 0,0377[3]	4,5 [0,3; 8,6] 0,0377[3]
Number of positive lymph nodes (Interaction p-value: 0,9936)					
0-3	37/427 (8,7)	12/418 (2,9)	3,02 [1,60; 5,71] 0,0007[2]	3,21 [1,65; 6,25] 0,0003[3]	5,8 [2,7; 8,9] 0,0003[3]
4-9	36/549 (6,6)	12/542 (2,2)	2,96 [1,56; 5,63] 0,0009[2]	3,10 [1,59; 6,02] 0,0005[3]	4,3 [1,9; 6,8] 0,0005[3]
≥ 10	23/307 (7,5)	8/304 (2,6)	2,85 [1,29; 6,26] 0,0093[2]	3,00 [1,32; 6,81] 0,0062[3]	4,9 [1,4; 8,3] 0,0062[3]
Tumor stage (Interaction p-value: 0,8913)					
IIA	11/113 (9,7)	2/114 (1,8)	5,55 [1,26; 24,47] 0,0236[2]	6,04 [1,31; 27,90] 0,0097[3]	8,0 [2,0; 14,0] 0,0097[3]
IIB	13/151 (8,6)	4/136 (2,9)	2,93 [0,98; 8,76] 0,0549[2]	3,11 [0,99; 9,78] 0,0422[3]	5,7 [0,4; 11,0] 0,0422[3]
IIIA	35/495 (7,1)	14/488 (2,9)	2,46 [1,34; 4,52] 0,0036[2]	2,58 [1,37; 4,85] 0,0025[3]	4,2 [1,5; 6,9] 0,0025[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	35/468 (7,5)	11/479 (2,3)	3,26 [1,67; 6,33] 0,0005[2]	3,44 [1,72; 6,86] 0,0002[3]	5,2 [2,4; 7,9] 0,0002[3]
Tumor grade (Interaction p-value: 0,9062)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G1	5/91 (5,5)	3/93 (3,2)	1,70 [0,42; 6,92] 0,4565[2]	1,74 [0,40; 7,52] 0,4945[4]	2,3 [-3,6; 8,2] 0,4945[4]
G2	47/612 (7,7)	16/602 (2,7)	2,89 [1,66; 5,04] 0,0002[2]	3,05 [1,71; 5,44] <,0001[3]	5,0 [2,6; 7,5] <,0001[3]
G3	41/527 (7,8)	13/506 (2,6)	3,03 [1,64; 5,58] 0,0004[2]	3,20 [1,69; 6,04] 0,0002[3]	5,2 [2,5; 7,9] 0,0002[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
First endocrine therapy (Interaction p-value: 0,5444)					
Tamoxifen	5/114 (4,4)	3/132 (2,3)	1,93 [0,47; 7,90] 0,3605[2]	1,97 [0,46; 8,44] 0,4772[4]	2,1 [-2,4; 6,7] 0,4772[4]
Aromatase inhibitor	91/1169 (7,8)	29/1132 (2,6)	3,04 [2,02; 4,58] <,0001[2]	3,21 [2,10; 4,92] <,0001[3]	5,2 [3,4; 7,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,3026)					
ECOG-PS 0	80/1070 (7,5)	23/1019 (2,3)	3,31 [2,10; 5,22] <,0001[2]	3,50 [2,18; 5,61] <,0001[3]	5,2 [3,4; 7,0] <,0001[3]
ECOG-PS 1	16/213 (7,5)	9/245 (3,7)	2,04 [0,92; 4,53] 0,0781[2]	2,13 [0,92; 4,92] 0,0713[3]	3,8 [-0,4; 8,1] 0,0713[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 329.1.2: Subgroups - adverse events according PT Dyspnoea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7885)					
< 65 years	64/918 (7,0)	34/936 (3,6)	1,92 [1,28; 2,88] 0,0016[2]	1,99 [1,30; 3,05] 0,0013[3]	3,3 [1,3; 5,4] 0,0013[3]
≥ 65 years	31/365 (8,5)	16/328 (4,9)	1,74 [0,97; 3,12] 0,0630[2]	1,81 [0,97; 3,37] 0,0588[3]	3,6 [-0,1; 7,3] 0,0588[3]
Prior treatment (Interaction p-value: 0,7259)					
Neoadjuvant chemotherapy	30/430 (7,0)	13/415 (3,1)	2,23 [1,18; 4,21] 0,0137[2]	2,32 [1,19; 4,51] 0,0110[3]	3,8 [0,9; 6,8] 0,0110[3]
Adjuvant chemotherapy	58/784 (7,4)	31/768 (4,0)	1,83 [1,20; 2,80] 0,0052[2]	1,90 [1,21; 2,97] 0,0044[3]	3,4 [1,1; 5,7] 0,0044[3]
No chemotherapy	7/69 (10,1)	6/81 (7,4)	1,37 [0,48; 3,88] 0,5542[2]	1,41 [0,45; 4,42] 0,5526[3]	2,7 [-6,4; 11,9] 0,5526[3]
Region (Interaction p-value: 0,1227)					
North America / Europe	81/678 (11,9)	37/649 (5,7)	2,10 [1,44; 3,05] 0,0001[2]	2,24 [1,50; 3,36] <,0001[3]	6,2 [3,2; 9,3] <,0001[3]
Asia	4/203 (2,0)	1/201 (0,5)	3,96 [0,45; 35,13] 0,2165[2]	4,02 [0,45; 36,28] 0,3719[4]	1,5 [-0,7; 3,6] 0,3719[4]
Other	10/402 (2,5)	12/414 (2,9)	0,86 [0,38; 1,96] 0,7174[2]	0,85 [0,37; 2,00] 0,7171[3]	-0,4 [-2,6; 1,8] 0,7171[3]
Primary tumor size (Interaction p-value: 0,3587)					
< 20 mm	24/331 (7,3)	17/334 (5,1)	1,42 [0,78; 2,60] 0,2496[2]	1,46 [0,77; 2,77] 0,2467[3]	2,2 [-1,5; 5,8] 0,2467[3]
≥ 20 but < 50 mm	47/646 (7,3)	26/653 (4,0)	1,83 [1,15; 2,91] 0,0113[2]	1,89 [1,16; 3,09] 0,0100[3]	3,3 [0,8; 5,8] 0,0100[3]
≥ 50 mm	23/289 (8,0)	7/265 (2,6)	3,01 [1,31; 6,91] 0,0092[2]	3,19 [1,34; 7,56] 0,0057[3]	5,3 [1,6; 9,0] 0,0057[3]
Number of positive lymph nodes (Interaction p-value: 0,7501)					
0-3	32/427 (7,5)	14/418 (3,3)	2,24 [1,21; 4,13] 0,0101[2]	2,34 [1,23; 4,45] 0,0079[3]	4,1 [1,1; 7,2] 0,0079[3]
4-9	37/549 (6,7)	20/542 (3,7)	1,83 [1,07; 3,11] 0,0262[2]	1,89 [1,08; 3,29] 0,0236[3]	3,0 [0,4; 5,7] 0,0236[3]
≥ 10	26/307 (8,5)	16/304 (5,3)	1,61 [0,88; 2,94] 0,1216[2]	1,67 [0,87; 3,17] 0,1173[3]	3,2 [-0,8; 7,2] 0,1173[3]
Tumor stage (Interaction p-value: 0,8872)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	7/113 (6,2)	2/114 (1,8)	3,53 [0,75; 16,63] 0,1106[2]	3,70 [0,75; 18,20] 0,1016[4]	4,4 [-0,6; 9,5] 0,1016[4]
IIB	9/151 (6,0)	4/136 (2,9)	2,03 [0,64; 6,43] 0,2306[2]	2,09 [0,63; 6,95] 0,2194[3]	3,0 [-1,7; 7,7] 0,2194[3]
IIIA	35/495 (7,1)	17/488 (3,5)	2,03 [1,15; 3,57] 0,0142[2]	2,11 [1,16; 3,82] 0,0120[3]	3,6 [0,8; 6,4] 0,0120[3]
IIIB	3/54 (5,6)	2/45 (4,4)	1,25 [0,22; 7,16] 0,8021[2]	1,26 [0,20; 7,92] 1,0000[4]	1,1 [-7,5; 9,7] 1,0000[4]
IIIC	41/468 (8,8)	25/479 (5,2)	1,68 [1,04; 2,71] 0,0347[2]	1,74 [1,04; 2,92] 0,0324[3]	3,5 [0,3; 6,8] 0,0324[3]
Tumor grade (Interaction p-value: 0,6495)					
G1	6/91 (6,6)	0/93 (0,0)	13,28 [0,76; 232,41] 0,0765[2]	14,22 [0,79; 256,15] 0,0134[4]	6,6 [1,5; 11,7] 0,0134[4]
G2	49/612 (8,0)	22/602 (3,7)	2,19 [1,34; 3,58] 0,0017[2]	2,29 [1,37; 3,84] 0,0012[3]	4,4 [1,7; 7,0] 0,0012[3]
G3	35/527 (6,6)	24/506 (4,7)	1,40 [0,85; 2,32] 0,1913[2]	1,43 [0,84; 2,44] 0,1888[3]	1,9 [-0,9; 4,7] 0,1888[3]
GX	5/51 (9,8)	4/59 (6,8)	1,45 [0,41; 5,10] 0,5662[2]	1,49 [0,38; 5,89] 0,7306[4]	3,0 [-7,4; 13,4] 0,7306[4]
Race (Interaction p-value: 0,2394)					
White	80/958 (8,4)	42/943 (4,5)	1,87 [1,30; 2,69] 0,0007[2]	1,95 [1,33; 2,87] 0,0005[3]	3,9 [1,7; 6,1] 0,0005[3]
Asian	6/250 (2,4)	1/242 (0,4)	5,81 [0,70; 47,89] 0,1022[2]	5,93 [0,71; 49,59] 0,1227[4]	2,0 [-0,1; 4,0] 0,1227[4]
Other	5/62 (8,1)	6/64 (9,4)	0,86 [0,28; 2,67] 0,7947[2]	0,85 [0,24; 2,94] 0,7945[3]	-1,3 [-11,2; 8,5] 0,7945[3]
First endocrine therapy (Interaction p-value: 0,4829)					
Tamoxifen	4/114 (3,5)	4/132 (3,0)	1,16 [0,30; 4,53] 0,8330[2]	1,16 [0,28; 4,76] 1,0000[4]	0,5 [-4,0; 4,9] 1,0000[4]
Aromatase inhibitor	91/1169 (7,8)	46/1132 (4,1)	1,92 [1,36; 2,70] 0,0002[2]	1,99 [1,38; 2,87] 0,0002[3]	3,7 [1,8; 5,6] 0,0002[3]
ECOG-PS (Interaction p-value: 0,5583)					
ECOG-PS 0	74/1070 (6,9)	35/1019 (3,4)	2,01 [1,36; 2,98] 0,0005[2]	2,09 [1,38; 3,15] 0,0003[3]	3,5 [1,6; 5,4] 0,0003[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	21/213 (9,9)	15/245 (6,1)	1,61 [0,85; 3,04] 0,1424[2]	1,68 [0,84; 3,34] 0,1383[3]	3,7 [-1,3; 8,7] 0,1383[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 330.1.2: Subgroups - adverse events according PT Dysuria from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8628)					
< 65 years	18/918 (2,0)	9/936 (1,0)	2,04 [0,92; 4,52] 0,0789[2]	2,06 [0,92; 4,61] 0,0725[3]	1,0 [-0,1; 2,1] 0,0725[3]
≥ 65 years	8/365 (2,2)	4/328 (1,2)	1,80 [0,55; 5,91] 0,3346[2]	1,82 [0,54; 6,08] 0,3273[3]	1,0 [-0,9; 2,9] 0,3273[3]
Prior treatment (Interaction p-value: 0,3165)					
Neoadjuvant chemotherapy	8/430 (1,9)	1/415 (0,2)	7,72 [0,97; 61,46] 0,0535[2]	7,85 [0,98; 63,03] 0,0383[4]	1,6 [0,3; 3,0] 0,0383[4]
Adjuvant chemotherapy	16/784 (2,0)	11/768 (1,4)	1,42 [0,67; 3,05] 0,3619[2]	1,43 [0,66; 3,11] 0,3593[3]	0,6 [-0,7; 1,9] 0,3593[3]
No chemotherapy	2/69 (2,9)	1/81 (1,2)	2,35 [0,22; 25,34] 0,4819[2]	2,39 [0,21; 26,92] 0,5945[4]	1,7 [-3,0; 6,3] 0,5945[4]
Region (Interaction p-value: 0,9332)					
North America / Europe	12/678 (1,8)	5/649 (0,8)	2,30 [0,81; 6,48] 0,1162[2]	2,32 [0,81; 6,62] 0,1056[3]	1,0 [-0,2; 2,2] 0,1056[3]
Asia	2/203 (1,0)	1/201 (0,5)	1,98 [0,18; 21,67] 0,5757[2]	1,99 [0,18; 22,12] 1,0000[4]	0,5 [-1,2; 2,2] 1,0000[4]
Other	12/402 (3,0)	7/414 (1,7)	1,77 [0,70; 4,44] 0,2269[2]	1,79 [0,70; 4,59] 0,2203[3]	1,3 [-0,8; 3,4] 0,2203[3]
Primary tumor size (Interaction p-value: 0,2659)					
< 20 mm	7/331 (2,1)	2/334 (0,6)	3,53 [0,74; 16,88] 0,1138[2]	3,59 [0,74; 17,39] 0,1057[4]	1,5 [-0,2; 3,3] 0,1057[4]
≥ 20 but < 50 mm	12/646 (1,9)	10/653 (1,5)	1,21 [0,53; 2,79] 0,6492[2]	1,22 [0,52; 2,84] 0,6487[3]	0,3 [-1,1; 1,7] 0,6487[3]
≥ 50 mm	6/289 (2,1)	1/265 (0,4)	5,50 [0,67; 45,40] 0,1133[2]	5,60 [0,67; 46,80] 0,1251[4]	1,7 [-0,1; 3,5] 0,1251[4]
Number of positive lymph nodes (Interaction p-value: 0,2065)					
0-3	8/427 (1,9)	7/418 (1,7)	1,12 [0,41; 3,06] 0,8268[2]	1,12 [0,40; 3,12] 0,8267[3]	0,2 [-1,6; 2,0] 0,8267[3]
4-9	9/549 (1,6)	5/542 (0,9)	1,78 [0,60; 5,27] 0,2998[2]	1,79 [0,60; 5,38] 0,2929[3]	0,7 [-0,6; 2,0] 0,2929[3]
≥ 10	9/307 (2,9)	1/304 (0,3)	8,91 [1,14; 69,92] 0,0374[2]	9,15 [1,15; 72,68] 0,0205[4]	2,6 [0,6; 4,6] 0,0205[4]
Tumor stage (Interaction p-value: 0,2775)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	2/113 (1,8)	1/114 (0,9)	2,02 [0,19; 21,94] 0,5642[2]	2,04 [0,18; 22,78] 0,6217[4]	0,9 [-2,1; 3,9] 0,6217[4]
IIB	1/151 (0,7)	4/136 (2,9)	0,23 [0,03; 1,99] 0,1799[2]	0,22 [0,02; 1,99] 0,1934[4]	-2,3 [-5,4; 0,8] 0,1934[4]
IIIA	10/495 (2,0)	3/488 (0,6)	3,29 [0,91; 11,87] 0,0694[2]	3,33 [0,91; 12,19] 0,0538[3]	1,4 [-0,0; 2,8] 0,0538[3]
IIIB	0/54 (0,0)	1/45 (2,2)	0,28 [0,01; 6,68] 0,4306[2]	0,27 [0,01; 6,85] 0,4545[4]	-2,2 [-6,5; 2,1] 0,4545[4]
IIIC	13/468 (2,8)	4/479 (0,8)	3,33 [1,09; 10,13] 0,0344[2]	3,39 [1,10; 10,48] 0,0244[3]	1,9 [0,2; 3,6] 0,0244[3]
Tumor grade (Interaction p-value: 0,6036)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	13/612 (2,1)	5/602 (0,8)	2,56 [0,92; 7,13] 0,0726[2]	2,59 [0,92; 7,31] 0,0622[3]	1,3 [-0,1; 2,6] 0,0622[3]
G3	8/527 (1,5)	8/506 (1,6)	0,96 [0,36; 2,54] 0,9347[2]	0,96 [0,36; 2,58] 0,9347[3]	-0,1 [-1,6; 1,4] 0,9347[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesterone receptor status (Interaction p-value: 0,6151)					
Negative	3/156 (1,9)	2/169 (1,2)	1,63 [0,28; 9,60] 0,5921[2]	1,64 [0,27; 9,93] 0,6739[4]	0,7 [-2,0; 3,4] 0,6739[4]
Positive	23/1089 (2,1)	11/1066 (1,0)	2,05 [1,00; 4,18] 0,0491[2]	2,07 [1,00; 4,27] 0,0442[3]	1,1 [0,0; 2,1] 0,0442[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,3724)					
White	22/958 (2,3)	9/943 (1,0)	2,41 [1,11; 5,20] 0,0255[2]	2,44 [1,12; 5,33] 0,0209[3]	1,3 [0,2; 2,5] 0,0209[3]
Asian	2/250 (0,8)	2/242 (0,8)	0,97 [0,14; 6,82] 0,9739[2]	0,97 [0,14; 6,93] 1,0000[4]	-0,0 [-1,6; 1,6] 1,0000[4]
Other	1/62 (1,6)	2/64 (3,1)	0,52 [0,05; 5,55] 0,5852[2]	0,51 [0,04; 5,75] 1,0000[4]	-1,5 [-6,8; 3,8] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,8879)					
Tamoxifen	2/114 (1,8)	1/132 (0,8)	2,32 [0,21; 25,21] 0,4906[2]	2,34 [0,21; 26,14] 0,5979[4]	1,0 [-1,8; 3,8] 0,5979[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	24/1169 (2,1)	12/1132 (1,1)	1,94 [0,97; 3,85] 0,0597[2]	1,96 [0,97; 3,93] 0,0550[3]	1,0 [-0,0; 2,0] 0,0550[3]
ECOG-PS (Interaction p-value: 0,7128)					
ECOG-PS 0	22/1070 (2,1)	10/1019 (1,0)	2,10 [1,00; 4,40] 0,0509[2]	2,12 [1,00; 4,50] 0,0456[3]	1,1 [0,0; 2,1] 0,0456[3]
ECOG-PS 1	4/213 (1,9)	3/245 (1,2)	1,53 [0,35; 6,78] 0,5726[2]	1,54 [0,34; 6,98] 0,7096[4]	0,7 [-1,6; 2,9] 0,7096[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 331.1.2: Subgroups - adverse events according PT Epistaxis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9887)					
Neoadjuvant chemotherapy	8/430 (1,9)	1/415 (0,2)	7,72 [0,97; 61,46] 0,0535[2]	7,85 [0,98; 63,03] 0,0383[4]	1,6 [0,3; 3,0] 0,0383[4]
Adjuvant chemotherapy	13/784 (1,7)	2/768 (0,3)	6,37 [1,44; 28,12] 0,0146[2]	6,46 [1,45; 28,71] 0,0049[3]	1,4 [0,4; 2,4] 0,0049[3]
No chemotherapy	2/69 (2,9)	0/81 (0,0)	5,86 [0,29; 119,97] 0,2512[2]	6,04 [0,28; 127,91] 0,2099[4]	2,9 [-1,1; 6,9] 0,2099[4]
Region (Interaction p-value: 0,3984)					
North America / Europe	18/678 (2,7)	2/649 (0,3)	8,62 [2,01; 36,98] 0,0038[2]	8,82 [2,04; 38,18] 0,0005[3]	2,3 [1,1; 3,6] 0,0005[3]
Asia	1/203 (0,5)	1/201 (0,5)	0,99 [0,06; 15,72] 0,9944[2]	0,99 [0,06; 15,94] 1,0000[4]	-0,0 [-1,4; 1,4] 1,0000[4]
Other	4/402 (1,0)	0/414 (0,0)	9,27 [0,50; 171,59] 0,1348[2]	9,36 [0,50; 174,44] 0,0585[4]	1,0 [0,0; 2,0] 0,0585[4]
Primary tumor size (Interaction p-value: 0,9937)					
< 20 mm	5/331 (1,5)	0/334 (0,0)	11,10 [0,62; 199,93] 0,1027[2]	11,27 [0,62; 204,62] 0,0301[4]	1,5 [0,2; 2,8] 0,0301[4]
≥ 20 but < 50 mm	11/646 (1,7)	2/653 (0,3)	5,56 [1,24; 24,98] 0,0253[2]	5,64 [1,24; 25,54] 0,0115[3]	1,4 [0,3; 2,5] 0,0115[3]
≥ 50 mm	7/289 (2,4)	1/265 (0,4)	6,42 [0,79; 51,82] 0,0810[2]	6,55 [0,80; 53,62] 0,0704[4]	2,0 [0,1; 4,0] 0,0704[4]
Number of positive lymph nodes (Interaction p-value: 0,6657)					
0-3	12/427 (2,8)	1/418 (0,2)	11,75 [1,53; 89,94] 0,0177[2]	12,06 [1,56; 93,15] 0,0024[3]	2,6 [0,9; 4,2] 0,0024[3]
4-9	8/549 (1,5)	1/542 (0,2)	7,90 [0,99; 62,93] 0,0510[2]	8,00 [1,00; 64,18] 0,0383[4]	1,3 [0,2; 2,3] 0,0383[4]
≥ 10	3/307 (1,0)	1/304 (0,3)	2,97 [0,31; 28,40] 0,3445[2]	2,99 [0,31; 28,91] 0,6238[4]	0,6 [-0,6; 1,9] 0,6238[4]
Tumor grade (Interaction p-value: 0,6207)					
G1	0/91 (0,0)	1/93 (1,1)	0,34 [0,01; 8,25] 0,5078[2]	0,34 [0,01; 8,38] 1,0000[4]	-1,1 [-3,2; 1,0] 1,0000[4]
G2	12/612 (2,0)	1/602 (0,2)	11,80 [1,54; 90,50] 0,0175[2]	12,02 [1,56; 92,73] 0,0024[3]	1,8 [0,6; 2,9] 0,0024[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G3	10/527 (1,9)	0/506 (0,0)	20,16 [1,18; 343,21] 0,0378[2]	20,55 [1,20; 351,68] 0,0019[4]	1,9 [0,7; 3,1] 0,0019[4]
GX	1/51 (2,0)	1/59 (1,7)	1,16 [0,07; 18,03] 0,9172[2]	1,16 [0,07; 19,03] 1,0000[4]	0,3 [-4,8; 5,3] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,2732)					
Negative	4/156 (2,6)	1/169 (0,6)	4,33 [0,49; 38,35] 0,1875[2]	4,42 [0,49; 39,99] 0,1985[4]	2,0 [-0,8; 4,7] 0,1985[4]
Positive	18/1089 (1,7)	2/1066 (0,2)	8,81 [2,05; 37,88] 0,0035[2]	8,94 [2,07; 38,63] 0,0004[3]	1,5 [0,7; 2,3] 0,0004[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,3168)					
White	22/958 (2,3)	2/943 (0,2)	10,83 [2,55; 45,92] 0,0012[2]	11,06 [2,59; 47,16] <,0001[3]	2,1 [1,1; 3,1] <,0001[3]
Asian	1/250 (0,4)	1/242 (0,4)	0,97 [0,06; 15,39] 0,9816[2]	0,97 [0,06; 15,56] 1,0000[4]	-0,0 [-1,1; 1,1] 1,0000[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,9729)					
ECOG-PS 0	17/1070 (1,6)	3/1019 (0,3)	5,40 [1,59; 18,36] 0,0070[2]	5,47 [1,60; 18,71] 0,0024[3]	1,3 [0,5; 2,1] 0,0024[3]
ECOG-PS 1	6/213 (2,8)	0/245 (0,0)	14,94 [0,85; 263,72] 0,0648[2]	15,38 [0,86; 274,65] 0,0097[4]	2,8 [0,6; 5,0] 0,0097[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 332.1.2: Subgroups - adverse events according PT Fall from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,2556)					
< 65 years	28/918 (3,1)	14/936 (1,5)	2,04 [1,08; 3,85] 0,0279[2]	2,07 [1,08; 3,96] 0,0245[3]	1,6 [0,2; 2,9] 0,0245[3]
≥ 65 years	17/365 (4,7)	13/328 (4,0)	1,18 [0,58; 2,38] 0,6544[2]	1,18 [0,57; 2,48] 0,6539[3]	0,7 [-2,3; 3,7] 0,6539[3]
Prior treatment (Interaction p-value: 0,3364)					
Neoadjuvant chemotherapy	8/430 (1,9)	8/415 (1,9)	0,97 [0,37; 2,55] 0,9428[2]	0,96 [0,36; 2,59] 0,9428[3]	-0,1 [-1,9; 1,8] 0,9428[3]
Adjuvant chemotherapy	29/784 (3,7)	16/768 (2,1)	1,78 [0,97; 3,24] 0,0617[2]	1,81 [0,97; 3,35] 0,0579[3]	1,6 [-0,0; 3,3] 0,0579[3]
No chemotherapy	8/69 (11,6)	3/81 (3,7)	3,13 [0,86; 11,34] 0,0823[2]	3,41 [0,87; 13,40] 0,0647[3]	7,9 [-0,7; 16,5] 0,0647[3]
Region (Interaction p-value: 0,8173)					
North America / Europe	35/678 (5,2)	21/649 (3,2)	1,60 [0,94; 2,71] 0,0842[2]	1,63 [0,94; 2,83] 0,0810[3]	1,9 [-0,2; 4,1] 0,0810[3]
Asia	2/203 (1,0)	2/201 (1,0)	0,99 [0,14; 6,96] 0,9921[2]	0,99 [0,14; 7,10] 1,0000[4]	-0,0 [-1,9; 1,9] 1,0000[4]
Other	8/402 (2,0)	4/414 (1,0)	2,06 [0,63; 6,79] 0,2349[2]	2,08 [0,62; 6,97] 0,2245[3]	1,0 [-0,6; 2,7] 0,2245[3]
Primary tumor size (Interaction p-value: 0,2966)					
< 20 mm	11/331 (3,3)	9/334 (2,7)	1,23 [0,52; 2,94] 0,6358[2]	1,24 [0,51; 3,04] 0,6351[3]	0,6 [-2,0; 3,2] 0,6351[3]
≥ 20 but < 50 mm	19/646 (2,9)	14/653 (2,1)	1,37 [0,69; 2,71] 0,3634[2]	1,38 [0,69; 2,78] 0,3612[3]	0,8 [-0,9; 2,5] 0,3612[3]
≥ 50 mm	15/289 (5,2)	4/265 (1,5)	3,44 [1,16; 10,23] 0,0264[2]	3,57 [1,17; 10,90] 0,0174[3]	3,7 [0,7; 6,6] 0,0174[3]
Number of positive lymph nodes (Interaction p-value: 0,7196)					
0-3	15/427 (3,5)	7/418 (1,7)	2,10 [0,86; 5,09] 0,1016[2]	2,14 [0,86; 5,30] 0,0934[3]	1,8 [-0,3; 4,0] 0,0934[3]
4-9	20/549 (3,6)	12/542 (2,2)	1,65 [0,81; 3,33] 0,1667[2]	1,67 [0,81; 3,45] 0,1619[3]	1,4 [-0,6; 3,4] 0,1619[3]
≥ 10	10/307 (3,3)	8/304 (2,6)	1,24 [0,50; 3,09] 0,6481[2]	1,25 [0,48; 3,20] 0,6474[3]	0,6 [-2,1; 3,3] 0,6474[3]
Tumor stage (Interaction p-value: 0,7764)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	4/113 (3,5)	2/114 (1,8)	2,02 [0,38; 10,80] 0,4121[2]	2,06 [0,37; 11,45] 0,4458[4]	1,8 [-2,4; 6,0] 0,4458[4]
IIB	3/151 (2,0)	2/136 (1,5)	1,35 [0,23; 7,96] 0,7396[2]	1,36 [0,22; 8,25] 1,0000[4]	0,5 [-2,5; 3,5] 1,0000[4]
IIIA	19/495 (3,8)	9/488 (1,8)	2,08 [0,95; 4,55] 0,0666[2]	2,12 [0,95; 4,74] 0,0602[3]	2,0 [-0,1; 4,1] 0,0602[3]
IIIB	1/54 (1,9)	2/45 (4,4)	0,42 [0,04; 4,45] 0,4686[2]	0,41 [0,04; 4,63] 0,5894[4]	-2,6 [-9,6; 4,4] 0,5894[4]
IIIC	18/468 (3,8)	12/479 (2,5)	1,54 [0,75; 3,15] 0,2427[2]	1,56 [0,74; 3,27] 0,2388[3]	1,3 [-0,9; 3,6] 0,2388[3]
Tumor grade (Interaction p-value: 0,9753)					
G1	4/91 (4,4)	0/93 (0,0)	9,20 [0,50; 168,39] 0,1348[2]	9,62 [0,51; 181,24] 0,0578[4]	4,4 [0,2; 8,6] 0,0578[4]
G2	24/612 (3,9)	17/602 (2,8)	1,39 [0,75; 2,56] 0,2922[2]	1,40 [0,75; 2,64] 0,2898[3]	1,1 [-0,9; 3,1] 0,2898[3]
G3	15/527 (2,8)	9/506 (1,8)	1,60 [0,71; 3,62] 0,2596[2]	1,62 [0,70; 3,73] 0,2548[3]	1,1 [-0,8; 2,9] 0,2548[3]
GX	2/51 (3,9)	1/59 (1,7)	2,31 [0,22; 24,78] 0,4880[2]	2,37 [0,21; 26,90] 0,5957[4]	2,2 [-4,0; 8,5] 0,5957[4]
Progesterone receptor status (Interaction p-value: 0,5246)					
Negative	7/156 (4,5)	2/169 (1,2)	3,79 [0,80; 17,98] 0,0933[2]	3,92 [0,80; 19,18] 0,0932[4]	3,3 [-0,3; 6,9] 0,0932[4]
Positive	36/1089 (3,3)	24/1066 (2,3)	1,47 [0,88; 2,44] 0,1395[2]	1,48 [0,88; 2,51] 0,1369[3]	1,1 [-0,3; 2,4] 0,1369[3]
Unknown	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Race (Interaction p-value: 0,8359)					
White	39/958 (4,1)	23/943 (2,4)	1,67 [1,00; 2,77] 0,0478[2]	1,70 [1,01; 2,86] 0,0452[3]	1,6 [0,0; 3,2] 0,0452[3]
Asian	2/250 (0,8)	2/242 (0,8)	0,97 [0,14; 6,82] 0,9739[2]	0,97 [0,14; 6,93] 1,0000[4]	-0,0 [-1,6; 1,6] 1,0000[4]
Other	4/62 (6,5)	2/64 (3,1)	2,06 [0,39; 10,87] 0,3924[2]	2,14 [0,38; 12,12] 0,4361[4]	3,3 [-4,1; 10,8] 0,4361[4]
ECOG-PS (Interaction p-value: 0,4934)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	29/1070 (2,7)	14/1019 (1,4)	1,97 [1,05; 3,71] 0,0351[2]	2,00 [1,05; 3,81] 0,0315[3]	1,3 [0,1; 2,5] 0,0315[3]
ECOG-PS 1	16/213 (7,5)	13/245 (5,3)	1,42 [0,70; 2,87] 0,3362[2]	1,45 [0,68; 3,09] 0,3337[3]	2,2 [-2,3; 6,7] 0,3337[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 333.1.2: Subgroups - adverse events according PT Fatigue from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5725)					
< 65 years	269/918 (29,3)	109/936 (11,6)	2,52 [2,05; 3,08] <,0001[2]	3,14 [2,46; 4,02] <,0001[3]	17,7 [14,1; 21,2] <,0001[3]
≥ 65 years	128/365 (35,1)	41/328 (12,5)	2,81 [2,04; 3,86] <,0001[2]	3,78 [2,56; 5,59] <,0001[3]	22,6 [16,5; 28,6] <,0001[3]
Prior treatment (Interaction p-value: 0,3466)					
Neoadjuvant chemotherapy	122/430 (28,4)	51/415 (12,3)	2,31 [1,71; 3,11] <,0001[2]	2,83 [1,97; 4,05] <,0001[3]	16,1 [10,8; 21,4] <,0001[3]
Adjuvant chemotherapy	250/784 (31,9)	92/768 (12,0)	2,66 [2,14; 3,31] <,0001[2]	3,44 [2,64; 4,48] <,0001[3]	19,9 [15,9; 23,9] <,0001[3]
No chemotherapy	25/69 (36,2)	7/81 (8,6)	4,19 [1,93; 9,09] 0,0003[2]	6,01 [2,40; 15,03] <,0001[3]	27,6 [14,7; 40,5] <,0001[3]
Region (Interaction p-value: 0,1480)					
North America / Europe	286/678 (42,2)	118/649 (18,2)	2,32 [1,93; 2,79] <,0001[2]	3,28 [2,55; 4,22] <,0001[3]	24,0 [19,2; 28,8] <,0001[3]
Asia	36/203 (17,7)	10/201 (5,0)	3,56 [1,82; 6,99] 0,0002[2]	4,12 [1,98; 8,55] <,0001[3]	12,8 [6,7; 18,8] <,0001[3]
Other	75/402 (18,7)	22/414 (5,3)	3,51 [2,23; 5,53] <,0001[2]	4,09 [2,49; 6,72] <,0001[3]	13,3 [9,0; 17,7] <,0001[3]
Primary tumor size (Interaction p-value: 0,5456)					
< 20 mm	100/331 (30,2)	45/334 (13,5)	2,24 [1,63; 3,08] <,0001[2]	2,78 [1,88; 4,11] <,0001[3]	16,7 [10,6; 22,9] <,0001[3]
≥ 20 but < 50 mm	189/646 (29,3)	70/653 (10,7)	2,73 [2,12; 3,51] <,0001[2]	3,44 [2,55; 4,65] <,0001[3]	18,5 [14,3; 22,8] <,0001[3]
≥ 50 mm	108/289 (37,4)	35/265 (13,2)	2,83 [2,01; 3,99] <,0001[2]	3,92 [2,56; 6,02] <,0001[3]	24,2 [17,3; 31,1] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,9746)					
0-3	126/427 (29,5)	48/418 (11,5)	2,57 [1,90; 3,48] <,0001[2]	3,23 [2,24; 4,65] <,0001[3]	18,0 [12,7; 23,3] <,0001[3]
4-9	165/549 (30,1)	61/542 (11,3)	2,67 [2,04; 3,49] <,0001[2]	3,39 [2,45; 4,68] <,0001[3]	18,8 [14,1; 23,5] <,0001[3]
≥ 10	106/307 (34,5)	41/304 (13,5)	2,56 [1,85; 3,54] <,0001[2]	3,38 [2,26; 5,07] <,0001[3]	21,0 [14,5; 27,6] <,0001[3]
Tumor stage (Interaction p-value: 0,2119)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	31/113 (27,4)	15/114 (13,2)	2,08 [1,19; 3,65] 0,0100[2]	2,50 [1,26; 4,94] 0,0075[3]	14,3 [4,0; 24,6] 0,0075[3]
IIB	42/151 (27,8)	13/136 (9,6)	2,91 [1,63; 5,18] 0,0003[2]	3,65 [1,86; 7,15] <,0001[3]	18,3 [9,6; 26,9] <,0001[3]
IIIA	151/495 (30,5)	49/488 (10,0)	3,04 [2,26; 4,09] <,0001[2]	3,93 [2,77; 5,59] <,0001[3]	20,5 [15,6; 25,3] <,0001[3]
IIIB	13/54 (24,1)	9/45 (20,0)	1,20 [0,57; 2,55] 0,6290[2]	1,27 [0,49; 3,31] 0,6273[3]	4,1 [-12,3; 20,4] 0,6273[3]
IIIC	160/468 (34,2)	64/479 (13,4)	2,56 [1,97; 3,32] <,0001[2]	3,37 [2,43; 4,66] <,0001[3]	20,8 [15,6; 26,1] <,0001[3]
Tumor grade (Interaction p-value: 0,9895)					
G1	27/91 (29,7)	10/93 (10,8)	2,76 [1,42; 5,37] 0,0028[2]	3,50 [1,58; 7,76] 0,0014[3]	18,9 [7,6; 30,2] 0,0014[3]
G2	196/612 (32,0)	76/602 (12,6)	2,54 [2,00; 3,22] <,0001[2]	3,26 [2,43; 4,38] <,0001[3]	19,4 [14,9; 24,0] <,0001[3]
G3	161/527 (30,6)	58/506 (11,5)	2,67 [2,03; 3,51] <,0001[2]	3,40 [2,44; 4,73] <,0001[3]	19,1 [14,3; 23,9] <,0001[3]
GX	12/51 (23,5)	5/59 (8,5)	2,78 [1,05; 7,35] 0,0398[2]	3,32 [1,08; 10,20] 0,0294[3]	15,1 [1,4; 28,7] 0,0294[3]
Progesterone receptor status (Interaction p-value: 0,6989)					
Negative	55/156 (35,3)	26/169 (15,4)	2,29 [1,52; 3,46] <,0001[2]	3,00 [1,76; 5,10] <,0001[3]	19,9 [10,6; 29,1] <,0001[3]
Positive	322/1089 (29,6)	115/1066 (10,8)	2,74 [2,25; 3,33] <,0001[2]	3,47 [2,75; 4,38] <,0001[3]	18,8 [15,5; 22,1] <,0001[3]
Unknown	6/10 (60,0)	2/7 (28,6)	2,10 [0,59; 7,52] 0,2544[2]	3,75 [0,47; 29,75] 0,3348[4]	31,4 [-13,8; 76,6] 0,3348[4]
Race (Interaction p-value: 0,3784)					
White	332/958 (34,7)	128/943 (13,6)	2,55 [2,13; 3,07] <,0001[2]	3,38 [2,69; 4,25] <,0001[3]	21,1 [17,4; 24,8] <,0001[3]
Asian	43/250 (17,2)	10/242 (4,1)	4,16 [2,14; 8,09] <,0001[2]	4,82 [2,36; 9,83] <,0001[3]	13,1 [7,8; 18,4] <,0001[3]
Other	17/62 (27,4)	7/64 (10,9)	2,51 [1,12; 5,62] 0,0258[2]	3,08 [1,17; 8,06] 0,0185[3]	16,5 [3,0; 30,0] 0,0185[3]
First endocrine therapy (Interaction p-value: 0,2999)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	34/114 (29,8)	11/132 (8,3)	3,58 [1,90; 6,73] <,0001[2]	4,68 [2,24; 9,76] <,0001[3]	21,5 [11,9; 31,1] <,0001[3]
Aromatase inhibitor	363/1169 (31,1)	139/1132 (12,3)	2,53 [2,12; 3,02] <,0001[2]	3,22 [2,59; 3,99] <,0001[3]	18,8 [15,5; 22,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,1324)					
ECOG-PS 0	319/1070 (29,8)	124/1019 (12,2)	2,45 [2,03; 2,96] <,0001[2]	3,07 [2,44; 3,85] <,0001[3]	17,6 [14,2; 21,0] <,0001[3]
ECOG-PS 1	78/213 (36,6)	26/245 (10,6)	3,45 [2,30; 5,17] <,0001[2]	4,87 [2,97; 7,97] <,0001[3]	26,0 [18,5; 33,5] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 334.1.2: Subgroups - adverse events according PT Flatulence from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,6259)					
Neoadjuvant chemotherapy	16/430 (3,7)	2/415 (0,5)	7,72 [1,79; 33,37] 0,0062[2]	7,98 [1,82; 34,93] 0,0011[3]	3,2 [1,3; 5,1] 0,0011[3]
Adjuvant chemotherapy	24/784 (3,1)	7/768 (0,9)	3,36 [1,46; 7,75] 0,0045[2]	3,43 [1,47; 8,02] 0,0025[3]	2,1 [0,8; 3,5] 0,0025[3]
No chemotherapy	2/69 (2,9)	0/81 (0,0)	5,86 [0,29; 119,97] 0,2512[2]	6,04 [0,28; 127,91] 0,2099[4]	2,9 [-1,1; 6,9] 0,2099[4]
Region (Interaction p-value: 0,9993)					
North America / Europe	37/678 (5,5)	7/649 (1,1)	5,06 [2,27; 11,27] <,0001[2]	5,29 [2,34; 11,96] <,0001[3]	4,4 [2,5; 6,3] <,0001[3]
Asia	0/203 (0,0)	1/201 (0,5)	0,33 [0,01; 8,05] 0,4965[2]	0,33 [0,01; 8,11] 0,4975[4]	-0,5 [-1,5; 0,5] 0,4975[4]
Other	5/402 (1,2)	1/414 (0,2)	5,15 [0,60; 43,88] 0,1338[2]	5,20 [0,61; 44,72] 0,1185[4]	1,0 [-0,2; 2,2] 0,1185[4]
Primary tumor size (Interaction p-value: 0,7675)					
< 20 mm	9/331 (2,7)	1/334 (0,3)	9,08 [1,16; 71,28] 0,0358[2]	9,31 [1,17; 73,88] 0,0109[4]	2,4 [0,6; 4,3] 0,0109[4]
≥ 20 but < 50 mm	20/646 (3,1)	5/653 (0,8)	4,04 [1,53; 10,71] 0,0049[2]	4,14 [1,54; 11,10] 0,0022[3]	2,3 [0,8; 3,8] 0,0022[3]
≥ 50 mm	13/289 (4,5)	3/265 (1,1)	3,97 [1,14; 13,79] 0,0298[2]	4,11 [1,16; 14,60] 0,0181[3]	3,4 [0,7; 6,1] 0,0181[3]
Number of positive lymph nodes (Interaction p-value: 0,1701)					
0-3	19/427 (4,4)	1/418 (0,2)	18,60 [2,50; 138,31] 0,0043[2]	19,42 [2,59; 145,73] <,0001[3]	4,2 [2,2; 6,2] <,0001[3]
4-9	15/549 (2,7)	4/542 (0,7)	3,70 [1,24; 11,08] 0,0193[2]	3,78 [1,25; 11,46] 0,0118[3]	2,0 [0,5; 3,5] 0,0118[3]
≥ 10	8/307 (2,6)	4/304 (1,3)	1,98 [0,60; 6,51] 0,2603[2]	2,01 [0,60; 6,74] 0,2505[3]	1,3 [-0,9; 3,5] 0,2505[3]
Tumor stage (Interaction p-value: 0,6794)					
IIA	3/113 (2,7)	0/114 (0,0)	7,06 [0,37; 135,16] 0,1943[2]	7,25 [0,37; 142,05] 0,1217[4]	2,7 [-0,3; 5,6] 0,1217[4]
IIB	7/151 (4,6)	1/136 (0,7)	6,30 [0,79; 50,59] 0,0831[2]	6,56 [0,80; 54,04] 0,0695[4]	3,9 [0,3; 7,5] 0,0695[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	20/495 (4,0)	3/488 (0,6)	6,57 [1,97; 21,98] 0,0022[2]	6,81 [2,01; 23,06] 0,0004[3]	3,4 [1,6; 5,3] 0,0004[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	10/468 (2,1)	5/479 (1,0)	2,05 [0,71; 5,94] 0,1878[2]	2,07 [0,70; 6,10] 0,1781[3]	1,1 [-0,5; 2,7] 0,1781[3]
Tumor grade (Interaction p-value: 0,4280)					
G1	1/91 (1,1)	1/93 (1,1)	1,02 [0,06; 16,09] 0,9877[2]	1,02 [0,06; 16,59] 1,0000[4]	0,0 [-3,0; 3,0] 1,0000[4]
G2	27/612 (4,4)	3/602 (0,5)	8,85 [2,70; 29,03] 0,0003[2]	9,22 [2,78; 30,54] <,0001[3]	3,9 [2,2; 5,6] <,0001[3]
G3	13/527 (2,5)	4/506 (0,8)	3,12 [1,02; 9,51] 0,0453[2]	3,17 [1,03; 9,80] 0,0343[3]	1,7 [0,1; 3,2] 0,0343[3]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,5419)					
Negative	2/156 (1,3)	1/169 (0,6)	2,17 [0,20; 23,66] 0,5261[2]	2,18 [0,20; 24,30] 0,6093[4]	0,7 [-1,4; 2,8] 0,6093[4]
Positive	40/1089 (3,7)	8/1066 (0,8)	4,89 [2,30; 10,41] <,0001[2]	5,04 [2,35; 10,83] <,0001[3]	2,9 [1,7; 4,2] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9996)					
White	41/958 (4,3)	7/943 (0,7)	5,77 [2,60; 12,79] <,0001[2]	5,98 [2,67; 13,39] <,0001[3]	3,5 [2,1; 4,9] <,0001[3]
Asian	0/250 (0,0)	1/242 (0,4)	0,32 [0,01; 7,88] 0,4879[2]	0,32 [0,01; 7,93] 0,4919[4]	-0,4 [-1,2; 0,4] 0,4919[4]
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
First endocrine therapy (Interaction p-value: 0,9953)					
Tamoxifen	4/114 (3,5)	1/132 (0,8)	4,63 [0,53; 40,85] 0,1675[2]	4,76 [0,52; 43,25] 0,1855[4]	2,8 [-0,9; 6,4] 0,1855[4]
Aromatase inhibitor	38/1169 (3,3)	8/1132 (0,7)	4,60 [2,16; 9,82] <,0001[2]	4,72 [2,19; 10,16] <,0001[3]	2,5 [1,4; 3,7] <,0001[3]
ECOG-PS (Interaction p-value: 0,3222)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	32/1070 (3,0)	8/1019 (0,8)	3,81 [1,76; 8,23] 0,0007[2]	3,90 [1,79; 8,50] 0,0002[3]	2,2 [1,1; 3,4] 0,0002[3]
ECOG-PS 1	10/213 (4,7)	1/245 (0,4)	11,50 [1,48; 89,12] 0,0194[2]	12,02 [1,53; 94,69] 0,0028[3]	4,3 [1,3; 7,2] 0,0028[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 335.1.2: Subgroups - adverse events according PT Gamma-glutamyltransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8367)					
< 65 years	30/918 (3,3)	13/936 (1,4)	2,35 [1,24; 4,48] 0,0093[2]	2,40 [1,24; 4,63] 0,0072[3]	1,9 [0,5; 3,3] 0,0072[3]
≥ 65 years	12/365 (3,3)	4/328 (1,2)	2,70 [0,88; 8,28] 0,0831[2]	2,75 [0,88; 8,62] 0,0703[3]	2,1 [-0,1; 4,2] 0,0703[3]
Prior treatment (Interaction p-value: 0,6676)					
Neoadjuvant chemotherapy	13/430 (3,0)	4/415 (1,0)	3,14 [1,03; 9,54] 0,0440[2]	3,20 [1,04; 9,91] 0,0330[3]	2,1 [0,2; 3,9] 0,0330[3]
Adjuvant chemotherapy	25/784 (3,2)	12/768 (1,6)	2,04 [1,03; 4,03] 0,0401[2]	2,08 [1,03; 4,16] 0,0357[3]	1,6 [0,1; 3,1] 0,0357[3]
No chemotherapy	4/69 (5,8)	1/81 (1,2)	4,70 [0,54; 41,03] 0,1620[2]	4,92 [0,54; 45,13] 0,1807[4]	4,6 [-1,5; 10,6] 0,1807[4]
Region (Interaction p-value: 0,7449)					
North America / Europe	16/678 (2,4)	8/649 (1,2)	1,91 [0,82; 4,44] 0,1305[2]	1,94 [0,82; 4,56] 0,1235[3]	1,1 [-0,3; 2,6] 0,1235[3]
Asia	8/203 (3,9)	3/201 (1,5)	2,64 [0,71; 9,81] 0,1471[2]	2,71 [0,71; 10,36] 0,1306[3]	2,4 [-0,7; 5,6] 0,1306[3]
Other	18/402 (4,5)	6/414 (1,4)	3,09 [1,24; 7,70] 0,0155[2]	3,19 [1,25; 8,11] 0,0105[3]	3,0 [0,7; 5,4] 0,0105[3]
Primary tumor size (Interaction p-value: 0,9898)					
< 20 mm	7/331 (2,1)	3/334 (0,9)	2,35 [0,61; 9,03] 0,2117[2]	2,38 [0,61; 9,30] 0,2213[4]	1,2 [-0,6; 3,1] 0,2213[4]
≥ 20 but < 50 mm	26/646 (4,0)	11/653 (1,7)	2,39 [1,19; 4,79] 0,0143[2]	2,45 [1,20; 5,00] 0,0112[3]	2,3 [0,5; 4,1] 0,0112[3]
≥ 50 mm	7/289 (2,4)	3/265 (1,1)	2,14 [0,56; 8,19] 0,2667[2]	2,17 [0,55; 8,47] 0,3440[4]	1,3 [-0,9; 3,5] 0,3440[4]
Number of positive lymph nodes (Interaction p-value: 0,8442)					
0-3	12/427 (2,8)	4/418 (1,0)	2,94 [0,95; 9,03] 0,0602[2]	2,99 [0,96; 9,36] 0,0481[3]	1,9 [0,0; 3,7] 0,0481[3]
4-9	16/549 (2,9)	6/542 (1,1)	2,63 [1,04; 6,68] 0,0415[2]	2,68 [1,04; 6,91] 0,0337[3]	1,8 [0,1; 3,5] 0,0337[3]
≥ 10	14/307 (4,6)	7/304 (2,3)	1,98 [0,81; 4,84] 0,1338[2]	2,03 [0,81; 5,09] 0,1256[3]	2,3 [-0,6; 5,1] 0,1256[3]
Tumor stage (Interaction p-value: 0,8851)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	3/113 (2,7)	1/114 (0,9)	3,03 [0,32; 28,66] 0,3343[2]	3,08 [0,32; 30,08] 0,3695[4]	1,8 [-1,6; 5,2] 0,3695[4]
IIB	4/151 (2,6)	3/136 (2,2)	1,20 [0,27; 5,27] 0,8083[2]	1,21 [0,27; 5,49] 1,0000[4]	0,4 [-3,1; 4,0] 1,0000[4]
IIIA	13/495 (2,6)	4/488 (0,8)	3,20 [1,05; 9,76] 0,0404[2]	3,26 [1,06; 10,08] 0,0298[3]	1,8 [0,2; 3,4] 0,0298[3]
IIIB	3/54 (5,6)	0/45 (0,0)	5,85 [0,31; 110,43] 0,2383[2]	6,18 [0,31; 122,97] 0,2486[4]	5,6 [-0,6; 11,7] 0,2486[4]
IIIC	19/468 (4,1)	9/479 (1,9)	2,16 [0,99; 4,73] 0,0537[2]	2,21 [0,99; 4,94] 0,0476[3]	2,2 [0,0; 4,3] 0,0476[3]
Tumor grade (Interaction p-value: 0,8658)					
G1	3/91 (3,3)	0/93 (0,0)	7,15 [0,37; 136,54] 0,1910[2]	7,40 [0,38; 145,22] 0,1189[4]	3,3 [-0,4; 7,0] 0,1189[4]
G2	19/612 (3,1)	8/602 (1,3)	2,34 [1,03; 5,30] 0,0421[2]	2,38 [1,03; 5,48] 0,0359[3]	1,8 [0,1; 3,4] 0,0359[3]
G3	16/527 (3,0)	9/506 (1,8)	1,71 [0,76; 3,83] 0,1943[2]	1,73 [0,76; 3,95] 0,1886[3]	1,3 [-0,6; 3,1] 0,1886[3]
GX	4/51 (7,8)	0/59 (0,0)	10,38 [0,57; 188,36] 0,1135[2]	11,27 [0,59; 214,65] 0,0433[4]	7,8 [0,5; 15,2] 0,0433[4]
Progesterone receptor status (Interaction p-value: 0,9972)					
Negative	6/156 (3,8)	0/169 (0,0)	14,08 [0,80; 247,83] 0,0708[2]	14,64 [0,82; 262,08] 0,0116[4]	3,8 [0,8; 6,9] 0,0116[4]
Positive	35/1089 (3,2)	17/1066 (1,6)	2,02 [1,14; 3,58] 0,0166[2]	2,05 [1,14; 3,68] 0,0143[3]	1,6 [0,3; 2,9] 0,0143[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Race (Interaction p-value: 0,8695)					
White	31/958 (3,2)	12/943 (1,3)	2,54 [1,31; 4,92] 0,0056[2]	2,59 [1,32; 5,08] 0,0040[3]	2,0 [0,6; 3,3] 0,0040[3]
Asian	8/250 (3,2)	3/242 (1,2)	2,58 [0,69; 9,62] 0,1576[2]	2,63 [0,69; 10,05] 0,1415[3]	2,0 [-0,6; 4,5] 0,1415[3]
Other	3/62 (4,8)	2/64 (3,1)	1,55 [0,27; 8,95] 0,6253[2]	1,58 [0,25; 9,77] 0,6774[4]	1,7 [-5,1; 8,5] 0,6774[4]
ECOG-PS (Interaction p-value: 0,5582)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	34/1070 (3,2)	12/1019 (1,2)	2,70 [1,41; 5,18] 0,0029[2]	2,75 [1,42; 5,35] 0,0018[3]	2,0 [0,8; 3,2] 0,0018[3]
ECOG-PS 1	8/213 (3,8)	5/245 (2,0)	1,84 [0,61; 5,54] 0,2781[2]	1,87 [0,60; 5,81] 0,2703[3]	1,7 [-1,4; 4,8] 0,2703[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 336.1.2: Subgroups - adverse events according PT Gastrointestinal pain from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9638)					
Neoadjuvant chemotherapy	4/430 (0,9)	0/415 (0,0)	8,69 [0,47; 160,84] 0,1466[2]	8,77 [0,47; 163,36] 0,1243[4]	0,9 [0,0; 1,8] 0,1243[4]
Adjuvant chemotherapy	10/784 (1,3)	1/768 (0,1)	9,80 [1,26; 76,34] 0,0294[2]	9,91 [1,27; 77,60] 0,0072[3]	1,1 [0,3; 2,0] 0,0072[3]
No chemotherapy	3/69 (4,3)	0/81 (0,0)	8,20 [0,43; 156,04] 0,1615[2]	8,58 [0,44; 169,04] 0,0950[4]	4,3 [-0,5; 9,2] 0,0950[4]
Primary tumor size (Interaction p-value: 0,9991)					
< 20 mm	1/331 (0,3)	0/334 (0,0)	3,03 [0,12; 74,04] 0,4971[2]	3,04 [0,12; 74,80] 0,4977[4]	0,3 [-0,3; 0,9] 0,4977[4]
≥ 20 but < 50 mm	11/646 (1,7)	0/653 (0,0)	23,25 [1,37; 393,70] 0,0293[2]	23,65 [1,39; 402,20] 0,0008[3]	1,7 [0,7; 2,7] 0,0008[3]
≥ 50 mm	5/289 (1,7)	1/265 (0,4)	4,58 [0,54; 38,99] 0,1632[2]	4,65 [0,54; 40,04] 0,2189[4]	1,4 [-0,3; 3,0] 0,2189[4]
Progesterone receptor status (Interaction p-value: 0,9621)					
Negative	3/156 (1,9)	0/169 (0,0)	7,58 [0,39; 145,58] 0,1792[2]	7,73 [0,40; 150,85] 0,1095[4]	1,9 [-0,2; 4,1] 0,1095[4]
Positive	13/1089 (1,2)	1/1066 (0,1)	12,73 [1,67; 97,11] 0,0142[2]	12,87 [1,68; 98,53] 0,0015[3]	1,1 [0,4; 1,8] 0,0015[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9920)					
White	16/958 (1,7)	1/943 (0,1)	15,75 [2,09; 118,52] 0,0074[2]	16,00 [2,12; 120,89] 0,0003[3]	1,6 [0,7; 2,4] 0,0003[3]
Asian	0/250 (0,0)	0/242 (0,0)	NE	NE	NE
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
ECOG-PS (Interaction p-value: 0,9793)					
ECOG-PS 0	16/1070 (1,5)	1/1019 (0,1)	15,24 [2,02; 114,69] 0,0082[2]	15,45 [2,05; 116,74] 0,0004[3]	1,4 [0,6; 2,1] 0,0004[3]
ECOG-PS 1	1/213 (0,5)	0/245 (0,0)	3,45 [0,14; 84,21] 0,4476[2]	3,47 [0,14; 85,53] 0,4651[4]	0,5 [-0,4; 1,4] 0,4651[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 337.1.2: Subgroups - adverse events according PT Haemorrhoids from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7499)					
< 65 years	20/918 (2,2)	9/936 (1,0)	2,27 [1,04; 4,95] 0,0402[2]	2,29 [1,04; 5,06] 0,0347[3]	1,2 [0,1; 2,3] 0,0347[3]
≥ 65 years	8/365 (2,2)	4/328 (1,2)	1,80 [0,55; 5,91] 0,3346[2]	1,82 [0,54; 6,08] 0,3273[3]	1,0 [-0,9; 2,9] 0,3273[3]
Prior treatment (Interaction p-value: 0,9096)					
Neoadjuvant chemotherapy	9/430 (2,1)	3/415 (0,7)	2,90 [0,79; 10,62] 0,1089[2]	2,94 [0,79; 10,92] 0,0924[3]	1,4 [-0,2; 2,9] 0,0924[3]
Adjuvant chemotherapy	19/784 (2,4)	9/768 (1,2)	2,07 [0,94; 4,54] 0,0703[2]	2,09 [0,94; 4,66] 0,0640[3]	1,3 [-0,1; 2,6] 0,0640[3]
No chemotherapy	0/69 (0,0)	1/81 (1,2)	0,39 [0,02; 9,43] 0,5628[2]	0,39 [0,02; 9,63] 1,0000[4]	-1,2 [-3,6; 1,2] 1,0000[4]
Region (Interaction p-value: 0,8266)					
North America / Europe	20/678 (2,9)	10/649 (1,5)	1,91 [0,90; 4,06] 0,0903[2]	1,94 [0,90; 4,18] 0,0843[3]	1,4 [-0,2; 3,0] 0,0843[3]
Asia	4/203 (2,0)	1/201 (0,5)	3,96 [0,45; 35,13] 0,2165[2]	4,02 [0,45; 36,28] 0,3719[4]	1,5 [-0,7; 3,6] 0,3719[4]
Other	4/402 (1,0)	2/414 (0,5)	2,06 [0,38; 11,18] 0,4025[2]	2,07 [0,38; 11,37] 0,4450[4]	0,5 [-0,7; 1,7] 0,4450[4]
Primary tumor size (Interaction p-value: 0,4866)					
< 20 mm	9/331 (2,7)	2/334 (0,6)	4,54 [0,99; 20,86] 0,0518[2]	4,64 [0,99; 21,64] 0,0321[3]	2,1 [0,2; 4,1] 0,0321[3]
≥ 20 but < 50 mm	13/646 (2,0)	8/653 (1,2)	1,64 [0,69; 3,94] 0,2657[2]	1,66 [0,68; 4,02] 0,2606[3]	0,8 [-0,6; 2,2] 0,2606[3]
≥ 50 mm	5/289 (1,7)	3/265 (1,1)	1,53 [0,37; 6,33] 0,5587[2]	1,54 [0,36; 6,50] 0,7267[4]	0,6 [-1,4; 2,6] 0,7267[4]
Number of positive lymph nodes (Interaction p-value: 0,4419)					
0-3	10/427 (2,3)	3/418 (0,7)	3,26 [0,90; 11,77] 0,0708[2]	3,32 [0,91; 12,14] 0,0551[3]	1,6 [-0,0; 3,3] 0,0551[3]
4-9	14/549 (2,6)	6/542 (1,1)	2,30 [0,89; 5,95] 0,0848[2]	2,34 [0,89; 6,13] 0,0756[3]	1,4 [-0,1; 3,0] 0,0756[3]
≥ 10	4/307 (1,3)	4/304 (1,3)	0,99 [0,25; 3,92] 0,9888[2]	0,99 [0,25; 4,00] 1,0000[4]	-0,0 [-1,8; 1,8] 1,0000[4]
Tumor stage (Interaction p-value: 0,9451)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	4/113 (3,5)	1/114 (0,9)	4,04 [0,46; 35,55] 0,2089[2]	4,15 [0,46; 37,69] 0,2125[4]	2,7 [-1,2; 6,5] 0,2125[4]
IIB	2/151 (1,3)	1/136 (0,7)	1,80 [0,17; 19,64] 0,6293[2]	1,81 [0,16; 20,21] 1,0000[4]	0,6 [-1,7; 2,9] 1,0000[4]
IIIA	13/495 (2,6)	6/488 (1,2)	2,14 [0,82; 5,57] 0,1210[2]	2,17 [0,82; 5,75] 0,1118[3]	1,4 [-0,3; 3,1] 0,1118[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	7/468 (1,5)	5/479 (1,0)	1,43 [0,46; 4,48] 0,5365[2]	1,44 [0,45; 4,57] 0,5342[3]	0,5 [-1,0; 1,9] 0,5342[3]
Tumor grade (Interaction p-value: 0,5528)					
G1	0/91 (0,0)	2/93 (2,2)	0,20 [0,01; 4,20] 0,3032[2]	0,20 [0,01; 4,22] 0,4973[4]	-2,2 [-5,1; 0,8] 0,4973[4]
G2	15/612 (2,5)	9/602 (1,5)	1,64 [0,72; 3,72] 0,2366[2]	1,66 [0,72; 3,81] 0,2316[3]	1,0 [-0,6; 2,5] 0,2316[3]
G3	12/527 (2,3)	2/506 (0,4)	5,76 [1,30; 25,61] 0,0214[2]	5,87 [1,31; 26,37] 0,0089[3]	1,9 [0,5; 3,3] 0,0089[3]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,2688)					
Negative	5/156 (3,2)	2/169 (1,2)	2,71 [0,53; 13,76] 0,2296[2]	2,76 [0,53; 14,46] 0,2669[4]	2,0 [-1,2; 5,2] 0,2669[4]
Positive	22/1089 (2,0)	11/1066 (1,0)	1,96 [0,95; 4,02] 0,0670[2]	1,98 [0,95; 4,10] 0,0618[3]	1,0 [-0,0; 2,0] 0,0618[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,8648)					
White	23/958 (2,4)	11/943 (1,2)	2,06 [1,01; 4,20] 0,0472[2]	2,08 [1,01; 4,30] 0,0423[3]	1,2 [0,0; 2,4] 0,0423[3]
Asian	4/250 (1,6)	1/242 (0,4)	3,87 [0,44; 34,40] 0,2244[2]	3,92 [0,43; 35,31] 0,3728[4]	1,2 [-0,6; 2,9] 0,3728[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,1457)					
ECOG-PS 0	24/1070 (2,2)	8/1019 (0,8)	2,86 [1,29; 6,33] 0,0097[2]	2,90 [1,30; 6,48] 0,0067[3]	1,5 [0,4; 2,5] 0,0067[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	4/213 (1,9)	5/245 (2,0)	0,92 [0,25; 3,38] 0,9003[2]	0,92 [0,24; 3,47] 1,0000[4]	-0,2 [-2,7; 2,4] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 338.1.2: Subgroups - adverse events according PT Headache from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,2780)					
< 65 years	181/918 (19,7)	117/936 (12,5)	1,58 [1,27; 1,95] <,0001[2]	1,72 [1,33; 2,21] <,0001[3]	7,2 [3,9; 10,6] <,0001[3]
≥ 65 years	43/365 (11,8)	32/328 (9,8)	1,21 [0,78; 1,86] 0,3929[2]	1,24 [0,76; 2,00] 0,3917[3]	2,0 [-2,6; 6,6] 0,3917[3]
Prior treatment (Interaction p-value: 0,9702)					
Neoadjuvant chemotherapy	77/430 (17,9)	49/415 (11,8)	1,52 [1,09; 2,11] 0,0139[2]	1,63 [1,11; 2,40] 0,0128[3]	6,1 [1,3; 10,9] 0,0128[3]
Adjuvant chemotherapy	135/784 (17,2)	91/768 (11,8)	1,45 [1,14; 1,86] 0,0030[2]	1,55 [1,16; 2,06] 0,0027[3]	5,4 [1,9; 8,9] 0,0027[3]
No chemotherapy	12/69 (17,4)	9/81 (11,1)	1,57 [0,70; 3,49] 0,2738[2]	1,68 [0,66; 4,28] 0,2692[3]	6,3 [-5,0; 17,5] 0,2692[3]
Region (Interaction p-value: 0,6096)					
North America / Europe	138/678 (20,4)	96/649 (14,8)	1,38 [1,09; 1,74] 0,0084[2]	1,47 [1,11; 1,96] 0,0079[3]	5,6 [1,5; 9,6] 0,0079[3]
Asia	30/203 (14,8)	20/201 (10,0)	1,49 [0,87; 2,53] 0,1444[2]	1,57 [0,86; 2,87] 0,1406[3]	4,8 [-1,6; 11,2] 0,1406[3]
Other	56/402 (13,9)	33/414 (8,0)	1,75 [1,16; 2,63] 0,0073[2]	1,87 [1,19; 2,94] 0,0063[3]	6,0 [1,7; 10,2] 0,0063[3]
Primary tumor size (Interaction p-value: 0,6283)					
< 20 mm	51/331 (15,4)	39/334 (11,7)	1,32 [0,89; 1,95] 0,1615[2]	1,38 [0,88; 2,16] 0,1596[3]	3,7 [-1,5; 8,9] 0,1596[3]
≥ 20 but < 50 mm	117/646 (18,1)	74/653 (11,3)	1,60 [1,22; 2,09] 0,0007[2]	1,73 [1,26; 2,37] 0,0006[3]	6,8 [2,9; 10,6] 0,0006[3]
≥ 50 mm	52/289 (18,0)	36/265 (13,6)	1,32 [0,90; 1,96] 0,1588[2]	1,40 [0,88; 2,22] 0,1562[3]	4,4 [-1,6; 10,5] 0,1562[3]
Number of positive lymph nodes (Interaction p-value: 0,7943)					
0-3	89/427 (20,8)	57/418 (13,6)	1,53 [1,13; 2,07] 0,0062[2]	1,67 [1,16; 2,40] 0,0056[3]	7,2 [2,1; 12,3] 0,0056[3]
4-9	86/549 (15,7)	62/542 (11,4)	1,37 [1,01; 1,86] 0,0428[2]	1,44 [1,01; 2,04] 0,0415[3]	4,2 [0,2; 8,3] 0,0415[3]
≥ 10	49/307 (16,0)	30/304 (9,9)	1,62 [1,06; 2,48] 0,0269[2]	1,73 [1,07; 2,82] 0,0248[3]	6,1 [0,8; 11,4] 0,0248[3]
Tumor stage (Interaction p-value: 0,9600)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	21/113 (18,6)	15/114 (13,2)	1,41 [0,77; 2,60] 0,2668[2]	1,51 [0,73; 3,10] 0,2631[3]	5,4 [-4,1; 14,9] 0,2631[3]
IIB	32/151 (21,2)	22/136 (16,2)	1,31 [0,80; 2,14] 0,2809[2]	1,39 [0,76; 2,54] 0,2777[3]	5,0 [-4,0; 14,0] 0,2777[3]
IIIA	85/495 (17,2)	52/488 (10,7)	1,61 [1,17; 2,22] 0,0036[2]	1,74 [1,20; 2,52] 0,0032[3]	6,5 [2,2; 10,8] 0,0032[3]
IIIB	8/54 (14,8)	5/45 (11,1)	1,33 [0,47; 3,79] 0,5895[2]	1,39 [0,42; 4,60] 0,5869[3]	3,7 [-9,5; 16,9] 0,5869[3]
IIIC	76/468 (16,2)	55/479 (11,5)	1,41 [1,02; 1,95] 0,0353[2]	1,49 [1,03; 2,17] 0,0340[3]	4,8 [0,4; 9,2] 0,0340[3]
Tumor grade (Interaction p-value: 0,2585)					
G1	13/91 (14,3)	5/93 (5,4)	2,66 [0,99; 7,15] 0,0530[2]	2,93 [1,00; 8,60] 0,0420[3]	8,9 [0,4; 17,4] 0,0420[3]
G2	117/612 (19,1)	83/602 (13,8)	1,39 [1,07; 1,79] 0,0130[2]	1,48 [1,09; 2,01] 0,0123[3]	5,3 [1,2; 9,5] 0,0123[3]
G3	84/527 (15,9)	58/506 (11,5)	1,39 [1,02; 1,90] 0,0381[2]	1,46 [1,02; 2,10] 0,0367[3]	4,5 [0,3; 8,7] 0,0367[3]
GX	10/51 (19,6)	3/59 (5,1)	3,86 [1,12; 13,25] 0,0321[2]	4,55 [1,18; 17,59] 0,0186[3]	14,5 [2,3; 26,8] 0,0186[3]
Race (Interaction p-value: 0,9997)					
White	175/958 (18,3)	116/943 (12,3)	1,48 [1,20; 1,84] 0,0003[2]	1,59 [1,24; 2,05] 0,0003[3]	6,0 [2,7; 9,2] 0,0003[3]
Asian	32/250 (12,8)	21/242 (8,7)	1,48 [0,88; 2,48] 0,1439[2]	1,54 [0,86; 2,76] 0,1404[3]	4,1 [-1,3; 9,6] 0,1404[3]
Other	13/62 (21,0)	9/64 (14,1)	1,49 [0,69; 3,24] 0,3123[2]	1,62 [0,64; 4,12] 0,3074[3]	6,9 [-6,3; 20,1] 0,3074[3]
First endocrine therapy (Interaction p-value: 0,8990)					
Tamoxifen	21/114 (18,4)	17/132 (12,9)	1,43 [0,79; 2,58] 0,2331[2]	1,53 [0,76; 3,06] 0,2304[3]	5,5 [-3,6; 14,7] 0,2304[3]
Aromatase inhibitor	203/1169 (17,4)	132/1132 (11,7)	1,49 [1,22; 1,82] 0,0001[2]	1,59 [1,26; 2,02] 0,0001[3]	5,7 [2,8; 8,6] 0,0001[3]
ECOG-PS (Interaction p-value: 0,6280)					
ECOG-PS 0	191/1070 (17,9)	126/1019 (12,4)	1,44 [1,17; 1,78] 0,0005[2]	1,54 [1,21; 1,96] 0,0005[3]	5,5 [2,4; 8,5] 0,0005[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	33/213 (15,5)	23/245 (9,4)	1,65 [1,00; 2,72] 0,0494[2]	1,77 [1,00; 3,12] 0,0467[3]	6,1 [0,0; 12,2] 0,0467[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 339.1.2: Subgroups - adverse events according PT Hot flush from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,2231)					
< 65 years	120/918 (13,1)	170/936 (18,2)	0,72 [0,58; 0,89] 0,0027[2]	0,68 [0,53; 0,87] 0,0026[3]	-5,1 [-8,4; -1,8] 0,0026[3]
≥ 65 years	27/365 (7,4)	46/328 (14,0)	0,53 [0,34; 0,83] 0,0055[2]	0,49 [0,30; 0,81] 0,0045[3]	-6,6 [-11,2; -2,0] 0,0045[3]
Prior treatment (Interaction p-value: 0,2986)					
Neoadjuvant chemotherapy	52/430 (12,1)	67/415 (16,1)	0,75 [0,54; 1,05] 0,0921[2]	0,71 [0,48; 1,06] 0,0905[3]	-4,1 [-8,7; 0,6] 0,0905[3]
Adjuvant chemotherapy	91/784 (11,6)	134/768 (17,4)	0,67 [0,52; 0,85] 0,0012[2]	0,62 [0,47; 0,83] 0,0011[3]	-5,8 [-9,3; -2,3] 0,0011[3]
No chemotherapy	4/69 (5,8)	15/81 (18,5)	0,31 [0,11; 0,90] 0,0310[2]	0,27 [0,09; 0,86] 0,0196[3]	-12,7 [-22,8; -2,6] 0,0196[3]
Region (Interaction p-value: 0,2172)					
North America / Europe	118/678 (17,4)	156/649 (24,0)	0,72 [0,58; 0,90] 0,0030[2]	0,67 [0,51; 0,87] 0,0028[3]	-6,6 [-11,0; -2,3] 0,0028[3]
Asia	9/203 (4,4)	23/201 (11,4)	0,39 [0,18; 0,82] 0,0127[2]	0,36 [0,16; 0,80] 0,0091[3]	-7,0 [-12,2; -1,8] 0,0091[3]
Other	20/402 (5,0)	37/414 (8,9)	0,56 [0,33; 0,94] 0,0292[2]	0,53 [0,30; 0,94] 0,0264[3]	-4,0 [-7,4; -0,5] 0,0264[3]
Primary tumor size (Interaction p-value: 0,8321)					
< 20 mm	40/331 (12,1)	55/334 (16,5)	0,73 [0,50; 1,07] 0,1085[2]	0,70 [0,45; 1,08] 0,1064[3]	-4,4 [-9,7; 0,9] 0,1064[3]
≥ 20 but < 50 mm	69/646 (10,7)	103/653 (15,8)	0,68 [0,51; 0,90] 0,0073[2]	0,64 [0,46; 0,89] 0,0068[3]	-5,1 [-8,8; -1,4] 0,0068[3]
≥ 50 mm	38/289 (13,1)	56/265 (21,1)	0,62 [0,43; 0,91] 0,0136[2]	0,57 [0,36; 0,89] 0,0124[3]	-8,0 [-14,3; -1,7] 0,0124[3]
Number of positive lymph nodes (Interaction p-value: 0,8553)					
0-3	58/427 (13,6)	90/418 (21,5)	0,63 [0,47; 0,85] 0,0027[2]	0,57 [0,40; 0,82] 0,0024[3]	-7,9 [-13,1; -2,8] 0,0024[3]
4-9	60/549 (10,9)	83/542 (15,3)	0,71 [0,52; 0,97] 0,0331[2]	0,68 [0,48; 0,97] 0,0319[3]	-4,4 [-8,4; -0,4] 0,0319[3]
≥ 10	29/307 (9,4)	43/304 (14,1)	0,67 [0,43; 1,04] 0,0744[2]	0,63 [0,38; 1,04] 0,0717[3]	-4,7 [-9,8; 0,4] 0,0717[3]
Tumor stage (Interaction p-value: 0,6133)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	14/113 (12,4)	23/114 (20,2)	0,61 [0,33; 1,13] 0,1180[2]	0,56 [0,27; 1,15] 0,1123[3]	-7,8 [-17,3; 1,8] 0,1123[3]
IIB	21/151 (13,9)	26/136 (19,1)	0,73 [0,43; 1,23] 0,2360[2]	0,68 [0,36; 1,28] 0,2337[3]	-5,2 [-13,8; 3,4] 0,2337[3]
IIIA	52/495 (10,5)	81/488 (16,6)	0,63 [0,46; 0,88] 0,0058[2]	0,59 [0,41; 0,86] 0,0052[3]	-6,1 [-10,4; -1,8] 0,0052[3]
IIIB	2/54 (3,7)	7/45 (15,6)	0,24 [0,05; 1,09] 0,0644[2]	0,21 [0,04; 1,06] 0,0749[4]	-11,9 [-23,6; -0,1] 0,0749[4]
IIIC	58/468 (12,4)	78/479 (16,3)	0,76 [0,56; 1,04] 0,0894[2]	0,73 [0,50; 1,05] 0,0878[3]	-3,9 [-8,3; 0,6] 0,0878[3]
Tumor grade (Interaction p-value: 0,6548)					
G1	5/91 (5,5)	12/93 (12,9)	0,43 [0,16; 1,16] 0,0951[2]	0,39 [0,13; 1,16] 0,0827[3]	-7,4 [-15,7; 0,9] 0,0827[3]
G2	73/612 (11,9)	99/602 (16,4)	0,73 [0,55; 0,96] 0,0249[2]	0,69 [0,50; 0,95] 0,0240[3]	-4,5 [-8,4; -0,6] 0,0240[3]
G3	67/527 (12,7)	99/506 (19,6)	0,65 [0,49; 0,86] 0,0030[2]	0,60 [0,43; 0,84] 0,0027[3]	-6,9 [-11,3; -2,4] 0,0027[3]
GX	2/51 (3,9)	6/59 (10,2)	0,39 [0,08; 1,83] 0,2300[2]	0,36 [0,07; 1,87] 0,2815[4]	-6,2 [-15,6; 3,1] 0,2815[4]
Race (Interaction p-value: 0,5133)					
White	118/958 (12,3)	174/943 (18,5)	0,67 [0,54; 0,83] 0,0002[2]	0,62 [0,48; 0,80] 0,0002[3]	-6,1 [-9,4; -2,9] 0,0002[3]
Asian	14/250 (5,6)	27/242 (11,2)	0,50 [0,27; 0,93] 0,0295[2]	0,47 [0,24; 0,92] 0,0258[3]	-5,6 [-10,4; -0,7] 0,0258[3]
Other	11/62 (17,7)	13/64 (20,3)	0,87 [0,42; 1,80] 0,7138[2]	0,85 [0,35; 2,06] 0,7133[3]	-2,6 [-16,3; 11,1] 0,7133[3]
First endocrine therapy (Interaction p-value: 0,2601)					
Tamoxifen	12/114 (10,5)	29/132 (22,0)	0,48 [0,26; 0,89] 0,0209[2]	0,42 [0,20; 0,86] 0,0163[3]	-11,4 [-20,5; -2,4] 0,0163[3]
Aromatase inhibitor	135/1169 (11,5)	187/1132 (16,5)	0,70 [0,57; 0,86] 0,0006[2]	0,66 [0,52; 0,84] 0,0006[3]	-5,0 [-7,8; -2,1] 0,0006[3]
ECOG-PS (Interaction p-value: 0,9862)					
ECOG-PS 0	120/1070 (11,2)	170/1019 (16,7)	0,67 [0,54; 0,84] 0,0003[2]	0,63 [0,49; 0,81] 0,0003[3]	-5,5 [-8,4; -2,5] 0,0003[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	27/213 (12,7)	46/245 (18,8)	0,68 [0,44; 1,05] 0,0789[2]	0,63 [0,38; 1,05] 0,0753[3]	-6,1 [-12,7; 0,5] 0,0753[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 340.1.2: Subgroups - adverse events according PT Hypokalaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9634)					
< 65 years	36/918 (3,9)	10/936 (1,1)	3,67 [1,83; 7,35] 0,0002[2]	3,78 [1,86; 7,66] <,0001[3]	2,9 [1,4; 4,3] <,0001[3]
≥ 65 years	21/365 (5,8)	5/328 (1,5)	3,77 [1,44; 9,90] 0,0069[2]	3,94 [1,47; 10,58] 0,0034[3]	4,2 [1,5; 7,0] 0,0034[3]
Prior treatment (Interaction p-value: 0,5340)					
Neoadjuvant chemotherapy	17/430 (4,0)	7/415 (1,7)	2,34 [0,98; 5,59] 0,0549[2]	2,40 [0,98; 5,85] 0,0474[3]	2,3 [0,0; 4,5] 0,0474[3]
Adjuvant chemotherapy	37/784 (4,7)	8/768 (1,0)	4,53 [2,12; 9,67] <,0001[2]	4,71 [2,18; 10,17] <,0001[3]	3,7 [2,0; 5,3] <,0001[3]
No chemotherapy	3/69 (4,3)	0/81 (0,0)	8,20 [0,43; 156,04] 0,1615[2]	8,58 [0,44; 169,04] 0,0950[4]	4,3 [-0,5; 9,2] 0,0950[4]
Region (Interaction p-value: 0,9345)					
North America / Europe	36/678 (5,3)	10/649 (1,5)	3,45 [1,72; 6,89] 0,0005[2]	3,58 [1,76; 7,28] 0,0002[3]	3,8 [1,8; 5,7] 0,0002[3]
Asia	12/203 (5,9)	3/201 (1,5)	3,96 [1,13; 13,82] 0,0309[2]	4,15 [1,15; 14,92] 0,0188[3]	4,4 [0,8; 8,1] 0,0188[3]
Other	9/402 (2,2)	2/414 (0,5)	4,63 [1,01; 21,32] 0,0489[2]	4,72 [1,01; 21,97] 0,0297[3]	1,8 [0,2; 3,3] 0,0297[3]
Primary tumor size (Interaction p-value: 0,8800)					
< 20 mm	19/331 (5,7)	6/334 (1,8)	3,20 [1,29; 7,90] 0,0119[2]	3,33 [1,31; 8,44] 0,0075[3]	3,9 [1,1; 6,8] 0,0075[3]
≥ 20 but < 50 mm	22/646 (3,4)	5/653 (0,8)	4,45 [1,69; 11,67] 0,0024[2]	4,57 [1,72; 12,14] 0,0009[3]	2,6 [1,1; 4,2] 0,0009[3]
≥ 50 mm	15/289 (5,2)	4/265 (1,5)	3,44 [1,16; 10,23] 0,0264[2]	3,57 [1,17; 10,90] 0,0174[3]	3,7 [0,7; 6,6] 0,0174[3]
Number of positive lymph nodes (Interaction p-value: 0,7892)					
0-3	19/427 (4,4)	6/418 (1,4)	3,10 [1,25; 7,68] 0,0146[2]	3,20 [1,26; 8,09] 0,0097[3]	3,0 [0,8; 5,3] 0,0097[3]
4-9	22/549 (4,0)	6/542 (1,1)	3,62 [1,48; 8,86] 0,0048[2]	3,73 [1,50; 9,27] 0,0025[3]	2,9 [1,0; 4,8] 0,0025[3]
≥ 10	16/307 (5,2)	3/304 (1,0)	5,28 [1,55; 17,94] 0,0076[2]	5,52 [1,59; 19,13] 0,0026[3]	4,2 [1,5; 6,9] 0,0026[3]
Tumor stage (Interaction p-value: 0,2019)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	10/113 (8,8)	2/114 (1,8)	5,04 [1,13; 22,51] 0,0340[2]	5,44 [1,16; 25,40] 0,0169[3]	7,1 [1,3; 12,9] 0,0169[3]
IIB	2/151 (1,3)	0/136 (0,0)	4,51 [0,22; 93,05] 0,3297[2]	4,57 [0,22; 95,94] 0,4996[4]	1,3 [-0,5; 3,1] 0,4996[4]
IIIA	21/495 (4,2)	6/488 (1,2)	3,45 [1,40; 8,48] 0,0069[2]	3,56 [1,42; 8,90] 0,0039[3]	3,0 [1,0; 5,0] 0,0039[3]
IIIB	1/54 (1,9)	3/45 (6,7)	0,28 [0,03; 2,58] 0,2599[2]	0,26 [0,03; 2,63] 0,3271[4]	-4,8 [-12,9; 3,3] 0,3271[4]
IIIC	22/468 (4,7)	4/479 (0,8)	5,63 [1,95; 16,21] 0,0014[2]	5,86 [2,00; 17,13] 0,0003[3]	3,9 [1,8; 5,9] 0,0003[3]
Tumor grade (Interaction p-value: 0,9338)					
G1	6/91 (6,6)	1/93 (1,1)	6,13 [0,75; 49,93] 0,0901[2]	6,49 [0,77; 55,06] 0,0630[4]	5,5 [0,0; 11,0] 0,0630[4]
G2	24/612 (3,9)	8/602 (1,3)	2,95 [1,34; 6,52] 0,0074[2]	3,03 [1,35; 6,80] 0,0048[3]	2,6 [0,8; 4,4] 0,0048[3]
G3	22/527 (4,2)	6/506 (1,2)	3,52 [1,44; 8,61] 0,0058[2]	3,63 [1,46; 9,03] 0,0031[3]	3,0 [1,0; 4,9] 0,0031[3]
GX	5/51 (9,8)	0/59 (0,0)	12,69 [0,72; 224,11] 0,0828[2]	14,08 [0,76; 261,07] 0,0192[4]	9,8 [1,6; 18,0] 0,0192[4]
Progesterone receptor status (Interaction p-value: 0,1714)					
Negative	6/156 (3,8)	2/169 (1,2)	3,25 [0,67; 15,86] 0,1451[2]	3,34 [0,66; 16,80] 0,1598[4]	2,7 [-0,8; 6,1] 0,1598[4]
Positive	50/1089 (4,6)	13/1066 (1,2)	3,76 [2,06; 6,89] <,0001[2]	3,90 [2,10; 7,22] <,0001[3]	3,4 [2,0; 4,8] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,8627)					
White	38/958 (4,0)	10/943 (1,1)	3,74 [1,87; 7,46] 0,0002[2]	3,85 [1,91; 7,78] <,0001[3]	2,9 [1,5; 4,3] <,0001[3]
Asian	14/250 (5,6)	3/242 (1,2)	4,52 [1,31; 15,52] 0,0167[2]	4,73 [1,34; 16,66] 0,0081[3]	4,4 [1,2; 7,5] 0,0081[3]
Other	5/62 (8,1)	2/64 (3,1)	2,58 [0,52; 12,81] 0,2462[2]	2,72 [0,51; 14,57] 0,2693[4]	4,9 [-3,1; 12,9] 0,2693[4]
First endocrine therapy (Interaction p-value: 0,4015)					
Tamoxifen	1/114 (0,9)	1/132 (0,8)	1,16 [0,07; 18,30] 0,9171[2]	1,16 [0,07; 18,75] 1,0000[4]	0,1 [-2,1; 2,4] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	56/1169 (4,8)	14/1132 (1,2)	3,87 [2,17; 6,92] <,0001[2]	4,02 [2,22; 7,26] <,0001[3]	3,6 [2,2; 4,9] <,0001[3]
ECOG-PS (Interaction p-value: 0,8542)					
ECOG-PS 0	45/1070 (4,2)	11/1019 (1,1)	3,90 [2,03; 7,49] <,0001[2]	4,02 [2,07; 7,82] <,0001[3]	3,1 [1,8; 4,5] <,0001[3]
ECOG-PS 1	12/213 (5,6)	4/245 (1,6)	3,45 [1,13; 10,54] 0,0297[2]	3,60 [1,14; 11,33] 0,0200[3]	4,0 [0,5; 7,5] 0,0200[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 341.1.2: Subgroups - adverse events according PT Hypotension from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9947)					
< 65 years	13/918 (1,4)	4/936 (0,4)	3,31 [1,08; 10,13] 0,0355[2]	3,35 [1,09; 10,30] 0,0255[3]	1,0 [0,1; 1,9] 0,0255[3]
≥ 65 years	11/365 (3,0)	3/328 (0,9)	3,29 [0,93; 11,71] 0,0653[2]	3,37 [0,93; 12,17] 0,0499[3]	2,1 [0,1; 4,1] 0,0499[3]
Prior treatment (Interaction p-value: 0,9585)					
Neoadjuvant chemotherapy	8/430 (1,9)	2/415 (0,5)	3,86 [0,82; 18,07] 0,0863[2]	3,91 [0,83; 18,54] 0,1078[4]	1,4 [-0,1; 2,8] 0,1078[4]
Adjuvant chemotherapy	15/784 (1,9)	5/768 (0,7)	2,94 [1,07; 8,05] 0,0359[2]	2,98 [1,08; 8,23] 0,0275[3]	1,3 [0,1; 2,4] 0,0275[3]
No chemotherapy	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Region (Interaction p-value: 0,1822)					
North America / Europe	20/678 (2,9)	4/649 (0,6)	4,79 [1,64; 13,93] 0,0041[2]	4,90 [1,67; 14,42] 0,0014[3]	2,3 [0,9; 3,7] 0,0014[3]
Asia	0/203 (0,0)	0/201 (0,0)	NE	NE	NE
Other	4/402 (1,0)	3/414 (0,7)	1,37 [0,31; 6,10] 0,6767[2]	1,38 [0,31; 6,19] 0,7217[4]	0,3 [-1,0; 1,5] 0,7217[4]
Primary tumor size (Interaction p-value: 0,5052)					
< 20 mm	8/331 (2,4)	1/334 (0,3)	8,07 [1,02; 64,18] 0,0483[2]	8,25 [1,03; 66,31] 0,0202[4]	2,1 [0,4; 3,9] 0,0202[4]
≥ 20 but < 50 mm	9/646 (1,4)	3/653 (0,5)	3,03 [0,82; 11,15] 0,0949[2]	3,06 [0,82; 11,36] 0,0786[3]	0,9 [-0,1; 2,0] 0,0786[3]
≥ 50 mm	6/289 (2,1)	3/265 (1,1)	1,83 [0,46; 7,26] 0,3876[2]	1,85 [0,46; 7,48] 0,5080[4]	0,9 [-1,1; 3,0] 0,5080[4]
Number of positive lymph nodes (Interaction p-value: 0,9696)					
0-3	8/427 (1,9)	2/418 (0,5)	3,92 [0,84; 18,33] 0,0831[2]	3,97 [0,84; 18,81] 0,1075[4]	1,4 [-0,1; 2,8] 0,1075[4]
4-9	10/549 (1,8)	3/542 (0,6)	3,29 [0,91; 11,89] 0,0692[2]	3,33 [0,91; 12,18] 0,0536[3]	1,3 [-0,0; 2,5] 0,0536[3]
≥ 10	6/307 (2,0)	2/304 (0,7)	2,97 [0,60; 14,60] 0,1802[2]	3,01 [0,60; 15,03] 0,2859[4]	1,3 [-0,5; 3,1] 0,2859[4]
Tumor stage (Interaction p-value: 0,8569)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	2/113 (1,8)	0/114 (0,0)	5,04 [0,24; 103,90] 0,2945[2]	5,13 [0,24; 108,15] 0,2467[4]	1,8 [-0,7; 4,2] 0,2467[4]
IIB	2/151 (1,3)	0/136 (0,0)	4,51 [0,22; 93,05] 0,3297[2]	4,57 [0,22; 95,94] 0,4996[4]	1,3 [-0,5; 3,1] 0,4996[4]
IIIA	10/495 (2,0)	2/488 (0,4)	4,93 [1,09; 22,38] 0,0388[2]	5,01 [1,09; 22,99] 0,0215[3]	1,6 [0,2; 3,0] 0,0215[3]
IIIB	1/54 (1,9)	0/45 (0,0)	2,51 [0,10; 60,13] 0,5703[2]	2,55 [0,10; 64,17] 1,0000[4]	1,9 [-1,7; 5,4] 1,0000[4]
IIIC	8/468 (1,7)	5/479 (1,0)	1,64 [0,54; 4,97] 0,3838[2]	1,65 [0,54; 5,08] 0,3788[3]	0,7 [-0,8; 2,2] 0,3788[3]
Tumor grade (Interaction p-value: 0,3177)					
G1	3/91 (3,3)	0/93 (0,0)	7,15 [0,37; 136,54] 0,1910[2]	7,40 [0,38; 145,22] 0,1189[4]	3,3 [-0,4; 7,0] 0,1189[4]
G2	5/612 (0,8)	5/602 (0,8)	0,98 [0,29; 3,38] 0,9791[2]	0,98 [0,28; 3,41] 1,0000[4]	-0,0 [-1,0; 1,0] 1,0000[4]
G3	13/527 (2,5)	2/506 (0,4)	6,24 [1,42; 27,52] 0,0156[2]	6,37 [1,43; 28,39] 0,0054[3]	2,1 [0,6; 3,5] 0,0054[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesterone receptor status (Interaction p-value: 0,2220)					
Negative	4/156 (2,6)	1/169 (0,6)	4,33 [0,49; 38,35] 0,1875[2]	4,42 [0,49; 39,99] 0,1985[4]	2,0 [-0,8; 4,7] 0,1985[4]
Positive	20/1089 (1,8)	6/1066 (0,6)	3,26 [1,32; 8,09] 0,0107[2]	3,31 [1,32; 8,26] 0,0068[3]	1,3 [0,4; 2,2] 0,0068[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9909)					
White	23/958 (2,4)	7/943 (0,7)	3,23 [1,39; 7,50] 0,0062[2]	3,29 [1,40; 7,70] 0,0037[3]	1,7 [0,5; 2,8] 0,0037[3]
Asian	0/250 (0,0)	0/242 (0,0)	NE	NE	NE
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
First endocrine therapy (Interaction p-value: 0,7427)					
Tamoxifen	2/114 (1,8)	1/132 (0,8)	2,32 [0,21; 25,21] 0,4906[2]	2,34 [0,21; 26,14] 0,5979[4]	1,0 [-1,8; 3,8] 0,5979[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	22/1169 (1,9)	6/1132 (0,5)	3,55 [1,45; 8,72] 0,0057[2]	3,60 [1,45; 8,91] 0,0031[3]	1,4 [0,5; 2,2] 0,0031[3]
ECOG-PS (Interaction p-value: 0,4362)					
ECOG-PS 0	23/1070 (2,1)	6/1019 (0,6)	3,65 [1,49; 8,93] 0,0045[2]	3,71 [1,50; 9,15] 0,0023[3]	1,6 [0,6; 2,5] 0,0023[3]
ECOG-PS 1	1/213 (0,5)	1/245 (0,4)	1,15 [0,07; 18,28] 0,9210[2]	1,15 [0,07; 18,51] 1,0000[4]	0,1 [-1,2; 1,3] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 342.1.2: Subgroups - adverse events according PT Joint stiffness from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5481)					
< 65 years	12/918 (1,3)	24/936 (2,6)	0,51 [0,26; 1,01] 0,0546[2]	0,50 [0,25; 1,01] 0,0499[3]	-1,3 [-2,5; -0,0] 0,0499[3]
≥ 65 years	2/365 (0,5)	6/328 (1,8)	0,30 [0,06; 1,47] 0,1381[2]	0,30 [0,06; 1,48] 0,1585[4]	-1,3 [-2,9; 0,4] 0,1585[4]
Prior treatment (Interaction p-value: 0,9763)					
Neoadjuvant chemotherapy	3/430 (0,7)	7/415 (1,7)	0,41 [0,11; 1,59] 0,1985[2]	0,41 [0,11; 1,59] 0,2164[4]	-1,0 [-2,5; 0,5] 0,2164[4]
Adjuvant chemotherapy	11/784 (1,4)	22/768 (2,9)	0,49 [0,24; 1,00] 0,0510[2]	0,48 [0,23; 1,00] 0,0460[3]	-1,5 [-2,9; -0,0] 0,0460[3]
No chemotherapy	0/69 (0,0)	1/81 (1,2)	0,39 [0,02; 9,43] 0,5628[2]	0,39 [0,02; 9,63] 1,0000[4]	-1,2 [-3,6; 1,2] 1,0000[4]
Region (Interaction p-value: 0,1941)					
North America / Europe	11/678 (1,6)	22/649 (3,4)	0,48 [0,23; 0,98] 0,0436[2]	0,47 [0,23; 0,98] 0,0388[3]	-1,8 [-3,5; -0,1] 0,0388[3]
Asia	3/203 (1,5)	8/201 (4,0)	0,37 [0,10; 1,38] 0,1390[2]	0,36 [0,09; 1,38] 0,1223[3]	-2,5 [-5,7; 0,7] 0,1223[3]
Other	0/402 (0,0)	0/414 (0,0)	NE	NE	NE
Primary tumor size (Interaction p-value: 0,4611)					
< 20 mm	5/331 (1,5)	6/334 (1,8)	0,84 [0,26; 2,73] 0,7729[2]	0,84 [0,25; 2,77] 0,7726[3]	-0,3 [-2,2; 1,7] 0,7726[3]
≥ 20 but < 50 mm	5/646 (0,8)	16/653 (2,5)	0,32 [0,12; 0,86] 0,0237[2]	0,31 [0,11; 0,85] 0,0166[3]	-1,7 [-3,0; -0,3] 0,0166[3]
≥ 50 mm	4/289 (1,4)	8/265 (3,0)	0,46 [0,14; 1,50] 0,1985[2]	0,45 [0,13; 1,52] 0,1867[3]	-1,6 [-4,1; 0,8] 0,1867[3]
Number of positive lymph nodes (Interaction p-value: 0,3010)					
0-3	4/427 (0,9)	8/418 (1,9)	0,49 [0,15; 1,61] 0,2403[2]	0,48 [0,14; 1,62] 0,2301[3]	-1,0 [-2,6; 0,6] 0,2301[3]
4-9	8/549 (1,5)	11/542 (2,0)	0,72 [0,29; 1,77] 0,4721[2]	0,71 [0,28; 1,79] 0,4700[3]	-0,6 [-2,1; 1,0] 0,4700[3]
≥ 10	2/307 (0,7)	11/304 (3,6)	0,18 [0,04; 0,81] 0,0249[2]	0,17 [0,04; 0,79] 0,0111[3]	-3,0 [-5,3; -0,7] 0,0111[3]
Tumor stage (Interaction p-value: 0,9010)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	2/113 (1,8)	2/114 (1,8)	1,01 [0,14; 7,04] 0,9929[2]	1,01 [0,14; 7,29] 1,0000[4]	0,0 [-3,4; 3,4] 1,0000[4]
IIB	1/151 (0,7)	2/136 (1,5)	0,45 [0,04; 4,91] 0,5128[2]	0,45 [0,04; 4,98] 0,6050[4]	-0,8 [-3,2; 1,6] 0,6050[4]
IIIA	6/495 (1,2)	11/488 (2,3)	0,54 [0,20; 1,44] 0,2179[2]	0,53 [0,20; 1,45] 0,2102[3]	-1,0 [-2,7; 0,6] 0,2102[3]
IIIB	0/54 (0,0)	0/45 (0,0)	NE	NE	NE
IIIC	5/468 (1,1)	15/479 (3,1)	0,34 [0,12; 0,93] 0,0358[2]	0,33 [0,12; 0,93] 0,0273[3]	-2,1 [-3,9; -0,2] 0,0273[3]
Tumor grade (Interaction p-value: 0,6809)					
G1	0/91 (0,0)	2/93 (2,2)	0,20 [0,01; 4,20] 0,3032[2]	0,20 [0,01; 4,22] 0,4973[4]	-2,2 [-5,1; 0,8] 0,4973[4]
G2	9/612 (1,5)	16/602 (2,7)	0,55 [0,25; 1,24] 0,1515[2]	0,55 [0,24; 1,25] 0,1453[3]	-1,2 [-2,8; 0,4] 0,1453[3]
G3	5/527 (0,9)	12/506 (2,4)	0,40 [0,14; 1,13] 0,0831[2]	0,39 [0,14; 1,13] 0,0724[3]	-1,4 [-3,0; 0,1] 0,0724[3]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,6142)					
Negative	3/156 (1,9)	2/169 (1,2)	1,63 [0,28; 9,60] 0,5921[2]	1,64 [0,27; 9,93] 0,6739[4]	0,7 [-2,0; 3,4] 0,6739[4]
Positive	11/1089 (1,0)	28/1066 (2,6)	0,38 [0,19; 0,77] 0,0068[2]	0,38 [0,19; 0,76] 0,0049[3]	-1,6 [-2,7; -0,5] 0,0049[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,8242)					
White	9/958 (0,9)	21/943 (2,2)	0,42 [0,19; 0,92] 0,0292[2]	0,42 [0,19; 0,91] 0,0243[3]	-1,3 [-2,4; -0,2] 0,0243[3]
Asian	4/250 (1,6)	8/242 (3,3)	0,48 [0,15; 1,59] 0,2309[2]	0,48 [0,14; 1,60] 0,2201[3]	-1,7 [-4,4; 1,0] 0,2201[3]
Other	1/62 (1,6)	1/64 (1,6)	1,03 [0,07; 16,14] 0,9819[2]	1,03 [0,06; 16,88] 1,0000[4]	0,1 [-4,3; 4,4] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,1656)					
Tamoxifen	2/114 (1,8)	1/132 (0,8)	2,32 [0,21; 25,21] 0,4906[2]	2,34 [0,21; 26,14] 0,5979[4]	1,0 [-1,8; 3,8] 0,5979[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	12/1169 (1,0)	29/1132 (2,6)	0,40 [0,21; 0,78] 0,0073[2]	0,39 [0,20; 0,78] 0,0054[3]	-1,5 [-2,6; -0,4] 0,0054[3]
ECOG-PS (Interaction p-value: 0,8813)					
ECOG-PS 0	13/1070 (1,2)	27/1019 (2,6)	0,46 [0,24; 0,88] 0,0198[2]	0,45 [0,23; 0,88] 0,0168[3]	-1,4 [-2,6; -0,3] 0,0168[3]
ECOG-PS 1	1/213 (0,5)	3/245 (1,2)	0,38 [0,04; 3,66] 0,4049[2]	0,38 [0,04; 3,69] 0,6270[4]	-0,8 [-2,4; 0,9] 0,6270[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 343.1.2: Subgroups - adverse events according PT Lacrimation increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1332)					
< 65 years	51/918 (5,6)	2/936 (0,2)	26,00 [6,35; 106,48] <,0001[2]	27,47 [6,67; 113,18] <,0001[3]	5,3 [3,8; 6,9] <,0001[3]
≥ 65 years	21/365 (5,8)	3/328 (0,9)	6,29 [1,89; 20,90] 0,0027[2]	6,61 [1,95; 22,38] 0,0005[3]	4,8 [2,2; 7,4] 0,0005[3]
Prior treatment (Interaction p-value: 0,6987)					
Neoadjuvant chemotherapy	28/430 (6,5)	1/415 (0,2)	27,02 [3,69; 197,71] 0,0012[2]	28,84 [3,90; 212,94] <,0001[3]	6,3 [3,9; 8,6] <,0001[3]
Adjuvant chemotherapy	42/784 (5,4)	4/768 (0,5)	10,29 [3,71; 28,55] <,0001[2]	10,81 [3,86; 30,30] <,0001[3]	4,8 [3,2; 6,5] <,0001[3]
No chemotherapy	2/69 (2,9)	0/81 (0,0)	5,86 [0,29; 119,97] 0,2512[2]	6,04 [0,28; 127,91] 0,2099[4]	2,9 [-1,1; 6,9] 0,2099[4]
Region (Interaction p-value: 0,9703)					
North America / Europe	52/678 (7,7)	4/649 (0,6)	12,44 [4,53; 34,21] <,0001[2]	13,39 [4,82; 37,25] <,0001[3]	7,1 [5,0; 9,1] <,0001[3]
Asia	4/203 (2,0)	0/201 (0,0)	8,91 [0,48; 164,45] 0,1414[2]	9,09 [0,49; 169,95] 0,1232[4]	2,0 [0,1; 3,9] 0,1232[4]
Other	16/402 (4,0)	1/414 (0,2)	16,48 [2,20; 123,67] 0,0064[2]	17,12 [2,26; 129,70] 0,0002[3]	3,7 [1,8; 5,7] 0,0002[3]
Primary tumor size (Interaction p-value: 0,7043)					
< 20 mm	16/331 (4,8)	2/334 (0,6)	8,07 [1,87; 34,83] 0,0051[2]	8,43 [1,92; 36,97] 0,0008[3]	4,2 [1,8; 6,7] 0,0008[3]
≥ 20 but < 50 mm	35/646 (5,4)	2/653 (0,3)	17,69 [4,27; 73,24] <,0001[2]	18,65 [4,47; 77,85] <,0001[3]	5,1 [3,3; 6,9] <,0001[3]
≥ 50 mm	20/289 (6,9)	1/265 (0,4)	18,34 [2,48; 135,70] 0,0044[2]	19,63 [2,62; 147,30] <,0001[3]	6,5 [3,5; 9,6] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,9973)					
0-3	19/427 (4,4)	2/418 (0,5)	9,30 [2,18; 39,68] 0,0026[2]	9,69 [2,24; 41,85] 0,0002[3]	4,0 [1,9; 6,0] 0,0002[3]
4-9	30/549 (5,5)	3/542 (0,6)	9,87 [3,03; 32,16] 0,0001[2]	10,39 [3,15; 34,24] <,0001[3]	4,9 [2,9; 6,9] <,0001[3]
≥ 10	23/307 (7,5)	0/304 (0,0)	46,54 [2,84; 762,82] 0,0071[2]	50,30 [3,04; 832,04] <,0001[3]	7,5 [4,5; 10,4] <,0001[3]
Tumor stage (Interaction p-value: 0,7221)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	6/113 (5,3)	1/114 (0,9)	6,05 [0,74; 49,48] 0,0930[2]	6,34 [0,75; 53,50] 0,0655[4]	4,4 [-0,0; 8,9] 0,0655[4]
IIB	5/151 (3,3)	1/136 (0,7)	4,50 [0,53; 38,07] 0,1670[2]	4,62 [0,53; 40,08] 0,2177[4]	2,6 [-0,6; 5,8] 0,2177[4]
IIIA	27/495 (5,5)	2/488 (0,4)	13,31 [3,18; 55,66] 0,0004[2]	14,02 [3,32; 59,28] <,0001[3]	5,0 [3,0; 7,1] <,0001[3]
IIIB	4/54 (7,4)	0/45 (0,0)	7,53 [0,42; 136,17] 0,1718[2]	8,11 [0,42; 154,79] 0,1236[4]	7,4 [0,4; 14,4] 0,1236[4]
IIIC	30/468 (6,4)	1/479 (0,2)	30,71 [4,20; 224,24] 0,0007[2]	32,74 [4,45; 241,09] <,0001[3]	6,2 [3,9; 8,5] <,0001[3]
Tumor grade (Interaction p-value: 0,3823)					
G1	3/91 (3,3)	1/93 (1,1)	3,07 [0,32; 28,93] 0,3279[2]	3,14 [0,32; 30,72] 0,3655[4]	2,2 [-2,0; 6,4] 0,3655[4]
G2	41/612 (6,7)	1/602 (0,2)	40,33 [5,57; 292,25] 0,0003[2]	43,15 [5,92; 314,76] <,0001[3]	6,5 [4,5; 8,5] <,0001[3]
G3	26/527 (4,9)	3/506 (0,6)	8,32 [2,53; 27,32] 0,0005[2]	8,70 [2,62; 28,93] <,0001[3]	4,3 [2,4; 6,3] <,0001[3]
GX	2/51 (3,9)	0/59 (0,0)	5,77 [0,28; 117,46] 0,2544[2]	6,01 [0,28; 128,14] 0,2127[4]	3,9 [-1,4; 9,2] 0,2127[4]
Progesterone receptor status (Interaction p-value: 0,9588)					
Negative	13/156 (8,3)	0/169 (0,0)	29,24 [1,75; 487,71] 0,0187[2]	31,89 [1,88; 541,19] 0,0001[3]	8,3 [4,0; 12,7] 0,0001[3]
Positive	58/1089 (5,3)	5/1066 (0,5)	11,36 [4,57; 28,20] <,0001[2]	11,94 [4,77; 29,88] <,0001[3]	4,9 [3,5; 6,3] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9997)					
White	64/958 (6,7)	5/943 (0,5)	12,60 [5,09; 31,17] <,0001[2]	13,43 [5,38; 33,52] <,0001[3]	6,2 [4,5; 7,8] <,0001[3]
Asian	5/250 (2,0)	0/242 (0,0)	10,65 [0,59; 191,56] 0,1086[2]	10,87 [0,60; 197,57] 0,0614[4]	2,0 [0,3; 3,7] 0,0614[4]
Other	3/62 (4,8)	0/64 (0,0)	7,22 [0,38; 137,01] 0,1879[2]	7,59 [0,38; 150,00] 0,1162[4]	4,8 [-0,5; 10,2] 0,1162[4]
First endocrine therapy (Interaction p-value: 0,6607)					
Tamoxifen	8/114 (7,0)	1/132 (0,8)	9,26 [1,18; 72,95] 0,0345[2]	9,89 [1,22; 80,30] 0,0133[4]	6,3 [1,3; 11,2] 0,0133[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	64/1169 (5,5)	4/1132 (0,4)	15,49 [5,66; 42,40] <,0001[2]	16,33 [5,93; 45,00] <,0001[3]	5,1 [3,8; 6,5] <,0001[3]
ECOG-PS (Interaction p-value: 0,9054)					
ECOG-PS 0	61/1070 (5,7)	4/1019 (0,4)	14,52 [5,30; 39,79] <,0001[2]	15,34 [5,56; 42,35] <,0001[3]	5,3 [3,9; 6,7] <,0001[3]
ECOG-PS 1	11/213 (5,2)	1/245 (0,4)	12,65 [1,65; 97,20] 0,0147[2]	13,29 [1,70; 103,79] 0,0015[3]	4,8 [1,7; 7,8] 0,0015[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 344.1.2: Subgroups - adverse events according PT Leukopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,6756)					
< 65 years	139/918 (15,1)	20/936 (2,1)	7,09 [4,47; 11,22] <,0001[2]	8,17 [5,07; 13,19] <,0001[3]	13,0 [10,5; 15,5] <,0001[3]
≥ 65 years	49/365 (13,4)	5/328 (1,5)	8,81 [3,55; 21,83] <,0001[2]	10,02 [3,94; 25,47] <,0001[3]	11,9 [8,2; 15,6] <,0001[3]
Prior treatment (Interaction p-value: 0,9377)					
Neoadjuvant chemotherapy	59/430 (13,7)	8/415 (1,9)	7,12 [3,44; 14,71] <,0001[2]	8,09 [3,82; 17,16] <,0001[3]	11,8 [8,3; 15,3] <,0001[3]
Adjuvant chemotherapy	120/784 (15,3)	16/768 (2,1)	7,35 [4,40; 12,26] <,0001[2]	8,49 [4,99; 14,46] <,0001[3]	13,2 [10,5; 15,9] <,0001[3]
No chemotherapy	9/69 (13,0)	1/81 (1,2)	10,57 [1,37; 81,32] 0,0236[2]	12,00 [1,48; 97,30] 0,0058[4]	11,8 [3,5; 20,1] 0,0058[4]
Region (Interaction p-value: 0,2470)					
North America / Europe	66/678 (9,7)	5/649 (0,8)	12,64 [5,12; 31,16] <,0001[2]	13,89 [5,56; 34,71] <,0001[3]	9,0 [6,6; 11,3] <,0001[3]
Asia	15/203 (7,4)	1/201 (0,5)	14,85 [1,98; 111,38] 0,0087[2]	15,96 [2,09; 121,99] 0,0004[3]	6,9 [3,2; 10,6] 0,0004[3]
Other	107/402 (26,6)	19/414 (4,6)	5,80 [3,63; 9,26] <,0001[2]	7,54 [4,52; 12,57] <,0001[3]	22,0 [17,3; 26,8] <,0001[3]
Primary tumor size (Interaction p-value: 0,5781)					
< 20 mm	49/331 (14,8)	6/334 (1,8)	8,24 [3,58; 18,97] <,0001[2]	9,50 [4,01; 22,50] <,0001[3]	13,0 [8,9; 17,1] <,0001[3]
≥ 20 but < 50 mm	96/646 (14,9)	15/653 (2,3)	6,47 [3,80; 11,03] <,0001[2]	7,42 [4,26; 12,94] <,0001[3]	12,6 [9,6; 15,5] <,0001[3]
≥ 50 mm	41/289 (14,2)	3/265 (1,1)	12,53 [3,93; 39,99] <,0001[2]	14,44 [4,41; 47,22] <,0001[3]	13,1 [8,8; 17,3] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,8757)					
0-3	54/427 (12,6)	6/418 (1,4)	8,81 [3,83; 20,26] <,0001[2]	9,94 [4,23; 23,37] <,0001[3]	11,2 [7,9; 14,6] <,0001[3]
4-9	89/549 (16,2)	13/542 (2,4)	6,76 [3,82; 11,95] <,0001[2]	7,87 [4,34; 14,28] <,0001[3]	13,8 [10,5; 17,2] <,0001[3]
≥ 10	45/307 (14,7)	6/304 (2,0)	7,43 [3,22; 17,15] <,0001[2]	8,53 [3,58; 20,32] <,0001[3]	12,7 [8,4; 16,9] <,0001[3]
Tumor stage (Interaction p-value: 0,9491)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	15/113 (13,3)	1/114 (0,9)	15,13 [2,03; 112,65] 0,0080[2]	17,30 [2,24; 133,31] 0,0003[3]	12,4 [5,9; 18,9] 0,0003[3]
IIB	19/151 (12,6)	3/136 (2,2)	5,70 [1,73; 18,85] 0,0043[2]	6,38 [1,84; 22,08] 0,0010[3]	10,4 [4,5; 16,2] 0,0010[3]
IIIA	75/495 (15,2)	10/488 (2,0)	7,39 [3,87; 14,13] <,0001[2]	8,54 [4,36; 16,73] <,0001[3]	13,1 [9,7; 16,5] <,0001[3]
IIIB	7/54 (13,0)	1/45 (2,2)	5,83 [0,75; 45,66] 0,0930[2]	6,55 [0,77; 55,43] 0,0682[4]	10,7 [0,8; 20,7] 0,0682[4]
IIIC	72/468 (15,4)	10/479 (2,1)	7,37 [3,85; 14,10] <,0001[2]	8,53 [4,34; 16,74] <,0001[3]	13,3 [9,8; 16,8] <,0001[3]
Tumor grade (Interaction p-value: 0,6126)					
G1	11/91 (12,1)	0/93 (0,0)	23,50 [1,41; 392,99] 0,0280[2]	26,71 [1,55; 460,48] 0,0005[3]	12,1 [5,4; 18,8] 0,0005[3]
G2	86/612 (14,1)	15/602 (2,5)	5,64 [3,30; 9,65] <,0001[2]	6,40 [3,65; 11,21] <,0001[3]	11,6 [8,5; 14,6] <,0001[3]
G3	83/527 (15,7)	8/506 (1,6)	9,96 [4,87; 20,37] <,0001[2]	11,64 [5,57; 24,31] <,0001[3]	14,2 [10,9; 17,5] <,0001[3]
GX	8/51 (15,7)	2/59 (3,4)	4,63 [1,03; 20,81] 0,0458[2]	5,30 [1,07; 26,24] 0,0423[4]	12,3 [1,3; 23,3] 0,0423[4]
Progesterone receptor status (Interaction p-value: 0,5536)					
Negative	25/156 (16,0)	5/169 (3,0)	5,42 [2,13; 13,80] 0,0004[2]	6,26 [2,33; 16,80] <,0001[3]	13,1 [6,8; 19,4] <,0001[3]
Positive	162/1089 (14,9)	20/1066 (1,9)	7,93 [5,02; 12,52] <,0001[2]	9,14 [5,70; 14,67] <,0001[3]	13,0 [10,7; 15,3] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,7761)					
White	159/958 (16,6)	21/943 (2,2)	7,45 [4,77; 11,64] <,0001[2]	8,74 [5,49; 13,91] <,0001[3]	14,4 [11,8; 16,9] <,0001[3]
Asian	20/250 (8,0)	2/242 (0,8)	9,68 [2,29; 40,97] 0,0020[2]	10,43 [2,41; 45,15] 0,0001[3]	7,2 [3,6; 10,7] 0,0001[3]
Other	9/62 (14,5)	2/64 (3,1)	4,65 [1,04; 20,65] 0,0436[2]	5,26 [1,09; 25,44] 0,0235[3]	11,4 [1,6; 21,1] 0,0235[3]
ECOG-PS (Interaction p-value: 0,1872)					
ECOG-PS 0	155/1070 (14,5)	17/1019 (1,7)	8,68 [5,30; 14,22] <,0001[2]	9,98 [6,00; 16,61] <,0001[3]	12,8 [10,6; 15,1] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	33/213 (15,5)	8/245 (3,3)	4,74 [2,24; 10,05] <,0001[2]	5,43 [2,45; 12,04] <,0001[3]	12,2 [6,9; 17,6] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 345.1.2: Subgroups - adverse events according PT Lymphocyte count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5167)					
< 65 years	74/918 (8,1)	21/936 (2,2)	3,59 [2,23; 5,78] <,0001[2]	3,82 [2,33; 6,26] <,0001[3]	5,8 [3,8; 7,8] <,0001[3]
≥ 65 years	38/365 (10,4)	7/328 (2,1)	4,88 [2,21; 10,77] <,0001[2]	5,33 [2,35; 12,11] <,0001[3]	8,3 [4,8; 11,8] <,0001[3]
Prior treatment (Interaction p-value: 0,9336)					
Neoadjuvant chemotherapy	41/430 (9,5)	10/415 (2,4)	3,96 [2,01; 7,79] <,0001[2]	4,27 [2,11; 8,64] <,0001[3]	7,1 [4,0; 10,3] <,0001[3]
Adjuvant chemotherapy	66/784 (8,4)	16/768 (2,1)	4,04 [2,36; 6,91] <,0001[2]	4,32 [2,48; 7,53] <,0001[3]	6,3 [4,1; 8,5] <,0001[3]
No chemotherapy	5/69 (7,2)	2/81 (2,5)	2,93 [0,59; 14,65] 0,1894[2]	3,09 [0,58; 16,44] 0,2485[4]	4,8 [-2,2; 11,8] 0,2485[4]
Region (Interaction p-value: 0,8395)					
North America / Europe	49/678 (7,2)	11/649 (1,7)	4,26 [2,24; 8,13] <,0001[2]	4,52 [2,33; 8,77] <,0001[3]	5,5 [3,3; 7,7] <,0001[3]
Asia	27/203 (13,3)	6/201 (3,0)	4,46 [1,88; 10,56] 0,0007[2]	4,99 [2,01; 12,36] 0,0002[3]	10,3 [5,1; 15,5] 0,0002[3]
Other	36/402 (9,0)	11/414 (2,7)	3,37 [1,74; 6,53] 0,0003[2]	3,60 [1,81; 7,18] 0,0001[3]	6,3 [3,1; 9,5] 0,0001[3]
Primary tumor size (Interaction p-value: 0,8893)					
< 20 mm	28/331 (8,5)	6/334 (1,8)	4,71 [1,98; 11,22] 0,0005[2]	5,05 [2,06; 12,37] <,0001[3]	6,7 [3,3; 10,0] <,0001[3]
≥ 20 but < 50 mm	50/646 (7,7)	13/653 (2,0)	3,89 [2,13; 7,09] <,0001[2]	4,13 [2,22; 7,68] <,0001[3]	5,7 [3,4; 8,1] <,0001[3]
≥ 50 mm	31/289 (10,7)	8/265 (3,0)	3,55 [1,66; 7,59] 0,0011[2]	3,86 [1,74; 8,56] 0,0004[3]	7,7 [3,6; 11,8] 0,0004[3]
Number of positive lymph nodes (Interaction p-value: 0,9934)					
0-3	36/427 (8,4)	9/418 (2,2)	3,92 [1,91; 8,03] 0,0002[2]	4,18 [1,99; 8,80] <,0001[3]	6,3 [3,3; 9,3] <,0001[3]
4-9	47/549 (8,6)	12/542 (2,2)	3,87 [2,07; 7,21] <,0001[2]	4,14 [2,17; 7,89] <,0001[3]	6,3 [3,7; 9,0] <,0001[3]
≥ 10	29/307 (9,4)	7/304 (2,3)	4,10 [1,82; 9,22] 0,0006[2]	4,43 [1,91; 10,27] 0,0002[3]	7,1 [3,5; 10,8] 0,0002[3]
Tumor stage (Interaction p-value: 0,8284)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	11/113 (9,7)	3/114 (2,6)	3,70 [1,06; 12,91] 0,0402[2]	3,99 [1,08; 14,71] 0,0261[3]	7,1 [0,9; 13,3] 0,0261[3]
IIB	13/151 (8,6)	2/136 (1,5)	5,85 [1,35; 25,48] 0,0185[2]	6,31 [1,40; 28,50] 0,0067[3]	7,1 [2,2; 12,0] 0,0067[3]
IIIA	44/495 (8,9)	15/488 (3,1)	2,89 [1,63; 5,13] 0,0003[2]	3,08 [1,69; 5,61] 0,0001[3]	5,8 [2,9; 8,8] 0,0001[3]
IIIB	6/54 (11,1)	0/45 (0,0)	10,87 [0,63; 187,90] 0,1007[2]	12,20 [0,67; 222,70] 0,0303[4]	11,1 [2,7; 19,5] 0,0303[4]
IIIC	37/468 (7,9)	8/479 (1,7)	4,73 [2,23; 10,06] <,0001[2]	5,05 [2,33; 10,97] <,0001[3]	6,2 [3,5; 8,9] <,0001[3]
Tumor grade (Interaction p-value: 0,3919)					
G1	10/91 (11,0)	0/93 (0,0)	21,46 [1,28; 360,85] 0,0332[2]	24,09 [1,39; 417,56] 0,0007[4]	11,0 [4,6; 17,4] 0,0007[4]
G2	49/612 (8,0)	18/602 (3,0)	2,68 [1,58; 4,54] 0,0003[2]	2,82 [1,63; 4,91] 0,0001[3]	5,0 [2,5; 7,6] 0,0001[3]
G3	47/527 (8,9)	8/506 (1,6)	5,64 [2,69; 11,82] <,0001[2]	6,10 [2,85; 13,03] <,0001[3]	7,3 [4,7; 10,0] <,0001[3]
GX	6/51 (11,8)	1/59 (1,7)	6,94 [0,86; 55,76] 0,0684[2]	7,73 [0,90; 66,56] 0,0477[4]	10,1 [0,6; 19,5] 0,0477[4]
Race (Interaction p-value: 0,9474)					
White	79/958 (8,2)	21/943 (2,2)	3,70 [2,31; 5,94] <,0001[2]	3,95 [2,42; 6,44] <,0001[3]	6,0 [4,0; 8,0] <,0001[3]
Asian	27/250 (10,8)	6/242 (2,5)	4,36 [1,83; 10,36] 0,0009[2]	4,76 [1,93; 11,75] 0,0002[3]	8,3 [4,0; 12,6] 0,0002[3]
Other	4/62 (6,5)	1/64 (1,6)	4,13 [0,47; 35,92] 0,1989[2]	4,34 [0,47; 40,01] 0,2039[4]	4,9 [-1,9; 11,7] 0,2039[4]
First endocrine therapy (Interaction p-value: 0,1159)					
Tamoxifen	5/114 (4,4)	4/132 (3,0)	1,45 [0,40; 5,26] 0,5745[2]	1,47 [0,38; 5,60] 0,7368[4]	1,4 [-3,4; 6,1] 0,7368[4]
Aromatase inhibitor	107/1169 (9,2)	24/1132 (2,1)	4,32 [2,79; 6,67] <,0001[2]	4,65 [2,96; 7,30] <,0001[3]	7,0 [5,2; 8,9] <,0001[3]
ECOG-PS (Interaction p-value: 0,1097)					
ECOG-PS 0	92/1070 (8,6)	26/1019 (2,6)	3,37 [2,20; 5,16] <,0001[2]	3,59 [2,30; 5,60] <,0001[3]	6,0 [4,1; 8,0] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	20/213 (9,4)	2/245 (0,8)	11,50 [2,72; 48,64] 0,0009[2]	12,59 [2,91; 54,53] <,0001[3]	8,6 [4,5; 12,6] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 346.1.2: Subgroups - adverse events according PT Lymphoedema from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,2668)					
< 65 years	116/918 (12,6)	75/936 (8,0)	1,58 [1,20; 2,08] 0,0012[2]	1,66 [1,22; 2,25] 0,0011[3]	4,6 [1,9; 7,4] 0,0011[3]
≥ 65 years	39/365 (10,7)	30/328 (9,1)	1,17 [0,74; 1,84] 0,5002[2]	1,19 [0,72; 1,96] 0,4994[3]	1,5 [-2,9; 6,0] 0,4994[3]
Prior treatment (Interaction p-value: 0,3956)					
Neoadjuvant chemotherapy	62/430 (14,4)	42/415 (10,1)	1,42 [0,99; 2,06] 0,0592[2]	1,50 [0,99; 2,27] 0,0573[3]	4,3 [-0,1; 8,7] 0,0573[3]
Adjuvant chemotherapy	86/784 (11,0)	61/768 (7,9)	1,38 [1,01; 1,89] 0,0430[2]	1,43 [1,01; 2,02] 0,0418[3]	3,0 [0,1; 5,9] 0,0418[3]
No chemotherapy	7/69 (10,1)	2/81 (2,5)	4,11 [0,88; 19,13] 0,0718[2]	4,46 [0,89; 22,23] 0,0809[4]	7,7 [-0,2; 15,6] 0,0809[4]
Region (Interaction p-value: 0,0942)					
North America / Europe	90/678 (13,3)	73/649 (11,2)	1,18 [0,88; 1,58] 0,2619[2]	1,21 [0,87; 1,68] 0,2610[3]	2,0 [-1,5; 5,6] 0,2610[3]
Asia	31/203 (15,3)	15/201 (7,5)	2,05 [1,14; 3,67] 0,0164[2]	2,23 [1,17; 4,28] 0,0135[3]	7,8 [1,7; 13,9] 0,0135[3]
Other	34/402 (8,5)	17/414 (4,1)	2,06 [1,17; 3,63] 0,0123[2]	2,16 [1,19; 3,93] 0,0102[3]	4,4 [1,0; 7,7] 0,0102[3]
Primary tumor size (Interaction p-value: 0,4585)					
< 20 mm	40/331 (12,1)	32/334 (9,6)	1,26 [0,81; 1,96] 0,3003[2]	1,30 [0,79; 2,12] 0,2988[3]	2,5 [-2,2; 7,2] 0,2988[3]
≥ 20 but < 50 mm	65/646 (10,1)	49/653 (7,5)	1,34 [0,94; 1,91] 0,1048[2]	1,38 [0,94; 2,03] 0,1033[3]	2,6 [-0,5; 5,6] 0,1033[3]
≥ 50 mm	48/289 (16,6)	24/265 (9,1)	1,83 [1,16; 2,91] 0,0099[2]	2,00 [1,19; 3,37] 0,0083[3]	7,6 [2,0; 13,1] 0,0083[3]
Number of positive lymph nodes (Interaction p-value: 0,3646)					
0-3	47/427 (11,0)	26/418 (6,2)	1,77 [1,12; 2,80] 0,0149[2]	1,86 [1,13; 3,07] 0,0133[3]	4,8 [1,0; 8,6] 0,0133[3]
4-9	65/549 (11,8)	42/542 (7,7)	1,53 [1,06; 2,21] 0,0245[2]	1,60 [1,06; 2,40] 0,0231[3]	4,1 [0,6; 7,6] 0,0231[3]
≥ 10	43/307 (14,0)	37/304 (12,2)	1,15 [0,76; 1,73] 0,5018[2]	1,18 [0,73; 1,88] 0,5013[3]	1,8 [-3,5; 7,2] 0,5013[3]
Tumor stage (Interaction p-value: 0,4473)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	13/113 (11,5)	12/114 (10,5)	1,09 [0,52; 2,29] 0,8140[2]	1,11 [0,48; 2,54] 0,8139[3]	1,0 [-7,2; 9,1] 0,8139[3]
IIB	15/151 (9,9)	6/136 (4,4)	2,25 [0,90; 5,64] 0,0831[2]	2,39 [0,90; 6,35] 0,0729[3]	5,5 [-0,4; 11,4] 0,0729[3]
IIIA	58/495 (11,7)	34/488 (7,0)	1,68 [1,12; 2,52] 0,0118[2]	1,77 [1,14; 2,76] 0,0106[3]	4,7 [1,1; 8,4] 0,0106[3]
IIIB	5/54 (9,3)	1/45 (2,2)	4,17 [0,51; 34,38] 0,1850[2]	4,49 [0,50; 39,93] 0,2162[4]	7,0 [-1,8; 15,9] 0,2162[4]
IIIC	63/468 (13,5)	52/479 (10,9)	1,24 [0,88; 1,75] 0,2209[2]	1,28 [0,86; 1,89] 0,2197[3]	2,6 [-1,6; 6,8] 0,2197[3]
Tumor grade (Interaction p-value: 0,2535)					
G1	14/91 (15,4)	8/93 (8,6)	1,79 [0,79; 4,06] 0,1642[2]	1,93 [0,77; 4,86] 0,1563[3]	6,8 [-2,6; 16,1] 0,1563[3]
G2	85/612 (13,9)	51/602 (8,5)	1,64 [1,18; 2,28] 0,0032[2]	1,74 [1,21; 2,52] 0,0028[3]	5,4 [1,9; 8,9] 0,0028[3]
G3	50/527 (9,5)	44/506 (8,7)	1,09 [0,74; 1,61] 0,6583[2]	1,10 [0,72; 1,68] 0,6582[3]	0,8 [-2,7; 4,3] 0,6582[3]
GX	6/51 (11,8)	2/59 (3,4)	3,47 [0,73; 16,45] 0,1170[2]	3,80 [0,73; 19,73] 0,1413[4]	8,4 [-1,6; 18,4] 0,1413[4]
Race (Interaction p-value: 0,2679)					
White	110/958 (11,5)	82/943 (8,7)	1,32 [1,01; 1,73] 0,0447[2]	1,36 [1,01; 1,84] 0,0438[3]	2,8 [0,1; 5,5] 0,0438[3]
Asian	35/250 (14,0)	16/242 (6,6)	2,12 [1,20; 3,72] 0,0092[2]	2,30 [1,24; 4,28] 0,0072[3]	7,4 [2,1; 12,7] 0,0072[3]
Other	10/62 (16,1)	5/64 (7,8)	2,06 [0,75; 5,70] 0,1616[2]	2,27 [0,73; 7,07] 0,1495[3]	8,3 [-3,0; 19,6] 0,1495[3]
ECOG-PS (Interaction p-value: 0,6391)					
ECOG-PS 0	134/1070 (12,5)	86/1019 (8,4)	1,48 [1,15; 1,92] 0,0026[2]	1,55 [1,17; 2,07] 0,0024[3]	4,1 [1,5; 6,7] 0,0024[3]
ECOG-PS 1	21/213 (9,9)	19/245 (7,8)	1,27 [0,70; 2,30] 0,4274[2]	1,30 [0,68; 2,49] 0,4263[3]	2,1 [-3,1; 7,3] 0,4263[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 347.1.2: Subgroups - adverse events according PT Lymphopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,3583)					
< 65 years	43/918 (4,7)	8/936 (0,9)	5,48 [2,59; 11,59] <,0001[2]	5,70 [2,67; 12,19] <,0001[3]	3,8 [2,3; 5,3] <,0001[3]
≥ 65 years	26/365 (7,1)	2/328 (0,6)	11,68 [2,79; 48,84] 0,0008[2]	12,50 [2,94; 53,09] <,0001[3]	6,5 [3,7; 9,3] <,0001[3]
Prior treatment (Interaction p-value: 0,1115)					
Neoadjuvant chemotherapy	23/430 (5,3)	3/415 (0,7)	7,40 [2,24; 24,46] 0,0010[2]	7,76 [2,31; 26,05] <,0001[3]	4,6 [2,3; 6,9] <,0001[3]
Adjuvant chemotherapy	45/784 (5,7)	5/768 (0,7)	8,82 [3,52; 22,09] <,0001[2]	9,29 [3,67; 23,54] <,0001[3]	5,1 [3,4; 6,8] <,0001[3]
No chemotherapy	1/69 (1,4)	2/81 (2,5)	0,59 [0,05; 6,33] 0,6607[2]	0,58 [0,05; 6,55] 1,0000[4]	-1,0 [-5,4; 3,4] 1,0000[4]
Region (Interaction p-value: 0,9477)					
North America / Europe	24/678 (3,5)	3/649 (0,5)	7,66 [2,32; 25,31] 0,0008[2]	7,90 [2,37; 26,37] <,0001[3]	3,1 [1,6; 4,6] <,0001[3]
Asia	4/203 (2,0)	0/201 (0,0)	8,91 [0,48; 164,45] 0,1414[2]	9,09 [0,49; 169,95] 0,1232[4]	2,0 [0,1; 3,9] 0,1232[4]
Other	41/402 (10,2)	7/414 (1,7)	6,03 [2,74; 13,29] <,0001[2]	6,60 [2,93; 14,90] <,0001[3]	8,5 [5,3; 11,7] <,0001[3]
Primary tumor size (Interaction p-value: 0,8694)					
< 20 mm	17/331 (5,1)	2/334 (0,6)	8,58 [2,00; 36,83] 0,0038[2]	8,99 [2,06; 39,22] 0,0004[3]	4,5 [2,0; 7,1] 0,0004[3]
≥ 20 but < 50 mm	34/646 (5,3)	5/653 (0,8)	6,87 [2,71; 17,46] <,0001[2]	7,20 [2,80; 18,53] <,0001[3]	4,5 [2,7; 6,3] <,0001[3]
≥ 50 mm	17/289 (5,9)	3/265 (1,1)	5,20 [1,54; 17,53] 0,0079[2]	5,46 [1,58; 18,84] 0,0028[3]	4,8 [1,8; 7,7] 0,0028[3]
Number of positive lymph nodes (Interaction p-value: 0,8581)					
0-3	12/427 (2,8)	2/418 (0,5)	5,87 [1,32; 26,08] 0,0199[2]	6,01 [1,34; 27,04] 0,0079[3]	2,3 [0,6; 4,0] 0,0079[3]
4-9	34/549 (6,2)	4/542 (0,7)	8,39 [3,00; 23,49] <,0001[2]	8,88 [3,13; 25,20] <,0001[3]	5,5 [3,3; 7,6] <,0001[3]
≥ 10	23/307 (7,5)	4/304 (1,3)	5,69 [1,99; 16,27] 0,0012[2]	6,07 [2,07; 17,78] 0,0002[3]	6,2 [3,0; 9,4] 0,0002[3]
Tumor stage (Interaction p-value: 0,8402)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	3/113 (2,7)	1/114 (0,9)	3,03 [0,32; 28,66] 0,3343[2]	3,08 [0,32; 30,08] 0,3695[4]	1,8 [-1,6; 5,2] 0,3695[4]
IIB	3/151 (2,0)	1/136 (0,7)	2,70 [0,28; 25,67] 0,3868[2]	2,74 [0,28; 26,62] 0,6244[4]	1,3 [-1,4; 3,9] 0,6244[4]
IIIA	29/495 (5,9)	3/488 (0,6)	9,53 [2,92; 31,08] 0,0002[2]	10,06 [3,04; 33,25] <,0001[3]	5,2 [3,1; 7,4] <,0001[3]
IIIB	4/54 (7,4)	0/45 (0,0)	7,53 [0,42; 136,17] 0,1718[2]	8,11 [0,42; 154,79] 0,1236[4]	7,4 [0,4; 14,4] 0,1236[4]
IIIC	30/468 (6,4)	5/479 (1,0)	6,14 [2,40; 15,69] 0,0001[2]	6,49 [2,50; 16,88] <,0001[3]	5,4 [3,0; 7,8] <,0001[3]
Tumor grade (Interaction p-value: 0,9860)					
G1	5/91 (5,5)	0/93 (0,0)	11,24 [0,63; 200,37] 0,0997[2]	11,89 [0,65; 218,22] 0,0280[4]	5,5 [0,8; 10,2] 0,0280[4]
G2	38/612 (6,2)	7/602 (1,2)	5,34 [2,40; 11,86] <,0001[2]	5,63 [2,49; 12,70] <,0001[3]	5,0 [3,0; 7,1] <,0001[3]
G3	22/527 (4,2)	3/506 (0,6)	7,04 [2,12; 23,38] 0,0014[2]	7,30 [2,17; 24,56] 0,0002[3]	3,6 [1,7; 5,4] 0,0002[3]
GX	4/51 (7,8)	0/59 (0,0)	10,38 [0,57; 188,36] 0,1135[2]	11,27 [0,59; 214,65] 0,0433[4]	7,8 [0,5; 15,2] 0,0433[4]
Race (Interaction p-value: 0,5271)					
White	58/958 (6,1)	8/943 (0,8)	7,14 [3,43; 14,86] <,0001[2]	7,53 [3,58; 15,86] <,0001[3]	5,2 [3,6; 6,8] <,0001[3]
Asian	5/250 (2,0)	0/242 (0,0)	10,65 [0,59; 191,56] 0,1086[2]	10,87 [0,60; 197,57] 0,0614[4]	2,0 [0,3; 3,7] 0,0614[4]
Other	5/62 (8,1)	2/64 (3,1)	2,58 [0,52; 12,81] 0,2462[2]	2,72 [0,51; 14,57] 0,2693[4]	4,9 [-3,1; 12,9] 0,2693[4]
ECOG-PS (Interaction p-value: 0,1364)					
ECOG-PS 0	58/1070 (5,4)	6/1019 (0,6)	9,21 [3,99; 21,24] <,0001[2]	9,68 [4,16; 22,53] <,0001[3]	4,8 [3,4; 6,3] <,0001[3]
ECOG-PS 1	11/213 (5,2)	4/245 (1,6)	3,16 [1,02; 9,79] 0,0457[2]	3,28 [1,03; 10,46] 0,0342[3]	3,5 [0,2; 6,9] 0,0342[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 348.1.2: Subgroups - adverse events according PT Malaise from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5659)					
< 65 years	24/918 (2,6)	8/936 (0,9)	3,06 [1,38; 6,77] 0,0058[2]	3,11 [1,39; 6,97] 0,0036[3]	1,8 [0,6; 2,9] 0,0036[3]
≥ 65 years	9/365 (2,5)	4/328 (1,2)	2,02 [0,63; 6,50] 0,2376[2]	2,05 [0,62; 6,71] 0,2273[3]	1,2 [-0,7; 3,2] 0,2273[3]
Prior treatment (Interaction p-value: 0,8826)					
Neoadjuvant chemotherapy	13/430 (3,0)	4/415 (1,0)	3,14 [1,03; 9,54] 0,0440[2]	3,20 [1,04; 9,91] 0,0330[3]	2,1 [0,2; 3,9] 0,0330[3]
Adjuvant chemotherapy	18/784 (2,3)	8/768 (1,0)	2,20 [0,96; 5,04] 0,0610[2]	2,23 [0,96; 5,17] 0,0542[3]	1,3 [-0,0; 2,5] 0,0542[3]
No chemotherapy	2/69 (2,9)	0/81 (0,0)	5,86 [0,29; 119,97] 0,2512[2]	6,04 [0,28; 127,91] 0,2099[4]	2,9 [-1,1; 6,9] 0,2099[4]
Region (Interaction p-value: 0,6895)					
North America / Europe	10/678 (1,5)	4/649 (0,6)	2,39 [0,75; 7,59] 0,1385[2]	2,41 [0,75; 7,74] 0,1260[3]	0,9 [-0,2; 1,9] 0,1260[3]
Asia	18/203 (8,9)	5/201 (2,5)	3,56 [1,35; 9,42] 0,0103[2]	3,81 [1,39; 10,48] 0,0057[3]	6,4 [1,9; 10,8] 0,0057[3]
Other	5/402 (1,2)	3/414 (0,7)	1,72 [0,41; 7,13] 0,4574[2]	1,73 [0,41; 7,27] 0,4998[4]	0,5 [-0,8; 1,9] 0,4998[4]
Primary tumor size (Interaction p-value: 0,4421)					
< 20 mm	5/331 (1,5)	2/334 (0,6)	2,52 [0,49; 12,91] 0,2667[2]	2,55 [0,49; 13,22] 0,2846[4]	0,9 [-0,6; 2,5] 0,2846[4]
≥ 20 but < 50 mm	19/646 (2,9)	5/653 (0,8)	3,84 [1,44; 10,23] 0,0071[2]	3,93 [1,46; 10,58] 0,0036[3]	2,2 [0,7; 3,6] 0,0036[3]
≥ 50 mm	8/289 (2,8)	5/265 (1,9)	1,47 [0,49; 4,43] 0,4965[2]	1,48 [0,48; 4,58] 0,4936[3]	0,9 [-1,6; 3,4] 0,4936[3]
Number of positive lymph nodes (Interaction p-value: 0,7573)					
0-3	5/427 (1,2)	1/418 (0,2)	4,89 [0,57; 41,72] 0,1463[2]	4,94 [0,57; 42,47] 0,2172[4]	0,9 [-0,2; 2,1] 0,2172[4]
4-9	13/549 (2,4)	6/542 (1,1)	2,14 [0,82; 5,59] 0,1206[2]	2,17 [0,82; 5,74] 0,1114[3]	1,3 [-0,3; 2,8] 0,1114[3]
≥ 10	15/307 (4,9)	5/304 (1,6)	2,97 [1,09; 8,07] 0,0328[2]	3,07 [1,10; 8,56] 0,0244[3]	3,2 [0,4; 6,0] 0,0244[3]
Tumor stage (Interaction p-value: 0,9395)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	0/113 (0,0)	0/114 (0,0)	NE	NE	NE
IIB	3/151 (2,0)	0/136 (0,0)	6,31 [0,33; 121,05] 0,2217[2]	6,43 [0,33; 125,70] 0,2494[4]	2,0 [-0,2; 4,2] 0,2494[4]
IIIA	9/495 (1,8)	5/488 (1,0)	1,77 [0,60; 5,26] 0,3006[2]	1,79 [0,60; 5,38] 0,2938[3]	0,8 [-0,7; 2,3] 0,2938[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	19/468 (4,1)	7/479 (1,5)	2,78 [1,18; 6,55] 0,0195[2]	2,85 [1,19; 6,85] 0,0144[3]	2,6 [0,5; 4,7] 0,0144[3]
Tumor grade (Interaction p-value: 0,6829)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	15/612 (2,5)	9/602 (1,5)	1,64 [0,72; 3,72] 0,2366[2]	1,66 [0,72; 3,81] 0,2316[3]	1,0 [-0,6; 2,5] 0,2316[3]
G3	13/527 (2,5)	3/506 (0,6)	4,16 [1,19; 14,51] 0,0253[2]	4,24 [1,20; 14,97] 0,0148[3]	1,9 [0,4; 3,4] 0,0148[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesterone receptor status (Interaction p-value: 0,9617)					
Negative	5/156 (3,2)	0/169 (0,0)	11,91 [0,66; 213,66] 0,0926[2]	12,31 [0,67; 224,42] 0,0246[4]	3,2 [0,4; 6,0] 0,0246[4]
Positive	27/1089 (2,5)	12/1066 (1,1)	2,20 [1,12; 4,32] 0,0218[2]	2,23 [1,13; 4,43] 0,0184[3]	1,4 [0,2; 2,5] 0,0184[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,7580)					
White	15/958 (1,6)	7/943 (0,7)	2,11 [0,86; 5,15] 0,1013[2]	2,13 [0,86; 5,24] 0,0933[3]	0,8 [-0,1; 1,8] 0,0933[3]
Asian	18/250 (7,2)	5/242 (2,1)	3,48 [1,31; 9,24] 0,0121[2]	3,68 [1,34; 10,07] 0,0070[3]	5,1 [1,5; 8,8] 0,0070[3]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,3669)					
Tamoxifen	2/114 (1,8)	2/132 (1,5)	1,16 [0,17; 8,09] 0,8825[2]	1,16 [0,16; 8,37] 1,0000[4]	0,2 [-2,9; 3,4] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	31/1169 (2,7)	10/1132 (0,9)	3,00 [1,48; 6,09] 0,0023[2]	3,06 [1,49; 6,26] 0,0013[3]	1,8 [0,7; 2,8] 0,0013[3]
ECOG-PS (Interaction p-value: 0,8133)					
ECOG-PS 0	30/1070 (2,8)	11/1019 (1,1)	2,60 [1,31; 5,15] 0,0064[2]	2,64 [1,32; 5,30] 0,0045[3]	1,7 [0,5; 2,9] 0,0045[3]
ECOG-PS 1	3/213 (1,4)	1/245 (0,4)	3,45 [0,36; 32,93] 0,2818[2]	3,49 [0,36; 33,76] 0,3420[4]	1,0 [-0,8; 2,8] 0,3420[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 349.1.2: Subgroups - adverse events according PT Mucosal inflammation from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,6616)					
< 65 years	30/918 (3,3)	8/936 (0,9)	3,82 [1,76; 8,30] 0,0007[2]	3,92 [1,79; 8,59] 0,0002[3]	2,4 [1,1; 3,7] 0,0002[3]
≥ 65 years	7/365 (1,9)	1/328 (0,3)	6,29 [0,78; 50,86] 0,0846[2]	6,39 [0,78; 52,25] 0,0718[4]	1,6 [0,1; 3,1] 0,0718[4]
Prior treatment (Interaction p-value: 0,2723)					
Neoadjuvant chemotherapy	8/430 (1,9)	4/415 (1,0)	1,93 [0,59; 6,36] 0,2798[2]	1,95 [0,58; 6,52] 0,2708[3]	0,9 [-0,7; 2,5] 0,2708[3]
Adjuvant chemotherapy	29/784 (3,7)	4/768 (0,5)	7,10 [2,51; 20,11] 0,0002[2]	7,34 [2,57; 20,97] <,0001[3]	3,2 [1,8; 4,6] <,0001[3]
No chemotherapy	0/69 (0,0)	1/81 (1,2)	0,39 [0,02; 9,43] 0,5628[2]	0,39 [0,02; 9,63] 1,0000[4]	-1,2 [-3,6; 1,2] 1,0000[4]
Region (Interaction p-value: 0,9719)					
North America / Europe	25/678 (3,7)	8/649 (1,2)	2,99 [1,36; 6,58] 0,0065[2]	3,07 [1,37; 6,85] 0,0041[3]	2,5 [0,8; 4,1] 0,0041[3]
Asia	4/203 (2,0)	1/201 (0,5)	3,96 [0,45; 35,13] 0,2165[2]	4,02 [0,45; 36,28] 0,3719[4]	1,5 [-0,7; 3,6] 0,3719[4]
Other	8/402 (2,0)	0/414 (0,0)	17,51 [1,01; 302,30] 0,0489[2]	17,86 [1,03; 310,49] 0,0033[4]	2,0 [0,6; 3,4] 0,0033[4]
Primary tumor size (Interaction p-value: 0,3830)					
< 20 mm	9/331 (2,7)	1/334 (0,3)	9,08 [1,16; 71,28] 0,0358[2]	9,31 [1,17; 73,88] 0,0109[4]	2,4 [0,6; 4,3] 0,0109[4]
≥ 20 but < 50 mm	19/646 (2,9)	4/653 (0,6)	4,80 [1,64; 14,04] 0,0041[2]	4,92 [1,66; 14,53] 0,0015[3]	2,3 [0,9; 3,8] 0,0015[3]
≥ 50 mm	9/289 (3,1)	4/265 (1,5)	2,06 [0,64; 6,62] 0,2234[2]	2,10 [0,64; 6,89] 0,2126[3]	1,6 [-0,9; 4,1] 0,2126[3]
Number of positive lymph nodes (Interaction p-value: 0,8521)					
0-3	15/427 (3,5)	3/418 (0,7)	4,89 [1,43; 16,78] 0,0115[2]	5,04 [1,45; 17,53] 0,0049[3]	2,8 [0,9; 4,7] 0,0049[3]
4-9	9/549 (1,6)	3/542 (0,6)	2,96 [0,81; 10,88] 0,1020[2]	2,99 [0,81; 11,12] 0,0856[3]	1,1 [-0,1; 2,3] 0,0856[3]
≥ 10	13/307 (4,2)	3/304 (1,0)	4,29 [1,24; 14,91] 0,0219[2]	4,44 [1,25; 15,73] 0,0120[3]	3,2 [0,7; 5,8] 0,0120[3]
Tumor stage (Interaction p-value: 0,9887)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	4/113 (3,5)	1/114 (0,9)	4,04 [0,46; 35,55] 0,2089[2]	4,15 [0,46; 37,69] 0,2125[4]	2,7 [-1,2; 6,5] 0,2125[4]
IIB	3/151 (2,0)	0/136 (0,0)	6,31 [0,33; 121,05] 0,2217[2]	6,43 [0,33; 125,70] 0,2494[4]	2,0 [-0,2; 4,2] 0,2494[4]
IIIA	12/495 (2,4)	4/488 (0,8)	2,96 [0,96; 9,11] 0,0588[2]	3,01 [0,96; 9,39] 0,0468[3]	1,6 [0,0; 3,2] 0,0468[3]
IIIB	0/54 (0,0)	0/45 (0,0)	NE	NE	NE
IIIC	18/468 (3,8)	4/479 (0,8)	4,61 [1,57; 13,51] 0,0054[2]	4,75 [1,60; 14,14] 0,0021[3]	3,0 [1,1; 4,9] 0,0021[3]
Tumor grade (Interaction p-value: 0,8854)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	20/612 (3,3)	4/602 (0,7)	4,92 [1,69; 14,30] 0,0035[2]	5,05 [1,72; 14,87] 0,0011[3]	2,6 [1,1; 4,2] 0,0011[3]
G3	14/527 (2,7)	5/506 (1,0)	2,69 [0,98; 7,41] 0,0559[2]	2,73 [0,98; 7,65] 0,0460[3]	1,7 [0,0; 3,3] 0,0460[3]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,1007)					
Negative	6/156 (3,8)	1/169 (0,6)	6,50 [0,79; 53,39] 0,0815[2]	6,72 [0,80; 56,46] 0,0582[4]	3,3 [0,0; 6,5] 0,0582[4]
Positive	31/1089 (2,8)	8/1066 (0,8)	3,79 [1,75; 8,21] 0,0007[2]	3,88 [1,77; 8,47] 0,0003[3]	2,1 [1,0; 3,2] 0,0003[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9885)					
White	33/958 (3,4)	7/943 (0,7)	4,64 [2,06; 10,44] 0,0002[2]	4,77 [2,10; 10,84] <,0001[3]	2,7 [1,4; 4,0] <,0001[3]
Asian	4/250 (1,6)	1/242 (0,4)	3,87 [0,44; 34,40] 0,2244[2]	3,92 [0,43; 35,31] 0,3728[4]	1,2 [-0,6; 2,9] 0,3728[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,8936)					
ECOG-PS 0	33/1070 (3,1)	8/1019 (0,8)	3,93 [1,82; 8,46] 0,0005[2]	4,02 [1,85; 8,75] 0,0002[3]	2,3 [1,1; 3,5] 0,0002[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	4/213 (1,9)	1/245 (0,4)	4,60 [0,52; 40,85] 0,1707[2]	4,67 [0,52; 42,11] 0,1885[4]	1,5 [-0,5; 3,5] 0,1885[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 350.1.2: Subgroups - adverse events according PT Muscle spasms from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1693)					
< 65 years	54/918 (5,9)	32/936 (3,4)	1,72 [1,12; 2,64] 0,0129[2]	1,77 [1,13; 2,76] 0,0117[3]	2,5 [0,5; 4,4] 0,0117[3]
≥ 65 years	19/365 (5,2)	17/328 (5,2)	1,00 [0,53; 1,90] 0,9893[2]	1,00 [0,51; 1,97] 0,9893[3]	0,0 [-3,3; 3,3] 0,9893[3]
Prior treatment (Interaction p-value: 0,9607)					
Neoadjuvant chemotherapy	23/430 (5,3)	15/415 (3,6)	1,48 [0,78; 2,80] 0,2274[2]	1,51 [0,78; 2,93] 0,2239[3]	1,7 [-1,0; 4,5] 0,2239[3]
Adjuvant chemotherapy	46/784 (5,9)	34/768 (4,4)	1,33 [0,86; 2,04] 0,2013[2]	1,35 [0,85; 2,12] 0,1995[3]	1,4 [-0,8; 3,6] 0,1995[3]
No chemotherapy	4/69 (5,8)	0/81 (0,0)	10,54 [0,58; 192,43] 0,1119[2]	11,20 [0,59; 211,78] 0,0427[4]	5,8 [0,3; 11,3] 0,0427[4]
Region (Interaction p-value: 0,7747)					
North America / Europe	52/678 (7,7)	37/649 (5,7)	1,35 [0,89; 2,02] 0,1538[2]	1,37 [0,89; 2,12] 0,1518[3]	2,0 [-0,7; 4,7] 0,1518[3]
Asia	8/203 (3,9)	5/201 (2,5)	1,58 [0,53; 4,76] 0,4124[2]	1,61 [0,52; 5,00] 0,4079[3]	1,5 [-2,0; 4,9] 0,4079[3]
Other	13/402 (3,2)	7/414 (1,7)	1,91 [0,77; 4,74] 0,1618[2]	1,94 [0,77; 4,92] 0,1541[3]	1,5 [-0,6; 3,7] 0,1541[3]
Primary tumor size (Interaction p-value: 0,0980)					
< 20 mm	17/331 (5,1)	13/334 (3,9)	1,32 [0,65; 2,67] 0,4414[2]	1,34 [0,64; 2,80] 0,4397[3]	1,2 [-1,9; 4,4] 0,4397[3]
≥ 20 but < 50 mm	33/646 (5,1)	30/653 (4,6)	1,11 [0,69; 1,80] 0,6664[2]	1,12 [0,67; 1,86] 0,6662[3]	0,5 [-1,8; 2,9] 0,6662[3]
≥ 50 mm	22/289 (7,6)	6/265 (2,3)	3,36 [1,38; 8,16] 0,0074[2]	3,56 [1,42; 8,91] 0,0041[3]	5,3 [1,8; 8,9] 0,0041[3]
Number of positive lymph nodes (Interaction p-value: 0,8500)					
0-3	29/427 (6,8)	17/418 (4,1)	1,67 [0,93; 2,99] 0,0849[2]	1,72 [0,93; 3,18] 0,0809[3]	2,7 [-0,3; 5,8] 0,0809[3]
4-9	31/549 (5,6)	23/542 (4,2)	1,33 [0,79; 2,25] 0,2873[2]	1,35 [0,78; 2,35] 0,2854[3]	1,4 [-1,2; 4,0] 0,2854[3]
≥ 10	13/307 (4,2)	9/304 (3,0)	1,43 [0,62; 3,30] 0,4008[2]	1,45 [0,61; 3,44] 0,3980[3]	1,3 [-1,7; 4,2] 0,3980[3]
Tumor stage (Interaction p-value: 0,1186)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	6/113 (5,3)	10/114 (8,8)	0,61 [0,23; 1,61] 0,3144[2]	0,58 [0,20; 1,66] 0,3082[3]	-3,5 [-10,1; 3,2] 0,3082[3]
IIB	13/151 (8,6)	4/136 (2,9)	2,93 [0,98; 8,76] 0,0549[2]	3,11 [0,99; 9,78] 0,0422[3]	5,7 [0,4; 11,0] 0,0422[3]
IIIA	29/495 (5,9)	18/488 (3,7)	1,59 [0,89; 2,82] 0,1146[2]	1,62 [0,89; 2,97] 0,1109[3]	2,2 [-0,5; 4,8] 0,1109[3]
IIIB	2/54 (3,7)	4/45 (8,9)	0,42 [0,08; 2,17] 0,2986[2]	0,39 [0,07; 2,26] 0,4065[4]	-5,2 [-14,9; 4,5] 0,4065[4]
IIIC	23/468 (4,9)	13/479 (2,7)	1,81 [0,93; 3,53] 0,0815[2]	1,85 [0,93; 3,70] 0,0767[3]	2,2 [-0,2; 4,6] 0,0767[3]
Tumor grade (Interaction p-value: 0,6990)					
G1	8/91 (8,8)	4/93 (4,3)	2,04 [0,64; 6,55] 0,2291[2]	2,14 [0,62; 7,39] 0,2175[3]	4,5 [-2,6; 11,6] 0,2175[3]
G2	31/612 (5,1)	25/602 (4,2)	1,22 [0,73; 2,04] 0,4494[2]	1,23 [0,72; 2,11] 0,4485[3]	0,9 [-1,4; 3,3] 0,4485[3]
G3	31/527 (5,9)	19/506 (3,8)	1,57 [0,90; 2,74] 0,1148[2]	1,60 [0,89; 2,87] 0,1112[3]	2,1 [-0,5; 4,7] 0,1112[3]
GX	3/51 (5,9)	1/59 (1,7)	3,47 [0,37; 32,34] 0,2745[2]	3,63 [0,37; 35,99] 0,3349[4]	4,2 [-3,1; 11,4] 0,3349[4]
Race (Interaction p-value: 0,6415)					
White	62/958 (6,5)	40/943 (4,2)	1,53 [1,04; 2,25] 0,0325[2]	1,56 [1,04; 2,35] 0,0310[3]	2,2 [0,2; 4,3] 0,0310[3]
Asian	9/250 (3,6)	7/242 (2,9)	1,24 [0,47; 3,29] 0,6590[2]	1,25 [0,46; 3,42] 0,6583[3]	0,7 [-2,4; 3,8] 0,6583[3]
Other	1/62 (1,6)	2/64 (3,1)	0,52 [0,05; 5,55] 0,5852[2]	0,51 [0,04; 5,75] 1,0000[4]	-1,5 [-6,8; 3,8] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,1720)					
Tamoxifen	7/114 (6,1)	10/132 (7,6)	0,81 [0,32; 2,06] 0,6589[2]	0,80 [0,29; 2,17] 0,6580[3]	-1,4 [-7,7; 4,9] 0,6580[3]
Aromatase inhibitor	66/1169 (5,6)	39/1132 (3,4)	1,64 [1,11; 2,41] 0,0124[2]	1,68 [1,12; 2,51] 0,0114[3]	2,2 [0,5; 3,9] 0,0114[3]
ECOG-PS (Interaction p-value: 0,1440)					
ECOG-PS 0	57/1070 (5,3)	42/1019 (4,1)	1,29 [0,88; 1,91] 0,1964[2]	1,31 [0,87; 1,97] 0,1949[3]	1,2 [-0,6; 3,0] 0,1949[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	16/213 (7,5)	7/245 (2,9)	2,63 [1,10; 6,27] 0,0292[2]	2,76 [1,11; 6,85] 0,0229[3]	4,7 [0,5; 8,8] 0,0229[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 351.1.2: Subgroups - adverse events according PT Nail disorder from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9811)					
Neoadjuvant chemotherapy	4/430 (0,9)	0/415 (0,0)	8,69 [0,47; 160,84] 0,1466[2]	8,77 [0,47; 163,36] 0,1243[4]	0,9 [0,0; 1,8] 0,1243[4]
Adjuvant chemotherapy	19/784 (2,4)	2/768 (0,3)	9,31 [2,18; 39,82] 0,0026[2]	9,51 [2,21; 40,98] 0,0002[3]	2,2 [1,0; 3,3] 0,0002[3]
No chemotherapy	0/69 (0,0)	0/81 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,2870)					
North America / Europe	17/678 (2,5)	1/649 (0,2)	16,27 [2,17; 121,93] 0,0066[2]	16,67 [2,21; 125,59] 0,0002[3]	2,4 [1,1; 3,6] 0,0002[3]
Asia	5/203 (2,5)	0/201 (0,0)	10,89 [0,61; 195,70] 0,1052[2]	11,17 [0,61; 203,28] 0,0610[4]	2,5 [0,3; 4,6] 0,0610[4]
Other	1/402 (0,2)	1/414 (0,2)	1,03 [0,06; 16,41] 0,9834[2]	1,03 [0,06; 16,52] 1,0000[4]	0,0 [-0,7; 0,7] 1,0000[4]
Primary tumor size (Interaction p-value: 0,9210)					
< 20 mm	6/331 (1,8)	0/334 (0,0)	13,12 [0,74; 231,92] 0,0790[2]	13,36 [0,75; 238,10] 0,0149[4]	1,8 [0,4; 3,2] 0,0149[4]
≥ 20 but < 50 mm	10/646 (1,5)	1/653 (0,2)	10,11 [1,30; 78,74] 0,0272[2]	10,25 [1,31; 80,32] 0,0061[3]	1,4 [0,4; 2,4] 0,0061[3]
≥ 50 mm	6/289 (2,1)	1/265 (0,4)	5,50 [0,67; 45,40] 0,1133[2]	5,60 [0,67; 46,80] 0,1251[4]	1,7 [-0,1; 3,5] 0,1251[4]
Number of positive lymph nodes (Interaction p-value: 0,9645)					
0-3	3/427 (0,7)	2/418 (0,5)	1,47 [0,25; 8,74] 0,6730[2]	1,47 [0,24; 8,85] 1,0000[4]	0,2 [-0,8; 1,3] 1,0000[4]
4-9	11/549 (2,0)	0/542 (0,0)	22,71 [1,34; 384,38] 0,0305[2]	23,17 [1,36; 394,19] 0,0009[3]	2,0 [0,8; 3,2] 0,0009[3]
≥ 10	9/307 (2,9)	0/304 (0,0)	18,81 [1,10; 321,84] 0,0428[2]	19,38 [1,12; 334,50] 0,0037[4]	2,9 [1,0; 4,8] 0,0037[4]
Tumor stage (Interaction p-value: 0,6122)					
IIA	0/113 (0,0)	0/114 (0,0)	NE	NE	NE
IIB	2/151 (1,3)	1/136 (0,7)	1,80 [0,17; 19,64] 0,6293[2]	1,81 [0,16; 20,21] 1,0000[4]	0,6 [-1,7; 2,9] 1,0000[4]
IIIA	9/495 (1,8)	1/488 (0,2)	8,87 [1,13; 69,77] 0,0380[2]	9,02 [1,14; 71,46] 0,0209[4]	1,6 [0,4; 2,9] 0,0209[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	1/54 (1,9)	0/45 (0,0)	2,51 [0,10; 60,13] 0,5703[2]	2,55 [0,10; 64,17] 1,0000[4]	1,9 [-1,7; 5,4] 1,0000[4]
IIIC	11/468 (2,4)	0/479 (0,0)	23,54 [1,39; 398,31] 0,0286[2]	24,11 [1,42; 410,26] 0,0007[3]	2,4 [1,0; 3,7] 0,0007[3]
Tumor grade (Interaction p-value: 0,9999)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	17/612 (2,8)	0/602 (0,0)	34,43 [2,08; 571,22] 0,0135[2]	35,41 [2,12; 590,19] <,0001[3]	2,8 [1,5; 4,1] <,0001[3]
G3	3/527 (0,6)	2/506 (0,4)	1,44 [0,24; 8,58] 0,6888[2]	1,44 [0,24; 8,67] 1,0000[4]	0,2 [-0,7; 1,0] 1,0000[4]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,9634)					
Negative	2/156 (1,3)	0/169 (0,0)	5,41 [0,26; 111,90] 0,2744[2]	5,49 [0,26; 115,15] 0,2296[4]	1,3 [-0,5; 3,0] 0,2296[4]
Positive	19/1089 (1,7)	2/1066 (0,2)	9,30 [2,17; 39,83] 0,0027[2]	9,45 [2,19; 40,66] 0,0002[3]	1,6 [0,7; 2,4] 0,0002[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9993)					
White	17/958 (1,8)	1/943 (0,1)	16,73 [2,23; 125,49] 0,0061[2]	17,02 [2,26; 128,13] 0,0002[3]	1,7 [0,8; 2,5] 0,0002[3]
Asian	6/250 (2,4)	0/242 (0,0)	12,59 [0,71; 222,20] 0,0838[2]	12,89 [0,72; 230,13] 0,0304[4]	2,4 [0,5; 4,3] 0,0304[4]
Other	0/62 (0,0)	1/64 (1,6)	0,34 [0,01; 8,28] 0,5109[2]	0,34 [0,01; 8,47] 1,0000[4]	-1,6 [-4,6; 1,5] 1,0000[4]
ECOG-PS (Interaction p-value: 0,0958)					
ECOG-PS 0	22/1070 (2,1)	1/1019 (0,1)	20,95 [2,83; 155,15] 0,0029[2]	21,37 [2,88; 158,84] <,0001[3]	2,0 [1,1; 2,8] <,0001[3]
ECOG-PS 1	1/213 (0,5)	1/245 (0,4)	1,15 [0,07; 18,28] 0,9210[2]	1,15 [0,07; 18,51] 1,0000[4]	0,1 [-1,2; 1,3] 1,0000[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 352.1.2: Subgroups - adverse events according PT Nausea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8548)					
< 65 years	263/918 (28,6)	68/936 (7,3)	3,94 [3,07; 5,07] <,0001[2]	5,13 [3,85; 6,82] <,0001[3]	21,4 [18,0; 24,7] <,0001[3]
≥ 65 years	122/365 (33,4)	29/328 (8,8)	3,78 [2,59; 5,51] <,0001[2]	5,18 [3,34; 8,03] <,0001[3]	24,6 [18,9; 30,3] <,0001[3]
Prior treatment (Interaction p-value: 0,4973)					
Neoadjuvant chemotherapy	126/430 (29,3)	32/415 (7,7)	3,80 [2,64; 5,47] <,0001[2]	4,96 [3,27; 7,52] <,0001[3]	21,6 [16,6; 26,6] <,0001[3]
Adjuvant chemotherapy	235/784 (30,0)	61/768 (7,9)	3,77 [2,90; 4,91] <,0001[2]	4,96 [3,66; 6,72] <,0001[3]	22,0 [18,3; 25,8] <,0001[3]
No chemotherapy	24/69 (34,8)	4/81 (4,9)	7,04 [2,57; 19,31] 0,0001[2]	10,27 [3,35; 31,48] <,0001[3]	29,8 [17,7; 42,0] <,0001[3]
Region (Interaction p-value: 0,2960)					
North America / Europe	270/678 (39,8)	74/649 (11,4)	3,49 [2,77; 4,41] <,0001[2]	5,14 [3,86; 6,85] <,0001[3]	28,4 [24,0; 32,8] <,0001[3]
Asia	37/203 (18,2)	6/201 (3,0)	6,11 [2,64; 14,15] <,0001[2]	7,24 [2,98; 17,59] <,0001[3]	15,2 [9,4; 21,1] <,0001[3]
Other	78/402 (19,4)	17/414 (4,1)	4,73 [2,85; 7,84] <,0001[2]	5,62 [3,26; 9,69] <,0001[3]	15,3 [11,0; 19,6] <,0001[3]
Primary tumor size (Interaction p-value: 0,9728)					
< 20 mm	100/331 (30,2)	25/334 (7,5)	4,04 [2,68; 6,09] <,0001[2]	5,35 [3,34; 8,56] <,0001[3]	22,7 [17,0; 28,4] <,0001[3]
≥ 20 but < 50 mm	192/646 (29,7)	51/653 (7,8)	3,81 [2,85; 5,08] <,0001[2]	4,99 [3,58; 6,96] <,0001[3]	21,9 [17,8; 26,0] <,0001[3]
≥ 50 mm	90/289 (31,1)	21/265 (7,9)	3,93 [2,52; 6,13] <,0001[2]	5,25 [3,15; 8,76] <,0001[3]	23,2 [17,0; 29,5] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,0811)					
0-3	148/427 (34,7)	29/418 (6,9)	5,00 [3,44; 7,27] <,0001[2]	7,12 [4,64; 10,90] <,0001[3]	27,7 [22,6; 32,9] <,0001[3]
4-9	149/549 (27,1)	49/542 (9,0)	3,00 [2,22; 4,05] <,0001[2]	3,75 [2,64; 5,31] <,0001[3]	18,1 [13,7; 22,5] <,0001[3]
≥ 10	88/307 (28,7)	19/304 (6,3)	4,59 [2,87; 7,34] <,0001[2]	6,03 [3,56; 10,20] <,0001[3]	22,4 [16,7; 28,2] <,0001[3]
Tumor stage (Interaction p-value: 0,3074)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	39/113 (34,5)	8/114 (7,0)	4,92 [2,41; 10,05] <,0001[2]	6,98 [3,09; 15,80] <,0001[3]	27,5 [17,6; 37,4] <,0001[3]
IIB	50/151 (33,1)	6/136 (4,4)	7,51 [3,32; 16,95] <,0001[2]	10,73 [4,42; 26,01] <,0001[3]	28,7 [20,4; 37,0] <,0001[3]
IIIA	147/495 (29,7)	43/488 (8,8)	3,37 [2,46; 4,62] <,0001[2]	4,37 [3,03; 6,31] <,0001[3]	20,9 [16,1; 25,6] <,0001[3]
IIIB	14/54 (25,9)	5/45 (11,1)	2,33 [0,91; 5,98] 0,0777[2]	2,80 [0,92; 8,51] 0,0624[3]	14,8 [-0,0; 29,7] 0,0624[3]
IIIC	135/468 (28,8)	35/479 (7,3)	3,95 [2,78; 5,60] <,0001[2]	5,14 [3,45; 7,66] <,0001[3]	21,5 [16,8; 26,3] <,0001[3]
Tumor grade (Interaction p-value: 0,1385)					
G1	27/91 (29,7)	5/93 (5,4)	5,52 [2,22; 13,70] 0,0002[2]	7,43 [2,71; 20,33] <,0001[3]	24,3 [13,8; 34,7] <,0001[3]
G2	181/612 (29,6)	60/602 (10,0)	2,97 [2,27; 3,88] <,0001[2]	3,79 [2,76; 5,21] <,0001[3]	19,6 [15,3; 23,9] <,0001[3]
G3	162/527 (30,7)	32/506 (6,3)	4,86 [3,39; 6,96] <,0001[2]	6,57 [4,39; 9,84] <,0001[3]	24,4 [19,9; 28,9] <,0001[3]
GX	15/51 (29,4)	0/59 (0,0)	35,77 [2,19; 583,27] 0,0120[2]	50,53 [2,93; 870,27] <,0001[3]	29,4 [16,9; 41,9] <,0001[3]
Progesterone receptor status (Interaction p-value: 0,9325)					
Negative	53/156 (34,0)	14/169 (8,3)	4,10 [2,37; 7,09] <,0001[2]	5,70 [3,01; 10,80] <,0001[3]	25,7 [17,2; 34,2] <,0001[3]
Positive	315/1089 (28,9)	79/1066 (7,4)	3,90 [3,10; 4,92] <,0001[2]	5,08 [3,91; 6,62] <,0001[3]	21,5 [18,4; 24,6] <,0001[3]
Unknown	4/10 (40,0)	1/7 (14,3)	2,80 [0,39; 20,02] 0,3049[2]	4,00 [0,34; 47,11] 0,3382[4]	25,7 [-14,2; 65,6] 0,3382[4]
Race (Interaction p-value: 0,4255)					
White	317/958 (33,1)	83/943 (8,8)	3,76 [3,00; 4,70] <,0001[2]	5,12 [3,94; 6,66] <,0001[3]	24,3 [20,8; 27,8] <,0001[3]
Asian	41/250 (16,4)	6/242 (2,5)	6,61 [2,86; 15,30] <,0001[2]	7,72 [3,21; 18,54] <,0001[3]	13,9 [8,9; 18,9] <,0001[3]
Other	20/62 (32,3)	6/64 (9,4)	3,44 [1,48; 7,99] 0,0041[2]	4,60 [1,70; 12,45] 0,0015[3]	22,9 [9,2; 36,5] 0,0015[3]
First endocrine therapy (Interaction p-value: 0,5281)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	30/114 (26,3)	7/132 (5,3)	4,96 [2,27; 10,86] <,0001[2]	6,38 [2,68; 15,19] <,0001[3]	21,0 [12,1; 30,0] <,0001[3]
Aromatase inhibitor	355/1169 (30,4)	90/1132 (8,0)	3,82 [3,08; 4,74] <,0001[2]	5,05 [3,94; 6,48] <,0001[3]	22,4 [19,3; 25,5] <,0001[3]
ECOG-PS (Interaction p-value: 0,2836)					
ECOG-PS 0	322/1070 (30,1)	74/1019 (7,3)	4,14 [3,27; 5,26] <,0001[2]	5,50 [4,20; 7,20] <,0001[3]	22,8 [19,7; 26,0] <,0001[3]
ECOG-PS 1	63/213 (29,6)	23/245 (9,4)	3,15 [2,03; 4,90] <,0001[2]	4,05 [2,41; 6,82] <,0001[3]	20,2 [13,1; 27,3] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 353.1.2: Subgroups - adverse events according PT Neutropenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,4765)					
< 65 years	222/918 (24,2)	24/936 (2,6)	9,43 [6,25; 14,23] <,0001[2]	12,12 [7,86; 18,68] <,0001[3]	21,6 [18,7; 24,6] <,0001[3]
≥ 65 years	75/365 (20,5)	5/328 (1,5)	13,48 [5,52; 32,92] <,0001[2]	16,71 [6,66; 41,88] <,0001[3]	19,0 [14,7; 23,4] <,0001[3]
Prior treatment (Interaction p-value: 0,9895)					
Neoadjuvant chemotherapy	116/430 (27,0)	12/415 (2,9)	9,33 [5,23; 16,64] <,0001[2]	12,41 [6,73; 22,89] <,0001[3]	24,1 [19,6; 28,6] <,0001[3]
Adjuvant chemotherapy	171/784 (21,8)	17/768 (2,2)	9,85 [6,05; 16,06] <,0001[2]	12,32 [7,40; 20,52] <,0001[3]	19,6 [16,5; 22,7] <,0001[3]
No chemotherapy	10/69 (14,5)	0/81 (0,0)	24,60 [1,47; 412,32] 0,0260[2]	28,76 [1,65; 500,60] 0,0003[4]	14,5 [6,2; 22,8] 0,0003[4]
Primary tumor size (Interaction p-value: 0,9297)					
< 20 mm	80/331 (24,2)	8/334 (2,4)	10,09 [4,96; 20,54] <,0001[2]	12,99 [6,16; 27,36] <,0001[3]	21,8 [16,9; 26,7] <,0001[3]
≥ 20 but < 50 mm	135/646 (20,9)	14/653 (2,1)	9,75 [5,68; 16,72] <,0001[2]	12,06 [6,87; 21,16] <,0001[3]	18,8 [15,4; 22,1] <,0001[3]
≥ 50 mm	77/289 (26,6)	6/265 (2,3)	11,77 [5,21; 26,55] <,0001[2]	15,68 [6,70; 36,69] <,0001[3]	24,4 [19,0; 29,8] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,7461)					
0-3	97/427 (22,7)	8/418 (1,9)	11,87 [5,85; 24,10] <,0001[2]	15,06 [7,22; 31,43] <,0001[3]	20,8 [16,6; 25,0] <,0001[3]
4-9	135/549 (24,6)	13/542 (2,4)	10,25 [5,88; 17,89] <,0001[2]	13,27 [7,40; 23,78] <,0001[3]	22,2 [18,4; 26,0] <,0001[3]
≥ 10	65/307 (21,2)	8/304 (2,6)	8,05 [3,93; 16,48] <,0001[2]	9,94 [4,68; 21,12] <,0001[3]	18,5 [13,6; 23,5] <,0001[3]
Tumor stage (Interaction p-value: 0,5933)					
IIA	21/113 (18,6)	3/114 (2,6)	7,06 [2,17; 23,01] 0,0012[2]	8,45 [2,44; 29,21] <,0001[3]	16,0 [8,2; 23,7] <,0001[3]
IIB	38/151 (25,2)	1/136 (0,7)	34,23 [4,76; 245,91] 0,0004[2]	45,40 [6,14; 335,87] <,0001[3]	24,4 [17,4; 31,5] <,0001[3]
IIIA	116/495 (23,4)	10/488 (2,0)	11,44 [6,07; 21,55] <,0001[2]	14,63 [7,56; 28,30] <,0001[3]	21,4 [17,4; 25,3] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	14/54 (25,9)	2/45 (4,4)	5,83 [1,40; 24,32] 0,0155[2]	7,53 [1,61; 35,20] 0,0038[3]	21,5 [8,3; 34,6] 0,0038[3]
IIIC	108/468 (23,1)	13/479 (2,7)	8,50 [4,85; 14,90] <,0001[2]	10,75 [5,95; 19,43] <,0001[3]	20,4 [16,3; 24,4] <,0001[3]
Tumor grade (Interaction p-value: 0,1854)					
G1	18/91 (19,8)	1/93 (1,1)	18,40 [2,51; 134,95] 0,0042[2]	22,68 [2,96; 173,93] <,0001[3]	18,7 [10,3; 27,2] <,0001[3]
G2	141/612 (23,0)	20/602 (3,3)	6,93 [4,40; 10,93] <,0001[2]	8,71 [5,37; 14,13] <,0001[3]	19,7 [16,1; 23,3] <,0001[3]
G3	127/527 (24,1)	7/506 (1,4)	17,42 [8,22; 36,92] <,0001[2]	22,63 [10,46; 48,99] <,0001[3]	22,7 [18,9; 26,5] <,0001[3]
GX	11/51 (21,6)	1/59 (1,7)	12,73 [1,70; 95,21] 0,0132[2]	15,95 [1,98; 128,49] 0,0009[3]	19,9 [8,1; 31,6] 0,0009[3]
Race (Interaction p-value: 0,3674)					
White	243/958 (25,4)	27/943 (2,9)	8,86 [6,01; 13,05] <,0001[2]	11,53 [7,66; 17,36] <,0001[3]	22,5 [19,5; 25,5] <,0001[3]
Asian	34/250 (13,6)	1/242 (0,4)	32,91 [4,54; 238,54] 0,0005[2]	37,94 [5,15; 279,48] <,0001[3]	13,2 [8,9; 17,5] <,0001[3]
Other	17/62 (27,4)	1/64 (1,6)	17,55 [2,41; 127,90] 0,0047[2]	23,80 [3,06; 185,38] <,0001[3]	25,9 [14,3; 37,4] <,0001[3]
First endocrine therapy (Interaction p-value: 0,4874)					
Tamoxifen	28/114 (24,6)	2/132 (1,5)	16,21 [3,95; 66,56] 0,0001[2]	21,16 [4,91; 91,14] <,0001[3]	23,0 [14,9; 31,2] <,0001[3]
Aromatase inhibitor	269/1169 (23,0)	27/1132 (2,4)	9,65 [6,55; 14,21] <,0001[2]	12,23 [8,16; 18,35] <,0001[3]	20,6 [18,1; 23,2] <,0001[3]
ECOG-PS (Interaction p-value: 0,2779)					
ECOG-PS 0	240/1070 (22,4)	20/1019 (2,0)	11,43 [7,30; 17,89] <,0001[2]	14,44 [9,07; 23,00] <,0001[3]	20,5 [17,8; 23,1] <,0001[3]
ECOG-PS 1	57/213 (26,8)	9/245 (3,7)	7,28 [3,70; 14,36] <,0001[2]	9,58 [4,61; 19,91] <,0001[3]	23,1 [16,7; 29,5] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 354.1.2: Subgroups - adverse events according PT Neutrophil count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1703)					
< 65 years	198/918 (21,6)	19/936 (2,0)	10,63 [6,70; 16,86] <,0001[2]	13,27 [8,21; 21,46] <,0001[3]	19,5 [16,7; 22,3] <,0001[3]
≥ 65 years	84/365 (23,0)	3/328 (0,9)	25,16 [8,03; 78,83] <,0001[2]	32,38 [10,13; 103,58] <,0001[3]	22,1 [17,7; 26,5] <,0001[3]
Prior treatment (Interaction p-value: 0,1821)					
Neoadjuvant chemotherapy	96/430 (22,3)	12/415 (2,9)	7,72 [4,30; 13,86] <,0001[2]	9,65 [5,21; 17,90] <,0001[3]	19,4 [15,2; 23,7] <,0001[3]
Adjuvant chemotherapy	177/784 (22,6)	10/768 (1,3)	17,34 [9,24; 32,53] <,0001[2]	22,10 [11,59; 42,17] <,0001[3]	21,3 [18,2; 24,3] <,0001[3]
No chemotherapy	9/69 (13,0)	0/81 (0,0)	22,26 [1,32; 375,60] 0,0314[2]	25,60 [1,46; 448,36] 0,0007[4]	13,0 [5,1; 21,0] 0,0007[4]
Region (Interaction p-value: 0,2979)					
North America / Europe	105/678 (15,5)	6/649 (0,9)	16,75 [7,41; 37,87] <,0001[2]	19,64 [8,56; 45,05] <,0001[3]	14,6 [11,7; 17,4] <,0001[3]
Asia	119/203 (58,6)	13/201 (6,5)	9,06 [5,29; 15,53] <,0001[2]	20,49 [10,94; 38,38] <,0001[3]	52,2 [44,6; 59,7] <,0001[3]
Other	58/402 (14,4)	3/414 (0,7)	19,91 [6,29; 63,03] <,0001[2]	23,10 [7,17; 74,37] <,0001[3]	13,7 [10,2; 17,2] <,0001[3]
Primary tumor size (Interaction p-value: 0,1639)					
< 20 mm	65/331 (19,6)	9/334 (2,7)	7,29 [3,69; 14,39] <,0001[2]	8,82 [4,31; 18,05] <,0001[3]	16,9 [12,3; 21,6] <,0001[3]
≥ 20 but < 50 mm	157/646 (24,3)	9/653 (1,4)	17,63 [9,09; 34,22] <,0001[2]	22,97 [11,62; 45,44] <,0001[3]	22,9 [19,5; 26,4] <,0001[3]
≥ 50 mm	53/289 (18,3)	3/265 (1,1)	16,20 [5,12; 51,22] <,0001[2]	19,61 [6,05; 63,60] <,0001[3]	17,2 [12,6; 21,8] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,8230)					
0-3	85/427 (19,9)	6/418 (1,4)	13,87 [6,13; 31,39] <,0001[2]	17,07 [7,37; 39,54] <,0001[3]	18,5 [14,5; 22,4] <,0001[3]
4-9	122/549 (22,2)	11/542 (2,0)	10,95 [5,98; 20,06] <,0001[2]	13,79 [7,35; 25,90] <,0001[3]	20,2 [16,5; 23,9] <,0001[3]
≥ 10	75/307 (24,4)	5/304 (1,6)	14,85 [6,09; 36,22] <,0001[2]	19,33 [7,69; 48,58] <,0001[3]	22,8 [17,8; 27,8] <,0001[3]
Tumor stage (Interaction p-value: 0,8304)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	25/113 (22,1)	1/114 (0,9)	25,22 [3,48; 183,00] 0,0014[2]	32,10 [4,27; 241,54] <,0001[3]	21,2 [13,4; 29,1] <,0001[3]
IIB	35/151 (23,2)	4/136 (2,9)	7,88 [2,88; 21,60] <,0001[2]	9,96 [3,44; 28,86] <,0001[3]	20,2 [12,9; 27,5] <,0001[3]
IIIA	104/495 (21,0)	7/488 (1,4)	14,65 [6,88; 31,16] <,0001[2]	18,28 [8,40; 39,75] <,0001[3]	19,6 [15,8; 23,3] <,0001[3]
IIIB	14/54 (25,9)	1/45 (2,2)	11,67 [1,60; 85,33] 0,0155[2]	15,40 [1,94; 122,46] 0,0011[3]	23,7 [11,2; 36,2] 0,0011[3]
IIIC	103/468 (22,0)	9/479 (1,9)	11,71 [6,00; 22,87] <,0001[2]	14,74 [7,36; 29,52] <,0001[3]	20,1 [16,2; 24,1] <,0001[3]
Tumor grade (Interaction p-value: 0,1338)					
G1	16/91 (17,6)	1/93 (1,1)	16,35 [2,21; 120,76] 0,0062[2]	19,63 [2,54; 151,42] 0,0001[3]	16,5 [8,4; 24,6] 0,0001[3]
G2	122/612 (19,9)	5/602 (0,8)	24,00 [9,88; 58,28] <,0001[2]	29,73 [12,06; 73,28] <,0001[3]	19,1 [15,9; 22,4] <,0001[3]
G3	126/527 (23,9)	12/506 (2,4)	10,08 [5,65; 18,00] <,0001[2]	12,94 [7,05; 23,73] <,0001[3]	21,5 [17,7; 25,4] <,0001[3]
GX	17/51 (33,3)	4/59 (6,8)	4,92 [1,77; 13,67] 0,0023[2]	6,88 [2,13; 22,15] 0,0004[3]	26,6 [12,1; 41,0] 0,0004[3]
Race (Interaction p-value: 0,4760)					
White	143/958 (14,9)	9/943 (1,0)	15,64 [8,02; 30,49] <,0001[2]	18,21 [9,22; 35,95] <,0001[3]	14,0 [11,6; 16,3] <,0001[3]
Asian	123/250 (49,2)	13/242 (5,4)	9,16 [5,32; 15,77] <,0001[2]	17,06 [9,26; 31,44] <,0001[3]	43,8 [37,0; 50,6] <,0001[3]
Other	14/62 (22,6)	0/64 (0,0)	29,92 [1,82; 490,96] 0,0173[2]	38,57 [2,24; 662,55] <,0001[3]	22,6 [12,2; 33,0] <,0001[3]
First endocrine therapy (Interaction p-value: 0,1073)					
Tamoxifen	19/114 (16,7)	4/132 (3,0)	5,50 [1,93; 15,70] 0,0014[2]	6,40 [2,11; 19,43] 0,0002[3]	13,6 [6,2; 21,1] 0,0002[3]
Aromatase inhibitor	263/1169 (22,5)	18/1132 (1,6)	14,15 [8,84; 22,65] <,0001[2]	17,97 [11,06; 29,19] <,0001[3]	20,9 [18,4; 23,4] <,0001[3]
ECOG-PS (Interaction p-value: 0,8210)					
ECOG-PS 0	245/1070 (22,9)	19/1019 (1,9)	12,28 [7,76; 19,43] <,0001[2]	15,63 [9,71; 25,15] <,0001[3]	21,0 [18,4; 23,7] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	37/213 (17,4)	3/245 (1,2)	14,19 [4,44; 45,35] <,0001[2]	16,96 [5,15; 55,88] <,0001[3]	16,1 [10,9; 21,4] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 355.1.2: Subgroups - adverse events according PT Oedema peripheral from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7980)					
< 65 years	58/918 (6,3)	33/936 (3,5)	1,79 [1,18; 2,72] 0,0062[2]	1,85 [1,19; 2,86] 0,0054[3]	2,8 [0,8; 4,8] 0,0054[3]
≥ 65 years	35/365 (9,6)	16/328 (4,9)	1,97 [1,11; 3,48] 0,0206[2]	2,07 [1,12; 3,81] 0,0177[3]	4,7 [0,9; 8,5] 0,0177[3]
Prior treatment (Interaction p-value: 0,6719)					
Neoadjuvant chemotherapy	30/430 (7,0)	12/415 (2,9)	2,41 [1,25; 4,65] 0,0085[2]	2,52 [1,27; 4,99] 0,0063[3]	4,1 [1,2; 7,0] 0,0063[3]
Adjuvant chemotherapy	56/784 (7,1)	32/768 (4,2)	1,71 [1,12; 2,62] 0,0125[2]	1,77 [1,13; 2,76] 0,0113[3]	3,0 [0,7; 5,3] 0,0113[3]
No chemotherapy	7/69 (10,1)	5/81 (6,2)	1,64 [0,55; 4,95] 0,3768[2]	1,72 [0,52; 5,67] 0,3715[3]	4,0 [-4,9; 12,8] 0,3715[3]
Region (Interaction p-value: 0,6722)					
North America / Europe	51/678 (7,5)	29/649 (4,5)	1,68 [1,08; 2,62] 0,0212[2]	1,74 [1,09; 2,78] 0,0195[3]	3,1 [0,5; 5,6] 0,0195[3]
Asia	16/203 (7,9)	9/201 (4,5)	1,76 [0,80; 3,89] 0,1622[2]	1,83 [0,79; 4,23] 0,1556[3]	3,4 [-1,3; 8,1] 0,1556[3]
Other	26/402 (6,5)	11/414 (2,7)	2,43 [1,22; 4,86] 0,0117[2]	2,53 [1,23; 5,20] 0,0089[3]	3,8 [1,0; 6,7] 0,0089[3]
Primary tumor size (Interaction p-value: 0,6935)					
< 20 mm	30/331 (9,1)	13/334 (3,9)	2,33 [1,24; 4,38] 0,0088[2]	2,46 [1,26; 4,81] 0,0067[3]	5,2 [1,4; 8,9] 0,0067[3]
≥ 20 but < 50 mm	46/646 (7,1)	28/653 (4,3)	1,66 [1,05; 2,62] 0,0296[2]	1,71 [1,06; 2,77] 0,0276[3]	2,8 [0,3; 5,4] 0,0276[3]
≥ 50 mm	15/289 (5,2)	7/265 (2,6)	1,96 [0,81; 4,74] 0,1332[2]	2,02 [0,81; 5,03] 0,1249[3]	2,5 [-0,7; 5,8] 0,1249[3]
Number of positive lymph nodes (Interaction p-value: 0,8809)					
0-3	27/427 (6,3)	16/418 (3,8)	1,65 [0,90; 3,02] 0,1031[2]	1,70 [0,90; 3,20] 0,0989[3]	2,5 [-0,5; 5,4] 0,0989[3]
4-9	41/549 (7,5)	20/542 (3,7)	2,02 [1,20; 3,41] 0,0080[2]	2,11 [1,22; 3,65] 0,0066[3]	3,8 [1,1; 6,5] 0,0066[3]
≥ 10	25/307 (8,1)	13/304 (4,3)	1,90 [0,99; 3,65] 0,0525[2]	1,98 [1,00; 3,96] 0,0478[3]	3,9 [0,1; 7,7] 0,0478[3]
Tumor stage (Interaction p-value: 0,7276)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	9/113 (8,0)	5/114 (4,4)	1,82 [0,63; 5,25] 0,2708[2]	1,89 [0,61; 5,82] 0,2624[3]	3,6 [-2,7; 9,8] 0,2624[3]
IIB	8/151 (5,3)	6/136 (4,4)	1,20 [0,43; 3,37] 0,7283[2]	1,21 [0,41; 3,59] 0,7278[3]	0,9 [-4,1; 5,9] 0,7278[3]
IIIA	36/495 (7,3)	18/488 (3,7)	1,97 [1,14; 3,42] 0,0159[2]	2,05 [1,15; 3,66] 0,0137[3]	3,6 [0,8; 6,4] 0,0137[3]
IIIB	3/54 (5,6)	3/45 (6,7)	0,83 [0,18; 3,93] 0,8177[2]	0,82 [0,16; 4,29] 1,0000[4]	-1,1 [-10,6; 8,4] 1,0000[4]
IIIC	36/468 (7,7)	17/479 (3,5)	2,17 [1,23; 3,80] 0,0070[2]	2,26 [1,25; 4,09] 0,0055[3]	4,1 [1,2; 7,1] 0,0055[3]
Tumor grade (Interaction p-value: 0,5910)					
G1	7/91 (7,7)	5/93 (5,4)	1,43 [0,47; 4,34] 0,5273[2]	1,47 [0,45; 4,80] 0,5247[3]	2,3 [-4,8; 9,5] 0,5247[3]
G2	41/612 (6,7)	19/602 (3,2)	2,12 [1,25; 3,61] 0,0056[2]	2,20 [1,26; 3,84] 0,0044[3]	3,5 [1,1; 6,0] 0,0044[3]
G3	40/527 (7,6)	24/506 (4,7)	1,60 [0,98; 2,62] 0,0606[2]	1,65 [0,98; 2,78] 0,0578[3]	2,8 [-0,1; 5,8] 0,0578[3]
GX	5/51 (9,8)	1/59 (1,7)	5,78 [0,70; 47,91] 0,1037[2]	6,30 [0,71; 55,86] 0,0942[4]	8,1 [-0,7; 16,9] 0,0942[4]
Race (Interaction p-value: 0,8178)					
White	67/958 (7,0)	36/943 (3,8)	1,83 [1,23; 2,72] 0,0027[2]	1,89 [1,25; 2,87] 0,0022[3]	3,2 [1,2; 5,2] 0,0022[3]
Asian	16/250 (6,4)	9/242 (3,7)	1,72 [0,78; 3,82] 0,1821[2]	1,77 [0,77; 4,09] 0,1758[3]	2,7 [-1,2; 6,5] 0,1758[3]
Other	8/62 (12,9)	3/64 (4,7)	2,75 [0,77; 9,90] 0,1211[2]	3,01 [0,76; 11,93] 0,1024[3]	8,2 [-1,6; 18,0] 0,1024[3]
First endocrine therapy (Interaction p-value: 0,7438)					
Tamoxifen	6/114 (5,3)	3/132 (2,3)	2,32 [0,59; 9,05] 0,2272[2]	2,39 [0,58; 9,78] 0,3097[4]	3,0 [-1,8; 7,8] 0,3097[4]
Aromatase inhibitor	87/1169 (7,4)	46/1132 (4,1)	1,83 [1,29; 2,59] 0,0007[2]	1,90 [1,32; 2,74] 0,0005[3]	3,4 [1,5; 5,3] 0,0005[3]
ECOG-PS (Interaction p-value: 0,7036)					
ECOG-PS 0	74/1070 (6,9)	36/1019 (3,5)	1,96 [1,33; 2,89] 0,0007[2]	2,03 [1,35; 3,05] 0,0005[3]	3,4 [1,5; 5,3] 0,0005[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	19/213 (8,9)	13/245 (5,3)	1,68 [0,85; 3,32] 0,1350[2]	1,75 [0,84; 3,63] 0,1302[3]	3,6 [-1,1; 8,4] 0,1302[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 356.1.2: Subgroups - adverse events according PT Onychoclasis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,6526)					
< 65 years	16/918 (1,7)	2/936 (0,2)	8,16 [1,88; 35,38] 0,0050[2]	8,28 [1,90; 36,13] 0,0008[3]	1,5 [0,6; 2,4] 0,0008[3]
≥ 65 years	5/365 (1,4)	1/328 (0,3)	4,49 [0,53; 38,26] 0,1691[2]	4,54 [0,53; 39,08] 0,2207[4]	1,1 [-0,3; 2,4] 0,2207[4]
Prior treatment (Interaction p-value: 0,9848)					
Neoadjuvant chemotherapy	7/430 (1,6)	1/415 (0,2)	6,76 [0,83; 54,67] 0,0733[2]	6,85 [0,84; 55,93] 0,0694[4]	1,4 [0,1; 2,7] 0,0694[4]
Adjuvant chemotherapy	11/784 (1,4)	2/768 (0,3)	5,39 [1,20; 24,23] 0,0281[2]	5,45 [1,20; 24,67] 0,0135[3]	1,1 [0,2; 2,0] 0,0135[3]
No chemotherapy	3/69 (4,3)	0/81 (0,0)	8,20 [0,43; 156,04] 0,1615[2]	8,58 [0,44; 169,04] 0,0950[4]	4,3 [-0,5; 9,2] 0,0950[4]
Region (Interaction p-value: 0,9779)					
North America / Europe	19/678 (2,8)	3/649 (0,5)	6,06 [1,80; 20,39] 0,0036[2]	6,21 [1,83; 21,08] 0,0008[3]	2,3 [1,0; 3,7] 0,0008[3]
Asia	0/203 (0,0)	0/201 (0,0)	NE	NE	NE
Other	2/402 (0,5)	0/414 (0,0)	5,15 [0,25; 106,92] 0,2896[2]	5,17 [0,25; 108,12] 0,2424[4]	0,5 [-0,2; 1,2] 0,2424[4]
Primary tumor size (Interaction p-value: 0,8159)					
< 20 mm	8/331 (2,4)	1/334 (0,3)	8,07 [1,02; 64,18] 0,0483[2]	8,25 [1,03; 66,31] 0,0202[4]	2,1 [0,4; 3,9] 0,0202[4]
≥ 20 but < 50 mm	9/646 (1,4)	1/653 (0,2)	9,10 [1,16; 71,60] 0,0359[2]	9,21 [1,16; 72,92] 0,0110[4]	1,2 [0,3; 2,2] 0,0110[4]
≥ 50 mm	4/289 (1,4)	1/265 (0,4)	3,67 [0,41; 32,61] 0,2437[2]	3,71 [0,41; 33,36] 0,3751[4]	1,0 [-0,5; 2,5] 0,3751[4]
Number of positive lymph nodes (Interaction p-value: 0,8371)					
0-3	10/427 (2,3)	1/418 (0,2)	9,79 [1,26; 76,13] 0,0293[2]	10,00 [1,27; 78,47] 0,0070[3]	2,1 [0,6; 3,6] 0,0070[3]
4-9	4/549 (0,7)	1/542 (0,2)	3,95 [0,44; 35,22] 0,2186[2]	3,97 [0,44; 35,64] 0,3739[4]	0,5 [-0,3; 1,3] 0,3739[4]
≥ 10	7/307 (2,3)	1/304 (0,3)	6,93 [0,86; 56,00] 0,0693[2]	7,07 [0,86; 57,81] 0,0686[4]	2,0 [0,2; 3,7] 0,0686[4]
Tumor stage (Interaction p-value: 0,9599)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	3/113 (2,7)	0/114 (0,0)	7,06 [0,37; 135,16] 0,1943[2]	7,25 [0,37; 142,05] 0,1217[4]	2,7 [-0,3; 5,6] 0,1217[4]
IIB	3/151 (2,0)	1/136 (0,7)	2,70 [0,28; 25,67] 0,3868[2]	2,74 [0,28; 26,62] 0,6244[4]	1,3 [-1,4; 3,9] 0,6244[4]
IIIA	6/495 (1,2)	1/488 (0,2)	5,92 [0,71; 48,95] 0,0992[2]	5,98 [0,72; 49,82] 0,1237[4]	1,0 [-0,0; 2,1] 0,1237[4]
IIIB	0/54 (0,0)	0/45 (0,0)	NE	NE	NE
IIIC	9/468 (1,9)	1/479 (0,2)	9,21 [1,17; 72,42] 0,0348[2]	9,37 [1,18; 74,27] 0,0105[4]	1,7 [0,4; 3,0] 0,0105[4]
Tumor grade (Interaction p-value: 0,9991)					
G1	0/91 (0,0)	1/93 (1,1)	0,34 [0,01; 8,25] 0,5078[2]	0,34 [0,01; 8,38] 1,0000[4]	-1,1 [-3,2; 1,0] 1,0000[4]
G2	14/612 (2,3)	0/602 (0,0)	28,53 [1,71; 477,13] 0,0197[2]	29,19 [1,74; 490,50] 0,0002[3]	2,3 [1,1; 3,5] 0,0002[3]
G3	7/527 (1,3)	2/506 (0,4)	3,36 [0,70; 16,10] 0,1294[2]	3,39 [0,70; 16,41] 0,1786[4]	0,9 [-0,2; 2,1] 0,1786[4]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9644)					
Negative	2/156 (1,3)	0/169 (0,0)	5,41 [0,26; 111,90] 0,2744[2]	5,49 [0,26; 115,15] 0,2296[4]	1,3 [-0,5; 3,0] 0,2296[4]
Positive	17/1089 (1,6)	3/1066 (0,3)	5,55 [1,63; 18,87] 0,0061[2]	5,62 [1,64; 19,23] 0,0020[3]	1,3 [0,5; 2,1] 0,0020[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9852)					
White	20/958 (2,1)	3/943 (0,3)	6,56 [1,96; 22,01] 0,0023[2]	6,68 [1,98; 22,56] 0,0004[3]	1,8 [0,8; 2,7] 0,0004[3]
Asian	1/250 (0,4)	0/242 (0,0)	2,90 [0,12; 70,95] 0,5132[2]	2,92 [0,12; 71,93] 1,0000[4]	0,4 [-0,4; 1,2] 1,0000[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,3336)					
Tamoxifen	2/114 (1,8)	1/132 (0,8)	2,32 [0,21; 25,21] 0,4906[2]	2,34 [0,21; 26,14] 0,5979[4]	1,0 [-1,8; 3,8] 0,5979[4]
Aromatase inhibitor	19/1169 (1,6)	2/1132 (0,2)	9,20 [2,15; 39,40] 0,0028[2]	9,33 [2,17; 40,17] 0,0003[3]	1,4 [0,7; 2,2] 0,0003[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: 0,3380)					
ECOG-PS 0	19/1070 (1,8)	2/1019 (0,2)	9,05 [2,11; 38,74] 0,0030[2]	9,19 [2,14; 39,57] 0,0003[3]	1,6 [0,7; 2,4] 0,0003[3]
ECOG-PS 1	2/213 (0,9)	1/245 (0,4)	2,30 [0,21; 25,19] 0,4951[2]	2,31 [0,21; 25,69] 0,5998[4]	0,5 [-1,0; 2,1] 0,5998[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 357.1.2: Subgroups - adverse events according PT Oral herpes from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,6298)					
< 65 years	11/918 (1,2)	3/936 (0,3)	3,74 [1,05; 13,36] 0,0424[2]	3,77 [1,05; 13,56] 0,0291[3]	0,9 [0,1; 1,7] 0,0291[3]
≥ 65 years	5/365 (1,4)	2/328 (0,6)	2,25 [0,44; 11,50] 0,3313[2]	2,26 [0,44; 11,75] 0,4555[4]	0,8 [-0,7; 2,2] 0,4555[4]
Prior treatment (Interaction p-value: 0,9996)					
Neoadjuvant chemotherapy	6/430 (1,4)	2/415 (0,5)	2,90 [0,59; 14,26] 0,1913[2]	2,92 [0,59; 14,56] 0,2873[4]	0,9 [-0,4; 2,2] 0,2873[4]
Adjuvant chemotherapy	9/784 (1,1)	3/768 (0,4)	2,94 [0,80; 10,81] 0,1049[2]	2,96 [0,80; 10,98] 0,0886[3]	0,8 [-0,1; 1,6] 0,0886[3]
No chemotherapy	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Primary tumor size (Interaction p-value: 0,7506)					
< 20 mm	4/331 (1,2)	0/334 (0,0)	9,08 [0,49; 168,01] 0,1383[2]	9,19 [0,49; 171,41] 0,0608[4]	1,2 [0,0; 2,4] 0,0608[4]
≥ 20 but < 50 mm	7/646 (1,1)	4/653 (0,6)	1,77 [0,52; 6,01] 0,3609[2]	1,78 [0,52; 6,10] 0,3543[3]	0,5 [-0,5; 1,5] 0,3543[3]
≥ 50 mm	5/289 (1,7)	1/265 (0,4)	4,58 [0,54; 38,99] 0,1632[2]	4,65 [0,54; 40,04] 0,2189[4]	1,4 [-0,3; 3,0] 0,2189[4]
Number of positive lymph nodes (Interaction p-value: 0,6509)					
0-3	9/427 (2,1)	2/418 (0,5)	4,41 [0,96; 20,27] 0,0569[2]	4,48 [0,96; 20,85] 0,0367[3]	1,6 [0,1; 3,1] 0,0367[3]
4-9	6/549 (1,1)	2/542 (0,4)	2,96 [0,60; 14,61] 0,1824[2]	2,98 [0,60; 14,85] 0,2873[4]	0,7 [-0,3; 1,7] 0,2873[4]
≥ 10	1/307 (0,3)	1/304 (0,3)	0,99 [0,06; 15,76] 0,9945[2]	0,99 [0,06; 15,90] 1,0000[4]	-0,0 [-0,9; 0,9] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,9624)					
Negative	4/156 (2,6)	0/169 (0,0)	9,75 [0,53; 179,55] 0,1256[2]	10,00 [0,53; 187,32] 0,0520[4]	2,6 [0,1; 5,0] 0,0520[4]
Positive	12/1089 (1,1)	5/1066 (0,5)	2,35 [0,83; 6,65] 0,1074[2]	2,36 [0,83; 6,73] 0,0968[3]	0,6 [-0,1; 1,4] 0,0968[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9578)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
White	13/958 (1,4)	3/943 (0,3)	4,27 [1,22; 14,92] 0,0232[2]	4,31 [1,22; 15,18] 0,0132[3]	1,0 [0,2; 1,9] 0,0132[3]
Asian	3/250 (1,2)	1/242 (0,4)	2,90 [0,30; 27,73] 0,3544[2]	2,93 [0,30; 28,34] 0,6237[4]	0,8 [-0,8; 2,4] 0,6237[4]
Other	0/62 (0,0)	1/64 (1,6)	0,34 [0,01; 8,28] 0,5109[2]	0,34 [0,01; 8,47] 1,0000[4]	-1,6 [-4,6; 1,5] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,5292)					
Tamoxifen	5/114 (4,4)	1/132 (0,8)	5,79 [0,69; 48,83] 0,1065[2]	6,01 [0,69; 52,21] 0,0988[4]	3,6 [-0,4; 7,7] 0,0988[4]
Aromatase inhibitor	11/1169 (0,9)	4/1132 (0,4)	2,66 [0,85; 8,34] 0,0926[2]	2,68 [0,85; 8,44] 0,0799[3]	0,6 [-0,1; 1,2] 0,0799[3]
ECOG-PS (Interaction p-value: 0,9325)					
ECOG-PS 0	13/1070 (1,2)	4/1019 (0,4)	3,10 [1,01; 9,46] 0,0475[2]	3,12 [1,01; 9,60] 0,0365[3]	0,8 [0,1; 1,6] 0,0365[3]
ECOG-PS 1	3/213 (1,4)	1/245 (0,4)	3,45 [0,36; 32,93] 0,2818[2]	3,49 [0,36; 33,76] 0,3420[4]	1,0 [-0,8; 2,8] 0,3420[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 358.1.2: Subgroups - adverse events according PT Osteoporosis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5287)					
< 65 years	21/918 (2,3)	31/936 (3,3)	0,69 [0,40; 1,19] 0,1844[2]	0,68 [0,39; 1,20] 0,1817[3]	-1,0 [-2,5; 0,5] 0,1817[3]
≥ 65 years	9/365 (2,5)	16/328 (4,9)	0,51 [0,23; 1,13] 0,0958[2]	0,49 [0,21; 1,13] 0,0891[3]	-2,4 [-5,2; 0,4] 0,0891[3]
Prior treatment (Interaction p-value: 0,8719)					
Neoadjuvant chemotherapy	9/430 (2,1)	15/415 (3,6)	0,58 [0,26; 1,31] 0,1891[2]	0,57 [0,25; 1,32] 0,1832[3]	-1,5 [-3,8; 0,7] 0,1832[3]
Adjuvant chemotherapy	20/784 (2,6)	29/768 (3,8)	0,68 [0,39; 1,18] 0,1706[2]	0,67 [0,37; 1,19] 0,1676[3]	-1,2 [-3,0; 0,5] 0,1676[3]
No chemotherapy	1/69 (1,4)	3/81 (3,7)	0,39 [0,04; 3,68] 0,4117[2]	0,38 [0,04; 3,76] 0,6248[4]	-2,3 [-7,2; 2,7] 0,6248[4]
Region (Interaction p-value: 0,6253)					
North America / Europe	14/678 (2,1)	17/649 (2,6)	0,79 [0,39; 1,59] 0,5049[2]	0,78 [0,38; 1,60] 0,5038[3]	-0,6 [-2,2; 1,1] 0,5038[3]
Asia	10/203 (4,9)	16/201 (8,0)	0,62 [0,29; 1,33] 0,2193[2]	0,60 [0,27; 1,35] 0,2140[3]	-3,0 [-7,8; 1,7] 0,2140[3]
Other	6/402 (1,5)	14/414 (3,4)	0,44 [0,17; 1,14] 0,0903[2]	0,43 [0,16; 1,14] 0,0810[3]	-1,9 [-4,0; 0,2] 0,0810[3]
Primary tumor size (Interaction p-value: 0,7436)					
< 20 mm	11/331 (3,3)	17/334 (5,1)	0,65 [0,31; 1,37] 0,2608[2]	0,64 [0,30; 1,39] 0,2567[3]	-1,8 [-4,8; 1,3] 0,2567[3]
≥ 20 but < 50 mm	13/646 (2,0)	18/653 (2,8)	0,73 [0,36; 1,48] 0,3817[2]	0,72 [0,35; 1,49] 0,3796[3]	-0,7 [-2,4; 0,9] 0,3796[3]
≥ 50 mm	6/289 (2,1)	12/265 (4,5)	0,46 [0,17; 1,20] 0,1135[2]	0,45 [0,17; 1,21] 0,1039[3]	-2,5 [-5,4; 0,5] 0,1039[3]
Number of positive lymph nodes (Interaction p-value: 0,5430)					
0-3	12/427 (2,8)	14/418 (3,3)	0,84 [0,39; 1,79] 0,6506[2]	0,83 [0,38; 1,83] 0,6501[3]	-0,5 [-2,9; 1,8] 0,6501[3]
4-9	11/549 (2,0)	23/542 (4,2)	0,47 [0,23; 0,96] 0,0379[2]	0,46 [0,22; 0,96] 0,0333[3]	-2,2 [-4,3; -0,2] 0,0333[3]
≥ 10	7/307 (2,3)	10/304 (3,3)	0,69 [0,27; 1,80] 0,4509[2]	0,69 [0,26; 1,83] 0,4482[3]	-1,0 [-3,6; 1,6] 0,4482[3]
Tumor stage (Interaction p-value: 0,3867)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	2/113 (1,8)	6/114 (5,3)	0,34 [0,07; 1,63] 0,1761[2]	0,32 [0,06; 1,64] 0,2803[4]	-3,5 [-8,3; 1,3] 0,2803[4]
IIB	5/151 (3,3)	1/136 (0,7)	4,50 [0,53; 38,07] 0,1670[2]	4,62 [0,53; 40,08] 0,2177[4]	2,6 [-0,6; 5,8] 0,2177[4]
IIIA	11/495 (2,2)	19/488 (3,9)	0,57 [0,27; 1,19] 0,1332[2]	0,56 [0,26; 1,19] 0,1277[3]	-1,7 [-3,8; 0,5] 0,1277[3]
IIIB	2/54 (3,7)	4/45 (8,9)	0,42 [0,08; 2,17] 0,2986[2]	0,39 [0,07; 2,26] 0,4065[4]	-5,2 [-14,9; 4,5] 0,4065[4]
IIIC	10/468 (2,1)	17/479 (3,5)	0,60 [0,28; 1,30] 0,1969[2]	0,59 [0,27; 1,31] 0,1917[3]	-1,4 [-3,5; 0,7] 0,1917[3]
Tumor grade (Interaction p-value: 0,5675)					
G1	2/91 (2,2)	2/93 (2,2)	1,02 [0,15; 7,10] 0,9825[2]	1,02 [0,14; 7,42] 1,0000[4]	0,0 [-4,2; 4,3] 1,0000[4]
G2	13/612 (2,1)	26/602 (4,3)	0,49 [0,26; 0,95] 0,0340[2]	0,48 [0,24; 0,94] 0,0301[3]	-2,2 [-4,2; -0,2] 0,0301[3]
G3	15/527 (2,8)	15/506 (3,0)	0,96 [0,47; 1,94] 0,9100[2]	0,96 [0,46; 1,98] 0,9100[3]	-0,1 [-2,2; 1,9] 0,9100[3]
GX	0/51 (0,0)	4/59 (6,8)	0,13 [0,01; 2,33] 0,1648[2]	0,12 [0,01; 2,28] 0,1221[4]	-6,8 [-13,2; -0,4] 0,1221[4]
Progesterone receptor status (Interaction p-value: 0,2964)					
Negative	2/156 (1,3)	10/169 (5,9)	0,22 [0,05; 0,97] 0,0460[2]	0,21 [0,04; 0,96] 0,0268[3]	-4,6 [-8,6; -0,7] 0,0268[3]
Positive	28/1089 (2,6)	36/1066 (3,4)	0,76 [0,47; 1,24] 0,2721[2]	0,76 [0,46; 1,25] 0,2705[3]	-0,8 [-2,2; 0,6] 0,2705[3]
Unknown	0/10 (0,0)	1/7 (14,3)	0,24 [0,01; 5,21] 0,3654[2]	0,21 [0,01; 5,86] 0,4118[4]	-14,3 [-40,2; 11,6] 0,4118[4]
Race (Interaction p-value: 0,9355)					
White	20/958 (2,1)	29/943 (3,1)	0,68 [0,39; 1,19] 0,1772[2]	0,67 [0,38; 1,20] 0,1743[3]	-1,0 [-2,4; 0,4] 0,1743[3]
Asian	10/250 (4,0)	17/242 (7,0)	0,57 [0,27; 1,22] 0,1469[2]	0,55 [0,25; 1,23] 0,1408[3]	-3,0 [-7,1; 1,0] 0,1408[3]
Other	0/62 (0,0)	1/64 (1,6)	0,34 [0,01; 8,28] 0,5109[2]	0,34 [0,01; 8,47] 1,0000[4]	-1,6 [-4,6; 1,5] 1,0000[4]
First endocrine therapy (Interaction p-value: 0,9518)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	1/114 (0,9)	2/132 (1,5)	0,58 [0,05; 6,30] 0,6536[2]	0,58 [0,05; 6,43] 1,0000[4]	-0,6 [-3,3; 2,1] 1,0000[4]
Aromatase inhibitor	29/1169 (2,5)	45/1132 (4,0)	0,62 [0,39; 0,99] 0,0443[2]	0,61 [0,38; 0,99] 0,0422[3]	-1,5 [-2,9; -0,0] 0,0422[3]
ECOG-PS (Interaction p-value: 0,3265)					
ECOG-PS 0	26/1070 (2,4)	35/1019 (3,4)	0,71 [0,43; 1,17] 0,1750[2]	0,70 [0,42; 1,17] 0,1727[3]	-1,0 [-2,5; 0,4] 0,1727[3]
ECOG-PS 1	4/213 (1,9)	12/245 (4,9)	0,38 [0,13; 1,17] 0,0924[2]	0,37 [0,12; 1,17] 0,0791[3]	-3,0 [-6,3; 0,2] 0,0791[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 359.1.2: Subgroups - adverse events according PT Palpitations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,3711)					
< 65 years	21/918 (2,3)	11/936 (1,2)	1,95 [0,94; 4,01] 0,0713[2]	1,97 [0,94; 4,11] 0,0660[3]	1,1 [-0,1; 2,3] 0,0660[3]
≥ 65 years	6/365 (1,6)	1/328 (0,3)	5,39 [0,65; 44,55] 0,1179[2]	5,47 [0,65; 45,64] 0,1269[4]	1,3 [-0,1; 2,8] 0,1269[4]
Prior treatment (Interaction p-value: 0,7686)					
Neoadjuvant chemotherapy	12/430 (2,8)	4/415 (1,0)	2,90 [0,94; 8,91] 0,0637[2]	2,95 [0,94; 9,22] 0,0514[3]	1,8 [0,0; 3,6] 0,0514[3]
Adjuvant chemotherapy	14/784 (1,8)	8/768 (1,0)	1,71 [0,72; 4,06] 0,2209[2]	1,73 [0,72; 4,14] 0,2151[3]	0,7 [-0,4; 1,9] 0,2151[3]
No chemotherapy	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Region (Interaction p-value: 0,5768)					
North America / Europe	18/678 (2,7)	9/649 (1,4)	1,91 [0,87; 4,23] 0,1084[2]	1,94 [0,86; 4,35] 0,1019[3]	1,3 [-0,2; 2,8] 0,1019[3]
Asia	6/203 (3,0)	1/201 (0,5)	5,94 [0,72; 48,90] 0,0976[2]	6,09 [0,73; 51,06] 0,1218[4]	2,5 [-0,1; 5,0] 0,1218[4]
Other	3/402 (0,7)	2/414 (0,5)	1,54 [0,26; 9,20] 0,6328[2]	1,55 [0,26; 9,32] 0,6822[4]	0,3 [-0,8; 1,3] 0,6822[4]
Primary tumor size (Interaction p-value: 0,6056)					
< 20 mm	7/331 (2,1)	2/334 (0,6)	3,53 [0,74; 16,88] 0,1138[2]	3,59 [0,74; 17,39] 0,1057[4]	1,5 [-0,2; 3,3] 0,1057[4]
≥ 20 but < 50 mm	13/646 (2,0)	8/653 (1,2)	1,64 [0,69; 3,94] 0,2657[2]	1,66 [0,68; 4,02] 0,2606[3]	0,8 [-0,6; 2,2] 0,2606[3]
≥ 50 mm	7/289 (2,4)	2/265 (0,8)	3,21 [0,67; 15,31] 0,1436[2]	3,26 [0,67; 15,85] 0,1798[4]	1,7 [-0,4; 3,7] 0,1798[4]
Number of positive lymph nodes (Interaction p-value: 0,9511)					
0-3	10/427 (2,3)	4/418 (1,0)	2,45 [0,77; 7,74] 0,1277[2]	2,48 [0,77; 7,98] 0,1148[3]	1,4 [-0,3; 3,1] 0,1148[3]
4-9	12/549 (2,2)	6/542 (1,1)	1,97 [0,75; 5,22] 0,1705[2]	2,00 [0,74; 5,36] 0,1619[3]	1,1 [-0,4; 2,6] 0,1619[3]
≥ 10	5/307 (1,6)	2/304 (0,7)	2,48 [0,48; 12,66] 0,2764[2]	2,50 [0,48; 12,99] 0,4505[4]	1,0 [-0,7; 2,7] 0,4505[4]
Tumor stage (Interaction p-value: 0,9422)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	2/113 (1,8)	2/114 (1,8)	1,01 [0,14; 7,04] 0,9929[2]	1,01 [0,14; 7,29] 1,0000[4]	0,0 [-3,4; 3,4] 1,0000[4]
IIB	2/151 (1,3)	1/136 (0,7)	1,80 [0,17; 19,64] 0,6293[2]	1,81 [0,16; 20,21] 1,0000[4]	0,6 [-1,7; 2,9] 1,0000[4]
IIIA	11/495 (2,2)	4/488 (0,8)	2,71 [0,87; 8,46] 0,0857[2]	2,75 [0,87; 8,70] 0,0729[3]	1,4 [-0,1; 2,9] 0,0729[3]
IIIB	1/54 (1,9)	0/45 (0,0)	2,51 [0,10; 60,13] 0,5703[2]	2,55 [0,10; 64,17] 1,0000[4]	1,9 [-1,7; 5,4] 1,0000[4]
IIIC	11/468 (2,4)	5/479 (1,0)	2,25 [0,79; 6,43] 0,1295[2]	2,28 [0,79; 6,62] 0,1188[3]	1,3 [-0,3; 3,0] 0,1188[3]
Tumor grade (Interaction p-value: 0,9992)					
G1	2/91 (2,2)	1/93 (1,1)	2,04 [0,19; 22,15] 0,5565[2]	2,07 [0,18; 23,21] 0,6189[4]	1,1 [-2,5; 4,8] 0,6189[4]
G2	13/612 (2,1)	6/602 (1,0)	2,13 [0,82; 5,57] 0,1227[2]	2,16 [0,81; 5,71] 0,1135[3]	1,1 [-0,3; 2,5] 0,1135[3]
G3	10/527 (1,9)	5/506 (1,0)	1,92 [0,66; 5,58] 0,2305[2]	1,94 [0,66; 5,71] 0,2219[3]	0,9 [-0,5; 2,4] 0,2219[3]
GX	2/51 (3,9)	0/59 (0,0)	5,77 [0,28; 117,46] 0,2544[2]	6,01 [0,28; 128,14] 0,2127[4]	3,9 [-1,4; 9,2] 0,2127[4]
Progesterone receptor status (Interaction p-value: 0,6594)					
Negative	4/156 (2,6)	3/169 (1,8)	1,44 [0,33; 6,35] 0,6265[2]	1,46 [0,32; 6,61] 0,7142[4]	0,8 [-2,4; 4,0] 0,7142[4]
Positive	23/1089 (2,1)	9/1066 (0,8)	2,50 [1,16; 5,38] 0,0190[2]	2,53 [1,17; 5,50] 0,0150[3]	1,3 [0,3; 2,3] 0,0150[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,4462)					
White	18/958 (1,9)	11/943 (1,2)	1,61 [0,76; 3,39] 0,2096[2]	1,62 [0,76; 3,45] 0,2051[3]	0,7 [-0,4; 1,8] 0,2051[3]
Asian	7/250 (2,8)	1/242 (0,4)	6,78 [0,84; 54,66] 0,0725[2]	6,94 [0,85; 56,85] 0,0684[4]	2,4 [0,2; 4,6] 0,0684[4]
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
ECOG-PS (Interaction p-value: 0,9584)					
ECOG-PS 0	23/1070 (2,1)	10/1019 (1,0)	2,19 [1,05; 4,58] 0,0372[2]	2,22 [1,05; 4,68] 0,0323[3]	1,2 [0,1; 2,2] 0,0323[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	4/213 (1,9)	2/245 (0,8)	2,30 [0,43; 12,44] 0,3332[2]	2,33 [0,42; 12,82] 0,4235[4]	1,1 [-1,1; 3,2] 0,4235[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 360.1.2: Subgroups - adverse events according PT Paronychia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8267)					
< 65 years	10/918 (1,1)	3/936 (0,3)	3,40 [0,94; 12,31] 0,0624[2]	3,43 [0,94; 12,49] 0,0473[3]	0,8 [0,0; 1,5] 0,0473[3]
≥ 65 years	5/365 (1,4)	1/328 (0,3)	4,49 [0,53; 38,26] 0,1691[2]	4,54 [0,53; 39,08] 0,2207[4]	1,1 [-0,3; 2,4] 0,2207[4]
Prior treatment (Interaction p-value: 0,9664)					
Neoadjuvant chemotherapy	1/430 (0,2)	0/415 (0,0)	2,90 [0,12; 70,88] 0,5146[2]	2,90 [0,12; 71,44] 1,0000[4]	0,2 [-0,2; 0,7] 1,0000[4]
Adjuvant chemotherapy	13/784 (1,7)	4/768 (0,5)	3,18 [1,04; 9,72] 0,0420[2]	3,22 [1,05; 9,92] 0,0314[3]	1,1 [0,1; 2,2] 0,0314[3]
No chemotherapy	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Region (Interaction p-value: 0,9932)					
North America / Europe	8/678 (1,2)	3/649 (0,5)	2,55 [0,68; 9,58] 0,1649[2]	2,57 [0,68; 9,73] 0,1495[3]	0,7 [-0,2; 1,7] 0,1495[3]
Asia	3/203 (1,5)	1/201 (0,5)	2,97 [0,31; 28,32] 0,3440[2]	3,00 [0,31; 29,09] 0,6232[4]	1,0 [-0,9; 2,9] 0,6232[4]
Other	4/402 (1,0)	0/414 (0,0)	9,27 [0,50; 171,59] 0,1348[2]	9,36 [0,50; 174,44] 0,0585[4]	1,0 [0,0; 2,0] 0,0585[4]
Progesterone receptor status (Interaction p-value: 0,5742)					
Negative	2/156 (1,3)	1/169 (0,6)	2,17 [0,20; 23,66] 0,5261[2]	2,18 [0,20; 24,30] 0,6093[4]	0,7 [-1,4; 2,8] 0,6093[4]
Positive	13/1089 (1,2)	3/1066 (0,3)	4,24 [1,21; 14,84] 0,0238[2]	4,28 [1,22; 15,07] 0,0136[3]	0,9 [0,2; 1,6] 0,0136[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9737)					
White	12/958 (1,3)	3/943 (0,3)	3,94 [1,11; 13,91] 0,0333[2]	3,97 [1,12; 14,13] 0,0213[3]	0,9 [0,1; 1,7] 0,0213[3]
Asian	3/250 (1,2)	1/242 (0,4)	2,90 [0,30; 27,73] 0,3544[2]	2,93 [0,30; 28,34] 0,6237[4]	0,8 [-0,8; 2,4] 0,6237[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,9731)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	12/1070 (1,1)	4/1019 (0,4)	2,86 [0,92; 8,83] 0,0682[2]	2,88 [0,93; 8,95] 0,0561[3]	0,7 [-0,0; 1,5] 0,0561[3]
ECOG-PS 1	3/213 (1,4)	0/245 (0,0)	8,05 [0,42; 154,90] 0,1670[2]	8,16 [0,42; 158,96] 0,0998[4]	1,4 [-0,2; 3,0] 0,0998[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 361.1.2: Subgroups - adverse events according PT Platelet count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8788)					
< 65 years	71/918 (7,7)	6/936 (0,6)	12,07 [5,27; 27,62] <,0001[2]	12,99 [5,62; 30,05] <,0001[3]	7,1 [5,3; 8,9] <,0001[3]
≥ 65 years	45/365 (12,3)	3/328 (0,9)	13,48 [4,23; 42,96] <,0001[2]	15,23 [4,69; 49,52] <,0001[3]	11,4 [7,9; 14,9] <,0001[3]
Prior treatment (Interaction p-value: 0,9965)					
Neoadjuvant chemotherapy	35/430 (8,1)	3/415 (0,7)	11,26 [3,49; 36,33] <,0001[2]	12,17 [3,71; 39,89] <,0001[3]	7,4 [4,7; 10,1] <,0001[3]
Adjuvant chemotherapy	73/784 (9,3)	6/768 (0,8)	11,92 [5,22; 27,23] <,0001[2]	13,04 [5,64; 30,16] <,0001[3]	8,5 [6,4; 10,7] <,0001[3]
No chemotherapy	8/69 (11,6)	0/81 (0,0)	19,91 [1,17; 338,90] 0,0386[2]	22,53 [1,28; 397,86] 0,0016[4]	11,6 [4,0; 19,1] 0,0016[4]
Region (Interaction p-value: 0,1252)					
North America / Europe	34/678 (5,0)	2/649 (0,3)	16,27 [3,93; 67,46] 0,0001[2]	17,08 [4,09; 71,39] <,0001[3]	4,7 [3,0; 6,4] <,0001[3]
Asia	56/203 (27,6)	2/201 (1,0)	27,72 [6,86; 112,08] <,0001[2]	37,90 [9,10; 157,83] <,0001[3]	26,6 [20,3; 32,9] <,0001[3]
Other	26/402 (6,5)	5/414 (1,2)	5,36 [2,08; 13,81] 0,0005[2]	5,66 [2,15; 14,88] <,0001[3]	5,3 [2,6; 7,9] <,0001[3]
Primary tumor size (Interaction p-value: 0,1525)					
< 20 mm	25/331 (7,6)	1/334 (0,3)	25,23 [3,44; 185,10] 0,0015[2]	27,21 [3,66; 201,99] <,0001[3]	7,3 [4,3; 10,2] <,0001[3]
≥ 20 but < 50 mm	68/646 (10,5)	4/653 (0,6)	17,18 [6,31; 46,83] <,0001[2]	19,09 [6,92; 52,65] <,0001[3]	9,9 [7,5; 12,4] <,0001[3]
≥ 50 mm	21/289 (7,3)	4/265 (1,5)	4,81 [1,67; 13,84] 0,0035[2]	5,11 [1,73; 15,10] 0,0011[3]	5,8 [2,4; 9,1] 0,0011[3]
Number of positive lymph nodes (Interaction p-value: 0,4747)					
0-3	29/427 (6,8)	1/418 (0,2)	28,39 [3,88; 207,45] 0,0010[2]	30,38 [4,12; 224,11] <,0001[3]	6,6 [4,1; 9,0] <,0001[3]
4-9	53/549 (9,7)	6/542 (1,1)	8,72 [3,78; 20,12] <,0001[2]	9,55 [4,07; 22,40] <,0001[3]	8,5 [5,9; 11,2] <,0001[3]
≥ 10	34/307 (11,1)	2/304 (0,7)	16,83 [4,08; 69,45] <,0001[2]	18,81 [4,48; 79,01] <,0001[3]	10,4 [6,8; 14,0] <,0001[3]
Tumor stage (Interaction p-value: 0,4743)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	9/113 (8,0)	0/114 (0,0)	19,17 [1,13; 325,44] 0,0410[2]	20,82 [1,20; 362,12] 0,0016[4]	8,0 [3,0; 13,0] 0,0016[4]
IIB	15/151 (9,9)	0/136 (0,0)	27,94 [1,69; 462,56] 0,0200[2]	31,00 [1,84; 523,28] 0,0002[3]	9,9 [5,2; 14,7] 0,0002[3]
IIIA	37/495 (7,5)	7/488 (1,4)	5,21 [2,35; 11,58] <,0001[2]	5,55 [2,45; 12,58] <,0001[3]	6,0 [3,5; 8,6] <,0001[3]
IIIB	7/54 (13,0)	0/45 (0,0)	12,55 [0,74; 213,82] 0,0804[2]	14,37 [0,80; 258,91] 0,0149[4]	13,0 [4,0; 21,9] 0,0149[4]
IIIC	48/468 (10,3)	2/479 (0,4)	24,56 [6,00; 100,49] <,0001[2]	27,26 [6,58; 112,83] <,0001[3]	9,8 [7,0; 12,6] <,0001[3]
Tumor grade (Interaction p-value: 0,5938)					
G1	6/91 (6,6)	0/93 (0,0)	13,28 [0,76; 232,41] 0,0765[2]	14,22 [0,79; 256,15] 0,0134[4]	6,6 [1,5; 11,7] 0,0134[4]
G2	54/612 (8,8)	7/602 (1,2)	7,59 [3,48; 16,54] <,0001[2]	8,23 [3,71; 18,23] <,0001[3]	7,7 [5,3; 10,1] <,0001[3]
G3	49/527 (9,3)	2/506 (0,4)	23,52 [5,75; 96,22] <,0001[2]	25,83 [6,25; 106,81] <,0001[3]	8,9 [6,4; 11,4] <,0001[3]
GX	6/51 (11,8)	0/59 (0,0)	15,00 [0,87; 259,93] 0,0628[2]	17,00 [0,93; 309,65] 0,0084[4]	11,8 [2,9; 20,6] 0,0084[4]
Race (Interaction p-value: 0,2780)					
White	56/958 (5,8)	6/943 (0,6)	9,19 [3,98; 21,22] <,0001[2]	9,70 [4,16; 22,61] <,0001[3]	5,2 [3,6; 6,8] <,0001[3]
Asian	56/250 (22,4)	2/242 (0,8)	27,10 [6,69; 109,84] <,0001[2]	34,64 [8,35; 143,75] <,0001[3]	21,6 [16,3; 26,9] <,0001[3]
Other	4/62 (6,5)	1/64 (1,6)	4,13 [0,47; 35,92] 0,1989[2]	4,34 [0,47; 40,01] 0,2039[4]	4,9 [-1,9; 11,7] 0,2039[4]
First endocrine therapy (Interaction p-value: 0,4631)					
Tamoxifen	5/114 (4,4)	1/132 (0,8)	5,79 [0,69; 48,83] 0,1065[2]	6,01 [0,69; 52,21] 0,0988[4]	3,6 [-0,4; 7,7] 0,0988[4]
Aromatase inhibitor	111/1169 (9,5)	8/1132 (0,7)	13,44 [6,59; 27,41] <,0001[2]	14,74 [7,16; 30,36] <,0001[3]	8,8 [7,0; 10,5] <,0001[3]
ECOG-PS (Interaction p-value: 0,6414)					
ECOG-PS 0	100/1070 (9,3)	7/1019 (0,7)	13,60 [6,35; 29,13] <,0001[2]	14,90 [6,89; 32,23] <,0001[3]	8,7 [6,8; 10,5] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	16/213 (7,5)	2/245 (0,8)	9,20 [2,14; 39,56] 0,0029[2]	9,87 [2,24; 43,43] 0,0002[3]	6,7 [3,0; 10,4] 0,0002[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 362.1.2: Subgroups - adverse events according PT Pneumonitis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,7212)					
Neoadjuvant chemotherapy	7/430 (1,6)	2/415 (0,5)	3,38 [0,71; 16,17] 0,1276[2]	3,42 [0,71; 16,55] 0,1780[4]	1,1 [-0,2; 2,5] 0,1780[4]
Adjuvant chemotherapy	10/784 (1,3)	1/768 (0,1)	9,80 [1,26; 76,34] 0,0294[2]	9,91 [1,27; 77,60] 0,0072[3]	1,1 [0,3; 2,0] 0,0072[3]
No chemotherapy	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Region (Interaction p-value: 0,7878)					
North America / Europe	9/678 (1,3)	1/649 (0,2)	8,62 [1,09; 67,81] 0,0408[2]	8,72 [1,10; 69,00] 0,0213[4]	1,2 [0,3; 2,1] 0,0213[4]
Asia	7/203 (3,4)	2/201 (1,0)	3,47 [0,73; 16,48] 0,1182[2]	3,55 [0,73; 17,32] 0,1748[4]	2,5 [-0,4; 5,3] 0,1748[4]
Other	2/402 (0,5)	0/414 (0,0)	5,15 [0,25; 106,92] 0,2896[2]	5,17 [0,25; 108,12] 0,2424[4]	0,5 [-0,2; 1,2] 0,2424[4]
Primary tumor size (Interaction p-value: 0,5329)					
< 20 mm	4/331 (1,2)	0/334 (0,0)	9,08 [0,49; 168,01] 0,1383[2]	9,19 [0,49; 171,41] 0,0608[4]	1,2 [0,0; 2,4] 0,0608[4]
≥ 20 but < 50 mm	11/646 (1,7)	1/653 (0,2)	11,12 [1,44; 85,88] 0,0209[2]	11,29 [1,45; 87,74] 0,0035[3]	1,5 [0,5; 2,6] 0,0035[3]
≥ 50 mm	2/289 (0,7)	1/265 (0,4)	1,83 [0,17; 20,11] 0,6196[2]	1,84 [0,17; 20,41] 1,0000[4]	0,3 [-0,9; 1,5] 1,0000[4]
Tumor grade (Interaction p-value: 0,9955)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	6/612 (1,0)	1/602 (0,2)	5,90 [0,71; 48,88] 0,0998[2]	5,95 [0,71; 49,57] 0,1240[4]	0,8 [-0,0; 1,7] 0,1240[4]
G3	9/527 (1,7)	1/506 (0,2)	8,64 [1,10; 67,96] 0,0404[2]	8,77 [1,11; 69,51] 0,0211[4]	1,5 [0,3; 2,7] 0,0211[4]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,3906)					
Negative	3/156 (1,9)	1/169 (0,6)	3,25 [0,34; 30,92] 0,3051[2]	3,29 [0,34; 32,00] 0,3537[4]	1,3 [-1,1; 3,8] 0,3537[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Positive	15/1089 (1,4)	2/1066 (0,2)	7,34 [1,68; 32,03] 0,0080[2]	7,43 [1,70; 32,57] 0,0018[3]	1,2 [0,5; 1,9] 0,0018[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,7758)					
White	10/958 (1,0)	1/943 (0,1)	9,84 [1,26; 76,74] 0,0291[2]	9,94 [1,27; 77,78] 0,0070[3]	0,9 [0,3; 1,6] 0,0070[3]
Asian	8/250 (3,2)	2/242 (0,8)	3,87 [0,83; 18,05] 0,0848[2]	3,97 [0,83; 18,87] 0,1063[4]	2,4 [-0,1; 4,8] 0,1063[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 363.1.2: Subgroups - adverse events according PT Pruritus from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5667)					
< 65 years	68/918 (7,4)	41/936 (4,4)	1,69 [1,16; 2,46] 0,0063[2]	1,75 [1,17; 2,60] 0,0056[3]	3,0 [0,9; 5,2] 0,0056[3]
≥ 65 years	41/365 (11,2)	18/328 (5,5)	2,05 [1,20; 3,49] 0,0085[2]	2,18 [1,23; 3,88] 0,0068[3]	5,7 [1,7; 9,8] 0,0068[3]
Prior treatment (Interaction p-value: 0,1400)					
Neoadjuvant chemotherapy	35/430 (8,1)	15/415 (3,6)	2,25 [1,25; 4,06] 0,0070[2]	2,36 [1,27; 4,40] 0,0053[3]	4,5 [1,4; 7,7] 0,0053[3]
Adjuvant chemotherapy	64/784 (8,2)	42/768 (5,5)	1,49 [1,02; 2,17] 0,0369[2]	1,54 [1,03; 2,30] 0,0354[3]	2,7 [0,2; 5,2] 0,0354[3]
No chemotherapy	10/69 (14,5)	2/81 (2,5)	5,87 [1,33; 25,88] 0,0194[2]	6,69 [1,41; 31,71] 0,0068[3]	12,0 [3,1; 21,0] 0,0068[3]
Region (Interaction p-value: 0,1887)					
North America / Europe	44/678 (6,5)	29/649 (4,5)	1,45 [0,92; 2,29] 0,1089[2]	1,48 [0,92; 2,40] 0,1065[3]	2,0 [-0,4; 4,5] 0,1065[3]
Asia	22/203 (10,8)	14/201 (7,0)	1,56 [0,82; 2,95] 0,1765[2]	1,62 [0,81; 3,27] 0,1720[3]	3,9 [-1,7; 9,4] 0,1720[3]
Other	43/402 (10,7)	16/414 (3,9)	2,77 [1,59; 4,83] 0,0003[2]	2,98 [1,65; 5,38] 0,0002[3]	6,8 [3,3; 10,4] 0,0002[3]
Primary tumor size (Interaction p-value: 0,1664)					
< 20 mm	17/331 (5,1)	16/334 (4,8)	1,07 [0,55; 2,09] 0,8375[2]	1,08 [0,53; 2,17] 0,8375[3]	0,3 [-3,0; 3,6] 0,8375[3]
≥ 20 but < 50 mm	56/646 (8,7)	30/653 (4,6)	1,89 [1,23; 2,90] 0,0038[2]	1,97 [1,25; 3,11] 0,0031[3]	4,1 [1,4; 6,8] 0,0031[3]
≥ 50 mm	36/289 (12,5)	13/265 (4,9)	2,54 [1,38; 4,68] 0,0028[2]	2,76 [1,43; 5,32] 0,0018[3]	7,6 [2,9; 12,2] 0,0018[3]
Number of positive lymph nodes (Interaction p-value: 0,3794)					
0-3	32/427 (7,5)	23/418 (5,5)	1,36 [0,81; 2,29] 0,2429[2]	1,39 [0,80; 2,42] 0,2406[3]	2,0 [-1,3; 5,3] 0,2406[3]
4-9	48/549 (8,7)	21/542 (3,9)	2,26 [1,37; 3,72] 0,0014[2]	2,38 [1,40; 4,03] 0,0010[3]	4,9 [2,0; 7,7] 0,0010[3]
≥ 10	29/307 (9,4)	15/304 (4,9)	1,91 [1,05; 3,50] 0,0347[2]	2,01 [1,05; 3,83] 0,0310[3]	4,5 [0,4; 8,6] 0,0310[3]
Tumor stage (Interaction p-value: 0,2314)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	7/113 (6,2)	6/114 (5,3)	1,18 [0,41; 3,39] 0,7629[2]	1,19 [0,39; 3,65] 0,7626[3]	0,9 [-5,1; 7,0] 0,7626[3]
IIB	10/151 (6,6)	11/136 (8,1)	0,82 [0,36; 1,87] 0,6346[2]	0,81 [0,33; 1,96] 0,6340[3]	-1,5 [-7,5; 4,6] 0,6340[3]
IIIA	46/495 (9,3)	20/488 (4,1)	2,27 [1,36; 3,78] 0,0016[2]	2,40 [1,40; 4,12] 0,0011[3]	5,2 [2,1; 8,3] 0,0011[3]
IIIB	7/54 (13,0)	4/45 (8,9)	1,46 [0,46; 4,67] 0,5249[2]	1,53 [0,42; 5,59] 0,5207[3]	4,1 [-8,1; 16,3] 0,5207[3]
IIIC	39/468 (8,3)	18/479 (3,8)	2,22 [1,29; 3,82] 0,0041[2]	2,33 [1,31; 4,13] 0,0031[3]	4,6 [1,5; 7,6] 0,0031[3]
Tumor grade (Interaction p-value: 0,2686)					
G1	6/91 (6,6)	4/93 (4,3)	1,53 [0,45; 5,25] 0,4966[2]	1,57 [0,43; 5,76] 0,5339[4]	2,3 [-4,3; 8,8] 0,5339[4]
G2	65/612 (10,6)	26/602 (4,3)	2,46 [1,58; 3,82] <,0001[2]	2,63 [1,65; 4,21] <,0001[3]	6,3 [3,4; 9,2] <,0001[3]
G3	36/527 (6,8)	27/506 (5,3)	1,28 [0,79; 2,08] 0,3170[2]	1,30 [0,78; 2,18] 0,3155[3]	1,5 [-1,4; 4,4] 0,3155[3]
GX	2/51 (3,9)	1/59 (1,7)	2,31 [0,22; 24,78] 0,4880[2]	2,37 [0,21; 26,90] 0,5957[4]	2,2 [-4,0; 8,5] 0,5957[4]
Race (Interaction p-value: 0,0779)					
White	77/958 (8,0)	33/943 (3,5)	2,30 [1,54; 3,42] <,0001[2]	2,41 [1,59; 3,66] <,0001[3]	4,5 [2,5; 6,6] <,0001[3]
Asian	25/250 (10,0)	15/242 (6,2)	1,61 [0,87; 2,98] 0,1276[2]	1,68 [0,86; 3,27] 0,1229[3]	3,8 [-1,0; 8,6] 0,1229[3]
Other	5/62 (8,1)	8/64 (12,5)	0,65 [0,22; 1,86] 0,4183[2]	0,61 [0,19; 1,99] 0,4132[3]	-4,4 [-15,0; 6,1] 0,4132[3]
First endocrine therapy (Interaction p-value: 0,5911)					
Tamoxifen	10/114 (8,8)	8/132 (6,1)	1,45 [0,59; 3,54] 0,4183[2]	1,49 [0,57; 3,91] 0,4155[3]	2,7 [-3,9; 9,3] 0,4155[3]
Aromatase inhibitor	99/1169 (8,5)	51/1132 (4,5)	1,88 [1,35; 2,61] 0,0002[2]	1,96 [1,38; 2,78] 0,0001[3]	4,0 [2,0; 6,0] 0,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 364.1.2: Subgroups - adverse events according PT Pyrexia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8454)					
< 65 years	83/918 (9,0)	39/936 (4,2)	2,17 [1,50; 3,14] <,0001[2]	2,29 [1,54; 3,38] <,0001[3]	4,9 [2,6; 7,1] <,0001[3]
≥ 65 years	16/365 (4,4)	6/328 (1,8)	2,40 [0,95; 6,05] 0,0644[2]	2,46 [0,95; 6,36] 0,0555[3]	2,6 [0,0; 5,1] 0,0555[3]
Prior treatment (Interaction p-value: 0,7315)					
Neoadjuvant chemotherapy	31/430 (7,2)	13/415 (3,1)	2,30 [1,22; 4,34] 0,0099[2]	2,40 [1,24; 4,66] 0,0077[3]	4,1 [1,1; 7,0] 0,0077[3]
Adjuvant chemotherapy	65/784 (8,3)	29/768 (3,8)	2,20 [1,43; 3,36] 0,0003[2]	2,30 [1,47; 3,61] 0,0002[3]	4,5 [2,2; 6,9] 0,0002[3]
No chemotherapy	3/69 (4,3)	3/81 (3,7)	1,17 [0,24; 5,63] 0,8411[2]	1,18 [0,23; 6,05] 1,0000[4]	0,6 [-5,7; 7,0] 1,0000[4]
Region (Interaction p-value: 0,8380)					
North America / Europe	49/678 (7,2)	24/649 (3,7)	1,95 [1,21; 3,15] 0,0058[2]	2,03 [1,23; 3,35] 0,0048[3]	3,5 [1,1; 6,0] 0,0048[3]
Asia	24/203 (11,8)	10/201 (5,0)	2,38 [1,17; 4,84] 0,0171[2]	2,56 [1,19; 5,51] 0,0132[3]	6,8 [1,5; 12,2] 0,0132[3]
Other	26/402 (6,5)	11/414 (2,7)	2,43 [1,22; 4,86] 0,0117[2]	2,53 [1,23; 5,20] 0,0089[3]	3,8 [1,0; 6,7] 0,0089[3]
Primary tumor size (Interaction p-value: 0,3460)					
< 20 mm	16/331 (4,8)	10/334 (3,0)	1,61 [0,74; 3,51] 0,2259[2]	1,65 [0,74; 3,68] 0,2210[3]	1,8 [-1,1; 4,8] 0,2210[3]
≥ 20 but < 50 mm	54/646 (8,4)	28/653 (4,3)	1,95 [1,25; 3,04] 0,0032[2]	2,04 [1,27; 3,26] 0,0026[3]	4,1 [1,4; 6,7] 0,0026[3]
≥ 50 mm	27/289 (9,3)	7/265 (2,6)	3,54 [1,57; 7,99] 0,0024[2]	3,80 [1,63; 8,88] 0,0010[3]	6,7 [2,8; 10,6] 0,0010[3]
Number of positive lymph nodes (Interaction p-value: 0,1466)					
0-3	35/427 (8,2)	13/418 (3,1)	2,64 [1,41; 4,91] 0,0023[2]	2,78 [1,45; 5,34] 0,0014[3]	5,1 [2,0; 8,2] 0,0014[3]
4-9	32/549 (5,8)	22/542 (4,1)	1,44 [0,85; 2,44] 0,1806[2]	1,46 [0,84; 2,55] 0,1778[3]	1,8 [-0,8; 4,3] 0,1778[3]
≥ 10	32/307 (10,4)	10/304 (3,3)	3,17 [1,59; 6,33] 0,0011[2]	3,42 [1,65; 7,09] 0,0005[3]	7,1 [3,2; 11,1] 0,0005[3]
Tumor stage (Interaction p-value: 0,2090)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	6/113 (5,3)	4/114 (3,5)	1,51 [0,44; 5,22] 0,5119[2]	1,54 [0,42; 5,62] 0,5386[4]	1,8 [-3,5; 7,1] 0,5386[4]
IIB	17/151 (11,3)	6/136 (4,4)	2,55 [1,04; 6,29] 0,0417[2]	2,75 [1,05; 7,19] 0,0329[3]	6,8 [0,7; 13,0] 0,0329[3]
IIIA	31/495 (6,3)	20/488 (4,1)	1,53 [0,88; 2,64] 0,1294[2]	1,56 [0,88; 2,78] 0,1261[3]	2,2 [-0,6; 4,9] 0,1261[3]
IIIB	3/54 (5,6)	3/45 (6,7)	0,83 [0,18; 3,93] 0,8177[2]	0,82 [0,16; 4,29] 1,0000[4]	-1,1 [-10,6; 8,4] 1,0000[4]
IIIC	42/468 (9,0)	12/479 (2,5)	3,58 [1,91; 6,72] <,0001[2]	3,84 [1,99; 7,39] <,0001[3]	6,5 [3,5; 9,4] <,0001[3]
Tumor grade (Interaction p-value: 0,1420)					
G1	4/91 (4,4)	7/93 (7,5)	0,58 [0,18; 1,93] 0,3773[2]	0,56 [0,16; 2,00] 0,3704[3]	-3,1 [-9,9; 3,7] 0,3704[3]
G2	50/612 (8,2)	18/602 (3,0)	2,73 [1,61; 4,63] 0,0002[2]	2,89 [1,66; 5,01] <,0001[3]	5,2 [2,6; 7,7] <,0001[3]
G3	40/527 (7,6)	20/506 (4,0)	1,92 [1,14; 3,24] 0,0144[2]	2,00 [1,15; 3,46] 0,0125[3]	3,6 [0,8; 6,5] 0,0125[3]
GX	5/51 (9,8)	0/59 (0,0)	12,69 [0,72; 224,11] 0,0828[2]	14,08 [0,76; 261,07] 0,0192[4]	9,8 [1,6; 18,0] 0,0192[4]
Race (Interaction p-value: 0,8684)					
White	65/958 (6,8)	28/943 (3,0)	2,29 [1,48; 3,53] 0,0002[2]	2,38 [1,51; 3,74] 0,0001[3]	3,8 [1,9; 5,7] 0,0001[3]
Asian	29/250 (11,6)	15/242 (6,2)	1,87 [1,03; 3,40] 0,0399[2]	1,99 [1,04; 3,80] 0,0358[3]	5,4 [0,4; 10,4] 0,0358[3]
Other	4/62 (6,5)	2/64 (3,1)	2,06 [0,39; 10,87] 0,3924[2]	2,14 [0,38; 12,12] 0,4361[4]	3,3 [-4,1; 10,8] 0,4361[4]
First endocrine therapy (Interaction p-value: 0,7409)					
Tamoxifen	9/114 (7,9)	4/132 (3,0)	2,61 [0,82; 8,23] 0,1029[2]	2,74 [0,82; 9,16] 0,0890[3]	4,9 [-0,9; 10,6] 0,0890[3]
Aromatase inhibitor	90/1169 (7,7)	41/1132 (3,6)	2,13 [1,48; 3,05] <,0001[2]	2,22 [1,52; 3,24] <,0001[3]	4,1 [2,2; 6,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,2473)					
ECOG-PS 0	83/1070 (7,8)	40/1019 (3,9)	1,98 [1,37; 2,85] 0,0003[2]	2,06 [1,40; 3,03] 0,0002[3]	3,8 [1,8; 5,8] 0,0002[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	16/213 (7,5)	5/245 (2,0)	3,68 [1,37; 9,88] 0,0097[2]	3,90 [1,40; 10,83] 0,0052[3]	5,5 [1,5; 9,4] 0,0052[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 365.1.2: Subgroups - adverse events according PT Rash from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5579)					
< 65 years	77/918 (8,4)	28/936 (3,0)	2,80 [1,84; 4,28] <,0001[2]	2,97 [1,91; 4,62] <,0001[3]	5,4 [3,3; 7,5] <,0001[3]
≥ 65 years	36/365 (9,9)	9/328 (2,7)	3,59 [1,76; 7,35] 0,0005[2]	3,88 [1,84; 8,18] 0,0001[3]	7,1 [3,6; 10,7] 0,0001[3]
Prior treatment (Interaction p-value: 0,1768)					
Neoadjuvant chemotherapy	28/430 (6,5)	14/415 (3,4)	1,93 [1,03; 3,61] 0,0399[2]	2,00 [1,03; 3,85] 0,0359[3]	3,1 [0,2; 6,0] 0,0359[3]
Adjuvant chemotherapy	73/784 (9,3)	21/768 (2,7)	3,41 [2,12; 5,48] <,0001[2]	3,65 [2,22; 6,00] <,0001[3]	6,6 [4,2; 8,9] <,0001[3]
No chemotherapy	12/69 (17,4)	2/81 (2,5)	7,04 [1,63; 30,39] 0,0089[2]	8,32 [1,79; 38,60] 0,0017[3]	14,9 [5,4; 24,5] 0,0017[3]
Region (Interaction p-value: 0,8347)					
North America / Europe	71/678 (10,5)	24/649 (3,7)	2,83 [1,81; 4,44] <,0001[2]	3,05 [1,89; 4,90] <,0001[3]	6,8 [4,1; 9,5] <,0001[3]
Asia	23/203 (11,3)	8/201 (4,0)	2,85 [1,30; 6,21] 0,0086[2]	3,08 [1,34; 7,07] 0,0055[3]	7,3 [2,2; 12,5] 0,0055[3]
Other	19/402 (4,7)	5/414 (1,2)	3,91 [1,48; 10,38] 0,0061[2]	4,06 [1,50; 10,97] 0,0029[3]	3,5 [1,2; 5,8] 0,0029[3]
Primary tumor size (Interaction p-value: 0,3991)					
< 20 mm	22/331 (6,6)	8/334 (2,4)	2,77 [1,25; 6,14] 0,0118[2]	2,90 [1,27; 6,61] 0,0083[3]	4,3 [1,1; 7,4] 0,0083[3]
≥ 20 but < 50 mm	62/646 (9,6)	17/653 (2,6)	3,69 [2,18; 6,23] <,0001[2]	3,97 [2,30; 6,87] <,0001[3]	7,0 [4,4; 9,6] <,0001[3]
≥ 50 mm	27/289 (9,3)	12/265 (4,5)	2,06 [1,07; 3,99] 0,0313[2]	2,17 [1,08; 4,38] 0,0269[3]	4,8 [0,6; 9,0] 0,0269[3]
Number of positive lymph nodes (Interaction p-value: 0,5830)					
0-3	37/427 (8,7)	11/418 (2,6)	3,29 [1,70; 6,37] 0,0004[2]	3,51 [1,77; 6,98] 0,0002[3]	6,0 [3,0; 9,1] 0,0002[3]
4-9	49/549 (8,9)	14/542 (2,6)	3,46 [1,93; 6,18] <,0001[2]	3,70 [2,02; 6,78] <,0001[3]	6,3 [3,6; 9,1] <,0001[3]
≥ 10	27/307 (8,8)	12/304 (3,9)	2,23 [1,15; 4,32] 0,0176[2]	2,35 [1,17; 4,72] 0,0143[3]	4,8 [1,0; 8,7] 0,0143[3]
Tumor stage (Interaction p-value: 0,8973)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	8/113 (7,1)	4/114 (3,5)	2,02 [0,63; 6,51] 0,2403[2]	2,10 [0,61; 7,17] 0,2293[3]	3,6 [-2,2; 9,4] 0,2293[3]
IIB	17/151 (11,3)	4/136 (2,9)	3,83 [1,32; 11,10] 0,0134[2]	4,19 [1,37; 12,77] 0,0069[3]	8,3 [2,5; 14,1] 0,0069[3]
IIIA	41/495 (8,3)	12/488 (2,5)	3,37 [1,79; 6,33] 0,0002[2]	3,58 [1,86; 6,90] <,0001[3]	5,8 [3,0; 8,6] <,0001[3]
IIIB	4/54 (7,4)	0/45 (0,0)	7,53 [0,42; 136,17] 0,1718[2]	8,11 [0,42; 154,79] 0,1236[4]	7,4 [0,4; 14,4] 0,1236[4]
IIIC	42/468 (9,0)	17/479 (3,5)	2,53 [1,46; 4,38] 0,0009[2]	2,68 [1,50; 4,78] 0,0006[3]	5,4 [2,4; 8,5] 0,0006[3]
Tumor grade (Interaction p-value: 0,7146)					
G1	9/91 (9,9)	4/93 (4,3)	2,30 [0,73; 7,20] 0,1529[2]	2,44 [0,72; 8,23] 0,1391[3]	5,6 [-1,8; 13,0] 0,1391[3]
G2	58/612 (9,5)	15/602 (2,5)	3,80 [2,18; 6,64] <,0001[2]	4,10 [2,30; 7,31] <,0001[3]	7,0 [4,4; 9,6] <,0001[3]
G3	43/527 (8,2)	15/506 (3,0)	2,75 [1,55; 4,89] 0,0006[2]	2,91 [1,59; 5,30] 0,0003[3]	5,2 [2,4; 8,0] 0,0003[3]
GX	3/51 (5,9)	2/59 (3,4)	1,74 [0,30; 9,98] 0,5369[2]	1,78 [0,29; 11,10] 0,6613[4]	2,5 [-5,4; 10,4] 0,6613[4]
Progesterone receptor status (Interaction p-value: 0,3015)					
Negative	12/156 (7,7)	5/169 (3,0)	2,60 [0,94; 7,21] 0,0664[2]	2,73 [0,94; 7,94] 0,0555[3]	4,7 [-0,2; 9,6] 0,0555[3]
Positive	100/1089 (9,2)	31/1066 (2,9)	3,16 [2,13; 4,68] <,0001[2]	3,38 [2,24; 5,10] <,0001[3]	6,3 [4,3; 8,3] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,6848)					
White	84/958 (8,8)	25/943 (2,7)	3,31 [2,14; 5,12] <,0001[2]	3,53 [2,24; 5,57] <,0001[3]	6,1 [4,1; 8,2] <,0001[3]
Asian	26/250 (10,4)	9/242 (3,7)	2,80 [1,34; 5,84] 0,0063[2]	3,00 [1,38; 6,55] 0,0040[3]	6,7 [2,2; 11,2] 0,0040[3]
Other	3/62 (4,8)	2/64 (3,1)	1,55 [0,27; 8,95] 0,6253[2]	1,58 [0,25; 9,77] 0,6774[4]	1,7 [-5,1; 8,5] 0,6774[4]
First endocrine therapy (Interaction p-value: 0,9436)					
Tamoxifen	10/114 (8,8)	4/132 (3,0)	2,89 [0,93; 8,98] 0,0658[2]	3,08 [0,94; 10,09] 0,0526[3]	5,7 [-0,2; 11,7] 0,0526[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	103/1169 (8,8)	33/1132 (2,9)	3,02 [2,06; 4,43] <,0001[2]	3,22 [2,15; 4,81] <,0001[3]	5,9 [4,0; 7,8] <,0001[3]
ECOG-PS (Interaction p-value: 0,5858)					
ECOG-PS 0	96/1070 (9,0)	29/1019 (2,8)	3,15 [2,10; 4,73] <,0001[2]	3,36 [2,20; 5,14] <,0001[3]	6,1 [4,1; 8,1] <,0001[3]
ECOG-PS 1	17/213 (8,0)	8/245 (3,3)	2,44 [1,08; 5,55] 0,0327[2]	2,57 [1,09; 6,08] 0,0267[3]	4,7 [0,5; 9,0] 0,0267[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 366.1.2: Subgroups - adverse events according PT Rash maculo-papular from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9127)					
Neoadjuvant chemotherapy	4/430 (0,9)	1/415 (0,2)	3,86 [0,43; 34,40] 0,2261[2]	3,89 [0,43; 34,92] 0,3739[4]	0,7 [-0,3; 1,7] 0,3739[4]
Adjuvant chemotherapy	14/784 (1,8)	2/768 (0,3)	6,86 [1,56; 30,07] 0,0107[2]	6,96 [1,58; 30,74] 0,0029[3]	1,5 [0,5; 2,5] 0,0029[3]
No chemotherapy	3/69 (4,3)	0/81 (0,0)	8,20 [0,43; 156,04] 0,1615[2]	8,58 [0,44; 169,04] 0,0950[4]	4,3 [-0,5; 9,2] 0,0950[4]
Region (Interaction p-value: 0,9994)					
North America / Europe	11/678 (1,6)	3/649 (0,5)	3,51 [0,98; 12,52] 0,0530[2]	3,55 [0,99; 12,79] 0,0387[3]	1,2 [0,1; 2,2] 0,0387[3]
Asia	4/203 (2,0)	0/201 (0,0)	8,91 [0,48; 164,45] 0,1414[2]	9,09 [0,49; 169,95] 0,1232[4]	2,0 [0,1; 3,9] 0,1232[4]
Other	6/402 (1,5)	0/414 (0,0)	13,39 [0,76; 236,86] 0,0768[2]	13,59 [0,76; 242,03] 0,0140[4]	1,5 [0,3; 2,7] 0,0140[4]
Primary tumor size (Interaction p-value: 0,9163)					
< 20 mm	4/331 (1,2)	1/334 (0,3)	4,04 [0,45; 35,92] 0,2109[2]	4,07 [0,45; 36,64] 0,2152[4]	0,9 [-0,4; 2,2] 0,2152[4]
≥ 20 but < 50 mm	14/646 (2,2)	2/653 (0,3)	7,08 [1,61; 31,01] 0,0094[2]	7,21 [1,63; 31,85] 0,0024[3]	1,9 [0,7; 3,1] 0,0024[3]
≥ 50 mm	2/289 (0,7)	0/265 (0,0)	4,59 [0,22; 95,09] 0,3248[2]	4,62 [0,22; 96,62] 0,5000[4]	0,7 [-0,3; 1,6] 0,5000[4]
Number of positive lymph nodes (Interaction p-value: 0,9518)					
0-3	6/427 (1,4)	1/418 (0,2)	5,87 [0,71; 48,58] 0,1005[2]	5,94 [0,71; 49,58] 0,1236[4]	1,2 [-0,0; 2,4] 0,1236[4]
4-9	9/549 (1,6)	1/542 (0,2)	8,89 [1,13; 69,89] 0,0379[2]	9,02 [1,14; 71,41] 0,0209[4]	1,5 [0,3; 2,6] 0,0209[4]
≥ 10	6/307 (2,0)	1/304 (0,3)	5,94 [0,72; 49,06] 0,0980[2]	6,04 [0,72; 50,47] 0,1229[4]	1,6 [-0,1; 3,3] 0,1229[4]
Tumor stage (Interaction p-value: 0,8790)					
IIA	2/113 (1,8)	0/114 (0,0)	5,04 [0,24; 103,90] 0,2945[2]	5,13 [0,24; 108,15] 0,2467[4]	1,8 [-0,7; 4,2] 0,2467[4]
IIB	2/151 (1,3)	1/136 (0,7)	1,80 [0,17; 19,64] 0,6293[2]	1,81 [0,16; 20,21] 1,0000[4]	0,6 [-1,7; 2,9] 1,0000[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	8/495 (1,6)	1/488 (0,2)	7,89 [0,99; 62,82] 0,0511[2]	8,00 [1,00; 64,21] 0,0382[4]	1,4 [0,2; 2,6] 0,0382[4]
IIIB	0/54 (0,0)	0/45 (0,0)	NE	NE	NE
IIIC	9/468 (1,9)	1/479 (0,2)	9,21 [1,17; 72,42] 0,0348[2]	9,37 [1,18; 74,27] 0,0105[4]	1,7 [0,4; 3,0] 0,0105[4]
Tumor grade (Interaction p-value: 0,9758)					
G1	3/91 (3,3)	0/93 (0,0)	7,15 [0,37; 136,54] 0,1910[2]	7,40 [0,38; 145,22] 0,1189[4]	3,3 [-0,4; 7,0] 0,1189[4]
G2	8/612 (1,3)	1/602 (0,2)	7,87 [0,99; 62,73] 0,0514[2]	7,96 [0,99; 63,84] 0,0384[4]	1,1 [0,2; 2,1] 0,0384[4]
G3	9/527 (1,7)	2/506 (0,4)	4,32 [0,94; 19,90] 0,0604[2]	4,38 [0,94; 20,36] 0,0399[3]	1,3 [0,1; 2,5] 0,0399[3]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,9645)					
Negative	2/156 (1,3)	0/169 (0,0)	5,41 [0,26; 111,90] 0,2744[2]	5,49 [0,26; 115,15] 0,2296[4]	1,3 [-0,5; 3,0] 0,2296[4]
Positive	19/1089 (1,7)	3/1066 (0,3)	6,20 [1,84; 20,89] 0,0032[2]	6,29 [1,86; 21,32] 0,0007[3]	1,5 [0,6; 2,3] 0,0007[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9997)					
White	14/958 (1,5)	3/943 (0,3)	4,59 [1,32; 15,93] 0,0163[2]	4,65 [1,33; 16,22] 0,0081[3]	1,1 [0,3; 2,0] 0,0081[3]
Asian	4/250 (1,6)	0/242 (0,0)	8,71 [0,47; 160,97] 0,1457[2]	8,85 [0,47; 165,34] 0,1237[4]	1,6 [0,0; 3,2] 0,1237[4]
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
ECOG-PS (Interaction p-value: 0,8318)					
ECOG-PS 0	16/1070 (1,5)	2/1019 (0,2)	7,62 [1,76; 33,05] 0,0067[2]	7,72 [1,77; 33,66] 0,0013[3]	1,3 [0,5; 2,1] 0,0013[3]
ECOG-PS 1	5/213 (2,3)	1/245 (0,4)	5,75 [0,68; 48,84] 0,1090[2]	5,87 [0,68; 50,61] 0,1013[4]	1,9 [-0,2; 4,1] 0,1013[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 367.1.2: Subgroups - adverse events according PT Seroma from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,6298)					
< 65 years	11/918 (1,2)	3/936 (0,3)	3,74 [1,05; 13,36] 0,0424[2]	3,77 [1,05; 13,56] 0,0291[3]	0,9 [0,1; 1,7] 0,0291[3]
≥ 65 years	5/365 (1,4)	2/328 (0,6)	2,25 [0,44; 11,50] 0,3313[2]	2,26 [0,44; 11,75] 0,4555[4]	0,8 [-0,7; 2,2] 0,4555[4]
Prior treatment (Interaction p-value: 0,3496)					
Neoadjuvant chemotherapy	1/430 (0,2)	2/415 (0,5)	0,48 [0,04; 5,30] 0,5513[2]	0,48 [0,04; 5,33] 0,6180[4]	-0,2 [-1,1; 0,6] 0,6180[4]
Adjuvant chemotherapy	11/784 (1,4)	3/768 (0,4)	3,59 [1,01; 12,82] 0,0489[2]	3,63 [1,01; 13,06] 0,0349[3]	1,0 [0,1; 1,9] 0,0349[3]
No chemotherapy	4/69 (5,8)	0/81 (0,0)	10,54 [0,58; 192,43] 0,1119[2]	11,20 [0,59; 211,78] 0,0427[4]	5,8 [0,3; 11,3] 0,0427[4]
Region (Interaction p-value: 0,7179)					
North America / Europe	14/678 (2,1)	4/649 (0,6)	3,35 [1,11; 10,13] 0,0321[2]	3,40 [1,11; 10,38] 0,0226[3]	1,4 [0,2; 2,7] 0,0226[3]
Asia	0/203 (0,0)	0/201 (0,0)	NE	NE	NE
Other	2/402 (0,5)	1/414 (0,2)	2,06 [0,19; 22,63] 0,5546[2]	2,07 [0,19; 22,86] 0,6191[4]	0,3 [-0,6; 1,1] 0,6191[4]
Tumor stage (Interaction p-value: 0,7479)					
IIA	0/113 (0,0)	1/114 (0,9)	0,34 [0,01; 8,17] 0,5031[2]	0,33 [0,01; 8,27] 1,0000[4]	-0,9 [-2,6; 0,8] 1,0000[4]
IIB	1/151 (0,7)	0/136 (0,0)	2,70 [0,11; 65,82] 0,5414[2]	2,72 [0,11; 67,35] 1,0000[4]	0,7 [-0,6; 2,0] 1,0000[4]
IIIA	9/495 (1,8)	1/488 (0,2)	8,87 [1,13; 69,77] 0,0380[2]	9,02 [1,14; 71,46] 0,0209[4]	1,6 [0,4; 2,9] 0,0209[4]
IIIB	1/54 (1,9)	1/45 (2,2)	0,83 [0,05; 12,95] 0,8964[2]	0,83 [0,05; 13,66] 1,0000[4]	-0,4 [-6,0; 5,2] 1,0000[4]
IIIC	5/468 (1,1)	2/479 (0,4)	2,56 [0,50; 13,12] 0,2600[2]	2,58 [0,50; 13,34] 0,2820[4]	0,7 [-0,4; 1,7] 0,2820[4]
Race (Interaction p-value: 0,9909)					
White	15/958 (1,6)	5/943 (0,5)	2,95 [1,08; 8,09] 0,0353[2]	2,98 [1,08; 8,24] 0,0269[3]	1,0 [0,1; 1,9] 0,0269[3]
Asian	0/250 (0,0)	0/242 (0,0)	NE	NE	NE

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
ECOG-PS (Interaction p-value: 0,7040)					
ECOG-PS 0	12/1070 (1,1)	4/1019 (0,4)	2,86 [0,92; 8,83] 0,0682[2]	2,88 [0,93; 8,95] 0,0561[3]	0,7 [-0,0; 1,5] 0,0561[3]
ECOG-PS 1	4/213 (1,9)	1/245 (0,4)	4,60 [0,52; 40,85] 0,1707[2]	4,67 [0,52; 42,11] 0,1885[4]	1,5 [-0,5; 3,5] 0,1885[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 368.1.2: Subgroups - adverse events according PT Stomatitis from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,6410)					
< 65 years	48/918 (5,2)	8/936 (0,9)	6,12 [2,91; 12,86] <,0001[2]	6,40 [3,01; 13,61] <,0001[3]	4,4 [2,8; 5,9] <,0001[3]
≥ 65 years	20/365 (5,5)	4/328 (1,2)	4,49 [1,55; 13,01] 0,0056[2]	4,70 [1,59; 13,88] 0,0022[3]	4,3 [1,6; 6,9] 0,0022[3]
Prior treatment (Interaction p-value: 0,7134)					
Neoadjuvant chemotherapy	16/430 (3,7)	4/415 (1,0)	3,86 [1,30; 11,45] 0,0149[2]	3,97 [1,32; 11,98] 0,0084[3]	2,8 [0,7; 4,8] 0,0084[3]
Adjuvant chemotherapy	48/784 (6,1)	7/768 (0,9)	6,72 [3,06; 14,75] <,0001[2]	7,09 [3,19; 15,77] <,0001[3]	5,2 [3,4; 7,0] <,0001[3]
No chemotherapy	4/69 (5,8)	1/81 (1,2)	4,70 [0,54; 41,03] 0,1620[2]	4,92 [0,54; 45,13] 0,1807[4]	4,6 [-1,5; 10,6] 0,1807[4]
Region (Interaction p-value: 0,9290)					
North America / Europe	31/678 (4,6)	6/649 (0,9)	4,95 [2,08; 11,78] 0,0003[2]	5,13 [2,13; 12,39] <,0001[3]	3,6 [1,9; 5,4] <,0001[3]
Asia	26/203 (12,8)	4/201 (2,0)	6,44 [2,29; 18,11] 0,0004[2]	7,23 [2,48; 21,13] <,0001[3]	10,8 [5,8; 15,8] <,0001[3]
Other	11/402 (2,7)	2/414 (0,5)	5,66 [1,26; 25,39] 0,0235[2]	5,80 [1,28; 26,31] 0,0102[3]	2,3 [0,5; 4,0] 0,0102[3]
Primary tumor size (Interaction p-value: 0,3263)					
< 20 mm	16/331 (4,8)	1/334 (0,3)	16,15 [2,15; 121,05] 0,0068[2]	16,91 [2,23; 128,29] 0,0002[3]	4,5 [2,2; 6,9] 0,0002[3]
≥ 20 but < 50 mm	33/646 (5,1)	6/653 (0,9)	5,56 [2,35; 13,18] <,0001[2]	5,81 [2,42; 13,95] <,0001[3]	4,2 [2,3; 6,0] <,0001[3]
≥ 50 mm	17/289 (5,9)	5/265 (1,9)	3,12 [1,17; 8,33] 0,0234[2]	3,25 [1,18; 8,94] 0,0161[3]	4,0 [0,8; 7,2] 0,0161[3]
Number of positive lymph nodes (Interaction p-value: 0,2772)					
0-3	23/427 (5,4)	1/418 (0,2)	22,52 [3,05; 165,96] 0,0022[2]	23,74 [3,19; 176,61] <,0001[3]	5,1 [3,0; 7,3] <,0001[3]
4-9	29/549 (5,3)	7/542 (1,3)	4,09 [1,81; 9,26] 0,0007[2]	4,26 [1,85; 9,82] 0,0002[3]	4,0 [1,9; 6,1] 0,0002[3]
≥ 10	16/307 (5,2)	4/304 (1,3)	3,96 [1,34; 11,71] 0,0128[2]	4,12 [1,36; 12,48] 0,0068[3]	3,9 [1,1; 6,7] 0,0068[3]
Tumor stage (Interaction p-value: 0,9978)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	6/113 (5,3)	1/114 (0,9)	6,05 [0,74; 49,48] 0,0930[2]	6,34 [0,75; 53,50] 0,0655[4]	4,4 [-0,0; 8,9] 0,0655[4]
IIB	7/151 (4,6)	0/136 (0,0)	13,52 [0,78; 234,52] 0,0737[2]	14,17 [0,80; 250,47] 0,0154[4]	4,6 [1,3; 8,0] 0,0154[4]
IIIA	26/495 (5,3)	5/488 (1,0)	5,13 [1,98; 13,24] 0,0007[2]	5,36 [2,04; 14,06] 0,0001[3]	4,2 [2,1; 6,4] 0,0001[3]
IIIB	3/54 (5,6)	0/45 (0,0)	5,85 [0,31; 110,43] 0,2383[2]	6,18 [0,31; 122,97] 0,2486[4]	5,6 [-0,6; 11,7] 0,2486[4]
IIIC	25/468 (5,3)	6/479 (1,3)	4,26 [1,77; 10,30] 0,0013[2]	4,45 [1,81; 10,95] 0,0004[3]	4,1 [1,8; 6,4] 0,0004[3]
Tumor grade (Interaction p-value: 0,5400)					
G1	4/91 (4,4)	0/93 (0,0)	9,20 [0,50; 168,39] 0,1348[2]	9,62 [0,51; 181,24] 0,0578[4]	4,4 [0,2; 8,6] 0,0578[4]
G2	31/612 (5,1)	9/602 (1,5)	3,39 [1,63; 7,06] 0,0011[2]	3,52 [1,66; 7,45] 0,0005[3]	3,6 [1,6; 5,6] 0,0005[3]
G3	30/527 (5,7)	3/506 (0,6)	9,60 [2,95; 31,26] 0,0002[2]	10,12 [3,07; 33,38] <,0001[3]	5,1 [3,0; 7,2] <,0001[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesterone receptor status (Interaction p-value: 0,9384)					
Negative	17/156 (10,9)	0/169 (0,0)	37,90 [2,30; 624,93] 0,0110[2]	42,53 [2,53; 713,50] <,0001[3]	10,9 [6,0; 15,8] <,0001[3]
Positive	51/1089 (4,7)	12/1066 (1,1)	4,16 [2,23; 7,76] <,0001[2]	4,32 [2,29; 8,14] <,0001[3]	3,6 [2,2; 5,0] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,8239)					
White	38/958 (4,0)	8/943 (0,8)	4,68 [2,19; 9,97] <,0001[2]	4,83 [2,24; 10,40] <,0001[3]	3,1 [1,8; 4,5] <,0001[3]
Asian	29/250 (11,6)	4/242 (1,7)	7,02 [2,50; 19,66] 0,0002[2]	7,81 [2,70; 22,57] <,0001[3]	9,9 [5,7; 14,2] <,0001[3]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,3279)					
Tamoxifen	8/114 (7,0)	3/132 (2,3)	3,09 [0,84; 11,36] 0,0899[2]	3,25 [0,84; 12,54] 0,0726[3]	4,7 [-0,6; 10,1] 0,0726[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	60/1169 (5,1)	9/1132 (0,8)	6,46 [3,22; 12,95] <,0001[2]	6,75 [3,33; 13,67] <,0001[3]	4,3 [3,0; 5,7] <,0001[3]
ECOG-PS (Interaction p-value: 0,4489)					
ECOG-PS 0	58/1070 (5,4)	11/1019 (1,1)	5,02 [2,65; 9,51] <,0001[2]	5,25 [2,74; 10,06] <,0001[3]	4,3 [2,8; 5,8] <,0001[3]
ECOG-PS 1	10/213 (4,7)	1/245 (0,4)	11,50 [1,48; 89,12] 0,0194[2]	12,02 [1,53; 94,69] 0,0028[3]	4,3 [1,3; 7,2] 0,0028[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 369.1.2: Subgroups - adverse events according PT Taste disorder from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7795)					
< 65 years	12/918 (1,3)	1/936 (0,1)	12,24 [1,59; 93,91] 0,0160[2]	12,38 [1,61; 95,44] 0,0020[3]	1,2 [0,4; 2,0] 0,0020[3]
≥ 65 years	9/365 (2,5)	1/328 (0,3)	8,09 [1,03; 63,49] 0,0468[2]	8,27 [1,04; 65,61] 0,0223[4]	2,2 [0,5; 3,9] 0,0223[4]
Prior treatment (Interaction p-value: 0,9720)					
Neoadjuvant chemotherapy	3/430 (0,7)	0/415 (0,0)	6,76 [0,35; 130,40] 0,2059[2]	6,80 [0,35; 132,12] 0,2493[4]	0,7 [-0,1; 1,5] 0,2493[4]
Adjuvant chemotherapy	17/784 (2,2)	2/768 (0,3)	8,33 [1,93; 35,92] 0,0045[2]	8,49 [1,95; 36,87] 0,0006[3]	1,9 [0,8; 3,0] 0,0006[3]
No chemotherapy	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Region (Interaction p-value: 0,9756)					
North America / Europe	14/678 (2,1)	2/649 (0,3)	6,70 [1,53; 29,37] 0,0116[2]	6,82 [1,54; 30,13] 0,0034[3]	1,8 [0,6; 2,9] 0,0034[3]
Asia	0/203 (0,0)	0/201 (0,0)	NE	NE	NE
Other	7/402 (1,7)	0/414 (0,0)	15,45 [0,89; 269,57] 0,0606[2]	15,72 [0,89; 276,16] 0,0069[4]	1,7 [0,5; 3,0] 0,0069[4]
Primary tumor size (Interaction p-value: 0,9210)					
< 20 mm	5/331 (1,5)	0/334 (0,0)	11,10 [0,62; 199,93] 0,1027[2]	11,27 [0,62; 204,62] 0,0301[4]	1,5 [0,2; 2,8] 0,0301[4]
≥ 20 but < 50 mm	10/646 (1,5)	1/653 (0,2)	10,11 [1,30; 78,74] 0,0272[2]	10,25 [1,31; 80,32] 0,0061[3]	1,4 [0,4; 2,4] 0,0061[3]
≥ 50 mm	6/289 (2,1)	1/265 (0,4)	5,50 [0,67; 45,40] 0,1133[2]	5,60 [0,67; 46,80] 0,1251[4]	1,7 [-0,1; 3,5] 0,1251[4]
Number of positive lymph nodes (Interaction p-value: 0,8184)					
0-3	3/427 (0,7)	0/418 (0,0)	6,85 [0,36; 132,26] 0,2025[2]	6,90 [0,36; 134,01] 0,2492[4]	0,7 [-0,1; 1,5] 0,2492[4]
4-9	13/549 (2,4)	1/542 (0,2)	12,83 [1,68; 97,77] 0,0138[2]	13,12 [1,71; 100,65] 0,0014[3]	2,2 [0,9; 3,5] 0,0014[3]
≥ 10	5/307 (1,6)	1/304 (0,3)	4,95 [0,58; 42,13] 0,1431[2]	5,02 [0,58; 43,19] 0,2165[4]	1,3 [-0,3; 2,9] 0,2165[4]
Tumor stage (Interaction p-value: 1,0000)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	1/113 (0,9)	0/114 (0,0)	3,03 [0,12; 73,51] 0,4963[2]	3,05 [0,12; 75,75] 0,4978[4]	0,9 [-0,8; 2,6] 0,4978[4]
IIB	0/151 (0,0)	0/136 (0,0)	NE	NE	NE
IIIA	10/495 (2,0)	0/488 (0,0)	20,70 [1,22; 352,34] 0,0361[2]	21,13 [1,23; 361,59] 0,0019[4]	2,0 [0,8; 3,3] 0,0019[4]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	8/468 (1,7)	2/479 (0,4)	4,09 [0,87; 19,18] 0,0736[2]	4,15 [0,88; 19,64] 0,0613[4]	1,3 [-0,0; 2,6] 0,0613[4]
Tumor grade (Interaction p-value: 0,5170)					
G1	2/91 (2,2)	1/93 (1,1)	2,04 [0,19; 22,15] 0,5565[2]	2,07 [0,18; 23,21] 0,6189[4]	1,1 [-2,5; 4,8] 0,6189[4]
G2	13/612 (2,1)	1/602 (0,2)	12,79 [1,68; 97,45] 0,0139[2]	13,04 [1,70; 100,02] 0,0014[3]	2,0 [0,8; 3,1] 0,0014[3]
G3	6/527 (1,1)	0/506 (0,0)	12,48 [0,71; 221,01] 0,0851[2]	12,63 [0,71; 224,71] 0,0310[4]	1,1 [0,2; 2,0] 0,0310[4]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,2089)					
Negative	6/156 (3,8)	1/169 (0,6)	6,50 [0,79; 53,39] 0,0815[2]	6,72 [0,80; 56,46] 0,0582[4]	3,3 [0,0; 6,5] 0,0582[4]
Positive	15/1089 (1,4)	1/1066 (0,1)	14,68 [1,94; 110,96] 0,0092[2]	14,87 [1,96; 112,80] 0,0005[3]	1,3 [0,6; 2,0] 0,0005[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9867)					
White	20/958 (2,1)	1/943 (0,1)	19,69 [2,65; 146,39] 0,0036[2]	20,09 [2,69; 149,96] <,0001[3]	2,0 [1,1; 2,9] <,0001[3]
Asian	1/250 (0,4)	0/242 (0,0)	2,90 [0,12; 70,95] 0,5132[2]	2,92 [0,12; 71,93] 1,0000[4]	0,4 [-0,4; 1,2] 1,0000[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,2949)					
Tamoxifen	3/114 (2,6)	1/132 (0,8)	3,47 [0,37; 32,93] 0,2779[2]	3,54 [0,36; 34,52] 0,3391[4]	1,9 [-1,4; 5,2] 0,3391[4]
Aromatase inhibitor	18/1169 (1,5)	1/1132 (0,1)	17,43 [2,33; 130,35] 0,0054[2]	17,69 [2,36; 132,71] 0,0001[3]	1,5 [0,7; 2,2] 0,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS (Interaction p-value: 0,5162)					
ECOG-PS 0	16/1070 (1,5)	1/1019 (0,1)	15,24 [2,02; 114,69] 0,0082[2]	15,45 [2,05; 116,74] 0,0004[3]	1,4 [0,6; 2,1] 0,0004[3]
ECOG-PS 1	5/213 (2,3)	1/245 (0,4)	5,75 [0,68; 48,84] 0,1090[2]	5,87 [0,68; 50,61] 0,1013[4]	1,9 [-0,2; 4,1] 0,1013[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 370.1.2: Subgroups - adverse events according PT Thrombocytopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1111)					
< 65 years	48/918 (5,2)	8/936 (0,9)	6,12 [2,91; 12,86] <,0001[2]	6,40 [3,01; 13,61] <,0001[3]	4,4 [2,8; 5,9] <,0001[3]
≥ 65 years	38/365 (10,4)	1/328 (0,3)	34,15 [4,71; 247,32] 0,0005[2]	38,00 [5,19; 278,41] <,0001[3]	10,1 [6,9; 13,3] <,0001[3]
Prior treatment (Interaction p-value: 0,9425)					
Neoadjuvant chemotherapy	24/430 (5,6)	3/415 (0,7)	7,72 [2,34; 25,45] 0,0008[2]	8,12 [2,43; 27,17] <,0001[3]	4,9 [2,5; 7,2] <,0001[3]
Adjuvant chemotherapy	61/784 (7,8)	6/768 (0,8)	9,96 [4,33; 22,90] <,0001[2]	10,72 [4,60; 24,94] <,0001[3]	7,0 [5,0; 9,0] <,0001[3]
No chemotherapy	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Region (Interaction p-value: 0,5761)					
North America / Europe	42/678 (6,2)	3/649 (0,5)	13,40 [4,17; 43,02] <,0001[2]	14,22 [4,39; 46,11] <,0001[3]	5,7 [3,8; 7,6] <,0001[3]
Asia	8/203 (3,9)	0/201 (0,0)	16,83 [0,98; 289,71] 0,0518[2]	17,52 [1,00; 305,63] 0,0073[4]	3,9 [1,3; 6,6] 0,0073[4]
Other	36/402 (9,0)	6/414 (1,4)	6,18 [2,63; 14,50] <,0001[2]	6,69 [2,79; 16,06] <,0001[3]	7,5 [4,5; 10,5] <,0001[3]
Primary tumor size (Interaction p-value: 0,6590)					
< 20 mm	19/331 (5,7)	2/334 (0,6)	9,59 [2,25; 40,83] 0,0022[2]	10,11 [2,34; 43,76] 0,0002[3]	5,1 [2,5; 7,8] 0,0002[3]
≥ 20 but < 50 mm	44/646 (6,8)	6/653 (0,9)	7,41 [3,18; 17,27] <,0001[2]	7,88 [3,33; 18,63] <,0001[3]	5,9 [3,8; 8,0] <,0001[3]
≥ 50 mm	22/289 (7,6)	1/265 (0,4)	20,17 [2,74; 148,62] 0,0032[2]	21,75 [2,91; 162,55] <,0001[3]	7,2 [4,1; 10,4] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,3425)					
0-3	25/427 (5,9)	4/418 (1,0)	6,12 [2,15; 17,43] 0,0007[2]	6,44 [2,22; 18,66] <,0001[3]	4,9 [2,5; 7,3] <,0001[3]
4-9	42/549 (7,7)	2/542 (0,4)	20,73 [5,04; 85,22] <,0001[2]	22,37 [5,39; 92,88] <,0001[3]	7,3 [5,0; 9,6] <,0001[3]
≥ 10	19/307 (6,2)	3/304 (1,0)	6,27 [1,88; 20,97] 0,0029[2]	6,62 [1,94; 22,61] 0,0006[3]	5,2 [2,3; 8,1] 0,0006[3]
Tumor stage (Interaction p-value: 0,9663)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	5/113 (4,4)	1/114 (0,9)	5,04 [0,60; 42,50] 0,1367[2]	5,23 [0,60; 45,51] 0,1192[4]	3,5 [-0,6; 7,7] 0,1192[4]
IIB	10/151 (6,6)	1/136 (0,7)	9,01 [1,17; 69,44] 0,0349[2]	9,57 [1,21; 75,81] 0,0095[3]	5,9 [1,7; 10,1] 0,0095[3]
IIIA	37/495 (7,5)	3/488 (0,6)	12,16 [3,77; 39,17] <,0001[2]	13,06 [4,00; 42,65] <,0001[3]	6,9 [4,4; 9,3] <,0001[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	32/468 (6,8)	4/479 (0,8)	8,19 [2,92; 22,97] <,0001[2]	8,72 [3,06; 24,84] <,0001[3]	6,0 [3,6; 8,4] <,0001[3]
Tumor grade (Interaction p-value: 0,9986)					
G1	4/91 (4,4)	0/93 (0,0)	9,20 [0,50; 168,39] 0,1348[2]	9,62 [0,51; 181,24] 0,0578[4]	4,4 [0,2; 8,6] 0,0578[4]
G2	37/612 (6,0)	4/602 (0,7)	9,10 [3,26; 25,37] <,0001[2]	9,62 [3,41; 27,16] <,0001[3]	5,4 [3,4; 7,4] <,0001[3]
G3	42/527 (8,0)	5/506 (1,0)	8,07 [3,22; 20,22] <,0001[2]	8,68 [3,40; 22,12] <,0001[3]	7,0 [4,5; 9,4] <,0001[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesterone receptor status (Interaction p-value: 0,5703)					
Negative	13/156 (8,3)	2/169 (1,2)	7,04 [1,61; 30,71] 0,0094[2]	7,59 [1,68; 34,20] 0,0021[3]	7,1 [2,5; 11,8] 0,0021[3]
Positive	73/1089 (6,7)	7/1066 (0,7)	10,21 [4,72; 22,07] <,0001[2]	10,87 [4,98; 23,72] <,0001[3]	6,0 [4,5; 7,6] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,1628)					
White	71/958 (7,4)	7/943 (0,7)	9,98 [4,62; 21,59] <,0001[2]	10,70 [4,90; 23,39] <,0001[3]	6,7 [4,9; 8,4] <,0001[3]
Asian	12/250 (4,8)	0/242 (0,0)	24,20 [1,44; 406,54] 0,0268[2]	25,42 [1,50; 431,75] 0,0006[3]	4,8 [2,2; 7,4] 0,0006[3]
Other	3/62 (4,8)	2/64 (3,1)	1,55 [0,27; 8,95] 0,6253[2]	1,58 [0,25; 9,77] 0,6774[4]	1,7 [-5,1; 8,5] 0,6774[4]
ECOG-PS (Interaction p-value: 0,4654)					
ECOG-PS 0	60/1070 (5,6)	7/1019 (0,7)	8,16 [3,75; 17,77] <,0001[2]	8,59 [3,91; 18,88] <,0001[3]	4,9 [3,5; 6,4] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	26/213 (12,2)	2/245 (0,8)	14,95 [3,59; 62,26] 0,0002[2]	16,89 [3,96; 72,07] <,0001[3]	11,4 [6,9; 15,9] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 371.1.2: Subgroups - adverse events according PT Urinary tract infection from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9075)					
< 65 years	81/918 (8,8)	49/936 (5,2)	1,69 [1,20; 2,37] 0,0028[2]	1,75 [1,21; 2,53] 0,0025[3]	3,6 [1,3; 5,9] 0,0025[3]
≥ 65 years	37/365 (10,1)	19/328 (5,8)	1,75 [1,03; 2,98] 0,0395[2]	1,83 [1,03; 3,26] 0,0362[3]	4,3 [0,3; 8,3] 0,0362[3]
Prior treatment (Interaction p-value: 0,0838)					
Neoadjuvant chemotherapy	35/430 (8,1)	10/415 (2,4)	3,38 [1,69; 6,73] 0,0005[2]	3,59 [1,75; 7,35] 0,0002[3]	5,7 [2,8; 8,7] 0,0002[3]
Adjuvant chemotherapy	77/784 (9,8)	53/768 (6,9)	1,42 [1,02; 1,99] 0,0392[2]	1,47 [1,02; 2,12] 0,0379[3]	2,9 [0,2; 5,7] 0,0379[3]
No chemotherapy	6/69 (8,7)	5/81 (6,2)	1,41 [0,45; 4,42] 0,5567[2]	1,45 [0,42; 4,97] 0,5547[3]	2,5 [-5,9; 11,0] 0,5547[3]
Region (Interaction p-value: 0,6528)					
North America / Europe	83/678 (12,2)	51/649 (7,9)	1,56 [1,12; 2,17] 0,0088[2]	1,64 [1,13; 2,36] 0,0081[3]	4,4 [1,2; 7,6] 0,0081[3]
Asia	5/203 (2,5)	2/201 (1,0)	2,48 [0,49; 12,61] 0,2752[2]	2,51 [0,48; 13,10] 0,4491[4]	1,5 [-1,1; 4,0] 0,4491[4]
Other	30/402 (7,5)	15/414 (3,6)	2,06 [1,13; 3,77] 0,0191[2]	2,15 [1,14; 4,05] 0,0163[3]	3,8 [0,7; 7,0] 0,0163[3]
Primary tumor size (Interaction p-value: 0,9063)					
< 20 mm	24/331 (7,3)	13/334 (3,9)	1,86 [0,97; 3,60] 0,0637[2]	1,93 [0,97; 3,86] 0,0589[3]	3,4 [-0,1; 6,8] 0,0589[3]
≥ 20 but < 50 mm	54/646 (8,4)	32/653 (4,9)	1,71 [1,12; 2,61] 0,0135[2]	1,77 [1,13; 2,78] 0,0122[3]	3,5 [0,8; 6,2] 0,0122[3]
≥ 50 mm	39/289 (13,5)	23/265 (8,7)	1,55 [0,95; 2,53] 0,0760[2]	1,64 [0,95; 2,83] 0,0725[3]	4,8 [-0,4; 10,0] 0,0725[3]
Number of positive lymph nodes (Interaction p-value: 0,8554)					
0-3	36/427 (8,4)	20/418 (4,8)	1,76 [1,04; 2,99] 0,0361[2]	1,83 [1,04; 3,22] 0,0331[3]	3,6 [0,3; 7,0] 0,0331[3]
4-9	50/549 (9,1)	27/542 (5,0)	1,83 [1,16; 2,88] 0,0090[2]	1,91 [1,18; 3,10] 0,0078[3]	4,1 [1,1; 7,2] 0,0078[3]
≥ 10	32/307 (10,4)	21/304 (6,9)	1,51 [0,89; 2,56] 0,1261[2]	1,57 [0,88; 2,79] 0,1227[3]	3,5 [-0,9; 8,0] 0,1227[3]
Tumor stage (Interaction p-value: 0,6520)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	13/113 (11,5)	6/114 (5,3)	2,19 [0,86; 5,55] 0,1000[2]	2,34 [0,86; 6,39] 0,0896[3]	6,2 [-0,9; 13,4] 0,0896[3]
IIB	9/151 (6,0)	9/136 (6,6)	0,90 [0,37; 2,20] 0,8187[2]	0,89 [0,34; 2,32] 0,8186[3]	-0,7 [-6,3; 5,0] 0,8186[3]
IIIA	48/495 (9,7)	27/488 (5,5)	1,75 [1,11; 2,76] 0,0156[2]	1,83 [1,12; 2,99] 0,0139[3]	4,2 [0,9; 7,5] 0,0139[3]
IIIB	3/54 (5,6)	1/45 (2,2)	2,50 [0,27; 23,21] 0,4203[2]	2,59 [0,26; 25,79] 0,6237[4]	3,3 [-4,1; 10,8] 0,6237[4]
IIIC	45/468 (9,6)	25/479 (5,2)	1,84 [1,15; 2,95] 0,0112[2]	1,93 [1,16; 3,21] 0,0097[3]	4,4 [1,1; 7,7] 0,0097[3]
Tumor grade (Interaction p-value: 0,7168)					
G1	7/91 (7,7)	4/93 (4,3)	1,79 [0,54; 5,90] 0,3399[2]	1,85 [0,52; 6,56] 0,3320[3]	3,4 [-3,5; 10,2] 0,3320[3]
G2	62/612 (10,1)	37/602 (6,1)	1,65 [1,11; 2,44] 0,0123[2]	1,72 [1,13; 2,63] 0,0112[3]	4,0 [0,9; 7,0] 0,0112[3]
G3	44/527 (8,3)	26/506 (5,1)	1,62 [1,02; 2,60] 0,0426[2]	1,68 [1,02; 2,78] 0,0401[3]	3,2 [0,2; 6,3] 0,0401[3]
GX	5/51 (9,8)	1/59 (1,7)	5,78 [0,70; 47,91] 0,1037[2]	6,30 [0,71; 55,86] 0,0942[4]	8,1 [-0,7; 16,9] 0,0942[4]
Race (Interaction p-value: 0,7490)					
White	105/958 (11,0)	57/943 (6,0)	1,81 [1,33; 2,47] 0,0002[2]	1,91 [1,37; 2,68] 0,0001[3]	4,9 [2,4; 7,4] 0,0001[3]
Asian	5/250 (2,0)	4/242 (1,7)	1,21 [0,33; 4,45] 0,7743[2]	1,21 [0,32; 4,58] 1,0000[4]	0,3 [-2,0; 2,7] 1,0000[4]
Other	8/62 (12,9)	6/64 (9,4)	1,38 [0,51; 3,74] 0,5309[2]	1,43 [0,47; 4,40] 0,5287[3]	3,5 [-7,5; 14,5] 0,5287[3]
First endocrine therapy (Interaction p-value: 0,1329)					
Tamoxifen	9/114 (7,9)	2/132 (1,5)	5,21 [1,15; 23,62] 0,0323[2]	5,57 [1,18; 26,34] 0,0158[3]	6,4 [1,0; 11,8] 0,0158[3]
Aromatase inhibitor	109/1169 (9,3)	66/1132 (5,8)	1,60 [1,19; 2,15] 0,0018[2]	1,66 [1,21; 2,28] 0,0016[3]	3,5 [1,3; 5,6] 0,0016[3]
ECOG-PS (Interaction p-value: 0,5950)					
ECOG-PS 0	92/1070 (8,6)	53/1019 (5,2)	1,65 [1,19; 2,29] 0,0026[2]	1,71 [1,21; 2,43] 0,0023[3]	3,4 [1,2; 5,6] 0,0023[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	26/213 (12,2)	15/245 (6,1)	1,99 [1,09; 3,66] 0,0262[2]	2,13 [1,10; 4,14] 0,0229[3]	6,1 [0,8; 11,4] 0,0229[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 372.1.2: Subgroups - adverse events according PT Viral infection from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,2126)					
< 65 years	13/918 (1,4)	1/936 (0,1)	13,25 [1,74; 101,12] 0,0127[2]	13,43 [1,75; 102,88] 0,0011[3]	1,3 [0,5; 2,1] 0,0011[3]
≥ 65 years	2/365 (0,5)	1/328 (0,3)	1,80 [0,16; 19,73] 0,6315[2]	1,80 [0,16; 19,96] 1,0000[4]	0,2 [-0,7; 1,2] 1,0000[4]
Prior treatment (Interaction p-value: 0,9831)					
Neoadjuvant chemotherapy	6/430 (1,4)	0/415 (0,0)	12,55 [0,71; 222,03] 0,0844[2]	12,72 [0,71; 226,59] 0,0308[4]	1,4 [0,3; 2,5] 0,0308[4]
Adjuvant chemotherapy	9/784 (1,1)	2/768 (0,3)	4,41 [0,96; 20,34] 0,0572[2]	4,45 [0,96; 20,65] 0,0372[3]	0,9 [0,1; 1,7] 0,0372[3]
No chemotherapy	0/69 (0,0)	0/81 (0,0)	NE	NE	NE
Region (Interaction p-value: 0,9779)					
North America / Europe	13/678 (1,9)	2/649 (0,3)	6,22 [1,41; 27,46] 0,0158[2]	6,32 [1,42; 28,13] 0,0056[3]	1,6 [0,5; 2,7] 0,0056[3]
Asia	0/203 (0,0)	0/201 (0,0)	NE	NE	NE
Other	2/402 (0,5)	0/414 (0,0)	5,15 [0,25; 106,92] 0,2896[2]	5,17 [0,25; 108,12] 0,2424[4]	0,5 [-0,2; 1,2] 0,2424[4]
Tumor grade (Interaction p-value: 0,5765)					
G1	1/91 (1,1)	0/93 (0,0)	3,07 [0,13; 74,28] 0,4910[2]	3,10 [0,12; 77,08] 0,4946[4]	1,1 [-1,0; 3,2] 0,4946[4]
G2	5/612 (0,8)	1/602 (0,2)	4,92 [0,58; 41,97] 0,1453[2]	4,95 [0,58; 42,50] 0,2177[4]	0,7 [-0,1; 1,4] 0,2177[4]
G3	9/527 (1,7)	1/506 (0,2)	8,64 [1,10; 67,96] 0,0404[2]	8,77 [1,11; 69,51] 0,0211[4]	1,5 [0,3; 2,7] 0,0211[4]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,9634)					
Negative	2/156 (1,3)	0/169 (0,0)	5,41 [0,26; 111,90] 0,2744[2]	5,49 [0,26; 115,15] 0,2296[4]	1,3 [-0,5; 3,0] 0,2296[4]
Positive	13/1089 (1,2)	2/1066 (0,2)	6,36 [1,44; 28,13] 0,0147[2]	6,43 [1,45; 28,55] 0,0050[3]	1,0 [0,3; 1,7] 0,0050[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9853)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
White	14/958 (1,5)	2/943 (0,2)	6,89 [1,57; 30,23] 0,0105[2]	6,98 [1,58; 30,79] 0,0029[3]	1,2 [0,4; 2,1] 0,0029[3]
Asian	1/250 (0,4)	0/242 (0,0)	2,90 [0,12; 70,95] 0,5132[2]	2,92 [0,12; 71,93] 1,0000[4]	0,4 [-0,4; 1,2] 1,0000[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,9757)					
ECOG-PS 0	13/1070 (1,2)	2/1019 (0,2)	6,19 [1,40; 27,36] 0,0162[2]	6,25 [1,41; 27,78] 0,0058[3]	1,0 [0,3; 1,7] 0,0058[3]
ECOG-PS 1	2/213 (0,9)	0/245 (0,0)	5,75 [0,28; 119,06] 0,2581[2]	5,80 [0,28; 121,56] 0,2157[4]	0,9 [-0,4; 2,2] 0,2157[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 373.1.2: Subgroups - adverse events according PT Vision blurred from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1761)					
< 65 years	23/918 (2,5)	6/936 (0,6)	3,91 [1,60; 9,55] 0,0028[2]	3,98 [1,61; 9,83] 0,0012[3]	1,9 [0,7; 3,0] 0,0012[3]
≥ 65 years	6/365 (1,6)	4/328 (1,2)	1,35 [0,38; 4,73] 0,6414[2]	1,35 [0,38; 4,84] 0,7557[4]	0,4 [-1,3; 2,2] 0,7557[4]
Prior treatment (Interaction p-value: 0,7756)					
Neoadjuvant chemotherapy	11/430 (2,6)	4/415 (1,0)	2,65 [0,85; 8,27] 0,0923[2]	2,70 [0,85; 8,54] 0,0793[3]	1,6 [-0,2; 3,4] 0,0793[3]
Adjuvant chemotherapy	17/784 (2,2)	5/768 (0,7)	3,33 [1,23; 8,98] 0,0175[2]	3,38 [1,24; 9,21] 0,0115[3]	1,5 [0,3; 2,7] 0,0115[3]
No chemotherapy	1/69 (1,4)	1/81 (1,2)	1,17 [0,07; 18,42] 0,9091[2]	1,18 [0,07; 19,17] 1,0000[4]	0,2 [-3,5; 3,9] 1,0000[4]
Region (Interaction p-value: 0,5704)					
North America / Europe	22/678 (3,2)	6/649 (0,9)	3,51 [1,43; 8,60] 0,0060[2]	3,59 [1,45; 8,92] 0,0033[3]	2,3 [0,8; 3,8] 0,0033[3]
Asia	3/203 (1,5)	1/201 (0,5)	2,97 [0,31; 28,32] 0,3440[2]	3,00 [0,31; 29,09] 0,6232[4]	1,0 [-0,9; 2,9] 0,6232[4]
Other	4/402 (1,0)	3/414 (0,7)	1,37 [0,31; 6,10] 0,6767[2]	1,38 [0,31; 6,19] 0,7217[4]	0,3 [-1,0; 1,5] 0,7217[4]
Primary tumor size (Interaction p-value: 0,2525)					
< 20 mm	11/331 (3,3)	2/334 (0,6)	5,55 [1,24; 24,85] 0,0250[2]	5,71 [1,25; 25,95] 0,0112[3]	2,7 [0,6; 4,8] 0,0112[3]
≥ 20 but < 50 mm	11/646 (1,7)	7/653 (1,1)	1,59 [0,62; 4,07] 0,3353[2]	1,60 [0,62; 4,15] 0,3308[3]	0,6 [-0,6; 1,9] 0,3308[3]
≥ 50 mm	7/289 (2,4)	1/265 (0,4)	6,42 [0,79; 51,82] 0,0810[2]	6,55 [0,80; 53,62] 0,0704[4]	2,0 [0,1; 4,0] 0,0704[4]
Number of positive lymph nodes (Interaction p-value: 0,9371)					
0-3	12/427 (2,8)	4/418 (1,0)	2,94 [0,95; 9,03] 0,0602[2]	2,99 [0,96; 9,36] 0,0481[3]	1,9 [0,0; 3,7] 0,0481[3]
4-9	13/549 (2,4)	5/542 (0,9)	2,57 [0,92; 7,15] 0,0713[2]	2,60 [0,92; 7,36] 0,0609[3]	1,4 [-0,1; 3,0] 0,0609[3]
≥ 10	4/307 (1,3)	1/304 (0,3)	3,96 [0,45; 35,23] 0,2171[2]	4,00 [0,44; 35,99] 0,3730[4]	1,0 [-0,4; 2,4] 0,3730[4]
Tumor stage (Interaction p-value: 0,5697)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	3/113 (2,7)	0/114 (0,0)	7,06 [0,37; 135,16] 0,1943[2]	7,25 [0,37; 142,05] 0,1217[4]	2,7 [-0,3; 5,6] 0,1217[4]
IIB	3/151 (2,0)	1/136 (0,7)	2,70 [0,28; 25,67] 0,3868[2]	2,74 [0,28; 26,62] 0,6244[4]	1,3 [-1,4; 3,9] 0,6244[4]
IIIA	13/495 (2,6)	3/488 (0,6)	4,27 [1,23; 14,90] 0,0227[2]	4,36 [1,23; 15,40] 0,0127[3]	2,0 [0,4; 3,6] 0,0127[3]
IIIB	1/54 (1,9)	2/45 (4,4)	0,42 [0,04; 4,45] 0,4686[2]	0,41 [0,04; 4,63] 0,5894[4]	-2,6 [-9,6; 4,4] 0,5894[4]
IIIC	9/468 (1,9)	4/479 (0,8)	2,30 [0,71; 7,43] 0,1626[2]	2,33 [0,71; 7,61] 0,1503[3]	1,1 [-0,4; 2,6] 0,1503[3]
Tumor grade (Interaction p-value: 0,7465)					
G1	0/91 (0,0)	0/93 (0,0)	NE	NE	NE
G2	15/612 (2,5)	7/602 (1,2)	2,11 [0,87; 5,13] 0,1006[2]	2,14 [0,86; 5,28] 0,0925[3]	1,3 [-0,2; 2,8] 0,0925[3]
G3	12/527 (2,3)	3/506 (0,6)	3,84 [1,09; 13,53] 0,0362[2]	3,91 [1,10; 13,93] 0,0237[3]	1,7 [0,2; 3,1] 0,0237[3]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,2115)					
Negative	4/156 (2,6)	1/169 (0,6)	4,33 [0,49; 38,35] 0,1875[2]	4,42 [0,49; 39,99] 0,1985[4]	2,0 [-0,8; 4,7] 0,1985[4]
Positive	24/1089 (2,2)	9/1066 (0,8)	2,61 [1,22; 5,59] 0,0135[2]	2,65 [1,22; 5,72] 0,0102[3]	1,4 [0,3; 2,4] 0,0102[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9528)					
White	22/958 (2,3)	8/943 (0,8)	2,71 [1,21; 6,05] 0,0152[2]	2,75 [1,22; 6,20] 0,0113[3]	1,4 [0,3; 2,6] 0,0113[3]
Asian	4/250 (1,6)	1/242 (0,4)	3,87 [0,44; 34,40] 0,2244[2]	3,92 [0,43; 35,31] 0,3728[4]	1,2 [-0,6; 2,9] 0,3728[4]
Other	3/62 (4,8)	1/64 (1,6)	3,10 [0,33; 28,97] 0,3218[2]	3,20 [0,32; 31,66] 0,3610[4]	3,3 [-2,9; 9,4] 0,3610[4]
First endocrine therapy (Interaction p-value: 0,9969)					
Tamoxifen	5/114 (4,4)	2/132 (1,5)	2,89 [0,57; 14,64] 0,1986[2]	2,98 [0,57; 15,67] 0,2546[4]	2,9 [-1,4; 7,2] 0,2546[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Aromatase inhibitor	24/1169 (2,1)	8/1132 (0,7)	2,91 [1,31; 6,44] 0,0086[2]	2,94 [1,32; 6,58] 0,0058[3]	1,3 [0,4; 2,3] 0,0058[3]
ECOG-PS (Interaction p-value: 0,7866)					
ECOG-PS 0	25/1070 (2,3)	8/1019 (0,8)	2,98 [1,35; 6,57] 0,0069[2]	3,02 [1,36; 6,73] 0,0045[3]	1,6 [0,5; 2,6] 0,0045[3]
ECOG-PS 1	4/213 (1,9)	2/245 (0,8)	2,30 [0,43; 12,44] 0,3332[2]	2,33 [0,42; 12,82] 0,4235[4]	1,1 [-1,1; 3,2] 0,4235[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 374.1.2: Subgroups - adverse events according PT Vitamin B12 deficiency from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,0713)					
< 65 years	12/918 (1,3)	1/936 (0,1)	12,24 [1,59; 93,91] 0,0160[2]	12,38 [1,61; 95,44] 0,0020[3]	1,2 [0,4; 2,0] 0,0020[3]
≥ 65 years	4/365 (1,1)	3/328 (0,9)	1,20 [0,27; 5,31] 0,8120[2]	1,20 [0,27; 5,40] 1,0000[4]	0,2 [-1,3; 1,7] 1,0000[4]
Region (Interaction p-value: 0,5278)					
North America / Europe	11/678 (1,6)	2/649 (0,3)	5,26 [1,17; 23,66] 0,0303[2]	5,34 [1,18; 24,16] 0,0151[3]	1,3 [0,3; 2,4] 0,0151[3]
Asia	0/203 (0,0)	0/201 (0,0)	NE	NE	NE
Other	5/402 (1,2)	2/414 (0,5)	2,57 [0,50; 13,19] 0,2567[2]	2,59 [0,50; 13,45] 0,2803[4]	0,8 [-0,5; 2,0] 0,2803[4]
Primary tumor size (Interaction p-value: 0,8845)					
< 20 mm	3/331 (0,9)	0/334 (0,0)	7,06 [0,37; 136,21] 0,1954[2]	7,13 [0,37; 138,53] 0,1228[4]	0,9 [-0,1; 1,9] 0,1228[4]
≥ 20 but < 50 mm	8/646 (1,2)	2/653 (0,3)	4,04 [0,86; 18,97] 0,0765[2]	4,08 [0,86; 19,29] 0,0631[4]	0,9 [-0,0; 1,9] 0,0631[4]
≥ 50 mm	5/289 (1,7)	2/265 (0,8)	2,29 [0,45; 11,72] 0,3189[2]	2,32 [0,45; 12,04] 0,4533[4]	1,0 [-0,9; 2,8] 0,4533[4]
Tumor stage (Interaction p-value: 1,0000)					
IIA	1/113 (0,9)	0/114 (0,0)	3,03 [0,12; 73,51] 0,4963[2]	3,05 [0,12; 75,75] 0,4978[4]	0,9 [-0,8; 2,6] 0,4978[4]
IIB	2/151 (1,3)	0/136 (0,0)	4,51 [0,22; 93,05] 0,3297[2]	4,57 [0,22; 95,94] 0,4996[4]	1,3 [-0,5; 3,1] 0,4996[4]
IIIA	6/495 (1,2)	0/488 (0,0)	12,82 [0,72; 226,89] 0,0819[2]	12,97 [0,73; 230,92] 0,0308[4]	1,2 [0,2; 2,2] 0,0308[4]
IIIB	0/54 (0,0)	0/45 (0,0)	NE	NE	NE
IIIC	7/468 (1,5)	4/479 (0,8)	1,79 [0,53; 6,08] 0,3498[2]	1,80 [0,52; 6,20] 0,3428[3]	0,7 [-0,7; 2,0] 0,3428[3]
Tumor grade (Interaction p-value: 0,8827)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	10/612 (1,6)	2/602 (0,3)	4,92 [1,08; 22,35] 0,0392[2]	4,98 [1,09; 22,84] 0,0219[3]	1,3 [0,2; 2,4] 0,0219[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G3	4/527 (0,8)	2/506 (0,4)	1,92 [0,35; 10,44] 0,4500[2]	1,93 [0,35; 10,57] 0,6870[4]	0,4 [-0,6; 1,3] 0,6870[4]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,5735)					
Negative	2/156 (1,3)	1/169 (0,6)	2,17 [0,20; 23,66] 0,5261[2]	2,18 [0,20; 24,30] 0,6093[4]	0,7 [-1,4; 2,8] 0,6093[4]
Positive	14/1089 (1,3)	3/1066 (0,3)	4,57 [1,32; 15,85] 0,0167[2]	4,61 [1,32; 16,10] 0,0084[3]	1,0 [0,3; 1,7] 0,0084[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9844)					
White	14/958 (1,5)	4/943 (0,4)	3,45 [1,14; 10,43] 0,0286[2]	3,48 [1,14; 10,62] 0,0196[3]	1,0 [0,2; 1,9] 0,0196[3]
Asian	1/250 (0,4)	0/242 (0,0)	2,90 [0,12; 70,95] 0,5132[2]	2,92 [0,12; 71,93] 1,0000[4]	0,4 [-0,4; 1,2] 1,0000[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,8919)					
ECOG-PS 0	13/1070 (1,2)	3/1019 (0,3)	4,13 [1,18; 14,44] 0,0265[2]	4,17 [1,18; 14,66] 0,0159[3]	0,9 [0,2; 1,7] 0,0159[3]
ECOG-PS 1	3/213 (1,4)	1/245 (0,4)	3,45 [0,36; 32,93] 0,2818[2]	3,49 [0,36; 33,76] 0,3420[4]	1,0 [-0,8; 2,8] 0,3420[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 375.1.2: Subgroups - adverse events according PT Vomiting from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5692)					
< 65 years	158/918 (17,2)	41/936 (4,4)	3,93 [2,82; 5,47] <,0001[2]	4,54 [3,18; 6,48] <,0001[3]	12,8 [10,1; 15,6] <,0001[3]
≥ 65 years	64/365 (17,5)	12/328 (3,7)	4,79 [2,63; 8,72] <,0001[2]	5,60 [2,96; 10,58] <,0001[3]	13,9 [9,5; 18,3] <,0001[3]
Prior treatment (Interaction p-value: 0,9715)					
Neoadjuvant chemotherapy	78/430 (18,1)	18/415 (4,3)	4,18 [2,55; 6,86] <,0001[2]	4,89 [2,87; 8,32] <,0001[3]	13,8 [9,7; 17,9] <,0001[3]
Adjuvant chemotherapy	132/784 (16,8)	32/768 (4,2)	4,04 [2,78; 5,87] <,0001[2]	4,66 [3,12; 6,95] <,0001[3]	12,7 [9,7; 15,6] <,0001[3]
No chemotherapy	12/69 (17,4)	3/81 (3,7)	4,70 [1,38; 15,96] 0,0132[2]	5,47 [1,48; 20,30] 0,0054[3]	13,7 [3,8; 23,5] 0,0054[3]
Region (Interaction p-value: 0,0767)					
North America / Europe	140/678 (20,6)	41/649 (6,3)	3,27 [2,35; 4,55] <,0001[2]	3,86 [2,67; 5,57] <,0001[3]	14,3 [10,8; 17,9] <,0001[3]
Asia	26/203 (12,8)	2/201 (1,0)	12,87 [3,10; 53,52] 0,0004[2]	14,62 [3,42; 62,46] <,0001[3]	11,8 [7,0; 16,6] <,0001[3]
Other	56/402 (13,9)	10/414 (2,4)	5,77 [2,98; 11,14] <,0001[2]	6,54 [3,29; 13,01] <,0001[3]	11,5 [7,8; 15,2] <,0001[3]
Primary tumor size (Interaction p-value: 0,7226)					
< 20 mm	53/331 (16,0)	11/334 (3,3)	4,86 [2,59; 9,14] <,0001[2]	5,60 [2,87; 10,93] <,0001[3]	12,7 [8,3; 17,1] <,0001[3]
≥ 20 but < 50 mm	109/646 (16,9)	30/653 (4,6)	3,67 [2,49; 5,42] <,0001[2]	4,22 [2,77; 6,42] <,0001[3]	12,3 [9,0; 15,6] <,0001[3]
≥ 50 mm	58/289 (20,1)	12/265 (4,5)	4,43 [2,44; 8,07] <,0001[2]	5,29 [2,77; 10,11] <,0001[3]	15,5 [10,3; 20,8] <,0001[3]
Tumor stage (Interaction p-value: 0,0567)					
IIA	17/113 (15,0)	4/114 (3,5)	4,29 [1,49; 12,35] 0,0070[2]	4,87 [1,58; 14,97] 0,0027[3]	11,5 [4,1; 18,9] 0,0027[3]
IIB	24/151 (15,9)	10/136 (7,4)	2,16 [1,07; 4,35] 0,0310[2]	2,38 [1,09; 5,18] 0,0254[3]	8,5 [1,2; 15,8] 0,0254[3]
IIIA	87/495 (17,6)	25/488 (5,1)	3,43 [2,24; 5,26] <,0001[2]	3,95 [2,48; 6,28] <,0001[3]	12,5 [8,6; 16,3] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	4/54 (7,4)	2/45 (4,4)	1,67 [0,32; 8,68] 0,5441[2]	1,72 [0,30; 9,85] 0,6859[4]	3,0 [-6,3; 12,2] 0,6859[4]
IIIC	90/468 (19,2)	12/479 (2,5)	7,68 [4,26; 13,83] <,0001[2]	9,27 [5,00; 17,18] <,0001[3]	16,7 [12,9; 20,6] <,0001[3]
Tumor grade (Interaction p-value: 0,7813)					
G1	13/91 (14,3)	3/93 (3,2)	4,43 [1,31; 15,03] 0,0170[2]	5,00 [1,37; 18,19] 0,0078[3]	11,1 [3,0; 19,1] 0,0078[3]
G2	106/612 (17,3)	28/602 (4,7)	3,72 [2,49; 5,56] <,0001[2]	4,29 [2,78; 6,62] <,0001[3]	12,7 [9,2; 16,1] <,0001[3]
G3	94/527 (17,8)	21/506 (4,2)	4,30 [2,72; 6,79] <,0001[2]	5,01 [3,07; 8,19] <,0001[3]	13,7 [10,0; 17,4] <,0001[3]
GX	9/51 (17,6)	1/59 (1,7)	10,41 [1,37; 79,41] 0,0238[2]	12,43 [1,52; 101,88] 0,0054[4]	16,0 [5,0; 26,9] 0,0054[4]
Race (Interaction p-value: 0,3570)					
White	180/958 (18,8)	46/943 (4,9)	3,85 [2,82; 5,26] <,0001[2]	4,51 [3,22; 6,32] <,0001[3]	13,9 [11,1; 16,7] <,0001[3]
Asian	29/250 (11,6)	3/242 (1,2)	9,36 [2,89; 30,31] 0,0002[2]	10,45 [3,14; 34,80] <,0001[3]	10,4 [6,2; 14,6] <,0001[3]
Other	11/62 (17,7)	3/64 (4,7)	3,78 [1,11; 12,92] 0,0336[2]	4,39 [1,16; 16,58] 0,0197[3]	13,1 [2,2; 23,9] 0,0197[3]
First endocrine therapy (Interaction p-value: 0,3697)					
Tamoxifen	18/114 (15,8)	3/132 (2,3)	6,95 [2,10; 22,98] 0,0015[2]	8,06 [2,31; 28,15] 0,0002[3]	13,5 [6,4; 20,7] 0,0002[3]
Aromatase inhibitor	204/1169 (17,5)	50/1132 (4,4)	3,95 [2,93; 5,32] <,0001[2]	4,57 [3,32; 6,31] <,0001[3]	13,0 [10,6; 15,5] <,0001[3]
ECOG-PS (Interaction p-value: 0,0935)					
ECOG-PS 0	181/1070 (16,9)	36/1019 (3,5)	4,79 [3,38; 6,78] <,0001[2]	5,56 [3,84; 8,04] <,0001[3]	13,4 [10,9; 15,9] <,0001[3]
ECOG-PS 1	41/213 (19,2)	17/245 (6,9)	2,77 [1,63; 4,74] 0,0002[2]	3,20 [1,76; 5,82] <,0001[3]	12,3 [6,1; 18,5] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 376.1.2: Subgroups - adverse events according PT Weight decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5196)					
< 65 years	35/918 (3,8)	8/936 (0,9)	4,46 [2,08; 9,56] 0,0001[2]	4,60 [2,12; 9,97] <,0001[3]	3,0 [1,6; 4,3] <,0001[3]
≥ 65 years	24/365 (6,6)	7/328 (2,1)	3,08 [1,35; 7,06] 0,0078[2]	3,23 [1,37; 7,59] 0,0047[3]	4,4 [1,5; 7,4] 0,0047[3]
Prior treatment (Interaction p-value: 0,8371)					
Neoadjuvant chemotherapy	22/430 (5,1)	6/415 (1,4)	3,54 [1,45; 8,64] 0,0055[2]	3,68 [1,48; 9,16] 0,0029[3]	3,7 [1,3; 6,0] 0,0029[3]
Adjuvant chemotherapy	31/784 (4,0)	8/768 (1,0)	3,80 [1,76; 8,21] 0,0007[2]	3,91 [1,79; 8,56] 0,0002[3]	2,9 [1,4; 4,5] 0,0002[3]
No chemotherapy	6/69 (8,7)	1/81 (1,2)	7,04 [0,87; 57,09] 0,0675[2]	7,62 [0,89; 64,93] 0,0485[4]	7,5 [0,4; 14,5] 0,0485[4]
Region (Interaction p-value: 0,6278)					
North America / Europe	32/678 (4,7)	10/649 (1,5)	3,06 [1,52; 6,18] 0,0018[2]	3,17 [1,54; 6,49] 0,0009[3]	3,2 [1,3; 5,0] 0,0009[3]
Asia	11/203 (5,4)	2/201 (1,0)	5,45 [1,22; 24,26] 0,0262[2]	5,70 [1,25; 26,05] 0,0118[3]	4,4 [1,0; 7,8] 0,0118[3]
Other	16/402 (4,0)	3/414 (0,7)	5,49 [1,61; 18,71] 0,0064[2]	5,68 [1,64; 19,64] 0,0020[3]	3,3 [1,2; 5,3] 0,0020[3]
Primary tumor size (Interaction p-value: 0,0928)					
< 20 mm	9/331 (2,7)	6/334 (1,8)	1,51 [0,54; 4,20] 0,4266[2]	1,53 [0,54; 4,34] 0,4230[3]	0,9 [-1,3; 3,2] 0,4230[3]
≥ 20 but < 50 mm	37/646 (5,7)	6/653 (0,9)	6,23 [2,65; 14,67] <,0001[2]	6,55 [2,75; 15,63] <,0001[3]	4,8 [2,9; 6,7] <,0001[3]
≥ 50 mm	13/289 (4,5)	2/265 (0,8)	5,96 [1,36; 26,17] 0,0180[2]	6,19 [1,38; 27,71] 0,0067[3]	3,7 [1,1; 6,4] 0,0067[3]
Number of positive lymph nodes (Interaction p-value: 0,9193)					
0-3	13/427 (3,0)	3/418 (0,7)	4,24 [1,22; 14,78] 0,0233[2]	4,34 [1,23; 15,36] 0,0131[3]	2,3 [0,5; 4,1] 0,0131[3]
4-9	32/549 (5,8)	9/542 (1,7)	3,51 [1,69; 7,28] 0,0007[2]	3,67 [1,73; 7,75] 0,0003[3]	4,2 [1,9; 6,4] 0,0003[3]
≥ 10	14/307 (4,6)	3/304 (1,0)	4,62 [1,34; 15,92] 0,0153[2]	4,79 [1,36; 16,86] 0,0072[3]	3,6 [1,0; 6,2] 0,0072[3]
Tumor stage (Interaction p-value: 0,9905)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	2/113 (1,8)	1/114 (0,9)	2,02 [0,19; 21,94] 0,5642[2]	2,04 [0,18; 22,78] 0,6217[4]	0,9 [-2,1; 3,9] 0,6217[4]
IIB	8/151 (5,3)	2/136 (1,5)	3,60 [0,78; 16,67] 0,1011[2]	3,75 [0,78; 17,97] 0,1080[4]	3,8 [-0,3; 7,9] 0,1080[4]
IIIA	31/495 (6,3)	8/488 (1,6)	3,82 [1,77; 8,23] 0,0006[2]	4,01 [1,82; 8,81] 0,0002[3]	4,6 [2,2; 7,0] 0,0002[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	16/468 (3,4)	4/479 (0,8)	4,09 [1,38; 12,16] 0,0111[2]	4,20 [1,39; 12,67] 0,0057[3]	2,6 [0,7; 4,4] 0,0057[3]
Tumor grade (Interaction p-value: 0,3837)					
G1	4/91 (4,4)	3/93 (3,2)	1,36 [0,31; 5,92] 0,6797[2]	1,38 [0,30; 6,34] 0,7190[4]	1,2 [-4,4; 6,7] 0,7190[4]
G2	36/612 (5,9)	6/602 (1,0)	5,90 [2,51; 13,90] <,0001[2]	6,21 [2,60; 14,85] <,0001[3]	4,9 [2,9; 6,9] <,0001[3]
G3	16/527 (3,0)	5/506 (1,0)	3,07 [1,13; 8,32] 0,0273[2]	3,14 [1,14; 8,63] 0,0197[3]	2,0 [0,3; 3,7] 0,0197[3]
GX	3/51 (5,9)	1/59 (1,7)	3,47 [0,37; 32,34] 0,2745[2]	3,63 [0,37; 35,99] 0,3349[4]	4,2 [-3,1; 11,4] 0,3349[4]
Progesterone receptor status (Interaction p-value: 0,9996)					
Negative	7/156 (4,5)	2/169 (1,2)	3,79 [0,80; 17,98] 0,0933[2]	3,92 [0,80; 19,18] 0,0932[4]	3,3 [-0,3; 6,9] 0,0932[4]
Positive	50/1089 (4,6)	13/1066 (1,2)	3,76 [2,06; 6,89] <,0001[2]	3,90 [2,10; 7,22] <,0001[3]	3,4 [2,0; 4,8] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Race (Interaction p-value: 0,5561)					
White	38/958 (4,0)	11/943 (1,2)	3,40 [1,75; 6,61] 0,0003[2]	3,50 [1,78; 6,89] 0,0001[3]	2,8 [1,4; 4,2] 0,0001[3]
Asian	17/250 (6,8)	2/242 (0,8)	8,23 [1,92; 35,23] 0,0045[2]	8,76 [2,00; 38,32] 0,0006[3]	6,0 [2,7; 9,3] 0,0006[3]
Other	4/62 (6,5)	1/64 (1,6)	4,13 [0,47; 35,92] 0,1989[2]	4,34 [0,47; 40,01] 0,2039[4]	4,9 [-1,9; 11,7] 0,2039[4]
First endocrine therapy (Interaction p-value: 0,6712)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	2/114 (1,8)	1/132 (0,8)	2,32 [0,21; 25,21] 0,4906[2]	2,34 [0,21; 26,14] 0,5979[4]	1,0 [-1,8; 3,8] 0,5979[4]
Aromatase inhibitor	57/1169 (4,9)	14/1132 (1,2)	3,94 [2,21; 7,03] <,0001[2]	4,09 [2,27; 7,39] <,0001[3]	3,6 [2,2; 5,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,5643)					
ECOG-PS 0	45/1070 (4,2)	12/1019 (1,2)	3,57 [1,90; 6,71] <,0001[2]	3,68 [1,94; 7,01] <,0001[3]	3,0 [1,7; 4,4] <,0001[3]
ECOG-PS 1	14/213 (6,6)	3/245 (1,2)	5,37 [1,56; 18,43] 0,0076[2]	5,68 [1,61; 20,03] 0,0025[3]	5,3 [1,7; 8,9] 0,0025[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 377.1.2: Subgroups - adverse events according PT Weight increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,4643)					
< 65 years	14/918 (1,5)	22/936 (2,4)	0,65 [0,33; 1,26] 0,2016[2]	0,64 [0,33; 1,27] 0,1978[3]	-0,8 [-2,1; 0,4] 0,1978[3]
≥ 65 years	5/365 (1,4)	11/328 (3,4)	0,41 [0,14; 1,16] 0,0936[2]	0,40 [0,14; 1,16] 0,0825[3]	-2,0 [-4,3; 0,3] 0,0825[3]
Prior treatment (Interaction p-value: 0,7461)					
Neoadjuvant chemotherapy	8/430 (1,9)	10/415 (2,4)	0,77 [0,31; 1,94] 0,5816[2]	0,77 [0,30; 1,96] 0,5805[3]	-0,5 [-2,5; 1,4] 0,5805[3]
Adjuvant chemotherapy	11/784 (1,4)	22/768 (2,9)	0,49 [0,24; 1,00] 0,0510[2]	0,48 [0,23; 1,00] 0,0460[3]	-1,5 [-2,9; -0,0] 0,0460[3]
No chemotherapy	0/69 (0,0)	1/81 (1,2)	0,39 [0,02; 9,43] 0,5628[2]	0,39 [0,02; 9,63] 1,0000[4]	-1,2 [-3,6; 1,2] 1,0000[4]
Region (Interaction p-value: 0,2086)					
North America / Europe	13/678 (1,9)	14/649 (2,2)	0,89 [0,42; 1,88] 0,7573[2]	0,89 [0,41; 1,90] 0,7571[3]	-0,2 [-1,8; 1,3] 0,7571[3]
Asia	1/203 (0,5)	6/201 (3,0)	0,17 [0,02; 1,36] 0,0939[2]	0,16 [0,02; 1,35] 0,0670[4]	-2,5 [-5,0; 0,0] 0,0670[4]
Other	5/402 (1,2)	13/414 (3,1)	0,40 [0,14; 1,10] 0,0758[2]	0,39 [0,14; 1,10] 0,0652[3]	-1,9 [-3,9; 0,1] 0,0652[3]
Tumor stage (Interaction p-value: 0,0913)					
IIA	5/113 (4,4)	1/114 (0,9)	5,04 [0,60; 42,50] 0,1367[2]	5,23 [0,60; 45,51] 0,1192[4]	3,5 [-0,6; 7,7] 0,1192[4]
IIB	3/151 (2,0)	1/136 (0,7)	2,70 [0,28; 25,67] 0,3868[2]	2,74 [0,28; 26,62] 0,6244[4]	1,3 [-1,4; 3,9] 0,6244[4]
IIIA	4/495 (0,8)	15/488 (3,1)	0,26 [0,09; 0,79] 0,0169[2]	0,26 [0,08; 0,78] 0,0099[3]	-2,3 [-4,0; -0,5] 0,0099[3]
IIIB	0/54 (0,0)	0/45 (0,0)	NE	NE	NE
IIIC	7/468 (1,5)	16/479 (3,3)	0,45 [0,19; 1,08] 0,0732[2]	0,44 [0,18; 1,08] 0,0652[3]	-1,8 [-3,8; 0,1] 0,0652[3]
Tumor grade (Interaction p-value: 0,9707)					
G1	0/91 (0,0)	3/93 (3,2)	0,15 [0,01; 2,79] 0,2009[2]	0,14 [0,01; 2,77] 0,2460[4]	-3,2 [-6,8; 0,4] 0,2460[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G2	8/612 (1,3)	13/602 (2,2)	0,61 [0,25; 1,45] 0,2600[2]	0,60 [0,25; 1,46] 0,2548[3]	-0,9 [-2,3; 0,6] 0,2548[3]
G3	11/527 (2,1)	13/506 (2,6)	0,81 [0,37; 1,80] 0,6080[2]	0,81 [0,36; 1,82] 0,6073[3]	-0,5 [-2,3; 1,4] 0,6073[3]
GX	0/51 (0,0)	4/59 (6,8)	0,13 [0,01; 2,33] 0,1648[2]	0,12 [0,01; 2,28] 0,1221[4]	-6,8 [-13,2; -0,4] 0,1221[4]
Progesterone receptor status (Interaction p-value: 0,9349)					
Negative	2/156 (1,3)	2/169 (1,2)	1,08 [0,15; 7,60] 0,9358[2]	1,08 [0,15; 7,79] 1,0000[4]	0,1 [-2,3; 2,5] 1,0000[4]
Positive	16/1089 (1,5)	30/1066 (2,8)	0,52 [0,29; 0,95] 0,0340[2]	0,51 [0,28; 0,95] 0,0308[3]	-1,3 [-2,6; -0,1] 0,0308[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,2337)					
White	17/958 (1,8)	24/943 (2,5)	0,70 [0,38; 1,29] 0,2503[2]	0,69 [0,37; 1,30] 0,2476[3]	-0,8 [-2,1; 0,5] 0,2476[3]
Asian	1/250 (0,4)	9/242 (3,7)	0,11 [0,01; 0,84] 0,0337[2]	0,10 [0,01; 0,83] 0,0099[4]	-3,3 [-5,8; -0,8] 0,0099[4]
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
First endocrine therapy (Interaction p-value: 0,4277)					
Tamoxifen	4/114 (3,5)	5/132 (3,8)	0,93 [0,25; 3,37] 0,9075[2]	0,92 [0,24; 3,53] 1,0000[4]	-0,3 [-5,0; 4,4] 1,0000[4]
Aromatase inhibitor	15/1169 (1,3)	28/1132 (2,5)	0,52 [0,28; 0,97] 0,0386[2]	0,51 [0,27; 0,96] 0,0350[3]	-1,2 [-2,3; -0,1] 0,0350[3]
ECOG-PS (Interaction p-value: 0,5085)					
ECOG-PS 0	15/1070 (1,4)	22/1019 (2,2)	0,65 [0,34; 1,24] 0,1933[2]	0,64 [0,33; 1,25] 0,1897[3]	-0,8 [-1,9; 0,4] 0,1897[3]
ECOG-PS 1	4/213 (1,9)	11/245 (4,5)	0,42 [0,14; 1,29] 0,1304[2]	0,41 [0,13; 1,30] 0,1173[3]	-2,6 [-5,8; 0,6] 0,1173[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 378.1.2: Subgroups - adverse events according PT White blood cell count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,2324)					
< 65 years	201/918 (21,9)	41/936 (4,4)	5,00 [3,62; 6,91] <,0001[2]	6,12 [4,31; 8,68] <,0001[3]	17,5 [14,5; 20,5] <,0001[3]
≥ 65 years	86/365 (23,6)	10/328 (3,0)	7,73 [4,08; 14,62] <,0001[2]	9,80 [4,99; 19,24] <,0001[3]	20,5 [15,8; 25,2] <,0001[3]
Prior treatment (Interaction p-value: 0,5861)					
Neoadjuvant chemotherapy	101/430 (23,5)	16/415 (3,9)	6,09 [3,66; 10,14] <,0001[2]	7,66 [4,43; 13,23] <,0001[3]	19,6 [15,2; 24,0] <,0001[3]
Adjuvant chemotherapy	175/784 (22,3)	34/768 (4,4)	5,04 [3,54; 7,18] <,0001[2]	6,20 [4,23; 9,10] <,0001[3]	17,9 [14,6; 21,2] <,0001[3]
No chemotherapy	11/69 (15,9)	1/81 (1,2)	12,91 [1,71; 97,52] 0,0131[2]	15,17 [1,91; 120,82] 0,0009[3]	14,7 [5,7; 23,7] 0,0009[3]
Region (Interaction p-value: 0,7141)					
North America / Europe	104/678 (15,3)	15/649 (2,3)	6,64 [3,90; 11,28] <,0001[2]	7,66 [4,41; 13,31] <,0001[3]	13,0 [10,1; 16,0] <,0001[3]
Asia	113/203 (55,7)	22/201 (10,9)	5,09 [3,37; 7,69] <,0001[2]	10,22 [6,06; 17,22] <,0001[3]	44,7 [36,6; 52,8] <,0001[3]
Other	70/402 (17,4)	14/414 (3,4)	5,15 [2,95; 8,99] <,0001[2]	6,02 [3,33; 10,89] <,0001[3]	14,0 [9,9; 18,1] <,0001[3]
Primary tumor size (Interaction p-value: 0,6181)					
< 20 mm	74/331 (22,4)	11/334 (3,3)	6,79 [3,67; 12,55] <,0001[2]	8,45 [4,40; 16,26] <,0001[3]	19,1 [14,2; 23,9] <,0001[3]
≥ 20 but < 50 mm	144/646 (22,3)	30/653 (4,6)	4,85 [3,32; 7,08] <,0001[2]	5,96 [3,95; 8,98] <,0001[3]	17,7 [14,1; 21,3] <,0001[3]
≥ 50 mm	60/289 (20,8)	9/265 (3,4)	6,11 [3,10; 12,07] <,0001[2]	7,45 [3,62; 15,36] <,0001[3]	17,4 [12,2; 22,5] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,9559)					
0-3	89/427 (20,8)	15/418 (3,6)	5,81 [3,42; 9,87] <,0001[2]	7,07 [4,02; 12,46] <,0001[3]	17,3 [13,0; 21,5] <,0001[3]
4-9	123/549 (22,4)	23/542 (4,2)	5,28 [3,44; 8,11] <,0001[2]	6,52 [4,10; 10,36] <,0001[3]	18,2 [14,3; 22,0] <,0001[3]
≥ 10	75/307 (24,4)	13/304 (4,3)	5,71 [3,24; 10,07] <,0001[2]	7,24 [3,92; 13,37] <,0001[3]	20,2 [14,8; 25,5] <,0001[3]
Tumor stage (Interaction p-value: 0,6302)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	26/113 (23,0)	2/114 (1,8)	13,12 [3,19; 53,96] 0,0004[2]	16,74 [3,87; 72,44] <,0001[3]	21,3 [13,1; 29,4] <,0001[3]
IIB	35/151 (23,2)	6/136 (4,4)	5,25 [2,28; 12,10] <,0001[2]	6,54 [2,65; 16,10] <,0001[3]	18,8 [11,2; 26,3] <,0001[3]
IIIA	108/495 (21,8)	22/488 (4,5)	4,84 [3,11; 7,52] <,0001[2]	5,91 [3,67; 9,53] <,0001[3]	17,3 [13,2; 21,4] <,0001[3]
IIIB	16/54 (29,6)	1/45 (2,2)	13,33 [1,84; 96,68] 0,0104[2]	18,53 [2,35; 146,29] 0,0003[3]	27,4 [14,5; 40,3] 0,0003[3]
IIIC	101/468 (21,6)	20/479 (4,2)	5,17 [3,25; 8,21] <,0001[2]	6,32 [3,83; 10,40] <,0001[3]	17,4 [13,3; 21,5] <,0001[3]
Tumor grade (Interaction p-value: 0,7340)					
G1	17/91 (18,7)	2/93 (2,2)	8,69 [2,07; 36,53] 0,0032[2]	10,45 [2,34; 46,70] 0,0002[3]	16,5 [8,0; 25,1] 0,0002[3]
G2	130/612 (21,2)	27/602 (4,5)	4,74 [3,18; 7,06] <,0001[2]	5,74 [3,73; 8,85] <,0001[3]	16,8 [13,1; 20,4] <,0001[3]
G3	119/527 (22,6)	18/506 (3,6)	6,35 [3,93; 10,26] <,0001[2]	7,91 [4,73; 13,21] <,0001[3]	19,0 [15,1; 22,9] <,0001[3]
GX	20/51 (39,2)	4/59 (6,8)	5,78 [2,12; 15,82] 0,0006[2]	8,87 [2,78; 28,31] <,0001[3]	32,4 [17,6; 47,3] <,0001[3]
Race (Interaction p-value: 0,8863)					
White	159/958 (16,6)	27/943 (2,9)	5,80 [3,89; 8,63] <,0001[2]	6,75 [4,44; 10,26] <,0001[3]	13,7 [11,1; 16,3] <,0001[3]
Asian	115/250 (46,0)	22/242 (9,1)	5,06 [3,32; 7,70] <,0001[2]	8,52 [5,15; 14,10] <,0001[3]	36,9 [29,7; 44,1] <,0001[3]
Other	12/62 (19,4)	2/64 (3,1)	6,19 [1,44; 26,55] 0,0141[2]	7,44 [1,59; 34,80] 0,0038[3]	16,2 [5,5; 26,9] 0,0038[3]
First endocrine therapy (Interaction p-value: 0,4062)					
Tamoxifen	16/114 (14,0)	5/132 (3,8)	3,71 [1,40; 9,80] 0,0083[2]	4,15 [1,47; 11,71] 0,0041[3]	10,2 [3,1; 17,4] 0,0041[3]
Aromatase inhibitor	271/1169 (23,2)	46/1132 (4,1)	5,70 [4,22; 7,71] <,0001[2]	7,12 [5,15; 9,86] <,0001[3]	19,1 [16,4; 21,8] <,0001[3]
ECOG-PS (Interaction p-value: 0,5827)					
ECOG-PS 0	246/1070 (23,0)	44/1019 (4,3)	5,32 [3,91; 7,25] <,0001[2]	6,62 [4,74; 9,24] <,0001[3]	18,7 [15,9; 21,5] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	41/213 (19,2)	7/245 (2,9)	6,74 [3,09; 14,70] <,0001[2]	8,10 [3,55; 18,50] <,0001[3]	16,4 [10,7; 22,1] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Anhang 4-G2.4.13: Häufige unerwünschte Ereignisse nach Schweregrad und nach SOC und PT - Subgruppenanalyse nicht-interagierender Subgruppen (Postmenopausale Patientinnen); Teil 2

Table 379.1.2: Subgroups - adverse events according SOC Blood and lymphatic system disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1802)					
< 65 years	407/918 (44,3)	88/936 (9,4)	4,72 [3,82; 5,83] <,0001[2]	7,68 [5,95; 9,91] <,0001[3]	34,9 [31,2; 38,7] <,0001[3]
≥ 65 years	184/365 (50,4)	26/328 (7,9)	6,36 [4,34; 9,32] <,0001[2]	11,81 [7,53; 18,52] <,0001[3]	42,5 [36,6; 48,4] <,0001[3]
Prior treatment (Interaction p-value: 0,9497)					
Neoadjuvant chemotherapy	204/430 (47,4)	37/415 (8,9)	5,32 [3,85; 7,35] <,0001[2]	9,22 [6,26; 13,58] <,0001[3]	38,5 [33,1; 44,0] <,0001[3]
Adjuvant chemotherapy	358/784 (45,7)	70/768 (9,1)	5,01 [3,96; 6,34] <,0001[2]	8,38 [6,31; 11,12] <,0001[3]	36,5 [32,5; 40,6] <,0001[3]
No chemotherapy	29/69 (42,0)	7/81 (8,6)	4,86 [2,27; 10,40] <,0001[2]	7,66 [3,08; 19,05] <,0001[3]	33,4 [20,2; 46,5] <,0001[3]
Primary tumor size (Interaction p-value: 0,7181)					
< 20 mm	149/331 (45,0)	30/334 (9,0)	5,01 [3,49; 7,19] <,0001[2]	8,30 [5,38; 12,79] <,0001[3]	36,0 [29,9; 42,2] <,0001[3]
≥ 20 but < 50 mm	306/646 (47,4)	64/653 (9,8)	4,83 [3,78; 6,18] <,0001[2]	8,28 [6,13; 11,19] <,0001[3]	37,6 [33,1; 42,0] <,0001[3]
≥ 50 mm	124/289 (42,9)	19/265 (7,2)	5,98 [3,80; 9,42] <,0001[2]	9,73 [5,78; 16,39] <,0001[3]	35,7 [29,2; 42,2] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,5649)					
0-3	171/427 (40,0)	30/418 (7,2)	5,58 [3,88; 8,03] <,0001[2]	8,64 [5,68; 13,13] <,0001[3]	32,9 [27,6; 38,1] <,0001[3]
4-9	270/549 (49,2)	50/542 (9,2)	5,33 [4,04; 7,04] <,0001[2]	9,52 [6,81; 13,32] <,0001[3]	40,0 [35,1; 44,8] <,0001[3]
≥ 10	150/307 (48,9)	34/304 (11,2)	4,37 [3,12; 6,12] <,0001[2]	7,59 [4,98; 11,56] <,0001[3]	37,7 [31,1; 44,3] <,0001[3]
Tumor stage (Interaction p-value: 0,4358)					
IIA	42/113 (37,2)	11/114 (9,6)	3,85 [2,09; 7,09] <,0001[2]	5,54 [2,67; 11,49] <,0001[3]	27,5 [17,1; 37,9] <,0001[3]
IIB	70/151 (46,4)	7/136 (5,1)	9,01 [4,29; 18,91] <,0001[2]	15,93 [6,98; 36,35] <,0001[3]	41,2 [32,4; 50,0] <,0001[3]
IIIA	230/495 (46,5)	45/488 (9,2)	5,04 [3,76; 6,76] <,0001[2]	8,54 [6,00; 12,17] <,0001[3]	37,2 [32,2; 42,3] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	27/54 (50,0)	3/45 (6,7)	7,50 [2,43; 23,11] 0,0004[2]	14,00 [3,87; 50,71] <,0001[3]	43,3 [28,1; 58,5] <,0001[3]
IIIC	221/468 (47,2)	48/479 (10,0)	4,71 [3,54; 6,27] <,0001[2]	8,03 [5,67; 11,39] <,0001[3]	37,2 [31,9; 42,5] <,0001[3]
Tumor grade (Interaction p-value: 0,7317)					
G1	37/91 (40,7)	5/93 (5,4)	7,56 [3,11; 18,38] <,0001[2]	12,06 [4,47; 32,57] <,0001[3]	35,3 [24,2; 46,4] <,0001[3]
G2	293/612 (47,9)	61/602 (10,1)	4,72 [3,67; 6,08] <,0001[2]	8,15 [5,98; 11,09] <,0001[3]	37,7 [33,1; 42,4] <,0001[3]
G3	229/527 (43,5)	42/506 (8,3)	5,24 [3,86; 7,11] <,0001[2]	8,49 [5,92; 12,17] <,0001[3]	35,2 [30,3; 40,0] <,0001[3]
GX	31/51 (60,8)	6/59 (10,2)	5,98 [2,71; 13,17] <,0001[2]	13,69 [4,97; 37,75] <,0001[3]	50,6 [35,2; 66,1] <,0001[3]
Progesterone receptor status (Interaction p-value: 0,0524)					
Negative	74/156 (47,4)	14/169 (8,3)	5,73 [3,38; 9,71] <,0001[2]	9,99 [5,32; 18,78] <,0001[3]	39,2 [30,3; 48,0] <,0001[3]
Positive	512/1089 (47,0)	97/1066 (9,1)	5,17 [4,23; 6,31] <,0001[2]	8,86 [6,97; 11,27] <,0001[3]	37,9 [34,5; 41,3] <,0001[3]
Unknown	1/10 (10,0)	2/7 (28,6)	0,35 [0,04; 3,15] 0,3491[2]	0,28 [0,02; 3,88] 0,5368[4]	-18,6 [-56,9; 19,7] 0,5368[4]
ECOG-PS (Interaction p-value: 0,2663)					
ECOG-PS 0	488/1070 (45,6)	86/1019 (8,4)	5,40 [4,37; 6,68] <,0001[2]	9,10 [7,07; 11,70] <,0001[3]	37,2 [33,7; 40,6] <,0001[3]
ECOG-PS 1	103/213 (48,4)	28/245 (11,4)	4,23 [2,91; 6,16] <,0001[2]	7,26 [4,51; 11,69] <,0001[3]	36,9 [29,1; 44,7] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 380.1.2: Subgroups - adverse events according SOC Cardiac disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7120)					
< 65 years	60/918 (6,5)	40/936 (4,3)	1,53 [1,04; 2,26] 0,0326[2]	1,57 [1,04; 2,36] 0,0311[3]	2,3 [0,2; 4,3] 0,0311[3]
≥ 65 years	30/365 (8,2)	20/328 (6,1)	1,35 [0,78; 2,33] 0,2836[2]	1,38 [0,77; 2,48] 0,2811[3]	2,1 [-1,7; 5,9] 0,2811[3]
Prior treatment (Interaction p-value: 0,9186)					
Neoadjuvant chemotherapy	35/430 (8,1)	23/415 (5,5)	1,47 [0,88; 2,44] 0,1385[2]	1,51 [0,88; 2,60] 0,1355[3]	2,6 [-0,8; 6,0] 0,1355[3]
Adjuvant chemotherapy	50/784 (6,4)	34/768 (4,4)	1,44 [0,94; 2,20] 0,0916[2]	1,47 [0,94; 2,30] 0,0895[3]	2,0 [-0,3; 4,2] 0,0895[3]
No chemotherapy	5/69 (7,2)	3/81 (3,7)	1,96 [0,48; 7,89] 0,3456[2]	2,03 [0,47; 8,83] 0,4711[4]	3,5 [-3,8; 10,9] 0,4711[4]
Region (Interaction p-value: 0,6115)					
North America / Europe	64/678 (9,4)	43/649 (6,6)	1,42 [0,98; 2,07] 0,0616[2]	1,47 [0,98; 2,20] 0,0598[3]	2,8 [-0,1; 5,7] 0,0598[3]
Asia	10/203 (4,9)	4/201 (2,0)	2,48 [0,79; 7,76] 0,1201[2]	2,55 [0,79; 8,27] 0,1067[3]	2,9 [-0,6; 6,5] 0,1067[3]
Other	16/402 (4,0)	13/414 (3,1)	1,27 [0,62; 2,60] 0,5181[2]	1,28 [0,61; 2,69] 0,5170[3]	0,8 [-1,7; 3,4] 0,5170[3]
Primary tumor size (Interaction p-value: 0,0615)					
< 20 mm	23/331 (6,9)	12/334 (3,6)	1,93 [0,98; 3,82] 0,0577[2]	2,00 [0,98; 4,10] 0,0527[3]	3,4 [-0,0; 6,7] 0,0527[3]
≥ 20 but < 50 mm	44/646 (6,8)	41/653 (6,3)	1,08 [0,72; 1,64] 0,6981[2]	1,09 [0,70; 1,69] 0,6980[3]	0,5 [-2,2; 3,2] 0,6980[3]
≥ 50 mm	23/289 (8,0)	7/265 (2,6)	3,01 [1,31; 6,91] 0,0092[2]	3,19 [1,34; 7,56] 0,0057[3]	5,3 [1,6; 9,0] 0,0057[3]
Tumor stage (Interaction p-value: 0,7507)					
IIA	10/113 (8,8)	5/114 (4,4)	2,02 [0,71; 5,72] 0,1865[2]	2,12 [0,70; 6,40] 0,1759[3]	4,5 [-2,0; 10,9] 0,1759[3]
IIB	9/151 (6,0)	4/136 (2,9)	2,03 [0,64; 6,43] 0,2306[2]	2,09 [0,63; 6,95] 0,2194[3]	3,0 [-1,7; 7,7] 0,2194[3]
IIIA	35/495 (7,1)	25/488 (5,1)	1,38 [0,84; 2,27] 0,2045[2]	1,41 [0,83; 2,39] 0,2022[3]	1,9 [-1,0; 4,9] 0,2022[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	2/54 (3,7)	3/45 (6,7)	0,56 [0,10; 3,18] 0,5091[2]	0,54 [0,09; 3,37] 0,6567[4]	-3,0 [-11,8; 5,9] 0,6567[4]
IIIC	34/468 (7,3)	23/479 (4,8)	1,51 [0,91; 2,53] 0,1140[2]	1,55 [0,90; 2,68] 0,1111[3]	2,5 [-0,6; 5,5] 0,1111[3]
Tumor grade (Interaction p-value: 0,9086)					
G1	6/91 (6,6)	4/93 (4,3)	1,53 [0,45; 5,25] 0,4966[2]	1,57 [0,43; 5,76] 0,5339[4]	2,3 [-4,3; 8,8] 0,5339[4]
G2	46/612 (7,5)	30/602 (5,0)	1,51 [0,97; 2,36] 0,0709[2]	1,55 [0,96; 2,49] 0,0685[3]	2,5 [-0,2; 5,3] 0,0685[3]
G3	36/527 (6,8)	23/506 (4,5)	1,50 [0,90; 2,50] 0,1166[2]	1,54 [0,90; 2,64] 0,1135[3]	2,3 [-0,5; 5,1] 0,1135[3]
GX	2/51 (3,9)	3/59 (5,1)	0,77 [0,13; 4,44] 0,7711[2]	0,76 [0,12; 4,75] 1,0000[4]	-1,2 [-8,9; 6,6] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,0648)					
Negative	7/156 (4,5)	7/169 (4,1)	1,08 [0,39; 3,02] 0,8783[2]	1,09 [0,37; 3,17] 0,8783[3]	0,3 [-4,1; 4,8] 0,8783[3]
Positive	83/1089 (7,6)	53/1066 (5,0)	1,53 [1,10; 2,14] 0,0122[2]	1,58 [1,11; 2,25] 0,0114[3]	2,6 [0,6; 4,7] 0,0114[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,3399)					
White	70/958 (7,3)	52/943 (5,5)	1,33 [0,94; 1,88] 0,1123[2]	1,35 [0,93; 1,96] 0,1108[3]	1,8 [-0,4; 4,0] 0,1108[3]
Asian	13/250 (5,2)	4/242 (1,7)	3,15 [1,04; 9,51] 0,0424[2]	3,26 [1,05; 10,15] 0,0313[3]	3,5 [0,4; 6,7] 0,0313[3]
Other	5/62 (8,1)	4/64 (6,3)	1,29 [0,36; 4,58] 0,6935[2]	1,32 [0,34; 5,15] 0,7417[4]	1,8 [-7,2; 10,8] 0,7417[4]
First endocrine therapy (Interaction p-value: 0,1847)					
Tamoxifen	7/114 (6,1)	2/132 (1,5)	4,05 [0,86; 19,12] 0,0771[2]	4,25 [0,87; 20,90] 0,0855[4]	4,6 [-0,2; 9,5] 0,0855[4]
Aromatase inhibitor	83/1169 (7,1)	58/1132 (5,1)	1,39 [1,00; 1,92] 0,0494[2]	1,42 [1,00; 2,00] 0,0481[3]	2,0 [0,0; 3,9] 0,0481[3]
ECOG-PS (Interaction p-value: 0,7539)					
ECOG-PS 0	71/1070 (6,6)	44/1019 (4,3)	1,54 [1,07; 2,22] 0,0214[2]	1,57 [1,07; 2,32] 0,0203[3]	2,3 [0,4; 4,3] 0,0203[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	19/213 (8,9)	16/245 (6,5)	1,37 [0,72; 2,59] 0,3390[2]	1,40 [0,70; 2,80] 0,3370[3]	2,4 [-2,5; 7,3] 0,3370[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 381.1.2: Subgroups - adverse events according SOC Eye disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9405)					
< 65 years	136/918 (14,8)	47/936 (5,0)	2,95 [2,14; 4,06] <,0001[2]	3,29 [2,33; 4,65] <,0001[3]	9,8 [7,1; 12,5] <,0001[3]
≥ 65 years	61/365 (16,7)	19/328 (5,8)	2,89 [1,76; 4,72] <,0001[2]	3,26 [1,90; 5,59] <,0001[3]	10,9 [6,3; 15,5] <,0001[3]
Prior treatment (Interaction p-value: 0,7241)					
Neoadjuvant chemotherapy	69/430 (16,0)	21/415 (5,1)	3,17 [1,98; 5,07] <,0001[2]	3,59 [2,16; 5,97] <,0001[3]	11,0 [6,9; 15,0] <,0001[3]
Adjuvant chemotherapy	120/784 (15,3)	43/768 (5,6)	2,73 [1,96; 3,82] <,0001[2]	3,05 [2,12; 4,38] <,0001[3]	9,7 [6,7; 12,7] <,0001[3]
No chemotherapy	8/69 (11,6)	2/81 (2,5)	4,70 [1,03; 21,38] 0,0455[2]	5,18 [1,06; 25,28] 0,0444[4]	9,1 [0,8; 17,4] 0,0444[4]
Region (Interaction p-value: 0,3707)					
North America / Europe	123/678 (18,1)	38/649 (5,9)	3,10 [2,19; 4,39] <,0001[2]	3,56 [2,43; 5,22] <,0001[3]	12,3 [8,9; 15,7] <,0001[3]
Asia	33/203 (16,3)	16/201 (8,0)	2,04 [1,16; 3,59] 0,0131[2]	2,24 [1,19; 4,22] 0,0107[3]	8,3 [2,0; 14,6] 0,0107[3]
Other	41/402 (10,2)	12/414 (2,9)	3,52 [1,88; 6,60] <,0001[2]	3,80 [1,97; 7,35] <,0001[3]	7,3 [3,9; 10,7] <,0001[3]
Primary tumor size (Interaction p-value: 0,7086)					
< 20 mm	48/331 (14,5)	14/334 (4,2)	3,46 [1,95; 6,15] <,0001[2]	3,88 [2,09; 7,18] <,0001[3]	10,3 [6,0; 14,7] <,0001[3]
≥ 20 but < 50 mm	96/646 (14,9)	34/653 (5,2)	2,85 [1,96; 4,16] <,0001[2]	3,18 [2,11; 4,78] <,0001[3]	9,7 [6,4; 12,9] <,0001[3]
≥ 50 mm	49/289 (17,0)	18/265 (6,8)	2,50 [1,49; 4,17] 0,0005[2]	2,80 [1,59; 4,95] 0,0002[3]	10,2 [4,9; 15,4] 0,0002[3]
Number of positive lymph nodes (Interaction p-value: 0,7523)					
0-3	68/427 (15,9)	20/418 (4,8)	3,33 [2,06; 5,38] <,0001[2]	3,77 [2,24; 6,33] <,0001[3]	11,1 [7,1; 15,2] <,0001[3]
4-9	77/549 (14,0)	29/542 (5,4)	2,62 [1,74; 3,95] <,0001[2]	2,89 [1,85; 4,50] <,0001[3]	8,7 [5,2; 12,1] <,0001[3]
≥ 10	52/307 (16,9)	17/304 (5,6)	3,03 [1,79; 5,12] <,0001[2]	3,44 [1,94; 6,11] <,0001[3]	11,3 [6,4; 16,3] <,0001[3]
Tumor stage (Interaction p-value: 0,4593)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	16/113 (14,2)	5/114 (4,4)	3,23 [1,22; 8,52] 0,0179[2]	3,60 [1,27; 10,18] 0,0111[3]	9,8 [2,3; 17,2] 0,0111[3]
IIB	22/151 (14,6)	7/136 (5,1)	2,83 [1,25; 6,42] 0,0127[2]	3,14 [1,30; 7,61] 0,0082[3]	9,4 [2,7; 16,2] 0,0082[3]
IIIA	74/495 (14,9)	20/488 (4,1)	3,65 [2,26; 5,88] <,0001[2]	4,11 [2,47; 6,86] <,0001[3]	10,9 [7,3; 14,5] <,0001[3]
IIIB	5/54 (9,3)	4/45 (8,9)	1,04 [0,30; 3,65] 0,9491[2]	1,05 [0,26; 4,15] 1,0000[4]	0,4 [-11,0; 11,7] 1,0000[4]
IIIC	79/468 (16,9)	30/479 (6,3)	2,70 [1,81; 4,02] <,0001[2]	3,04 [1,95; 4,73] <,0001[3]	10,6 [6,6; 14,6] <,0001[3]
Tumor grade (Interaction p-value: 0,3739)					
G1	9/91 (9,9)	6/93 (6,5)	1,53 [0,57; 4,13] 0,3985[2]	1,59 [0,54; 4,67] 0,3941[3]	3,4 [-4,5; 11,3] 0,3941[3]
G2	98/612 (16,0)	31/602 (5,1)	3,11 [2,11; 4,58] <,0001[2]	3,51 [2,30; 5,35] <,0001[3]	10,9 [7,5; 14,3] <,0001[3]
G3	84/527 (15,9)	25/506 (4,9)	3,23 [2,10; 4,96] <,0001[2]	3,65 [2,29; 5,81] <,0001[3]	11,0 [7,3; 14,6] <,0001[3]
GX	5/51 (9,8)	4/59 (6,8)	1,45 [0,41; 5,10] 0,5662[2]	1,49 [0,38; 5,89] 0,7306[4]	3,0 [-7,4; 13,4] 0,7306[4]
Race (Interaction p-value: 0,3433)					
White	148/958 (15,4)	43/943 (4,6)	3,39 [2,44; 4,70] <,0001[2]	3,82 [2,69; 5,44] <,0001[3]	10,9 [8,2; 13,5] <,0001[3]
Asian	37/250 (14,8)	17/242 (7,0)	2,11 [1,22; 3,64] 0,0075[2]	2,30 [1,26; 4,21] 0,0058[3]	7,8 [2,3; 13,2] 0,0058[3]
Other	9/62 (14,5)	3/64 (4,7)	3,10 [0,88; 10,91] 0,0785[2]	3,45 [0,89; 13,42] 0,0602[3]	9,8 [-0,4; 20,0] 0,0602[3]
First endocrine therapy (Interaction p-value: 0,2874)					
Tamoxifen	22/114 (19,3)	12/132 (9,1)	2,12 [1,10; 4,10] 0,0248[2]	2,39 [1,13; 5,08] 0,0207[3]	10,2 [1,5; 19,0] 0,0207[3]
Aromatase inhibitor	175/1169 (15,0)	54/1132 (4,8)	3,14 [2,34; 4,21] <,0001[2]	3,51 [2,56; 4,83] <,0001[3]	10,2 [7,8; 12,6] <,0001[3]
ECOG-PS (Interaction p-value: 0,3337)					
ECOG-PS 0	170/1070 (15,9)	52/1019 (5,1)	3,11 [2,31; 4,20] <,0001[2]	3,51 [2,54; 4,85] <,0001[3]	10,8 [8,2; 13,4] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	27/213 (12,7)	14/245 (5,7)	2,22 [1,19; 4,12] 0,0116[2]	2,40 [1,22; 4,70] 0,0092[3]	7,0 [1,6; 12,3] 0,0092[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 382.1.2: Subgroups - adverse events according SOC Gastrointestinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1125)					
< 65 years	822/918 (89,5)	295/936 (31,5)	2,84 [2,58; 3,13] <,0001[2]	18,61 [14,46; 23,95] <,0001[3]	58,0 [54,5; 61,6] <,0001[3]
≥ 65 years	320/365 (87,7)	117/328 (35,7)	2,46 [2,11; 2,86] <,0001[2]	12,82 [8,72; 18,85] <,0001[3]	52,0 [45,8; 58,2] <,0001[3]
Prior treatment (Interaction p-value: 0,7415)					
Neoadjuvant chemotherapy	377/430 (87,7)	128/415 (30,8)	2,84 [2,45; 3,30] <,0001[2]	15,95 [11,18; 22,75] <,0001[3]	56,8 [51,4; 62,3] <,0001[3]
Adjuvant chemotherapy	705/784 (89,9)	256/768 (33,3)	2,70 [2,43; 2,99] <,0001[2]	17,85 [13,53; 23,54] <,0001[3]	56,6 [52,6; 60,5] <,0001[3]
No chemotherapy	60/69 (87,0)	28/81 (34,6)	2,52 [1,84; 3,44] <,0001[2]	12,62 [5,46; 29,14] <,0001[3]	52,4 [39,3; 65,4] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,3014)					
0-3	377/427 (88,3)	130/418 (31,1)	2,84 [2,45; 3,29] <,0001[2]	16,70 [11,65; 23,95] <,0001[3]	57,2 [51,8; 62,6] <,0001[3]
4-9	487/549 (88,7)	170/542 (31,4)	2,83 [2,49; 3,21] <,0001[2]	17,19 [12,47; 23,68] <,0001[3]	57,3 [52,6; 62,1] <,0001[3]
≥ 10	278/307 (90,6)	112/304 (36,8)	2,46 [2,11; 2,86] <,0001[2]	16,43 [10,50; 25,72] <,0001[3]	53,7 [47,4; 60,0] <,0001[3]
Tumor stage (Interaction p-value: 0,0509)					
IIA	99/113 (87,6)	32/114 (28,1)	3,12 [2,31; 4,22] <,0001[2]	18,12 [9,06; 36,23] <,0001[3]	59,5 [49,3; 69,8] <,0001[3]
IIB	131/151 (86,8)	37/136 (27,2)	3,19 [2,41; 4,23] <,0001[2]	17,53 [9,59; 32,04] <,0001[3]	59,5 [50,3; 68,8] <,0001[3]
IIIA	445/495 (89,9)	145/488 (29,7)	3,03 [2,63; 3,48] <,0001[2]	21,05 [14,82; 29,90] <,0001[3]	60,2 [55,3; 65,0] <,0001[3]
IIIB	45/54 (83,3)	17/45 (37,8)	2,21 [1,49; 3,27] <,0001[2]	8,24 [3,23; 20,99] <,0001[3]	45,6 [28,3; 62,9] <,0001[3]
IIIC	420/468 (89,7)	179/479 (37,4)	2,40 [2,13; 2,71] <,0001[2]	14,66 [10,32; 20,84] <,0001[3]	52,4 [47,2; 57,5] <,0001[3]
Tumor grade (Interaction p-value: 0,0766)					
G1	83/91 (91,2)	32/93 (34,4)	2,65 [1,99; 3,53] <,0001[2]	19,78 [8,52; 45,92] <,0001[3]	56,8 [45,5; 68,1] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G2	550/612 (89,9)	215/602 (35,7)	2,52 [2,25; 2,81] <,0001[2]	15,97 [11,70; 21,79] <,0001[3]	54,2 [49,6; 58,7] <,0001[3]
G3	463/527 (87,9)	151/506 (29,8)	2,94 [2,57; 3,38] <,0001[2]	17,01 [12,31; 23,50] <,0001[3]	58,0 [53,1; 62,9] <,0001[3]
GX	44/51 (86,3)	11/59 (18,6)	4,63 [2,69; 7,97] <,0001[2]	27,43 [9,77; 76,99] <,0001[3]	67,6 [53,9; 81,3] <,0001[3]
Progesterone receptor status (Interaction p-value: 0,5509)					
Negative	140/156 (89,7)	59/169 (34,9)	2,57 [2,08; 3,18] <,0001[2]	16,31 [8,90; 29,91] <,0001[3]	54,8 [46,2; 63,5] <,0001[3]
Positive	967/1089 (88,8)	342/1066 (32,1)	2,77 [2,53; 3,03] <,0001[2]	16,78 [13,36; 21,08] <,0001[3]	56,7 [53,3; 60,1] <,0001[3]
Unknown	9/10 (90,0)	1/7 (14,3)	6,30 [1,01; 39,13] 0,0482[2]	54,00 [2,80; 1040,05] 0,0037[4]	75,7 [43,8; 100,0] 0,0037[4]
Race (Interaction p-value: 0,1567)					
White	851/958 (88,8)	317/943 (33,6)	2,64 [2,41; 2,90] <,0001[2]	15,71 [12,33; 20,01] <,0001[3]	55,2 [51,6; 58,8] <,0001[3]
Asian	222/250 (88,8)	66/242 (27,3)	3,26 [2,64; 4,02] <,0001[2]	21,14 [13,03; 34,32] <,0001[3]	61,5 [54,7; 68,4] <,0001[3]
Other	56/62 (90,3)	24/64 (37,5)	2,41 [1,74; 3,34] <,0001[2]	15,56 [5,82; 41,54] <,0001[3]	52,8 [38,9; 66,8] <,0001[3]
First endocrine therapy (Interaction p-value: 0,8103)					
Tamoxifen	96/114 (84,2)	42/132 (31,8)	2,65 [2,04; 3,44] <,0001[2]	11,43 [6,13; 21,30] <,0001[3]	52,4 [42,0; 62,8] <,0001[3]
Aromatase inhibitor	1046/1169 (89,5)	370/1132 (32,7)	2,74 [2,51; 2,98] <,0001[2]	17,51 [13,99; 21,92] <,0001[3]	56,8 [53,5; 60,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,1697)					
ECOG-PS 0	955/1070 (89,3)	324/1019 (31,8)	2,81 [2,56; 3,08] <,0001[2]	17,81 [14,10; 22,51] <,0001[3]	57,5 [54,0; 60,9] <,0001[3]
ECOG-PS 1	187/213 (87,8)	88/245 (35,9)	2,44 [2,05; 2,91] <,0001[2]	12,83 [7,89; 20,87] <,0001[3]	51,9 [44,4; 59,3] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 383.1.2: Subgroups - adverse events according SOC General disorders and administration site conditions from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9855)					
< 65 years	499/918 (54,4)	298/936 (31,8)	1,71 [1,53; 1,91] <,0001[2]	2,55 [2,11; 3,08] <,0001[3]	22,5 [18,1; 26,9] <,0001[3]
≥ 65 years	217/365 (59,5)	114/328 (34,8)	1,71 [1,44; 2,03] <,0001[2]	2,75 [2,02; 3,75] <,0001[3]	24,7 [17,5; 31,9] <,0001[3]
Prior treatment (Interaction p-value: 0,6483)					
Neoadjuvant chemotherapy	242/430 (56,3)	134/415 (32,3)	1,74 [1,48; 2,05] <,0001[2]	2,70 [2,04; 3,57] <,0001[3]	24,0 [17,5; 30,5] <,0001[3]
Adjuvant chemotherapy	436/784 (55,6)	256/768 (33,3)	1,67 [1,48; 1,88] <,0001[2]	2,51 [2,04; 3,08] <,0001[3]	22,3 [17,5; 27,1] <,0001[3]
No chemotherapy	38/69 (55,1)	22/81 (27,2)	2,03 [1,34; 3,07] 0,0009[2]	3,29 [1,66; 6,50] 0,0005[3]	27,9 [12,7; 43,1] 0,0005[3]
Primary tumor size (Interaction p-value: 0,7328)					
< 20 mm	180/331 (54,4)	100/334 (29,9)	1,82 [1,50; 2,20] <,0001[2]	2,79 [2,03; 3,84] <,0001[3]	24,4 [17,2; 31,7] <,0001[3]
≥ 20 but < 50 mm	357/646 (55,3)	218/653 (33,4)	1,66 [1,46; 1,88] <,0001[2]	2,46 [1,97; 3,09] <,0001[3]	21,9 [16,6; 27,1] <,0001[3]
≥ 50 mm	173/289 (59,9)	93/265 (35,1)	1,71 [1,41; 2,06] <,0001[2]	2,76 [1,95; 3,89] <,0001[3]	24,8 [16,7; 32,8] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,7037)					
0-3	234/427 (54,8)	141/418 (33,7)	1,62 [1,38; 1,91] <,0001[2]	2,38 [1,80; 3,15] <,0001[3]	21,1 [14,5; 27,6] <,0001[3]
4-9	291/549 (53,0)	161/542 (29,7)	1,78 [1,53; 2,08] <,0001[2]	2,67 [2,08; 3,42] <,0001[3]	23,3 [17,6; 29,0] <,0001[3]
≥ 10	191/307 (62,2)	110/304 (36,2)	1,72 [1,45; 2,04] <,0001[2]	2,90 [2,09; 4,03] <,0001[3]	26,0 [18,4; 33,7] <,0001[3]
Tumor stage (Interaction p-value: 0,4629)					
IIA	55/113 (48,7)	38/114 (33,3)	1,46 [1,06; 2,01] 0,0209[2]	1,90 [1,11; 3,24] 0,0188[3]	15,3 [2,7; 28,0] 0,0188[3]
IIB	82/151 (54,3)	45/136 (33,1)	1,64 [1,24; 2,17] 0,0005[2]	2,40 [1,49; 3,88] 0,0003[3]	21,2 [10,0; 32,4] 0,0003[3]
IIIA	269/495 (54,3)	141/488 (28,9)	1,88 [1,60; 2,21] <,0001[2]	2,93 [2,25; 3,81] <,0001[3]	25,4 [19,5; 31,4] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	23/54 (42,6)	15/45 (33,3)	1,28 [0,76; 2,14] 0,3521[2]	1,48 [0,65; 3,37] 0,3455[3]	9,3 [-9,8; 28,3] 0,3455[3]
IIIC	286/468 (61,1)	173/479 (36,1)	1,69 [1,47; 1,94] <,0001[2]	2,78 [2,14; 3,62] <,0001[3]	25,0 [18,8; 31,2] <,0001[3]
Tumor grade (Interaction p-value: 0,1050)					
G1	51/91 (56,0)	29/93 (31,2)	1,80 [1,26; 2,56] 0,0011[2]	2,81 [1,54; 5,14] 0,0007[3]	24,9 [11,0; 38,7] 0,0007[3]
G2	342/612 (55,9)	208/602 (34,6)	1,62 [1,42; 1,84] <,0001[2]	2,40 [1,90; 3,02] <,0001[3]	21,3 [15,9; 26,8] <,0001[3]
G3	294/527 (55,8)	166/506 (32,8)	1,70 [1,47; 1,97] <,0001[2]	2,58 [2,01; 3,33] <,0001[3]	23,0 [17,1; 28,9] <,0001[3]
GX	27/51 (52,9)	8/59 (13,6)	3,90 [1,95; 7,82] 0,0001[2]	7,17 [2,84; 18,11] <,0001[3]	39,4 [23,1; 55,6] <,0001[3]
Progesterone receptor status (Interaction p-value: 0,7816)					
Negative	96/156 (61,5)	63/169 (37,3)	1,65 [1,31; 2,08] <,0001[2]	2,69 [1,72; 4,22] <,0001[3]	24,3 [13,7; 34,8] <,0001[3]
Positive	594/1089 (54,5)	334/1066 (31,3)	1,74 [1,57; 1,93] <,0001[2]	2,63 [2,21; 3,14] <,0001[3]	23,2 [19,2; 27,3] <,0001[3]
Unknown	8/10 (80,0)	4/7 (57,1)	1,40 [0,69; 2,85] 0,3546[2]	3,00 [0,35; 25,87] 0,5928[4]	22,9 [-21,4; 67,1] 0,5928[4]
Race (Interaction p-value: 0,6356)					
White	568/958 (59,3)	330/943 (35,0)	1,69 [1,53; 1,88] <,0001[2]	2,71 [2,25; 3,26] <,0001[3]	24,3 [19,9; 28,6] <,0001[3]
Asian	107/250 (42,8)	58/242 (24,0)	1,79 [1,37; 2,33] <,0001[2]	2,37 [1,61; 3,50] <,0001[3]	18,8 [10,7; 27,0] <,0001[3]
Other	33/62 (53,2)	16/64 (25,0)	2,13 [1,31; 3,46] 0,0022[2]	3,41 [1,61; 7,26] 0,0012[3]	28,2 [11,9; 44,6] 0,0012[3]
First endocrine therapy (Interaction p-value: 0,5172)					
Tamoxifen	62/114 (54,4)	38/132 (28,8)	1,89 [1,38; 2,59] <,0001[2]	2,95 [1,74; 5,00] <,0001[3]	25,6 [13,6; 37,6] <,0001[3]
Aromatase inhibitor	654/1169 (55,9)	374/1132 (33,0)	1,69 [1,54; 1,87] <,0001[2]	2,57 [2,17; 3,05] <,0001[3]	22,9 [19,0; 26,9] <,0001[3]
ECOG-PS (Interaction p-value: 0,8806)					
ECOG-PS 0	592/1070 (55,3)	330/1019 (32,4)	1,71 [1,54; 1,90] <,0001[2]	2,59 [2,16; 3,09] <,0001[3]	22,9 [18,8; 27,1] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	124/213 (58,2)	82/245 (33,5)	1,74 [1,41; 2,15] <,0001[2]	2,77 [1,89; 4,05] <,0001[3]	24,7 [15,9; 33,6] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 384.1.2: Subgroups - adverse events according SOC Infections and infestations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,4121)					
< 65 years	447/918 (48,7)	345/936 (36,9)	1,32 [1,19; 1,47] <,0001[2]	1,63 [1,35; 1,96] <,0001[3]	11,8 [7,4; 16,3] <,0001[3]
≥ 65 years	160/365 (43,8)	119/328 (36,3)	1,21 [1,00; 1,45] 0,0445[2]	1,37 [1,01; 1,86] 0,0429[3]	7,6 [0,3; 14,8] 0,0429[3]
Prior treatment (Interaction p-value: 0,5060)					
Neoadjuvant chemotherapy	203/430 (47,2)	142/415 (34,2)	1,38 [1,17; 1,63] 0,0002[2]	1,72 [1,30; 2,27] 0,0001[3]	13,0 [6,4; 19,6] 0,0001[3]
Adjuvant chemotherapy	374/784 (47,7)	297/768 (38,7)	1,23 [1,10; 1,38] 0,0004[2]	1,45 [1,18; 1,77] 0,0003[3]	9,0 [4,1; 13,9] 0,0003[3]
No chemotherapy	30/69 (43,5)	25/81 (30,9)	1,41 [0,92; 2,15] 0,1120[2]	1,72 [0,88; 3,37] 0,1101[3]	12,6 [-2,8; 28,0] 0,1101[3]
Region (Interaction p-value: 0,0671)					
North America / Europe	352/678 (51,9)	270/649 (41,6)	1,25 [1,11; 1,40] 0,0002[2]	1,52 [1,22; 1,88] 0,0002[3]	10,3 [5,0; 15,7] 0,0002[3]
Asia	102/203 (50,2)	92/201 (45,8)	1,10 [0,90; 1,35] 0,3688[2]	1,20 [0,81; 1,77] 0,3680[3]	4,5 [-5,3; 14,2] 0,3680[3]
Other	153/402 (38,1)	102/414 (24,6)	1,54 [1,25; 1,91] <,0001[2]	1,88 [1,39; 2,54] <,0001[3]	13,4 [7,1; 19,7] <,0001[3]
Primary tumor size (Interaction p-value: 0,2662)					
< 20 mm	156/331 (47,1)	107/334 (32,0)	1,47 [1,21; 1,79] <,0001[2]	1,89 [1,38; 2,59] <,0001[3]	15,1 [7,7; 22,4] <,0001[3]
≥ 20 but < 50 mm	285/646 (44,1)	238/653 (36,4)	1,21 [1,06; 1,38] 0,0050[2]	1,38 [1,10; 1,72] 0,0048[3]	7,7 [2,4; 13,0] 0,0048[3]
≥ 50 mm	158/289 (54,7)	112/265 (42,3)	1,29 [1,09; 1,54] 0,0041[2]	1,65 [1,18; 2,31] 0,0035[3]	12,4 [4,1; 20,7] 0,0035[3]
Number of positive lymph nodes (Interaction p-value: 0,9777)					
0-3	203/427 (47,5)	152/418 (36,4)	1,31 [1,11; 1,54] 0,0011[2]	1,59 [1,20; 2,09] 0,0010[3]	11,2 [4,6; 17,8] 0,0010[3]
4-9	254/549 (46,3)	196/542 (36,2)	1,28 [1,11; 1,48] 0,0008[2]	1,52 [1,19; 1,94] 0,0007[3]	10,1 [4,3; 15,9] 0,0007[3]
≥ 10	150/307 (48,9)	116/304 (38,2)	1,28 [1,07; 1,54] 0,0082[2]	1,55 [1,12; 2,14] 0,0076[3]	10,7 [2,9; 18,5] 0,0076[3]
Tumor stage (Interaction p-value: 0,8804)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	58/113 (51,3)	44/114 (38,6)	1,33 [0,99; 1,78] 0,0565[2]	1,68 [0,99; 2,84] 0,0539[3]	12,7 [-0,1; 25,6] 0,0539[3]
IIB	68/151 (45,0)	49/136 (36,0)	1,25 [0,94; 1,66] 0,1250[2]	1,45 [0,90; 2,34] 0,1212[3]	9,0 [-2,3; 20,3] 0,1212[3]
IIIA	237/495 (47,9)	171/488 (35,0)	1,37 [1,17; 1,59] <,0001[2]	1,70 [1,32; 2,20] <,0001[3]	12,8 [6,7; 18,9] <,0001[3]
IIIB	23/54 (42,6)	16/45 (35,6)	1,20 [0,73; 1,98] 0,4796[2]	1,34 [0,60; 3,04] 0,4755[3]	7,0 [-12,2; 26,3] 0,4755[3]
IIIC	219/468 (46,8)	183/479 (38,2)	1,22 [1,05; 1,42] 0,0078[2]	1,42 [1,10; 1,84] 0,0075[3]	8,6 [2,3; 14,9] 0,0075[3]
Tumor grade (Interaction p-value: 0,6696)					
G1	42/91 (46,2)	27/93 (29,0)	1,59 [1,08; 2,34] 0,0191[2]	2,10 [1,14; 3,85] 0,0165[3]	17,1 [3,3; 30,9] 0,0165[3]
G2	291/612 (47,5)	224/602 (37,2)	1,28 [1,12; 1,46] 0,0003[2]	1,53 [1,22; 1,92] 0,0003[3]	10,3 [4,8; 15,9] 0,0003[3]
G3	247/527 (46,9)	190/506 (37,5)	1,25 [1,08; 1,44] 0,0026[2]	1,47 [1,14; 1,88] 0,0024[3]	9,3 [3,3; 15,3] 0,0024[3]
GX	26/51 (51,0)	21/59 (35,6)	1,43 [0,93; 2,22] 0,1064[2]	1,88 [0,88; 4,04] 0,1038[3]	15,4 [-3,0; 33,8] 0,1038[3]
Progesterone receptor status (Interaction p-value: 0,6164)					
Negative	78/156 (50,0)	71/169 (42,0)	1,19 [0,94; 1,51] 0,1494[2]	1,38 [0,89; 2,14] 0,1488[3]	8,0 [-2,8; 18,8] 0,1488[3]
Positive	513/1089 (47,1)	378/1066 (35,5)	1,33 [1,20; 1,47] <,0001[2]	1,62 [1,36; 1,93] <,0001[3]	11,6 [7,5; 15,8] <,0001[3]
Unknown	6/10 (60,0)	4/7 (57,1)	1,05 [0,46; 2,38] 0,9068[2]	1,13 [0,16; 7,99] 1,0000[4]	2,9 [-44,7; 50,5] 1,0000[4]
Race (Interaction p-value: 0,0799)					
White	451/958 (47,1)	345/943 (36,6)	1,29 [1,16; 1,43] <,0001[2]	1,54 [1,28; 1,85] <,0001[3]	10,5 [6,1; 14,9] <,0001[3]
Asian	117/250 (46,8)	96/242 (39,7)	1,18 [0,96; 1,45] 0,1122[2]	1,34 [0,94; 1,91] 0,1105[3]	7,1 [-1,6; 15,9] 0,1105[3]
Other	32/62 (51,6)	15/64 (23,4)	2,20 [1,33; 3,65] 0,0021[2]	3,48 [1,62; 7,48] 0,0011[3]	28,2 [12,0; 44,4] 0,0011[3]
First endocrine therapy (Interaction p-value: 0,9358)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	63/114 (55,3)	57/132 (43,2)	1,28 [0,99; 1,65] 0,0590[2]	1,63 [0,98; 2,69] 0,0587[3]	12,1 [-0,4; 24,5] 0,0587[3]
Aromatase inhibitor	544/1169 (46,5)	407/1132 (36,0)	1,29 [1,17; 1,43] <,0001[2]	1,55 [1,31; 1,83] <,0001[3]	10,6 [6,6; 14,6] <,0001[3]
ECOG-PS (Interaction p-value: 0,5846)					
ECOG-PS 0	504/1070 (47,1)	377/1019 (37,0)	1,27 [1,15; 1,41] <,0001[2]	1,52 [1,27; 1,81] <,0001[3]	10,1 [5,9; 14,3] <,0001[3]
ECOG-PS 1	103/213 (48,4)	87/245 (35,5)	1,36 [1,09; 1,69] 0,0056[2]	1,70 [1,17; 2,47] 0,0054[3]	12,8 [3,8; 21,8] 0,0054[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 385.1.2: Subgroups - adverse events according SOC Investigations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,2502)					
< 65 years	442/918 (48,1)	198/936 (21,2)	2,28 [1,98; 2,62] <,0001[2]	3,46 [2,82; 4,24] <,0001[3]	27,0 [22,8; 31,2] <,0001[3]
≥ 65 years	181/365 (49,6)	83/328 (25,3)	1,96 [1,58; 2,42] <,0001[2]	2,90 [2,10; 4,01] <,0001[3]	24,3 [17,3; 31,2] <,0001[3]
Prior treatment (Interaction p-value: 0,7095)					
Neoadjuvant chemotherapy	217/430 (50,5)	101/415 (24,3)	2,07 [1,71; 2,52] <,0001[2]	3,17 [2,36; 4,25] <,0001[3]	26,1 [19,9; 32,4] <,0001[3]
Adjuvant chemotherapy	377/784 (48,1)	167/768 (21,7)	2,21 [1,90; 2,58] <,0001[2]	3,33 [2,67; 4,16] <,0001[3]	26,3 [21,8; 30,9] <,0001[3]
No chemotherapy	29/69 (42,0)	13/81 (16,0)	2,62 [1,48; 4,63] 0,0009[2]	3,79 [1,77; 8,12] 0,0004[3]	26,0 [11,9; 40,1] 0,0004[3]
Primary tumor size (Interaction p-value: 0,4280)					
< 20 mm	162/331 (48,9)	65/334 (19,5)	2,51 [1,97; 3,21] <,0001[2]	3,97 [2,81; 5,61] <,0001[3]	29,5 [22,6; 36,3] <,0001[3]
≥ 20 but < 50 mm	316/646 (48,9)	150/653 (23,0)	2,13 [1,81; 2,50] <,0001[2]	3,21 [2,53; 4,08] <,0001[3]	25,9 [20,9; 31,0] <,0001[3]
≥ 50 mm	135/289 (46,7)	61/265 (23,0)	2,03 [1,58; 2,61] <,0001[2]	2,93 [2,03; 4,23] <,0001[3]	23,7 [16,0; 31,4] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,1933)					
0-3	206/427 (48,2)	78/418 (18,7)	2,59 [2,07; 3,23] <,0001[2]	4,06 [2,98; 5,54] <,0001[3]	29,6 [23,5; 35,6] <,0001[3]
4-9	257/549 (46,8)	124/542 (22,9)	2,05 [1,71; 2,45] <,0001[2]	2,97 [2,28; 3,85] <,0001[3]	23,9 [18,5; 29,4] <,0001[3]
≥ 10	160/307 (52,1)	79/304 (26,0)	2,01 [1,61; 2,49] <,0001[2]	3,10 [2,21; 4,36] <,0001[3]	26,1 [18,7; 33,6] <,0001[3]
Tumor stage (Interaction p-value: 0,3128)					
IIA	60/113 (53,1)	19/114 (16,7)	3,19 [2,04; 4,97] <,0001[2]	5,66 [3,06; 10,48] <,0001[3]	36,4 [25,0; 47,9] <,0001[3]
IIB	69/151 (45,7)	29/136 (21,3)	2,14 [1,49; 3,09] <,0001[2]	3,10 [1,84; 5,22] <,0001[3]	24,4 [13,9; 34,9] <,0001[3]
IIIA	237/495 (47,9)	115/488 (23,6)	2,03 [1,69; 2,44] <,0001[2]	2,98 [2,27; 3,92] <,0001[3]	24,3 [18,5; 30,1] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	25/54 (46,3)	6/45 (13,3)	3,47 [1,56; 7,72] 0,0022[2]	5,60 [2,04; 15,42] 0,0004[3]	33,0 [16,4; 49,6] 0,0004[3]
IIIC	231/468 (49,4)	112/479 (23,4)	2,11 [1,75; 2,54] <,0001[2]	3,19 [2,42; 4,22] <,0001[3]	26,0 [20,1; 31,9] <,0001[3]
Tumor grade (Interaction p-value: 0,9394)					
G1	34/91 (37,4)	18/93 (19,4)	1,93 [1,18; 3,16] 0,0089[2]	2,49 [1,28; 4,84] 0,0067[3]	18,0 [5,2; 30,8] 0,0067[3]
G2	302/612 (49,3)	137/602 (22,8)	2,17 [1,83; 2,56] <,0001[2]	3,31 [2,58; 4,24] <,0001[3]	26,6 [21,4; 31,8] <,0001[3]
G3	256/527 (48,6)	109/506 (21,5)	2,26 [1,87; 2,72] <,0001[2]	3,44 [2,62; 4,52] <,0001[3]	27,0 [21,5; 32,6] <,0001[3]
GX	30/51 (58,8)	15/59 (25,4)	2,31 [1,41; 3,79] 0,0009[2]	4,19 [1,87; 9,41] 0,0004[3]	33,4 [15,9; 50,9] 0,0004[3]
Progesterone receptor status (Interaction p-value: 0,8306)					
Negative	79/156 (50,6)	37/169 (21,9)	2,31 [1,67; 3,20] <,0001[2]	3,66 [2,26; 5,92] <,0001[3]	28,7 [18,7; 38,8] <,0001[3]
Positive	524/1089 (48,1)	237/1066 (22,2)	2,16 [1,90; 2,46] <,0001[2]	3,24 [2,69; 3,91] <,0001[3]	25,9 [22,0; 29,8] <,0001[3]
Unknown	5/10 (50,0)	1/7 (14,3)	3,50 [0,51; 23,81] 0,2004[2]	6,00 [0,52; 69,75] 0,3043[4]	35,7 [-4,7; 76,1] 0,3043[4]
Race (Interaction p-value: 0,1390)					
White	418/958 (43,6)	202/943 (21,4)	2,04 [1,77; 2,35] <,0001[2]	2,84 [2,32; 3,47] <,0001[3]	22,2 [18,1; 26,3] <,0001[3]
Asian	165/250 (66,0)	67/242 (27,7)	2,38 [1,91; 2,98] <,0001[2]	5,07 [3,45; 7,45] <,0001[3]	38,3 [30,2; 46,5] <,0001[3]
Other	32/62 (51,6)	9/64 (14,1)	3,67 [1,91; 7,04] <,0001[2]	6,52 [2,75; 15,45] <,0001[3]	37,6 [22,5; 52,6] <,0001[3]
First endocrine therapy (Interaction p-value: 0,3696)					
Tamoxifen	46/114 (40,4)	20/132 (15,2)	2,66 [1,68; 4,22] <,0001[2]	3,79 [2,07; 6,94] <,0001[3]	25,2 [14,3; 36,1] <,0001[3]
Aromatase inhibitor	577/1169 (49,4)	261/1132 (23,1)	2,14 [1,90; 2,42] <,0001[2]	3,25 [2,72; 3,89] <,0001[3]	26,3 [22,5; 30,1] <,0001[3]
ECOG-PS (Interaction p-value: 0,2042)					
ECOG-PS 0	533/1070 (49,8)	225/1019 (22,1)	2,26 [1,98; 2,57] <,0001[2]	3,50 [2,90; 4,24] <,0001[3]	27,7 [23,8; 31,7] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	90/213 (42,3)	56/245 (22,9)	1,85 [1,40; 2,44] <,0001[2]	2,47 [1,65; 3,70] <,0001[3]	19,4 [10,9; 27,9] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 386.1.2: Subgroups - adverse events according SOC Metabolism and nutrition disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5004)					
< 65 years	234/918 (25,5)	147/936 (15,7)	1,62 [1,35; 1,95] <,0001[2]	1,84 [1,46; 2,31] <,0001[3]	9,8 [6,1; 13,4] <,0001[3]
≥ 65 years	129/365 (35,3)	64/328 (19,5)	1,81 [1,40; 2,35] <,0001[2]	2,25 [1,59; 3,19] <,0001[3]	15,8 [9,3; 22,3] <,0001[3]
Prior treatment (Interaction p-value: 0,3862)					
Neoadjuvant chemotherapy	117/430 (27,2)	77/415 (18,6)	1,47 [1,14; 1,89] 0,0031[2]	1,64 [1,18; 2,27] 0,0028[3]	8,7 [3,0; 14,3] 0,0028[3]
Adjuvant chemotherapy	226/784 (28,8)	122/768 (15,9)	1,81 [1,49; 2,21] <,0001[2]	2,14 [1,67; 2,75] <,0001[3]	12,9 [8,9; 17,0] <,0001[3]
No chemotherapy	20/69 (29,0)	12/81 (14,8)	1,96 [1,03; 3,71] 0,0397[2]	2,35 [1,05; 5,24] 0,0347[3]	14,2 [1,0; 27,4] 0,0347[3]
Number of positive lymph nodes (Interaction p-value: 0,3288)					
0-3	116/427 (27,2)	66/418 (15,8)	1,72 [1,31; 2,25] <,0001[2]	1,99 [1,42; 2,79] <,0001[3]	11,4 [5,9; 16,9] <,0001[3]
4-9	163/549 (29,7)	86/542 (15,9)	1,87 [1,48; 2,36] <,0001[2]	2,24 [1,67; 3,01] <,0001[3]	13,8 [8,9; 18,7] <,0001[3]
≥ 10	84/307 (27,4)	59/304 (19,4)	1,41 [1,05; 1,89] 0,0215[2]	1,56 [1,07; 2,29] 0,0202[3]	8,0 [1,3; 14,6] 0,0202[3]
Tumor stage (Interaction p-value: 0,4066)					
IIA	29/113 (25,7)	21/114 (18,4)	1,39 [0,85; 2,29] 0,1916[2]	1,53 [0,81; 2,88] 0,1880[3]	7,2 [-3,5; 18,0] 0,1880[3]
IIB	33/151 (21,9)	17/136 (12,5)	1,75 [1,02; 2,99] 0,0416[2]	1,96 [1,03; 3,71] 0,0370[3]	9,4 [0,7; 18,0] 0,0370[3]
IIIA	149/495 (30,1)	75/488 (15,4)	1,96 [1,53; 2,51] <,0001[2]	2,37 [1,74; 3,24] <,0001[3]	14,7 [9,6; 19,9] <,0001[3]
IIIB	12/54 (22,2)	10/45 (22,2)	1,00 [0,48; 2,10] 1,0000[2]	1,00 [0,39; 2,59] 1,0000[3]	0,0 [-16,4; 16,4] 1,0000[3]
IIIC	138/468 (29,5)	87/479 (18,2)	1,62 [1,28; 2,06] <,0001[2]	1,88 [1,39; 2,56] <,0001[3]	11,3 [5,9; 16,7] <,0001[3]
Tumor grade (Interaction p-value: 0,2028)					
G1	28/91 (30,8)	15/93 (16,1)	1,91 [1,09; 3,33] 0,0229[2]	2,31 [1,14; 4,70] 0,0190[3]	14,6 [2,6; 26,7] 0,0190[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G2	188/612 (30,7)	103/602 (17,1)	1,80 [1,45; 2,22] <,0001[2]	2,15 [1,64; 2,82] <,0001[3]	13,6 [8,9; 18,3] <,0001[3]
G3	127/527 (24,1)	85/506 (16,8)	1,43 [1,12; 1,83] 0,0041[2]	1,57 [1,16; 2,14] 0,0037[3]	7,3 [2,4; 12,2] 0,0037[3]
GX	19/51 (37,3)	7/59 (11,9)	3,14 [1,44; 6,86] 0,0041[2]	4,41 [1,67; 11,66] 0,0018[3]	25,4 [9,8; 41,0] 0,0018[3]
Progesterone receptor status (Interaction p-value: 0,7745)					
Negative	49/156 (31,4)	27/169 (16,0)	1,97 [1,30; 2,98] 0,0015[2]	2,41 [1,41; 4,10] 0,0010[3]	15,4 [6,3; 24,6] 0,0010[3]
Positive	307/1089 (28,2)	179/1066 (16,8)	1,68 [1,43; 1,98] <,0001[2]	1,95 [1,58; 2,39] <,0001[3]	11,4 [7,9; 14,9] <,0001[3]
Unknown	2/10 (20,0)	1/7 (14,3)	1,40 [0,16; 12,60] 0,7641[2]	1,50 [0,11; 20,68] 1,0000[4]	5,7 [-30,2; 41,6] 1,0000[4]
Race (Interaction p-value: 0,2320)					
White	264/958 (27,6)	162/943 (17,2)	1,60 [1,35; 1,91] <,0001[2]	1,83 [1,47; 2,29] <,0001[3]	10,4 [6,7; 14,1] <,0001[3]
Asian	61/250 (24,4)	25/242 (10,3)	2,36 [1,54; 3,63] <,0001[2]	2,80 [1,69; 4,64] <,0001[3]	14,1 [7,5; 20,6] <,0001[3]
Other	29/62 (46,8)	20/64 (31,3)	1,50 [0,95; 2,35] 0,0790[2]	1,93 [0,93; 4,00] 0,0739[3]	15,5 [-1,3; 32,4] 0,0739[3]
First endocrine therapy (Interaction p-value: 0,2740)					
Tamoxifen	28/114 (24,6)	14/132 (10,6)	2,32 [1,28; 4,18] 0,0053[2]	2,74 [1,36; 5,52] 0,0037[3]	14,0 [4,5; 23,4] 0,0037[3]
Aromatase inhibitor	335/1169 (28,7)	197/1132 (17,4)	1,65 [1,41; 1,92] <,0001[2]	1,91 [1,56; 2,33] <,0001[3]	11,3 [7,8; 14,7] <,0001[3]
ECOG-PS (Interaction p-value: 0,9942)					
ECOG-PS 0	295/1070 (27,6)	165/1019 (16,2)	1,70 [1,44; 2,02] <,0001[2]	1,97 [1,59; 2,44] <,0001[3]	11,4 [7,9; 14,9] <,0001[3]
ECOG-PS 1	68/213 (31,9)	46/245 (18,8)	1,70 [1,23; 2,36] 0,0014[2]	2,03 [1,32; 3,12] 0,0012[3]	13,1 [5,2; 21,1] 0,0012[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 387.1.2: Subgroups - adverse events according SOC Musculoskeletal and connective tissue disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,0579)					
< 65 years	463/918 (50,4)	542/936 (57,9)	0,87 [0,80; 0,95] 0,0013[2]	0,74 [0,62; 0,89] 0,0012[3]	-7,5 [-12,0; -2,9] 0,0012[3]
≥ 65 years	168/365 (46,0)	203/328 (61,9)	0,74 [0,65; 0,86] <,0001[2]	0,53 [0,39; 0,71] <,0001[3]	-15,9 [-23,2; -8,5] <,0001[3]
Prior treatment (Interaction p-value: 0,9299)					
Neoadjuvant chemotherapy	217/430 (50,5)	247/415 (59,5)	0,85 [0,75; 0,96] 0,0084[2]	0,69 [0,53; 0,91] 0,0082[3]	-9,1 [-15,7; -2,4] 0,0082[3]
Adjuvant chemotherapy	388/784 (49,5)	460/768 (59,9)	0,83 [0,75; 0,91] <,0001[2]	0,66 [0,54; 0,80] <,0001[3]	-10,4 [-15,3; -5,5] <,0001[3]
No chemotherapy	26/69 (37,7)	38/81 (46,9)	0,80 [0,55; 1,18] 0,2605[2]	0,68 [0,36; 1,32] 0,2545[3]	-9,2 [-25,0; 6,5] 0,2545[3]
Region (Interaction p-value: 0,9341)					
North America / Europe	400/678 (59,0)	457/649 (70,4)	0,84 [0,77; 0,91] <,0001[2]	0,60 [0,48; 0,76] <,0001[3]	-11,4 [-16,5; -6,3] <,0001[3]
Asia	87/203 (42,9)	106/201 (52,7)	0,81 [0,66; 1,00] 0,0482[2]	0,67 [0,45; 1,00] 0,0469[3]	-9,9 [-19,6; -0,2] 0,0469[3]
Other	144/402 (35,8)	182/414 (44,0)	0,81 [0,69; 0,97] 0,0183[2]	0,71 [0,54; 0,94] 0,0176[3]	-8,1 [-14,8; -1,4] 0,0176[3]
Primary tumor size (Interaction p-value: 0,7852)					
< 20 mm	171/331 (51,7)	199/334 (59,6)	0,87 [0,76; 0,99] 0,0407[2]	0,73 [0,53; 0,99] 0,0399[3]	-7,9 [-15,4; -0,4] 0,0399[3]
≥ 20 but < 50 mm	297/646 (46,0)	368/653 (56,4)	0,82 [0,73; 0,91] 0,0002[2]	0,66 [0,53; 0,82] 0,0002[3]	-10,4 [-15,8; -5,0] 0,0002[3]
≥ 50 mm	158/289 (54,7)	172/265 (64,9)	0,84 [0,73; 0,97] 0,0143[2]	0,65 [0,46; 0,92] 0,0142[3]	-10,2 [-18,4; -2,1] 0,0142[3]
Number of positive lymph nodes (Interaction p-value: 0,1676)					
0-3	223/427 (52,2)	244/418 (58,4)	0,89 [0,79; 1,01] 0,0728[2]	0,78 [0,59; 1,02] 0,0723[3]	-6,1 [-12,8; 0,5] 0,0723[3]
4-9	272/549 (49,5)	319/542 (58,9)	0,84 [0,75; 0,94] 0,0021[2]	0,69 [0,54; 0,87] 0,0020[3]	-9,3 [-15,2; -3,4] 0,0020[3]
≥ 10	136/307 (44,3)	182/304 (59,9)	0,74 [0,63; 0,86] 0,0001[2]	0,53 [0,39; 0,74] 0,0001[3]	-15,6 [-23,4; -7,7] 0,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,3708)					
IIA	62/113 (54,9)	66/114 (57,9)	0,95 [0,75; 1,19] 0,6458[2]	0,88 [0,52; 1,49] 0,6456[3]	-3,0 [-15,9; 9,9] 0,6456[3]
IIB	77/151 (51,0)	78/136 (57,4)	0,89 [0,72; 1,10] 0,2799[2]	0,77 [0,49; 1,23] 0,2804[3]	-6,4 [-17,9; 5,2] 0,2804[3]
IIIA	250/495 (50,5)	283/488 (58,0)	0,87 [0,78; 0,98] 0,0188[2]	0,74 [0,57; 0,95] 0,0185[3]	-7,5 [-13,7; -1,3] 0,0185[3]
IIIB	22/54 (40,7)	25/45 (55,6)	0,73 [0,48; 1,11] 0,1424[2]	0,55 [0,25; 1,22] 0,1416[3]	-14,8 [-34,4; 4,7] 0,1416[3]
IIIC	219/468 (46,8)	292/479 (61,0)	0,77 [0,68; 0,87] <,0001[2]	0,56 [0,44; 0,73] <,0001[3]	-14,2 [-20,5; -7,9] <,0001[3]
Tumor grade (Interaction p-value: 0,4186)					
G1	50/91 (54,9)	50/93 (53,8)	1,02 [0,78; 1,33] 0,8722[2]	1,05 [0,59; 1,87] 0,8722[3]	1,2 [-13,2; 15,6] 0,8722[3]
G2	314/612 (51,3)	380/602 (63,1)	0,81 [0,74; 0,90] <,0001[2]	0,62 [0,49; 0,77] <,0001[3]	-11,8 [-17,3; -6,3] <,0001[3]
G3	246/527 (46,7)	289/506 (57,1)	0,82 [0,73; 0,92] 0,0008[2]	0,66 [0,51; 0,84] 0,0008[3]	-10,4 [-16,5; -4,4] 0,0008[3]
GX	20/51 (39,2)	25/59 (42,4)	0,93 [0,59; 1,46] 0,7377[2]	0,88 [0,41; 1,88] 0,7370[3]	-3,2 [-21,6; 15,2] 0,7370[3]
Progesterone receptor status (Interaction p-value: 0,5508)					
Negative	80/156 (51,3)	100/169 (59,2)	0,87 [0,71; 1,06] 0,1560[2]	0,73 [0,47; 1,13] 0,1529[3]	-7,9 [-18,7; 2,9] 0,1529[3]
Positive	529/1089 (48,6)	624/1066 (58,5)	0,83 [0,77; 0,90] <,0001[2]	0,67 [0,56; 0,79] <,0001[3]	-10,0 [-14,2; -5,8] <,0001[3]
Unknown	6/10 (60,0)	3/7 (42,9)	1,40 [0,52; 3,78] 0,5070[2]	2,00 [0,28; 14,20] 0,6372[4]	17,1 [-30,5; 64,7] 0,6372[4]
Race (Interaction p-value: 0,8828)					
White	498/958 (52,0)	583/943 (61,8)	0,84 [0,78; 0,91] <,0001[2]	0,67 [0,56; 0,80] <,0001[3]	-9,8 [-14,3; -5,4] <,0001[3]
Asian	96/250 (38,4)	115/242 (47,5)	0,81 [0,66; 0,99] 0,0420[2]	0,69 [0,48; 0,99] 0,0410[3]	-9,1 [-17,8; -0,4] 0,0410[3]
Other	31/62 (50,0)	36/64 (56,3)	0,89 [0,64; 1,24] 0,4837[2]	0,78 [0,39; 1,57] 0,4821[3]	-6,3 [-23,6; 11,1] 0,4821[3]
First endocrine therapy (Interaction p-value: 0,2749)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	50/114 (43,9)	60/132 (45,5)	0,96 [0,73; 1,28] 0,8021[2]	0,94 [0,57; 1,55] 0,8019[3]	-1,6 [-14,0; 10,9] 0,8019[3]
Aromatase inhibitor	581/1169 (49,7)	685/1132 (60,5)	0,82 [0,76; 0,88] <,0001[2]	0,64 [0,55; 0,76] <,0001[3]	-10,8 [-14,9; -6,8] <,0001[3]
ECOG-PS (Interaction p-value: 0,8173)					
ECOG-PS 0	530/1070 (49,5)	603/1019 (59,2)	0,84 [0,77; 0,91] <,0001[2]	0,68 [0,57; 0,81] <,0001[3]	-9,6 [-13,9; -5,4] <,0001[3]
ECOG-PS 1	101/213 (47,4)	142/245 (58,0)	0,82 [0,69; 0,98] 0,0263[2]	0,65 [0,45; 0,95] 0,0242[3]	-10,5 [-19,7; -1,4] 0,0242[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 388.1.2: Subgroups - adverse events according SOC Nervous system disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5067)					
< 65 years	362/918 (39,4)	254/936 (27,1)	1,45 [1,27; 1,66] <,0001[2]	1,75 [1,44; 2,13] <,0001[3]	12,3 [8,0; 16,6] <,0001[3]
≥ 65 years	138/365 (37,8)	93/328 (28,4)	1,33 [1,07; 1,66] 0,0092[2]	1,54 [1,12; 2,12] 0,0084[3]	9,5 [2,5; 16,4] 0,0084[3]
Prior treatment (Interaction p-value: 0,3910)					
Neoadjuvant chemotherapy	166/430 (38,6)	112/415 (27,0)	1,43 [1,17; 1,74] 0,0004[2]	1,70 [1,27; 2,28] 0,0003[3]	11,6 [5,3; 17,9] 0,0003[3]
Adjuvant chemotherapy	304/784 (38,8)	217/768 (28,3)	1,37 [1,19; 1,58] <,0001[2]	1,61 [1,30; 1,99] <,0001[3]	10,5 [5,9; 15,2] <,0001[3]
No chemotherapy	30/69 (43,5)	18/81 (22,2)	1,96 [1,20; 3,19] 0,0071[2]	2,69 [1,33; 5,46] 0,0054[3]	21,3 [6,5; 36,0] 0,0054[3]
Region (Interaction p-value: 0,4024)					
North America / Europe	320/678 (47,2)	226/649 (34,8)	1,36 [1,19; 1,55] <,0001[2]	1,67 [1,34; 2,09] <,0001[3]	12,4 [7,1; 17,6] <,0001[3]
Asia	68/203 (33,5)	51/201 (25,4)	1,32 [0,97; 1,79] 0,0754[2]	1,48 [0,96; 2,28] 0,0733[3]	8,1 [-0,7; 17,0] 0,0733[3]
Other	112/402 (27,9)	70/414 (16,9)	1,65 [1,26; 2,15] 0,0002[2]	1,90 [1,35; 2,66] 0,0002[3]	11,0 [5,3; 16,6] 0,0002[3]
Primary tumor size (Interaction p-value: 0,8622)					
< 20 mm	121/331 (36,6)	85/334 (25,4)	1,44 [1,14; 1,81] 0,0022[2]	1,69 [1,21; 2,35] 0,0020[3]	11,1 [4,1; 18,1] 0,0020[3]
≥ 20 but < 50 mm	253/646 (39,2)	178/653 (27,3)	1,44 [1,23; 1,68] <,0001[2]	1,72 [1,36; 2,17] <,0001[3]	11,9 [6,8; 17,0] <,0001[3]
≥ 50 mm	121/289 (41,9)	83/265 (31,3)	1,34 [1,07; 1,67] 0,0111[2]	1,58 [1,11; 2,24] 0,0101[3]	10,5 [2,6; 18,5] 0,0101[3]
Number of positive lymph nodes (Interaction p-value: 0,9421)					
0-3	181/427 (42,4)	122/418 (29,2)	1,45 [1,21; 1,75] <,0001[2]	1,79 [1,34; 2,37] <,0001[3]	13,2 [6,8; 19,6] <,0001[3]
4-9	202/549 (36,8)	141/542 (26,0)	1,41 [1,18; 1,69] 0,0002[2]	1,66 [1,28; 2,14] 0,0001[3]	10,8 [5,3; 16,2] 0,0001[3]
≥ 10	117/307 (38,1)	84/304 (27,6)	1,38 [1,09; 1,74] 0,0064[2]	1,61 [1,15; 2,27] 0,0058[3]	10,5 [3,1; 17,9] 0,0058[3]
Tumor stage (Interaction p-value: 0,7476)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	41/113 (36,3)	34/114 (29,8)	1,22 [0,84; 1,77] 0,3028[2]	1,34 [0,77; 2,33] 0,3009[3]	6,5 [-5,8; 18,7] 0,3009[3]
IIB	69/151 (45,7)	45/136 (33,1)	1,38 [1,03; 1,86] 0,0323[2]	1,70 [1,05; 2,75] 0,0293[3]	12,6 [1,4; 23,8] 0,0293[3]
IIIA	194/495 (39,2)	127/488 (26,0)	1,51 [1,25; 1,81] <,0001[2]	1,83 [1,40; 2,40] <,0001[3]	13,2 [7,4; 19,0] <,0001[3]
IIIB	20/54 (37,0)	9/45 (20,0)	1,85 [0,94; 3,66] 0,0757[2]	2,35 [0,94; 5,88] 0,0636[3]	17,0 [-0,4; 34,4] 0,0636[3]
IIIC	174/468 (37,2)	132/479 (27,6)	1,35 [1,12; 1,63] 0,0017[2]	1,56 [1,18; 2,05] 0,0015[3]	9,6 [3,7; 15,6] 0,0015[3]
Tumor grade (Interaction p-value: 0,1380)					
G1	34/91 (37,4)	19/93 (20,4)	1,83 [1,13; 2,96] 0,0140[2]	2,32 [1,20; 4,49] 0,0112[3]	16,9 [4,1; 29,8] 0,0112[3]
G2	258/612 (42,2)	182/602 (30,2)	1,39 [1,20; 1,62] <,0001[2]	1,68 [1,33; 2,13] <,0001[3]	11,9 [6,6; 17,3] <,0001[3]
G3	188/527 (35,7)	138/506 (27,3)	1,31 [1,09; 1,57] 0,0040[2]	1,48 [1,13; 1,93] 0,0037[3]	8,4 [2,8; 14,0] 0,0037[3]
GX	20/51 (39,2)	8/59 (13,6)	2,89 [1,39; 6,00] 0,0043[2]	4,11 [1,62; 10,46] 0,0021[3]	25,7 [9,7; 41,7] 0,0021[3]
Progesterone receptor status (Interaction p-value: 0,3126)					
Negative	57/156 (36,5)	53/169 (31,4)	1,17 [0,86; 1,58] 0,3248[2]	1,26 [0,80; 2,00] 0,3244[3]	5,2 [-5,1; 15,5] 0,3244[3]
Positive	428/1089 (39,3)	286/1066 (26,8)	1,46 [1,29; 1,66] <,0001[2]	1,77 [1,47; 2,12] <,0001[3]	12,5 [8,5; 16,4] <,0001[3]
Unknown	4/10 (40,0)	1/7 (14,3)	2,80 [0,39; 20,02] 0,3049[2]	4,00 [0,34; 47,11] 0,3382[4]	25,7 [-14,2; 65,6] 0,3382[4]
Race (Interaction p-value: 0,8761)					
White	389/958 (40,6)	262/943 (27,8)	1,46 [1,29; 1,66] <,0001[2]	1,78 [1,47; 2,15] <,0001[3]	12,8 [8,6; 17,0] <,0001[3]
Asian	79/250 (31,6)	56/242 (23,1)	1,37 [1,02; 1,83] 0,0373[2]	1,53 [1,03; 2,29] 0,0355[3]	8,5 [0,6; 16,3] 0,0355[3]
Other	26/62 (41,9)	20/64 (31,3)	1,34 [0,84; 2,14] 0,2168[2]	1,59 [0,77; 3,30] 0,2130[3]	10,7 [-6,0; 27,4] 0,2130[3]
First endocrine therapy (Interaction p-value: 0,2637)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	38/114 (33,3)	38/132 (28,8)	1,16 [0,80; 1,68] 0,4415[2]	1,24 [0,72; 2,13] 0,4417[3]	4,5 [-7,1; 16,1] 0,4417[3]
Aromatase inhibitor	462/1169 (39,5)	309/1132 (27,3)	1,45 [1,29; 1,63] <,0001[2]	1,74 [1,46; 2,07] <,0001[3]	12,2 [8,4; 16,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,3469)					
ECOG-PS 0	414/1070 (38,7)	285/1019 (28,0)	1,38 [1,22; 1,57] <,0001[2]	1,63 [1,35; 1,95] <,0001[3]	10,7 [6,7; 14,7] <,0001[3]
ECOG-PS 1	86/213 (40,4)	62/245 (25,3)	1,60 [1,22; 2,09] 0,0007[2]	2,00 [1,34; 2,97] 0,0006[3]	15,1 [6,5; 23,6] 0,0006[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 389.1.2: Subgroups - adverse events according SOC Renal and urinary disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,6782)					
< 65 years	63/918 (6,9)	46/936 (4,9)	1,40 [0,97; 2,02] 0,0762[2]	1,43 [0,96; 2,11] 0,0746[3]	1,9 [-0,2; 4,1] 0,0746[3]
≥ 65 years	39/365 (10,7)	22/328 (6,7)	1,59 [0,97; 2,63] 0,0684[2]	1,66 [0,96; 2,87] 0,0650[3]	4,0 [-0,2; 8,1] 0,0650[3]
Prior treatment (Interaction p-value: 0,2380)					
Neoadjuvant chemotherapy	31/430 (7,2)	15/415 (3,6)	1,99 [1,09; 3,64] 0,0245[2]	2,07 [1,10; 3,90] 0,0213[3]	3,6 [0,6; 6,6] 0,0213[3]
Adjuvant chemotherapy	62/784 (7,9)	49/768 (6,4)	1,24 [0,86; 1,78] 0,2440[2]	1,26 [0,85; 1,86] 0,2429[3]	1,5 [-1,0; 4,1] 0,2429[3]
No chemotherapy	9/69 (13,0)	4/81 (4,9)	2,64 [0,85; 8,20] 0,0930[2]	2,89 [0,85; 9,83] 0,0787[3]	8,1 [-1,1; 17,3] 0,0787[3]
Region (Interaction p-value: 0,7533)					
North America / Europe	64/678 (9,4)	42/649 (6,5)	1,46 [1,00; 2,12] 0,0479[2]	1,51 [1,00; 2,26] 0,0462[3]	3,0 [0,1; 5,9] 0,0462[3]
Asia	13/203 (6,4)	11/201 (5,5)	1,17 [0,54; 2,55] 0,6925[2]	1,18 [0,52; 2,70] 0,6921[3]	0,9 [-3,7; 5,5] 0,6921[3]
Other	25/402 (6,2)	15/414 (3,6)	1,72 [0,92; 3,21] 0,0904[2]	1,76 [0,92; 3,40] 0,0860[3]	2,6 [-0,4; 5,6] 0,0860[3]
Primary tumor size (Interaction p-value: 0,1276)					
< 20 mm	31/331 (9,4)	14/334 (4,2)	2,23 [1,21; 4,12] 0,0101[2]	2,36 [1,23; 4,53] 0,0079[3]	5,2 [1,4; 9,0] 0,0079[3]
≥ 20 but < 50 mm	47/646 (7,3)	43/653 (6,6)	1,10 [0,74; 1,65] 0,6243[2]	1,11 [0,73; 1,71] 0,6241[3]	0,7 [-2,1; 3,5] 0,6241[3]
≥ 50 mm	22/289 (7,6)	11/265 (4,2)	1,83 [0,91; 3,71] 0,0915[2]	1,90 [0,90; 4,00] 0,0855[3]	3,5 [-0,4; 7,3] 0,0855[3]
Number of positive lymph nodes (Interaction p-value: 0,4969)					
0-3	31/427 (7,3)	26/418 (6,2)	1,17 [0,71; 1,93] 0,5473[2]	1,18 [0,69; 2,02] 0,5468[3]	1,0 [-2,3; 4,4] 0,5468[3]
4-9	45/549 (8,2)	28/542 (5,2)	1,59 [1,01; 2,50] 0,0475[2]	1,64 [1,01; 2,67] 0,0452[3]	3,0 [0,1; 6,0] 0,0452[3]
≥ 10	26/307 (8,5)	14/304 (4,6)	1,84 [0,98; 3,45] 0,0581[2]	1,92 [0,98; 3,75] 0,0535[3]	3,9 [-0,0; 7,8] 0,0535[3]
Tumor stage (Interaction p-value: 0,2382)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	11/113 (9,7)	5/114 (4,4)	2,22 [0,80; 6,18] 0,1272[2]	2,35 [0,79; 7,00] 0,1155[3]	5,3 [-1,3; 12,0] 0,1155[3]
IIB	10/151 (6,6)	10/136 (7,4)	0,90 [0,39; 2,10] 0,8083[2]	0,89 [0,36; 2,22] 0,8083[3]	-0,7 [-6,6; 5,2] 0,8083[3]
IIIA	38/495 (7,7)	24/488 (4,9)	1,56 [0,95; 2,56] 0,0782[2]	1,61 [0,95; 2,72] 0,0752[3]	2,8 [-0,3; 5,8] 0,0752[3]
IIIB	1/54 (1,9)	4/45 (8,9)	0,21 [0,02; 1,80] 0,1537[2]	0,19 [0,02; 1,80] 0,1738[4]	-7,0 [-16,1; 2,0] 0,1738[4]
IIIC	42/468 (9,0)	25/479 (5,2)	1,72 [1,07; 2,77] 0,0264[2]	1,79 [1,07; 2,99] 0,0242[3]	3,8 [0,5; 7,0] 0,0242[3]
Tumor grade (Interaction p-value: 0,9972)					
G1	6/91 (6,6)	4/93 (4,3)	1,53 [0,45; 5,25] 0,4966[2]	1,57 [0,43; 5,76] 0,5339[4]	2,3 [-4,3; 8,8] 0,5339[4]
G2	45/612 (7,4)	30/602 (5,0)	1,48 [0,94; 2,31] 0,0888[2]	1,51 [0,94; 2,44] 0,0864[3]	2,4 [-0,3; 5,1] 0,0864[3]
G3	48/527 (9,1)	32/506 (6,3)	1,44 [0,94; 2,21] 0,0966[2]	1,48 [0,93; 2,36] 0,0942[3]	2,8 [-0,5; 6,0] 0,0942[3]
GX	3/51 (5,9)	2/59 (3,4)	1,74 [0,30; 9,98] 0,5369[2]	1,78 [0,29; 11,10] 0,6613[4]	2,5 [-5,4; 10,4] 0,6613[4]
First endocrine therapy (Interaction p-value: 0,6585)					
Tamoxifen	6/114 (5,3)	6/132 (4,5)	1,16 [0,38; 3,49] 0,7946[2]	1,17 [0,37; 3,72] 0,7944[3]	0,7 [-4,7; 6,1] 0,7944[3]
Aromatase inhibitor	96/1169 (8,2)	62/1132 (5,5)	1,50 [1,10; 2,04] 0,0101[2]	1,54 [1,11; 2,15] 0,0095[3]	2,7 [0,7; 4,8] 0,0095[3]
ECOG-PS (Interaction p-value: 0,5177)					
ECOG-PS 0	83/1070 (7,8)	56/1019 (5,5)	1,41 [1,02; 1,96] 0,0394[2]	1,45 [1,02; 2,05] 0,0382[3]	2,3 [0,1; 4,4] 0,0382[3]
ECOG-PS 1	19/213 (8,9)	12/245 (4,9)	1,82 [0,91; 3,66] 0,0928[2]	1,90 [0,90; 4,02] 0,0874[3]	4,0 [-0,7; 8,7] 0,0874[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 390.1.2: Subgroups - adverse events according SOC Reproductive system and breast disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,4085)					
< 65 years	99/918 (10,8)	131/936 (14,0)	0,77 [0,60; 0,98] 0,0368[2]	0,74 [0,56; 0,98] 0,0360[3]	-3,2 [-6,2; -0,2] 0,0360[3]
≥ 65 years	26/365 (7,1)	38/328 (11,6)	0,61 [0,38; 0,99] 0,0452[2]	0,59 [0,35; 0,99] 0,0428[3]	-4,5 [-8,8; -0,1] 0,0428[3]
Prior treatment (Interaction p-value: 0,9432)					
Neoadjuvant chemotherapy	35/430 (8,1)	49/415 (11,8)	0,69 [0,46; 1,04] 0,0770[2]	0,66 [0,42; 1,04] 0,0749[3]	-3,7 [-7,7; 0,4] 0,0749[3]
Adjuvant chemotherapy	86/784 (11,0)	113/768 (14,7)	0,75 [0,57; 0,97] 0,0282[2]	0,71 [0,53; 0,96] 0,0274[3]	-3,7 [-7,1; -0,4] 0,0274[3]
No chemotherapy	4/69 (5,8)	7/81 (8,6)	0,67 [0,20; 2,20] 0,5093[2]	0,65 [0,18; 2,32] 0,5053[3]	-2,8 [-11,1; 5,4] 0,5053[3]
Region (Interaction p-value: 0,8801)					
North America / Europe	83/678 (12,2)	108/649 (16,6)	0,74 [0,56; 0,96] 0,0232[2]	0,70 [0,51; 0,95] 0,0225[3]	-4,4 [-8,2; -0,6] 0,0225[3]
Asia	9/203 (4,4)	15/201 (7,5)	0,59 [0,27; 1,33] 0,2038[2]	0,58 [0,25; 1,35] 0,1978[3]	-3,0 [-7,6; 1,6] 0,1978[3]
Other	33/402 (8,2)	46/414 (11,1)	0,74 [0,48; 1,13] 0,1632[2]	0,72 [0,45; 1,14] 0,1610[3]	-2,9 [-6,9; 1,1] 0,1610[3]
Primary tumor size (Interaction p-value: 0,9390)					
< 20 mm	30/331 (9,1)	39/334 (11,7)	0,78 [0,49; 1,22] 0,2710[2]	0,75 [0,46; 1,25] 0,2692[3]	-2,6 [-7,2; 2,0] 0,2692[3]
≥ 20 but < 50 mm	62/646 (9,6)	89/653 (13,6)	0,70 [0,52; 0,96] 0,0244[2]	0,67 [0,48; 0,95] 0,0234[3]	-4,0 [-7,5; -0,6] 0,0234[3]
≥ 50 mm	32/289 (11,1)	41/265 (15,5)	0,72 [0,46; 1,10] 0,1284[2]	0,68 [0,41; 1,12] 0,1262[3]	-4,4 [-10,1; 1,3] 0,1262[3]
Number of positive lymph nodes (Interaction p-value: 0,7449)					
0-3	46/427 (10,8)	55/418 (13,2)	0,82 [0,57; 1,18] 0,2863[2]	0,80 [0,53; 1,21] 0,2853[3]	-2,4 [-6,8; 2,0] 0,2853[3]
4-9	49/549 (8,9)	71/542 (13,1)	0,68 [0,48; 0,96] 0,0289[2]	0,65 [0,44; 0,96] 0,0276[3]	-4,2 [-7,9; -0,5] 0,0276[3]
≥ 10	30/307 (9,8)	43/304 (14,1)	0,69 [0,45; 1,07] 0,0983[2]	0,66 [0,40; 1,08] 0,0957[3]	-4,4 [-9,5; 0,8] 0,0957[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,6235)					
IIA	13/113 (11,5)	11/114 (9,6)	1,19 [0,56; 2,55] 0,6500[2]	1,22 [0,52; 2,84] 0,6494[3]	1,9 [-6,1; 9,9] 0,6494[3]
IIB	16/151 (10,6)	24/136 (17,6)	0,60 [0,33; 1,08] 0,0894[2]	0,55 [0,28; 1,09] 0,0850[3]	-7,1 [-15,1; 1,0] 0,0850[3]
IIIA	46/495 (9,3)	68/488 (13,9)	0,67 [0,47; 0,95] 0,0244[2]	0,63 [0,43; 0,94] 0,0231[3]	-4,6 [-8,6; -0,6] 0,0231[3]
IIIB	4/54 (7,4)	3/45 (6,7)	1,11 [0,26; 4,71] 0,8863[2]	1,12 [0,24; 5,29] 1,0000[4]	0,7 [-9,4; 10,8] 1,0000[4]
IIIC	46/468 (9,8)	63/479 (13,2)	0,75 [0,52; 1,07] 0,1109[2]	0,72 [0,48; 1,08] 0,1091[3]	-3,3 [-7,4; 0,7] 0,1091[3]
Tumor grade (Interaction p-value: 0,2540)					
G1	3/91 (3,3)	12/93 (12,9)	0,26 [0,07; 0,88] 0,0299[2]	0,23 [0,06; 0,84] 0,0173[3]	-9,6 [-17,3; -1,9] 0,0173[3]
G2	73/612 (11,9)	88/602 (14,6)	0,82 [0,61; 1,09] 0,1681[2]	0,79 [0,57; 1,10] 0,1671[3]	-2,7 [-6,5; 1,1] 0,1671[3]
G3	45/527 (8,5)	65/506 (12,8)	0,66 [0,46; 0,95] 0,0262[2]	0,63 [0,42; 0,95] 0,0249[3]	-4,3 [-8,1; -0,5] 0,0249[3]
GX	4/51 (7,8)	4/59 (6,8)	1,16 [0,30; 4,39] 0,8305[2]	1,17 [0,28; 4,94] 1,0000[4]	1,1 [-8,7; 10,8] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,3519)					
Negative	13/156 (8,3)	12/169 (7,1)	1,17 [0,55; 2,49] 0,6772[2]	1,19 [0,53; 2,69] 0,6769[3]	1,2 [-4,6; 7,0] 0,6769[3]
Positive	107/1089 (9,8)	150/1066 (14,1)	0,70 [0,55; 0,88] 0,0025[2]	0,67 [0,51; 0,87] 0,0024[3]	-4,2 [-7,0; -1,5] 0,0024[3]
Unknown	1/10 (10,0)	2/7 (28,6)	0,35 [0,04; 3,15] 0,3491[2]	0,28 [0,02; 3,88] 0,5368[4]	-18,6 [-56,9; 19,7] 0,5368[4]
Race (Interaction p-value: 0,6551)					
White	107/958 (11,2)	136/943 (14,4)	0,77 [0,61; 0,98] 0,0344[2]	0,75 [0,57; 0,98] 0,0337[3]	-3,3 [-6,3; -0,3] 0,0337[3]
Asian	11/250 (4,4)	19/242 (7,9)	0,56 [0,27; 1,15] 0,1156[2]	0,54 [0,25; 1,16] 0,1097[3]	-3,5 [-7,7; 0,8] 0,1097[3]
Other	6/62 (9,7)	10/64 (15,6)	0,62 [0,24; 1,60] 0,3229[2]	0,58 [0,20; 1,70] 0,3161[3]	-5,9 [-17,5; 5,6] 0,3161[3]
First endocrine therapy (Interaction p-value: 0,8277)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tamoxifen	13/114 (11,4)	22/132 (16,7)	0,68 [0,36; 1,30] 0,2438[2]	0,64 [0,31; 1,34] 0,2387[3]	-5,3 [-13,9; 3,4] 0,2387[3]
Aromatase inhibitor	112/1169 (9,6)	147/1132 (13,0)	0,74 [0,59; 0,93] 0,0101[2]	0,71 [0,55; 0,92] 0,0098[3]	-3,4 [-6,0; -0,8] 0,0098[3]
ECOG-PS (Interaction p-value: 0,2007)					
ECOG-PS 0	108/1070 (10,1)	132/1019 (13,0)	0,78 [0,61; 0,99] 0,0411[2]	0,75 [0,58; 0,99] 0,0404[3]	-2,9 [-5,6; -0,1] 0,0404[3]
ECOG-PS 1	17/213 (8,0)	37/245 (15,1)	0,53 [0,31; 0,91] 0,0216[2]	0,49 [0,27; 0,89] 0,0184[3]	-7,1 [-12,9; -1,3] 0,0184[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 391.1.2: Subgroups - adverse events according SOC Respiratory, thoracic and mediastinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,3302)					
< 65 years	259/918 (28,2)	185/936 (19,8)	1,43 [1,21; 1,68] <,0001[2]	1,60 [1,29; 1,98] <,0001[3]	8,4 [4,6; 12,3] <,0001[3]
≥ 65 years	117/365 (32,1)	63/328 (19,2)	1,67 [1,28; 2,18] 0,0002[2]	1,98 [1,40; 2,82] 0,0001[3]	12,8 [6,4; 19,3] 0,0001[3]
Prior treatment (Interaction p-value: 0,6911)					
Neoadjuvant chemotherapy	125/430 (29,1)	80/415 (19,3)	1,51 [1,18; 1,93] 0,0011[2]	1,72 [1,25; 2,36] 0,0009[3]	9,8 [4,1; 15,5] 0,0009[3]
Adjuvant chemotherapy	227/784 (29,0)	153/768 (19,9)	1,45 [1,21; 1,74] <,0001[2]	1,64 [1,30; 2,07] <,0001[3]	9,0 [4,8; 13,3] <,0001[3]
No chemotherapy	24/69 (34,8)	15/81 (18,5)	1,88 [1,07; 3,29] 0,0272[2]	2,35 [1,11; 4,96] 0,0236[3]	16,3 [2,2; 30,3] 0,0236[3]
Region (Interaction p-value: 0,6902)					
North America / Europe	248/678 (36,6)	153/649 (23,6)	1,55 [1,31; 1,84] <,0001[2]	1,87 [1,47; 2,38] <,0001[3]	13,0 [8,1; 17,9] <,0001[3]
Asia	57/203 (28,1)	41/201 (20,4)	1,38 [0,97; 1,95] 0,0742[2]	1,52 [0,96; 2,41] 0,0717[3]	7,7 [-0,6; 16,0] 0,0717[3]
Other	71/402 (17,7)	54/414 (13,0)	1,35 [0,98; 1,88] 0,0686[2]	1,43 [0,97; 2,10] 0,0671[3]	4,6 [-0,3; 9,6] 0,0671[3]
Primary tumor size (Interaction p-value: 0,9638)					
< 20 mm	86/331 (26,0)	60/334 (18,0)	1,45 [1,08; 1,94] 0,0134[2]	1,60 [1,11; 2,33] 0,0125[3]	8,0 [1,8; 14,3] 0,0125[3]
≥ 20 but < 50 mm	190/646 (29,4)	128/653 (19,6)	1,50 [1,23; 1,83] <,0001[2]	1,71 [1,32; 2,21] <,0001[3]	9,8 [5,2; 14,5] <,0001[3]
≥ 50 mm	95/289 (32,9)	57/265 (21,5)	1,53 [1,15; 2,03] 0,0033[2]	1,79 [1,22; 2,62] 0,0028[3]	11,4 [4,0; 18,7] 0,0028[3]
Number of positive lymph nodes (Interaction p-value: 0,7357)					
0-3	137/427 (32,1)	86/418 (20,6)	1,56 [1,23; 1,97] 0,0002[2]	1,82 [1,33; 2,49] 0,0001[3]	11,5 [5,6; 17,4] 0,0001[3]
4-9	141/549 (25,7)	91/542 (16,8)	1,53 [1,21; 1,94] 0,0004[2]	1,71 [1,27; 2,30] 0,0003[3]	8,9 [4,1; 13,7] 0,0003[3]
≥ 10	98/307 (31,9)	71/304 (23,4)	1,37 [1,05; 1,77] 0,0190[2]	1,54 [1,08; 2,20] 0,0179[3]	8,6 [1,5; 15,6] 0,0179[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,7141)					
IIA	30/113 (26,5)	21/114 (18,4)	1,44 [0,88; 2,36] 0,1464[2]	1,60 [0,85; 3,01] 0,1424[3]	8,1 [-2,7; 18,9] 0,1424[3]
IIB	49/151 (32,5)	30/136 (22,1)	1,47 [1,00; 2,17] 0,0529[2]	1,70 [1,00; 2,88] 0,0491[3]	10,4 [0,2; 20,6] 0,0491[3]
IIIA	137/495 (27,7)	80/488 (16,4)	1,69 [1,32; 2,16] <,0001[2]	1,95 [1,43; 2,66] <,0001[3]	11,3 [6,2; 16,4] <,0001[3]
IIIB	16/54 (29,6)	8/45 (17,8)	1,67 [0,79; 3,53] 0,1824[2]	1,95 [0,74; 5,10] 0,1706[3]	11,9 [-4,7; 28,4] 0,1706[3]
IIIC	142/468 (30,3)	109/479 (22,8)	1,33 [1,08; 1,65] 0,0086[2]	1,48 [1,11; 1,98] 0,0082[3]	7,6 [2,0; 13,2] 0,0082[3]
Tumor grade (Interaction p-value: 0,3587)					
G1	24/91 (26,4)	11/93 (11,8)	2,23 [1,16; 4,28] 0,0160[2]	2,67 [1,22; 5,84] 0,0120[3]	14,5 [3,4; 25,7] 0,0120[3]
G2	178/612 (29,1)	126/602 (20,9)	1,39 [1,14; 1,69] 0,0012[2]	1,55 [1,19; 2,01] 0,0010[3]	8,2 [3,3; 13,0] 0,0010[3]
G3	158/527 (30,0)	102/506 (20,2)	1,49 [1,20; 1,85] 0,0003[2]	1,70 [1,27; 2,26] 0,0003[3]	9,8 [4,6; 15,1] 0,0003[3]
GX	16/51 (31,4)	8/59 (13,6)	2,31 [1,08; 4,95] 0,0308[2]	2,91 [1,13; 7,55] 0,0241[3]	17,8 [2,4; 33,3] 0,0241[3]
Race (Interaction p-value: 0,7148)					
White	287/958 (30,0)	185/943 (19,6)	1,53 [1,30; 1,79] <,0001[2]	1,75 [1,42; 2,17] <,0001[3]	10,3 [6,5; 14,2] <,0001[3]
Asian	69/250 (27,6)	49/242 (20,2)	1,36 [0,99; 1,88] 0,0583[2]	1,50 [0,99; 2,28] 0,0562[3]	7,4 [-0,2; 14,9] 0,0562[3]
Other	13/62 (21,0)	11/64 (17,2)	1,22 [0,59; 2,51] 0,5899[2]	1,28 [0,52; 3,12] 0,5890[3]	3,8 [-9,9; 17,5] 0,5890[3]
First endocrine therapy (Interaction p-value: 0,6671)					
Tamoxifen	30/114 (26,3)	21/132 (15,9)	1,65 [1,01; 2,72] 0,0477[2]	1,89 [1,01; 3,53] 0,0447[3]	10,4 [0,2; 20,6] 0,0447[3]
Aromatase inhibitor	346/1169 (29,6)	227/1132 (20,1)	1,48 [1,28; 1,71] <,0001[2]	1,68 [1,38; 2,03] <,0001[3]	9,5 [6,0; 13,1] <,0001[3]
ECOG-PS (Interaction p-value: 0,0600)					
ECOG-PS 0	296/1070 (27,7)	201/1019 (19,7)	1,40 [1,20; 1,64] <,0001[2]	1,56 [1,27; 1,91] <,0001[3]	7,9 [4,3; 11,6] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	80/213 (37,6)	47/245 (19,2)	1,96 [1,44; 2,67] <,0001[2]	2,53 [1,66; 3,86] <,0001[3]	18,4 [10,2; 26,5] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 392.1.2: Subgroups - adverse events according SOC Skin and subcutaneous tissue disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1076)					
< 65 years	344/918 (37,5)	212/936 (22,6)	1,65 [1,43; 1,91] <,0001[2]	2,05 [1,67; 2,51] <,0001[3]	14,8 [10,7; 18,9] <,0001[3]
≥ 65 years	164/365 (44,9)	71/328 (21,6)	2,08 [1,64; 2,63] <,0001[2]	2,95 [2,11; 4,12] <,0001[3]	23,3 [16,5; 30,1] <,0001[3]
Prior treatment (Interaction p-value: 0,0952)					
Neoadjuvant chemotherapy	166/430 (38,6)	88/415 (21,2)	1,82 [1,46; 2,27] <,0001[2]	2,34 [1,72; 3,17] <,0001[3]	17,4 [11,3; 23,5] <,0001[3]
Adjuvant chemotherapy	306/784 (39,0)	181/768 (23,6)	1,66 [1,42; 1,93] <,0001[2]	2,08 [1,67; 2,59] <,0001[3]	15,5 [10,9; 20,0] <,0001[3]
No chemotherapy	36/69 (52,2)	14/81 (17,3)	3,02 [1,78; 5,11] <,0001[2]	5,22 [2,48; 11,00] <,0001[3]	34,9 [20,5; 49,3] <,0001[3]
Primary tumor size (Interaction p-value: 0,7453)					
< 20 mm	114/331 (34,4)	64/334 (19,2)	1,80 [1,38; 2,34] <,0001[2]	2,22 [1,55; 3,16] <,0001[3]	15,3 [8,6; 21,9] <,0001[3]
≥ 20 but < 50 mm	256/646 (39,6)	143/653 (21,9)	1,81 [1,52; 2,15] <,0001[2]	2,34 [1,84; 2,99] <,0001[3]	17,7 [12,8; 22,7] <,0001[3]
≥ 50 mm	131/289 (45,3)	74/265 (27,9)	1,62 [1,29; 2,05] <,0001[2]	2,14 [1,50; 3,05] <,0001[3]	17,4 [9,5; 25,3] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,8102)					
0-3	171/427 (40,0)	94/418 (22,5)	1,78 [1,44; 2,20] <,0001[2]	2,30 [1,71; 3,11] <,0001[3]	17,6 [11,4; 23,7] <,0001[3]
4-9	208/549 (37,9)	112/542 (20,7)	1,83 [1,51; 2,23] <,0001[2]	2,34 [1,79; 3,07] <,0001[3]	17,2 [11,9; 22,5] <,0001[3]
≥ 10	129/307 (42,0)	77/304 (25,3)	1,66 [1,31; 2,10] <,0001[2]	2,14 [1,51; 3,01] <,0001[3]	16,7 [9,3; 24,1] <,0001[3]
Tumor stage (Interaction p-value: 0,9949)					
IIA	41/113 (36,3)	24/114 (21,1)	1,72 [1,12; 2,65] 0,0134[2]	2,14 [1,18; 3,86] 0,0111[3]	15,2 [3,6; 26,8] 0,0111[3]
IIB	61/151 (40,4)	31/136 (22,8)	1,77 [1,23; 2,55] 0,0021[2]	2,30 [1,37; 3,85] 0,0014[3]	17,6 [7,1; 28,1] 0,0014[3]
IIIA	195/495 (39,4)	106/488 (21,7)	1,81 [1,48; 2,22] <,0001[2]	2,34 [1,77; 3,10] <,0001[3]	17,7 [12,0; 23,3] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	21/54 (38,9)	11/45 (24,4)	1,59 [0,86; 2,94] 0,1376[2]	1,97 [0,82; 4,71] 0,1260[3]	14,4 [-3,6; 32,5] 0,1260[3]
IIIC	189/468 (40,4)	111/479 (23,2)	1,74 [1,43; 2,12] <,0001[2]	2,25 [1,70; 2,98] <,0001[3]	17,2 [11,4; 23,0] <,0001[3]
Tumor grade (Interaction p-value: 0,1881)					
G1	37/91 (40,7)	19/93 (20,4)	1,99 [1,24; 3,19] 0,0042[2]	2,67 [1,39; 5,14] 0,0029[3]	20,2 [7,2; 33,2] 0,0029[3]
G2	262/612 (42,8)	131/602 (21,8)	1,97 [1,65; 2,35] <,0001[2]	2,69 [2,09; 3,46] <,0001[3]	21,0 [15,9; 26,2] <,0001[3]
G3	196/527 (37,2)	118/506 (23,3)	1,59 [1,31; 1,93] <,0001[2]	1,95 [1,48; 2,55] <,0001[3]	13,9 [8,3; 19,4] <,0001[3]
GX	12/51 (23,5)	13/59 (22,0)	1,07 [0,54; 2,13] 0,8519[2]	1,09 [0,45; 2,66] 0,8519[3]	1,5 [-14,2; 17,2] 0,8519[3]
Progesterone receptor status (Interaction p-value: 0,5689)					
Negative	63/156 (40,4)	45/169 (26,6)	1,52 [1,11; 2,08] 0,0095[2]	1,87 [1,17; 2,98] 0,0085[3]	13,8 [3,6; 23,9] 0,0085[3]
Positive	430/1089 (39,5)	235/1066 (22,0)	1,79 [1,57; 2,05] <,0001[2]	2,31 [1,91; 2,79] <,0001[3]	17,4 [13,6; 21,3] <,0001[3]
Unknown	4/10 (40,0)	1/7 (14,3)	2,80 [0,39; 20,02] 0,3049[2]	4,00 [0,34; 47,11] 0,3382[4]	25,7 [-14,2; 65,6] 0,3382[4]
Race (Interaction p-value: 0,1582)					
White	378/958 (39,5)	196/943 (20,8)	1,90 [1,64; 2,20] <,0001[2]	2,48 [2,03; 3,05] <,0001[3]	18,7 [14,6; 22,7] <,0001[3]
Asian	101/250 (40,4)	63/242 (26,0)	1,55 [1,20; 2,01] 0,0009[2]	1,93 [1,31; 2,82] 0,0007[3]	14,4 [6,1; 22,6] 0,0007[3]
Other	20/62 (32,3)	17/64 (26,6)	1,21 [0,70; 2,09] 0,4841[2]	1,32 [0,61; 2,84] 0,4828[3]	5,7 [-10,2; 21,6] 0,4828[3]
First endocrine therapy (Interaction p-value: 0,5676)					
Tamoxifen	44/114 (38,6)	32/132 (24,2)	1,59 [1,09; 2,33] 0,0165[2]	1,96 [1,14; 3,40] 0,0151[3]	14,4 [2,8; 25,9] 0,0151[3]
Aromatase inhibitor	464/1169 (39,7)	251/1132 (22,2)	1,79 [1,57; 2,04] <,0001[2]	2,31 [1,92; 2,77] <,0001[3]	17,5 [13,8; 21,2] <,0001[3]
ECOG-PS (Interaction p-value: 0,4558)					
ECOG-PS 0	424/1070 (39,6)	223/1019 (21,9)	1,81 [1,58; 2,08] <,0001[2]	2,34 [1,93; 2,84] <,0001[3]	17,7 [13,9; 21,6] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	84/213 (39,4)	60/245 (24,5)	1,61 [1,22; 2,12] 0,0007[2]	2,01 [1,35; 3,00] 0,0006[3]	14,9 [6,5; 23,4] 0,0006[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 393.1.2: Subgroups - serious adverse events according SOC Gastrointestinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,9571)					
Neoadjuvant chemotherapy	8/430 (1,9)	3/415 (0,7)	2,57 [0,69; 9,63] 0,1604[2]	2,60 [0,69; 9,88] 0,1447[3]	1,1 [-0,4; 2,7] 0,1447[3]
Adjuvant chemotherapy	21/784 (2,7)	10/768 (1,3)	2,06 [0,98; 4,34] 0,0582[2]	2,09 [0,98; 4,46] 0,0526[3]	1,4 [-0,0; 2,8] 0,0526[3]
No chemotherapy	2/69 (2,9)	1/81 (1,2)	2,35 [0,22; 25,34] 0,4819[2]	2,39 [0,21; 26,92] 0,5945[4]	1,7 [-3,0; 6,3] 0,5945[4]
Region (Interaction p-value: 0,5637)					
North America / Europe	21/678 (3,1)	11/649 (1,7)	1,83 [0,89; 3,76] 0,1015[2]	1,85 [0,89; 3,88] 0,0960[3]	1,4 [-0,2; 3,0] 0,0960[3]
Asia	4/203 (2,0)	2/201 (1,0)	1,98 [0,37; 10,69] 0,4271[2]	2,00 [0,36; 11,04] 0,6852[4]	1,0 [-1,4; 3,3] 0,6852[4]
Other	6/402 (1,5)	1/414 (0,2)	6,18 [0,75; 51,10] 0,0911[2]	6,26 [0,75; 52,21] 0,0655[4]	1,3 [-0,0; 2,5] 0,0655[4]
Primary tumor size (Interaction p-value: 0,9408)					
< 20 mm	5/331 (1,5)	2/334 (0,6)	2,52 [0,49; 12,91] 0,2667[2]	2,55 [0,49; 13,22] 0,2846[4]	0,9 [-0,6; 2,5] 0,2846[4]
≥ 20 but < 50 mm	18/646 (2,8)	8/653 (1,2)	2,27 [1,00; 5,19] 0,0511[2]	2,31 [1,00; 5,35] 0,0446[3]	1,6 [0,0; 3,1] 0,0446[3]
≥ 50 mm	8/289 (2,8)	4/265 (1,5)	1,83 [0,56; 6,02] 0,3173[2]	1,86 [0,55; 6,24] 0,3093[3]	1,3 [-1,1; 3,7] 0,3093[3]
Number of positive lymph nodes (Interaction p-value: 0,2721)					
0-3	12/427 (2,8)	3/418 (0,7)	3,92 [1,11; 13,78] 0,0334[2]	4,00 [1,12; 14,28] 0,0213[3]	2,1 [0,3; 3,9] 0,0213[3]
4-9	8/549 (1,5)	7/542 (1,3)	1,13 [0,41; 3,09] 0,8143[2]	1,13 [0,41; 3,14] 0,8142[3]	0,2 [-1,2; 1,5] 0,8142[3]
≥ 10	11/307 (3,6)	4/304 (1,3)	2,72 [0,88; 8,46] 0,0832[2]	2,79 [0,88; 8,85] 0,0702[3]	2,3 [-0,2; 4,7] 0,0702[3]
Tumor stage (Interaction p-value: 0,9734)					
IIA	2/113 (1,8)	0/114 (0,0)	5,04 [0,24; 103,90] 0,2945[2]	5,13 [0,24; 108,15] 0,2467[4]	1,8 [-0,7; 4,2] 0,2467[4]
IIB	5/151 (3,3)	0/136 (0,0)	9,91 [0,55; 177,65] 0,1192[2]	10,25 [0,56; 187,10] 0,0620[4]	3,3 [0,5; 6,2] 0,0620[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIA	9/495 (1,8)	7/488 (1,4)	1,27 [0,48; 3,38] 0,6353[2]	1,27 [0,47; 3,44] 0,6345[3]	0,4 [-1,2; 2,0] 0,6345[3]
IIIB	1/54 (1,9)	0/45 (0,0)	2,51 [0,10; 60,13] 0,5703[2]	2,55 [0,10; 64,17] 1,0000[4]	1,9 [-1,7; 5,4] 1,0000[4]
IIIC	14/468 (3,0)	7/479 (1,5)	2,05 [0,83; 5,03] 0,1180[2]	2,08 [0,83; 5,20] 0,1099[3]	1,5 [-0,4; 3,4] 0,1099[3]
Tumor grade (Interaction p-value: 0,2747)					
G1	1/91 (1,1)	3/93 (3,2)	0,34 [0,04; 3,21] 0,3471[2]	0,33 [0,03; 3,27] 0,6210[4]	-2,1 [-6,3; 2,1] 0,6210[4]
G2	13/612 (2,1)	6/602 (1,0)	2,13 [0,82; 5,57] 0,1227[2]	2,16 [0,81; 5,71] 0,1135[3]	1,1 [-0,3; 2,5] 0,1135[3]
G3	17/527 (3,2)	4/506 (0,8)	4,08 [1,38; 12,04] 0,0109[2]	4,18 [1,40; 12,52] 0,0056[3]	2,4 [0,7; 4,1] 0,0056[3]
GX	0/51 (0,0)	1/59 (1,7)	0,38 [0,02; 9,24] 0,5558[2]	0,38 [0,02; 9,50] 1,0000[4]	-1,7 [-5,0; 1,6] 1,0000[4]
Race (Interaction p-value: 0,8621)					
White	22/958 (2,3)	11/943 (1,2)	1,97 [0,96; 4,04] 0,0645[2]	1,99 [0,96; 4,13] 0,0593[3]	1,1 [-0,0; 2,3] 0,0593[3]
Asian	6/250 (2,4)	2/242 (0,8)	2,90 [0,59; 14,25] 0,1889[2]	2,95 [0,59; 14,77] 0,2856[4]	1,6 [-0,6; 3,8] 0,2856[4]
Other	3/62 (4,8)	1/64 (1,6)	3,10 [0,33; 28,97] 0,3218[2]	3,20 [0,32; 31,66] 0,3610[4]	3,3 [-2,9; 9,4] 0,3610[4]
ECOG-PS (Interaction p-value: 0,1446)					
ECOG-PS 0	21/1070 (2,0)	12/1019 (1,2)	1,67 [0,82; 3,37] 0,1550[2]	1,68 [0,82; 3,43] 0,1504[3]	0,8 [-0,3; 1,8] 0,1504[3]
ECOG-PS 1	10/213 (4,7)	2/245 (0,8)	5,75 [1,27; 25,96] 0,0229[2]	5,99 [1,30; 27,63] 0,0095[3]	3,9 [0,8; 6,9] 0,0095[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 394.1.2: Subgroups - serious adverse events according SOC Infections and infestations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5578)					
< 65 years	45/918 (4,9)	24/936 (2,6)	1,91 [1,17; 3,11] 0,0091[2]	1,96 [1,18; 3,24] 0,0078[3]	2,3 [0,6; 4,1] 0,0078[3]
≥ 65 years	25/365 (6,8)	9/328 (2,7)	2,50 [1,18; 5,27] 0,0164[2]	2,61 [1,20; 5,67] 0,0125[3]	4,1 [1,0; 7,2] 0,0125[3]
Prior treatment (Interaction p-value: 0,1862)					
Neoadjuvant chemotherapy	26/430 (6,0)	11/415 (2,7)	2,28 [1,14; 4,56] 0,0195[2]	2,36 [1,15; 4,85] 0,0159[3]	3,4 [0,7; 6,1] 0,0159[3]
Adjuvant chemotherapy	43/784 (5,5)	18/768 (2,3)	2,34 [1,36; 4,02] 0,0021[2]	2,42 [1,38; 4,23] 0,0015[3]	3,1 [1,2; 5,1] 0,0015[3]
No chemotherapy	1/69 (1,4)	4/81 (4,9)	0,29 [0,03; 2,56] 0,2677[2]	0,28 [0,03; 2,59] 0,3747[4]	-3,5 [-9,0; 2,0] 0,3747[4]
Region (Interaction p-value: 0,1491)					
North America / Europe	43/678 (6,3)	24/649 (3,7)	1,72 [1,05; 2,79] 0,0302[2]	1,76 [1,06; 2,94] 0,0279[3]	2,6 [0,3; 5,0] 0,0279[3]
Asia	7/203 (3,4)	5/201 (2,5)	1,39 [0,45; 4,30] 0,5714[2]	1,40 [0,44; 4,49] 0,5695[3]	1,0 [-2,3; 4,3] 0,5695[3]
Other	20/402 (5,0)	4/414 (1,0)	5,15 [1,78; 14,93] 0,0026[2]	5,37 [1,82; 15,84] 0,0007[3]	4,0 [1,7; 6,3] 0,0007[3]
Number of positive lymph nodes (Interaction p-value: 0,7659)					
0-3	25/427 (5,9)	14/418 (3,3)	1,75 [0,92; 3,32] 0,0873[2]	1,79 [0,92; 3,50] 0,0826[3]	2,5 [-0,3; 5,3] 0,0826[3]
4-9	27/549 (4,9)	12/542 (2,2)	2,22 [1,14; 4,34] 0,0195[2]	2,28 [1,15; 4,56] 0,0162[3]	2,7 [0,5; 4,9] 0,0162[3]
≥ 10	18/307 (5,9)	7/304 (2,3)	2,55 [1,08; 6,01] 0,0329[2]	2,64 [1,09; 6,42] 0,0263[3]	3,6 [0,4; 6,7] 0,0263[3]
Tumor stage (Interaction p-value: 0,1866)					
IIA	5/113 (4,4)	2/114 (1,8)	2,52 [0,50; 12,73] 0,2628[2]	2,59 [0,49; 13,65] 0,2803[4]	2,7 [-1,8; 7,2] 0,2803[4]
IIB	8/151 (5,3)	9/136 (6,6)	0,80 [0,32; 2,02] 0,6370[2]	0,79 [0,30; 2,11] 0,6363[3]	-1,3 [-6,8; 4,2] 0,6363[3]
IIIA	31/495 (6,3)	9/488 (1,8)	3,40 [1,63; 7,06] 0,0011[2]	3,56 [1,67; 7,55] 0,0005[3]	4,4 [2,0; 6,9] 0,0005[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	3/54 (5,6)	2/45 (4,4)	1,25 [0,22; 7,16] 0,8021[2]	1,26 [0,20; 7,92] 1,0000[4]	1,1 [-7,5; 9,7] 1,0000[4]
IIIC	23/468 (4,9)	11/479 (2,3)	2,14 [1,06; 4,34] 0,0350[2]	2,20 [1,06; 4,56] 0,0304[3]	2,6 [0,2; 5,0] 0,0304[3]
Race (Interaction p-value: 0,9144)					
White	56/958 (5,8)	27/943 (2,9)	2,04 [1,30; 3,20] 0,0019[2]	2,11 [1,32; 3,36] 0,0015[3]	3,0 [1,2; 4,8] 0,0015[3]
Asian	10/250 (4,0)	6/242 (2,5)	1,61 [0,60; 4,37] 0,3469[2]	1,64 [0,59; 4,58] 0,3418[3]	1,5 [-1,6; 4,6] 0,3418[3]
Other	4/62 (6,5)	0/64 (0,0)	9,29 [0,51; 168,95] 0,1322[2]	9,92 [0,52; 188,28] 0,0557[4]	6,5 [0,3; 12,6] 0,0557[4]
ECOG-PS (Interaction p-value: 0,6915)					
ECOG-PS 0	53/1070 (5,0)	25/1019 (2,5)	2,02 [1,26; 3,22] 0,0032[2]	2,07 [1,28; 3,36] 0,0026[3]	2,5 [0,9; 4,1] 0,0026[3]
ECOG-PS 1	17/213 (8,0)	8/245 (3,3)	2,44 [1,08; 5,55] 0,0327[2]	2,57 [1,09; 6,08] 0,0267[3]	4,7 [0,5; 9,0] 0,0267[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 395.1.2: Subgroups - serious adverse events according SOC Metabolism and nutrition disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,9655)					
Negative	1/156 (0,6)	0/169 (0,0)	3,25 [0,13; 79,16] 0,4696[2]	3,27 [0,13; 80,87] 0,4800[4]	0,6 [-0,6; 1,9] 0,4800[4]
Positive	12/1089 (1,1)	4/1066 (0,4)	2,94 [0,95; 9,08] 0,0613[2]	2,96 [0,95; 9,20] 0,0494[3]	0,7 [0,0; 1,4] 0,0494[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9997)					
White	7/958 (0,7)	4/943 (0,4)	1,72 [0,51; 5,87] 0,3843[2]	1,73 [0,50; 5,92] 0,3783[3]	0,3 [-0,4; 1,0] 0,3783[3]
Asian	4/250 (1,6)	0/242 (0,0)	8,71 [0,47; 160,97] 0,1457[2]	8,85 [0,47; 165,34] 0,1237[4]	1,6 [0,0; 3,2] 0,1237[4]
Other	2/62 (3,2)	0/64 (0,0)	5,16 [0,25; 105,34] 0,2864[2]	5,33 [0,25; 113,30] 0,2401[4]	3,2 [-1,2; 7,6] 0,2401[4]
ECOG-PS (Interaction p-value: 0,7629)					
ECOG-PS 0	11/1070 (1,0)	3/1019 (0,3)	3,49 [0,98; 12,48] 0,0543[2]	3,52 [0,98; 12,65] 0,0400[3]	0,7 [0,0; 1,4] 0,0400[3]
ECOG-PS 1	2/213 (0,9)	1/245 (0,4)	2,30 [0,21; 25,19] 0,4951[2]	2,31 [0,21; 25,69] 0,5998[4]	0,5 [-1,0; 2,1] 0,5998[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 396.1.2: Subgroups - serious adverse events according SOC Vascular disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7519)					
< 65 years	9/918 (1,0)	4/936 (0,4)	2,29 [0,71; 7,42] 0,1658[2]	2,31 [0,71; 7,52] 0,1536[3]	0,6 [-0,2; 1,3] 0,1536[3]
≥ 65 years	7/365 (1,9)	2/328 (0,6)	3,15 [0,66; 15,03] 0,1511[2]	3,19 [0,66; 15,45] 0,1825[4]	1,3 [-0,3; 2,9] 0,1825[4]
Prior treatment (Interaction p-value: 0,7215)					
Neoadjuvant chemotherapy	8/430 (1,9)	2/415 (0,5)	3,86 [0,82; 18,07] 0,0863[2]	3,91 [0,83; 18,54] 0,1078[4]	1,4 [-0,1; 2,8] 0,1078[4]
Adjuvant chemotherapy	7/784 (0,9)	4/768 (0,5)	1,71 [0,50; 5,83] 0,3883[2]	1,72 [0,50; 5,90] 0,3824[3]	0,4 [-0,5; 1,2] 0,3824[3]
No chemotherapy	1/69 (1,4)	0/81 (0,0)	3,51 [0,15; 84,90] 0,4392[2]	3,57 [0,14; 89,04] 0,4600[4]	1,4 [-1,4; 4,3] 0,4600[4]
Region (Interaction p-value: 0,9315)					
North America / Europe	10/678 (1,5)	5/649 (0,8)	1,91 [0,66; 5,57] 0,2334[2]	1,93 [0,66; 5,67] 0,2249[3]	0,7 [-0,4; 1,8] 0,2249[3]
Asia	3/203 (1,5)	0/201 (0,0)	6,93 [0,36; 133,33] 0,1994[2]	7,03 [0,36; 137,07] 0,2482[4]	1,5 [-0,2; 3,1] 0,2482[4]
Other	3/402 (0,7)	1/414 (0,2)	3,09 [0,32; 29,58] 0,3277[2]	3,11 [0,32; 29,98] 0,3669[4]	0,5 [-0,5; 1,5] 0,3669[4]
Primary tumor size (Interaction p-value: 0,3037)					
< 20 mm	3/331 (0,9)	3/334 (0,9)	1,01 [0,21; 4,96] 0,9911[2]	1,01 [0,20; 5,04] 1,0000[4]	0,0 [-1,4; 1,4] 1,0000[4]
≥ 20 but < 50 mm	11/646 (1,7)	2/653 (0,3)	5,56 [1,24; 24,98] 0,0253[2]	5,64 [1,24; 25,54] 0,0115[3]	1,4 [0,3; 2,5] 0,0115[3]
≥ 50 mm	2/289 (0,7)	1/265 (0,4)	1,83 [0,17; 20,11] 0,6196[2]	1,84 [0,17; 20,41] 1,0000[4]	0,3 [-0,9; 1,5] 1,0000[4]
Tumor stage (Interaction p-value: 0,7379)					
IIA	0/113 (0,0)	0/114 (0,0)	NE	NE	NE
IIB	2/151 (1,3)	0/136 (0,0)	4,51 [0,22; 93,05] 0,3297[2]	4,57 [0,22; 95,94] 0,4996[4]	1,3 [-0,5; 3,1] 0,4996[4]
IIIA	5/495 (1,0)	3/488 (0,6)	1,64 [0,39; 6,84] 0,4949[2]	1,65 [0,39; 6,94] 0,7255[4]	0,4 [-0,7; 1,5] 0,7255[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	1/54 (1,9)	1/45 (2,2)	0,83 [0,05; 12,95] 0,8964[2]	0,83 [0,05; 13,66] 1,0000[4]	-0,4 [-6,0; 5,2] 1,0000[4]
IIIC	8/468 (1,7)	2/479 (0,4)	4,09 [0,87; 19,18] 0,0736[2]	4,15 [0,88; 19,64] 0,0613[4]	1,3 [-0,0; 2,6] 0,0613[4]
Tumor grade (Interaction p-value: 0,8559)					
G1	1/91 (1,1)	1/93 (1,1)	1,02 [0,06; 16,09] 0,9877[2]	1,02 [0,06; 16,59] 1,0000[4]	0,0 [-3,0; 3,0] 1,0000[4]
G2	12/612 (2,0)	5/602 (0,8)	2,36 [0,84; 6,66] 0,1045[2]	2,39 [0,84; 6,82] 0,0938[3]	1,1 [-0,2; 2,4] 0,0938[3]
G3	3/527 (0,6)	0/506 (0,0)	6,72 [0,35; 129,80] 0,2072[2]	6,76 [0,35; 131,20] 0,2496[4]	0,6 [-0,1; 1,2] 0,2496[4]
GX	0/51 (0,0)	0/59 (0,0)	NE	NE	NE
Progesterone receptor status (Interaction p-value: 0,5571)					
Negative	2/156 (1,3)	1/169 (0,6)	2,17 [0,20; 23,66] 0,5261[2]	2,18 [0,20; 24,30] 0,6093[4]	0,7 [-1,4; 2,8] 0,6093[4]
Positive	14/1089 (1,3)	5/1066 (0,5)	2,74 [0,99; 7,58] 0,0521[2]	2,76 [0,99; 7,70] 0,0426[3]	0,8 [0,0; 1,6] 0,0426[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9997)					
White	11/958 (1,1)	5/943 (0,5)	2,17 [0,76; 6,21] 0,1505[2]	2,18 [0,75; 6,30] 0,1403[3]	0,6 [-0,2; 1,4] 0,1403[3]
Asian	4/250 (1,6)	0/242 (0,0)	8,71 [0,47; 160,97] 0,1457[2]	8,85 [0,47; 165,34] 0,1237[4]	1,6 [0,0; 3,2] 0,1237[4]
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
First endocrine therapy (Interaction p-value: 0,5754)					
Tamoxifen	4/114 (3,5)	1/132 (0,8)	4,63 [0,53; 40,85] 0,1675[2]	4,76 [0,52; 43,25] 0,1855[4]	2,8 [-0,9; 6,4] 0,1855[4]
Aromatase inhibitor	12/1169 (1,0)	5/1132 (0,4)	2,32 [0,82; 6,58] 0,1120[2]	2,34 [0,82; 6,66] 0,1015[3]	0,6 [-0,1; 1,3] 0,1015[3]
ECOG-PS (Interaction p-value: 0,4066)					
ECOG-PS 0	11/1070 (1,0)	5/1019 (0,5)	2,10 [0,73; 6,01] 0,1689[2]	2,11 [0,73; 6,08] 0,1591[3]	0,5 [-0,2; 1,3] 0,1591[3]
ECOG-PS 1	5/213 (2,3)	1/245 (0,4)	5,75 [0,68; 48,84] 0,1090[2]	5,87 [0,68; 50,61] 0,1013[4]	1,9 [-0,2; 4,1] 0,1013[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.					

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Table 397.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Alanine aminotransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,4360)					
< 65 years	24/918 (2,6)	6/936 (0,6)	4,08 [1,67; 9,93] 0,0020[2]	4,16 [1,69; 10,23] 0,0008[3]	2,0 [0,8; 3,1] 0,0008[3]
≥ 65 years	11/365 (3,0)	1/328 (0,3)	9,88 [1,28; 76,15] 0,0279[2]	10,16 [1,30; 79,14] 0,0063[3]	2,7 [0,9; 4,6] 0,0063[3]
Prior treatment (Interaction p-value: 0,4166)					
Neoadjuvant chemotherapy	17/430 (4,0)	2/415 (0,5)	8,20 [1,91; 35,29] 0,0047[2]	8,50 [1,95; 37,02] 0,0007[3]	3,5 [1,5; 5,4] 0,0007[3]
Adjuvant chemotherapy	11/784 (1,4)	4/768 (0,5)	2,69 [0,86; 8,42] 0,0884[2]	2,72 [0,86; 8,57] 0,0757[3]	0,9 [-0,1; 1,9] 0,0757[3]
No chemotherapy	7/69 (10,1)	1/81 (1,2)	8,22 [1,04; 65,16] 0,0462[2]	9,03 [1,08; 75,35] 0,0243[4]	8,9 [1,4; 16,4] 0,0243[4]
Region (Interaction p-value: 0,9345)					
North America / Europe	12/678 (1,8)	2/649 (0,3)	5,74 [1,29; 25,56] 0,0218[2]	5,83 [1,30; 26,15] 0,0092[3]	1,5 [0,4; 2,5] 0,0092[3]
Asia	11/203 (5,4)	2/201 (1,0)	5,45 [1,22; 24,26] 0,0262[2]	5,70 [1,25; 26,05] 0,0118[3]	4,4 [1,0; 7,8] 0,0118[3]
Other	12/402 (3,0)	3/414 (0,7)	4,12 [1,17; 14,49] 0,0274[2]	4,22 [1,18; 15,05] 0,0163[3]	2,3 [0,4; 4,1] 0,0163[3]
Primary tumor size (Interaction p-value: 0,6182)					
< 20 mm	8/331 (2,4)	1/334 (0,3)	8,07 [1,02; 64,18] 0,0483[2]	8,25 [1,03; 66,31] 0,0202[4]	2,1 [0,4; 3,9] 0,0202[4]
≥ 20 but < 50 mm	20/646 (3,1)	3/653 (0,5)	6,74 [2,01; 22,57] 0,0020[2]	6,92 [2,05; 23,41] 0,0003[3]	2,6 [1,2; 4,1] 0,0003[3]
≥ 50 mm	6/289 (2,1)	2/265 (0,8)	2,75 [0,56; 13,51] 0,2127[2]	2,79 [0,56; 13,94] 0,2892[4]	1,3 [-0,6; 3,3] 0,2892[4]
Number of positive lymph nodes (Interaction p-value: 0,4551)					
0-3	13/427 (3,0)	2/418 (0,5)	6,36 [1,44; 28,02] 0,0144[2]	6,53 [1,46; 29,12] 0,0047[3]	2,6 [0,8; 4,3] 0,0047[3]
4-9	12/549 (2,2)	0/542 (0,0)	24,68 [1,46; 415,83] 0,0261[2]	25,23 [1,49; 427,24] 0,0005[3]	2,2 [1,0; 3,4] 0,0005[3]
≥ 10	10/307 (3,3)	5/304 (1,6)	1,98 [0,68; 5,73] 0,2072[2]	2,01 [0,68; 5,96] 0,1978[3]	1,6 [-0,8; 4,1] 0,1978[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,9619)					
IIA	1/113 (0,9)	1/114 (0,9)	1,01 [0,06; 15,93] 0,9950[2]	1,01 [0,06; 16,33] 1,0000[4]	0,0 [-2,4; 2,4] 1,0000[4]
IIB	4/151 (2,6)	1/136 (0,7)	3,60 [0,41; 31,84] 0,2490[2]	3,67 [0,41; 33,28] 0,3741[4]	1,9 [-1,0; 4,9] 0,3741[4]
IIIA	12/495 (2,4)	0/488 (0,0)	24,65 [1,46; 415,13] 0,0261[2]	25,26 [1,49; 427,80] 0,0005[3]	2,4 [1,1; 3,8] 0,0005[3]
IIIB	3/54 (5,6)	0/45 (0,0)	5,85 [0,31; 110,43] 0,2383[2]	6,18 [0,31; 122,97] 0,2486[4]	5,6 [-0,6; 11,7] 0,2486[4]
IIIC	15/468 (3,2)	5/479 (1,0)	3,07 [1,12; 8,38] 0,0285[2]	3,14 [1,13; 8,71] 0,0207[3]	2,2 [0,3; 4,0] 0,0207[3]
Tumor grade (Interaction p-value: 0,8374)					
G1	1/91 (1,1)	0/93 (0,0)	3,07 [0,13; 74,28] 0,4910[2]	3,10 [0,12; 77,08] 0,4946[4]	1,1 [-1,0; 3,2] 0,4946[4]
G2	17/612 (2,8)	5/602 (0,8)	3,34 [1,24; 9,01] 0,0169[2]	3,41 [1,25; 9,31] 0,0110[3]	1,9 [0,5; 3,4] 0,0110[3]
G3	16/527 (3,0)	2/506 (0,4)	7,68 [1,78; 33,24] 0,0064[2]	7,89 [1,80; 34,49] 0,0012[3]	2,6 [1,1; 4,2] 0,0012[3]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,4288)					
Negative	4/156 (2,6)	2/169 (1,2)	2,17 [0,40; 11,66] 0,3680[2]	2,20 [0,40; 12,17] 0,4323[4]	1,4 [-1,6; 4,3] 0,4323[4]
Positive	31/1089 (2,8)	5/1066 (0,5)	6,07 [2,37; 15,55] 0,0002[2]	6,22 [2,41; 16,05] <,0001[3]	2,4 [1,3; 3,4] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,5663)					
White	22/958 (2,3)	3/943 (0,3)	7,22 [2,17; 24,04] 0,0013[2]	7,36 [2,20; 24,69] 0,0002[3]	2,0 [1,0; 3,0] 0,0002[3]
Asian	11/250 (4,4)	3/242 (1,2)	3,55 [1,00; 12,57] 0,0496[2]	3,67 [1,01; 13,31] 0,0351[3]	3,2 [0,3; 6,1] 0,0351[3]
Other	2/62 (3,2)	1/64 (1,6)	2,06 [0,19; 22,19] 0,5497[2]	2,10 [0,19; 23,77] 0,6160[4]	1,7 [-3,7; 7,0] 0,6160[4]
ECOG-PS (Interaction p-value: 0,9733)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	31/1070 (2,9)	7/1019 (0,7)	4,22 [1,87; 9,53] 0,0005[2]	4,31 [1,89; 9,84] 0,0002[3]	2,2 [1,1; 3,3] 0,0002[3]
ECOG-PS 1	4/213 (1,9)	0/245 (0,0)	10,35 [0,56; 191,06] 0,1163[2]	10,55 [0,56; 197,03] 0,0461[4]	1,9 [0,1; 3,7] 0,0461[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 398.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Anaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9746)					
< 65 years	18/918 (2,0)	3/936 (0,3)	6,12 [1,81; 20,70] 0,0036[2]	6,22 [1,83; 21,19] 0,0008[3]	1,6 [0,7; 2,6] 0,0008[3]
≥ 65 years	21/365 (5,8)	3/328 (0,9)	6,29 [1,89; 20,90] 0,0027[2]	6,61 [1,95; 22,38] 0,0005[3]	4,8 [2,2; 7,4] 0,0005[3]
Prior treatment (Interaction p-value: 0,9809)					
Neoadjuvant chemotherapy	11/430 (2,6)	2/415 (0,5)	5,31 [1,18; 23,80] 0,0292[2]	5,42 [1,19; 24,61] 0,0142[3]	2,1 [0,4; 3,7] 0,0142[3]
Adjuvant chemotherapy	26/784 (3,3)	4/768 (0,5)	6,37 [2,23; 18,16] 0,0005[2]	6,55 [2,28; 18,86] <,0001[3]	2,8 [1,4; 4,1] <,0001[3]
No chemotherapy	2/69 (2,9)	0/81 (0,0)	5,86 [0,29; 119,97] 0,2512[2]	6,04 [0,28; 127,91] 0,2099[4]	2,9 [-1,1; 6,9] 0,2099[4]
Region (Interaction p-value: 0,9070)					
North America / Europe	20/678 (2,9)	4/649 (0,6)	4,79 [1,64; 13,93] 0,0041[2]	4,90 [1,67; 14,42] 0,0014[3]	2,3 [0,9; 3,7] 0,0014[3]
Asia	5/203 (2,5)	0/201 (0,0)	10,89 [0,61; 195,70] 0,1052[2]	11,17 [0,61; 203,28] 0,0610[4]	2,5 [0,3; 4,6] 0,0610[4]
Other	14/402 (3,5)	2/414 (0,5)	7,21 [1,65; 31,52] 0,0087[2]	7,43 [1,68; 32,92] 0,0020[3]	3,0 [1,1; 4,9] 0,0020[3]
Primary tumor size (Interaction p-value: 0,9311)					
< 20 mm	9/331 (2,7)	1/334 (0,3)	9,08 [1,16; 71,28] 0,0358[2]	9,31 [1,17; 73,88] 0,0109[4]	2,4 [0,6; 4,3] 0,0109[4]
≥ 20 but < 50 mm	23/646 (3,6)	4/653 (0,6)	5,81 [2,02; 16,71] 0,0011[2]	5,99 [2,06; 17,42] 0,0002[3]	2,9 [1,4; 4,5] 0,0002[3]
≥ 50 mm	7/289 (2,4)	1/265 (0,4)	6,42 [0,79; 51,82] 0,0810[2]	6,55 [0,80; 53,62] 0,0704[4]	2,0 [0,1; 4,0] 0,0704[4]
Number of positive lymph nodes (Interaction p-value: 0,5751)					
0-3	8/427 (1,9)	2/418 (0,5)	3,92 [0,84; 18,33] 0,0831[2]	3,97 [0,84; 18,81] 0,1075[4]	1,4 [-0,1; 2,8] 0,1075[4]
4-9	16/549 (2,9)	3/542 (0,6)	5,27 [1,54; 17,97] 0,0080[2]	5,39 [1,56; 18,62] 0,0029[3]	2,4 [0,8; 3,9] 0,0029[3]
≥ 10	15/307 (4,9)	1/304 (0,3)	14,85 [1,97; 111,75] 0,0088[2]	15,57 [2,04; 118,59] 0,0004[3]	4,6 [2,1; 7,1] 0,0004[3]
Tumor stage (Interaction p-value: 0,9611)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	1/113 (0,9)	0/114 (0,0)	3,03 [0,12; 73,51] 0,4963[2]	3,05 [0,12; 75,75] 0,4978[4]	0,9 [-0,8; 2,6] 0,4978[4]
IIB	5/151 (3,3)	0/136 (0,0)	9,91 [0,55; 177,65] 0,1192[2]	10,25 [0,56; 187,10] 0,0620[4]	3,3 [0,5; 6,2] 0,0620[4]
IIIA	16/495 (3,2)	4/488 (0,8)	3,94 [1,33; 11,71] 0,0135[2]	4,04 [1,34; 12,18] 0,0074[3]	2,4 [0,7; 4,2] 0,0074[3]
IIIB	1/54 (1,9)	0/45 (0,0)	2,51 [0,10; 60,13] 0,5703[2]	2,55 [0,10; 64,17] 1,0000[4]	1,9 [-1,7; 5,4] 1,0000[4]
IIIC	16/468 (3,4)	2/479 (0,4)	8,19 [1,89; 35,41] 0,0049[2]	8,44 [1,93; 36,92] 0,0007[3]	3,0 [1,3; 4,7] 0,0007[3]
Tumor grade (Interaction p-value: 0,9903)					
G1	3/91 (3,3)	0/93 (0,0)	7,15 [0,37; 136,54] 0,1910[2]	7,40 [0,38; 145,22] 0,1189[4]	3,3 [-0,4; 7,0] 0,1189[4]
G2	24/612 (3,9)	4/602 (0,7)	5,90 [2,06; 16,91] 0,0009[2]	6,10 [2,10; 17,69] 0,0002[3]	3,3 [1,6; 4,9] 0,0002[3]
G3	9/527 (1,7)	2/506 (0,4)	4,32 [0,94; 19,90] 0,0604[2]	4,38 [0,94; 20,36] 0,0399[3]	1,3 [0,1; 2,5] 0,0399[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesterone receptor status (Interaction p-value: 0,6390)					
Negative	3/156 (1,9)	2/169 (1,2)	1,63 [0,28; 9,60] 0,5921[2]	1,64 [0,27; 9,93] 0,6739[4]	0,7 [-2,0; 3,4] 0,6739[4]
Positive	36/1089 (3,3)	4/1066 (0,4)	8,81 [3,15; 24,67] <,0001[2]	9,08 [3,22; 25,59] <,0001[3]	2,9 [1,8; 4,1] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9889)					
White	25/958 (2,6)	5/943 (0,5)	4,92 [1,89; 12,80] 0,0011[2]	5,03 [1,92; 13,19] 0,0003[3]	2,1 [1,0; 3,2] 0,0003[3]
Asian	10/250 (4,0)	0/242 (0,0)	20,33 [1,20; 345,05] 0,0371[2]	21,17 [1,23; 363,38] 0,0018[4]	4,0 [1,6; 6,4] 0,0018[4]
Other	4/62 (6,5)	1/64 (1,6)	4,13 [0,47; 35,92] 0,1989[2]	4,34 [0,47; 40,01] 0,2039[4]	4,9 [-1,9; 11,7] 0,2039[4]
ECOG-PS (Interaction p-value: 0,9706)					
ECOG-PS 0	26/1070 (2,4)	6/1019 (0,6)	4,13 [1,71; 9,98] 0,0017[2]	4,20 [1,72; 10,26] 0,0006[3]	1,8 [0,8; 2,9] 0,0006[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	13/213 (6,1)	0/245 (0,0)	31,04 [1,86; 519,00] 0,0168[2]	33,06 [1,95; 559,56] <,0001[3]	6,1 [2,9; 9,3] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 399.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Aspartate aminotransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8653)					
< 65 years	15/918 (1,6)	3/936 (0,3)	5,10 [1,48; 17,55] 0,0098[2]	5,17 [1,49; 17,91] 0,0039[3]	1,3 [0,4; 2,2] 0,0039[3]
≥ 65 years	7/365 (1,9)	1/328 (0,3)	6,29 [0,78; 50,86] 0,0846[2]	6,39 [0,78; 52,25] 0,0718[4]	1,6 [0,1; 3,1] 0,0718[4]
Prior treatment (Interaction p-value: 0,2493)					
Neoadjuvant chemotherapy	15/430 (3,5)	1/415 (0,2)	14,48 [1,92; 109,10] 0,0095[2]	14,96 [1,97; 113,80] 0,0005[3]	3,2 [1,5; 5,0] 0,0005[3]
Adjuvant chemotherapy	3/784 (0,4)	2/768 (0,3)	1,47 [0,25; 8,77] 0,6729[2]	1,47 [0,25; 8,83] 1,0000[4]	0,1 [-0,4; 0,7] 1,0000[4]
No chemotherapy	4/69 (5,8)	1/81 (1,2)	4,70 [0,54; 41,03] 0,1620[2]	4,92 [0,54; 45,13] 0,1807[4]	4,6 [-1,5; 10,6] 0,1807[4]
Region (Interaction p-value: 0,8121)					
North America / Europe	6/678 (0,9)	0/649 (0,0)	12,44 [0,70; 220,46] 0,0856[2]	12,56 [0,71; 223,32] 0,0311[4]	0,9 [0,2; 1,6] 0,0311[4]
Asia	7/203 (3,4)	1/201 (0,5)	6,93 [0,86; 55,82] 0,0689[2]	7,14 [0,87; 58,59] 0,0676[4]	3,0 [0,3; 5,6] 0,0676[4]
Other	9/402 (2,2)	3/414 (0,7)	3,09 [0,84; 11,33] 0,0889[2]	3,14 [0,84; 11,67] 0,0724[3]	1,5 [-0,1; 3,2] 0,0724[3]
Primary tumor size (Interaction p-value: 0,9040)					
< 20 mm	7/331 (2,1)	1/334 (0,3)	7,06 [0,87; 57,09] 0,0667[2]	7,19 [0,88; 58,80] 0,0373[4]	1,8 [0,2; 3,5] 0,0373[4]
≥ 20 but < 50 mm	12/646 (1,9)	3/653 (0,5)	4,04 [1,15; 14,26] 0,0298[2]	4,10 [1,15; 14,60] 0,0184[3]	1,4 [0,2; 2,6] 0,0184[3]
≥ 50 mm	3/289 (1,0)	0/265 (0,0)	6,42 [0,33; 123,72] 0,2180[2]	6,49 [0,33; 126,18] 0,2501[4]	1,0 [-0,1; 2,2] 0,2501[4]
Number of positive lymph nodes (Interaction p-value: 0,7696)					
0-3	9/427 (2,1)	1/418 (0,2)	8,81 [1,12; 69,23] 0,0386[2]	8,98 [1,13; 71,18] 0,0208[4]	1,9 [0,4; 3,3] 0,0208[4]
4-9	6/549 (1,1)	1/542 (0,2)	5,92 [0,72; 49,04] 0,0990[2]	5,98 [0,72; 49,82] 0,1238[4]	0,9 [-0,0; 1,9] 0,1238[4]
≥ 10	7/307 (2,3)	2/304 (0,7)	3,47 [0,73; 16,55] 0,1192[2]	3,52 [0,73; 17,10] 0,1765[4]	1,6 [-0,3; 3,5] 0,1765[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,9711)					
IIA	2/113 (1,8)	1/114 (0,9)	2,02 [0,19; 21,94] 0,5642[2]	2,04 [0,18; 22,78] 0,6217[4]	0,9 [-2,1; 3,9] 0,6217[4]
IIB	3/151 (2,0)	0/136 (0,0)	6,31 [0,33; 121,05] 0,2217[2]	6,43 [0,33; 125,70] 0,2494[4]	2,0 [-0,2; 4,2] 0,2494[4]
IIIA	6/495 (1,2)	1/488 (0,2)	5,92 [0,71; 48,95] 0,0992[2]	5,98 [0,72; 49,82] 0,1237[4]	1,0 [-0,0; 2,1] 0,1237[4]
IIIB	1/54 (1,9)	0/45 (0,0)	2,51 [0,10; 60,13] 0,5703[2]	2,55 [0,10; 64,17] 1,0000[4]	1,9 [-1,7; 5,4] 1,0000[4]
IIIC	10/468 (2,1)	2/479 (0,4)	5,12 [1,13; 23,23] 0,0344[2]	5,21 [1,13; 23,90] 0,0180[3]	1,7 [0,3; 3,2] 0,0180[3]
Tumor grade (Interaction p-value: 0,7851)					
G1	1/91 (1,1)	0/93 (0,0)	3,07 [0,13; 74,28] 0,4910[2]	3,10 [0,12; 77,08] 0,4946[4]	1,1 [-1,0; 3,2] 0,4946[4]
G2	9/612 (1,5)	3/602 (0,5)	2,95 [0,80; 10,85] 0,1033[2]	2,98 [0,80; 11,06] 0,0869[3]	1,0 [-0,1; 2,1] 0,0869[3]
G3	11/527 (2,1)	1/506 (0,2)	10,56 [1,37; 81,51] 0,0238[2]	10,77 [1,38; 83,69] 0,0046[3]	1,9 [0,6; 3,2] 0,0046[3]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,3666)					
Negative	3/156 (1,9)	1/169 (0,6)	3,25 [0,34; 30,92] 0,3051[2]	3,29 [0,34; 32,00] 0,3537[4]	1,3 [-1,1; 3,8] 0,3537[4]
Positive	19/1089 (1,7)	3/1066 (0,3)	6,20 [1,84; 20,89] 0,0032[2]	6,29 [1,86; 21,32] 0,0007[3]	1,5 [0,6; 2,3] 0,0007[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,1050)					
White	14/958 (1,5)	1/943 (0,1)	13,78 [1,82; 104,59] 0,0112[2]	13,97 [1,83; 106,45] 0,0008[3]	1,4 [0,6; 2,1] 0,0008[3]
Asian	7/250 (2,8)	1/242 (0,4)	6,78 [0,84; 54,66] 0,0725[2]	6,94 [0,85; 56,85] 0,0684[4]	2,4 [0,2; 4,6] 0,0684[4]
Other	1/62 (1,6)	2/64 (3,1)	0,52 [0,05; 5,55] 0,5852[2]	0,51 [0,04; 5,75] 1,0000[4]	-1,5 [-6,8; 3,8] 1,0000[4]
ECOG-PS (Interaction p-value: 0,6693)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	19/1070 (1,8)	3/1019 (0,3)	6,03 [1,79; 20,32] 0,0037[2]	6,12 [1,81; 20,75] 0,0009[3]	1,5 [0,6; 2,3] 0,0009[3]
ECOG-PS 1	3/213 (1,4)	1/245 (0,4)	3,45 [0,36; 32,93] 0,2818[2]	3,49 [0,36; 33,76] 0,3420[4]	1,0 [-0,8; 2,8] 0,3420[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 400.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Diarrhoea from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,6740)					
< 65 years	77/918 (8,4)	1/936 (0,1)	78,51 [10,94; 563,28] <,0001[2]	85,61 [11,88; 616,84] <,0001[3]	8,3 [6,5; 10,1] <,0001[3]
≥ 65 years	48/365 (13,2)	1/328 (0,3)	43,13 [5,99; 310,74] 0,0002[2]	49,51 [6,79; 360,88] <,0001[3]	12,8 [9,3; 16,4] <,0001[3]
Prior treatment (Interaction p-value: 0,9543)					
Neoadjuvant chemotherapy	48/430 (11,2)	1/415 (0,2)	46,33 [6,42; 334,08] 0,0001[2]	52,02 [7,15; 378,72] <,0001[3]	10,9 [7,9; 13,9] <,0001[3]
Adjuvant chemotherapy	73/784 (9,3)	1/768 (0,1)	71,51 [9,96; 513,20] <,0001[2]	78,75 [10,92; 568,07] <,0001[3]	9,2 [7,1; 11,2] <,0001[3]
No chemotherapy	4/69 (5,8)	0/81 (0,0)	10,54 [0,58; 192,43] 0,1119[2]	11,20 [0,59; 211,78] 0,0427[4]	5,8 [0,3; 11,3] 0,0427[4]
Region (Interaction p-value: 0,9994)					
North America / Europe	67/678 (9,9)	2/649 (0,3)	32,07 [7,89; 130,34] <,0001[2]	35,47 [8,65; 145,41] <,0001[3]	9,6 [7,3; 11,9] <,0001[3]
Asia	13/203 (6,4)	0/201 (0,0)	26,74 [1,60; 446,72] 0,0222[2]	28,56 [1,69; 483,76] 0,0003[3]	6,4 [3,0; 9,8] 0,0003[3]
Other	45/402 (11,2)	0/414 (0,0)	93,71 [5,79; 1515,99] 0,0014[2]	105,51 [6,48; 1718,80] <,0001[3]	11,2 [8,1; 14,3] <,0001[3]
Primary tumor size (Interaction p-value: 0,7882)					
< 20 mm	27/331 (8,2)	0/334 (0,0)	55,50 [3,40; 906,05] 0,0048[2]	60,42 [3,67; 994,75] <,0001[3]	8,2 [5,2; 11,1] <,0001[3]
≥ 20 but < 50 mm	68/646 (10,5)	1/653 (0,2)	68,74 [9,57; 493,54] <,0001[2]	76,71 [10,62; 554,17] <,0001[3]	10,4 [8,0; 12,8] <,0001[3]
≥ 50 mm	28/289 (9,7)	1/265 (0,4)	25,67 [3,52; 187,39] 0,0014[2]	28,32 [3,83; 209,69] <,0001[3]	9,3 [5,8; 12,8] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,9946)					
0-3	51/427 (11,9)	1/418 (0,2)	49,93 [6,93; 359,61] 0,0001[2]	56,56 [7,78; 411,30] <,0001[3]	11,7 [8,6; 14,8] <,0001[3]
4-9	44/549 (8,0)	1/542 (0,2)	43,44 [6,01; 314,16] 0,0002[2]	47,14 [6,47; 343,39] <,0001[3]	7,8 [5,5; 10,1] <,0001[3]
≥ 10	30/307 (9,8)	0/304 (0,0)	60,41 [3,71; 983,42] 0,0040[2]	66,94 [4,07; 1099,81] <,0001[3]	9,8 [6,5; 13,1] <,0001[3]
Tumor stage (Interaction p-value: 0,9968)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	11/113 (9,7)	0/114 (0,0)	23,20 [1,38; 389,08] 0,0288[2]	25,69 [1,50; 441,49] 0,0006[3]	9,7 [4,3; 15,2] 0,0006[3]
IIB	16/151 (10,6)	0/136 (0,0)	29,74 [1,80; 491,08] 0,0177[2]	33,24 [1,97; 559,68] <,0001[3]	10,6 [5,7; 15,5] <,0001[3]
IIIA	35/495 (7,1)	1/488 (0,2)	34,51 [4,75; 250,87] 0,0005[2]	37,05 [5,06; 271,57] <,0001[3]	6,9 [4,6; 9,2] <,0001[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	60/468 (12,8)	1/479 (0,2)	61,41 [8,55; 441,29] <,0001[2]	70,29 [9,70; 509,45] <,0001[3]	12,6 [9,6; 15,7] <,0001[3]
Race (Interaction p-value: 0,9998)					
White	103/958 (10,8)	2/943 (0,2)	50,69 [12,55; 204,83] <,0001[2]	56,68 [13,94; 230,39] <,0001[3]	10,5 [8,6; 12,5] <,0001[3]
Asian	14/250 (5,6)	0/242 (0,0)	28,08 [1,68; 468,05] 0,0202[2]	29,74 [1,76; 501,31] 0,0002[3]	5,6 [2,7; 8,5] 0,0002[3]
Other	6/62 (9,7)	0/64 (0,0)	13,41 [0,77; 233,15] 0,0748[2]	14,84 [0,82; 269,32] 0,0125[4]	9,7 [2,3; 17,0] 0,0125[4]
ECOG-PS (Interaction p-value: 0,9752)					
ECOG-PS 0	105/1070 (9,8)	2/1019 (0,2)	50,00 [12,37; 202,02] <,0001[2]	55,33 [13,62; 224,78] <,0001[3]	9,6 [7,8; 11,4] <,0001[3]
ECOG-PS 1	20/213 (9,4)	0/245 (0,0)	47,13 [2,87; 774,60] 0,0070[2]	52,02 [3,13; 865,51] <,0001[3]	9,4 [5,5; 13,3] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 401.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Fatigue from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9307)					
< 65 years	17/918 (1,9)	1/936 (0,1)	17,33 [2,31; 129,98] 0,0055[2]	17,64 [2,34; 132,84] 0,0001[3]	1,7 [0,8; 2,6] 0,0001[3]
≥ 65 years	17/365 (4,7)	1/328 (0,3)	15,28 [2,04; 114,16] 0,0079[2]	15,97 [2,11; 120,71] 0,0003[3]	4,4 [2,1; 6,6] 0,0003[3]
Prior treatment (Interaction p-value: 0,8091)					
Neoadjuvant chemotherapy	9/430 (2,1)	1/415 (0,2)	8,69 [1,11; 68,26] 0,0399[2]	8,85 [1,12; 70,17] 0,0210[4]	1,9 [0,4; 3,3] 0,0210[4]
Adjuvant chemotherapy	23/784 (2,9)	1/768 (0,1)	22,53 [3,05; 166,42] 0,0023[2]	23,18 [3,12; 172,08] <,0001[3]	2,8 [1,6; 4,0] <,0001[3]
No chemotherapy	2/69 (2,9)	0/81 (0,0)	5,86 [0,29; 119,97] 0,2512[2]	6,04 [0,28; 127,91] 0,2099[4]	2,9 [-1,1; 6,9] 0,2099[4]
Region (Interaction p-value: 0,9995)					
North America / Europe	23/678 (3,4)	2/649 (0,3)	11,01 [2,61; 46,50] 0,0011[2]	11,36 [2,67; 48,38] <,0001[3]	3,1 [1,7; 4,5] <,0001[3]
Asia	1/203 (0,5)	0/201 (0,0)	2,97 [0,12; 72,49] 0,5042[2]	2,99 [0,12; 73,71] 1,0000[4]	0,5 [-0,5; 1,5] 1,0000[4]
Other	10/402 (2,5)	0/414 (0,0)	21,63 [1,27; 367,82] 0,0335[2]	22,18 [1,30; 379,73] 0,0008[4]	2,5 [1,0; 4,0] 0,0008[4]
Primary tumor size (Interaction p-value: 0,9993)					
< 20 mm	8/331 (2,4)	0/334 (0,0)	17,15 [0,99; 295,99] 0,0505[2]	17,58 [1,01; 305,79] 0,0036[4]	2,4 [0,8; 4,1] 0,0036[4]
≥ 20 but < 50 mm	15/646 (2,3)	2/653 (0,3)	7,58 [1,74; 33,02] 0,0070[2]	7,74 [1,76; 33,97] 0,0014[3]	2,0 [0,8; 3,3] 0,0014[3]
≥ 50 mm	11/289 (3,8)	0/265 (0,0)	21,10 [1,25; 356,25] 0,0345[2]	21,93 [1,29; 373,94] 0,0013[3]	3,8 [1,6; 6,0] 0,0013[3]
Number of positive lymph nodes (Interaction p-value: 0,9979)					
0-3	12/427 (2,8)	1/418 (0,2)	11,75 [1,53; 89,94] 0,0177[2]	12,06 [1,56; 93,15] 0,0024[3]	2,6 [0,9; 4,2] 0,0024[3]
4-9	11/549 (2,0)	1/542 (0,2)	10,86 [1,41; 83,83] 0,0222[2]	11,06 [1,42; 85,97] 0,0040[3]	1,8 [0,6; 3,0] 0,0040[3]
≥ 10	11/307 (3,6)	0/304 (0,0)	22,78 [1,35; 384,79] 0,0302[2]	23,62 [1,39; 402,64] 0,0009[3]	3,6 [1,5; 5,7] 0,0009[3]
Tumor stage (Interaction p-value: 0,9982)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	4/113 (3,5)	0/114 (0,0)	9,08 [0,49; 166,70] 0,1374[2]	9,41 [0,50; 176,86] 0,0598[4]	3,5 [0,1; 6,9] 0,0598[4]
IIB	5/151 (3,3)	0/136 (0,0)	9,91 [0,55; 177,65] 0,1192[2]	10,25 [0,56; 187,10] 0,0620[4]	3,3 [0,5; 6,2] 0,0620[4]
IIIA	11/495 (2,2)	1/488 (0,2)	10,84 [1,41; 83,68] 0,0222[2]	11,07 [1,42; 86,06] 0,0040[3]	2,0 [0,7; 3,4] 0,0040[3]
IIIB	0/54 (0,0)	0/45 (0,0)	NE	NE	NE
IIIC	14/468 (3,0)	1/479 (0,2)	14,33 [1,89; 108,53] 0,0100[2]	14,74 [1,93; 112,55] 0,0006[3]	2,8 [1,2; 4,4] 0,0006[3]
Tumor grade (Interaction p-value: 1,0000)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	14/612 (2,3)	0/602 (0,0)	28,53 [1,71; 477,13] 0,0197[2]	29,19 [1,74; 490,50] 0,0002[3]	2,3 [1,1; 3,5] 0,0002[3]
G3	17/527 (3,2)	2/506 (0,4)	8,16 [1,90; 35,14] 0,0048[2]	8,40 [1,93; 36,55] 0,0007[3]	2,8 [1,2; 4,4] 0,0007[3]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,9606)					
Negative	5/156 (3,2)	0/169 (0,0)	11,91 [0,66; 213,66] 0,0926[2]	12,31 [0,67; 224,42] 0,0246[4]	3,2 [0,4; 6,0] 0,0246[4]
Positive	29/1089 (2,7)	2/1066 (0,2)	14,19 [3,40; 59,34] 0,0003[2]	14,55 [3,46; 61,15] <,0001[3]	2,5 [1,5; 3,5] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9864)					
White	32/958 (3,3)	2/943 (0,2)	15,75 [3,79; 65,53] 0,0002[2]	16,26 [3,89; 68,04] <,0001[3]	3,1 [2,0; 4,3] <,0001[3]
Asian	1/250 (0,4)	0/242 (0,0)	2,90 [0,12; 70,95] 0,5132[2]	2,92 [0,12; 71,93] 1,0000[4]	0,4 [-0,4; 1,2] 1,0000[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,9742)					
ECOG-PS 0	26/1070 (2,4)	2/1019 (0,2)	12,38 [2,95; 52,03] 0,0006[2]	12,66 [3,00; 53,49] <,0001[3]	2,2 [1,3; 3,2] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	8/213 (3,8)	0/245 (0,0)	19,54 [1,13; 336,58] 0,0407[2]	20,31 [1,17; 353,98] 0,0020[4]	3,8 [1,2; 6,3] 0,0020[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 402.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Gamma-glutamyltransferase increased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Prior treatment (Interaction p-value: 0,8567)					
Neoadjuvant chemotherapy	6/430 (1,4)	1/415 (0,2)	5,79 [0,70; 47,89] 0,1033[2]	5,86 [0,70; 48,87] 0,1239[4]	1,2 [-0,1; 2,4] 0,1239[4]
Adjuvant chemotherapy	12/784 (1,5)	3/768 (0,4)	3,92 [1,11; 13,83] 0,0338[2]	3,96 [1,11; 14,10] 0,0217[3]	1,1 [0,2; 2,1] 0,0217[3]
No chemotherapy	2/69 (2,9)	1/81 (1,2)	2,35 [0,22; 25,34] 0,4819[2]	2,39 [0,21; 26,92] 0,5945[4]	1,7 [-3,0; 6,3] 0,5945[4]
Region (Interaction p-value: 0,9495)					
North America / Europe	8/678 (1,2)	2/649 (0,3)	3,83 [0,82; 17,96] 0,0887[2]	3,86 [0,82; 18,26] 0,1089[4]	0,9 [-0,0; 1,8] 0,1089[4]
Asia	4/203 (2,0)	0/201 (0,0)	8,91 [0,48; 164,45] 0,1414[2]	9,09 [0,49; 169,95] 0,1232[4]	2,0 [0,1; 3,9] 0,1232[4]
Other	8/402 (2,0)	3/414 (0,7)	2,75 [0,73; 10,28] 0,1335[2]	2,78 [0,73; 10,56] 0,1171[3]	1,3 [-0,3; 2,9] 0,1171[3]
Primary tumor size (Interaction p-value: 0,0936)					
< 20 mm	2/331 (0,6)	3/334 (0,9)	0,67 [0,11; 4,00] 0,6629[2]	0,67 [0,11; 4,04] 1,0000[4]	-0,3 [-1,6; 1,0] 1,0000[4]
≥ 20 but < 50 mm	13/646 (2,0)	1/653 (0,2)	13,14 [1,72; 100,16] 0,0129[2]	13,39 [1,75; 102,66] 0,0012[3]	1,9 [0,7; 3,0] 0,0012[3]
≥ 50 mm	4/289 (1,4)	1/265 (0,4)	3,67 [0,41; 32,61] 0,2437[2]	3,71 [0,41; 33,36] 0,3751[4]	1,0 [-0,5; 2,5] 0,3751[4]
Number of positive lymph nodes (Interaction p-value: 0,2457)					
0-3	7/427 (1,6)	1/418 (0,2)	6,85 [0,85; 55,45] 0,0712[2]	6,95 [0,85; 56,74] 0,0691[4]	1,4 [0,1; 2,7] 0,0691[4]
4-9	9/549 (1,6)	1/542 (0,2)	8,89 [1,13; 69,89] 0,0379[2]	9,02 [1,14; 71,41] 0,0209[4]	1,5 [0,3; 2,6] 0,0209[4]
≥ 10	4/307 (1,3)	3/304 (1,0)	1,32 [0,30; 5,85] 0,7145[2]	1,32 [0,29; 5,97] 1,0000[4]	0,3 [-1,4; 2,0] 1,0000[4]
Tumor grade (Interaction p-value: 0,8949)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	9/612 (1,5)	4/602 (0,7)	2,21 [0,69; 7,15] 0,1841[2]	2,23 [0,68; 7,28] 0,1724[3]	0,8 [-0,3; 2,0] 0,1724[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
G3	6/527 (1,1)	1/506 (0,2)	5,76 [0,70; 47,68] 0,1044[2]	5,82 [0,70; 48,48] 0,1243[4]	0,9 [-0,0; 1,9] 0,1243[4]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesterone receptor status (Interaction p-value: 0,9644)					
Negative	2/156 (1,3)	0/169 (0,0)	5,41 [0,26; 111,90] 0,2744[2]	5,49 [0,26; 115,15] 0,2296[4]	1,3 [-0,5; 3,0] 0,2296[4]
Positive	18/1089 (1,7)	5/1066 (0,5)	3,52 [1,31; 9,46] 0,0124[2]	3,57 [1,32; 9,64] 0,0075[3]	1,2 [0,3; 2,0] 0,0075[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9288)					
White	14/958 (1,5)	4/943 (0,4)	3,45 [1,14; 10,43] 0,0286[2]	3,48 [1,14; 10,62] 0,0196[3]	1,0 [0,2; 1,9] 0,0196[3]
Asian	4/250 (1,6)	0/242 (0,0)	8,71 [0,47; 160,97] 0,1457[2]	8,85 [0,47; 165,34] 0,1237[4]	1,6 [0,0; 3,2] 0,1237[4]
Other	2/62 (3,2)	1/64 (1,6)	2,06 [0,19; 22,19] 0,5497[2]	2,10 [0,19; 23,77] 0,6160[4]	1,7 [-3,7; 7,0] 0,6160[4]
ECOG-PS (Interaction p-value: 0,8795)					
ECOG-PS 0	16/1070 (1,5)	4/1019 (0,4)	3,81 [1,28; 11,36] 0,0164[2]	3,85 [1,28; 11,56] 0,0097[3]	1,1 [0,3; 1,9] 0,0097[3]
ECOG-PS 1	4/213 (1,9)	1/245 (0,4)	4,60 [0,52; 40,85] 0,1707[2]	4,67 [0,52; 42,11] 0,1885[4]	1,5 [-0,5; 3,5] 0,1885[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 403.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Hypokalaemia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7515)					
< 65 years	10/918 (1,1)	2/936 (0,2)	5,10 [1,12; 23,20] 0,0351[2]	5,14 [1,12; 23,54] 0,0187[3]	0,9 [0,1; 1,6] 0,0187[3]
≥ 65 years	8/365 (2,2)	2/328 (0,6)	3,59 [0,77; 16,81] 0,1040[2]	3,65 [0,77; 17,33] 0,1119[4]	1,6 [-0,1; 3,3] 0,1119[4]
Prior treatment (Interaction p-value: 0,4368)					
Neoadjuvant chemotherapy	6/430 (1,4)	3/415 (0,7)	1,93 [0,49; 7,67] 0,3501[2]	1,94 [0,48; 7,82] 0,5061[4]	0,7 [-0,7; 2,0] 0,5061[4]
Adjuvant chemotherapy	10/784 (1,3)	1/768 (0,1)	9,80 [1,26; 76,34] 0,0294[2]	9,91 [1,27; 77,60] 0,0072[3]	1,1 [0,3; 2,0] 0,0072[3]
No chemotherapy	2/69 (2,9)	0/81 (0,0)	5,86 [0,29; 119,97] 0,2512[2]	6,04 [0,28; 127,91] 0,2099[4]	2,9 [-1,1; 6,9] 0,2099[4]
Region (Interaction p-value: 0,9244)					
North America / Europe	11/678 (1,6)	2/649 (0,3)	5,26 [1,17; 23,66] 0,0303[2]	5,34 [1,18; 24,16] 0,0151[3]	1,3 [0,3; 2,4] 0,0151[3]
Asia	4/203 (2,0)	1/201 (0,5)	3,96 [0,45; 35,13] 0,2165[2]	4,02 [0,45; 36,28] 0,3719[4]	1,5 [-0,7; 3,6] 0,3719[4]
Other	3/402 (0,7)	1/414 (0,2)	3,09 [0,32; 29,58] 0,3277[2]	3,11 [0,32; 29,98] 0,3669[4]	0,5 [-0,5; 1,5] 0,3669[4]
Primary tumor size (Interaction p-value: 0,8010)					
< 20 mm	5/331 (1,5)	1/334 (0,3)	5,05 [0,59; 42,95] 0,1386[2]	5,11 [0,59; 43,95] 0,1219[4]	1,2 [-0,2; 2,6] 0,1219[4]
≥ 20 but < 50 mm	6/646 (0,9)	0/653 (0,0)	13,14 [0,74; 232,78] 0,0790[2]	13,26 [0,75; 235,93] 0,0150[4]	0,9 [0,2; 1,7] 0,0150[4]
≥ 50 mm	7/289 (2,4)	3/265 (1,1)	2,14 [0,56; 8,19] 0,2667[2]	2,17 [0,55; 8,47] 0,3440[4]	1,3 [-0,9; 3,5] 0,3440[4]
Number of positive lymph nodes (Interaction p-value: 0,3954)					
0-3	2/427 (0,5)	2/418 (0,5)	0,98 [0,14; 6,92] 0,9830[2]	0,98 [0,14; 6,98] 1,0000[4]	-0,0 [-0,9; 0,9] 1,0000[4]
4-9	11/549 (2,0)	2/542 (0,4)	5,43 [1,21; 24,38] 0,0273[2]	5,52 [1,22; 25,02] 0,0128[3]	1,6 [0,4; 2,9] 0,0128[3]
≥ 10	5/307 (1,6)	0/304 (0,0)	10,89 [0,60; 196,14] 0,1054[2]	11,07 [0,61; 201,12] 0,0615[4]	1,6 [0,2; 3,0] 0,0615[4]
Tumor stage (Interaction p-value: 0,9974)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	1/113 (0,9)	0/114 (0,0)	3,03 [0,12; 73,51] 0,4963[2]	3,05 [0,12; 75,75] 0,4978[4]	0,9 [-0,8; 2,6] 0,4978[4]
IIB	0/151 (0,0)	0/136 (0,0)	NE	NE	NE
IIIA	10/495 (2,0)	1/488 (0,2)	9,86 [1,27; 76,72] 0,0288[2]	10,04 [1,28; 78,74] 0,0068[3]	1,8 [0,5; 3,1] 0,0068[3]
IIIB	0/54 (0,0)	2/45 (4,4)	0,17 [0,01; 3,40] 0,2444[2]	0,16 [0,01; 3,41] 0,2041[4]	-4,4 [-10,5; 1,6] 0,2041[4]
IIIC	7/468 (1,5)	1/479 (0,2)	7,16 [0,88; 58,01] 0,0650[2]	7,26 [0,89; 59,22] 0,0363[4]	1,3 [0,1; 2,5] 0,0363[4]
Progesterone receptor status (Interaction p-value: 0,9583)					
Negative	1/156 (0,6)	1/169 (0,6)	1,08 [0,07; 17,17] 0,9547[2]	1,08 [0,07; 17,48] 1,0000[4]	0,0 [-1,7; 1,8] 1,0000[4]
Positive	17/1089 (1,6)	3/1066 (0,3)	5,55 [1,63; 18,87] 0,0061[2]	5,62 [1,64; 19,23] 0,0020[3]	1,3 [0,5; 2,1] 0,0020[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9968)					
White	13/958 (1,4)	3/943 (0,3)	4,27 [1,22; 14,92] 0,0232[2]	4,31 [1,22; 15,18] 0,0132[3]	1,0 [0,2; 1,9] 0,0132[3]
Asian	4/250 (1,6)	1/242 (0,4)	3,87 [0,44; 34,40] 0,2244[2]	3,92 [0,43; 35,31] 0,3728[4]	1,2 [-0,6; 2,9] 0,3728[4]
Other	1/62 (1,6)	0/64 (0,0)	3,10 [0,13; 74,56] 0,4864[2]	3,15 [0,13; 78,72] 0,4921[4]	1,6 [-1,5; 4,7] 0,4921[4]
ECOG-PS (Interaction p-value: 0,8062)					
ECOG-PS 0	15/1070 (1,4)	3/1019 (0,3)	4,76 [1,38; 16,40] 0,0134[2]	4,82 [1,39; 16,68] 0,0062[3]	1,1 [0,3; 1,9] 0,0062[3]
ECOG-PS 1	3/213 (1,4)	1/245 (0,4)	3,45 [0,36; 32,93] 0,2818[2]	3,49 [0,36; 33,76] 0,3420[4]	1,0 [-0,8; 2,8] 0,3420[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 404.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Leukopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,5705)					
< 65 years	32/918 (3,5)	1/936 (0,1)	32,63 [4,47; 238,27] 0,0006[2]	33,77 [4,60; 247,66] <,0001[3]	3,4 [2,2; 4,6] <,0001[3]
≥ 65 years	16/365 (4,4)	1/328 (0,3)	14,38 [1,92; 107,82] 0,0095[2]	14,99 [1,98; 113,68] 0,0005[3]	4,1 [1,9; 6,3] 0,0005[3]
Prior treatment (Interaction p-value: 0,9718)					
Neoadjuvant chemotherapy	14/430 (3,3)	0/415 (0,0)	27,99 [1,68; 467,71] 0,0204[2]	28,93 [1,72; 486,56] 0,0002[3]	3,3 [1,6; 4,9] 0,0002[3]
Adjuvant chemotherapy	32/784 (4,1)	2/768 (0,3)	15,67 [3,77; 65,17] 0,0002[2]	16,30 [3,89; 68,25] <,0001[3]	3,8 [2,4; 5,3] <,0001[3]
No chemotherapy	2/69 (2,9)	0/81 (0,0)	5,86 [0,29; 119,97] 0,2512[2]	6,04 [0,28; 127,91] 0,2099[4]	2,9 [-1,1; 6,9] 0,2099[4]
Region (Interaction p-value: 0,9992)					
North America / Europe	20/678 (2,9)	0/649 (0,0)	39,25 [2,38; 647,60] 0,0103[2]	40,44 [2,44; 670,02] <,0001[3]	2,9 [1,7; 4,2] <,0001[3]
Asia	5/203 (2,5)	0/201 (0,0)	10,89 [0,61; 195,70] 0,1052[2]	11,17 [0,61; 203,28] 0,0610[4]	2,5 [0,3; 4,6] 0,0610[4]
Other	23/402 (5,7)	2/414 (0,5)	11,84 [2,81; 49,91] 0,0008[2]	12,50 [2,93; 53,38] <,0001[3]	5,2 [2,9; 7,6] <,0001[3]
Primary tumor size (Interaction p-value: 0,9996)					
< 20 mm	10/331 (3,0)	0/334 (0,0)	21,19 [1,25; 360,14] 0,0346[2]	21,85 [1,28; 374,40] 0,0009[4]	3,0 [1,2; 4,9] 0,0009[4]
≥ 20 but < 50 mm	26/646 (4,0)	2/653 (0,3)	13,14 [3,13; 55,14] 0,0004[2]	13,65 [3,23; 57,75] <,0001[3]	3,7 [2,1; 5,3] <,0001[3]
≥ 50 mm	11/289 (3,8)	0/265 (0,0)	21,10 [1,25; 356,25] 0,0345[2]	21,93 [1,29; 373,94] 0,0013[3]	3,8 [1,6; 6,0] 0,0013[3]
Number of positive lymph nodes (Interaction p-value: 0,9762)					
0-3	10/427 (2,3)	0/418 (0,0)	20,56 [1,21; 349,71] 0,0365[2]	21,05 [1,23; 360,39] 0,0019[4]	2,3 [0,9; 3,8] 0,0019[4]
4-9	22/549 (4,0)	1/542 (0,2)	21,72 [2,94; 160,57] 0,0026[2]	22,58 [3,03; 168,15] <,0001[3]	3,8 [2,1; 5,5] <,0001[3]
≥ 10	16/307 (5,2)	1/304 (0,3)	15,84 [2,11; 118,73] 0,0072[2]	16,66 [2,20; 126,43] 0,0002[3]	4,9 [2,3; 7,5] 0,0002[3]
Tumor stage (Interaction p-value: 1,0000)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	3/113 (2,7)	0/114 (0,0)	7,06 [0,37; 135,16] 0,1943[2]	7,25 [0,37; 142,05] 0,1217[4]	2,7 [-0,3; 5,6] 0,1217[4]
IIB	5/151 (3,3)	0/136 (0,0)	9,91 [0,55; 177,65] 0,1192[2]	10,25 [0,56; 187,10] 0,0620[4]	3,3 [0,5; 6,2] 0,0620[4]
IIIA	20/495 (4,0)	1/488 (0,2)	19,72 [2,66; 146,34] 0,0036[2]	20,51 [2,74; 153,40] <,0001[3]	3,8 [2,1; 5,6] <,0001[3]
IIIB	0/54 (0,0)	0/45 (0,0)	NE	NE	NE
IIIC	20/468 (4,3)	1/479 (0,2)	20,47 [2,76; 151,91] 0,0032[2]	21,34 [2,85; 159,66] <,0001[3]	4,1 [2,2; 5,9] <,0001[3]
Tumor grade (Interaction p-value: 0,9991)					
G1	4/91 (4,4)	0/93 (0,0)	9,20 [0,50; 168,39] 0,1348[2]	9,62 [0,51; 181,24] 0,0578[4]	4,4 [0,2; 8,6] 0,0578[4]
G2	21/612 (3,4)	2/602 (0,3)	10,33 [2,43; 43,86] 0,0016[2]	10,66 [2,49; 45,66] <,0001[3]	3,1 [1,6; 4,6] <,0001[3]
G3	20/527 (3,8)	0/506 (0,0)	39,37 [2,39; 649,20] 0,0102[2]	40,92 [2,47; 678,38] <,0001[3]	3,8 [2,2; 5,4] <,0001[3]
GX	3/51 (5,9)	0/59 (0,0)	8,08 [0,43; 152,76] 0,1637[2]	8,59 [0,43; 170,32] 0,0965[4]	5,9 [-0,6; 12,3] 0,0965[4]
Progesterone receptor status (Interaction p-value: 0,9595)					
Negative	7/156 (4,5)	0/169 (0,0)	16,24 [0,94; 282,05] 0,0556[2]	17,01 [0,96; 300,29] 0,0055[4]	4,5 [1,2; 7,7] 0,0055[4]
Positive	41/1089 (3,8)	2/1066 (0,2)	20,07 [4,87; 82,75] <,0001[2]	20,81 [5,02; 86,27] <,0001[3]	3,6 [2,4; 4,7] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9997)					
White	37/958 (3,9)	2/943 (0,2)	18,21 [4,40; 75,34] <,0001[2]	18,90 [4,54; 78,65] <,0001[3]	3,7 [2,4; 4,9] <,0001[3]
Asian	7/250 (2,8)	0/242 (0,0)	14,52 [0,83; 252,88] 0,0664[2]	14,94 [0,85; 263,00] 0,0150[4]	2,8 [0,8; 4,8] 0,0150[4]
Other	4/62 (6,5)	0/64 (0,0)	9,29 [0,51; 168,95] 0,1322[2]	9,92 [0,52; 188,28] 0,0557[4]	6,5 [0,3; 12,6] 0,0557[4]
ECOG-PS (Interaction p-value: 0,5302)					
ECOG-PS 0	36/1070 (3,4)	1/1019 (0,1)	34,28 [4,71; 249,59] 0,0005[2]	35,44 [4,85; 258,99] <,0001[3]	3,3 [2,2; 4,4] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	12/213 (5,6)	1/245 (0,4)	13,80 [1,81; 105,28] 0,0113[2]	14,57 [1,88; 112,99] 0,0008[3]	5,2 [2,0; 8,4] 0,0008[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 405.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Lymphocyte count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9118)					
< 65 years	25/918 (2,7)	3/936 (0,3)	8,50 [2,57; 28,04] 0,0004[2]	8,71 [2,62; 28,94] <,0001[3]	2,4 [1,3; 3,5] <,0001[3]
≥ 65 years	17/365 (4,7)	2/328 (0,6)	7,64 [1,78; 32,81] 0,0063[2]	7,96 [1,83; 34,73] 0,0011[3]	4,0 [1,7; 6,4] 0,0011[3]
Prior treatment (Interaction p-value: 0,8981)					
Neoadjuvant chemotherapy	18/430 (4,2)	4/415 (1,0)	4,34 [1,48; 12,72] 0,0074[2]	4,49 [1,51; 13,38] 0,0033[3]	3,2 [1,1; 5,3] 0,0033[3]
Adjuvant chemotherapy	22/784 (2,8)	0/768 (0,0)	44,08 [2,68; 725,41] 0,0081[2]	45,35 [2,75; 748,99] <,0001[3]	2,8 [1,7; 4,0] <,0001[3]
No chemotherapy	2/69 (2,9)	1/81 (1,2)	2,35 [0,22; 25,34] 0,4819[2]	2,39 [0,21; 26,92] 0,5945[4]	1,7 [-3,0; 6,3] 0,5945[4]
Region (Interaction p-value: 0,5953)					
North America / Europe	27/678 (4,0)	2/649 (0,3)	12,92 [3,09; 54,12] 0,0005[2]	13,42 [3,18; 56,65] <,0001[3]	3,7 [2,1; 5,2] <,0001[3]
Asia	9/203 (4,4)	2/201 (1,0)	4,46 [0,97; 20,37] 0,0540[2]	4,62 [0,98; 21,64] 0,0337[3]	3,4 [0,3; 6,6] 0,0337[3]
Other	6/402 (1,5)	1/414 (0,2)	6,18 [0,75; 51,10] 0,0911[2]	6,26 [0,75; 52,21] 0,0655[4]	1,3 [-0,0; 2,5] 0,0655[4]
Primary tumor size (Interaction p-value: 0,9875)					
< 20 mm	12/331 (3,6)	0/334 (0,0)	25,23 [1,50; 424,32] 0,0250[2]	26,17 [1,54; 443,91] 0,0004[3]	3,6 [1,6; 5,6] 0,0004[3]
≥ 20 but < 50 mm	15/646 (2,3)	2/653 (0,3)	7,58 [1,74; 33,02] 0,0070[2]	7,74 [1,76; 33,97] 0,0014[3]	2,0 [0,8; 3,3] 0,0014[3]
≥ 50 mm	14/289 (4,8)	2/265 (0,8)	6,42 [1,47; 27,98] 0,0133[2]	6,69 [1,51; 29,74] 0,0041[3]	4,1 [1,4; 6,8] 0,0041[3]
Number of positive lymph nodes (Interaction p-value: 0,8207)					
0-3	13/427 (3,0)	0/418 (0,0)	26,43 [1,58; 443,21] 0,0228[2]	27,26 [1,62; 460,07] 0,0003[3]	3,0 [1,4; 4,7] 0,0003[3]
4-9	13/549 (2,4)	3/542 (0,6)	4,28 [1,23; 14,93] 0,0226[2]	4,36 [1,23; 15,38] 0,0127[3]	1,8 [0,4; 3,2] 0,0127[3]
≥ 10	16/307 (5,2)	2/304 (0,7)	7,92 [1,84; 34,16] 0,0055[2]	8,30 [1,89; 36,43] 0,0009[3]	4,6 [1,9; 7,2] 0,0009[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,9172)					
IIA	4/113 (3,5)	0/114 (0,0)	9,08 [0,49; 166,70] 0,1374[2]	9,41 [0,50; 176,86] 0,0598[4]	3,5 [0,1; 6,9] 0,0598[4]
IIB	5/151 (3,3)	0/136 (0,0)	9,91 [0,55; 177,65] 0,1192[2]	10,25 [0,56; 187,10] 0,0620[4]	3,3 [0,5; 6,2] 0,0620[4]
IIIA	12/495 (2,4)	3/488 (0,6)	3,94 [1,12; 13,89] 0,0327[2]	4,02 [1,13; 14,32] 0,0207[3]	1,8 [0,3; 3,3] 0,0207[3]
IIIB	1/54 (1,9)	0/45 (0,0)	2,51 [0,10; 60,13] 0,5703[2]	2,55 [0,10; 64,17] 1,0000[4]	1,9 [-1,7; 5,4] 1,0000[4]
IIIC	20/468 (4,3)	2/479 (0,4)	10,24 [2,41; 43,54] 0,0016[2]	10,65 [2,47; 45,81] <,0001[3]	3,9 [1,9; 5,8] <,0001[3]
Tumor grade (Interaction p-value: 0,9018)					
G1	5/91 (5,5)	0/93 (0,0)	11,24 [0,63; 200,37] 0,0997[2]	11,89 [0,65; 218,22] 0,0280[4]	5,5 [0,8; 10,2] 0,0280[4]
G2	19/612 (3,1)	3/602 (0,5)	6,23 [1,85; 20,94] 0,0031[2]	6,40 [1,88; 21,73] 0,0007[3]	2,6 [1,1; 4,1] 0,0007[3]
G3	14/527 (2,7)	1/506 (0,2)	13,44 [1,77; 101,85] 0,0119[2]	13,78 [1,81; 105,19] 0,0010[3]	2,5 [1,0; 3,9] 0,0010[3]
GX	4/51 (7,8)	1/59 (1,7)	4,63 [0,53; 40,09] 0,1643[2]	4,94 [0,53; 45,67] 0,1806[4]	6,1 [-1,9; 14,2] 0,1806[4]
Race (Interaction p-value: 0,6891)					
White	31/958 (3,2)	3/943 (0,3)	10,17 [3,12; 33,16] 0,0001[2]	10,48 [3,19; 34,39] <,0001[3]	2,9 [1,7; 4,1] <,0001[3]
Asian	9/250 (3,6)	2/242 (0,8)	4,36 [0,95; 19,96] 0,0581[2]	4,48 [0,96; 20,96] 0,0375[3]	2,8 [0,2; 5,3] 0,0375[3]
Other	2/62 (3,2)	0/64 (0,0)	5,16 [0,25; 105,34] 0,2864[2]	5,33 [0,25; 113,30] 0,2401[4]	3,2 [-1,2; 7,6] 0,2401[4]
ECOG-PS (Interaction p-value: 0,9727)					
ECOG-PS 0	34/1070 (3,2)	5/1019 (0,5)	6,48 [2,54; 16,49] <,0001[2]	6,66 [2,59; 17,09] <,0001[3]	2,7 [1,6; 3,8] <,0001[3]
ECOG-PS 1	8/213 (3,8)	0/245 (0,0)	19,54 [1,13; 336,58] 0,0407[2]	20,31 [1,17; 353,98] 0,0020[4]	3,8 [1,2; 6,3] 0,0020[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 406.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Lymphopenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8343)					
< 65 years	12/918 (1,3)	1/936 (0,1)	12,24 [1,59; 93,91] 0,0160[2]	12,38 [1,61; 95,44] 0,0020[3]	1,2 [0,4; 2,0] 0,0020[3]
≥ 65 years	10/365 (2,7)	1/328 (0,3)	8,99 [1,16; 69,82] 0,0358[2]	9,21 [1,17; 72,35] 0,0105[3]	2,4 [0,7; 4,2] 0,0105[3]
Prior treatment (Interaction p-value: 0,9512)					
Neoadjuvant chemotherapy	9/430 (2,1)	0/415 (0,0)	18,34 [1,07; 314,08] 0,0447[2]	18,73 [1,09; 322,84] 0,0038[4]	2,1 [0,7; 3,4] 0,0038[4]
Adjuvant chemotherapy	13/784 (1,7)	1/768 (0,1)	12,73 [1,67; 97,11] 0,0141[2]	12,93 [1,69; 99,10] 0,0015[3]	1,5 [0,6; 2,5] 0,0015[3]
No chemotherapy	0/69 (0,0)	1/81 (1,2)	0,39 [0,02; 9,43] 0,5628[2]	0,39 [0,02; 9,63] 1,0000[4]	-1,2 [-3,6; 1,2] 1,0000[4]
Region (Interaction p-value: 0,8267)					
North America / Europe	6/678 (0,9)	1/649 (0,2)	5,74 [0,69; 47,58] 0,1051[2]	5,79 [0,69; 48,19] 0,1246[4]	0,7 [-0,0; 1,5] 0,1246[4]
Asia	2/203 (1,0)	0/201 (0,0)	4,95 [0,24; 102,48] 0,3008[2]	5,00 [0,24; 104,80] 0,4988[4]	1,0 [-0,4; 2,3] 0,4988[4]
Other	14/402 (3,5)	1/414 (0,2)	14,42 [1,90; 109,13] 0,0098[2]	14,90 [1,95; 113,86] 0,0006[3]	3,2 [1,4; 5,1] 0,0006[3]
Primary tumor size (Interaction p-value: 0,6739)					
< 20 mm	3/331 (0,9)	0/334 (0,0)	7,06 [0,37; 136,21] 0,1954[2]	7,13 [0,37; 138,53] 0,1228[4]	0,9 [-0,1; 1,9] 0,1228[4]
≥ 20 but < 50 mm	14/646 (2,2)	1/653 (0,2)	14,15 [1,87; 107,30] 0,0104[2]	14,44 [1,89; 110,16] 0,0007[3]	2,0 [0,9; 3,2] 0,0007[3]
≥ 50 mm	4/289 (1,4)	1/265 (0,4)	3,67 [0,41; 32,61] 0,2437[2]	3,71 [0,41; 33,36] 0,3751[4]	1,0 [-0,5; 2,5] 0,3751[4]
Number of positive lymph nodes (Interaction p-value: 0,9175)					
0-3	2/427 (0,5)	0/418 (0,0)	4,89 [0,24; 101,65] 0,3048[2]	4,92 [0,24; 102,74] 0,4995[4]	0,5 [-0,2; 1,1] 0,4995[4]
4-9	13/549 (2,4)	1/542 (0,2)	12,83 [1,68; 97,77] 0,0138[2]	13,12 [1,71; 100,65] 0,0014[3]	2,2 [0,9; 3,5] 0,0014[3]
≥ 10	7/307 (2,3)	1/304 (0,3)	6,93 [0,86; 56,00] 0,0693[2]	7,07 [0,86; 57,81] 0,0686[4]	2,0 [0,2; 3,7] 0,0686[4]
Tumor stage (Interaction p-value: 0,9998)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	0/113 (0,0)	0/114 (0,0)	NE	NE	NE
IIB	1/151 (0,7)	0/136 (0,0)	2,70 [0,11; 65,82] 0,5414[2]	2,72 [0,11; 67,35] 1,0000[4]	0,7 [-0,6; 2,0] 1,0000[4]
IIIA	9/495 (1,8)	1/488 (0,2)	8,87 [1,13; 69,77] 0,0380[2]	9,02 [1,14; 71,46] 0,0209[4]	1,6 [0,4; 2,9] 0,0209[4]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	10/468 (2,1)	1/479 (0,2)	10,24 [1,32; 79,64] 0,0263[2]	10,44 [1,33; 81,85] 0,0056[3]	1,9 [0,6; 3,3] 0,0056[3]
Tumor grade (Interaction p-value: 0,9999)					
G1	2/91 (2,2)	0/93 (0,0)	5,11 [0,25; 104,97] 0,2903[2]	5,22 [0,25; 110,31] 0,2432[4]	2,2 [-0,8; 5,2] 0,2432[4]
G2	13/612 (2,1)	2/602 (0,3)	6,39 [1,45; 28,21] 0,0143[2]	6,51 [1,46; 28,98] 0,0047[3]	1,8 [0,6; 3,0] 0,0047[3]
G3	6/527 (1,1)	0/506 (0,0)	12,48 [0,71; 221,01] 0,0851[2]	12,63 [0,71; 224,71] 0,0310[4]	1,1 [0,2; 2,0] 0,0310[4]
GX	1/51 (2,0)	0/59 (0,0)	3,46 [0,14; 83,15] 0,4439[2]	3,53 [0,14; 88,69] 0,4636[4]	2,0 [-1,8; 5,8] 0,4636[4]
Progesterone receptor status (Interaction p-value: 0,9631)					
Negative	1/156 (0,6)	1/169 (0,6)	1,08 [0,07; 17,17] 0,9547[2]	1,08 [0,07; 17,48] 1,0000[4]	0,0 [-1,7; 1,8] 1,0000[4]
Positive	21/1089 (1,9)	1/1066 (0,1)	20,56 [2,77; 152,55] 0,0031[2]	20,94 [2,81; 155,96] <,0001[3]	1,8 [1,0; 2,7] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,5468)					
White	17/958 (1,8)	1/943 (0,1)	16,73 [2,23; 125,49] 0,0061[2]	17,02 [2,26; 128,13] 0,0002[3]	1,7 [0,8; 2,5] 0,0002[3]
Asian	2/250 (0,8)	0/242 (0,0)	4,84 [0,23; 100,31] 0,3079[2]	4,88 [0,23; 102,16] 0,4991[4]	0,8 [-0,3; 1,9] 0,4991[4]
Other	3/62 (4,8)	1/64 (1,6)	3,10 [0,33; 28,97] 0,3218[2]	3,20 [0,32; 31,66] 0,3610[4]	3,3 [-2,9; 9,4] 0,3610[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.					

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Table 407.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Neutropenia from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,9139)					
< 65 years	105/918 (11,4)	3/936 (0,3)	35,69 [11,37; 112,03] <,0001[2]	40,17 [12,70; 127,04] <,0001[3]	11,1 [9,0; 13,2] <,0001[3]
≥ 65 years	35/365 (9,6)	1/328 (0,3)	31,45 [4,33; 228,29] 0,0007[2]	34,68 [4,72; 254,64] <,0001[3]	9,3 [6,2; 12,4] <,0001[3]
Prior treatment (Interaction p-value: 0,8359)					
Neoadjuvant chemotherapy	55/430 (12,8)	1/415 (0,2)	53,08 [7,38; 381,81] <,0001[2]	60,72 [8,36; 440,94] <,0001[3]	12,5 [9,4; 15,7] <,0001[3]
Adjuvant chemotherapy	81/784 (10,3)	3/768 (0,4)	26,45 [8,39; 83,37] <,0001[2]	29,38 [9,24; 93,43] <,0001[3]	9,9 [7,8; 12,1] <,0001[3]
No chemotherapy	4/69 (5,8)	0/81 (0,0)	10,54 [0,58; 192,43] 0,1119[2]	11,20 [0,59; 211,78] 0,0427[4]	5,8 [0,3; 11,3] 0,0427[4]
Region (Interaction p-value: 0,9784)					
North America / Europe	69/678 (10,2)	2/649 (0,3)	33,02 [8,13; 134,15] <,0001[2]	36,65 [8,95; 150,16] <,0001[3]	9,9 [7,6; 12,2] <,0001[3]
Asia	19/203 (9,4)	0/201 (0,0)	38,62 [2,35; 635,29] 0,0106[2]	42,59 [2,55; 710,46] <,0001[3]	9,4 [5,4; 13,4] <,0001[3]
Other	52/402 (12,9)	2/414 (0,5)	26,78 [6,57; 109,19] <,0001[2]	30,61 [7,40; 126,55] <,0001[3]	12,5 [9,1; 15,8] <,0001[3]
Primary tumor size (Interaction p-value: 0,9309)					
< 20 mm	40/331 (12,1)	0/334 (0,0)	81,73 [5,05; 1323,69] 0,0019[2]	92,95 [5,69; 1518,27] <,0001[3]	12,1 [8,6; 15,6] <,0001[3]
≥ 20 but < 50 mm	63/646 (9,8)	3/653 (0,5)	21,23 [6,70; 67,25] <,0001[2]	23,41 [7,31; 74,96] <,0001[3]	9,3 [6,9; 11,6] <,0001[3]
≥ 50 mm	36/289 (12,5)	1/265 (0,4)	33,01 [4,56; 239,08] 0,0005[2]	37,57 [5,11; 276,04] <,0001[3]	12,1 [8,2; 16,0] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,9108)					
0-3	50/427 (11,7)	1/418 (0,2)	48,95 [6,79; 352,69] 0,0001[2]	55,31 [7,60; 402,31] <,0001[3]	11,5 [8,4; 14,6] <,0001[3]
4-9	61/549 (11,1)	2/542 (0,4)	30,11 [7,40; 122,53] <,0001[2]	33,75 [8,21; 138,76] <,0001[3]	10,7 [8,1; 13,4] <,0001[3]
≥ 10	29/307 (9,4)	1/304 (0,3)	28,72 [3,94; 209,48] 0,0009[2]	31,61 [4,28; 233,58] <,0001[3]	9,1 [5,8; 12,5] <,0001[3]
Tumor stage (Interaction p-value: 0,5902)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIA	10/113 (8,8)	0/114 (0,0)	21,18 [1,26; 357,25] 0,0342[2]	23,23 [1,34; 401,41] 0,0008[4]	8,8 [3,6; 14,1] 0,0008[4]
IIB	21/151 (13,9)	0/136 (0,0)	38,76 [2,37; 633,73] 0,0103[2]	44,98 [2,70; 750,14] <,0001[3]	13,9 [8,4; 19,4] <,0001[3]
IIIA	57/495 (11,5)	1/488 (0,2)	56,19 [7,81; 404,21] <,0001[2]	63,38 [8,74; 459,61] <,0001[3]	11,3 [8,5; 14,2] <,0001[3]
IIIB	6/54 (11,1)	1/45 (2,2)	5,00 [0,62; 40,01] 0,1293[2]	5,50 [0,64; 47,51] 0,1226[4]	8,9 [-0,5; 18,3] 0,1226[4]
IIIC	46/468 (9,8)	2/479 (0,4)	23,54 [5,75; 96,42] <,0001[2]	26,00 [6,27; 107,74] <,0001[3]	9,4 [6,7; 12,2] <,0001[3]
Progesterone receptor status (Interaction p-value: 0,9279)					
Negative	21/156 (13,5)	0/169 (0,0)	46,56 [2,84; 762,19] 0,0071[2]	53,79 [3,23; 896,07] <,0001[3]	13,5 [8,1; 18,8] <,0001[3]
Positive	119/1089 (10,9)	4/1066 (0,4)	29,12 [10,79; 78,59] <,0001[2]	32,57 [11,98; 88,55] <,0001[3]	10,6 [8,7; 12,4] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,9997)					
White	104/958 (10,9)	4/943 (0,4)	25,59 [9,47; 69,19] <,0001[2]	28,59 [10,49; 77,94] <,0001[3]	10,4 [8,4; 12,4] <,0001[3]
Asian	25/250 (10,0)	0/242 (0,0)	49,37 [3,02; 806,51] 0,0062[2]	54,84 [3,32; 906,17] <,0001[3]	10,0 [6,3; 13,7] <,0001[3]
Other	11/62 (17,7)	0/64 (0,0)	23,73 [1,43; 394,21] 0,0272[2]	28,81 [1,66; 500,49] 0,0004[3]	17,7 [8,2; 27,3] 0,0004[3]
ECOG-PS (Interaction p-value: 0,9020)					
ECOG-PS 0	113/1070 (10,6)	3/1019 (0,3)	35,87 [11,43; 112,53] <,0001[2]	39,99 [12,66; 126,28] <,0001[3]	10,3 [8,4; 12,1] <,0001[3]
ECOG-PS 1	27/213 (12,7)	1/245 (0,4)	31,06 [4,26; 226,62] 0,0007[2]	35,42 [4,77; 263,03] <,0001[3]	12,3 [7,7; 16,8] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
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Table 408.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Neutrophil count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,3246)					
< 65 years	91/918 (9,9)	2/936 (0,2)	46,39 [11,46; 187,77] <,0001[2]	51,39 [12,62; 209,26] <,0001[3]	9,7 [7,7; 11,7] <,0001[3]
≥ 65 years	38/365 (10,4)	2/328 (0,6)	17,07 [4,15; 70,22] <,0001[2]	18,94 [4,53; 79,16] <,0001[3]	9,8 [6,6; 13,0] <,0001[3]
Prior treatment (Interaction p-value: 0,9404)					
Neoadjuvant chemotherapy	52/430 (12,1)	2/415 (0,5)	25,09 [6,15; 102,35] <,0001[2]	28,41 [6,87; 117,43] <,0001[3]	11,6 [8,5; 14,8] <,0001[3]
Adjuvant chemotherapy	73/784 (9,3)	2/768 (0,3)	35,76 [8,81; 145,17] <,0001[2]	39,32 [9,62; 160,82] <,0001[3]	9,1 [7,0; 11,1] <,0001[3]
No chemotherapy	4/69 (5,8)	0/81 (0,0)	10,54 [0,58; 192,43] 0,1119[2]	11,20 [0,59; 211,78] 0,0427[4]	5,8 [0,3; 11,3] 0,0427[4]
Region (Interaction p-value: 0,8027)					
North America / Europe	47/678 (6,9)	1/649 (0,2)	44,99 [6,23; 325,13] 0,0002[2]	48,27 [6,64; 350,89] <,0001[3]	6,8 [4,8; 8,7] <,0001[3]
Asia	63/203 (31,0)	3/201 (1,5)	20,79 [6,64; 65,12] <,0001[2]	29,70 [9,14; 96,49] <,0001[3]	29,5 [23,0; 36,1] <,0001[3]
Other	19/402 (4,7)	0/414 (0,0)	40,16 [2,43; 662,93] 0,0098[2]	42,15 [2,54; 700,54] <,0001[3]	4,7 [2,7; 6,8] <,0001[3]
Primary tumor size (Interaction p-value: 0,7147)					
< 20 mm	30/331 (9,1)	2/334 (0,6)	15,14 [3,65; 62,82] 0,0002[2]	16,54 [3,92; 69,82] <,0001[3]	8,5 [5,3; 11,7] <,0001[3]
≥ 20 but < 50 mm	69/646 (10,7)	2/653 (0,3)	34,87 [8,59; 141,65] <,0001[2]	38,92 [9,50; 159,48] <,0001[3]	10,4 [8,0; 12,8] <,0001[3]
≥ 50 mm	29/289 (10,0)	0/265 (0,0)	54,12 [3,32; 881,30] 0,0051[2]	60,13 [3,66; 989,27] <,0001[3]	10,0 [6,6; 13,5] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,6017)					
0-3	44/427 (10,3)	1/418 (0,2)	43,07 [5,96; 311,19] 0,0002[2]	47,91 [6,57; 349,39] <,0001[3]	10,1 [7,1; 13,0] <,0001[3]
4-9	51/549 (9,3)	1/542 (0,2)	50,35 [6,98; 363,04] 0,0001[2]	55,40 [7,63; 402,41] <,0001[3]	9,1 [6,7; 11,6] <,0001[3]
≥ 10	34/307 (11,1)	2/304 (0,7)	16,83 [4,08; 69,45] <,0001[2]	18,81 [4,48; 79,01] <,0001[3]	10,4 [6,8; 14,0] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 1,0000)					
IIA	12/113 (10,6)	0/114 (0,0)	25,22 [1,51; 420,91] 0,0246[2]	28,20 [1,65; 482,36] 0,0003[3]	10,6 [4,9; 16,3] 0,0003[3]
IIB	18/151 (11,9)	1/136 (0,7)	16,21 [2,19; 119,83] 0,0063[2]	18,27 [2,40; 138,82] 0,0001[3]	11,2 [5,8; 16,5] 0,0001[3]
IIIA	44/495 (8,9)	0/488 (0,0)	87,74 [5,42; 1420,78] 0,0016[2]	96,29 [5,91; 1568,18] <,0001[3]	8,9 [6,4; 11,4] <,0001[3]
IIIB	3/54 (5,6)	0/45 (0,0)	5,85 [0,31; 110,43] 0,2383[2]	6,18 [0,31; 122,97] 0,2486[4]	5,6 [-0,6; 11,7] 0,2486[4]
IIIC	51/468 (10,9)	3/479 (0,6)	17,40 [5,47; 55,36] <,0001[2]	19,41 [6,01; 62,64] <,0001[3]	10,3 [7,4; 13,2] <,0001[3]
Tumor grade (Interaction p-value: 0,9525)					
G1	6/91 (6,6)	0/93 (0,0)	13,28 [0,76; 232,41] 0,0765[2]	14,22 [0,79; 256,15] 0,0134[4]	6,6 [1,5; 11,7] 0,0134[4]
G2	57/612 (9,3)	0/602 (0,0)	113,12 [7,01; 1826,30] 0,0009[2]	124,73 [7,69; 2023,07] <,0001[3]	9,3 [7,0; 11,6] <,0001[3]
G3	58/527 (11,0)	3/506 (0,6)	18,56 [5,85; 58,86] <,0001[2]	20,73 [6,45; 66,63] <,0001[3]	10,4 [7,7; 13,2] <,0001[3]
GX	8/51 (15,7)	1/59 (1,7)	9,25 [1,20; 71,52] 0,0329[2]	10,79 [1,30; 89,53] 0,0115[4]	14,0 [3,5; 24,5] 0,0115[4]
Progesterone receptor status (Interaction p-value: 0,9965)					
Negative	20/156 (12,8)	0/169 (0,0)	44,39 [2,71; 727,88] 0,0079[2]	50,91 [3,05; 849,41] <,0001[3]	12,8 [7,6; 18,1] <,0001[3]
Positive	107/1089 (9,8)	3/1066 (0,3)	34,91 [11,12; 109,63] <,0001[2]	38,61 [12,22; 122,01] <,0001[3]	9,5 [7,7; 11,3] <,0001[3]
Unknown	2/10 (20,0)	0/7 (0,0)	3,64 [0,20; 65,86] 0,3824[2]	4,41 [0,18; 107,28] 0,4853[4]	20,0 [-4,8; 44,8] 0,4853[4]
Race (Interaction p-value: 0,6907)					
White	58/958 (6,1)	1/943 (0,1)	57,09 [7,92; 411,33] <,0001[2]	60,71 [8,39; 439,20] <,0001[3]	5,9 [4,4; 7,5] <,0001[3]
Asian	65/250 (26,0)	3/242 (1,2)	20,97 [6,68; 65,83] <,0001[2]	27,99 [8,66; 90,48] <,0001[3]	24,8 [19,1; 30,4] <,0001[3]
Other	5/62 (8,1)	0/64 (0,0)	11,35 [0,64; 201,02] 0,0976[2]	12,34 [0,67; 228,05] 0,0265[4]	8,1 [1,3; 14,8] 0,0265[4]
ECOG-PS (Interaction p-value: 0,4896)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	115/1070 (10,7)	3/1019 (0,3)	36,51 [11,64; 114,49] <,0001[2]	40,78 [12,92; 128,75] <,0001[3]	10,5 [8,6; 12,3] <,0001[3]
ECOG-PS 1	14/213 (6,6)	1/245 (0,4)	16,10 [2,14; 121,44] 0,0070[2]	17,17 [2,24; 131,67] 0,0002[3]	6,2 [2,7; 9,6] 0,0002[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 409.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT Platelet count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Progesterone receptor status (Interaction p-value: 0,9724)					
Negative	1/156 (0,6)	0/169 (0,0)	3,25 [0,13; 79,16] 0,4696[2]	3,27 [0,13; 80,87] 0,4800[4]	0,6 [-0,6; 1,9] 0,4800[4]
Positive	12/1089 (1,1)	0/1066 (0,0)	24,47 [1,45; 412,81] 0,0265[2]	24,74 [1,46; 418,46] 0,0006[3]	1,1 [0,5; 1,7] 0,0006[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 410.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according PT White blood cell count decreased from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1256)					
< 65 years	74/918 (8,1)	1/936 (0,1)	75,45 [10,51; 541,61] <,0001[2]	81,98 [11,37; 591,00] <,0001[3]	8,0 [6,2; 9,7] <,0001[3]
≥ 65 years	25/365 (6,8)	2/328 (0,6)	11,23 [2,68; 47,06] 0,0009[2]	11,99 [2,82; 51,01] <,0001[3]	6,2 [3,5; 9,0] <,0001[3]
Prior treatment (Interaction p-value: 0,9482)					
Neoadjuvant chemotherapy	41/430 (9,5)	1/415 (0,2)	39,57 [5,47; 286,34] 0,0003[2]	43,63 [5,97; 318,75] <,0001[3]	9,3 [6,5; 12,1] <,0001[3]
Adjuvant chemotherapy	54/784 (6,9)	2/768 (0,3)	26,45 [6,47; 108,10] <,0001[2]	28,33 [6,88; 116,62] <,0001[3]	6,6 [4,8; 8,4] <,0001[3]
No chemotherapy	4/69 (5,8)	0/81 (0,0)	10,54 [0,58; 192,43] 0,1119[2]	11,20 [0,59; 211,78] 0,0427[4]	5,8 [0,3; 11,3] 0,0427[4]
Region (Interaction p-value: 0,9680)					
North America / Europe	34/678 (5,0)	1/649 (0,2)	32,55 [4,47; 237,06] 0,0006[2]	34,21 [4,67; 250,67] <,0001[3]	4,9 [3,2; 6,5] <,0001[3]
Asia	48/203 (23,6)	2/201 (1,0)	23,76 [5,85; 96,46] <,0001[2]	30,81 [7,37; 128,76] <,0001[3]	22,7 [16,6; 28,7] <,0001[3]
Other	17/402 (4,2)	0/414 (0,0)	36,04 [2,17; 597,33] 0,0123[2]	37,63 [2,26; 627,93] <,0001[3]	4,2 [2,3; 6,2] <,0001[3]
Primary tumor size (Interaction p-value: 0,9636)					
< 20 mm	23/331 (6,9)	3/334 (0,9)	7,74 [2,35; 25,52] 0,0008[2]	8,24 [2,45; 27,72] <,0001[3]	6,1 [3,1; 9,0] <,0001[3]
≥ 20 but < 50 mm	48/646 (7,4)	0/653 (0,0)	98,05 [6,06; 1586,70] 0,0012[2]	105,91 [6,52; 1721,40] <,0001[3]	7,4 [5,4; 9,5] <,0001[3]
≥ 50 mm	27/289 (9,3)	0/265 (0,0)	50,45 [3,09; 822,94] 0,0059[2]	55,63 [3,38; 916,71] <,0001[3]	9,3 [6,0; 12,7] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,5299)					
0-3	29/427 (6,8)	0/418 (0,0)	57,76 [3,54; 942,22] 0,0044[2]	61,96 [3,77; 1017,47] <,0001[3]	6,8 [4,4; 9,2] <,0001[3]
4-9	47/549 (8,6)	1/542 (0,2)	46,40 [6,42; 335,11] 0,0001[2]	50,65 [6,96; 368,48] <,0001[3]	8,4 [6,0; 10,7] <,0001[3]
≥ 10	23/307 (7,5)	2/304 (0,7)	11,39 [2,71; 47,88] 0,0009[2]	12,23 [2,86; 52,34] <,0001[3]	6,8 [3,8; 9,9] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 1,0000)					
IIA	7/113 (6,2)	0/114 (0,0)	15,13 [0,87; 261,84] 0,0618[2]	16,13 [0,91; 285,81] 0,0069[4]	6,2 [1,8; 10,6] 0,0069[4]
IIB	12/151 (7,9)	0/136 (0,0)	22,53 [1,35; 376,99] 0,0302[2]	24,46 [1,43; 417,24] 0,0008[3]	7,9 [3,6; 12,3] 0,0008[3]
IIIA	42/495 (8,5)	0/488 (0,0)	83,80 [5,17; 1357,91] 0,0018[2]	91,56 [5,62; 1492,17] <,0001[3]	8,5 [6,0; 10,9] <,0001[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	35/468 (7,5)	3/479 (0,6)	11,94 [3,70; 38,56] <,0001[2]	12,83 [3,92; 42,00] <,0001[3]	6,9 [4,4; 9,3] <,0001[3]
Tumor grade (Interaction p-value: 0,6983)					
G1	8/91 (8,8)	1/93 (1,1)	8,18 [1,04; 64,06] 0,0455[2]	8,87 [1,09; 72,41] 0,0177[4]	7,7 [1,5; 13,9] 0,0177[4]
G2	46/612 (7,5)	0/602 (0,0)	91,48 [5,65; 1481,12] 0,0015[2]	98,91 [6,08; 1608,79] <,0001[3]	7,5 [5,4; 9,6] <,0001[3]
G3	38/527 (7,2)	1/506 (0,2)	36,49 [5,03; 264,74] 0,0004[2]	39,24 [5,37; 286,94] <,0001[3]	7,0 [4,8; 9,3] <,0001[3]
GX	7/51 (13,7)	1/59 (1,7)	8,10 [1,03; 63,63] 0,0467[2]	9,23 [1,09; 77,77] 0,0236[4]	12,0 [2,0; 22,0] 0,0236[4]
Progesterone receptor status (Interaction p-value: 0,9999)					
Negative	15/156 (9,6)	0/169 (0,0)	33,57 [2,03; 556,31] 0,0142[2]	37,13 [2,20; 626,11] <,0001[3]	9,6 [5,0; 14,2] <,0001[3]
Positive	83/1089 (7,6)	3/1066 (0,3)	27,08 [8,59; 85,42] <,0001[2]	29,23 [9,21; 92,80] <,0001[3]	7,3 [5,7; 8,9] <,0001[3]
Unknown	1/10 (10,0)	0/7 (0,0)	2,18 [0,10; 46,92] 0,6182[2]	2,37 [0,08; 66,88] 1,0000[4]	10,0 [-8,6; 28,6] 1,0000[4]
Race (Interaction p-value: 0,8722)					
White	46/958 (4,8)	1/943 (0,1)	45,28 [6,26; 327,66] 0,0002[2]	47,51 [6,54; 345,24] <,0001[3]	4,7 [3,3; 6,1] <,0001[3]
Asian	49/250 (19,6)	2/242 (0,8)	23,72 [5,83; 96,44] <,0001[2]	29,25 [7,03; 121,79] <,0001[3]	18,8 [13,7; 23,8] <,0001[3]
Other	3/62 (4,8)	0/64 (0,0)	7,22 [0,38; 137,01] 0,1879[2]	7,59 [0,38; 150,00] 0,1162[4]	4,8 [-0,5; 10,2] 0,1162[4]
ECOG-PS (Interaction p-value: 0,9749)					

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 0	86/1070 (8,0)	3/1019 (0,3)	27,30 [8,66; 86,04] <,0001[2]	29,60 [9,33; 93,90] <,0001[3]	7,7 [6,1; 9,4] <,0001[3]
ECOG-PS 1	13/213 (6,1)	0/245 (0,0)	31,04 [1,86; 519,00] 0,0168[2]	33,06 [1,95; 559,56] <,0001[3]	6,1 [2,9; 9,3] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: randomized, controlled study; RR: relative risk.

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Table 411.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Blood and lymphatic system disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7919)					
< 65 years	141/918 (15,4)	10/936 (1,1)	14,38 [7,62; 27,13] <,0001[2]	16,80 [8,79; 32,14] <,0001[3]	14,3 [11,9; 16,7] <,0001[3]
≥ 65 years	69/365 (18,9)	5/328 (1,5)	12,40 [5,07; 30,36] <,0001[2]	15,06 [5,99; 37,84] <,0001[3]	17,4 [13,1; 21,6] <,0001[3]
Prior treatment (Interaction p-value: 0,8821)					
Neoadjuvant chemotherapy	75/430 (17,4)	5/415 (1,2)	14,48 [5,91; 35,44] <,0001[2]	17,32 [6,93; 43,31] <,0001[3]	16,2 [12,5; 20,0] <,0001[3]
Adjuvant chemotherapy	128/784 (16,3)	9/768 (1,2)	13,93 [7,14; 27,19] <,0001[2]	16,46 [8,30; 32,61] <,0001[3]	15,2 [12,5; 17,9] <,0001[3]
No chemotherapy	7/69 (10,1)	1/81 (1,2)	8,22 [1,04; 65,16] 0,0462[2]	9,03 [1,08; 75,35] 0,0243[4]	8,9 [1,4; 16,4] 0,0243[4]
Region (Interaction p-value: 0,9879)					
North America / Europe	104/678 (15,3)	8/649 (1,2)	12,44 [6,11; 25,34] <,0001[2]	14,52 [7,01; 30,06] <,0001[3]	14,1 [11,3; 16,9] <,0001[3]
Asia	28/203 (13,8)	0/201 (0,0)	56,44 [3,47; 918,22] 0,0046[2]	65,44 [3,97; 1079,80] <,0001[3]	13,8 [9,0; 18,5] <,0001[3]
Other	78/402 (19,4)	7/414 (1,7)	11,48 [5,36; 24,56] <,0001[2]	14,00 [6,37; 30,75] <,0001[3]	17,7 [13,7; 21,8] <,0001[3]
Primary tumor size (Interaction p-value: 0,2541)					
< 20 mm	55/331 (16,6)	1/334 (0,3)	55,50 [7,73; 398,70] <,0001[2]	66,36 [9,12; 482,61] <,0001[3]	16,3 [12,3; 20,4] <,0001[3]
≥ 20 but < 50 mm	108/646 (16,7)	11/653 (1,7)	9,92 [5,39; 18,28] <,0001[2]	11,72 [6,23; 22,02] <,0001[3]	15,0 [12,0; 18,1] <,0001[3]
≥ 50 mm	45/289 (15,6)	3/265 (1,1)	13,75 [4,33; 43,73] <,0001[2]	16,11 [4,94; 52,50] <,0001[3]	14,4 [10,1; 18,8] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,6933)					
0-3	62/427 (14,5)	3/418 (0,7)	20,23 [6,40; 63,94] <,0001[2]	23,50 [7,31; 75,49] <,0001[3]	13,8 [10,4; 17,2] <,0001[3]
4-9	94/549 (17,1)	7/542 (1,3)	13,26 [6,21; 28,31] <,0001[2]	15,79 [7,25; 34,38] <,0001[3]	15,8 [12,5; 19,1] <,0001[3]
≥ 10	54/307 (17,6)	5/304 (1,6)	10,69 [4,34; 26,37] <,0001[2]	12,76 [5,03; 32,39] <,0001[3]	15,9 [11,5; 20,4] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,9920)					
IIA	13/113 (11,5)	0/114 (0,0)	27,24 [1,64; 452,75] 0,0212[2]	30,76 [1,81; 524,06] 0,0002[3]	11,5 [5,6; 17,4] 0,0002[3]
IIB	28/151 (18,5)	0/136 (0,0)	51,38 [3,17; 833,49] 0,0056[2]	63,00 [3,81; 1042,86] <,0001[3]	18,5 [12,3; 24,7] <,0001[3]
IIIA	83/495 (16,8)	7/488 (1,4)	11,69 [5,46; 25,03] <,0001[2]	13,84 [6,33; 30,27] <,0001[3]	15,3 [11,9; 18,8] <,0001[3]
IIIB	8/54 (14,8)	1/45 (2,2)	6,67 [0,87; 51,32] 0,0685[2]	7,65 [0,92; 63,72] 0,0374[4]	12,6 [2,2; 23,0] 0,0374[4]
IIIC	78/468 (16,7)	7/479 (1,5)	11,40 [5,32; 24,45] <,0001[2]	13,49 [6,15; 29,56] <,0001[3]	15,2 [11,7; 18,7] <,0001[3]
Progesterone receptor status (Interaction p-value: 0,8104)					
Negative	27/156 (17,3)	3/169 (1,8)	9,75 [3,02; 31,50] 0,0001[2]	11,58 [3,44; 39,02] <,0001[3]	15,5 [9,3; 21,8] <,0001[3]
Positive	183/1089 (16,8)	12/1066 (1,1)	14,93 [8,38; 26,61] <,0001[2]	17,74 [9,83; 32,03] <,0001[3]	15,7 [13,4; 18,0] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,5217)					
White	153/958 (16,0)	12/943 (1,3)	12,55 [7,02; 22,43] <,0001[2]	14,75 [8,13; 26,74] <,0001[3]	14,7 [12,3; 17,1] <,0001[3]
Asian	40/250 (16,0)	0/242 (0,0)	78,42 [4,85; 1268,18] 0,0021[2]	93,31 [5,70; 1526,81] <,0001[3]	16,0 [11,5; 20,5] <,0001[3]
Other	17/62 (27,4)	3/64 (4,7)	5,85 [1,80; 18,97] 0,0033[2]	7,68 [2,12; 27,80] 0,0005[3]	22,7 [10,5; 35,0] 0,0005[3]
ECOG-PS (Interaction p-value: 0,9058)					
ECOG-PS 0	164/1070 (15,3)	11/1019 (1,1)	14,20 [7,76; 25,99] <,0001[2]	16,59 [8,95; 30,74] <,0001[3]	14,2 [12,0; 16,5] <,0001[3]
ECOG-PS 1	46/213 (21,6)	4/245 (1,6)	13,23 [4,84; 36,14] <,0001[2]	16,60 [5,86; 46,98] <,0001[3]	20,0 [14,2; 25,7] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 412.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Gastrointestinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,2066)					
< 65 years	92/918 (10,0)	9/936 (1,0)	10,42 [5,29; 20,54] <,0001[2]	11,47 [5,75; 22,89] <,0001[3]	9,1 [7,0; 11,1] <,0001[3]
≥ 65 years	56/365 (15,3)	9/328 (2,7)	5,59 [2,81; 11,12] <,0001[2]	6,42 [3,12; 13,21] <,0001[3]	12,6 [8,5; 16,7] <,0001[3]
Prior treatment (Interaction p-value: 0,7016)					
Neoadjuvant chemotherapy	57/430 (13,3)	5/415 (1,2)	11,00 [4,45; 27,17] <,0001[2]	12,53 [4,97; 31,60] <,0001[3]	12,1 [8,7; 15,4] <,0001[3]
Adjuvant chemotherapy	85/784 (10,8)	12/768 (1,6)	6,94 [3,82; 12,59] <,0001[2]	7,66 [4,15; 14,14] <,0001[3]	9,3 [6,9; 11,6] <,0001[3]
No chemotherapy	6/69 (8,7)	1/81 (1,2)	7,04 [0,87; 57,09] 0,0675[2]	7,62 [0,89; 64,93] 0,0485[4]	7,5 [0,4; 14,5] 0,0485[4]
Region (Interaction p-value: 0,3028)					
North America / Europe	85/678 (12,5)	13/649 (2,0)	6,26 [3,53; 11,11] <,0001[2]	7,01 [3,87; 12,71] <,0001[3]	10,5 [7,8; 13,2] <,0001[3]
Asia	13/203 (6,4)	2/201 (1,0)	6,44 [1,47; 28,16] 0,0134[2]	6,81 [1,52; 30,57] 0,0040[3]	5,4 [1,8; 9,0] 0,0040[3]
Other	50/402 (12,4)	3/414 (0,7)	17,16 [5,40; 54,58] <,0001[2]	19,46 [6,02; 62,93] <,0001[3]	11,7 [8,4; 15,0] <,0001[3]
Primary tumor size (Interaction p-value: 0,8652)					
< 20 mm	30/331 (9,1)	4/334 (1,2)	7,57 [2,70; 21,24] 0,0001[2]	8,22 [2,86; 23,61] <,0001[3]	7,9 [4,6; 11,2] <,0001[3]
≥ 20 but < 50 mm	80/646 (12,4)	9/653 (1,4)	8,99 [4,55; 17,74] <,0001[2]	10,11 [5,03; 20,33] <,0001[3]	11,0 [8,3; 13,7] <,0001[3]
≥ 50 mm	36/289 (12,5)	5/265 (1,9)	6,60 [2,63; 16,57] <,0001[2]	7,40 [2,86; 19,16] <,0001[3]	10,6 [6,4; 14,7] <,0001[3]
Number of positive lymph nodes (Interaction p-value: 0,4922)					
0-3	63/427 (14,8)	5/418 (1,2)	12,33 [5,01; 30,36] <,0001[2]	14,30 [5,69; 35,93] <,0001[3]	13,6 [10,0; 17,1] <,0001[3]
4-9	51/549 (9,3)	8/542 (1,5)	6,29 [3,02; 13,14] <,0001[2]	6,84 [3,21; 14,55] <,0001[3]	7,8 [5,2; 10,4] <,0001[3]
≥ 10	34/307 (11,1)	5/304 (1,6)	6,73 [2,67; 16,99] <,0001[2]	7,45 [2,87; 19,32] <,0001[3]	9,4 [5,6; 13,2] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,8903)					
IIA	14/113 (12,4)	1/114 (0,9)	14,12 [1,89; 105,62] 0,0099[2]	15,98 [2,06; 123,71] 0,0005[3]	11,5 [5,2; 17,8] 0,0005[3]
IIB	22/151 (14,6)	0/136 (0,0)	40,56 [2,48; 662,27] 0,0094[2]	47,43 [2,85; 790,00] <,0001[3]	14,6 [8,9; 20,2] <,0001[3]
IIIA	42/495 (8,5)	8/488 (1,6)	5,18 [2,46; 10,91] <,0001[2]	5,56 [2,58; 11,98] <,0001[3]	6,8 [4,1; 9,5] <,0001[3]
IIIB	2/54 (3,7)	0/45 (0,0)	4,18 [0,21; 84,92] 0,3517[2]	4,33 [0,20; 92,62] 0,4991[4]	3,7 [-1,3; 8,7] 0,4991[4]
IIIC	67/468 (14,3)	9/479 (1,9)	7,62 [3,84; 15,10] <,0001[2]	8,73 [4,30; 17,72] <,0001[3]	12,4 [9,0; 15,8] <,0001[3]
Tumor grade (Interaction p-value: 0,2053)					
G1	10/91 (11,0)	3/93 (3,2)	3,41 [0,97; 11,98] 0,0561[2]	3,70 [0,98; 13,93] 0,0399[3]	7,8 [0,4; 15,1] 0,0399[3]
G2	61/612 (10,0)	9/602 (1,5)	6,67 [3,34; 13,30] <,0001[2]	7,29 [3,59; 14,83] <,0001[3]	8,5 [5,9; 11,0] <,0001[3]
G3	75/527 (14,2)	5/506 (1,0)	14,40 [5,87; 35,32] <,0001[2]	16,63 [6,66; 41,48] <,0001[3]	13,2 [10,1; 16,3] <,0001[3]
GX	2/51 (3,9)	1/59 (1,7)	2,31 [0,22; 24,78] 0,4880[2]	2,37 [0,21; 26,90] 0,5957[4]	2,2 [-4,0; 8,5] 0,5957[4]
Race (Interaction p-value: 0,9915)					
White	122/958 (12,7)	14/943 (1,5)	8,58 [4,97; 14,80] <,0001[2]	9,68 [5,53; 16,97] <,0001[3]	11,3 [9,0; 13,5] <,0001[3]
Asian	16/250 (6,4)	2/242 (0,8)	7,74 [1,80; 33,32] 0,0060[2]	8,21 [1,87; 36,08] 0,0010[3]	5,6 [2,3; 8,8] 0,0010[3]
Other	8/62 (12,9)	1/64 (1,6)	8,26 [1,06; 64,10] 0,0435[2]	9,33 [1,13; 77,01] 0,0160[4]	11,3 [2,5; 20,2] 0,0160[4]
ECOG-PS (Interaction p-value: 0,7567)					
ECOG-PS 0	123/1070 (11,5)	15/1019 (1,5)	7,81 [4,60; 13,26] <,0001[2]	8,69 [5,05; 14,97] <,0001[3]	10,0 [8,0; 12,1] <,0001[3]
ECOG-PS 1	25/213 (11,7)	3/245 (1,2)	9,59 [2,94; 31,30] 0,0002[2]	10,73 [3,19; 36,07] <,0001[3]	10,5 [6,0; 15,0] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.					

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Table 413.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC General disorders and administration site conditions from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,7481)					
< 65 years	32/918 (3,5)	4/936 (0,4)	8,16 [2,90; 22,97] <,0001[2]	8,42 [2,96; 23,89] <,0001[3]	3,1 [1,8; 4,3] <,0001[3]
≥ 65 years	21/365 (5,8)	3/328 (0,9)	6,29 [1,89; 20,90] 0,0027[2]	6,61 [1,95; 22,38] 0,0005[3]	4,8 [2,2; 7,4] 0,0005[3]
Prior treatment (Interaction p-value: 0,4960)					
Neoadjuvant chemotherapy	16/430 (3,7)	1/415 (0,2)	15,44 [2,06; 115,92] 0,0078[2]	16,00 [2,11; 121,20] 0,0003[3]	3,5 [1,6; 5,3] 0,0003[3]
Adjuvant chemotherapy	35/784 (4,5)	5/768 (0,7)	6,86 [2,70; 17,41] <,0001[2]	7,13 [2,78; 18,30] <,0001[3]	3,8 [2,3; 5,4] <,0001[3]
No chemotherapy	2/69 (2,9)	1/81 (1,2)	2,35 [0,22; 25,34] 0,4819[2]	2,39 [0,21; 26,92] 0,5945[4]	1,7 [-3,0; 6,3] 0,5945[4]
Region (Interaction p-value: 0,4836)					
North America / Europe	32/678 (4,7)	6/649 (0,9)	5,11 [2,15; 12,13] 0,0002[2]	5,31 [2,20; 12,78] <,0001[3]	3,8 [2,0; 5,6] <,0001[3]
Asia	2/203 (1,0)	0/201 (0,0)	4,95 [0,24; 102,48] 0,3008[2]	5,00 [0,24; 104,80] 0,4988[4]	1,0 [-0,4; 2,3] 0,4988[4]
Other	19/402 (4,7)	1/414 (0,2)	19,57 [2,63; 145,48] 0,0037[2]	20,49 [2,73; 153,78] <,0001[3]	4,5 [2,4; 6,6] <,0001[3]
Primary tumor size (Interaction p-value: 0,6870)					
< 20 mm	13/331 (3,9)	1/334 (0,3)	13,12 [1,73; 99,71] 0,0129[2]	13,61 [1,77; 104,67] 0,0011[3]	3,6 [1,5; 5,8] 0,0011[3]
≥ 20 but < 50 mm	28/646 (4,3)	5/653 (0,8)	5,66 [2,20; 14,57] 0,0003[2]	5,87 [2,25; 15,30] <,0001[3]	3,6 [1,9; 5,3] <,0001[3]
≥ 50 mm	12/289 (4,2)	1/265 (0,4)	11,00 [1,44; 84,05] 0,0208[2]	11,44 [1,48; 88,57] 0,0034[3]	3,8 [1,4; 6,2] 0,0034[3]
Number of positive lymph nodes (Interaction p-value: 0,6966)					
0-3	15/427 (3,5)	1/418 (0,2)	14,68 [1,95; 110,66] 0,0091[2]	15,18 [2,00; 115,46] 0,0005[3]	3,3 [1,5; 5,1] 0,0005[3]
4-9	22/549 (4,0)	3/542 (0,6)	7,24 [2,18; 24,05] 0,0012[2]	7,50 [2,23; 25,21] 0,0001[3]	3,5 [1,7; 5,2] 0,0001[3]
≥ 10	16/307 (5,2)	3/304 (1,0)	5,28 [1,55; 17,94] 0,0076[2]	5,52 [1,59; 19,13] 0,0026[3]	4,2 [1,5; 6,9] 0,0026[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,4381)					
IIA	6/113 (5,3)	0/114 (0,0)	13,11 [0,75; 230,08] 0,0783[2]	13,85 [0,77; 248,76] 0,0142[4]	5,3 [1,2; 9,4] 0,0142[4]
IIB	6/151 (4,0)	0/136 (0,0)	11,72 [0,67; 206,07] 0,0925[2]	12,20 [0,68; 218,55] 0,0309[4]	4,0 [0,9; 7,1] 0,0309[4]
IIIA	21/495 (4,2)	1/488 (0,2)	20,70 [2,80; 153,31] 0,0030[2]	21,58 [2,89; 161,04] <,0001[3]	4,0 [2,2; 5,9] <,0001[3]
IIIB	1/54 (1,9)	1/45 (2,2)	0,83 [0,05; 12,95] 0,8964[2]	0,83 [0,05; 13,66] 1,0000[4]	-0,4 [-6,0; 5,2] 1,0000[4]
IIIC	19/468 (4,1)	5/479 (1,0)	3,89 [1,46; 10,33] 0,0064[2]	4,01 [1,49; 10,83] 0,0032[3]	3,0 [1,0; 5,0] 0,0032[3]
Tumor grade (Interaction p-value: 0,9167)					
G1	3/91 (3,3)	0/93 (0,0)	7,15 [0,37; 136,54] 0,1910[2]	7,40 [0,38; 145,22] 0,1189[4]	3,3 [-0,4; 7,0] 0,1189[4]
G2	20/612 (3,3)	3/602 (0,5)	6,56 [1,96; 21,95] 0,0023[2]	6,75 [1,99; 22,82] 0,0004[3]	2,8 [1,3; 4,3] 0,0004[3]
G3	27/527 (5,1)	3/506 (0,6)	8,64 [2,64; 28,31] 0,0004[2]	9,05 [2,73; 30,04] <,0001[3]	4,5 [2,5; 6,5] <,0001[3]
GX	3/51 (5,9)	1/59 (1,7)	3,47 [0,37; 32,34] 0,2745[2]	3,63 [0,37; 35,99] 0,3349[4]	4,2 [-3,1; 11,4] 0,3349[4]
Race (Interaction p-value: 0,9844)					
White	50/958 (5,2)	7/943 (0,7)	7,03 [3,20; 15,43] <,0001[2]	7,36 [3,32; 16,32] <,0001[3]	4,5 [3,0; 6,0] <,0001[3]
Asian	2/250 (0,8)	0/242 (0,0)	4,84 [0,23; 100,31] 0,3079[2]	4,88 [0,23; 102,16] 0,4991[4]	0,8 [-0,3; 1,9] 0,4991[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
First endocrine therapy (Interaction p-value: 0,4917)					
Tamoxifen	3/114 (2,6)	1/132 (0,8)	3,47 [0,37; 32,93] 0,2779[2]	3,54 [0,36; 34,52] 0,3391[4]	1,9 [-1,4; 5,2] 0,3391[4]
Aromatase inhibitor	50/1169 (4,3)	6/1132 (0,5)	8,07 [3,47; 18,75] <,0001[2]	8,39 [3,58; 19,64] <,0001[3]	3,7 [2,5; 5,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,2392)					
ECOG-PS 0	43/1070 (4,0)	4/1019 (0,4)	10,24 [3,69; 28,42] <,0001[2]	10,62 [3,80; 29,71] <,0001[3]	3,6 [2,4; 4,9] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
ECOG-PS 1	10/213 (4,7)	3/245 (1,2)	3,83 [1,07; 13,75] 0,0392[2]	3,97 [1,08; 14,63] 0,0257[3]	3,5 [0,3; 6,6] 0,0257[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 414.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Infections and infestations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,6823)					
< 65 years	46/918 (5,0)	25/936 (2,7)	1,88 [1,16; 3,03] 0,0099[2]	1,92 [1,17; 3,16] 0,0087[3]	2,3 [0,6; 4,1] 0,0087[3]
≥ 65 years	25/365 (6,8)	10/328 (3,0)	2,25 [1,10; 4,61] 0,0271[2]	2,34 [1,11; 4,95] 0,0225[3]	3,8 [0,6; 7,0] 0,0225[3]
Prior treatment (Interaction p-value: 0,2742)					
Neoadjuvant chemotherapy	24/430 (5,6)	12/415 (2,9)	1,93 [0,98; 3,81] 0,0579[2]	1,99 [0,98; 4,02] 0,0529[3]	2,7 [-0,0; 5,4] 0,0529[3]
Adjuvant chemotherapy	44/784 (5,6)	18/768 (2,3)	2,39 [1,40; 4,11] 0,0015[2]	2,48 [1,42; 4,33] 0,0010[3]	3,3 [1,3; 5,2] 0,0010[3]
No chemotherapy	3/69 (4,3)	5/81 (6,2)	0,70 [0,17; 2,84] 0,6224[2]	0,69 [0,16; 3,00] 0,7264[4]	-1,8 [-8,9; 5,3] 0,7264[4]
Region (Interaction p-value: 0,1753)					
North America / Europe	48/678 (7,1)	24/649 (3,7)	1,91 [1,19; 3,09] 0,0078[2]	1,98 [1,20; 3,28] 0,0066[3]	3,4 [1,0; 5,8] 0,0066[3]
Asia	7/203 (3,4)	7/201 (3,5)	0,99 [0,35; 2,77] 0,9850[2]	0,99 [0,34; 2,87] 0,9850[3]	-0,0 [-3,6; 3,5] 0,9850[3]
Other	16/402 (4,0)	4/414 (1,0)	4,12 [1,39; 12,22] 0,0107[2]	4,25 [1,41; 12,82] 0,0054[3]	3,0 [0,9; 5,1] 0,0054[3]
Number of positive lymph nodes (Interaction p-value: 0,6632)					
0-3	27/427 (6,3)	15/418 (3,6)	1,76 [0,95; 3,26] 0,0718[2]	1,81 [0,95; 3,46] 0,0674[3]	2,7 [-0,2; 5,7] 0,0674[3]
4-9	22/549 (4,0)	12/542 (2,2)	1,81 [0,90; 3,62] 0,0935[2]	1,84 [0,90; 3,76] 0,0883[3]	1,8 [-0,3; 3,8] 0,0883[3]
≥ 10	22/307 (7,2)	8/304 (2,6)	2,72 [1,23; 6,02] 0,0133[2]	2,86 [1,25; 6,52] 0,0095[3]	4,5 [1,1; 7,9] 0,0095[3]
Tumor stage (Interaction p-value: 0,5516)					
IIA	6/113 (5,3)	3/114 (2,6)	2,02 [0,52; 7,87] 0,3122[2]	2,07 [0,51; 8,51] 0,3327[4]	2,7 [-2,4; 7,8] 0,3327[4]
IIB	10/151 (6,6)	9/136 (6,6)	1,00 [0,42; 2,39] 0,9987[2]	1,00 [0,39; 2,54] 0,9987[3]	0,0 [-5,8; 5,8] 0,9987[3]
IIIA	25/495 (5,1)	10/488 (2,0)	2,46 [1,20; 5,08] 0,0144[2]	2,54 [1,21; 5,35] 0,0111[3]	3,0 [0,7; 5,3] 0,0111[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	2/54 (3,7)	1/45 (2,2)	1,67 [0,16; 17,79] 0,6724[2]	1,69 [0,15; 19,30] 1,0000[4]	1,5 [-5,1; 8,1] 1,0000[4]
IIIC	28/468 (6,0)	12/479 (2,5)	2,39 [1,23; 4,64] 0,0102[2]	2,48 [1,24; 4,93] 0,0078[3]	3,5 [0,9; 6,0] 0,0078[3]
Tumor grade (Interaction p-value: 0,0891)					
G1	5/91 (5,5)	4/93 (4,3)	1,28 [0,35; 4,61] 0,7083[2]	1,29 [0,34; 4,98] 0,7457[4]	1,2 [-5,0; 7,4] 0,7457[4]
G2	35/612 (5,7)	9/602 (1,5)	3,83 [1,85; 7,89] 0,0003[2]	4,00 [1,90; 8,39] <,0001[3]	4,2 [2,1; 6,3] <,0001[3]
G3	27/527 (5,1)	21/506 (4,2)	1,23 [0,71; 2,15] 0,4586[2]	1,25 [0,70; 2,24] 0,4576[3]	1,0 [-1,6; 3,5] 0,4576[3]
GX	3/51 (5,9)	1/59 (1,7)	3,47 [0,37; 32,34] 0,2745[2]	3,63 [0,37; 35,99] 0,3349[4]	4,2 [-3,1; 11,4] 0,3349[4]
Race (Interaction p-value: 0,8038)					
White	56/958 (5,8)	28/943 (3,0)	1,97 [1,26; 3,07] 0,0028[2]	2,03 [1,28; 3,22] 0,0023[3]	2,9 [1,0; 4,7] 0,0023[3]
Asian	10/250 (4,0)	7/242 (2,9)	1,38 [0,54; 3,57] 0,5035[2]	1,40 [0,52; 3,74] 0,5013[3]	1,1 [-2,1; 4,3] 0,5013[3]
Other	5/62 (8,1)	0/64 (0,0)	11,35 [0,64; 201,02] 0,0976[2]	12,34 [0,67; 228,05] 0,0265[4]	8,1 [1,3; 14,8] 0,0265[4]
ECOG-PS (Interaction p-value: 0,7773)					
ECOG-PS 0	55/1070 (5,1)	25/1019 (2,5)	2,10 [1,32; 3,34] 0,0018[2]	2,15 [1,33; 3,48] 0,0014[3]	2,7 [1,1; 4,3] 0,0014[3]
ECOG-PS 1	16/213 (7,5)	10/245 (4,1)	1,84 [0,85; 3,97] 0,1198[2]	1,91 [0,85; 4,30] 0,1136[3]	3,4 [-0,9; 7,8] 0,1136[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 415.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Investigations from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,2217)					
< 65 years	175/918 (19,1)	19/936 (2,0)	9,39 [5,90; 14,94] <,0001[2]	11,37 [7,01; 18,43] <,0001[3]	17,0 [14,3; 19,7] <,0001[3]
≥ 65 years	71/365 (19,5)	11/328 (3,4)	5,80 [3,13; 10,75] <,0001[2]	6,96 [3,62; 13,39] <,0001[3]	16,1 [11,6; 20,6] <,0001[3]
Prior treatment (Interaction p-value: 0,3027)					
Neoadjuvant chemotherapy	102/430 (23,7)	13/415 (3,1)	7,57 [4,32; 13,27] <,0001[2]	9,62 [5,30; 17,44] <,0001[3]	20,6 [16,2; 24,9] <,0001[3]
Adjuvant chemotherapy	131/784 (16,7)	13/768 (1,7)	9,87 [5,63; 17,30] <,0001[2]	11,65 [6,53; 20,80] <,0001[3]	15,0 [12,3; 17,8] <,0001[3]
No chemotherapy	13/69 (18,8)	4/81 (4,9)	3,82 [1,30; 11,16] 0,0145[2]	4,47 [1,38; 14,43] 0,0074[3]	13,9 [3,5; 24,3] 0,0074[3]
Region (Interaction p-value: 0,3604)					
North America / Europe	110/678 (16,2)	13/649 (2,0)	8,10 [4,61; 14,25] <,0001[2]	9,47 [5,27; 17,02] <,0001[3]	14,2 [11,2; 17,2] <,0001[3]
Asia	89/203 (43,8)	8/201 (4,0)	11,02 [5,49; 22,11] <,0001[2]	18,83 [8,81; 40,26] <,0001[3]	39,9 [32,5; 47,2] <,0001[3]
Other	47/402 (11,7)	9/414 (2,2)	5,38 [2,67; 10,83] <,0001[2]	5,96 [2,88; 12,33] <,0001[3]	9,5 [6,1; 13,0] <,0001[3]
Primary tumor size (Interaction p-value: 0,8444)					
< 20 mm	51/331 (15,4)	7/334 (2,1)	7,35 [3,39; 15,96] <,0001[2]	8,51 [3,80; 19,05] <,0001[3]	13,3 [9,1; 17,5] <,0001[3]
≥ 20 but < 50 mm	134/646 (20,7)	16/653 (2,5)	8,47 [5,10; 14,05] <,0001[2]	10,42 [6,13; 17,73] <,0001[3]	18,3 [14,9; 21,6] <,0001[3]
≥ 50 mm	57/289 (19,7)	5/265 (1,9)	10,45 [4,25; 25,68] <,0001[2]	12,78 [5,04; 32,42] <,0001[3]	17,8 [13,0; 22,7] <,0001[3]
Tumor stage (Interaction p-value: 0,5619)					
IIA	18/113 (15,9)	1/114 (0,9)	18,16 [2,47; 133,75] 0,0044[2]	21,41 [2,81; 163,36] <,0001[3]	15,1 [8,1; 22,0] <,0001[3]
IIB	28/151 (18,5)	3/136 (2,2)	8,41 [2,61; 27,03] 0,0004[2]	10,09 [2,99; 34,04] <,0001[3]	16,3 [9,7; 23,0] <,0001[3]
IIIA	88/495 (17,8)	8/488 (1,6)	10,84 [5,32; 22,12] <,0001[2]	12,97 [6,22; 27,07] <,0001[3]	16,1 [12,6; 19,7] <,0001[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
IIIB	10/54 (18,5)	0/45 (0,0)	17,56 [1,06; 291,70] 0,0456[2]	21,47 [1,22; 377,56] 0,0017[4]	18,5 [8,2; 28,9] 0,0017[4]
IIIC	101/468 (21,6)	18/479 (3,8)	5,74 [3,54; 9,33] <,0001[2]	7,05 [4,19; 11,85] <,0001[3]	17,8 [13,7; 21,9] <,0001[3]
Tumor grade (Interaction p-value: 0,6117)					
G1	16/91 (17,6)	1/93 (1,1)	16,35 [2,21; 120,76] 0,0062[2]	19,63 [2,54; 151,42] 0,0001[3]	16,5 [8,4; 24,6] 0,0001[3]
G2	117/612 (19,1)	17/602 (2,8)	6,77 [4,12; 11,12] <,0001[2]	8,13 [4,82; 13,72] <,0001[3]	16,3 [12,9; 19,7] <,0001[3]
G3	98/527 (18,6)	9/506 (1,8)	10,45 [5,34; 20,47] <,0001[2]	12,61 [6,30; 25,27] <,0001[3]	16,8 [13,3; 20,3] <,0001[3]
GX	15/51 (29,4)	3/59 (5,1)	5,78 [1,77; 18,85] 0,0036[2]	7,78 [2,10; 28,78] 0,0006[3]	24,3 [10,6; 38,0] 0,0006[3]
Race (Interaction p-value: 0,7382)					
White	139/958 (14,5)	19/943 (2,0)	7,20 [4,50; 11,53] <,0001[2]	8,25 [5,06; 13,45] <,0001[3]	12,5 [10,1; 14,9] <,0001[3]
Asian	92/250 (36,8)	9/242 (3,7)	9,90 [5,11; 19,17] <,0001[2]	15,07 [7,38; 30,78] <,0001[3]	33,1 [26,6; 39,5] <,0001[3]
Other	14/62 (22,6)	2/64 (3,1)	7,23 [1,71; 30,49] 0,0071[2]	9,04 [1,96; 41,70] 0,0010[3]	19,5 [8,2; 30,7] 0,0010[3]
First endocrine therapy (Interaction p-value: 0,8445)					
Tamoxifen	12/114 (10,5)	2/132 (1,5)	6,95 [1,59; 30,39] 0,0100[2]	7,65 [1,67; 34,94] 0,0023[3]	9,0 [3,0; 15,0] 0,0023[3]
Aromatase inhibitor	234/1169 (20,0)	28/1132 (2,5)	8,09 [5,52; 11,87] <,0001[2]	9,87 [6,60; 14,74] <,0001[3]	17,5 [15,1; 20,0] <,0001[3]
ECOG-PS (Interaction p-value: 0,6450)					
ECOG-PS 0	211/1070 (19,7)	24/1019 (2,4)	8,37 [5,54; 12,66] <,0001[2]	10,18 [6,61; 15,69] <,0001[3]	17,4 [14,8; 19,9] <,0001[3]
ECOG-PS 1	35/213 (16,4)	6/245 (2,4)	6,71 [2,88; 15,64] <,0001[2]	7,83 [3,22; 19,03] <,0001[3]	14,0 [8,6; 19,3] <,0001[3]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 416.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Metabolism and nutrition disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,8935)					
< 65 years	36/918 (3,9)	15/936 (1,6)	2,45 [1,35; 4,44] 0,0032[2]	2,51 [1,36; 4,61] 0,0023[3]	2,3 [0,8; 3,8] 0,0023[3]
≥ 65 years	29/365 (7,9)	10/328 (3,0)	2,61 [1,29; 5,26] 0,0076[2]	2,74 [1,32; 5,72] 0,0052[3]	4,9 [1,6; 8,2] 0,0052[3]
Prior treatment (Interaction p-value: 0,3638)					
Neoadjuvant chemotherapy	18/430 (4,2)	10/415 (2,4)	1,74 [0,81; 3,72] 0,1550[2]	1,77 [0,81; 3,88] 0,1492[3]	1,8 [-0,6; 4,2] 0,1492[3]
Adjuvant chemotherapy	41/784 (5,2)	14/768 (1,8)	2,87 [1,58; 5,22] 0,0006[2]	2,97 [1,61; 5,50] 0,0003[3]	3,4 [1,6; 5,2] 0,0003[3]
No chemotherapy	6/69 (8,7)	1/81 (1,2)	7,04 [0,87; 57,09] 0,0675[2]	7,62 [0,89; 64,93] 0,0485[4]	7,5 [0,4; 14,5] 0,0485[4]
Region (Interaction p-value: 0,2285)					
North America / Europe	33/678 (4,9)	14/649 (2,2)	2,26 [1,22; 4,18] 0,0096[2]	2,32 [1,23; 4,38] 0,0076[3]	2,7 [0,7; 4,7] 0,0076[3]
Asia	13/203 (6,4)	1/201 (0,5)	12,87 [1,70; 97,48] 0,0134[2]	13,68 [1,77; 105,62] 0,0012[3]	5,9 [2,4; 9,4] 0,0012[3]
Other	19/402 (4,7)	10/414 (2,4)	1,96 [0,92; 4,16] 0,0807[2]	2,00 [0,92; 4,36] 0,0747[3]	2,3 [-0,2; 4,9] 0,0747[3]
Primary tumor size (Interaction p-value: 0,2806)					
< 20 mm	17/331 (5,1)	10/334 (3,0)	1,72 [0,80; 3,69] 0,1674[2]	1,75 [0,79; 3,89] 0,1617[3]	2,1 [-0,9; 5,1] 0,1617[3]
≥ 20 but < 50 mm	29/646 (4,5)	12/653 (1,8)	2,44 [1,26; 4,74] 0,0084[2]	2,51 [1,27; 4,96] 0,0063[3]	2,7 [0,8; 4,6] 0,0063[3]
≥ 50 mm	18/289 (6,2)	3/265 (1,1)	5,50 [1,64; 18,47] 0,0058[2]	5,80 [1,69; 19,93] 0,0017[3]	5,1 [2,0; 8,2] 0,0017[3]
Number of positive lymph nodes (Interaction p-value: 0,8170)					
0-3	17/427 (4,0)	8/418 (1,9)	2,08 [0,91; 4,77] 0,0835[2]	2,13 [0,91; 4,98] 0,0762[3]	2,1 [-0,2; 4,3] 0,0762[3]
4-9	30/549 (5,5)	10/542 (1,8)	2,96 [1,46; 6,00] 0,0026[2]	3,08 [1,49; 6,35] 0,0015[3]	3,6 [1,4; 5,8] 0,0015[3]
≥ 10	18/307 (5,9)	7/304 (2,3)	2,55 [1,08; 6,01] 0,0329[2]	2,64 [1,09; 6,42] 0,0263[3]	3,6 [0,4; 6,7] 0,0263[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,4388)					
IIA	4/113 (3,5)	1/114 (0,9)	4,04 [0,46; 35,55] 0,2089[2]	4,15 [0,46; 37,69] 0,2125[4]	2,7 [-1,2; 6,5] 0,2125[4]
IIB	4/151 (2,6)	3/136 (2,2)	1,20 [0,27; 5,27] 0,8083[2]	1,21 [0,27; 5,49] 1,0000[4]	0,4 [-3,1; 4,0] 1,0000[4]
IIIA	25/495 (5,1)	8/488 (1,6)	3,08 [1,40; 6,76] 0,0050[2]	3,19 [1,43; 7,15] 0,0030[3]	3,4 [1,2; 5,6] 0,0030[3]
IIIB	1/54 (1,9)	2/45 (4,4)	0,42 [0,04; 4,45] 0,4686[2]	0,41 [0,04; 4,63] 0,5894[4]	-2,6 [-9,6; 4,4] 0,5894[4]
IIIC	31/468 (6,6)	11/479 (2,3)	2,88 [1,47; 5,67] 0,0021[2]	3,02 [1,50; 6,08] 0,0012[3]	4,3 [1,7; 6,9] 0,0012[3]
Progesterone receptor status (Interaction p-value: 0,1624)					
Negative	4/156 (2,6)	4/169 (2,4)	1,08 [0,28; 4,26] 0,9087[2]	1,09 [0,27; 4,42] 1,0000[4]	0,2 [-3,2; 3,6] 1,0000[4]
Positive	61/1089 (5,6)	21/1066 (2,0)	2,84 [1,74; 4,64] <,0001[2]	2,95 [1,79; 4,88] <,0001[3]	3,6 [2,0; 5,2] <,0001[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,4109)					
White	44/958 (4,6)	20/943 (2,1)	2,17 [1,29; 3,65] 0,0036[2]	2,22 [1,30; 3,80] 0,0028[3]	2,5 [0,9; 4,1] 0,0028[3]
Asian	13/250 (5,2)	2/242 (0,8)	6,29 [1,43; 27,59] 0,0147[2]	6,58 [1,47; 29,48] 0,0048[3]	4,4 [1,4; 7,4] 0,0048[3]
Other	7/62 (11,3)	3/64 (4,7)	2,41 [0,65; 8,90] 0,1873[2]	2,59 [0,64; 10,50] 0,2021[4]	6,6 [-2,8; 16,0] 0,2021[4]
First endocrine therapy (Interaction p-value: 0,6905)					
Tamoxifen	6/114 (5,3)	2/132 (1,5)	3,47 [0,72; 16,87] 0,1226[2]	3,61 [0,71; 18,26] 0,1495[4]	3,7 [-0,9; 8,3] 0,1495[4]
Aromatase inhibitor	59/1169 (5,0)	23/1132 (2,0)	2,48 [1,55; 3,99] 0,0002[2]	2,56 [1,57; 4,18] <,0001[3]	3,0 [1,5; 4,5] <,0001[3]
ECOG-PS (Interaction p-value: 0,9291)					
ECOG-PS 0	51/1070 (4,8)	19/1019 (1,9)	2,56 [1,52; 4,30] 0,0004[2]	2,63 [1,54; 4,49] 0,0002[3]	2,9 [1,4; 4,4] 0,0002[3]
ECOG-PS 1	14/213 (6,6)	6/245 (2,4)	2,68 [1,05; 6,86] 0,0392[2]	2,80 [1,06; 7,43] 0,0312[3]	4,1 [0,3; 8,0] 0,0312[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.					

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Table 417.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Renal and urinary disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Region (Interaction p-value: 0,5905)					
North America / Europe	10/678 (1,5)	2/649 (0,3)	4,79 [1,05; 21,76] 0,0427[2]	4,84 [1,06; 22,19] 0,0248[3]	1,2 [0,2; 2,2] 0,0248[3]
Asia	2/203 (1,0)	1/201 (0,5)	1,98 [0,18; 21,67] 0,5757[2]	1,99 [0,18; 22,12] 1,0000[4]	0,5 [-1,2; 2,2] 1,0000[4]
Other	1/402 (0,2)	1/414 (0,2)	1,03 [0,06; 16,41] 0,9834[2]	1,03 [0,06; 16,52] 1,0000[4]	0,0 [-0,7; 0,7] 1,0000[4]
Primary tumor size (Interaction p-value: 0,8618)					
< 20 mm	3/331 (0,9)	1/334 (0,3)	3,03 [0,32; 28,95] 0,3363[2]	3,05 [0,32; 29,43] 0,3716[4]	0,6 [-0,6; 1,8] 0,3716[4]
≥ 20 but < 50 mm	8/646 (1,2)	2/653 (0,3)	4,04 [0,86; 18,97] 0,0765[2]	4,08 [0,86; 19,29] 0,0631[4]	0,9 [-0,0; 1,9] 0,0631[4]
≥ 50 mm	2/289 (0,7)	1/265 (0,4)	1,83 [0,17; 20,11] 0,6196[2]	1,84 [0,17; 20,41] 1,0000[4]	0,3 [-0,9; 1,5] 1,0000[4]
Progesterone receptor status (Interaction p-value: 0,9998)					
Negative	0/156 (0,0)	0/169 (0,0)	NE	NE	NE
Positive	13/1089 (1,2)	4/1066 (0,4)	3,18 [1,04; 9,73] 0,0424[2]	3,21 [1,04; 9,87] 0,0318[3]	0,8 [0,1; 1,6] 0,0318[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,8444)					
White	8/958 (0,8)	2/943 (0,2)	3,94 [0,84; 18,49] 0,0825[2]	3,96 [0,84; 18,71] 0,1086[4]	0,6 [-0,0; 1,3] 0,1086[4]
Asian	2/250 (0,8)	1/242 (0,4)	1,94 [0,18; 21,21] 0,5886[2]	1,94 [0,18; 21,57] 1,0000[4]	0,4 [-1,0; 1,8] 1,0000[4]
Other	2/62 (3,2)	1/64 (1,6)	2,06 [0,19; 22,19] 0,5497[2]	2,10 [0,19; 23,77] 0,6160[4]	1,7 [-3,7; 7,0] 0,6160[4]
ECOG-PS (Interaction p-value: 0,9718)					
ECOG-PS 0	9/1070 (0,8)	4/1019 (0,4)	2,14 [0,66; 6,94] 0,2035[2]	2,15 [0,66; 7,01] 0,1925[3]	0,4 [-0,2; 1,1] 0,1925[3]
ECOG-PS 1	4/213 (1,9)	0/245 (0,0)	10,35 [0,56; 191,06] 0,1163[2]	10,55 [0,56; 197,03] 0,0461[4]	1,9 [0,1; 3,7] 0,0461[4]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 15.07.2025 Safety Population - Postmenopausal 1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.					

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Table 418.1.2: Subgroups - adverse events with CTCAE Grade ≥3 according SOC Respiratory, thoracic and mediastinal disorders from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Age (Interaction p-value: 0,1373)					
< 65 years	13/918 (1,4)	8/936 (0,9)	1,66 [0,69; 3,98] 0,2586[2]	1,67 [0,69; 4,04] 0,2534[3]	0,6 [-0,4; 1,5] 0,2534[3]
≥ 65 years	10/365 (2,7)	1/328 (0,3)	8,99 [1,16; 69,82] 0,0358[2]	9,21 [1,17; 72,35] 0,0105[3]	2,4 [0,7; 4,2] 0,0105[3]
Prior treatment (Interaction p-value: 0,7322)					
Neoadjuvant chemotherapy	4/430 (0,9)	3/415 (0,7)	1,29 [0,29; 5,71] 0,7402[2]	1,29 [0,29; 5,80] 1,0000[4]	0,2 [-1,0; 1,4] 1,0000[4]
Adjuvant chemotherapy	16/784 (2,0)	6/768 (0,8)	2,61 [1,03; 6,64] 0,0437[2]	2,65 [1,03; 6,80] 0,0358[3]	1,3 [0,1; 2,4] 0,0358[3]
No chemotherapy	3/69 (4,3)	0/81 (0,0)	8,20 [0,43; 156,04] 0,1615[2]	8,58 [0,44; 169,04] 0,0950[4]	4,3 [-0,5; 9,2] 0,0950[4]
Region (Interaction p-value: 0,9634)					
North America / Europe	16/678 (2,4)	6/649 (0,9)	2,55 [1,01; 6,48] 0,0488[2]	2,59 [1,01; 6,66] 0,0407[3]	1,4 [0,1; 2,8] 0,0407[3]
Asia	3/203 (1,5)	1/201 (0,5)	2,97 [0,31; 28,32] 0,3440[2]	3,00 [0,31; 29,09] 0,6232[4]	1,0 [-0,9; 2,9] 0,6232[4]
Other	4/402 (1,0)	2/414 (0,5)	2,06 [0,38; 11,18] 0,4025[2]	2,07 [0,38; 11,37] 0,4450[4]	0,5 [-0,7; 1,7] 0,4450[4]
Primary tumor size (Interaction p-value: 0,5459)					
< 20 mm	3/331 (0,9)	1/334 (0,3)	3,03 [0,32; 28,95] 0,3363[2]	3,05 [0,32; 29,43] 0,3716[4]	0,6 [-0,6; 1,8] 0,3716[4]
≥ 20 but < 50 mm	18/646 (2,8)	6/653 (0,9)	3,03 [1,21; 7,59] 0,0178[2]	3,09 [1,22; 7,84] 0,0125[3]	1,9 [0,4; 3,3] 0,0125[3]
≥ 50 mm	2/289 (0,7)	2/265 (0,8)	0,92 [0,13; 6,46] 0,9307[2]	0,92 [0,13; 6,55] 1,0000[4]	-0,1 [-1,5; 1,4] 1,0000[4]
Number of positive lymph nodes (Interaction p-value: 0,9150)					
0-3	9/427 (2,1)	3/418 (0,7)	2,94 [0,80; 10,77] 0,1042[2]	2,98 [0,80; 11,08] 0,0877[3]	1,4 [-0,2; 3,0] 0,0877[3]
4-9	6/549 (1,1)	3/542 (0,6)	1,97 [0,50; 7,85] 0,3342[2]	1,99 [0,49; 7,98] 0,5061[4]	0,5 [-0,5; 1,6] 0,5061[4]
≥ 10	8/307 (2,6)	3/304 (1,0)	2,64 [0,71; 9,86] 0,1486[2]	2,68 [0,71; 10,22] 0,1324[3]	1,6 [-0,5; 3,7] 0,1324[3]

Subgroup	Abemaciclib+ET[1] Pat. with event n/N (%)	ET[1] Pat. with event n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Tumor stage (Interaction p-value: 0,9587)					
IIA	2/113 (1,8)	0/114 (0,0)	5,04 [0,24; 103,90] 0,2945[2]	5,13 [0,24; 108,15] 0,2467[4]	1,8 [-0,7; 4,2] 0,2467[4]
IIB	6/151 (4,0)	1/136 (0,7)	5,40 [0,66; 44,32] 0,1161[2]	5,59 [0,66; 47,00] 0,1240[4]	3,2 [-0,2; 6,7] 0,1240[4]
IIIA	7/495 (1,4)	3/488 (0,6)	2,30 [0,60; 8,84] 0,2254[2]	2,32 [0,60; 9,02] 0,3414[4]	0,8 [-0,5; 2,0] 0,3414[4]
IIIB	0/54 (0,0)	1/45 (2,2)	0,28 [0,01; 6,68] 0,4306[2]	0,27 [0,01; 6,85] 0,4545[4]	-2,2 [-6,5; 2,1] 0,4545[4]
IIIC	8/468 (1,7)	4/479 (0,8)	2,05 [0,62; 6,75] 0,2394[2]	2,07 [0,62; 6,91] 0,2291[3]	0,9 [-0,6; 2,3] 0,2291[3]
Progesterone receptor status (Interaction p-value: 0,2934)					
Negative	5/156 (3,2)	2/169 (1,2)	2,71 [0,53; 13,76] 0,2296[2]	2,76 [0,53; 14,46] 0,2669[4]	2,0 [-1,2; 5,2] 0,2669[4]
Positive	18/1089 (1,7)	6/1066 (0,6)	2,94 [1,17; 7,37] 0,0217[2]	2,97 [1,17; 7,51] 0,0159[3]	1,1 [0,2; 2,0] 0,0159[3]
Unknown	0/10 (0,0)	0/7 (0,0)	NE	NE	NE
Race (Interaction p-value: 0,6777)					
White	17/958 (1,8)	8/943 (0,8)	2,09 [0,91; 4,82] 0,0834[2]	2,11 [0,91; 4,92] 0,0763[3]	0,9 [-0,1; 1,9] 0,0763[3]
Asian	6/250 (2,4)	1/242 (0,4)	5,81 [0,70; 47,89] 0,1022[2]	5,93 [0,71; 49,59] 0,1227[4]	2,0 [-0,1; 4,0] 0,1227[4]
Other	0/62 (0,0)	0/64 (0,0)	NE	NE	NE
ECOG-PS (Interaction p-value: 0,1515)					
ECOG-PS 0	15/1070 (1,4)	8/1019 (0,8)	1,79 [0,76; 4,19] 0,1832[2]	1,80 [0,76; 4,26] 0,1769[3]	0,6 [-0,3; 1,5] 0,1769[3]
ECOG-PS 1	8/213 (3,8)	1/245 (0,4)	9,20 [1,16; 72,98] 0,0357[2]	9,52 [1,18; 76,76] 0,0143[4]	3,3 [0,7; 6,0] 0,0143[4]

Data cut-off: 15.07.2025
Safety Population - Postmenopausal
1: According to appropriate comparator by GBA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ECOG-PS: Eastern Cooperative Oncology Group - Performance Status; ET: endocrine therapy; mm: millimeter; n: number of patients with event; N: total number of patients in analysis; NE: not evaluated; OR: odds ratio; RCT: randomized, controlled study; RR: relative risk; SOC: system organ class.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/programs/primary/tfl/german_dossier/t_gba3c1_bp_aespt_sub_pos.sas

Output Location:
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr6/data/analysis/shared/adam,
/lillyce/qa/ly2835219/i3y_mc_jpcf/misc11/data/analysis/shared/adamgba
01NOV2025 / 10:47

Anhang 4-G3: Ergänzende Ergebnisdarstellung des Datenschnitts vom 01.07.2022

Anhang 4-G3.1: Gesundheitszustand anhand der EQ-5D VAS

Anhang 4-G3.1.1: Subgruppenanalysen nicht-interagierender Subgruppen

Tabelle 104.1.2: Subgruppen für die Veränderung der EQ-5D VAS aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,5037)																					
Neoadjuvante Chemotherapie	276 79,01 (14,60)	262 78,28 (15,87)	256 79,68 (16,07)	256 80,38 (16,00)	233 81,80 (14,05)	235 81,18 (16,30)	221 81,81 (15,83)	218 82,93 (14,81)	200 83,39 (15,42)	1,51 (0,67)	263 79,14 (15,55)	246 78,96 (14,95)	248 81,33 (14,18)	220 81,05 (15,24)	217 80,59 (16,92)	198 81,51 (15,47)	183 82,17 (13,75)	181 82,02 (14,95)	167 81,77 (15,75)	1,04 (0,70)	0,47 [-1,44;2,38] 0,6288 0,04 [-0,13;0,21]
Adjuvante Chemotherapie	396 77,73 (15,51)	385 78,74 (15,23)	377 79,69 (16,10)	367 80,05 (15,61)	356 80,36 (14,72)	347 81,63 (14,83)	328 82,88 (13,77)	331 83,73 (13,57)	304 82,86 (14,07)	2,77 (0,45)	373 78,93 (15,41)	364 79,74 (15,22)	352 81,93 (14,67)	350 82,67 (13,54)	325 82,57 (14,87)	314 82,73 (14,86)	312 84,96 (11,78)	313 84,02 (13,69)	291 83,93 (13,52)	3,50 (0,46)	-0,72 [-1,99;0,55] 0,2650 -0,08 [-0,22;0,06]
Keine Chemotherapie	7 72,14 (23,95)	7 80,71 (14,56)	6 78,33 (12,50)	6 71,67 (19,41)	6 79,17 (20,35)	6 77,50 (18,91)	6 76,67 (22,29)	5 76,00 (24,85)	4 87,50 (12,58)	7,03 (5,71)	3 60,00 (13,23)	3 65,00 (22,91)	3 81,67 (7,64)	3 70,00 (0,00)	3 80,00 (0,00)	3 68,33 (16,07)	3 76,67 (2,89)	3 86,67 (5,77)	2 70,00 (28,28)	10,86 (8,41)	-3,83 [-28,52;20,86] 0,7230 -0,23 [-1,46;0,99]
Region (p-Wert des Interaktionsterms: 0,8635)																					
Nordamerika / Europa	271 74,72 (14,90)	251 74,89 (15,75)	242 75,87 (16,71)	237 75,91 (16,40)	213 77,80 (15,23)	215 77,03 (17,33)	200 78,83 (16,67)	198 79,25 (16,21)	170 78,45 (16,96)	2,38 (0,65)	247 74,62 (17,31)	230 75,06 (17,11)	220 77,53 (16,74)	200 78,07 (16,06)	186 77,94 (17,44)	180 78,01 (18,08)	170 80,04 (14,92)	173 78,60 (16,56)	159 79,69 (17,25)	2,82 (0,69)	-0,44 [-2,31;1,43] 0,6468 -0,04 [-0,21;0,13]
Asien	231 79,49 (15,23)	229 79,16 (15,38)	226 80,97 (15,32)	224 81,64 (14,36)	216 81,77 (13,78)	213 82,00 (14,77)	212 83,64 (12,62)	207 84,22 (12,85)	207 84,31 (13,82)	2,30 (0,60)	211 80,82 (13,64)	206 80,80 (14,23)	208 83,04 (12,11)	201 83,43 (12,16)	192 83,79 (13,80)	187 83,59 (13,20)	182 85,10 (10,75)	179 85,15 (11,90)	169 84,15 (13,09)	2,86 (0,63)	-0,56 [-2,26;1,14] 0,5171 -0,06 [-0,25;0,12]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	177 81,81 (14,76)	174 83,13 (13,83)	171 83,36 (14,92)	168 83,99 (15,51)	166 83,80 (13,80)	160 86,50 (11,59)	143 85,51 (13,73)	149 87,55 (11,42)	131 87,23 (10,27)	2,54 (0,68)	181 82,60 (13,45)	177 83,25 (11,85)	175 85,29 (12,49)	172 84,86 (13,19)	167 83,71 (14,97)	148 85,47 (12,08)	146 86,84 (10,52)	145 86,65 (12,02)	132 85,83 (11,42)	2,23 (0,68)	0,31 [-1,58;2,20] 0,7475 0,03 [-0,17;0,24]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,4187)																					
< 20 mm	178 78,56 (13,73)	174 78,39 (14,50)	163 79,57 (15,04)	165 79,27 (16,59)	157 80,13 (14,61)	158 80,21 (16,12)	153 82,56 (13,94)	156 83,77 (12,85)	148 82,13 (14,77)	1,78 (0,73)	166 78,47 (16,47)	154 77,44 (15,91)	156 81,05 (15,24)	147 81,34 (14,93)	146 81,14 (16,57)	140 82,02 (15,58)	132 83,39 (12,83)	133 82,30 (15,02)	120 82,26 (15,75)	1,97 (0,76)	-0,19 [-2,26;1,89] 0,8592 -0,02 [-0,23;0,19]
≥ 20 bis < 50 mm	314 78,78 (15,45)	299 79,07 (16,09)	302 80,40 (15,68)	290 80,63 (15,22)	277 81,07 (14,71)	268 82,04 (15,05)	251 82,27 (14,53)	249 83,30 (15,13)	227 83,69 (14,39)	2,30 (0,56)	311 78,68 (15,44)	304 79,89 (15,04)	299 82,25 (13,93)	288 82,12 (14,76)	269 81,95 (16,42)	256 82,38 (15,29)	250 83,98 (13,00)	242 84,09 (13,66)	234 83,41 (14,11)	3,17 (0,56)	-0,88 [-2,43;0,68] 0,2679 -0,09 [-0,25;0,07]
≥ 50 mm	171 76,27 (16,52)	165 77,75 (15,45)	161 78,34 (17,56)	159 79,68 (16,25)	146 81,15 (14,15)	149 81,19 (15,53)	138 82,29 (15,60)	136 82,45 (14,06)	120 83,02 (15,00)	2,95 (0,79)	154 79,91 (14,36)	147 79,98 (14,66)	140 80,75 (14,72)	130 82,17 (12,28)	125 81,93 (12,99)	112 81,52 (14,49)	109 84,01 (11,26)	115 82,34 (14,30)	100 82,99 (13,71)	1,87 (0,85)	1,08 [-1,21;3,37] 0,3560 0,10 [-0,11;0,32]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,2262)																					
0-3	233 77,72 (14,53)	224 76,79 (16,05)	210 77,87 (16,18)	212 78,66 (15,88)	195 79,17 (15,32)	195 79,37 (16,95)	185 80,39 (16,15)	180 82,59 (15,59)	165 81,10 (16,55)	1,27 (0,72)	233 77,84 (15,95)	222 78,73 (15,19)	214 80,19 (15,67)	203 80,09 (14,83)	197 80,23 (16,54)	185 80,09 (15,87)	178 83,22 (12,73)	177 81,50 (15,30)	173 81,58 (15,11)	1,98 (0,72)	-0,71 [-2,71;1,28] 0,4816 -0,07 [-0,25;0,12]
4-9	310 76,76 (16,06)	300 77,77 (15,16)	298 79,10 (16,17)	292 79,41 (15,84)	279 80,19 (14,17)	278 81,03 (15,12)	259 81,39 (14,57)	259 82,50 (13,63)	238 82,23 (14,15)	2,49 (0,52)	291 79,70 (14,92)	281 79,69 (15,17)	279 82,28 (13,26)	262 82,64 (13,57)	251 83,04 (13,69)	241 82,90 (14,72)	238 83,89 (12,67)	235 83,85 (13,60)	215 83,83 (13,61)	3,19 (0,54)	-0,70 [-2,18;0,78] 0,3528 -0,08 [-0,24;0,08]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 10	136 82,26 (13,89)	130 83,53 (14,16)	131 83,88 (14,85)	125 84,20 (15,01)	121 85,38 (13,09)	115 85,78 (12,60)	111 88,05 (10,71)	115 86,42 (12,68)	105 88,23 (10,71)	3,70 (0,84)	115 79,17 (15,99)	110 79,77 (15,17)	110 83,07 (14,63)	108 83,96 (14,29)	97 81,61 (18,43)	89 84,56 (14,17)	82 85,29 (12,02)	85 85,56 (12,76)	72 84,50 (15,16)	2,23 (0,92)	1,48 [-0,97;3,93] 0,2359 0,15 [-0,10;0,40]
Tumorstadium (p-Wert des Interaktionsterms: 0,8562)																					
IIA	70 78,91 (12,87)	67 77,75 (14,35)	64 79,52 (14,74)	64 75,42 (19,06)	63 77,28 (16,07)	61 76,70 (17,70)	59 79,81 (16,70)	59 82,02 (14,86)	55 79,73 (16,26)	-0,21 (1,19)	68 77,79 (17,56)	63 78,87 (13,95)	62 80,48 (14,98)	56 78,66 (15,38)	57 79,28 (17,49)	56 79,89 (15,29)	55 83,29 (12,21)	50 80,56 (16,43)	49 81,78 (13,29)	1,97 (1,22)	-2,17 [-5,56;1,21] 0,2064 -0,22 [-0,55;0,12]
IIB	62 78,06 (12,97)	59 77,54 (15,97)	56 80,07 (12,98)	57 80,89 (12,04)	49 81,14 (13,18)	52 80,94 (13,35)	49 80,47 (12,65)	50 83,92 (14,57)	48 82,98 (13,61)	2,07 (1,43)	82 78,22 (14,57)	80 79,79 (15,58)	79 80,71 (16,00)	76 79,76 (15,74)	75 79,31 (18,32)	69 80,17 (17,24)	65 84,05 (13,03)	69 82,75 (13,74)	68 82,47 (14,04)	1,67 (1,23)	0,40 [-3,35;4,14] 0,8344 0,04 [-0,29;0,37]
IIIA	304 76,74 (16,32)	296 77,80 (15,50)	293 79,09 (16,62)	288 80,32 (15,27)	274 80,43 (14,99)	273 81,18 (15,49)	249 81,51 (15,41)	249 82,83 (14,04)	229 82,36 (15,06)	2,91 (0,56)	264 79,29 (15,11)	252 79,43 (14,80)	249 81,42 (13,77)	238 82,25 (13,62)	225 82,76 (13,12)	212 82,53 (15,11)	211 83,50 (12,51)	210 83,78 (13,68)	195 83,93 (12,69)	3,15 (0,60)	-0,25 [-1,86;1,37] 0,7643 -0,03 [-0,19;0,14]
IIIB	17 73,29 (21,06)	17 74,24 (17,13)	15 71,60 (19,27)	16 76,00 (17,20)	12 77,92 (11,37)	13 76,38 (22,56)	13 77,08 (20,41)	13 75,38 (14,06)	13 77,31 (19,30)	-1,21 (2,29)	17 86,29 (9,92)	16 84,38 (11,81)	16 83,50 (15,32)	13 83,46 (12,81)	10 87,00 (11,83)	11 85,18 (13,13)	13 83,85 (9,16)	12 80,00 (17,32)	11 81,82 (15,85)	0,05 (2,36)	-1,26 [-8,20;5,68] 0,7129 -0,13 [-0,79;0,53]
IIIC	222 80,36 (14,35)	211 80,55 (15,51)	207 81,13 (16,05)	200 81,39 (16,20)	193 82,92 (13,66)	186 83,84 (14,19)	182 85,51 (12,48)	181 85,01 (13,87)	160 85,85 (12,84)	2,61 (0,66)	207 78,56 (15,96)	201 78,86 (16,09)	196 82,60 (14,44)	189 83,44 (13,95)	178 82,06 (16,95)	167 83,13 (14,24)	154 84,55 (12,96)	156 84,05 (13,94)	137 82,77 (17,18)	2,62 (0,69)	-0,01 [-1,88;1,86] 0,9926 -0,00 [-0,19;0,19]
Tumorgrading (p-Wert des Interaktionsterms: 0,3390)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
G1	58 77,98 (17,24)	55 78,53 (15,16)	53 79,72 (14,90)	53 78,36 (17,35)	53 80,51 (13,86)	52 80,96 (16,34)	49 81,53 (14,01)	51 82,43 (14,92)	46 81,76 (16,58)	2,58 (1,30)	45 78,64 (16,15)	42 76,98 (15,74)	42 80,00 (14,65)	41 79,29 (16,95)	40 80,18 (16,28)	38 79,13 (17,79)	37 79,46 (13,87)	37 81,54 (16,26)	33 82,67 (14,60)	1,91 (1,47)	0,66 [-3,24;4,57] 0,7361 0,07 [-0,32;0,46]
G2	305 78,06 (15,73)	293 78,18 (15,46)	291 79,71 (16,41)	281 80,12 (15,49)	266 81,48 (13,73)	266 81,32 (15,12)	249 82,24 (15,24)	248 83,49 (13,53)	227 83,83 (13,17)	2,26 (0,55)	278 79,25 (16,36)	268 80,50 (15,45)	261 82,47 (15,28)	250 83,24 (13,95)	231 83,23 (14,61)	228 83,77 (14,84)	218 84,42 (13,08)	219 83,75 (15,76)	200 83,55 (15,49)	2,98 (0,58)	-0,72 [-2,30;0,85] 0,3685 -0,07 [-0,24;0,09]
G3	271 77,57 (14,36)	262 77,98 (15,93)	253 78,83 (16,18)	252 79,66 (15,84)	235 79,48 (15,46)	229 80,67 (15,58)	217 81,95 (14,60)	216 82,72 (14,85)	195 81,99 (15,27)	2,18 (0,63)	279 78,45 (14,58)	268 78,79 (14,64)	266 80,99 (13,92)	248 81,36 (14,02)	243 80,31 (16,94)	217 81,04 (14,89)	213 84,12 (11,66)	209 83,07 (12,39)	198 82,79 (13,48)	2,59 (0,62)	-0,41 [-2,14;1,32] 0,6399 -0,04 [-0,21;0,13]
GX	42 82,98 (14,27)	41 84,76 (12,14)	39 84,31 (13,85)	40 84,43 (15,67)	38 85,58 (14,00)	38 86,37 (15,77)	37 86,30 (12,70)	36 86,86 (13,52)	37 85,51 (16,69)	3,55 (1,46)	35 80,31 (15,53)	33 77,86 (16,46)	32 83,28 (11,12)	32 80,13 (14,01)	29 83,97 (11,52)	30 81,83 (14,92)	28 84,00 (12,94)	30 83,27 (10,62)	27 82,04 (14,23)	0,73 (1,60)	2,82 [-1,51;7,15] 0,1979 0,30 [-0,15;0,75]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4500)																					
Negativ	62 75,98 (15,03)	59 76,64 (16,99)	56 76,46 (17,72)	59 75,49 (19,86)	52 80,78 (14,38)	53 78,08 (16,34)	49 75,76 (17,06)	49 77,84 (16,03)	49 77,51 (17,57)	0,78 (1,55)	53 80,40 (16,51)	52 80,46 (16,58)	51 83,22 (12,92)	44 83,02 (15,12)	43 84,31 (14,51)	40 84,20 (14,33)	40 84,38 (13,72)	37 85,54 (14,36)	36 84,53 (14,44)	3,53 (1,71)	-2,76 [-7,35;1,84] 0,2367 -0,22 [-0,59;0,14]
Positiv	596 78,37 (15,32)	577 78,99 (15,06)	566 79,99 (15,62)	553 80,56 (15,39)	529 80,92 (14,51)	522 81,75 (15,38)	492 82,97 (14,44)	491 83,84 (13,91)	448 83,75 (14,14)	2,55 (0,39)	570 78,99 (15,08)	548 79,37 (14,85)	540 81,79 (14,34)	516 82,01 (13,81)	488 81,50 (15,85)	461 82,32 (14,79)	450 83,96 (12,46)	449 83,39 (13,75)	414 83,16 (14,20)	2,57 (0,40)	-0,02 [-1,12;1,08] 0,9697 -0,00 [-0,12;0,11]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Unbekannt	6 84,00 (17,44)	6 73,33 (24,43)	5 77,80 (38,94)	5 90,00 (10,00)	3 93,33 (11,55)	3 87,00 (20,81)	3 90,00 (8,66)	3 93,33 (2,89)	3 94,00 (7,81)	-1,33 (5,60)	8 67,00 (26,76)	7 65,71 (25,24)	7 67,29 (23,20)	6 74,67 (24,43)	6 81,33 (14,51)	8 65,13 (26,25)	4 78,75 (16,01)	7 73,43 (25,45)	6 77,17 (22,14)	0,24 (4,60)	-1,57 [-20,48;17,34] 0,8421 -0,11 [-1,10;0,88]
Ethnizität (p-Wert des Interaktionsterms: 0,9821)																					
Weiß	385 76,75 (15,10)	368 77,64 (15,16)	354 78,33 (16,41)	348 78,64 (16,39)	325 79,68 (14,91)	322 80,29 (15,92)	292 80,89 (16,10)	296 81,85 (15,05)	266 81,65 (14,94)	2,48 (0,54)	374 77,19 (16,59)	356 77,86 (15,90)	344 80,26 (15,98)	327 80,59 (15,30)	311 80,07 (16,87)	293 80,65 (16,59)	279 82,39 (13,80)	282 81,58 (15,47)	263 81,76 (15,54)	2,54 (0,55)	-0,07 [-1,58;1,44] 0,9301 -0,01 [-0,15;0,14]
Asiatisch	257 79,58 (15,13)	253 79,45 (15,65)	251 81,37 (15,31)	248 82,19 (13,87)	238 82,12 (13,92)	235 82,45 (14,90)	232 83,89 (12,86)	231 84,47 (13,20)	219 84,36 (14,25)	2,63 (0,56)	226 80,72 (13,40)	221 81,06 (13,92)	222 83,34 (11,89)	216 83,69 (12,05)	202 83,91 (13,50)	194 83,55 (13,14)	191 85,09 (10,62)	186 85,15 (11,87)	174 84,15 (12,93)	3,08 (0,61)	-0,45 [-2,07;1,18] 0,5900 -0,05 [-0,23;0,13]
Andere	26 85,19 (17,80)	24 87,79 (12,87)	25 83,36 (16,47)	24 81,46 (22,79)	24 86,77 (14,19)	22 88,09 (13,33)	22 88,00 (12,05)	20 90,80 (9,77)	18 89,44 (11,36)	-0,33 (1,47)	28 87,21 (13,48)	27 85,59 (14,17)	27 86,20 (12,53)	26 84,35 (15,94)	25 83,80 (14,60)	22 88,82 (7,94)	22 89,68 (9,47)	23 87,43 (12,61)	18 90,39 (9,52)	-0,33 (1,43)	0,01 [-4,11;4,13] 0,9972 0,00 [-0,53;0,53]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,8123)																					
Tamoxifen	479 77,47 (15,03)	462 77,81 (15,65)	446 78,96 (16,15)	442 79,06 (16,20)	413 79,87 (14,39)	410 80,42 (15,55)	386 81,71 (14,07)	390 82,58 (14,01)	352 82,23 (14,55)	2,20 (0,47)	470 78,52 (15,41)	447 79,16 (14,67)	438 81,17 (14,21)	417 81,35 (14,41)	396 80,94 (16,30)	378 81,19 (15,73)	362 83,44 (12,35)	368 82,49 (14,32)	340 81,96 (14,93)	2,38 (0,47)	-0,18 [-1,49;1,12] 0,7861 -0,02 [-0,14;0,11]
Aromatase-Inhibitor	200 79,92 (15,65)	192 80,42 (14,88)	193 81,34 (15,70)	187 82,58 (14,58)	182 83,28 (14,54)	178 83,67 (15,02)	169 83,93 (16,02)	164 85,14 (14,45)	156 85,07 (14,51)	2,52 (0,64)	169 80,05 (15,72)	166 79,87 (16,43)	165 83,05 (14,97)	156 83,69 (13,57)	149 83,96 (13,75)	137 84,92 (12,96)	136 85,04 (13,15)	129 85,64 (13,41)	120 86,28 (12,53)	3,28 (0,70)	-0,76 [-2,63;1,12] 0,4279 -0,08 [-0,29;0,12]
ECOG-PS (p-Wert des Interaktionsterms: 0,3183)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
ECOG-PS 0	601 78,15 (15,18)	581 78,24 (15,29)	565 79,29 (16,22)	560 79,77 (15,91)	526 80,58 (14,33)	522 81,38 (15,18)	491 82,17 (14,69)	490 83,27 (13,65)	451 83,04 (14,07)	2,04 (0,41)	566 79,43 (15,37)	543 79,63 (15,05)	533 81,80 (14,41)	509 82,21 (14,25)	486 81,89 (15,95)	459 82,66 (14,83)	445 84,21 (12,48)	438 83,50 (14,13)	410 83,51 (14,27)	2,45 (0,42)	-0,41 [-1,55;0,74] 0,4874 -0,04 [-0,16;0,07]
ECOG-PS 1	78 78,53 (15,83)	73 81,27 (16,64)	74 82,64 (14,37)	69 82,84 (14,72)	69 83,45 (15,66)	66 81,67 (17,61)	64 84,08 (14,86)	64 83,88 (17,81)	57 83,63 (18,33)	4,32 (1,12)	73 75,05 (15,97)	70 77,24 (15,92)	70 80,77 (14,63)	64 80,20 (13,89)	59 80,79 (13,45)	56 78,27 (16,95)	53 81,09 (13,22)	59 81,88 (14,30)	50 79,66 (15,58)	3,78 (1,17)	0,54 [-2,66;3,75] 0,7381 0,05 [-0,26;0,37]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3:6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung der EQ-5D VAS = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung der EQ-5D VAS haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; EQ-5D: European Quality of Life Questionnaire 5 Dimensions; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; VAS: Visuelle Analogskala.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t104_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 104.2.2: Subgruppen für die Veränderung der EQ-5D VAS aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,9963)																					
< 65 Jahre	790 78,36 (16,34)	752 77,49 (15,71)	732 78,61 (15,23)	696 79,40 (15,52)	685 79,04 (14,89)	645 78,71 (16,35)	619 80,76 (14,52)	614 80,62 (14,77)	572 80,96 (14,85)	0,24 (0,36)	823 78,96 (14,94)	782 80,09 (14,38)	783 80,93 (14,54)	738 80,23 (15,22)	701 80,81 (15,23)	666 80,60 (15,54)	621 82,28 (14,20)	617 81,52 (15,86)	571 82,15 (15,03)	1,62 (0,36)	-1,38 [-2,38;-0,38] 0,0068 -0,13 [-0,23;-0,04]
≥ 65 Jahre	300 77,63 (16,37)	282 74,88 (16,76)	266 77,79 (14,47)	268 76,68 (16,31)	243 76,24 (16,21)	236 78,25 (14,39)	216 79,76 (14,08)	211 78,81 (14,36)	195 78,39 (15,44)	-1,49 (0,59)	270 77,27 (14,83)	259 77,27 (16,65)	253 77,94 (14,98)	239 78,70 (14,28)	235 77,48 (14,98)	226 78,22 (16,51)	212 79,08 (15,11)	209 77,48 (15,21)	184 79,99 (13,86)	-0,00 (0,61)	-1,49 [-3,15;0,17] 0,0778 -0,15 [-0,31;0,02]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,6466)																					
Neoadjuvante Chemotherapie	358 78,50 (17,25)	334 77,29 (16,05)	320 79,34 (14,31)	307 79,59 (15,05)	291 78,91 (15,89)	264 79,31 (15,74)	256 80,96 (15,24)	247 80,89 (15,28)	230 80,34 (15,59)	-0,38 (0,54)	359 79,37 (14,63)	344 79,67 (15,12)	334 80,91 (14,25)	310 79,75 (15,33)	298 80,90 (14,06)	270 79,84 (15,97)	259 82,20 (13,04)	257 80,26 (15,61)	227 81,55 (14,79)	0,67 (0,54)	-1,05 [-2,55;0,45] 0,1686 -0,10 [-0,25;0,04]
Adjuvante Chemotherapie	673 78,53 (15,66)	644 76,80 (15,97)	628 78,38 (15,01)	606 79,01 (15,49)	589 78,27 (14,95)	573 78,72 (15,66)	537 80,52 (14,02)	539 79,98 (14,50)	502 80,27 (14,94)	-0,14 (0,39)	670 78,42 (15,01)	636 79,61 (14,59)	643 80,20 (14,78)	613 80,51 (14,29)	590 80,04 (15,77)	576 80,60 (15,34)	531 81,50 (14,96)	526 81,25 (15,71)	495 81,98 (14,89)	1,62 (0,39)	-1,76 [-2,85;-0,67] 0,0016 -0,17 [-0,28;-0,07]
Keine Chemotherapie	59 71,97 (17,34)	56 73,54 (16,63)	50 72,44 (18,42)	51 68,63 (19,90)	48 75,04 (15,55)	44 72,39 (17,87)	42 77,40 (13,98)	39 77,85 (13,25)	35 80,60 (12,83)	-0,23 (1,28)	64 75,14 (15,33)	61 75,51 (18,27)	59 76,14 (15,88)	54 73,12 (19,13)	48 73,40 (14,08)	46 73,33 (19,29)	43 76,56 (16,20)	43 72,65 (15,90)	33 76,76 (12,28)	-0,10 (1,23)	-0,14 [-3,66;3,38] 0,9385 -0,01 [-0,37;0,34]
Region (p-Wert des Interaktionsterms: 0,3130)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	539 76,42 (16,87)	498 74,21 (16,79)	470 75,89 (16,46)	451 76,17 (17,30)	429 76,56 (16,11)	407 76,97 (16,48)	378 79,31 (15,27)	375 79,40 (15,26)	349 78,60 (16,10)	-0,03 (0,47)	516 75,00 (15,02)	474 76,90 (15,44)	473 77,06 (15,75)	431 76,97 (16,23)	420 77,74 (15,72)	397 77,10 (17,05)	365 78,69 (16,01)	371 77,91 (16,18)	327 79,10 (15,49)	1,68 (0,48)	-1,72 [-3,05;-0,39] 0,0113 -0,16 [-0,28;-0,04]
Asien	190 81,05 (14,50)	187 77,33 (15,24)	184 79,70 (13,52)	181 79,58 (14,31)	177 79,56 (13,90)	164 79,88 (14,67)	165 80,56 (15,03)	163 79,47 (14,70)	153 81,07 (14,69)	-1,70 (0,70)	189 82,92 (12,65)	188 81,48 (13,41)	184 82,44 (13,19)	178 82,15 (12,93)	174 81,88 (13,56)	171 82,98 (12,42)	167 82,32 (13,39)	164 81,90 (15,01)	160 83,13 (13,50)	-0,09 (0,70)	-1,61 [-3,55;0,33] 0,1032 -0,17 [-0,37;0,03]
Andere	361 79,24 (16,19)	349 80,15 (14,67)	344 81,10 (13,10)	332 81,50 (13,76)	322 79,94 (14,66)	310 80,02 (15,44)	292 82,00 (12,68)	287 81,52 (13,83)	265 82,12 (13,51)	0,44 (0,49)	388 81,12 (14,75)	379 81,46 (14,81)	379 83,03 (13,22)	368 82,13 (13,86)	342 81,75 (15,10)	324 81,98 (15,29)	301 84,35 (12,42)	291 83,02 (15,25)	268 83,80 (14,18)	1,41 (0,47)	-0,96 [-2,30;0,37] 0,1557 -0,10 [-0,25;0,04]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,9340)																					
< 20 mm	275 77,40 (16,71)	257 76,75 (15,54)	244 78,61 (14,44)	244 77,77 (16,23)	234 76,99 (16,42)	224 78,20 (14,99)	221 80,62 (14,70)	215 80,19 (14,13)	203 80,17 (14,94)	-0,03 (0,61)	295 79,24 (14,33)	279 79,75 (14,34)	279 80,76 (14,08)	261 79,89 (14,82)	259 80,50 (15,04)	236 80,50 (16,10)	223 82,02 (14,67)	219 81,57 (14,50)	201 82,52 (15,71)	1,22 (0,59)	-1,26 [-2,93;0,42] 0,1404 -0,12 [-0,29;0,04]
≥ 20 bis < 50 mm	560 79,28 (15,69)	541 77,78 (15,78)	521 78,99 (14,67)	502 79,61 (15,33)	481 78,93 (14,99)	456 79,72 (15,57)	437 81,31 (13,55)	423 81,08 (14,47)	393 81,40 (13,99)	-0,31 (0,43)	564 78,99 (15,02)	541 79,92 (15,13)	534 80,58 (14,69)	506 80,06 (15,50)	483 80,32 (14,81)	476 80,06 (15,79)	434 81,77 (13,87)	441 80,66 (15,97)	412 81,54 (14,46)	0,95 (0,43)	-1,25 [-2,44;-0,07] 0,0387 -0,12 [-0,24;-0,01]
≥ 50 mm	238 76,50 (17,03)	221 74,45 (16,87)	218 76,68 (16,26)	205 77,10 (16,47)	198 78,01 (14,68)	187 76,37 (17,50)	163 78,16 (16,04)	175 77,77 (15,93)	158 77,80 (17,23)	-0,10 (0,69)	223 76,29 (15,24)	210 77,30 (15,60)	213 78,14 (15,56)	199 79,20 (14,09)	186 78,06 (16,62)	171 78,99 (15,87)	167 79,70 (15,94)	158 78,30 (17,09)	134 80,46 (14,60)	1,70 (0,71)	-1,80 [-3,73;0,13] 0,0681 -0,17 [-0,35;0,01]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,9135)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	361 76,85 (16,80)	345 75,72 (15,89)	329 77,77 (14,74)	314 78,27 (15,36)	307 77,35 (15,74)	290 77,77 (17,48)	275 79,84 (15,03)	268 79,96 (14,58)	247 80,36 (15,17)	0,36 (0,55)	354 78,22 (15,34)	337 79,39 (15,22)	337 80,42 (14,57)	316 79,98 (14,57)	305 80,38 (14,64)	283 80,42 (14,48)	269 82,42 (12,54)	259 80,26 (15,37)	238 81,22 (14,85)	2,10 (0,56)	-1,74 [-3,29;-0,20] 0,0270 -0,17 [-0,31;-0,02]
4-9	470 79,07 (16,13)	444 77,92 (15,29)	434 78,86 (15,19)	423 78,12 (16,74)	406 78,41 (15,10)	381 79,39 (14,21)	364 81,08 (13,50)	368 80,15 (14,55)	347 80,50 (14,86)	-0,59 (0,45)	480 78,58 (14,86)	458 79,45 (15,06)	458 80,34 (14,26)	431 79,70 (15,14)	416 79,71 (16,31)	406 79,86 (16,52)	376 81,28 (15,00)	377 80,68 (16,29)	352 81,60 (15,00)	0,81 (0,44)	-1,40 [-2,64;-0,16] 0,0271 -0,14 [-0,27;-0,02]
≥ 10	259 78,35 (16,03)	245 76,20 (17,42)	235 78,38 (15,17)	227 80,14 (14,44)	215 79,47 (14,95)	210 78,25 (16,29)	196 80,35 (15,15)	189 80,43 (15,15)	173 79,84 (15,27)	-0,31 (0,67)	259 78,90 (14,50)	246 79,29 (14,73)	241 79,63 (15,72)	230 79,98 (15,40)	215 79,92 (13,88)	203 79,68 (16,23)	188 80,46 (15,97)	190 80,47 (15,40)	165 82,24 (14,24)	0,75 (0,67)	-1,06 [-2,92;0,79] 0,2612 -0,10 [-0,27;0,07]
Tumorstadium (p-Wert des Interaktionsterms: 0,8190)																					
IIA	91 78,27 (16,33)	86 77,93 (13,53)	82 79,76 (12,71)	83 80,09 (12,86)	79 78,03 (15,11)	77 79,79 (13,23)	75 79,99 (15,56)	67 81,04 (13,83)	63 80,46 (14,40)	1,26 (1,02)	95 77,73 (16,58)	92 79,74 (14,06)	89 78,90 (14,11)	86 79,15 (15,11)	81 80,53 (13,46)	79 81,29 (13,87)	77 82,75 (11,96)	71 80,15 (15,29)	63 80,33 (18,35)	1,75 (1,00)	-0,49 [-3,30;2,33] 0,7327 -0,05 [-0,34;0,24]
IIB	129 79,88 (14,63)	124 77,75 (14,74)	118 79,93 (13,12)	114 80,18 (14,85)	114 78,67 (15,41)	105 79,50 (17,67)	96 82,56 (12,44)	99 82,04 (13,11)	89 83,73 (12,35)	-0,81 (0,95)	110 80,83 (13,26)	103 80,84 (16,15)	102 83,21 (14,19)	97 80,52 (14,70)	90 80,91 (14,75)	92 80,60 (13,68)	84 82,02 (13,23)	84 80,13 (16,27)	79 81,47 (14,36)	-0,14 (1,02)	-0,67 [-3,42;2,08] 0,6301 -0,06 [-0,32;0,19]
IIIA	427 77,90 (16,67)	405 76,06 (16,22)	392 78,44 (15,20)	384 77,57 (16,50)	363 77,65 (15,52)	343 78,24 (15,23)	323 79,76 (14,13)	335 79,39 (14,86)	310 79,99 (15,10)	-0,55 (0,47)	428 77,86 (15,38)	405 79,06 (15,30)	412 79,95 (14,34)	386 80,15 (14,17)	372 79,73 (16,49)	362 80,29 (15,48)	333 81,47 (14,78)	334 80,69 (15,59)	311 81,56 (14,72)	1,70 (0,46)	-2,25 [-3,55;-0,95] 0,0007 -0,23 [-0,37;-0,10]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIIB	45 76,64 (18,52)	43 79,09 (16,14)	42 77,21 (16,25)	41 77,29 (19,07)	40 78,68 (16,34)	35 79,14 (18,98)	36 81,36 (14,42)	29 82,21 (14,47)	33 78,27 (17,86)	0,63 (1,58)	41 79,07 (14,98)	39 81,41 (15,85)	39 81,00 (14,90)	36 80,61 (15,50)	35 78,57 (16,61)	32 76,09 (24,35)	32 81,53 (16,68)	29 76,66 (22,19)	28 82,25 (12,76)	0,75 (1,65)	-0,12 [-4,68;4,44] 0,9576 -0,01 [-0,43;0,41]
IIIC	396 78,13 (16,28)	375 76,67 (16,77)	363 77,63 (15,77)	340 79,14 (15,51)	330 78,91 (14,98)	319 78,28 (16,17)	303 80,60 (15,00)	294 79,94 (15,20)	270 79,67 (15,49)	-0,23 (0,54)	417 78,72 (14,46)	400 79,03 (14,60)	392 79,84 (15,29)	370 79,41 (15,91)	356 79,94 (14,28)	325 79,51 (16,19)	306 80,93 (14,90)	306 80,77 (15,35)	272 81,92 (14,35)	0,88 (0,53)	-1,11 [-2,60;0,37] 0,1423 -0,10 [-0,24;0,03]
Tumorgrading (p-Wert des Interaktionsterms: 0,7295)																					
G1	83 78,65 (17,14)	78 76,45 (15,80)	81 76,94 (18,37)	73 79,05 (17,68)	72 77,22 (14,88)	73 76,38 (16,57)	67 81,22 (13,22)	68 79,65 (14,09)	61 82,44 (12,64)	-0,30 (1,14)	83 79,73 (16,52)	82 80,04 (16,20)	80 82,24 (13,23)	75 80,89 (15,03)	74 78,01 (19,32)	72 81,94 (15,37)	64 82,70 (15,16)	66 82,91 (14,73)	58 83,19 (14,65)	1,45 (1,14)	-1,75 [-4,93;1,43] 0,2791 -0,17 [-0,47;0,14]
G2	517 77,44 (16,43)	493 76,09 (16,42)	473 77,67 (14,81)	453 78,11 (15,89)	433 78,61 (15,05)	410 78,33 (16,01)	381 80,70 (14,09)	393 79,58 (15,06)	364 79,20 (15,82)	-0,07 (0,44)	521 77,96 (14,80)	490 78,83 (14,84)	495 79,83 (14,00)	471 79,53 (14,70)	444 79,08 (15,25)	426 79,60 (15,45)	401 80,17 (14,78)	398 79,94 (15,66)	367 80,93 (14,32)	1,15 (0,44)	-1,22 [-2,43;-0,00] 0,0493 -0,12 [-0,24;-0,00]
G3	442 78,71 (16,01)	418 77,50 (15,44)	399 79,50 (14,17)	393 79,15 (14,95)	380 78,40 (15,45)	358 79,22 (15,67)	349 80,28 (14,84)	324 80,76 (14,62)	309 80,94 (14,53)	-0,03 (0,50)	431 78,33 (14,80)	411 79,43 (15,21)	405 79,49 (15,84)	378 79,37 (15,59)	367 80,80 (14,41)	347 79,94 (15,99)	325 82,42 (13,95)	318 80,07 (16,30)	293 81,51 (15,42)	1,27 (0,51)	-1,30 [-2,70;0,11] 0,0702 -0,12 [-0,26;0,01]
GX	46 80,33 (16,85)	43 78,86 (16,98)	43 79,21 (17,68)	43 79,31 (19,00)	41 77,78 (15,58)	38 80,47 (13,96)	36 79,78 (15,40)	38 82,34 (12,32)	32 82,75 (14,64)	-2,76 (1,59)	54 84,26 (13,75)	54 82,44 (13,50)	52 86,75 (11,58)	49 85,22 (12,17)	48 84,01 (13,21)	44 80,61 (18,98)	41 84,05 (14,30)	41 84,68 (14,45)	34 86,76 (13,97)	0,15 (1,46)	-2,90 [-7,21;1,40] 0,1835 -0,27 [-0,67;0,13]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4545)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Negativ	134 75,11 (16,26)	130 73,65 (16,87)	121 76,74 (16,15)	120 76,82 (16,62)	114 77,82 (14,86)	99 76,67 (16,82)	94 78,68 (13,71)	97 78,33 (14,15)	87 76,87 (16,03)	-0,11 (0,86)	144 79,37 (15,36)	140 78,10 (16,87)	134 81,09 (15,12)	127 79,62 (17,06)	119 81,08 (16,06)	111 80,75 (14,31)	100 79,83 (16,15)	98 81,01 (14,08)	88 83,39 (12,11)	1,34 (0,83)	-1,45 [-3,80;0,90] 0,2260 -0,15 [-0,38;0,09]
Positiv	925 78,55 (16,33)	875 77,22 (15,85)	847 78,48 (14,90)	819 78,75 (15,72)	791 78,29 (15,43)	757 78,69 (15,59)	718 80,58 (14,50)	705 80,31 (14,81)	659 80,73 (14,85)	-0,29 (0,34)	924 78,31 (14,87)	880 79,45 (14,71)	880 80,03 (14,55)	828 79,76 (14,69)	796 79,66 (15,07)	761 79,66 (16,05)	717 81,56 (14,24)	708 80,29 (15,98)	649 81,22 (15,06)	1,16 (0,34)	-1,45 [-2,38;-0,51] 0,0025 -0,14 [-0,23;-0,05]
Unbekannt	9 74,44 (12,61)	9 70,22 (19,08)	9 79,56 (7,13)	7 83,14 (13,38)	5 88,00 (10,93)	7 81,14 (26,22)	8 83,38 (17,56)	7 85,14 (10,81)	5 85,20 (17,11)	0,15 (3,10)	7 89,71 (12,05)	6 92,83 (7,52)	6 92,33 (8,45)	6 93,67 (6,22)	6 95,17 (3,60)	6 96,83 (3,82)	5 98,40 (2,07)	6 96,00 (5,69)	5 95,20 (4,87)	11,15 (3,55)	-11,00 [-21,58;-0,43] 0,0423 -1,11 [-2,12;-0,10]
Ethnizität (p-Wert des Interaktionsterms: 0,9744)																					
Weiß	796 76,82 (16,64)	747 75,95 (16,21)	726 77,46 (15,35)	698 77,64 (16,27)	667 77,03 (15,64)	636 77,44 (16,15)	590 79,76 (14,19)	586 79,67 (14,45)	551 79,44 (15,19)	-0,03 (0,37)	804 77,32 (15,18)	759 78,53 (15,09)	756 79,14 (14,75)	705 78,53 (15,55)	679 78,86 (15,74)	645 78,80 (16,61)	592 80,51 (14,86)	594 79,64 (15,94)	528 80,57 (15,23)	1,33 (0,37)	-1,35 [-2,38;-0,33] 0,0097 -0,13 [-0,23;-0,03]
Asiatisch	228 80,98 (14,01)	223 77,78 (14,85)	216 80,39 (13,19)	213 80,22 (14,23)	209 80,34 (13,65)	193 80,60 (14,68)	193 81,43 (14,92)	192 80,38 (14,34)	174 81,76 (14,40)	-0,82 (0,64)	218 82,12 (13,06)	215 81,49 (13,31)	212 82,76 (13,02)	207 82,34 (12,69)	197 82,27 (13,37)	190 83,09 (12,28)	186 83,08 (12,63)	180 82,51 (14,46)	178 83,51 (13,04)	0,86 (0,65)	-1,68 [-3,48;0,12] 0,0668 -0,17 [-0,36;0,01]
Andere	55 86,55 (14,26)	53 85,65 (11,77)	47 84,30 (14,31)	45 86,33 (9,58)	43 87,12 (13,68)	42 86,81 (12,09)	45 86,38 (11,69)	39 85,82 (17,11)	34 87,79 (10,73)	-0,68 (1,23)	58 84,34 (14,12)	55 85,13 (16,53)	56 87,17 (14,88)	53 89,17 (11,45)	50 85,97 (13,40)	46 86,20 (13,01)	45 90,80 (10,31)	41 86,07 (17,84)	40 89,08 (14,18)	0,67 (1,19)	-1,35 [-4,75;2,05] 0,4329 -0,15 [-0,52;0,22]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,8821)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Tamoxifen	103 79,85 (15,96)	99 79,13 (15,42)	96 80,34 (13,83)	97 81,31 (13,31)	93 79,70 (14,80)	92 81,07 (14,82)	89 83,18 (13,31)	87 83,21 (14,61)	89 83,13 (13,84)	0,92 (0,97)	122 79,78 (13,93)	120 81,42 (13,84)	120 82,48 (13,70)	113 82,73 (12,73)	104 81,76 (15,86)	94 83,67 (14,08)	90 84,43 (12,40)	88 84,15 (15,48)	87 85,98 (13,78)	2,58 (0,90)	-1,67 [-4,27;0,94] 0,2086 -0,17 [-0,43;0,09]
Aromatase-Inhibitor	987 77,98 (16,38)	935 76,53 (16,08)	902 78,18 (15,14)	867 78,35 (16,01)	835 78,15 (15,34)	789 78,29 (15,95)	746 80,18 (14,50)	738 79,79 (14,66)	678 79,94 (15,16)	-0,33 (0,33)	971 78,39 (15,04)	921 79,13 (15,15)	916 79,90 (14,81)	864 79,48 (15,24)	832 79,75 (15,15)	798 79,57 (15,96)	743 81,10 (14,69)	738 80,06 (15,78)	668 81,05 (14,82)	1,02 (0,33)	-1,35 [-2,25;-0,44] 0,0037 -0,13 [-0,22;-0,04]
ECOG-PS (p-Wert des Interaktionsterms: 0,8583)																					
ECOG-PS 0	921 78,96 (15,77)	872 76,95 (16,03)	845 78,62 (15,10)	823 78,92 (15,59)	791 78,69 (15,13)	758 78,81 (15,65)	712 80,86 (14,29)	709 80,47 (14,57)	663 80,63 (14,92)	-0,58 (0,33)	881 79,25 (14,75)	838 79,85 (14,49)	837 80,39 (14,64)	790 80,12 (14,89)	761 80,12 (15,34)	727 80,22 (15,78)	672 81,59 (14,22)	670 80,83 (15,52)	607 81,92 (14,56)	0,77 (0,34)	-1,35 [-2,28;-0,43] 0,0042 -0,14 [-0,23;-0,04]
ECOG-PS 1	169 73,80 (18,64)	162 75,83 (16,06)	153 77,12 (14,65)	141 77,01 (16,80)	137 76,06 (16,04)	123 77,21 (16,98)	123 78,39 (14,92)	116 78,22 (15,25)	104 78,25 (15,67)	1,53 (0,89)	212 75,60 (15,30)	203 77,49 (16,95)	199 79,37 (14,96)	187 78,73 (15,49)	175 79,33 (14,76)	165 79,00 (16,01)	161 80,93 (15,59)	156 79,06 (16,87)	148 80,38 (15,62)	3,30 (0,78)	-1,78 [-4,11;0,55] 0,1346 -0,16 [-0,36;0,05]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3:6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung der EQ-5D VAS = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung der EQ-5D VAS haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; EQ-5D: European Quality of Life Questionnaire 5 Dimensions; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; VAS: Visuelle Analogskala.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t104_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba

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Anhang 4-G3.2: Symptomatik anhand des FACIT-Fatigue

Anhang 4-G3.2.1: Subgruppenanalysen nicht-interagierender Subgruppen

Tabelle 115.1.2: Subgruppen für die Veränderung des FACIT-Fatigue aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Region (p-Wert des Interaktionsterms: 0,6106)																					
Nordamerika / Europa	272 39,96 (9,75)	254 37,72 (10,49)	245 38,32 (10,83)	242 38,68 (9,87)	209 39,08 (10,51)	214 38,72 (11,34)	196 40,77 (10,23)	198 41,28 (9,82)	175 40,39 (10,58)	-0,74 (0,40)	250 39,25 (9,82)	236 39,18 (10,50)	219 40,23 (10,23)	205 39,88 (10,61)	194 40,94 (10,43)	186 40,66 (10,53)	177 41,83 (9,72)	177 40,24 (11,53)	157 40,99 (10,72)	0,67 (0,42)	-1,41 [-2,54;-0,27] 0,0150 -0,21 [-0,39;-0,04]
Asien	231 42,09 (8,12)	230 40,42 (8,78)	226 41,21 (8,33)	225 41,18 (9,10)	220 40,55 (9,34)	215 40,87 (9,69)	213 42,46 (8,98)	210 42,21 (9,08)	206 42,48 (9,28)	-0,74 (0,34)	210 41,98 (7,12)	207 42,03 (7,63)	207 42,64 (7,28)	202 43,23 (7,07)	191 43,05 (7,27)	186 42,92 (7,75)	181 43,76 (6,87)	180 43,31 (7,19)	169 42,96 (7,93)	0,72 (0,36)	-1,46 [-2,44;-0,48] 0,0035 -0,28 [-0,47;-0,09]
Andere	175 40,22 (9,58)	171 39,92 (9,70)	166 40,64 (10,06)	165 40,44 (9,69)	160 40,30 (9,79)	156 41,00 (9,90)	138 41,20 (9,55)	145 41,43 (8,96)	129 40,95 (9,54)	0,08 (0,45)	176 40,44 (8,97)	172 41,01 (8,87)	165 42,19 (7,65)	161 41,16 (8,94)	161 40,97 (9,33)	145 41,48 (9,06)	139 42,81 (8,27)	137 41,67 (8,39)	124 41,23 (9,95)	0,57 (0,45)	-0,49 [-1,75;0,78] 0,4494 -0,08 [-0,29;0,13]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,1193)																					
< 20 mm	175 40,53 (8,82)	169 38,87 (9,34)	162 39,97 (9,79)	166 39,23 (10,11)	154 39,92 (9,86)	151 39,28 (10,90)	148 40,78 (10,40)	152 41,40 (9,62)	145 40,27 (10,06)	-0,69 (0,49)	163 40,02 (8,84)	157 39,81 (9,30)	149 41,19 (8,91)	146 40,19 (9,76)	145 41,31 (9,16)	137 41,84 (9,14)	131 42,95 (8,39)	128 41,70 (10,30)	114 42,18 (9,36)	0,82 (0,51)	-1,51 [-2,90;-0,12] 0,0332 -0,23 [-0,45;-0,02]
≥ 20 bis < 50 mm	315 40,97 (9,58)	302 39,05 (10,53)	301 40,01 (9,97)	295 40,44 (9,72)	273 40,00 (10,09)	271 40,38 (10,31)	246 41,64 (9,46)	253 41,55 (9,54)	233 41,81 (9,89)	-0,68 (0,32)	310 40,41 (8,83)	300 40,98 (9,11)	293 41,99 (8,33)	281 42,18 (8,60)	269 41,87 (9,13)	258 41,66 (9,24)	248 42,60 (8,74)	242 41,98 (8,79)	231 41,81 (9,57)	0,90 (0,33)	-1,58 [-2,48;-0,67] 0,0007 -0,27 [-0,43;-0,12]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 50 mm	170 40,44 (9,16)	167 39,74 (8,88)	159 39,49 (10,07)	155 39,85 (8,84)	147 39,72 (9,61)	149 40,15 (10,28)	139 41,90 (9,09)	135 41,86 (8,78)	118 41,46 (9,60)	-0,26 (0,44)	155 41,05 (8,89)	150 40,74 (9,51)	141 41,26 (9,09)	133 41,12 (9,45)	126 41,58 (9,30)	115 41,51 (9,54)	111 43,20 (7,76)	117 41,36 (9,56)	100 41,25 (9,94)	-0,02 (0,47)	-0,24 [-1,51;1,02] 0,7053 -0,04 [-0,26;0,18]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,2657)																					
0-3	232 40,60 (9,14)	220 38,33 (9,96)	212 39,46 (9,86)	214 38,89 (9,81)	191 39,23 (10,11)	192 39,55 (10,60)	182 40,99 (10,24)	179 41,28 (9,29)	167 40,69 (10,31)	-1,09 (0,42)	230 39,92 (8,49)	221 40,51 (8,81)	211 41,01 (9,08)	203 40,39 (9,05)	197 40,87 (9,26)	186 40,85 (8,81)	179 41,96 (8,09)	176 41,24 (8,88)	168 40,92 (9,87)	0,39 (0,42)	-1,48 [-2,65;-0,31] 0,0131 -0,23 [-0,41;-0,05]
4-9	310 39,84 (9,56)	303 38,72 (9,87)	296 39,41 (10,02)	291 39,65 (9,42)	274 38,91 (9,94)	279 39,12 (10,65)	256 40,66 (9,46)	258 40,66 (9,62)	239 40,56 (9,79)	-0,41 (0,33)	289 40,88 (9,10)	281 40,89 (9,26)	271 41,82 (8,31)	255 41,85 (9,07)	250 42,50 (8,50)	240 42,17 (9,24)	234 43,21 (8,49)	231 42,11 (9,08)	211 42,58 (8,97)	0,95 (0,34)	-1,36 [-2,30;-0,43] 0,0041 -0,24 [-0,40;-0,07]
≥ 10	136 43,11 (8,15)	132 41,96 (8,79)	129 41,99 (9,36)	127 42,80 (9,21)	124 43,43 (8,67)	114 43,51 (8,77)	109 44,50 (8,23)	116 44,55 (8,06)	104 44,35 (8,62)	-0,06 (0,48)	117 40,58 (8,83)	113 40,34 (10,00)	109 42,32 (8,57)	110 42,40 (9,16)	99 41,24 (10,31)	91 42,21 (9,97)	84 43,50 (8,67)	87 41,85 (10,91)	71 41,52 (10,43)	0,52 (0,53)	-0,58 [-1,99;0,83] 0,4184 -0,10 [-0,35;0,14]
Tumorgrading (p-Wert des Interaktionsterms: 0,9678)																					
G1	58 42,16 (8,00)	57 40,04 (8,28)	52 41,37 (8,96)	51 41,24 (9,31)	52 40,92 (9,29)	51 40,96 (10,19)	49 41,76 (9,51)	52 42,04 (8,95)	45 41,11 (10,07)	-0,96 (0,74)	46 41,46 (9,50)	45 41,69 (8,26)	39 42,95 (7,77)	39 42,85 (7,38)	38 42,37 (9,21)	39 41,41 (10,11)	38 42,79 (8,57)	36 42,25 (10,51)	32 42,41 (9,41)	0,68 (0,84)	-1,64 [-3,85;0,58] 0,1461 -0,29 [-0,68;0,10]
G2	304 40,70 (9,64)	293 39,34 (10,02)	288 39,91 (10,20)	286 39,98 (9,84)	265 39,99 (9,82)	266 39,94 (10,55)	249 41,73 (9,52)	249 41,83 (9,71)	229 41,46 (9,66)	-0,43 (0,34)	280 40,72 (9,25)	269 41,00 (9,70)	262 42,15 (8,38)	249 41,92 (9,45)	237 42,30 (8,89)	232 42,55 (9,19)	217 43,25 (8,49)	223 41,99 (9,64)	200 42,22 (9,77)	0,83 (0,36)	-1,26 [-2,23;-0,29] 0,0113 -0,21 [-0,37;-0,05]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
G3	272 40,07 (9,26)	262 38,59 (9,97)	256 39,47 (9,83)	253 39,42 (9,39)	232 39,38 (10,19)	228 39,71 (10,57)	210 40,96 (9,87)	214 40,99 (9,11)	197 40,79 (10,15)	-0,57 (0,37)	274 39,85 (8,52)	266 39,89 (9,05)	257 40,65 (9,01)	246 40,75 (8,86)	240 40,72 (9,55)	215 40,75 (9,16)	211 42,21 (8,40)	204 41,36 (8,86)	190 41,17 (9,61)	0,54 (0,37)	-1,11 [-2,14;-0,08] 0,0346 -0,18 [-0,35;-0,01]
GX	41 43,41 (6,80)	40 41,53 (8,63)	38 41,55 (8,53)	39 42,64 (9,17)	37 42,19 (8,94)	37 42,51 (8,58)	36 43,31 (8,48)	35 44,23 (7,42)	36 44,44 (8,05)	-0,59 (0,91)	34 41,85 (6,66)	33 42,39 (7,93)	31 43,35 (8,29)	32 40,92 (10,14)	29 43,55 (7,29)	29 42,34 (8,77)	29 43,72 (7,68)	29 42,28 (9,56)	26 42,08 (8,20)	0,30 (1,00)	-0,90 [-3,59;1,80] 0,5081 -0,15 [-0,61;0,30]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,1319)																					
Negativ	63 38,30 (9,80)	59 36,54 (10,64)	57 38,04 (11,08)	59 37,58 (10,73)	56 37,81 (10,11)	54 37,30 (11,41)	49 37,14 (11,42)	51 38,92 (11,03)	49 38,29 (11,81)	-0,71 (0,90)	53 40,06 (8,49)	51 40,16 (11,58)	50 41,46 (9,91)	43 43,07 (8,15)	43 43,35 (8,29)	40 42,60 (8,78)	40 42,45 (8,74)	37 43,97 (7,42)	35 43,40 (9,19)	2,49 (1,00)	-3,20 [-5,87;-0,54] 0,0190 -0,45 [-0,82;-0,08]
Positiv	593 40,98 (9,18)	575 39,46 (9,75)	561 40,06 (9,79)	553 40,19 (9,55)	518 40,11 (9,93)	516 40,33 (10,36)	482 41,85 (9,37)	489 41,91 (9,14)	449 41,71 (9,61)	-0,57 (0,24)	567 40,51 (8,89)	550 40,73 (8,98)	528 41,70 (8,49)	511 41,25 (9,15)	488 41,45 (9,26)	463 41,65 (9,23)	445 42,82 (8,37)	444 41,70 (9,36)	404 41,68 (9,55)	0,52 (0,25)	-1,08 [-1,76;-0,40] 0,0018 -0,18 [-0,30;-0,07]
Unbekannt	6 40,67 (8,43)	6 39,33 (7,47)	6 46,33 (2,07)	5 46,40 (5,03)	3 47,00 (3,61)	4 44,25 (6,95)	4 47,75 (3,20)	3 44,33 (5,13)	3 47,67 (4,04)	2,61 (2,37)	7 37,43 (10,16)	6 35,83 (13,01)	7 37,86 (10,37)	6 39,00 (13,11)	6 44,50 (8,73)	7 36,43 (13,56)	5 41,40 (11,59)	7 34,86 (13,32)	6 37,83 (14,39)	0,03 (1,93)	2,58 [-4,11;9,27] 0,4206 0,44 [-0,59;1,47]
Ethnizität (p-Wert des Interaktionsterms: 0,9213)																					
Weiß	385 39,91 (9,71)	368 38,41 (10,23)	353 38,92 (10,67)	349 39,06 (9,92)	316 39,36 (10,40)	318 39,38 (10,90)	283 40,78 (9,99)	295 41,04 (9,50)	269 40,55 (9,93)	-0,46 (0,32)	370 39,68 (9,69)	352 39,80 (10,18)	334 41,13 (9,35)	321 40,32 (9,98)	314 40,92 (9,96)	295 40,91 (10,06)	280 42,09 (9,27)	279 40,76 (10,42)	254 40,96 (10,63)	0,64 (0,33)	-1,10 [-2,01;-0,19] 0,0181 -0,17 [-0,32;-0,03]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Asiatisch	258 41,87 (8,34)	255 40,43 (8,86)	252 41,34 (8,47)	250 41,49 (8,92)	242 40,72 (9,25)	238 41,04 (9,72)	234 42,57 (8,96)	233 42,28 (9,08)	219 42,51 (9,55)	-0,42 (0,32)	226 41,85 (7,14)	223 41,98 (7,46)	220 42,75 (7,21)	217 43,26 (7,04)	201 42,94 (7,46)	193 42,84 (7,83)	189 43,77 (6,92)	187 43,29 (7,13)	174 42,98 (7,89)	0,82 (0,35)	-1,24 [-2,18;-0,30] 0,0095 -0,24 [-0,42;-0,06]
Andere	25 42,16 (9,86)	24 40,75 (10,36)	23 41,52 (8,85)	24 39,38 (10,44)	23 41,39 (9,41)	20 41,85 (10,81)	21 42,76 (10,10)	19 44,11 (8,58)	17 41,88 (10,17)	-1,25 (1,12)	28 39,89 (8,92)	28 41,54 (7,92)	27 39,85 (8,91)	26 40,31 (10,60)	24 40,69 (9,83)	22 42,00 (9,04)	21 42,76 (8,23)	22 40,68 (10,84)	16 42,75 (8,06)	0,58 (1,07)	-1,83 [-4,96;1,30] 0,2443 -0,33 [-0,87;0,22]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,4124)																					
Tamoxifen	477 40,32 (9,19)	458 38,85 (9,75)	443 39,34 (10,01)	441 39,37 (9,62)	407 39,19 (10,02)	406 39,52 (10,52)	378 41,00 (9,48)	386 41,03 (9,30)	352 40,58 (9,83)	-0,71 (0,28)	466 40,33 (8,85)	447 40,55 (9,25)	427 41,70 (8,37)	412 41,47 (8,95)	394 41,50 (9,14)	380 41,20 (9,52)	361 42,48 (8,39)	364 41,35 (9,23)	331 41,20 (9,89)	0,55 (0,28)	-1,26 [-2,04;-0,48] 0,0016 -0,21 [-0,33;-0,08]
Aromatase-Inhibitor	201 41,79 (9,24)	197 40,17 (9,80)	194 41,35 (9,43)	191 41,55 (9,42)	182 41,68 (9,41)	179 41,46 (10,06)	169 42,73 (9,79)	167 43,16 (9,19)	158 43,15 (9,64)	-0,16 (0,40)	170 40,89 (8,81)	168 40,93 (9,21)	164 41,41 (9,32)	156 41,35 (9,52)	152 42,16 (9,16)	137 43,09 (8,23)	136 43,65 (8,35)	130 42,89 (9,61)	119 43,44 (8,41)	0,97 (0,44)	-1,13 [-2,29;0,03] 0,0570 -0,20 [-0,40;0,01]
ECOG-PS (p-Wert des Interaktionsterms: 0,9953)																					
ECOG-PS 0	600 40,88 (9,19)	578 39,39 (9,57)	564 39,90 (10,04)	561 39,97 (9,59)	521 39,81 (9,98)	519 40,09 (10,44)	482 41,50 (9,70)	486 41,62 (9,35)	453 41,31 (9,88)	-0,67 (0,24)	564 40,83 (8,62)	545 40,84 (9,19)	521 41,91 (8,49)	505 41,71 (8,96)	486 41,96 (8,98)	461 42,02 (8,99)	445 43,00 (8,26)	435 41,97 (9,25)	401 42,13 (9,40)	0,58 (0,25)	-1,25 [-1,93;-0,57] 0,0003 -0,21 [-0,33;-0,10]
ECOG-PS 1	78 39,81 (9,50)	77 38,17 (11,21)	73 40,30 (8,51)	71 40,49 (9,79)	68 41,09 (9,17)	66 40,36 (10,27)	65 41,78 (8,93)	67 42,09 (9,06)	57 41,91 (9,57)	0,48 (0,74)	72 37,76 (10,03)	70 39,21 (9,46)	70 39,46 (9,47)	63 39,21 (9,98)	60 39,49 (10,16)	56 39,09 (10,68)	52 41,17 (9,34)	59 40,14 (9,97)	49 39,06 (10,51)	1,15 (0,78)	-0,67 [-2,80;1,47] 0,5384 -0,10 [-0,42;0,22]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Datenschnitt: 01.07.2022 Safety-Population 1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACIT-Fatigue Score = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACIT-Fatigue Score haben. Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACIT: Functional Assessment of Chronic Illness Therapy; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.																				

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t115_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 115.2.2: Subgruppen für die Veränderung des FACIT-Fatigue aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,4075)																					
< 65 Jahre	788 40,23 (9,37)	751 38,54 (9,93)	721 39,02 (9,94)	681 39,63 (9,51)	669 39,29 (9,61)	637 39,37 (9,70)	609 40,52 (9,22)	615 40,56 (9,39)	561 40,72 (9,40)	-0,81 (0,22)	809 39,47 (9,76)	756 40,07 (9,24)	757 39,89 (9,58)	719 40,29 (9,31)	683 40,57 (9,59)	649 40,73 (9,47)	613 41,32 (9,23)	604 41,03 (9,50)	561 41,32 (9,38)	0,61 (0,22)	-1,42 [-2,04;-0,81] <,0001 -0,23 [-0,33;-0,13]
≥ 65 Jahre	288 40,20 (9,47)	267 37,63 (9,81)	256 38,88 (9,04)	246 38,20 (9,21)	229 37,79 (10,05)	210 38,99 (9,17)	200 40,17 (9,00)	193 39,91 (8,71)	175 39,79 (9,18)	-2,01 (0,36)	269 39,78 (9,04)	253 40,38 (8,82)	247 40,36 (8,85)	239 39,89 (8,41)	231 39,66 (8,85)	220 40,11 (8,87)	204 39,53 (8,69)	201 39,16 (9,14)	177 39,21 (9,43)	-0,39 (0,36)	-1,62 [-2,61;-0,62] 0,0015 -0,27 [-0,44;-0,10]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,3202)																					
Neoadjuvante Chemotherapie	355 40,63 (9,35)	332 38,61 (9,70)	312 39,28 (9,77)	295 39,64 (9,25)	279 39,12 (9,99)	259 39,77 (9,58)	244 40,45 (9,40)	239 40,87 (8,97)	222 40,99 (9,67)	-1,32 (0,34)	352 38,99 (9,86)	330 40,10 (9,34)	322 39,66 (9,50)	305 39,65 (9,78)	285 40,37 (9,10)	260 39,98 (10,13)	255 40,78 (9,26)	250 40,28 (9,35)	220 40,44 (9,68)	0,16 (0,34)	-1,48 [-2,44;-0,53] 0,0024 -0,23 [-0,38;-0,08]
Adjuvante Chemotherapie	663 40,13 (9,43)	632 38,38 (9,95)	614 39,02 (9,67)	580 39,39 (9,37)	572 38,79 (9,65)	546 39,31 (9,48)	523 40,54 (9,10)	530 40,20 (9,50)	484 40,28 (9,28)	-0,91 (0,24)	660 39,96 (9,35)	617 40,30 (8,94)	621 40,24 (9,35)	600 40,65 (8,66)	579 40,47 (9,52)	560 40,93 (8,90)	518 40,99 (9,09)	512 40,87 (9,46)	485 41,13 (9,30)	0,49 (0,24)	-1,39 [-2,05;-0,74] <,0001 -0,23 [-0,34;-0,12]
Keine Chemotherapie	58 38,78 (9,22)	54 35,49 (10,31)	51 36,82 (9,62)	52 35,55 (10,71)	47 39,04 (9,55)	42 35,67 (10,11)	42 38,95 (8,60)	39 40,36 (7,02)	30 40,37 (8,16)	-2,80 (0,79)	66 38,45 (10,31)	62 38,90 (10,07)	61 39,51 (9,47)	53 38,09 (9,45)	50 38,64 (9,86)	49 39,57 (9,47)	44 40,05 (8,86)	43 38,53 (9,59)	33 38,67 (9,56)	0,32 (0,75)	-3,13 [-5,29;-0,96] 0,0051 -0,51 [-0,87;-0,16]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,2716)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
< 20 mm	272 40,02 (9,70)	253 38,25 (10,12)	243 38,96 (9,94)	239 38,92 (9,47)	226 38,57 (10,24)	216 39,15 (9,60)	214 40,22 (9,78)	207 40,68 (9,47)	198 40,17 (9,69)	-1,22 (0,37)	292 39,71 (9,66)	272 40,36 (9,12)	274 40,73 (9,15)	255 40,42 (9,17)	247 40,95 (9,04)	229 41,36 (8,94)	222 41,48 (8,82)	212 41,20 (8,93)	198 41,13 (8,90)	0,68 (0,36)	-1,90 [-2,92;-0,88] 0,0003 -0,31 [-0,47;-0,14]
≥ 20 bis < 50 mm	552 40,55 (9,34)	530 38,72 (9,53)	505 39,62 (9,47)	481 39,82 (9,16)	463 39,14 (9,79)	441 39,88 (9,22)	420 41,07 (8,54)	419 40,56 (9,31)	377 40,73 (9,28)	-0,92 (0,26)	554 39,66 (9,46)	519 40,15 (9,30)	517 40,08 (9,30)	499 40,17 (9,08)	474 40,22 (9,69)	467 40,22 (9,51)	424 40,68 (9,26)	428 40,34 (9,60)	398 40,56 (9,72)	0,17 (0,26)	-1,09 [-1,82;-0,36] 0,0034 -0,18 [-0,29;-0,06]
≥ 50 mm	235 39,81 (9,22)	219 37,21 (10,65)	213 37,46 (9,96)	194 38,17 (10,11)	194 38,73 (8,95)	176 38,02 (10,32)	161 39,02 (9,78)	170 39,62 (8,84)	148 40,33 (8,98)	-1,58 (0,41)	221 38,83 (9,94)	207 39,64 (8,94)	203 38,62 (10,03)	193 39,67 (9,16)	186 39,58 (9,24)	164 40,24 (9,43)	162 40,25 (9,30)	156 40,07 (9,87)	135 40,86 (9,50)	0,35 (0,42)	-1,93 [-3,08;-0,77] 0,0011 -0,31 [-0,49;-0,12]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,8418)																					
0-3	359 40,06 (9,43)	339 37,83 (10,33)	326 39,17 (9,55)	303 39,47 (9,59)	296 39,08 (9,70)	280 39,51 (9,53)	271 40,03 (9,46)	267 40,51 (8,66)	246 40,70 (9,16)	-0,98 (0,33)	351 39,18 (9,69)	326 39,81 (9,31)	332 39,77 (9,01)	311 39,80 (9,33)	302 40,29 (9,02)	284 39,70 (9,73)	266 40,49 (9,15)	255 40,09 (9,87)	239 40,11 (9,51)	0,47 (0,33)	-1,45 [-2,36;-0,53] 0,0020 -0,23 [-0,38;-0,09]
4-9	465 40,19 (9,46)	440 38,73 (9,47)	423 38,93 (9,81)	404 38,85 (9,52)	398 38,73 (9,77)	370 39,03 (9,61)	350 40,65 (8,86)	360 40,36 (9,36)	331 40,30 (9,71)	-1,22 (0,29)	471 39,72 (9,64)	441 40,37 (9,21)	444 40,10 (9,43)	422 40,22 (9,15)	404 40,39 (9,71)	392 40,72 (9,29)	365 40,91 (9,50)	367 40,81 (9,33)	337 41,17 (9,59)	0,25 (0,28)	-1,48 [-2,27;-0,69] 0,0003 -0,24 [-0,37;-0,11]
≥ 10	252 40,52 (9,25)	239 38,18 (10,05)	228 38,84 (9,77)	220 39,70 (9,11)	204 38,99 (9,76)	197 39,40 (9,58)	188 40,60 (9,31)	181 40,33 (9,83)	159 40,61 (8,90)	-1,13 (0,39)	256 39,75 (9,35)	242 40,18 (8,79)	228 40,19 (9,94)	225 40,69 (8,65)	208 40,33 (9,42)	193 41,55 (8,65)	186 41,35 (8,32)	183 40,72 (9,06)	162 41,11 (8,97)	0,41 (0,39)	-1,54 [-2,63;-0,45] 0,0059 -0,25 [-0,42;-0,07]
Tumorstadium (p-Wert des Interaktionsterms: 0,0594)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIA	89 40,70 (9,56)	84 39,05 (9,67)	81 39,95 (8,74)	80 39,61 (9,69)	75 39,08 (10,38)	73 40,04 (9,11)	72 39,49 (10,80)	66 40,82 (10,01)	64 41,05 (9,43)	-0,61 (0,68)	93 37,73 (10,84)	88 40,20 (8,73)	89 39,24 (9,14)	85 39,24 (9,66)	78 40,58 (8,74)	79 39,92 (9,88)	76 40,26 (9,32)	71 39,18 (9,93)	62 39,61 (9,18)	1,09 (0,67)	-1,70 [-3,59;0,18] 0,0766 -0,27 [-0,56;0,03]
IIB	129 40,47 (9,25)	121 39,31 (9,64)	115 40,58 (8,18)	110 40,72 (8,83)	108 40,45 (9,42)	101 40,40 (9,33)	95 41,55 (7,79)	100 41,42 (7,79)	92 41,65 (9,06)	-0,25 (0,50)	110 40,26 (9,39)	104 39,40 (10,49)	100 39,67 (9,68)	97 39,63 (9,45)	91 38,98 (9,90)	94 39,06 (9,70)	89 40,08 (9,64)	85 38,40 (10,96)	81 38,64 (10,67)	-0,92 (0,54)	0,67 [-0,79;2,12] 0,3691 0,12 [-0,14;0,37]
IIIA	421 39,96 (9,04)	397 37,92 (9,88)	380 38,40 (9,75)	361 37,98 (9,82)	354 38,11 (9,83)	328 38,50 (9,74)	312 39,90 (9,01)	325 39,73 (9,51)	291 39,85 (9,76)	-1,61 (0,30)	423 39,64 (9,56)	391 40,40 (8,78)	401 39,93 (9,32)	380 40,44 (8,66)	367 40,49 (9,45)	348 40,86 (9,01)	325 41,27 (8,76)	327 40,87 (9,36)	301 41,43 (9,08)	0,50 (0,30)	-2,12 [-2,95;-1,28] <,0001 -0,34 [-0,48;-0,21]
IIIB	47 40,32 (9,43)	45 39,07 (8,76)	45 40,16 (10,52)	42 41,19 (9,02)	43 41,02 (9,14)	39 40,87 (9,40)	36 41,81 (9,19)	33 42,61 (6,89)	34 41,76 (9,23)	0,02 (0,87)	40 39,63 (10,58)	38 40,53 (10,76)	37 40,57 (10,25)	34 40,35 (11,10)	33 42,64 (9,03)	31 40,61 (11,72)	30 40,03 (12,98)	27 40,78 (10,28)	27 40,89 (11,78)	0,66 (0,95)	-0,64 [-3,20;1,92] 0,6186 -0,11 [-0,53;0,31]
IIIC	388 40,32 (9,80)	370 38,10 (10,20)	354 38,75 (10,17)	332 39,83 (9,09)	316 38,98 (9,58)	304 39,35 (9,57)	292 40,67 (9,32)	283 40,45 (9,41)	253 40,51 (8,97)	-1,12 (0,32)	410 39,66 (9,26)	386 40,04 (9,08)	375 40,27 (9,43)	360 40,29 (9,15)	343 40,24 (9,43)	315 40,83 (9,15)	296 40,90 (8,89)	293 41,13 (8,80)	265 41,01 (9,19)	0,33 (0,31)	-1,45 [-2,33;-0,58] 0,0012 -0,23 [-0,37;-0,09]
Tumorgrading (p-Wert des Interaktionsterms: 0,6677)																					
G1	79 38,57 (9,52)	77 38,74 (9,52)	78 37,73 (10,82)	69 39,59 (9,47)	68 38,52 (9,33)	67 38,55 (10,14)	63 40,24 (9,50)	64 40,92 (8,63)	56 40,89 (8,69)	0,18 (0,69)	81 40,79 (9,70)	76 41,67 (8,14)	78 41,79 (9,14)	72 41,63 (8,32)	75 41,71 (9,45)	69 42,84 (8,34)	63 43,21 (7,46)	65 42,14 (9,37)	58 42,03 (9,30)	1,68 (0,68)	-1,49 [-3,42;0,44] 0,1293 -0,24 [-0,55;0,07]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
G2	510 40,25 (9,70)	481 37,61 (10,51)	457 38,55 (10,15)	432 38,89 (9,83)	421 38,86 (9,69)	392 38,90 (9,68)	373 40,51 (9,20)	381 40,12 (9,45)	340 40,36 (9,50)	-1,52 (0,28)	514 39,21 (9,69)	475 39,85 (9,28)	480 39,44 (9,88)	461 39,70 (9,16)	429 39,62 (9,75)	410 40,01 (9,63)	386 40,47 (9,36)	384 40,46 (9,03)	353 40,56 (9,58)	0,10 (0,28)	-1,62 [-2,40;-0,84] <,0001 -0,26 [-0,38;-0,13]
G3	441 40,50 (9,11)	416 38,91 (9,33)	399 39,70 (8,97)	382 39,53 (9,08)	367 39,02 (9,82)	348 39,76 (9,35)	335 40,28 (9,12)	324 40,49 (9,31)	307 40,54 (9,27)	-0,96 (0,29)	426 39,48 (9,50)	402 40,04 (9,10)	394 40,09 (8,99)	373 40,44 (9,18)	362 40,49 (9,13)	345 40,48 (9,32)	325 40,62 (9,29)	314 40,26 (10,09)	292 40,66 (9,47)	0,46 (0,29)	-1,41 [-2,22;-0,60] 0,0007 -0,23 [-0,37;-0,10]
GX	44 40,52 (8,08)	42 39,64 (8,64)	41 39,71 (9,10)	42 40,31 (8,63)	40 39,73 (10,07)	38 40,76 (8,89)	36 42,00 (8,56)	37 42,11 (7,23)	32 41,00 (10,05)	-0,68 (0,88)	53 41,68 (7,79)	52 41,38 (9,32)	49 42,27 (7,07)	49 41,12 (7,64)	46 43,38 (7,46)	42 42,74 (7,05)	41 42,78 (7,21)	40 41,05 (8,25)	32 42,44 (8,01)	0,01 (0,80)	-0,69 [-3,05;1,67] 0,5633 -0,12 [-0,52;0,28]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,3722)																					
Negativ	136 38,65 (10,38)	129 36,91 (11,00)	123 37,64 (10,99)	118 38,53 (9,54)	112 38,33 (10,08)	99 38,24 (10,25)	95 39,69 (9,77)	100 40,06 (8,55)	85 40,12 (8,72)	-0,87 (0,50)	143 39,90 (10,52)	133 39,72 (9,71)	134 39,89 (9,99)	125 40,13 (10,13)	116 40,55 (9,35)	109 40,39 (10,19)	99 40,25 (9,65)	97 40,41 (8,71)	88 41,22 (8,80)	0,19 (0,48)	-1,07 [-2,43;0,30] 0,1248 -0,18 [-0,42;0,05]
Positiv	909 40,31 (9,26)	858 38,42 (9,66)	825 39,02 (9,52)	786 39,22 (9,42)	765 38,84 (9,75)	725 39,29 (9,44)	689 40,39 (9,10)	686 40,39 (9,37)	633 40,41 (9,48)	-1,17 (0,21)	908 39,37 (9,42)	852 40,17 (9,00)	847 39,95 (9,33)	810 40,15 (8,88)	777 40,24 (9,41)	738 40,53 (9,18)	698 40,94 (9,00)	686 40,52 (9,53)	629 40,68 (9,54)	0,43 (0,21)	-1,61 [-2,18;-1,03] <,0001 -0,26 [-0,35;-0,16]
Unbekannt	9 42,33 (6,95)	9 35,78 (11,97)	8 42,88 (8,22)	6 44,50 (9,99)	5 44,00 (4,95)	7 41,86 (11,68)	8 42,13 (11,24)	7 43,71 (8,34)	4 48,50 (2,65)	-1,06 (1,91)	7 46,00 (6,40)	6 47,67 (6,09)	6 47,33 (3,20)	6 47,50 (4,46)	6 47,83 (2,64)	6 46,67 (5,35)	5 49,80 (2,28)	6 49,67 (2,34)	5 48,60 (2,70)	4,24 (2,21)	-5,30 [-11,67;1,07] 0,0955 -0,87 [-1,85;0,11]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,8153)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Tamoxifen	99 40,05 (8,67)	94 38,50 (9,09)	96 38,60 (10,24)	90 39,57 (9,21)	90 38,52 (10,68)	89 39,51 (9,33)	79 40,67 (9,11)	84 40,31 (9,82)	86 40,50 (8,79)	-0,68 (0,64)	120 39,96 (8,94)	114 41,04 (8,68)	117 40,88 (8,55)	111 41,02 (9,53)	104 41,03 (9,58)	92 41,78 (9,22)	91 42,73 (7,74)	87 42,32 (9,07)	86 42,58 (8,01)	0,95 (0,59)	-1,63 [-3,34;0,09] 0,0627 -0,25 [-0,52;0,01]
Aromatase-Inhibitor	977 40,24 (9,47)	924 38,28 (9,98)	881 39,03 (9,65)	837 39,22 (9,47)	808 38,95 (9,63)	758 39,25 (9,60)	730 40,41 (9,18)	724 40,42 (9,17)	650 40,50 (9,43)	-1,18 (0,20)	958 39,50 (9,66)	895 40,03 (9,19)	887 39,89 (9,51)	847 40,09 (9,03)	810 40,25 (9,39)	777 40,43 (9,32)	726 40,64 (9,26)	718 40,35 (9,47)	652 40,58 (9,58)	0,29 (0,20)	-1,47 [-2,02;-0,92] <,0001 -0,24 [-0,33;-0,15]
ECOG-PS (p-Wert des Interaktionsterms: 0,6455)																					
ECOG-PS 0	908 40,69 (9,18)	857 38,75 (9,83)	827 39,36 (9,53)	792 39,41 (9,41)	765 39,15 (9,72)	725 39,48 (9,56)	689 40,67 (9,21)	693 40,59 (9,22)	639 40,65 (9,42)	-1,27 (0,20)	873 40,26 (9,28)	817 40,73 (8,73)	812 40,50 (9,08)	783 40,64 (8,90)	744 40,76 (9,37)	713 40,93 (9,24)	667 41,23 (9,01)	656 40,98 (9,30)	596 41,25 (9,21)	0,19 (0,21)	-1,45 [-2,02;-0,88] <,0001 -0,24 [-0,33;-0,14]
ECOG-PS 1	168 37,73 (10,11)	161 35,93 (9,95)	150 36,92 (10,40)	135 38,31 (9,64)	133 37,51 (9,78)	122 38,06 (9,55)	120 39,07 (8,84)	115 39,29 (9,24)	97 39,48 (8,83)	-0,46 (0,52)	205 36,53 (10,25)	192 37,65 (10,35)	192 37,93 (10,42)	175 38,17 (9,68)	170 38,53 (9,42)	156 38,92 (9,54)	150 39,29 (9,46)	149 38,72 (9,84)	142 38,98 (10,11)	1,23 (0,46)	-1,69 [-3,06;-0,32] 0,0157 -0,25 [-0,46;-0,05]

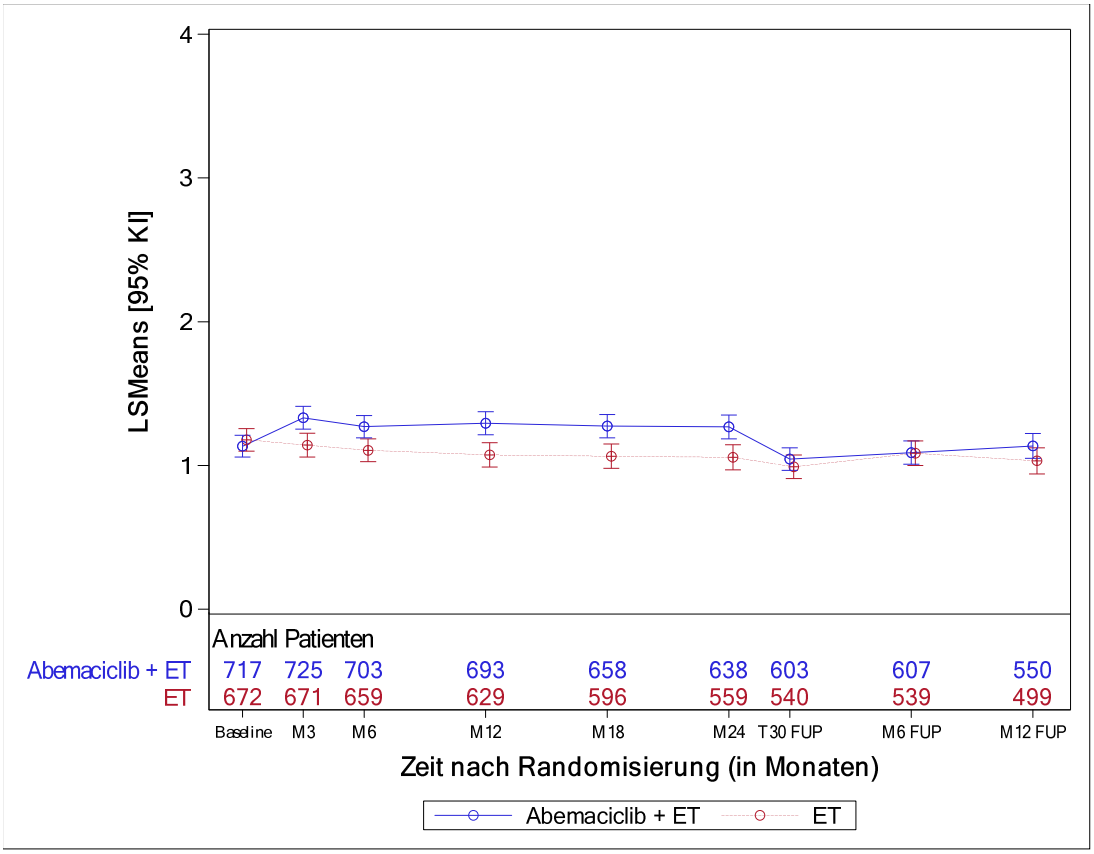
Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACIT-Fatigue Score = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACIT-Fatigue Score haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACIT: Functional Assessment of Chronic Illness Therapy; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t115_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba

29OCT2025 / 08:23

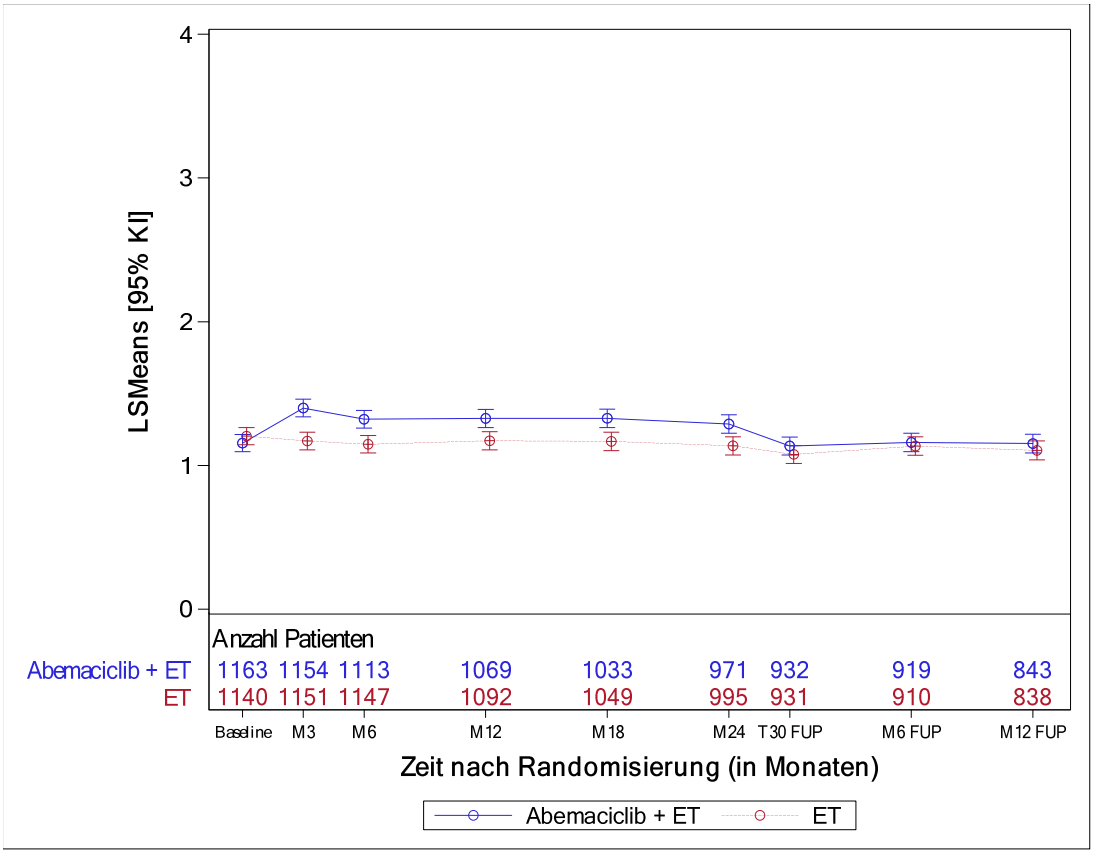
Anhang 4-G3.2.2: Verlaufskurven der Einzelitems des FACIT-Fatigue

Verlaufskurven - FACIT-Fatigue: I feel fatigued
Kohorte 1 Population - Safety - Prämenopausal



Datenschnitt: 01.07.2022
Prämenopausal: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
LSMeans aus dem MMRM Modell: FACIT-Fatigue Score = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACIT: Functional Assessment of Chronic Illness Therapy; FUP: Follow-up; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; T: Tag.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/f_gba3c1_lineplot_qol_primgba.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/f_lp_facitfr1_pgba_premp_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
23OCT2025 / 02:27

Verlaufskurven - FACIT-Fatigue: I feel fatigued
Kohorte 1 Population - Safety - Postmenopausal



Datenschnitt: 01.07.2022
Postmenopausal: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
LSMeans aus dem MMRM Modell: FACIT-Fatigue Score = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACIT: Functional Assessment of Chronic Illness Therapy; FUP: Follow-up; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; T: Tag.
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/f_gba3c1_lineplot_qol_primgba.sas
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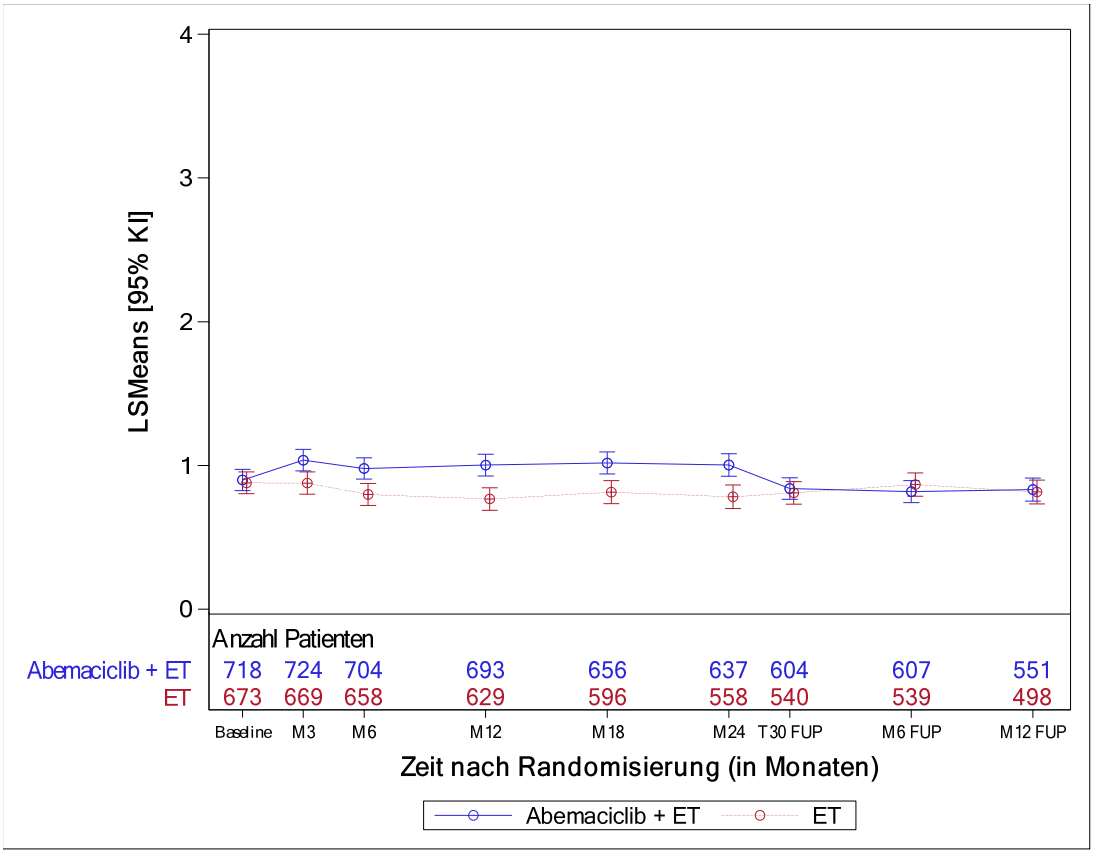
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
23OCT2025 / 02:27

Verlaufskurven - FACIT-Fatigue: I feel weak all over
Kohorte 1 Population - Safety - Prämenopausal



Datenschnitt: 01.07.2022
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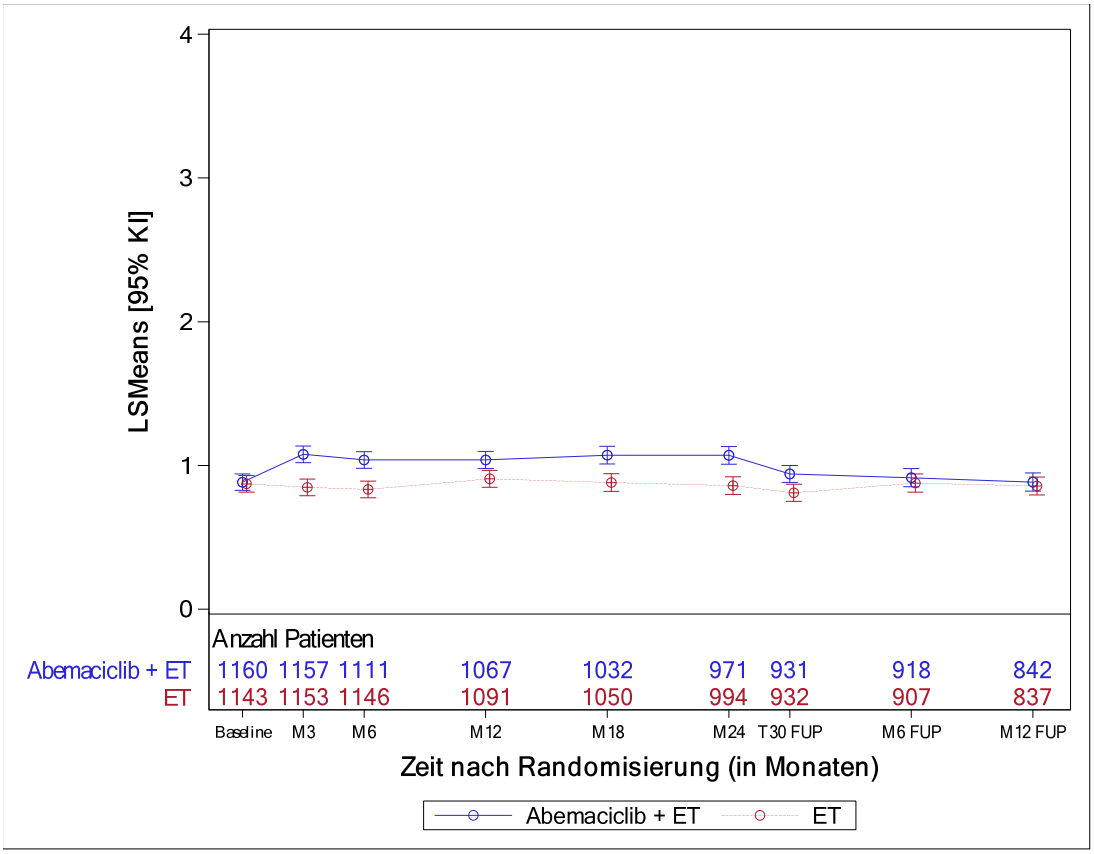
23OCT2025 / 02:27

Verlaufskurven - FACIT-Fatigue: I feel weak all over
Kohorte 1 Population - Safety - Postmenopausal



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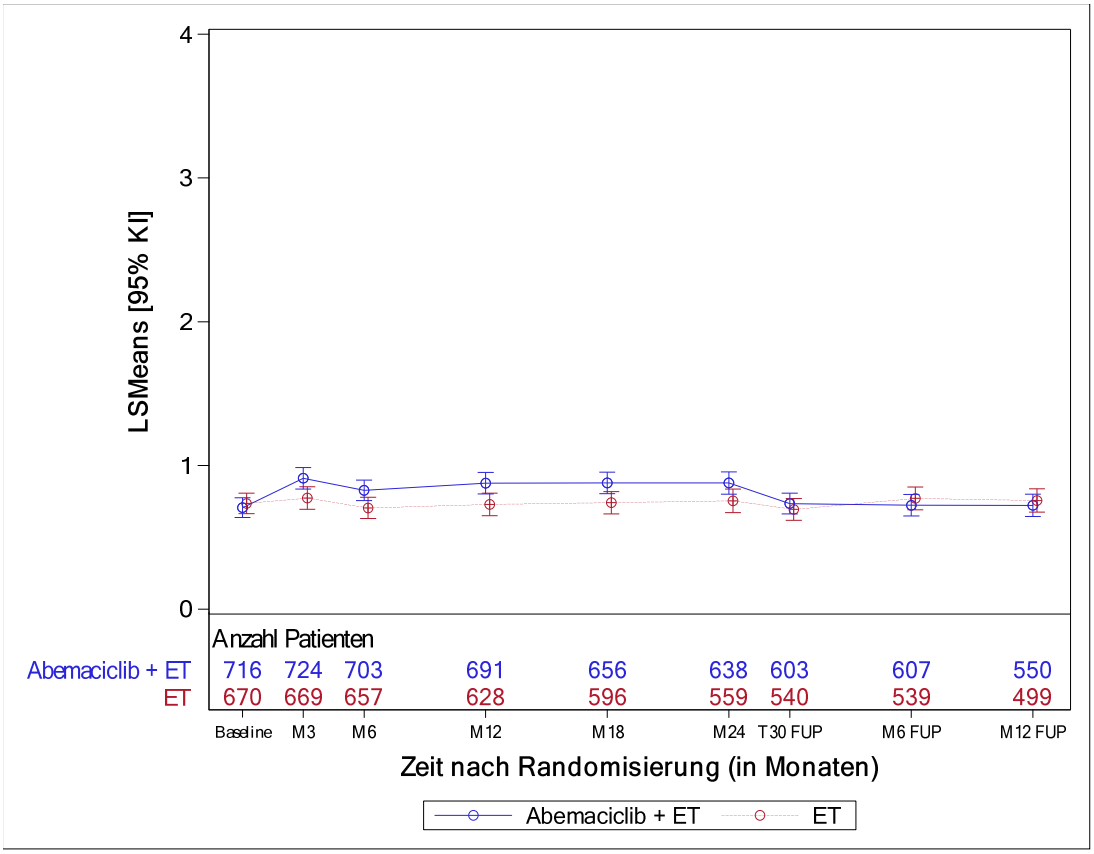
23OCT2025 / 02:27

Verlaufskurven - FACIT-Fatigue: I feel listless ('washed out')
Kohorte 1 Population - Safety - Prämenopausal



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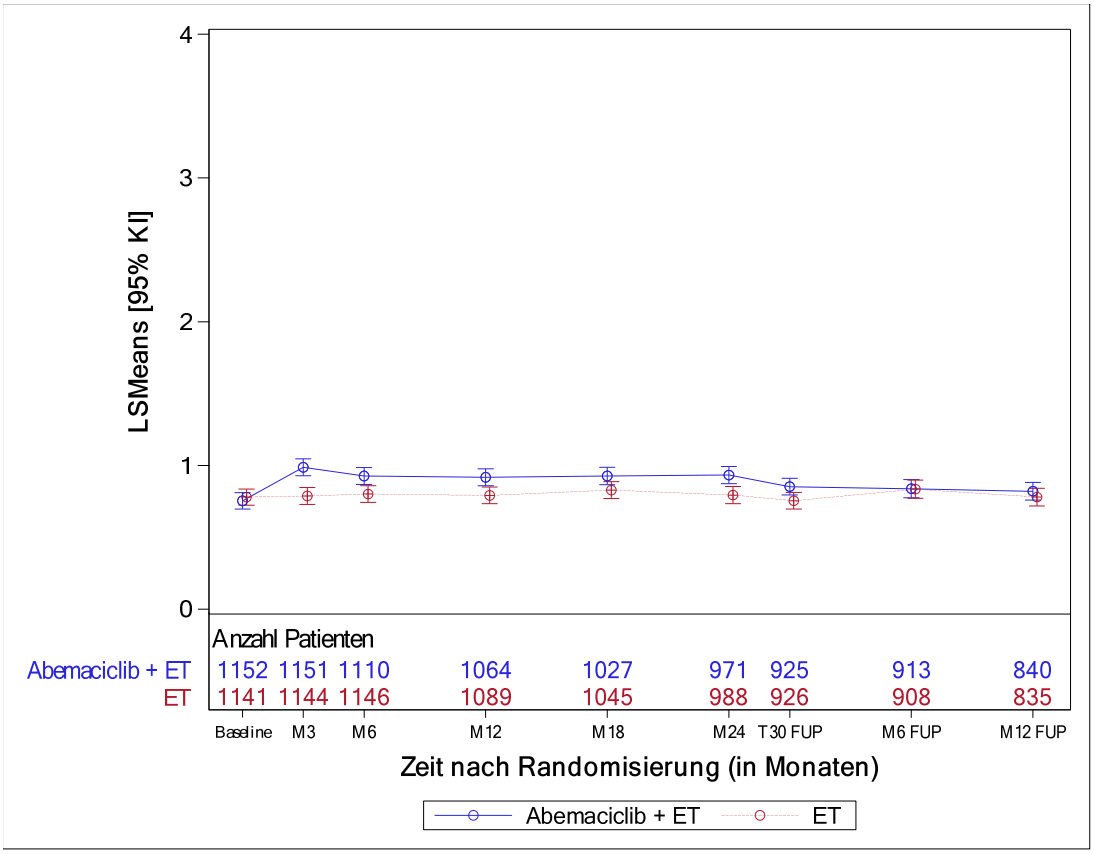
Kohorte 1 Population - Safety - Postmenopausal



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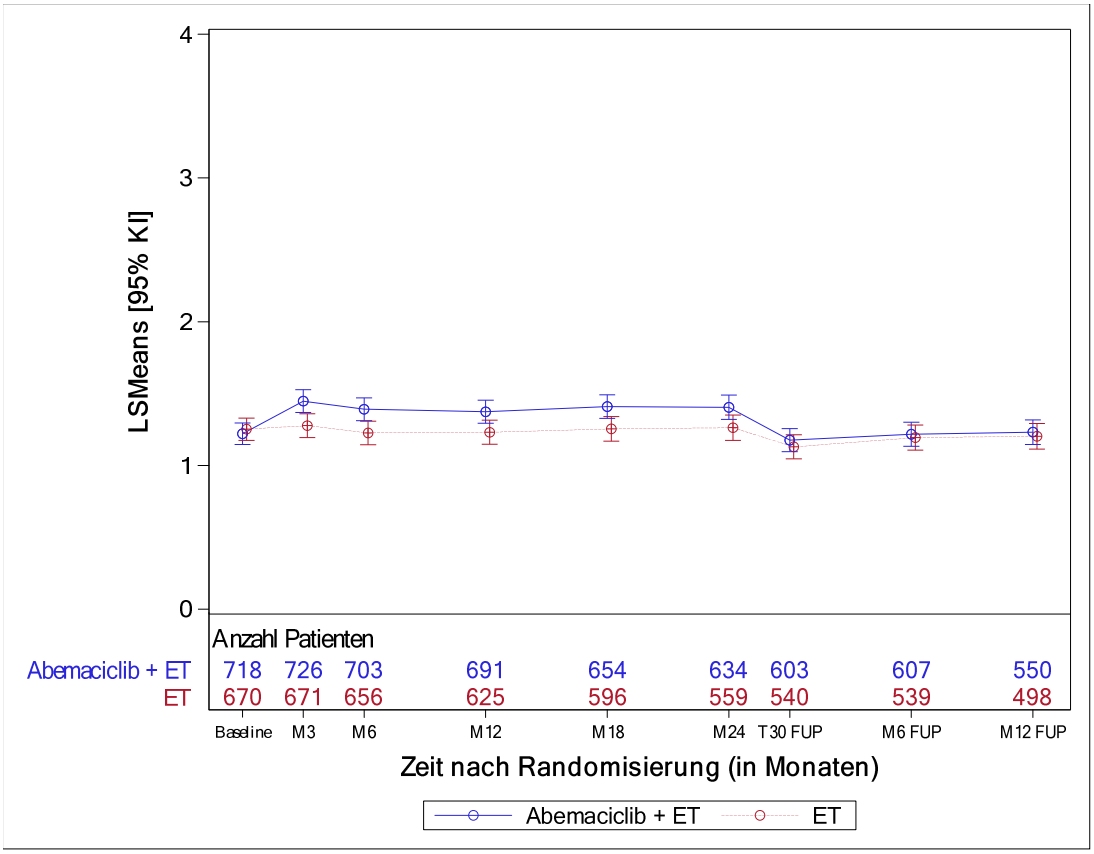
Verlaufskurven - FACIT-Fatigue: I feel tired
Kohorte 1 Population - Safety - Prämenopausal



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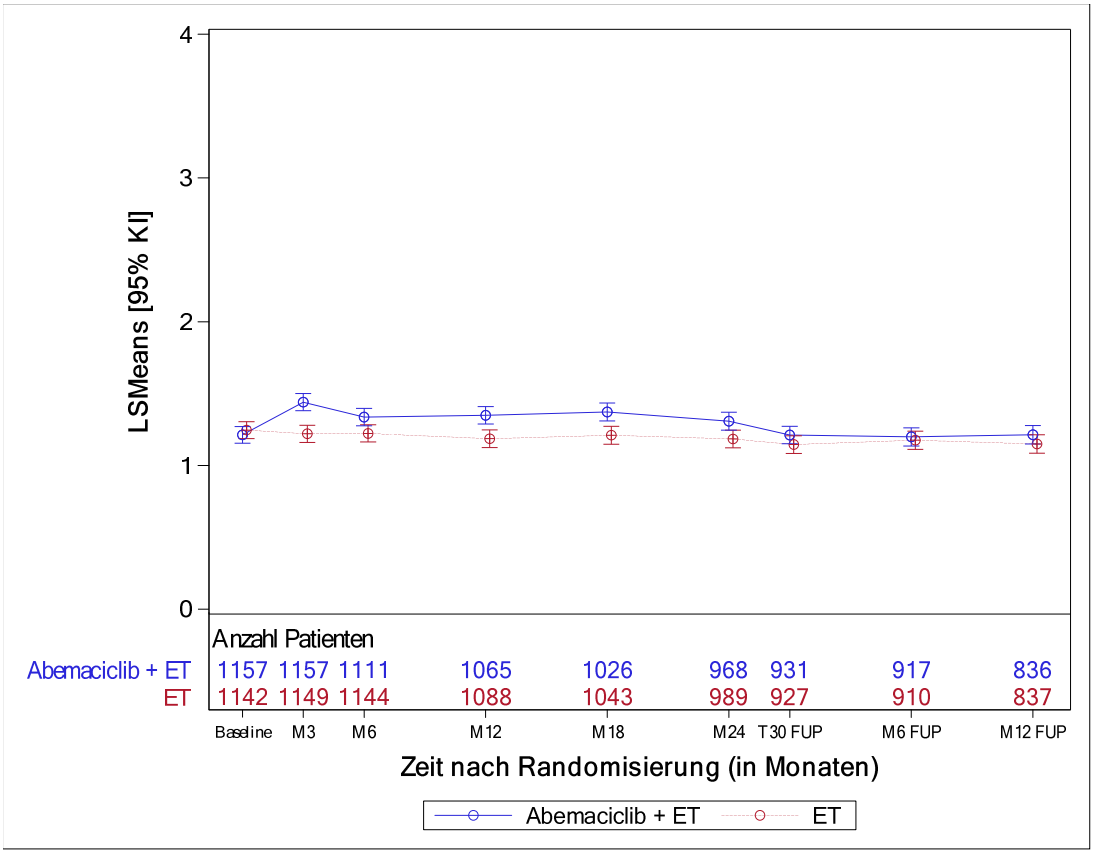
Verlaufskurven - FACIT-Fatigue: I feel tired
Kohorte 1 Population - Safety - Postmenopausal



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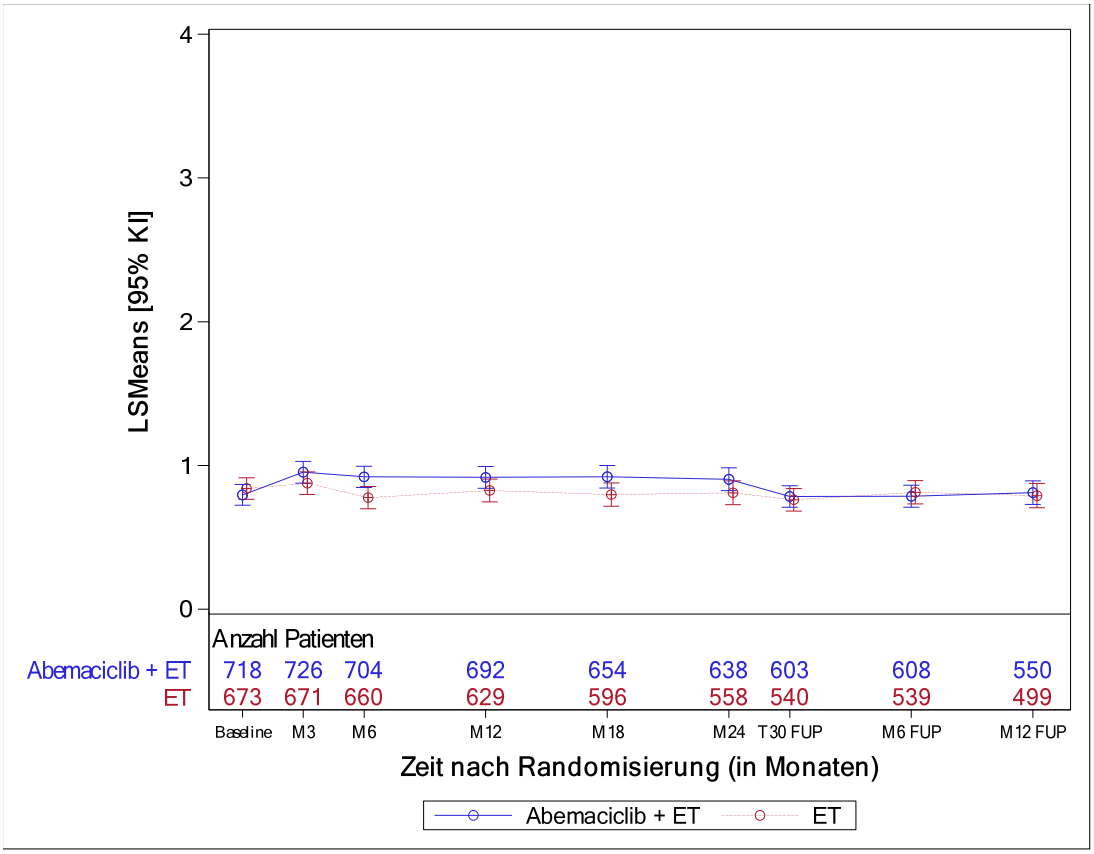
23OCT2025 / 02:27

Verlaufskurven - FACIT-Fatigue: I have trouble starting things because I am tired
Kohorte 1 Population - Safety - Prämenopausal



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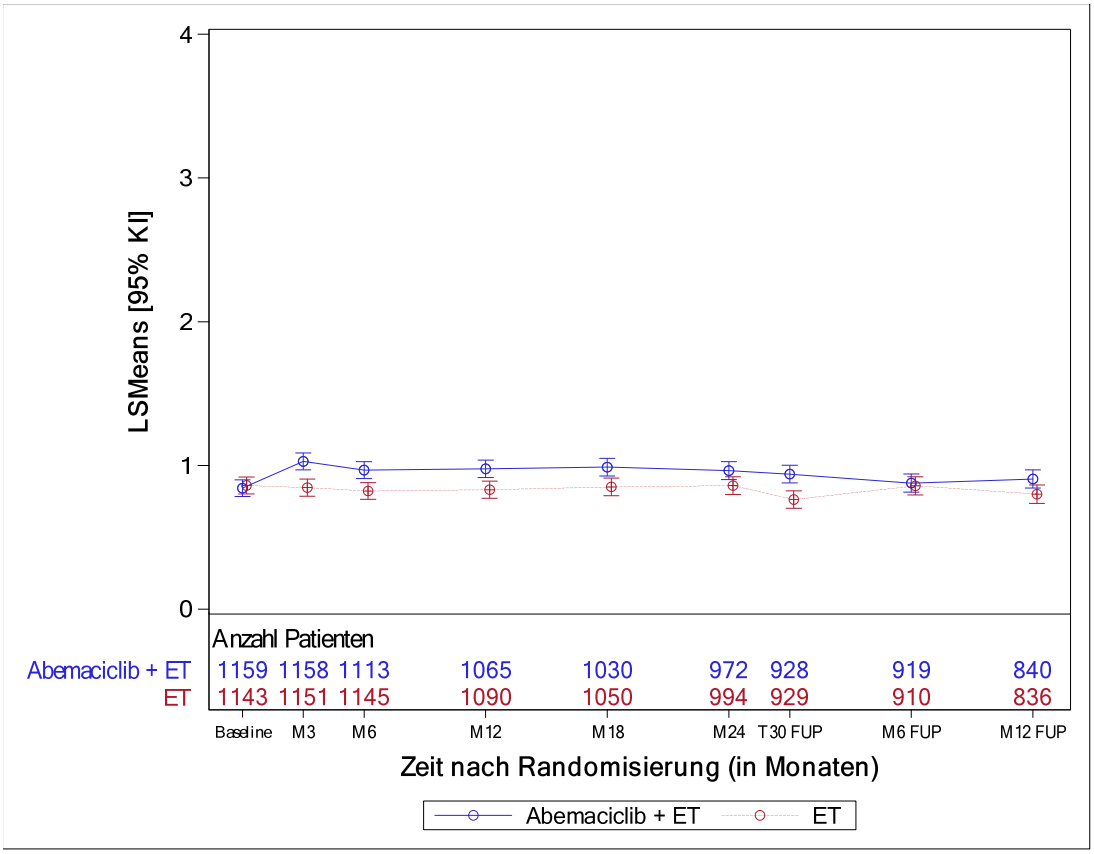
Verlaufskurven - FACIT-Fatigue: I have trouble starting things because I am tired
Kohorte 1 Population - Safety - Postmenopausal



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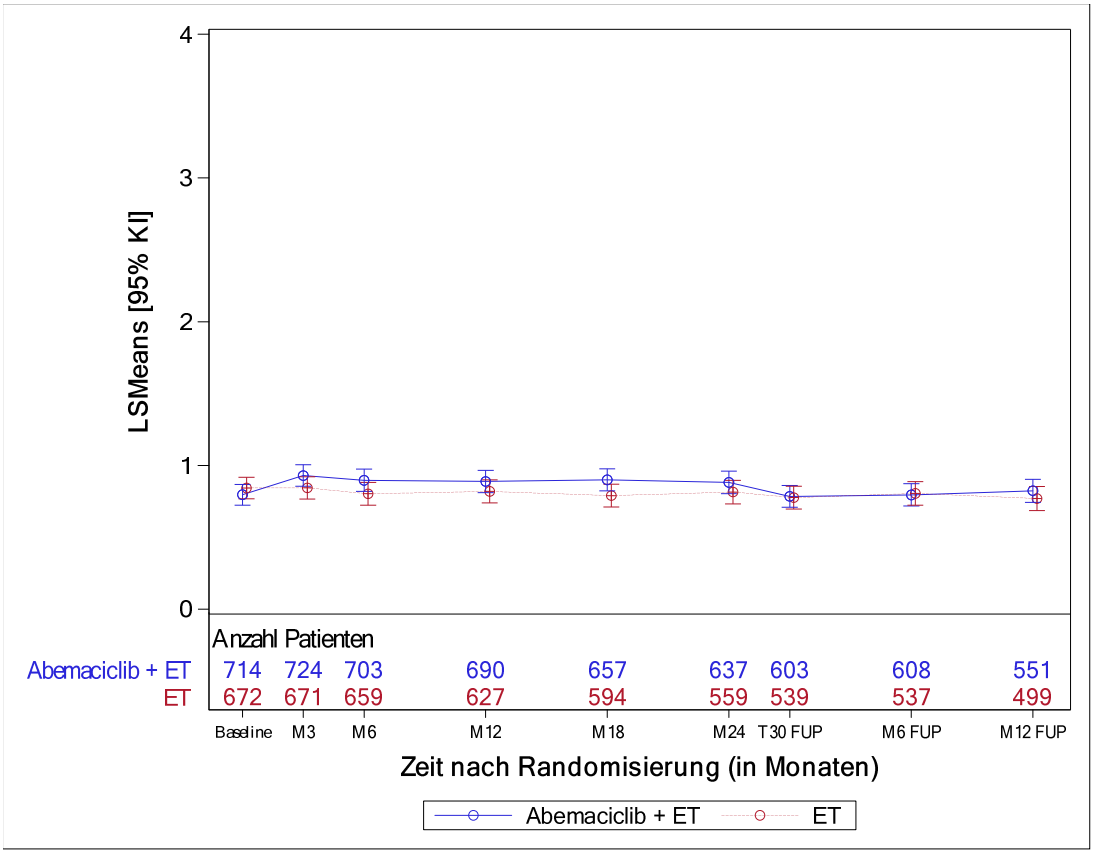
23OCT2025 / 02:27

Verlaufskurven - FACIT-Fatigue: I have trouble finishing things because I am tired
Kohorte 1 Population - Safety - Prämenopausal



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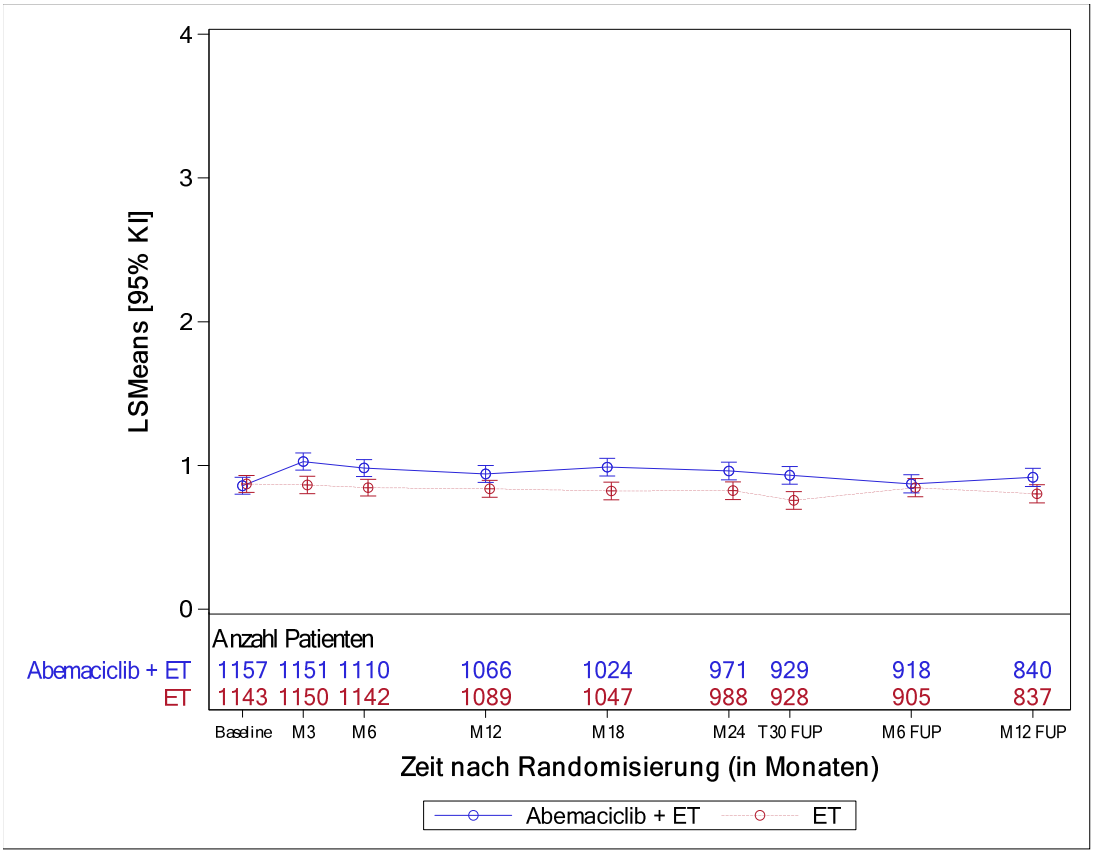
Verlaufskurven - FACIT-Fatigue: I have trouble finishing things because I am tired
Kohorte 1 Population - Safety - Postmenopausal



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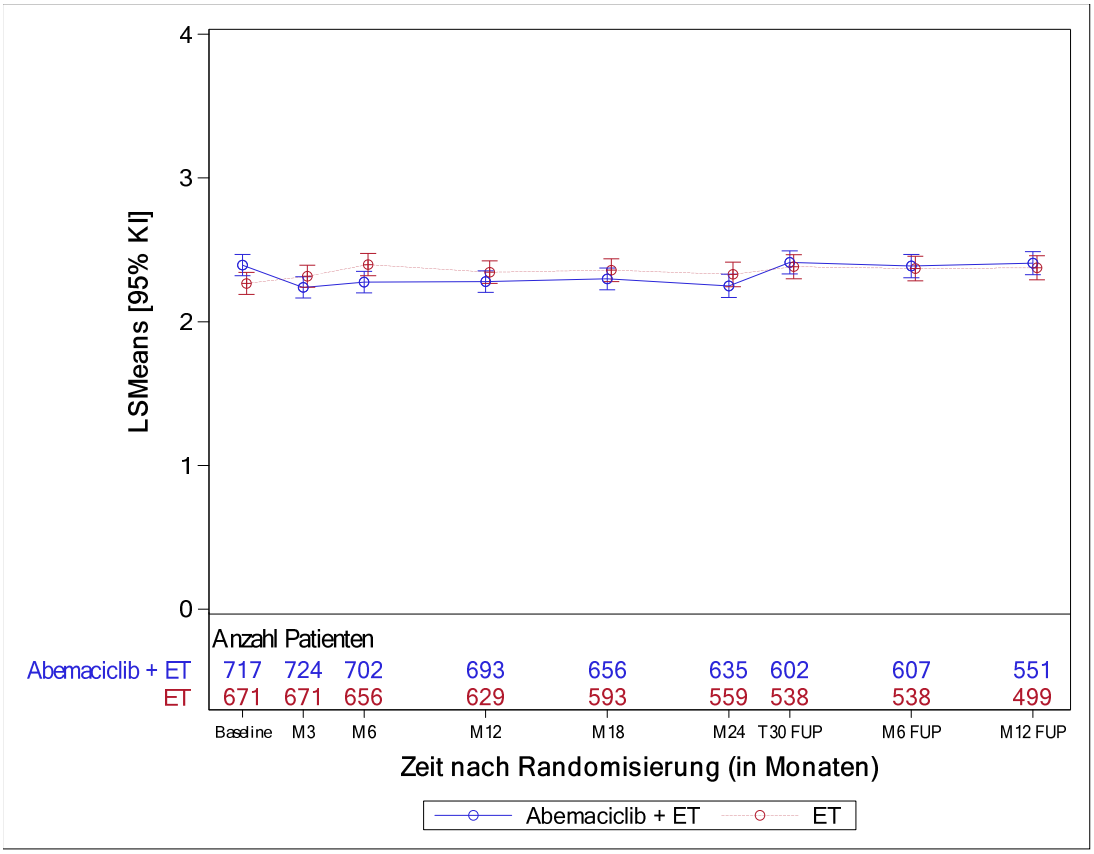
Verlaufskurven - FACIT-Fatigue: I have energy
Kohorte 1 Population - Safety - Prämenopausal



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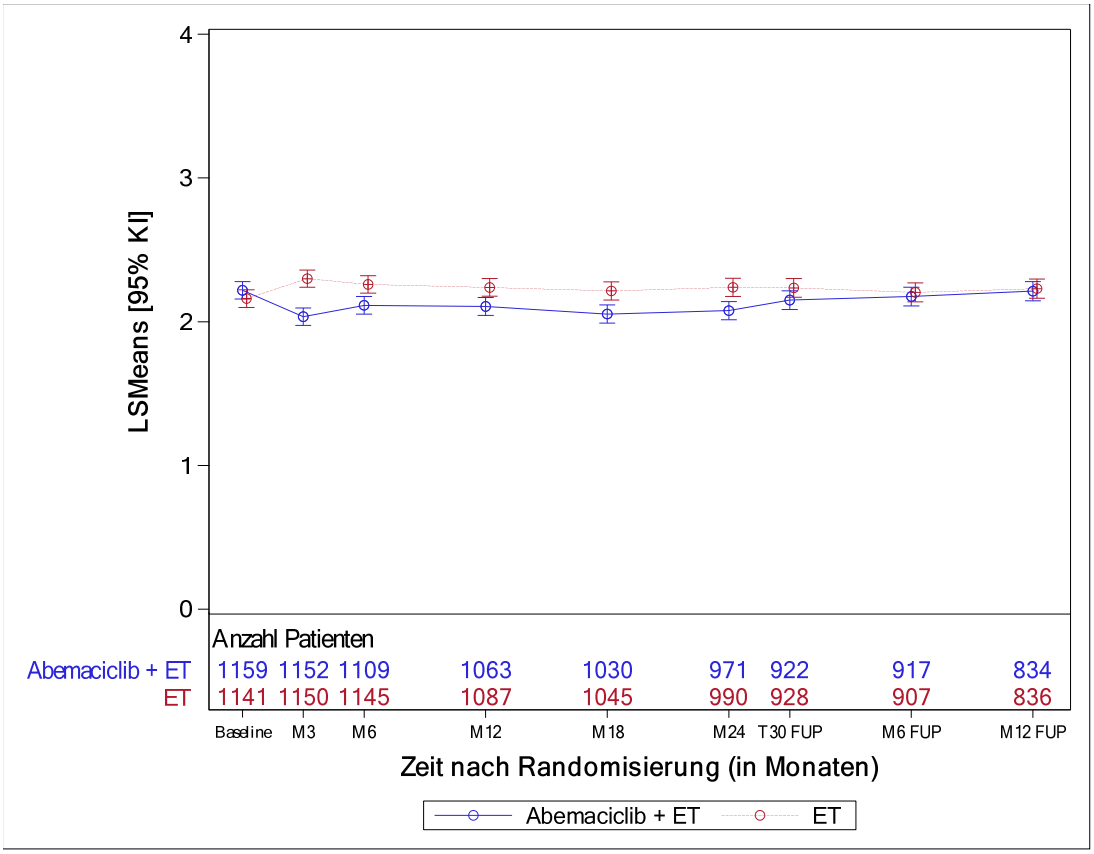
Verlaufskurven - FACIT-Fatigue: I have energy
Kohorte 1 Population - Safety - Postmenopausal



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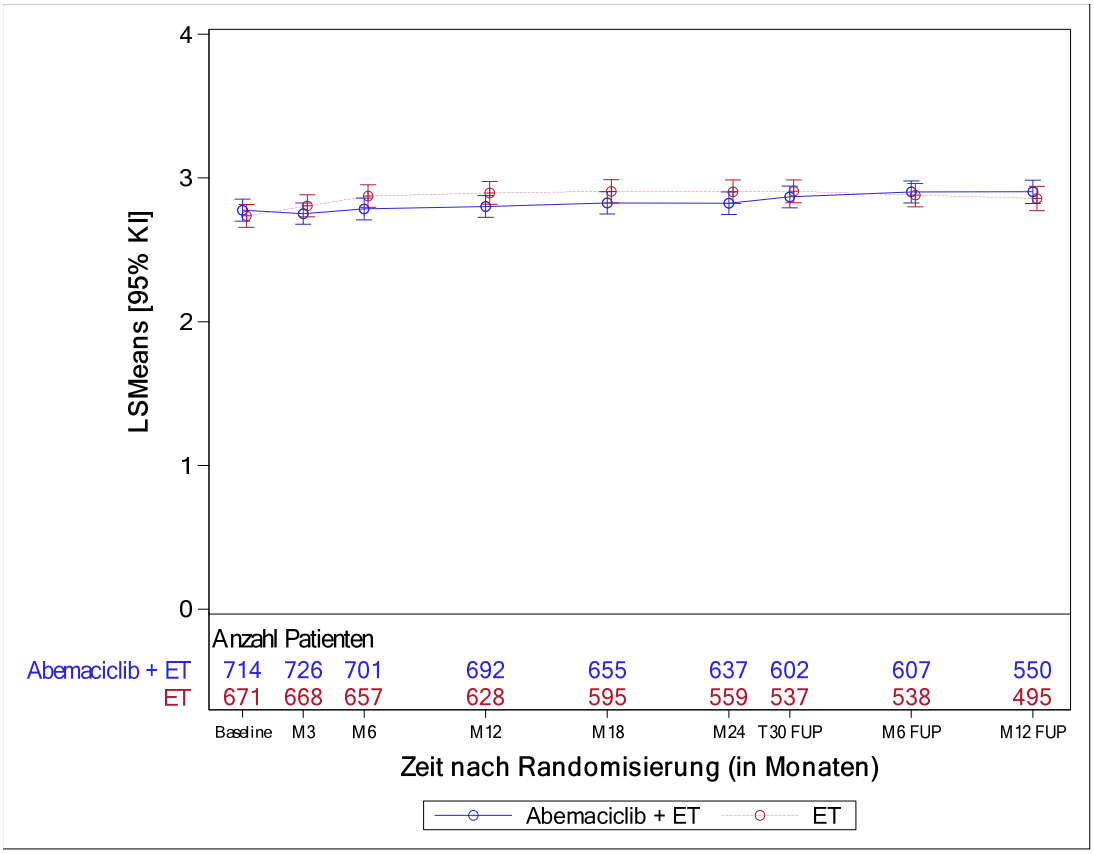
Verlaufskurven - FACIT-Fatigue: I am able to do usual activities
Kohorte 1 Population - Safety - Prämenopausal



Datenschnitt: 01.07.2022
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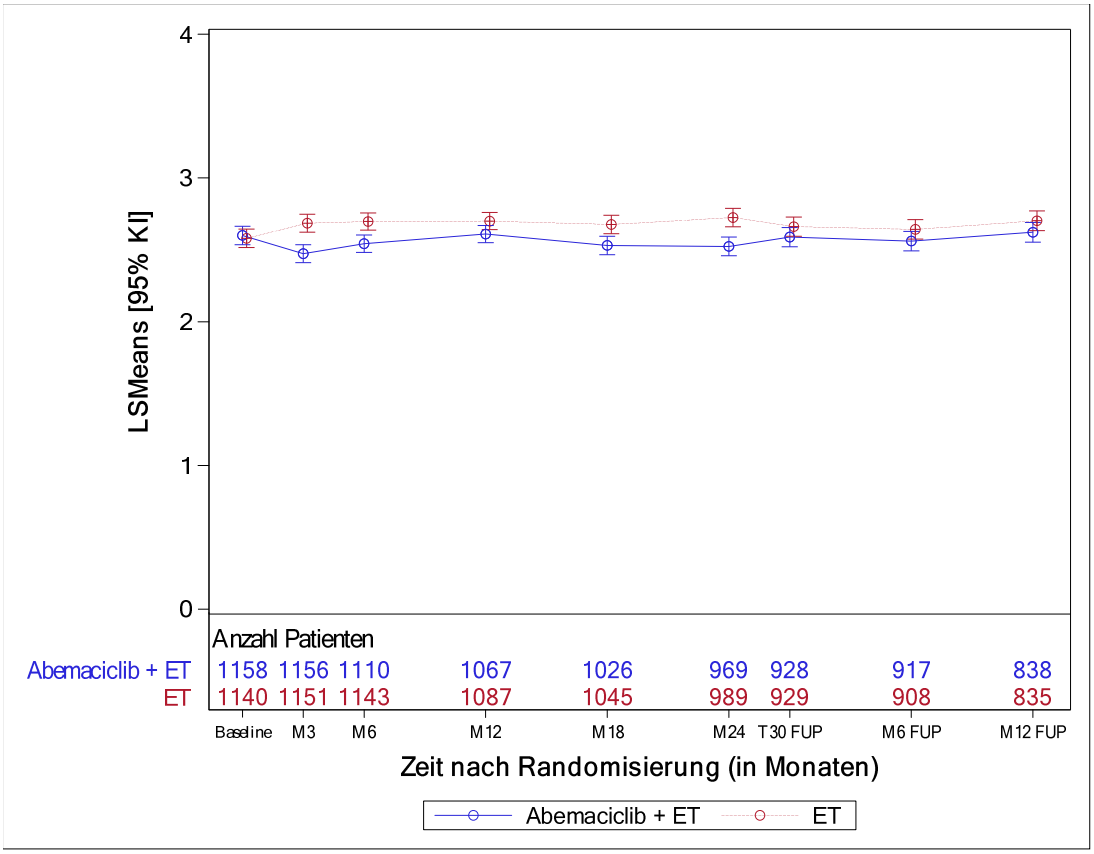
Verlaufskurven - FACIT-Fatigue: I am able to do usual activities
Kohorte 1 Population - Safety - Postmenopausal



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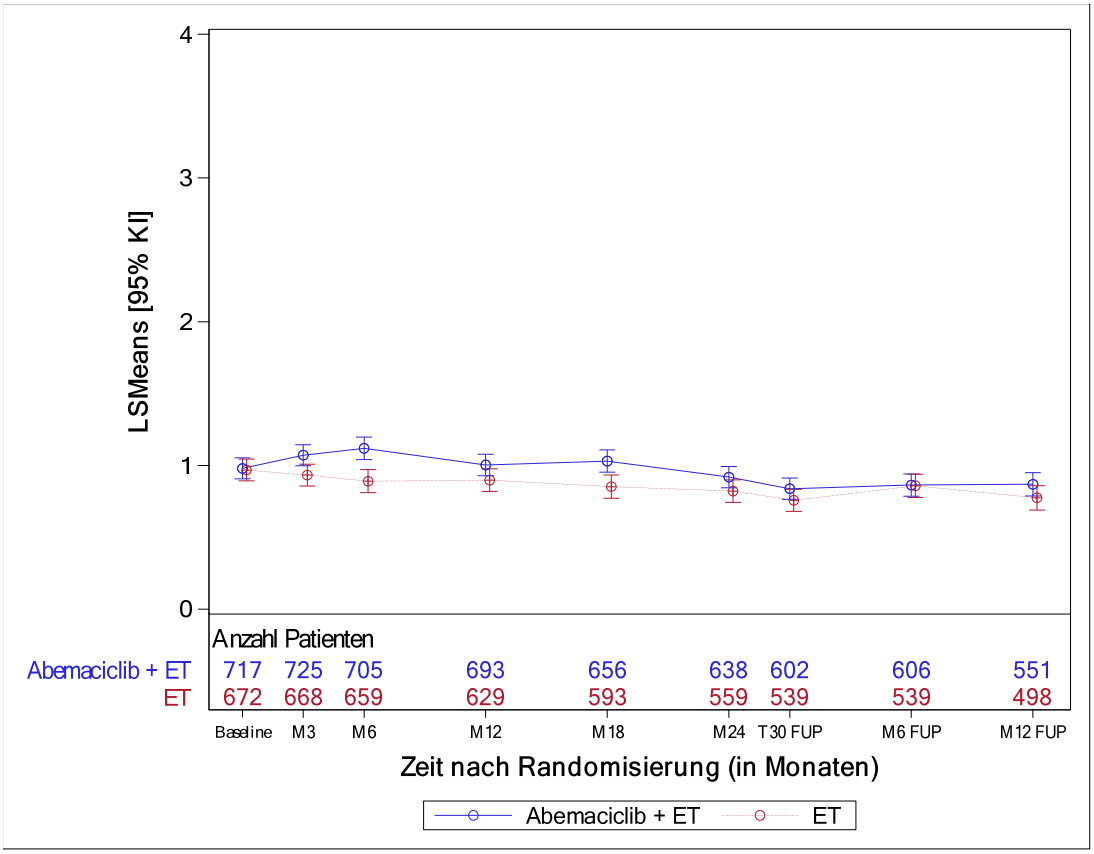
Verlaufskurven - FACIT-Fatigue: I need to sleep during the day
Kohorte 1 Population - Safety - Prämenopausal



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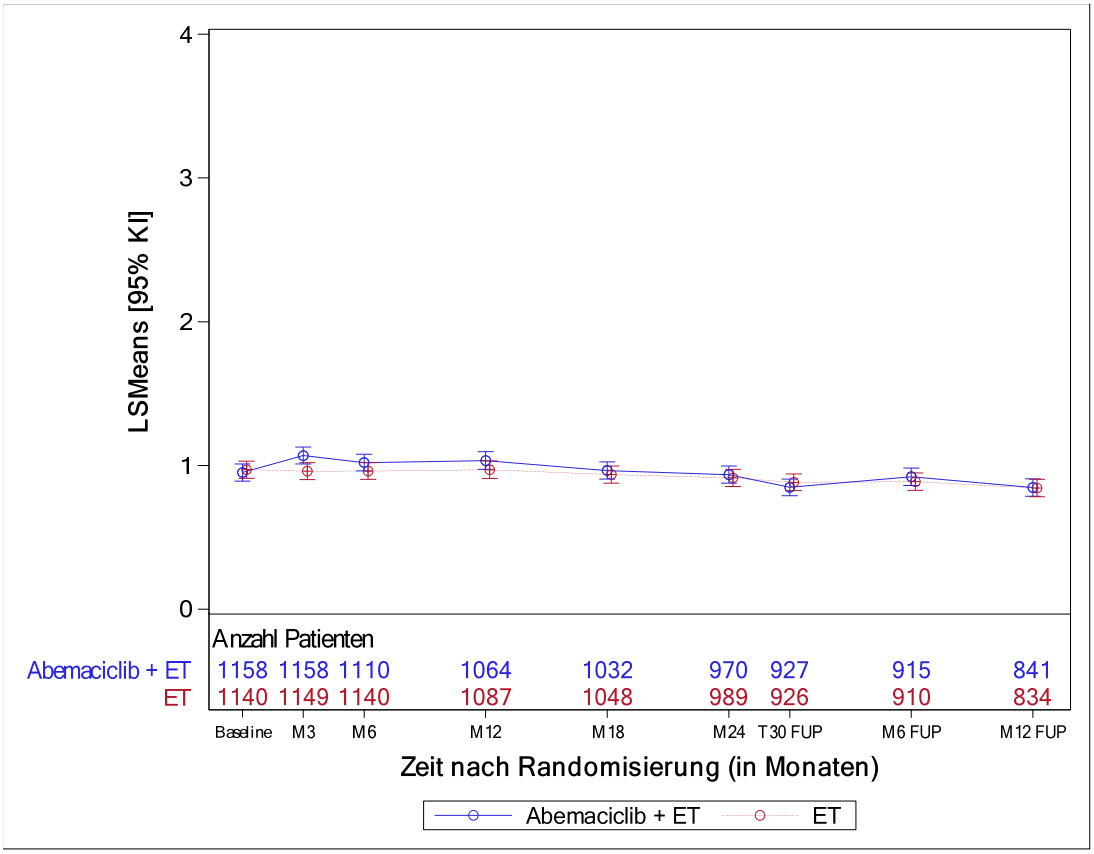
Kohorte 1 Population - Safety - Postmenopausal



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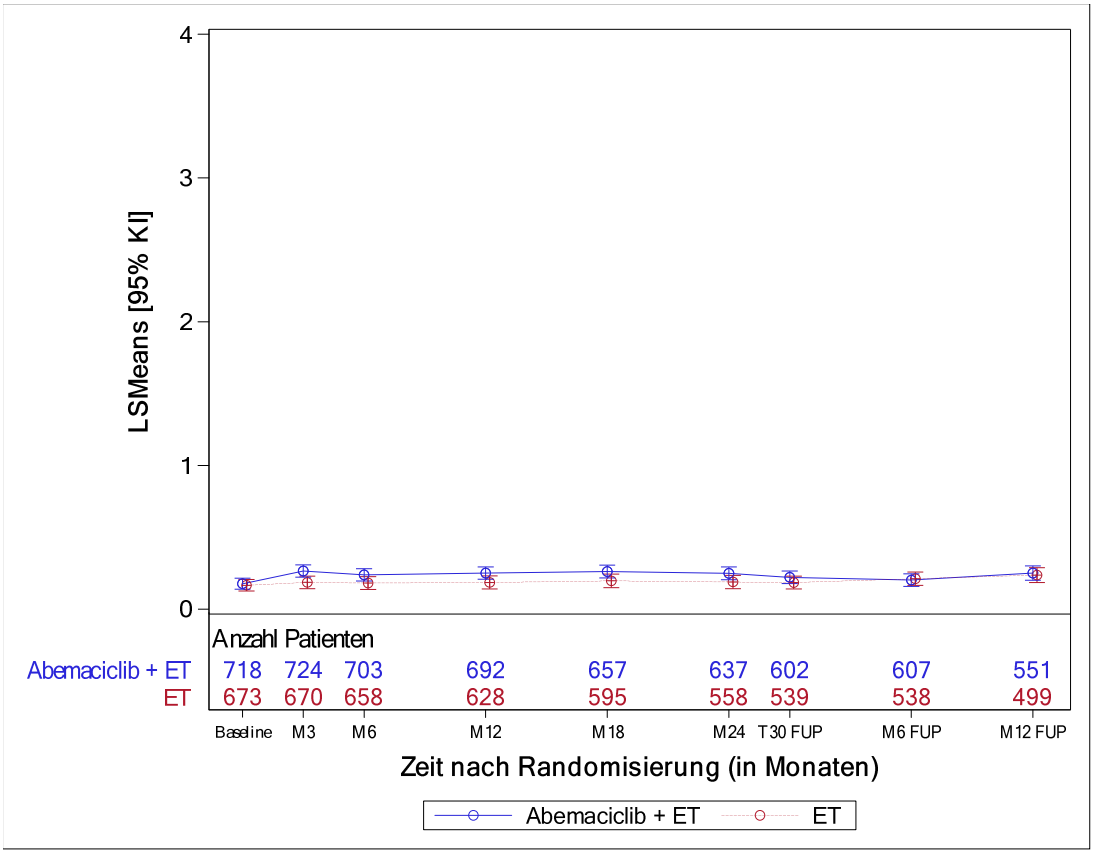
Verlaufskurven - FACIT-Fatigue: I am too tired to eat
Kohorte 1 Population - Safety - Prämenopausal



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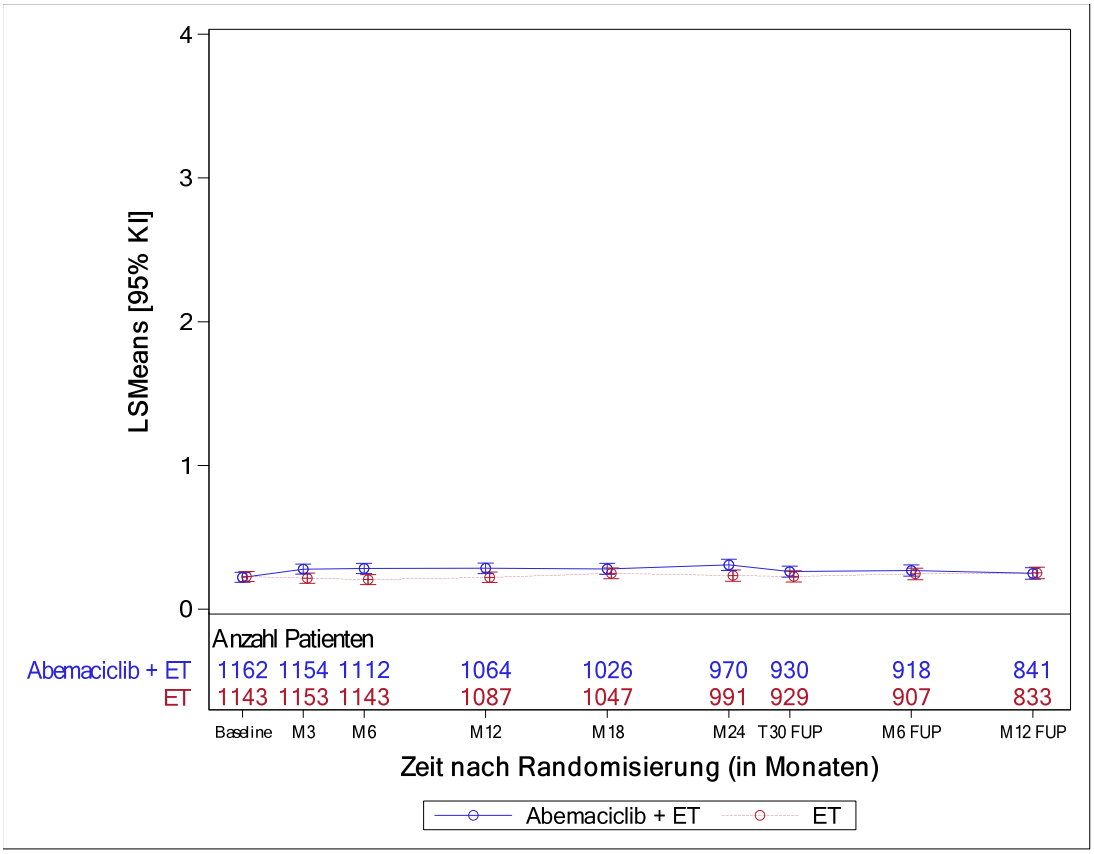
Kohorte 1 Population - Safety - Postmenopausal



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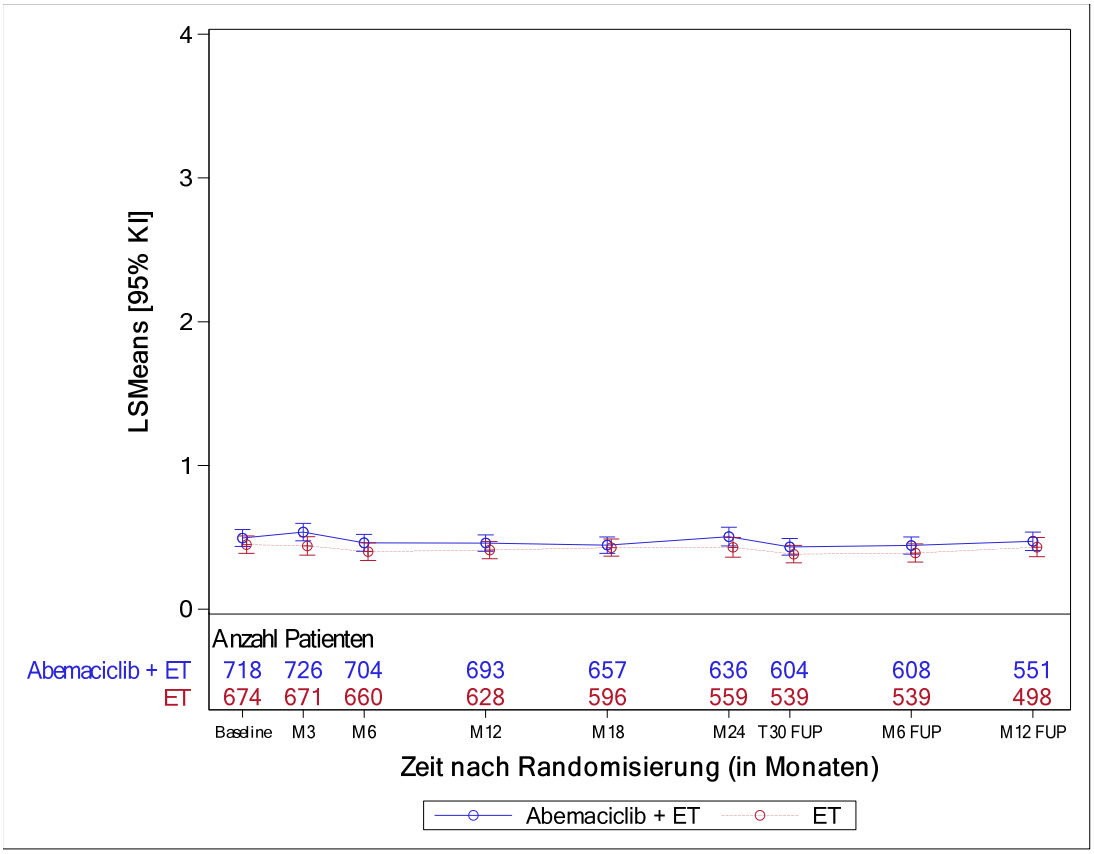
Verlaufskurven - FACIT-Fatigue: I need help doing my usual activities
Kohorte 1 Population - Safety - Prämenopausal



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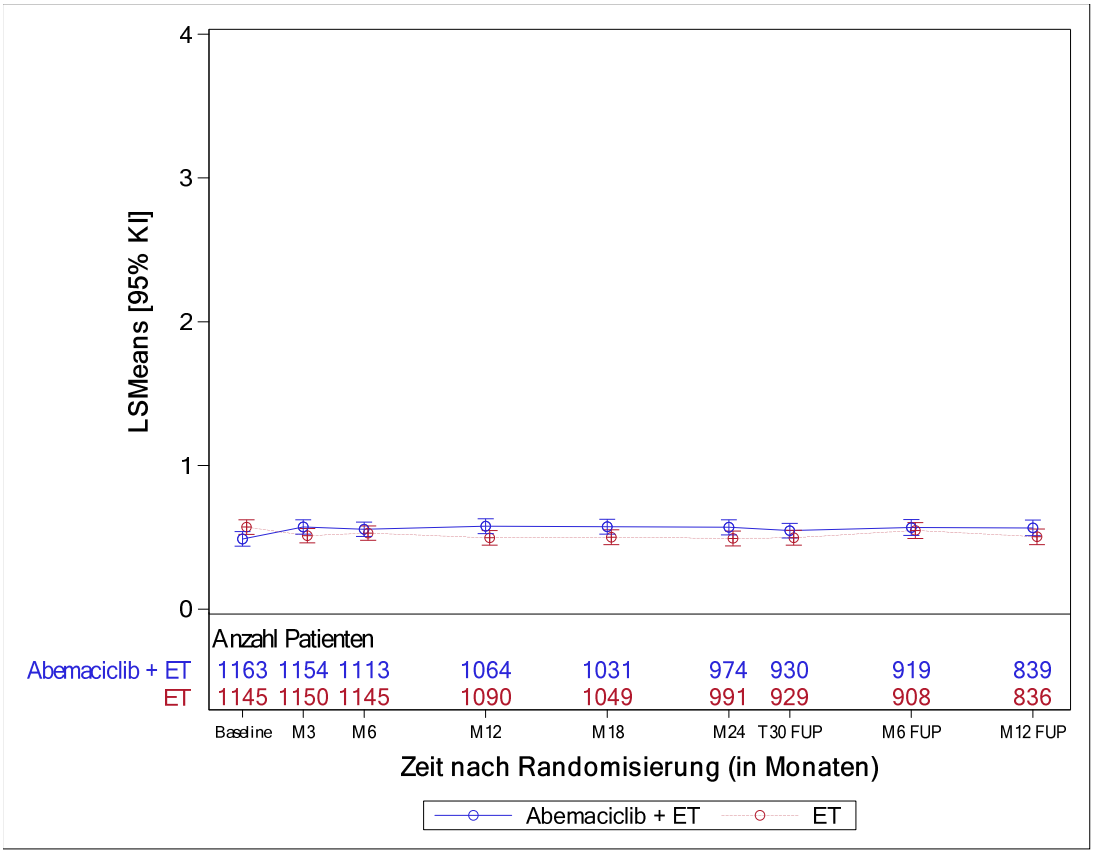

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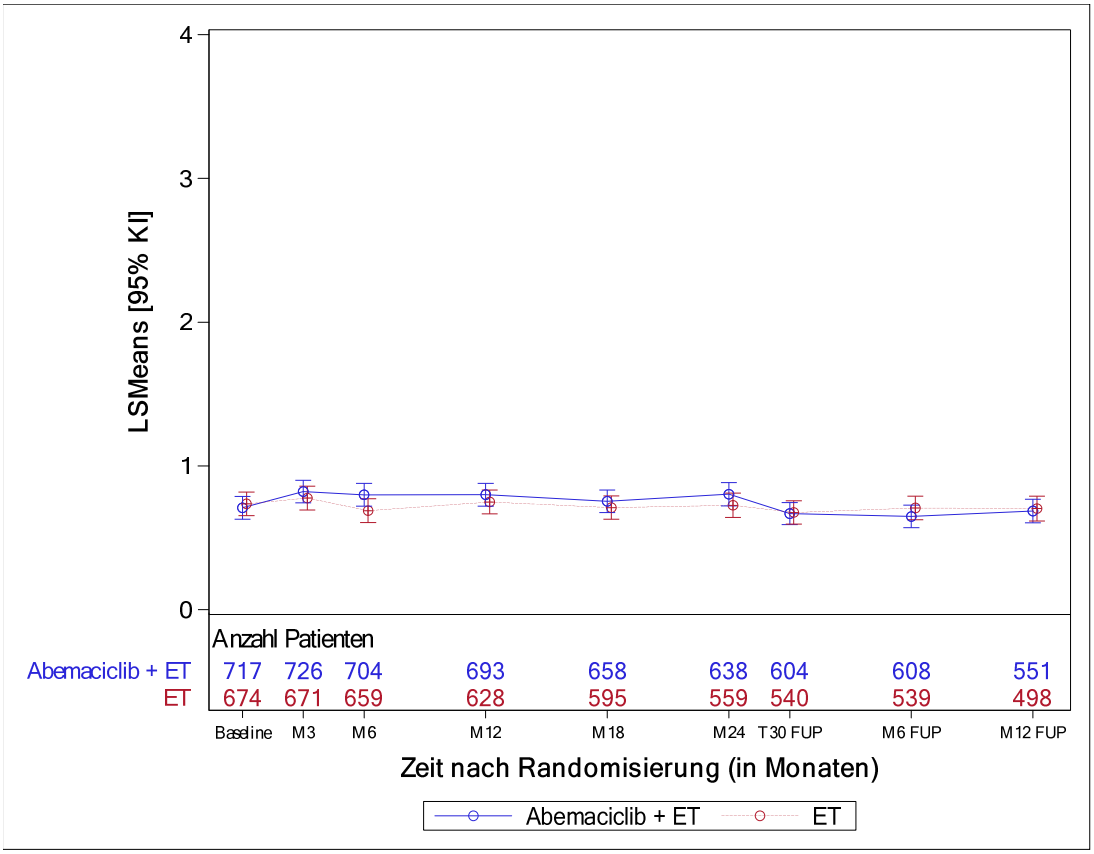
Verlaufskurven - FACIT-Fatigue: I am frustrated by being too tired to do the things I want to do
Kohorte 1 Population - Safety - Prämenopausal



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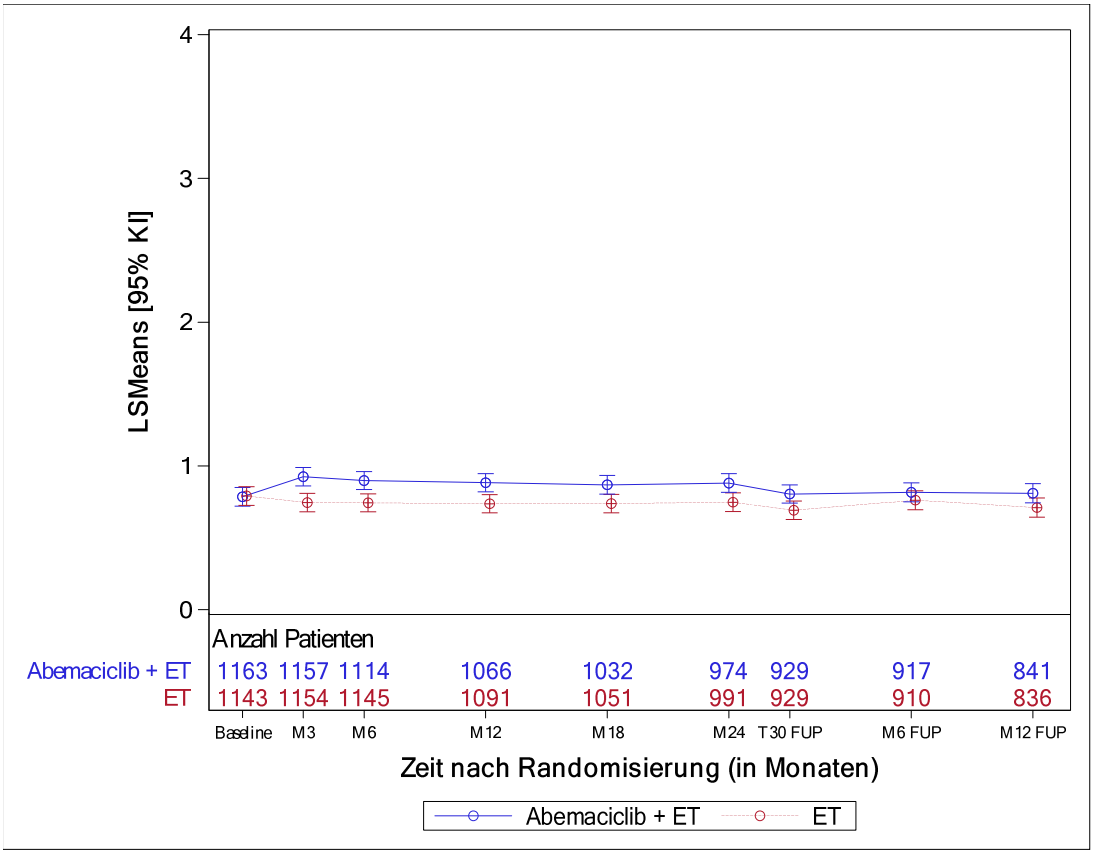

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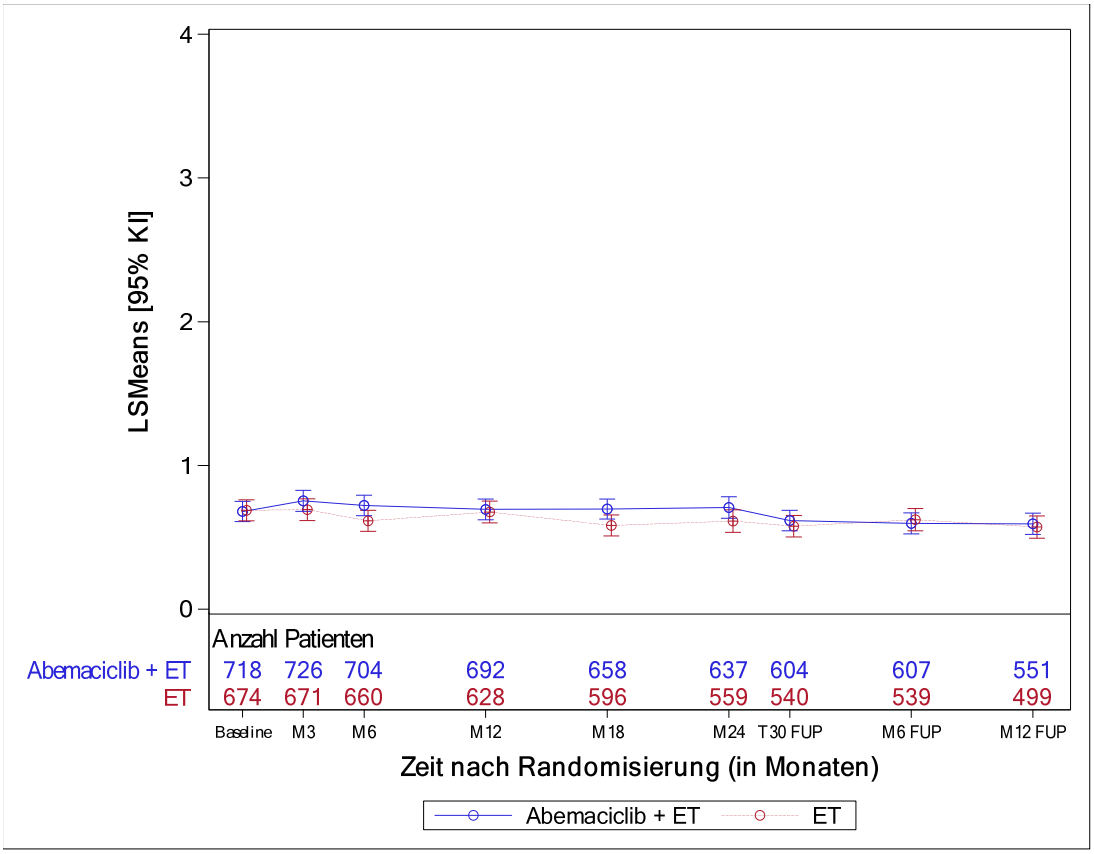

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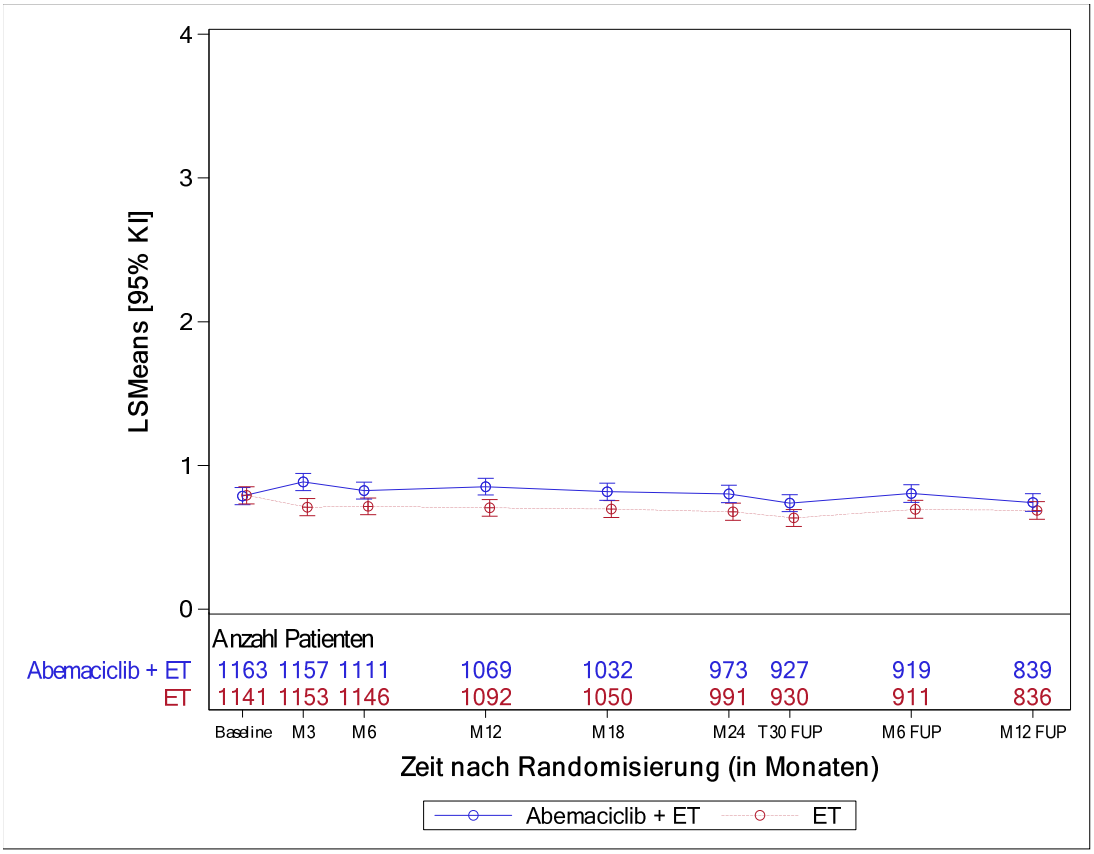
Verlaufskurven - FACIT-Fatigue: I have to limit my social activity because I am tired
Kohorte 1 Population - Safety - Postmenopausal



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Anhang 4-G3.3: Symptomatik anhand des FACT-ES

Anhang 4-G3.3.1: Subgruppenanalysen nicht-interagierender Subgruppen

Tabelle 113.1.2: Subgruppen für die Veränderung des FACT-ES 19 aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,4338)																					
Neoadjuvante Chemotherapie	281 61,17 (9,02)	273 58,34 (10,07)	262 58,01 (11,27)	263 57,41 (11,99)	241 57,13 (11,69)	238 57,66 (12,08)	224 59,15 (11,40)	224 59,54 (10,81)	202 59,79 (11,09)	-3,00 (0,44)	268 59,87 (9,91)	259 58,29 (9,87)	256 58,91 (10,29)	232 58,66 (10,73)	223 58,37 (10,88)	203 58,81 (11,01)	188 59,16 (10,45)	185 58,52 (11,37)	172 58,76 (11,83)	-1,86 (0,46)	-1,14 [-2,39;0,10] 0,0720 -0,15 [-0,32;0,01]
Adjuvante Chemotherapie	407 60,40 (9,45)	400 57,42 (10,55)	391 57,63 (10,99)	385 57,16 (11,11)	373 56,86 (11,78)	362 57,49 (12,29)	343 59,02 (11,05)	347 58,47 (11,87)	317 58,59 (11,98)	-2,68 (0,34)	379 59,96 (9,87)	372 59,36 (9,81)	363 59,08 (9,80)	353 58,82 (10,07)	333 58,46 (10,83)	320 58,28 (11,30)	321 59,64 (11,00)	320 59,25 (11,02)	294 59,23 (11,20)	-1,12 (0,36)	-1,56 [-2,54;-0,59] 0,0017 -0,22 [-0,37;-0,08]
Keine Chemotherapie	7 67,43 (10,53)	7 60,43 (11,72)	6 58,00 (12,46)	6 58,83 (11,62)	6 58,83 (9,39)	6 58,83 (8,84)	6 63,33 (8,33)	5 61,60 (8,38)	4 65,25 (5,12)	-5,28 (2,15)	3 56,00 (6,24)	3 51,67 (3,79)	3 52,00 (1,00)	3 53,67 (5,13)	3 56,00 (4,00)	3 55,33 (10,69)	3 54,00 (5,20)	3 61,33 (7,77)	2 61,50 (7,78)	-1,61 (3,22)	-3,67 [-13,22;5,88] 0,4000 -0,59 [-1,83;0,66]
Region (p-Wert des Interaktionsterms: 0,5671)																					
Nordamerika / Europa	282 59,86 (8,74)	269 56,72 (9,84)	256 56,46 (10,66)	255 56,02 (10,75)	228 55,36 (11,03)	227 56,07 (11,57)	211 57,64 (10,68)	213 58,28 (10,41)	180 58,43 (10,44)	-2,97 (0,40)	256 58,55 (10,43)	245 57,60 (10,25)	235 57,97 (10,27)	210 57,59 (10,94)	198 56,86 (11,49)	189 56,63 (12,11)	180 57,76 (10,98)	181 57,34 (12,04)	165 57,89 (11,69)	-1,21 (0,42)	-1,77 [-2,91;-0,63] 0,0025 -0,26 [-0,43;-0,09]
Asien	233 62,35 (8,88)	232 59,09 (9,84)	229 59,11 (10,55)	227 58,37 (11,47)	223 58,43 (11,67)	217 58,77 (12,14)	216 61,11 (10,83)	212 60,62 (11,53)	210 60,70 (11,81)	-2,83 (0,45)	212 62,35 (8,07)	211 61,29 (8,49)	210 61,01 (9,13)	204 60,90 (9,10)	193 60,77 (9,37)	188 61,26 (9,59)	184 61,36 (10,17)	182 61,19 (9,98)	172 60,75 (10,61)	-1,51 (0,48)	-1,32 [-2,62;-0,02] 0,0459 -0,19 [-0,38;-0,00]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	180 60,20 (10,43)	179 57,83 (11,61)	174 57,99 (12,21)	172 57,70 (12,32)	169 57,26 (12,43)	162 58,04 (12,86)	146 58,29 (11,93)	151 57,40 (12,45)	133 57,49 (12,56)	-2,51 (0,59)	182 58,96 (10,46)	178 57,81 (10,27)	177 57,90 (10,25)	174 57,56 (10,51)	168 57,53 (11,13)	149 57,27 (11,16)	148 59,05 (10,93)	145 58,32 (10,94)	131 58,35 (11,87)	-1,57 (0,58)	-0,94 [-2,57;0,69] 0,2564 -0,12 [-0,33;0,09]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3535)																					
< 20 mm	179 60,82 (8,99)	176 57,92 (9,34)	167 56,94 (10,58)	171 56,01 (11,45)	160 55,79 (11,44)	158 55,54 (12,53)	152 57,49 (11,12)	157 57,60 (11,68)	148 57,84 (11,79)	-3,76 (0,52)	169 58,34 (9,88)	164 57,16 (10,10)	162 57,01 (10,25)	153 56,57 (10,56)	150 56,45 (10,66)	141 57,02 (10,99)	136 57,86 (10,54)	135 56,66 (11,59)	123 57,55 (11,52)	-2,12 (0,53)	-1,64 [-3,11;-0,18] 0,0279 -0,24 [-0,45;-0,03]
≥ 20 bis < 50 mm	326 60,74 (9,46)	316 57,35 (11,41)	314 57,99 (11,46)	307 57,72 (11,56)	290 57,32 (12,30)	282 58,30 (12,41)	265 60,02 (11,29)	266 59,32 (11,54)	239 59,95 (11,93)	-2,51 (0,41)	315 59,87 (10,13)	309 59,17 (9,86)	305 59,44 (10,17)	291 59,10 (10,48)	273 59,13 (11,08)	262 58,91 (11,48)	255 59,93 (11,16)	247 59,68 (11,26)	235 59,31 (11,56)	-0,89 (0,42)	-1,62 [-2,78;-0,46] 0,0062 -0,22 [-0,37;-0,06]
≥ 50 mm	172 60,59 (9,52)	170 58,27 (9,58)	163 57,95 (11,08)	160 57,49 (11,30)	154 57,10 (10,90)	152 57,96 (11,20)	142 58,71 (10,88)	140 59,22 (11,09)	122 58,56 (10,84)	-2,53 (0,50)	158 61,30 (9,20)	153 59,78 (9,42)	147 59,83 (9,05)	136 59,69 (9,22)	130 58,75 (10,18)	116 58,76 (10,75)	114 59,70 (10,06)	119 59,85 (10,08)	104 59,88 (10,94)	-1,90 (0,53)	-0,63 [-2,05;0,80] 0,3854 -0,10 [-0,31;0,12]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,5641)																					
0-3	238 60,68 (9,49)	230 57,32 (10,17)	219 57,37 (10,67)	221 56,40 (11,68)	202 56,61 (11,66)	199 56,75 (12,35)	192 58,35 (11,34)	188 58,56 (11,23)	169 58,50 (11,93)	-3,25 (0,46)	237 59,49 (9,04)	230 58,35 (9,20)	224 58,47 (9,52)	210 57,80 (9,28)	201 57,10 (10,31)	189 57,13 (10,37)	183 58,25 (10,06)	180 58,07 (11,06)	175 57,86 (11,17)	-2,20 (0,46)	-1,05 [-2,33;0,23] 0,1073 -0,15 [-0,33;0,03]
4-9	317 60,01 (9,57)	311 56,97 (10,93)	306 57,04 (11,61)	301 56,81 (11,45)	290 56,19 (11,77)	287 57,24 (12,10)	265 58,77 (11,24)	268 58,45 (12,02)	245 58,74 (11,55)	-2,65 (0,41)	294 59,95 (10,67)	288 59,08 (9,99)	283 59,29 (10,10)	266 59,02 (10,81)	255 59,03 (11,00)	244 59,07 (11,62)	242 59,75 (11,38)	238 59,29 (10,98)	218 59,47 (11,32)	-0,94 (0,43)	-1,71 [-2,88;-0,54] 0,0043 -0,23 [-0,39;-0,07]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 10	140 62,71 (8,12)	139 60,55 (8,93)	134 60,16 (10,30)	132 59,81 (10,82)	128 59,37 (11,42)	120 59,69 (11,87)	116 61,16 (10,51)	120 60,49 (10,37)	109 60,85 (11,21)	-2,59 (0,54)	119 60,61 (9,40)	116 59,48 (10,68)	115 59,19 (10,61)	112 59,77 (10,88)	103 59,42 (11,16)	93 59,61 (11,40)	87 61,02 (10,32)	90 60,09 (11,64)	75 60,73 (12,04)	-0,92 (0,59)	-1,67 [-3,25;-0,10] 0,0368 -0,26 [-0,51;-0,02]
Tumorstadium (p-Wert des Interaktionsterms: 0,2361)																					
IIA	71 59,93 (10,35)	69 57,01 (10,22)	67 55,61 (11,00)	68 53,99 (12,05)	65 53,90 (12,02)	61 53,41 (12,68)	59 54,76 (11,96)	60 55,40 (11,62)	55 56,25 (12,62)	-4,86 (0,78)	69 58,13 (8,87)	67 56,84 (9,13)	66 58,65 (8,63)	60 56,97 (8,80)	58 57,40 (8,71)	55 57,62 (10,29)	56 59,23 (9,93)	51 58,41 (11,19)	50 58,96 (10,58)	-0,93 (0,80)	-3,94 [-6,15;-1,72] 0,0006 -0,60 [-0,93;-0,26]
IIB	65 60,52 (8,92)	63 57,68 (10,86)	59 59,90 (9,23)	61 57,93 (11,40)	52 58,27 (11,06)	55 57,62 (11,69)	54 60,98 (10,65)	53 60,21 (10,56)	51 60,80 (10,58)	-2,29 (0,99)	85 59,64 (9,49)	82 58,66 (9,57)	83 57,89 (9,96)	77 57,31 (10,10)	76 56,51 (10,66)	72 56,38 (10,89)	67 57,75 (10,37)	70 57,54 (11,10)	68 57,07 (10,77)	-3,24 (0,86)	0,95 [-1,63;3,53] 0,4684 0,12 [-0,20;0,44]
IIIA	310 60,14 (9,76)	305 56,93 (10,93)	300 56,83 (11,77)	296 56,82 (11,49)	283 56,55 (11,93)	280 57,50 (12,06)	254 58,90 (11,05)	258 58,57 (12,00)	235 58,59 (11,65)	-2,50 (0,41)	266 59,49 (10,57)	259 58,69 (9,94)	253 59,07 (10,11)	243 59,00 (10,42)	229 58,58 (11,03)	215 58,51 (11,56)	214 59,48 (10,96)	213 59,48 (10,65)	198 58,99 (11,69)	-0,94 (0,45)	-1,56 [-2,75;-0,37] 0,0103 -0,22 [-0,38;-0,05]
IIIB	18 55,78 (12,87)	18 53,56 (12,15)	16 53,81 (11,70)	17 53,59 (13,53)	13 47,77 (9,43)	14 52,43 (14,34)	14 54,36 (13,34)	14 52,43 (11,93)	14 56,07 (12,60)	-3,80 (2,06)	17 65,41 (7,48)	17 65,06 (7,81)	16 64,38 (7,55)	13 62,92 (7,71)	11 63,18 (10,78)	12 64,83 (4,76)	13 61,62 (9,94)	12 62,75 (5,51)	11 62,18 (7,51)	-0,60 (2,17)	-3,20 [-9,50;3,11] 0,3075 -0,35 [-1,01;0,30]
IIIC	227 62,26 (7,82)	221 59,60 (9,10)	213 59,41 (10,33)	208 58,99 (10,87)	203 58,72 (11,24)	193 59,25 (11,87)	189 60,49 (10,71)	189 60,58 (10,47)	165 60,44 (11,38)	-2,66 (0,43)	212 60,66 (9,46)	208 59,35 (10,03)	203 58,91 (10,32)	194 59,14 (10,74)	185 59,01 (11,14)	172 59,12 (11,24)	162 59,95 (11,05)	162 58,90 (12,02)	141 59,94 (11,82)	-1,54 (0,45)	-1,13 [-2,36;0,11] 0,0740 -0,17 [-0,36;0,02]
Tumorgrading (p-Wert des Interaktionsterms: 0,2926)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
G1	59 62,29 (7,64)	58 60,47 (8,15)	54 59,37 (10,14)	54 58,67 (10,37)	55 58,60 (10,44)	53 59,04 (11,42)	51 59,90 (9,36)	53 60,09 (11,05)	47 59,47 (10,79)	-2,01 (0,99)	47 58,32 (10,11)	45 57,53 (9,40)	43 55,51 (10,65)	43 56,02 (10,95)	40 54,90 (12,08)	39 55,92 (11,82)	39 56,54 (11,52)	38 55,53 (12,56)	34 55,85 (12,15)	-2,97 (1,12)	0,95 [-2,04;3,95] 0,5291 0,12 [-0,26;0,51]
G2	311 60,56 (9,31)	304 57,67 (10,14)	297 57,68 (11,09)	295 56,72 (11,58)	280 56,73 (11,67)	275 57,32 (12,22)	257 59,45 (11,01)	257 59,15 (11,32)	234 59,18 (11,48)	-2,74 (0,37)	285 60,55 (10,24)	277 59,86 (10,41)	273 60,40 (9,77)	257 60,08 (10,26)	240 59,46 (10,89)	235 59,47 (11,08)	225 60,24 (10,69)	227 59,92 (11,35)	205 59,88 (11,78)	-0,89 (0,39)	-1,85 [-2,91;-0,80] 0,0006 -0,28 [-0,44;-0,12]
G3	280 60,16 (9,67)	274 57,09 (10,94)	266 57,23 (11,27)	263 57,08 (11,30)	244 56,27 (11,82)	237 56,96 (12,31)	225 57,88 (11,58)	227 57,72 (11,56)	202 58,02 (11,90)	-2,99 (0,45)	280 59,10 (9,58)	275 57,84 (9,43)	271 57,88 (9,98)	252 57,60 (10,17)	246 57,35 (10,54)	219 57,48 (11,05)	215 58,73 (10,77)	210 58,28 (10,83)	199 58,31 (11,06)	-1,67 (0,45)	-1,32 [-2,57;-0,07] 0,0384 -0,18 [-0,34;-0,01]
GX	42 63,88 (8,29)	41 59,85 (10,72)	39 59,56 (11,18)	39 60,38 (12,48)	38 60,61 (12,47)	38 60,84 (11,30)	37 62,51 (11,32)	36 62,72 (10,78)	37 63,92 (10,68)	-3,10 (1,20)	36 63,36 (7,36)	35 61,36 (7,67)	33 60,82 (9,16)	34 60,09 (9,87)	31 63,61 (8,23)	31 61,19 (11,30)	31 62,23 (9,95)	31 61,74 (8,63)	28 62,54 (9,53)	-1,79 (1,30)	-1,31 [-4,83;2,22] 0,4621 -0,17 [-0,61;0,28]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,1735)																					
Negativ	63 58,70 (9,96)	60 55,57 (10,94)	57 55,35 (12,50)	60 54,47 (13,64)	57 53,89 (13,03)	54 53,93 (12,92)	50 53,78 (12,47)	51 55,33 (12,48)	50 56,18 (12,42)	-4,03 (0,92)	53 59,26 (8,87)	52 58,67 (9,30)	51 59,04 (8,94)	44 58,84 (8,29)	43 58,74 (9,05)	39 59,56 (8,93)	40 59,60 (10,00)	37 60,62 (9,79)	36 59,78 (10,50)	0,75 (1,02)	-4,78 [-7,51;-2,06] 0,0007 -0,65 [-1,02;-0,27]
Positiv	610 60,92 (9,31)	598 57,96 (10,38)	583 57,94 (11,00)	575 57,48 (11,31)	547 57,23 (11,63)	537 57,85 (12,15)	506 59,48 (11,00)	510 59,15 (11,39)	461 59,38 (11,58)	-2,74 (0,29)	580 59,99 (9,96)	567 58,97 (9,76)	557 59,04 (10,04)	530 58,68 (10,45)	501 58,32 (10,97)	472 58,43 (11,33)	460 59,45 (10,84)	457 58,95 (11,13)	420 59,05 (11,45)	-1,60 (0,30)	-1,14 [-1,96;-0,33] 0,0059 -0,16 [-0,27;-0,05]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Unbekannt	6 61,67 (5,79)	6 55,17 (10,30)	6 62,17 (8,08)	5 63,40 (4,98)	4 64,75 (4,57)	4 67,25 (1,26)	4 68,25 (1,71)	3 64,67 (4,04)	3 64,00 (6,24)	-0,21 (2,53)	8 57,13 (12,21)	7 52,43 (17,77)	8 55,38 (13,52)	6 57,67 (15,19)	6 59,00 (14,89)	8 52,75 (14,50)	5 54,00 (15,57)	8 54,00 (17,19)	7 53,57 (15,93)	-1,91 (2,04)	1,69 [-5,48;8,86] 0,6188 0,27 [-0,73;1,26]
Ethnizität (p-Wert des Interaktionsterms: 0,6219)																					
Weiß	398 59,56 (9,49)	388 56,54 (10,37)	370 56,34 (11,20)	368 55,92 (11,20)	341 55,45 (11,46)	335 56,30 (11,92)	304 57,30 (11,00)	313 56,94 (11,20)	277 57,70 (10,95)	-3,04 (0,36)	381 58,27 (10,49)	367 57,34 (10,22)	359 57,46 (10,27)	337 57,11 (10,74)	324 56,80 (11,08)	302 56,42 (11,79)	290 57,78 (10,89)	290 57,48 (11,58)	267 57,66 (11,93)	-1,37 (0,37)	-1,67 [-2,68;-0,67] 0,0012 -0,23 [-0,37;-0,09]
Asiatisch	260 62,54 (8,85)	258 59,65 (9,96)	255 59,78 (10,65)	252 59,29 (11,46)	246 59,07 (11,70)	240 59,26 (12,26)	237 61,49 (10,70)	236 61,14 (11,42)	223 60,70 (12,22)	-2,40 (0,43)	228 62,46 (8,19)	227 61,29 (8,62)	224 61,34 (9,15)	219 61,27 (9,20)	203 60,90 (9,60)	195 61,33 (9,62)	193 61,48 (10,18)	189 61,25 (9,96)	177 60,78 (10,62)	-1,41 (0,47)	-0,99 [-2,25;0,26] 0,1201 -0,14 [-0,32;0,04]
Andere	26 61,31 (9,10)	25 58,92 (11,25)	25 58,56 (11,14)	25 56,52 (12,67)	24 57,19 (11,70)	22 58,18 (12,67)	23 58,57 (12,18)	20 60,40 (10,82)	18 59,61 (12,87)	-3,87 (1,50)	29 60,34 (9,31)	28 59,68 (9,73)	28 58,39 (9,96)	27 57,74 (10,05)	25 58,24 (13,49)	22 58,73 (10,43)	22 61,14 (11,81)	23 58,52 (12,42)	18 60,89 (9,36)	-1,67 (1,44)	-2,20 [-6,38;1,98] 0,2952 -0,29 [-0,82;0,25]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,3144)																					
Tamoxifen	492 60,32 (9,58)	481 57,70 (10,41)	462 57,11 (11,26)	462 56,83 (11,44)	433 56,27 (11,64)	424 56,87 (12,04)	400 58,48 (11,15)	405 58,39 (11,47)	363 58,40 (11,46)	-2,82 (0,32)	477 59,84 (9,77)	463 58,71 (9,98)	451 58,94 (9,83)	428 58,79 (10,11)	404 57,94 (10,89)	386 57,89 (11,27)	373 58,87 (10,75)	376 58,48 (11,01)	345 58,49 (11,45)	-1,61 (0,32)	-1,22 [-2,11;-0,33] 0,0072 -0,17 [-0,30;-0,05]
Aromatase-Inhibitor	203 61,90 (8,52)	199 58,13 (10,30)	197 59,37 (10,56)	192 58,35 (11,47)	187 58,62 (11,72)	182 59,18 (12,33)	173 60,58 (11,07)	171 60,15 (11,32)	160 60,70 (11,85)	-2,86 (0,51)	173 60,07 (10,16)	171 59,36 (9,44)	171 59,08 (10,41)	160 58,56 (10,86)	155 59,63 (10,55)	140 60,05 (10,78)	139 60,92 (10,72)	132 60,49 (11,36)	123 60,70 (11,17)	-0,86 (0,56)	-1,99 [-3,49;-0,49] 0,0094 -0,27 [-0,47;-0,07]
ECOG-PS (p-Wert des Interaktionsterms: 0,1921)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
ECOG-PS 0	617 60,56 (9,38)	603 57,51 (10,24)	584 57,30 (11,19)	582 56,76 (11,43)	548 56,48 (11,61)	538 57,12 (12,19)	507 58,69 (11,28)	509 58,44 (11,57)	466 58,68 (11,60)	-3,05 (0,29)	576 60,02 (9,84)	561 58,98 (9,83)	549 59,06 (9,81)	523 58,87 (10,20)	497 58,57 (10,63)	468 58,63 (11,08)	457 59,41 (10,67)	447 59,00 (11,20)	417 59,23 (11,35)	-1,46 (0,30)	-1,58 [-2,39;-0,77] 0,0001 -0,22 [-0,34;-0,11]
ECOG-PS 1	78 62,51 (8,60)	77 60,26 (11,11)	75 61,55 (9,60)	72 61,50 (10,87)	72 60,82 (11,83)	68 61,06 (11,50)	66 62,39 (9,67)	67 62,51 (9,81)	57 62,53 (11,24)	-1,08 (0,81)	74 59,03 (10,07)	73 58,12 (9,89)	73 58,34 (11,28)	65 57,63 (11,17)	62 57,12 (12,22)	58 57,17 (11,87)	55 59,60 (11,66)	61 58,98 (10,68)	51 57,80 (11,92)	-1,04 (0,84)	-0,03 [-2,37;2,30] 0,9776 -0,00 [-0,32;0,31]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-ES 19 Score = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-ES 19 Score haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-ES: Functional Assessment of Cancer Therapy - Endokrine Symptome; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t113_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 113.2.2: Subgruppen für die Veränderung des FACT-ES 19 aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,1227)																					
< 65 Jahre	804 62,73 (9,00)	779 60,34 (9,84)	754 60,23 (10,07)	721 60,11 (10,10)	702 60,02 (10,09)	660 59,71 (10,36)	637 61,18 (9,71)	633 61,25 (9,65)	584 61,31 (9,97)	-2,28 (0,23)	832 61,98 (9,11)	798 61,48 (9,54)	798 60,78 (9,80)	756 60,43 (9,81)	721 60,77 (9,79)	681 60,84 (9,88)	640 61,29 (9,90)	632 61,03 (9,91)	586 60,90 (10,24)	-1,25 (0,22)	-1,03 [-1,65;-0,41] 0,0012 -0,16 [-0,26;-0,06]
≥ 65 Jahre	303 66,28 (7,12)	293 64,36 (7,78)	276 65,39 (7,12)	272 63,88 (7,79)	253 63,58 (8,47)	237 63,63 (8,04)	225 65,24 (7,69)	216 64,59 (7,46)	199 64,45 (8,25)	-2,09 (0,29)	278 66,45 (7,16)	269 65,15 (7,50)	261 65,31 (6,95)	255 64,98 (7,26)	245 64,15 (7,81)	237 64,23 (8,16)	220 64,26 (7,83)	214 64,31 (7,93)	191 64,50 (7,66)	-1,81 (0,30)	-0,27 [-1,09;0,55] 0,5139 -0,05 [-0,22;0,11]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,6277)																					
Neoadjuvante Chemotherapie	363 64,39 (8,63)	344 61,50 (9,60)	329 62,07 (9,45)	317 61,51 (9,47)	297 61,30 (9,74)	271 61,21 (9,96)	260 62,71 (9,11)	254 62,74 (9,06)	234 62,62 (9,28)	-2,37 (0,34)	365 62,72 (9,01)	352 62,21 (9,42)	342 61,34 (9,41)	323 61,11 (9,61)	304 61,49 (9,42)	278 61,46 (9,94)	268 61,78 (10,07)	265 61,61 (9,89)	235 61,60 (9,82)	-1,59 (0,33)	-0,79 [-1,72;0,14] 0,0974 -0,12 [-0,27;0,02]
Adjuvante Chemotherapie	685 63,20 (8,78)	672 61,30 (9,46)	649 61,14 (9,83)	621 60,82 (9,78)	607 60,61 (9,92)	582 60,40 (10,01)	558 61,80 (9,65)	555 61,61 (9,35)	512 61,74 (9,81)	-2,09 (0,23)	679 63,08 (8,66)	652 62,22 (8,97)	656 61,88 (9,34)	632 61,52 (9,30)	613 61,40 (9,52)	592 61,51 (9,49)	548 61,84 (9,28)	539 61,76 (9,48)	509 61,70 (9,92)	-1,38 (0,23)	-0,71 [-1,36;-0,07] 0,0301 -0,12 [-0,22;-0,01]
Keine Chemotherapie	59 65,27 (7,14)	56 62,62 (9,34)	52 64,69 (7,85)	55 62,69 (9,47)	51 63,18 (8,78)	44 62,41 (8,95)	44 64,95 (6,87)	40 64,78 (8,64)	37 63,97 (9,62)	-2,50 (0,60)	66 65,45 (9,92)	63 65,37 (9,99)	61 65,16 (9,15)	56 64,95 (9,48)	49 65,37 (7,86)	48 65,83 (7,47)	44 66,32 (7,59)	42 64,83 (7,73)	33 64,33 (6,94)	-0,74 (0,58)	-1,76 [-3,42;-0,09] 0,0386 -0,37 [-0,73;-0,02]
Region (p-Wert des Interaktionsterms: 0,2694)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	548 63,01 (8,96)	518 60,07 (10,09)	491 60,47 (9,85)	469 60,27 (9,85)	443 59,69 (10,22)	411 59,52 (10,46)	396 60,92 (9,73)	390 60,96 (9,45)	356 60,70 (9,67)	-2,85 (0,25)	528 62,03 (9,21)	492 61,09 (9,83)	489 60,43 (9,73)	453 60,14 (9,82)	435 59,99 (9,89)	417 60,19 (9,85)	383 60,33 (9,91)	386 60,49 (9,95)	344 60,08 (10,24)	-1,88 (0,26)	-0,98 [-1,69;-0,27] 0,0066 -0,17 [-0,29;-0,05]
Asien	195 65,93 (7,17)	194 63,87 (8,11)	188 62,79 (9,50)	187 62,35 (9,38)	182 62,26 (9,45)	171 61,77 (9,80)	171 63,64 (9,28)	168 63,39 (9,08)	157 63,69 (9,20)	-2,85 (0,43)	193 65,80 (7,38)	192 65,03 (8,04)	188 64,95 (7,96)	185 63,92 (8,83)	181 64,35 (8,13)	175 64,42 (8,43)	173 65,01 (7,92)	169 64,27 (8,32)	164 64,31 (8,43)	-1,25 (0,43)	-1,59 [-2,79;-0,39] 0,0094 -0,26 [-0,46;-0,07]
Andere	364 63,56 (8,79)	360 62,09 (8,98)	351 62,59 (9,27)	337 61,69 (9,47)	330 61,95 (9,26)	315 61,78 (9,17)	295 63,19 (8,77)	291 62,88 (8,94)	270 63,04 (9,67)	-0,90 (0,32)	389 63,21 (8,81)	383 62,78 (8,61)	382 62,27 (9,20)	373 62,16 (8,97)	350 62,27 (9,13)	326 62,22 (9,45)	304 62,54 (9,35)	291 62,28 (9,38)	269 62,42 (9,58)	-0,76 (0,31)	-0,14 [-1,02;0,74] 0,7523 -0,02 [-0,17;0,12]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3305)																					
< 20 mm	280 62,41 (9,24)	267 60,41 (9,93)	257 60,24 (10,45)	253 59,93 (10,41)	242 59,65 (10,38)	233 59,66 (10,82)	230 61,52 (9,80)	220 61,24 (9,28)	208 61,19 (10,07)	-2,32 (0,36)	297 62,95 (9,11)	286 62,32 (9,47)	283 62,49 (9,47)	269 61,91 (9,98)	260 61,69 (10,04)	240 61,88 (10,08)	231 62,35 (10,18)	222 61,81 (9,50)	207 60,72 (10,75)	-1,05 (0,35)	-1,27 [-2,27;-0,27] 0,0126 -0,21 [-0,37;-0,04]
≥ 20 bis < 50 mm	569 63,90 (8,68)	559 61,71 (9,44)	530 61,98 (9,79)	516 61,43 (9,62)	492 61,40 (9,71)	465 61,26 (9,91)	449 62,60 (9,54)	438 62,38 (9,55)	402 62,22 (9,91)	-2,04 (0,26)	572 63,06 (8,66)	552 62,41 (9,23)	548 61,99 (9,12)	526 61,50 (9,52)	503 61,72 (9,32)	492 61,56 (9,62)	446 61,98 (9,50)	451 62,08 (9,51)	420 62,30 (9,69)	-1,33 (0,26)	-0,70 [-1,42;0,01] 0,0539 -0,11 [-0,23;0,00]
≥ 50 mm	241 64,54 (7,96)	230 61,72 (9,21)	227 62,19 (8,32)	211 61,73 (8,75)	206 61,35 (9,45)	185 60,58 (8,97)	169 62,07 (8,50)	178 62,42 (8,56)	160 62,66 (8,48)	-2,38 (0,39)	230 63,13 (9,16)	218 62,18 (8,87)	218 60,66 (9,94)	205 61,10 (8,57)	195 61,12 (9,02)	177 61,63 (8,81)	174 61,61 (8,62)	164 61,09 (9,78)	142 61,54 (8,51)	-2,11 (0,40)	-0,27 [-1,37;0,83] 0,6308 -0,04 [-0,23;0,14]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,9305)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	368 63,01 (9,27)	358 60,32 (9,98)	343 61,02 (9,93)	323 60,95 (9,53)	320 60,45 (10,14)	297 60,21 (10,04)	286 61,41 (9,46)	282 61,43 (9,47)	259 61,86 (9,53)	-2,13 (0,32)	359 62,77 (8,67)	343 61,91 (9,00)	345 61,39 (9,01)	326 61,44 (9,04)	314 61,73 (8,96)	294 61,34 (8,98)	279 61,63 (9,29)	267 61,42 (10,06)	246 60,97 (9,50)	-1,37 (0,32)	-0,77 [-1,66;0,12] 0,0898 -0,13 [-0,27;0,02]
4-9	475 63,82 (8,58)	458 61,77 (9,37)	444 61,55 (9,80)	434 60,99 (9,91)	412 61,17 (9,79)	386 60,68 (10,36)	374 62,34 (9,56)	372 62,43 (9,28)	350 62,29 (9,96)	-2,32 (0,29)	487 63,05 (9,17)	469 62,39 (9,58)	469 61,89 (9,81)	446 61,58 (10,07)	430 61,39 (10,09)	418 61,79 (10,06)	387 62,31 (10,00)	386 62,28 (9,26)	359 62,13 (10,12)	-1,34 (0,28)	-0,98 [-1,77;-0,19] 0,0156 -0,16 [-0,28;-0,03]
≥ 10	264 64,46 (7,90)	256 62,39 (8,87)	243 62,59 (8,87)	236 61,70 (9,41)	223 61,32 (9,39)	214 61,60 (9,01)	202 63,22 (8,89)	195 62,44 (8,89)	174 62,10 (9,25)	-2,19 (0,36)	264 63,64 (8,60)	255 63,09 (8,76)	245 62,61 (9,05)	239 61,74 (8,76)	222 61,96 (8,82)	206 62,12 (9,41)	194 62,14 (8,77)	193 61,63 (9,41)	172 62,22 (9,44)	-1,58 (0,36)	-0,61 [-1,61;0,39] 0,2310 -0,10 [-0,28;0,07]
Tumorstadium (p-Wert des Interaktionsterms: 0,6292)																					
IIA	93 61,16 (9,68)	91 59,68 (10,06)	87 59,45 (10,44)	83 58,99 (10,69)	83 58,16 (10,83)	80 58,60 (10,73)	79 60,13 (10,17)	72 60,18 (9,93)	67 60,85 (9,57)	-1,74 (0,60)	95 61,71 (9,10)	92 61,44 (9,06)	89 61,17 (9,23)	87 61,76 (8,50)	81 61,72 (8,59)	81 61,10 (8,49)	78 61,29 (9,26)	73 60,49 (9,60)	66 60,41 (9,73)	-0,43 (0,59)	-1,31 [-2,97;0,35] 0,1205 -0,23 [-0,51;0,06]
IIB	133 63,57 (9,85)	129 60,80 (10,59)	122 62,10 (9,96)	120 61,48 (9,71)	118 61,55 (10,14)	109 60,41 (10,73)	103 62,08 (9,71)	104 61,95 (9,82)	97 62,28 (9,79)	-2,32 (0,55)	112 64,02 (7,98)	106 62,01 (9,66)	106 62,13 (8,50)	101 60,38 (10,42)	95 61,14 (9,13)	96 60,85 (9,64)	91 61,01 (9,88)	87 60,77 (10,61)	82 60,55 (10,27)	-2,99 (0,60)	0,67 [-0,94;2,27] 0,4162 0,10 [-0,15;0,36]
IIIA	430 63,59 (8,55)	417 61,60 (9,32)	402 61,40 (9,66)	390 60,72 (9,87)	368 60,98 (9,75)	343 60,62 (10,16)	329 61,95 (9,49)	338 61,71 (9,60)	310 61,85 (10,17)	-2,21 (0,30)	437 63,09 (8,72)	417 62,45 (8,98)	425 61,76 (9,58)	401 61,70 (9,28)	388 61,51 (9,44)	372 61,94 (9,48)	346 62,51 (9,45)	342 61,99 (8,98)	318 62,06 (9,45)	-1,26 (0,30)	-0,95 [-1,79;-0,11] 0,0263 -0,15 [-0,28;-0,02]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIIB	47 64,96 (10,05)	45 63,11 (10,64)	45 63,44 (11,04)	44 62,55 (10,11)	43 63,33 (9,63)	39 62,21 (11,47)	36 63,56 (10,10)	33 65,94 (6,98)	35 64,29 (9,07)	-1,82 (0,74)	41 64,63 (9,34)	40 64,28 (9,26)	40 63,35 (9,05)	36 64,78 (9,00)	35 64,03 (8,95)	33 63,70 (7,55)	31 65,03 (7,17)	29 65,48 (6,53)	28 65,14 (8,35)	-0,92 (0,79)	-0,90 [-3,05;1,25] 0,4084 -0,18 [-0,60;0,24]
IIIC	402 64,27 (7,87)	389 61,67 (8,99)	372 61,97 (9,12)	354 61,80 (9,06)	341 61,11 (9,47)	324 61,30 (9,02)	313 62,93 (8,84)	300 62,58 (8,60)	272 62,31 (9,09)	-2,35 (0,30)	423 63,01 (9,15)	410 62,50 (9,37)	397 61,98 (9,50)	384 61,45 (9,56)	365 61,66 (9,77)	334 61,67 (10,11)	313 61,76 (9,67)	313 62,02 (10,00)	281 61,82 (10,12)	-1,36 (0,29)	-0,99 [-1,82;-0,17] 0,0184 -0,16 [-0,30;-0,03]
Tumorgrading (p-Wert des Interaktionsterms: 0,8714)																					
G1	82 62,76 (8,80)	80 62,51 (9,07)	82 61,05 (10,57)	75 61,53 (9,47)	73 60,64 (10,60)	71 60,86 (8,97)	68 62,31 (9,10)	67 61,88 (10,00)	61 62,02 (10,07)	-1,44 (0,69)	84 64,58 (8,46)	83 64,43 (8,40)	81 63,86 (7,96)	75 62,85 (9,00)	77 63,06 (8,94)	71 63,62 (8,51)	66 63,39 (8,30)	67 63,52 (7,89)	59 62,78 (8,87)	-0,99 (0,68)	-0,45 [-2,36;1,46] 0,6401 -0,07 [-0,38;0,23]
G2	525 63,95 (8,44)	509 61,32 (9,56)	487 61,66 (9,63)	467 60,99 (9,72)	446 60,96 (9,59)	418 60,91 (9,92)	394 62,48 (9,36)	402 62,10 (9,29)	368 62,12 (9,64)	-2,37 (0,27)	533 62,35 (9,09)	508 61,81 (9,24)	507 60,95 (9,72)	491 60,76 (9,69)	463 60,80 (9,71)	441 60,94 (9,67)	412 61,56 (9,53)	409 61,26 (9,43)	380 61,34 (9,61)	-1,58 (0,26)	-0,79 [-1,53;-0,05] 0,0364 -0,13 [-0,25;-0,01]
G3	451 63,55 (8,97)	436 61,35 (9,56)	415 61,65 (9,46)	404 61,17 (9,51)	392 60,86 (9,93)	366 60,47 (10,13)	361 61,80 (9,67)	339 61,93 (9,25)	321 61,98 (9,61)	-2,15 (0,29)	435 63,23 (8,74)	418 62,24 (9,18)	414 62,07 (9,32)	391 61,81 (9,29)	375 61,90 (9,26)	359 61,73 (9,76)	338 62,09 (9,82)	326 61,97 (10,14)	301 61,84 (10,37)	-1,27 (0,30)	-0,87 [-1,69;-0,05] 0,0373 -0,14 [-0,27;-0,01]
GX	47 64,60 (7,70)	45 62,24 (8,50)	44 62,55 (9,70)	45 62,64 (10,15)	42 63,50 (8,70)	40 62,53 (9,05)	37 64,41 (6,65)	39 64,36 (7,51)	32 63,38 (9,93)	-2,03 (0,72)	54 67,24 (6,69)	54 66,07 (9,10)	53 66,64 (6,36)	50 65,76 (7,44)	48 65,11 (8,05)	44 66,11 (7,24)	42 64,14 (8,15)	41 64,07 (7,90)	34 64,12 (7,88)	-1,63 (0,67)	-0,39 [-2,37;1,58] 0,6933 -0,08 [-0,47;0,31]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,2326)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Negativ	137 63,61 (8,70)	134 61,22 (9,42)	127 61,15 (10,41)	124 60,60 (9,90)	117 61,22 (9,53)	105 60,90 (9,78)	98 62,77 (9,12)	102 62,22 (9,15)	90 61,42 (8,53)	-2,30 (0,46)	148 63,52 (8,54)	142 63,26 (9,33)	140 62,60 (9,03)	134 61,81 (9,25)	125 61,92 (9,58)	116 61,86 (9,32)	105 61,48 (9,26)	102 61,80 (8,75)	91 62,43 (9,24)	-1,37 (0,45)	-0,93 [-2,19;0,34] 0,1521 -0,17 [-0,40;0,06]
Positiv	939 63,60 (8,70)	907 61,30 (9,50)	872 61,51 (9,58)	844 61,04 (9,65)	814 60,79 (9,89)	767 60,53 (9,96)	738 62,02 (9,48)	723 62,01 (9,28)	672 62,08 (9,81)	-2,25 (0,20)	935 63,02 (8,92)	901 62,27 (9,15)	895 61,77 (9,43)	854 61,52 (9,43)	819 61,58 (9,42)	780 61,69 (9,64)	735 62,15 (9,54)	722 61,85 (9,67)	665 61,74 (9,81)	-1,40 (0,20)	-0,85 [-1,41;-0,29] 0,0032 -0,14 [-0,23;-0,05]
Unbekannt	9 67,00 (5,39)	9 62,44 (12,05)	9 66,00 (7,62)	7 70,29 (4,86)	5 70,20 (5,81)	7 67,71 (8,96)	8 68,88 (4,73)	7 68,14 (5,21)	5 70,80 (5,81)	1,05 (1,59)	7 63,86 (9,39)	6 69,00 (6,57)	6 64,17 (7,68)	6 67,67 (4,32)	6 66,00 (4,38)	6 65,83 (7,03)	5 66,00 (5,79)	6 67,67 (5,16)	5 65,80 (3,77)	2,70 (1,79)	-1,66 [-6,94;3,63] 0,5069 -0,33 [-1,27;0,61]
Ethnizität (p-Wert des Interaktionsterms: 0,2566)																					
Weiß	808 62,88 (8,94)	777 60,45 (9,64)	752 60,96 (9,50)	721 60,48 (9,58)	692 60,06 (9,79)	645 60,07 (9,83)	612 61,35 (9,35)	605 61,39 (9,13)	561 61,24 (9,55)	-2,25 (0,21)	818 62,52 (9,00)	778 61,73 (9,31)	776 61,16 (9,45)	733 60,68 (9,57)	699 60,77 (9,55)	667 60,98 (9,71)	613 61,10 (9,75)	610 61,03 (9,66)	546 60,79 (9,88)	-1,51 (0,21)	-0,74 [-1,31;-0,16] 0,0126 -0,12 [-0,22;-0,03]
Asiatisch	233 66,32 (7,34)	231 64,56 (8,22)	221 63,78 (9,57)	219 63,44 (9,39)	214 63,45 (9,45)	200 62,69 (9,79)	199 64,22 (9,06)	197 63,97 (9,00)	179 64,39 (9,08)	-2,29 (0,41)	222 65,40 (7,64)	220 65,00 (8,03)	216 65,03 (8,14)	214 64,33 (8,75)	206 64,66 (8,19)	194 64,51 (8,45)	192 65,04 (8,01)	186 64,32 (8,73)	182 64,49 (8,68)	-0,82 (0,42)	-1,48 [-2,63;-0,32] 0,0121 -0,24 [-0,42;-0,05]
Andere	54 65,17 (7,30)	52 63,42 (8,78)	48 62,60 (9,77)	45 62,13 (8,89)	43 63,65 (8,79)	42 62,67 (9,13)	44 65,55 (7,59)	39 63,59 (10,87)	35 65,17 (10,44)	-0,87 (0,97)	57 63,18 (9,99)	57 62,09 (10,73)	55 61,11 (10,72)	52 62,90 (8,87)	50 61,06 (10,82)	46 61,02 (10,16)	45 63,40 (9,43)	40 62,70 (9,78)	40 63,75 (10,84)	-2,17 (0,94)	1,30 [-1,39;3,99] 0,3400 0,18 [-0,19;0,56]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,6347)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Tamoxifen	104 61,16 (8,79)	101 58,89 (9,73)	100 59,15 (10,18)	98 58,94 (10,23)	97 57,81 (11,57)	95 57,40 (11,62)	90 59,18 (11,10)	89 58,96 (10,59)	90 59,71 (11,26)	-2,36 (0,64)	124 61,55 (8,86)	123 61,31 (9,09)	122 60,02 (9,66)	117 60,09 (10,16)	109 60,00 (8,72)	98 60,60 (10,14)	94 60,89 (9,27)	91 61,04 (9,45)	89 60,85 (11,22)	-1,04 (0,59)	-1,32 [-3,03;0,40] 0,1312 -0,20 [-0,46;0,06]
Aromatase-Inhibitor	1003 63,97 (8,62)	971 61,70 (9,43)	930 61,88 (9,55)	895 61,38 (9,58)	858 61,32 (9,54)	802 61,14 (9,67)	772 62,59 (9,11)	760 62,47 (9,02)	693 62,42 (9,39)	-2,20 (0,19)	986 63,29 (8,86)	944 62,55 (9,22)	937 62,14 (9,33)	894 61,77 (9,33)	857 61,84 (9,52)	820 61,85 (9,50)	766 62,19 (9,52)	755 61,96 (9,56)	688 61,90 (9,59)	-1,45 (0,19)	-0,75 [-1,28;-0,22] 0,0056 -0,12 [-0,21;-0,04]
ECOG-PS (p-Wert des Interaktionsterms: 0,6068)																					
ECOG-PS 0	933 63,71 (8,67)	903 61,50 (9,52)	869 61,46 (9,74)	846 60,96 (9,76)	813 60,89 (9,83)	768 60,82 (9,93)	736 62,22 (9,37)	729 62,21 (9,24)	677 62,07 (9,75)	-2,31 (0,20)	898 63,32 (8,71)	862 62,48 (9,09)	858 61,88 (9,33)	822 61,60 (9,29)	789 61,66 (9,44)	752 61,77 (9,63)	699 62,07 (9,60)	689 61,85 (9,50)	628 61,81 (9,77)	-1,56 (0,20)	-0,75 [-1,30;-0,20] 0,0076 -0,12 [-0,22;-0,03]
ECOG-PS 1	174 63,63 (8,69)	169 61,09 (9,37)	161 62,46 (9,10)	147 62,22 (9,04)	142 61,40 (9,74)	129 60,31 (10,11)	126 62,33 (9,55)	120 61,45 (9,36)	106 62,32 (9,03)	-1,60 (0,50)	212 62,18 (9,50)	205 62,10 (9,70)	201 61,94 (9,62)	189 61,46 (10,09)	177 61,49 (9,47)	166 61,47 (9,36)	161 61,97 (9,07)	157 61,92 (9,79)	149 61,67 (9,90)	-0,72 (0,44)	-0,88 [-2,20;0,43] 0,1864 -0,14 [-0,34;0,06]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-ES 19 Score = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-ES 19 Score haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-ES: Functional Assessment of Cancer Therapy - Endokrine Symptome; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t113_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba

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Tabelle 114.1.2: Subgruppen für die Veränderung des ESS 18 aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,5281)																					
Neoadjuvante Chemotherapie	281 58,43 (8,41)	273 55,39 (9,49)	262 55,24 (10,54)	263 54,72 (11,21)	241 54,57 (10,91)	238 54,97 (11,28)	224 56,57 (10,57)	224 56,98 (10,04)	202 57,17 (10,21)	-2,89 (0,41)	268 57,12 (9,12)	259 55,68 (9,10)	256 56,29 (9,51)	232 56,03 (9,92)	223 55,70 (10,10)	203 56,02 (10,22)	188 56,44 (9,72)	185 55,88 (10,59)	172 56,09 (11,03)	-1,74 (0,43)	-1,15 [-2,32;0,02] 0,0535 -0,17 [-0,33;0,00]
Adjuvante Chemotherapie	407 57,77 (8,74)	400 54,63 (9,88)	391 54,86 (10,37)	385 54,47 (10,37)	373 54,09 (11,06)	362 54,74 (11,46)	343 56,36 (10,24)	347 55,92 (11,07)	317 55,91 (11,19)	-2,73 (0,32)	379 57,37 (9,13)	372 56,78 (9,15)	363 56,55 (9,20)	353 56,30 (9,43)	333 55,82 (10,01)	320 55,72 (10,55)	321 56,93 (10,25)	320 56,65 (10,25)	294 56,53 (10,40)	-1,12 (0,34)	-1,61 [-2,53;-0,70] 0,0006 -0,25 [-0,39;-0,11]
Keine Chemotherapie	7 63,86 (10,29)	7 56,86 (11,39)	6 54,67 (12,23)	6 56,00 (10,95)	6 55,83 (8,89)	6 56,33 (8,26)	6 60,33 (7,94)	5 59,00 (8,89)	4 62,50 (5,74)	-4,83 (1,98)	3 53,33 (6,51)	3 49,00 (3,61)	3 50,33 (1,15)	3 52,00 (4,58)	3 53,67 (3,06)	3 53,00 (9,54)	3 51,33 (4,73)	3 58,00 (7,55)	2 59,00 (5,66)	-1,29 (2,94)	-3,54 [-11,96;4,88] 0,3618 -0,62 [-1,87;0,64]
Region (p-Wert des Interaktionsterms: 0,5710)																					
Nordamerika / Europa	282 57,27 (8,22)	269 53,99 (9,26)	256 53,98 (10,06)	255 53,56 (10,06)	228 52,94 (10,35)	227 53,66 (10,78)	211 55,36 (10,01)	213 55,97 (9,76)	180 56,07 (9,83)	-2,79 (0,37)	256 55,96 (9,68)	245 55,17 (9,51)	235 55,50 (9,59)	210 55,22 (10,16)	198 54,44 (10,65)	189 54,16 (11,26)	180 55,26 (10,27)	181 54,96 (11,24)	165 55,39 (10,87)	-1,05 (0,39)	-1,74 [-2,81;-0,68] 0,0014 -0,28 [-0,45;-0,11]
Asien	233 59,60 (8,18)	232 56,10 (9,22)	229 56,04 (9,93)	227 55,49 (10,68)	223 55,49 (11,02)	217 55,78 (11,37)	216 58,12 (10,05)	212 57,80 (10,75)	210 57,84 (10,91)	-3,03 (0,43)	212 59,63 (7,35)	211 58,48 (7,88)	210 58,33 (8,44)	204 58,08 (8,52)	193 57,75 (8,69)	188 58,33 (8,93)	184 58,39 (9,46)	182 58,34 (9,24)	172 57,85 (9,85)	-1,63 (0,45)	-1,39 [-2,62;-0,16] 0,0264 -0,21 [-0,40;-0,02]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	180 57,46 (9,58)	179 54,94 (10,91)	174 55,16 (11,50)	172 54,91 (11,56)	169 54,53 (11,55)	162 55,25 (12,00)	146 55,71 (10,99)	151 54,88 (11,55)	133 54,77 (11,66)	-2,47 (0,55)	182 56,29 (9,63)	178 55,25 (9,56)	177 55,35 (9,60)	174 55,08 (9,83)	168 55,03 (10,37)	149 54,76 (10,47)	148 56,42 (10,19)	145 55,68 (10,22)	131 55,69 (11,09)	-1,44 (0,55)	-1,03 [-2,57;0,51] 0,1897 -0,14 [-0,34;0,07]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,4747)																					
< 20 mm	179 58,15 (8,46)	176 55,07 (8,92)	167 54,32 (9,98)	171 53,43 (10,79)	160 53,21 (10,67)	158 52,92 (11,71)	152 55,09 (10,28)	157 55,14 (10,94)	148 55,23 (11,01)	-3,66 (0,48)	169 55,81 (9,11)	164 54,79 (9,44)	162 54,69 (9,53)	153 54,22 (9,79)	150 53,97 (9,94)	141 54,50 (10,21)	136 55,25 (9,86)	135 54,24 (10,85)	123 54,96 (10,79)	-1,96 (0,50)	-1,70 [-3,06;-0,33] 0,0150 -0,26 [-0,47;-0,05]
≥ 20 bis < 50 mm	326 58,02 (8,72)	316 54,50 (10,68)	314 55,17 (10,77)	307 54,97 (10,78)	290 54,58 (11,59)	282 55,55 (11,59)	265 57,28 (10,49)	266 56,76 (10,74)	239 57,27 (11,07)	-2,50 (0,39)	315 57,19 (9,35)	309 56,50 (9,16)	305 56,77 (9,53)	291 56,44 (9,80)	273 56,40 (10,29)	262 56,19 (10,76)	255 57,15 (10,44)	247 56,96 (10,50)	235 56,55 (10,71)	-0,91 (0,40)	-1,58 [-2,68;-0,49] 0,0047 -0,22 [-0,38;-0,07]
≥ 50 mm	172 57,94 (8,81)	170 55,37 (8,89)	163 55,13 (10,43)	160 54,78 (10,50)	154 54,42 (10,17)	152 55,17 (10,41)	142 56,04 (10,12)	140 56,61 (10,29)	122 55,95 (10,07)	-2,58 (0,47)	158 58,58 (8,51)	153 57,15 (8,69)	147 57,24 (8,40)	136 57,18 (8,58)	130 56,12 (9,31)	116 56,16 (9,90)	114 57,05 (9,20)	119 57,24 (9,27)	104 57,22 (10,15)	-1,77 (0,50)	-0,81 [-2,16;0,54] 0,2369 -0,13 [-0,35;0,09]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,5350)																					
0-3	238 57,95 (8,82)	230 54,41 (9,56)	219 54,67 (10,01)	221 53,81 (10,90)	202 53,91 (10,89)	199 54,04 (11,57)	192 55,78 (10,56)	188 55,95 (10,54)	169 55,88 (11,16)	-3,15 (0,43)	237 56,79 (8,45)	230 55,80 (8,51)	224 55,90 (8,88)	210 55,26 (8,60)	201 54,50 (9,52)	189 54,58 (9,68)	183 55,62 (9,36)	180 55,46 (10,29)	175 55,19 (10,35)	-2,06 (0,43)	-1,09 [-2,28;0,10] 0,0734 -0,16 [-0,34;0,02]
4-9	317 57,44 (8,88)	311 54,19 (10,26)	306 54,28 (10,95)	301 54,13 (10,70)	290 53,62 (11,04)	287 54,58 (11,30)	265 56,18 (10,43)	268 56,01 (11,15)	245 56,16 (10,72)	-2,68 (0,39)	294 57,34 (9,81)	288 56,50 (9,34)	283 56,72 (9,38)	266 56,45 (10,05)	255 56,38 (10,18)	244 56,37 (10,83)	242 57,00 (10,63)	238 56,70 (10,20)	218 56,77 (10,50)	-0,95 (0,41)	-1,73 [-2,84;-0,62] 0,0023 -0,25 [-0,41;-0,09]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 10	140 59,86 (7,48)	139 57,58 (8,32)	134 57,22 (9,68)	132 56,91 (10,12)	128 56,40 (10,75)	120 56,81 (10,96)	116 58,36 (9,63)	120 57,79 (9,64)	109 57,97 (10,38)	-2,62 (0,51)	119 57,93 (8,58)	116 56,77 (9,81)	115 56,65 (9,97)	112 57,21 (10,22)	103 56,68 (10,37)	93 56,90 (10,56)	87 58,23 (9,53)	90 57,37 (10,85)	75 58,03 (11,34)	-0,90 (0,55)	-1,73 [-3,21;-0,25] 0,0223 -0,29 [-0,53;-0,04]
Tumorstadium (p-Wert des Interaktionsterms: 0,1914)																					
IIA	71 57,15 (9,77)	69 54,04 (9,81)	67 52,91 (10,27)	68 51,56 (11,29)	65 51,30 (11,17)	61 50,87 (11,93)	59 52,51 (11,17)	60 52,95 (10,94)	55 53,73 (11,85)	-4,66 (0,72)	69 55,62 (8,32)	67 54,63 (8,46)	66 56,33 (7,89)	60 54,65 (8,08)	58 54,90 (7,93)	55 55,24 (9,54)	56 56,64 (9,23)	51 55,96 (10,40)	50 56,36 (9,69)	-0,81 (0,74)	-3,85 [-5,88;-1,81] 0,0003 -0,63 [-0,97;-0,29]
IIB	65 57,85 (8,18)	63 54,68 (10,28)	59 57,15 (8,61)	61 55,16 (10,65)	52 55,52 (10,47)	55 55,02 (10,98)	54 58,11 (10,22)	53 57,53 (9,88)	51 58,18 (9,82)	-2,23 (0,93)	85 56,78 (8,79)	82 55,87 (8,84)	83 55,18 (9,46)	77 54,62 (9,39)	76 53,87 (9,88)	72 53,79 (10,28)	67 55,12 (9,68)	70 54,84 (10,29)	68 54,44 (9,93)	-2,99 (0,81)	0,76 [-1,68;3,19] 0,5401 0,10 [-0,22;0,42]
IIIA	310 57,52 (9,06)	305 54,11 (10,28)	300 54,03 (11,13)	296 54,16 (10,73)	283 53,96 (11,17)	280 54,79 (11,23)	254 56,29 (10,23)	258 56,10 (11,10)	235 56,01 (10,79)	-2,52 (0,39)	266 56,91 (9,75)	259 56,19 (9,31)	253 56,49 (9,40)	243 56,45 (9,69)	229 55,99 (10,20)	215 55,89 (10,78)	214 56,76 (10,26)	213 56,89 (9,91)	198 56,28 (10,86)	-0,93 (0,42)	-1,59 [-2,72;-0,47] 0,0057 -0,23 [-0,40;-0,07]
IIIB	18 53,22 (11,89)	18 51,11 (10,91)	16 51,44 (10,80)	17 51,06 (12,74)	13 45,46 (8,93)	14 49,79 (13,28)	14 52,00 (12,15)	14 50,14 (11,67)	14 53,57 (11,86)	-3,54 (1,95)	17 62,24 (6,94)	17 61,94 (7,39)	16 61,63 (6,60)	13 60,08 (7,10)	11 60,55 (9,52)	12 61,83 (4,45)	13 58,77 (9,21)	12 60,17 (4,95)	11 59,64 (6,62)	-0,51 (2,05)	-3,03 [-8,98;2,92] 0,3049 -0,35 [-1,01;0,30]
IIIC	227 59,50 (7,19)	221 56,74 (8,42)	213 56,62 (9,65)	208 56,18 (10,15)	203 55,86 (10,53)	193 56,41 (11,04)	189 57,79 (9,84)	189 57,90 (9,76)	165 57,64 (10,60)	-2,67 (0,41)	212 57,97 (8,69)	208 56,65 (9,25)	203 56,36 (9,63)	194 56,57 (10,05)	185 56,24 (10,37)	172 56,35 (10,41)	162 57,19 (10,24)	162 56,22 (11,19)	141 57,21 (11,08)	-1,55 (0,43)	-1,12 [-2,29;0,04] 0,0582 -0,18 [-0,37;0,01]
Tumorgrading (p-Wert des Interaktionsterms: 0,4003)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
G1	59 59,44 (6,93)	58 57,45 (7,50)	54 56,50 (9,37)	54 55,83 (9,52)	55 55,98 (9,59)	53 56,34 (10,50)	51 57,22 (8,48)	53 57,51 (10,24)	47 56,85 (9,89)	-1,94 (0,94)	47 55,72 (9,46)	45 55,16 (8,94)	43 53,40 (10,17)	43 53,84 (10,36)	40 52,65 (11,28)	39 53,51 (11,12)	39 54,23 (10,67)	38 53,16 (11,79)	34 53,50 (11,38)	-2,61 (1,06)	0,68 [-2,16;3,52] 0,6373 0,09 [-0,29;0,48]
G2	311 57,92 (8,62)	304 54,89 (9,51)	297 54,97 (10,44)	295 54,12 (10,82)	280 54,14 (10,91)	275 54,64 (11,38)	257 56,84 (10,21)	257 56,62 (10,49)	234 56,63 (10,61)	-2,70 (0,35)	285 57,85 (9,37)	277 57,15 (9,60)	273 57,71 (9,05)	257 57,33 (9,57)	240 56,68 (10,14)	235 56,68 (10,34)	225 57,40 (10,02)	227 57,18 (10,58)	205 57,04 (11,04)	-0,94 (0,37)	-1,76 [-2,76;-0,77] 0,0006 -0,28 [-0,45;-0,12]
G3	280 57,49 (8,98)	274 54,17 (10,29)	266 54,45 (10,59)	263 54,36 (10,60)	244 53,51 (11,13)	237 54,23 (11,53)	225 55,30 (10,75)	227 55,22 (10,83)	202 55,35 (11,16)	-2,99 (0,42)	280 56,50 (8,91)	275 55,35 (8,80)	271 55,40 (9,34)	252 55,20 (9,47)	246 54,85 (9,73)	219 54,99 (10,24)	215 56,11 (9,99)	210 55,80 (10,08)	199 55,77 (10,19)	-1,54 (0,42)	-1,45 [-2,61;-0,28] 0,0152 -0,21 [-0,37;-0,04]
GX	42 61,02 (7,86)	41 56,98 (9,99)	39 56,46 (10,79)	39 57,38 (11,64)	38 57,55 (11,66)	38 57,82 (10,55)	37 59,65 (10,50)	36 59,81 (10,08)	37 60,70 (10,03)	-3,15 (1,15)	36 60,44 (6,97)	35 58,50 (7,31)	33 58,00 (8,55)	34 57,37 (9,12)	31 60,23 (7,63)	31 58,32 (10,73)	31 59,32 (9,25)	31 58,71 (7,82)	28 59,46 (8,88)	-1,78 (1,25)	-1,37 [-4,76;2,02] 0,4223 -0,18 [-0,63;0,26]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,2503)																					
Negativ	63 56,14 (9,31)	60 52,85 (10,36)	57 52,58 (11,66)	60 51,85 (12,70)	57 51,39 (12,25)	54 51,48 (12,02)	50 51,56 (11,49)	51 53,08 (11,69)	50 53,84 (11,41)	-3,92 (0,86)	53 56,68 (8,18)	52 55,79 (8,86)	51 56,24 (8,47)	44 56,18 (7,75)	43 55,93 (8,54)	39 56,69 (8,32)	40 56,80 (9,24)	37 57,76 (9,13)	36 56,86 (9,85)	0,48 (0,95)	-4,40 [-6,95;-1,86] 0,0009 -0,64 [-1,01;-0,27]
Positiv	610 58,22 (8,63)	598 55,08 (9,73)	583 55,16 (10,36)	575 54,78 (10,56)	547 54,51 (10,88)	537 55,09 (11,33)	506 56,81 (10,19)	510 56,55 (10,59)	461 56,69 (10,79)	-2,73 (0,27)	580 57,32 (9,21)	567 56,39 (9,05)	557 56,50 (9,34)	530 56,14 (9,71)	501 55,68 (10,14)	472 55,81 (10,54)	460 56,75 (10,08)	457 56,35 (10,34)	420 56,39 (10,64)	-1,51 (0,28)	-1,22 [-1,99;-0,46] 0,0018 -0,18 [-0,30;-0,07]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Unbekannt	6 59,83 (5,08)	6 53,17 (9,13)	6 59,33 (7,84)	5 60,20 (4,97)	4 61,75 (3,77)	4 64,25 (1,50)	4 65,25 (2,50)	3 62,00 (3,61)	3 61,67 (5,51)	-1,30 (2,60)	8 54,88 (10,80)	7 50,43 (16,29)	8 52,75 (12,67)	6 54,50 (15,53)	6 56,00 (14,14)	8 49,88 (13,98)	5 50,40 (15,04)	8 51,75 (16,45)	7 50,86 (14,96)	-1,91 (2,09)	0,60 [-6,86;8,07] 0,8628 0,09 [-0,90;1,08]
Ethnizität (p-Wert des Interaktionsterms: 0,5782)																					
Weiß	398 56,94 (8,85)	388 53,75 (9,72)	370 53,74 (10,55)	368 53,33 (10,47)	341 52,94 (10,70)	335 53,74 (11,12)	304 54,94 (10,28)	313 54,62 (10,48)	277 55,20 (10,25)	-2,93 (0,34)	381 55,70 (9,71)	367 54,92 (9,49)	359 55,00 (9,59)	337 54,70 (9,99)	324 54,38 (10,30)	302 53,96 (11,01)	290 55,21 (10,19)	290 54,96 (10,80)	267 55,11 (11,11)	-1,25 (0,34)	-1,68 [-2,62;-0,73] 0,0005 -0,25 [-0,39;-0,11]
Asiatisch	260 59,75 (8,15)	258 56,67 (9,34)	255 56,72 (10,05)	252 56,41 (10,69)	246 56,13 (11,06)	240 56,26 (11,48)	237 58,49 (9,93)	236 58,31 (10,64)	223 57,85 (11,30)	-2,56 (0,41)	228 59,74 (7,48)	227 58,48 (7,99)	224 58,63 (8,48)	219 58,45 (8,63)	203 57,89 (8,91)	195 58,40 (8,96)	193 58,52 (9,49)	189 58,42 (9,24)	177 57,88 (9,87)	-1,53 (0,45)	-1,04 [-2,23;0,16] 0,0892 -0,15 [-0,33;0,02]
Andere	26 58,65 (8,22)	25 56,08 (10,52)	25 55,76 (10,41)	25 54,16 (11,88)	24 54,48 (10,90)	22 55,73 (11,61)	23 56,04 (11,08)	20 57,75 (10,06)	18 56,78 (12,05)	-3,76 (1,39)	29 57,24 (8,51)	28 56,75 (9,28)	28 55,80 (9,53)	27 55,44 (9,48)	25 55,64 (12,38)	22 56,36 (9,42)	22 58,77 (10,46)	23 56,26 (11,35)	18 58,17 (8,64)	-1,14 (1,33)	-2,62 [-6,49;1,25] 0,1798 -0,37 [-0,90;0,17]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,1884)																					
Tamoxifen	492 57,65 (8,94)	481 54,79 (9,81)	462 54,28 (10,63)	462 54,14 (10,71)	433 53,61 (10,93)	424 54,14 (11,24)	400 55,86 (10,37)	405 55,82 (10,74)	363 55,83 (10,68)	-2,83 (0,30)	477 57,19 (9,02)	463 56,04 (9,28)	451 56,26 (9,18)	428 56,13 (9,43)	404 55,25 (10,09)	386 55,25 (10,48)	373 56,11 (10,03)	376 55,83 (10,26)	345 55,81 (10,64)	-1,61 (0,30)	-1,21 [-2,05;-0,38] 0,0046 -0,18 [-0,31;-0,06]
Aromatase-Inhibitor	203 59,18 (7,77)	199 55,36 (9,57)	197 56,71 (9,79)	192 55,66 (10,64)	187 55,87 (10,92)	182 56,49 (11,47)	173 57,93 (10,16)	171 57,63 (10,40)	160 57,86 (10,98)	-2,79 (0,48)	173 57,39 (9,40)	171 56,98 (8,72)	171 56,81 (9,64)	160 56,28 (10,09)	155 57,09 (9,72)	140 57,40 (10,07)	139 58,35 (9,89)	132 57,93 (10,50)	123 57,98 (10,40)	-0,66 (0,52)	-2,13 [-3,52;-0,74] 0,0029 -0,31 [-0,52;-0,11]
ECOG-PS (p-Wert des Interaktionsterms: 0,1651)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
ECOG-PS 0	617 57,90 (8,71)	603 54,67 (9,60)	584 54,53 (10,52)	582 54,06 (10,69)	548 53,79 (10,89)	538 54,40 (11,37)	507 56,06 (10,47)	509 55,90 (10,79)	466 56,05 (10,80)	-3,04 (0,27)	576 57,37 (9,09)	561 56,40 (9,14)	549 56,50 (9,15)	523 56,29 (9,52)	497 55,90 (9,84)	468 55,93 (10,35)	457 56,68 (9,96)	447 56,34 (10,43)	417 56,51 (10,55)	-1,43 (0,28)	-1,61 [-2,37;-0,85] <,0001 -0,24 [-0,35;-0,13]
ECOG-PS 1	78 59,68 (7,93)	77 57,26 (10,49)	75 58,76 (8,94)	72 58,82 (9,91)	72 58,11 (10,90)	68 58,32 (10,59)	66 59,76 (8,74)	67 59,84 (8,96)	57 59,67 (10,34)	-0,93 (0,74)	74 56,32 (9,28)	73 55,51 (9,09)	73 55,78 (10,44)	65 55,22 (10,31)	62 54,60 (11,35)	58 54,91 (10,85)	55 57,07 (10,72)	61 56,66 (9,89)	51 55,29 (11,09)	-0,82 (0,77)	-0,11 [-2,24;2,03] 0,9219 -0,02 [-0,33;0,30]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des ESS 18 Score = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des ESS 18 Score haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; ESS: Endocrine symptom scale; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t114_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 114.2.2: Subgruppen für die Veränderung des ESS 18 aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,1162)																					
< 65 Jahre	804 60,13 (8,29)	779 57,68 (9,11)	754 57,64 (9,36)	721 57,59 (9,40)	702 57,56 (9,38)	660 57,33 (9,64)	637 58,79 (8,95)	633 58,99 (8,86)	584 58,96 (9,20)	-2,12 (0,21)	832 59,50 (8,46)	798 59,13 (8,82)	798 58,50 (9,07)	756 58,28 (9,11)	721 58,55 (9,05)	681 58,61 (9,13)	640 58,95 (9,13)	632 58,69 (9,14)	586 58,58 (9,46)	-1,03 (0,21)	-1,09 [-1,67;-0,52] 0,0002 -0,18 [-0,28;-0,09]
≥ 65 Jahre	303 63,55 (6,47)	293 61,64 (7,15)	276 62,60 (6,49)	272 61,35 (7,16)	253 61,05 (7,71)	237 61,19 (7,38)	225 62,71 (7,02)	216 62,25 (6,85)	199 62,15 (7,40)	-1,85 (0,26)	278 63,81 (6,40)	269 62,76 (6,76)	261 62,96 (6,20)	255 62,65 (6,50)	245 61,89 (7,04)	237 61,93 (7,35)	220 61,94 (6,96)	214 61,93 (7,20)	191 62,14 (6,95)	-1,47 (0,27)	-0,37 [-1,12;0,37] 0,3256 -0,08 [-0,24;0,08]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,6422)																					
Neoadjuvante Chemotherapie	363 61,72 (7,91)	344 58,80 (8,90)	329 59,38 (8,75)	317 58,95 (8,77)	297 58,81 (9,05)	271 58,77 (9,19)	260 60,27 (8,38)	254 60,42 (8,31)	234 60,23 (8,43)	-2,17 (0,31)	365 60,18 (8,38)	352 59,79 (8,73)	342 59,06 (8,69)	323 58,90 (8,88)	304 59,29 (8,67)	278 59,21 (9,23)	268 59,41 (9,31)	265 59,26 (9,13)	235 59,21 (9,14)	-1,31 (0,31)	-0,86 [-1,72;0,01] 0,0514 -0,14 [-0,29;0,00]
Adjuvante Chemotherapie	685 60,60 (8,09)	672 58,65 (8,75)	649 58,54 (9,14)	621 58,31 (9,13)	607 58,15 (9,19)	582 58,03 (9,34)	558 59,41 (8,91)	555 59,36 (8,62)	512 59,43 (9,08)	-1,93 (0,22)	679 60,60 (7,99)	652 59,92 (8,26)	656 59,59 (8,61)	632 59,35 (8,61)	613 59,17 (8,79)	592 59,28 (8,71)	548 59,54 (8,49)	539 59,40 (8,72)	509 59,39 (9,11)	-1,15 (0,22)	-0,78 [-1,38;-0,19] 0,0102 -0,14 [-0,25;-0,03]
Keine Chemotherapie	59 62,51 (6,70)	56 59,90 (8,75)	52 61,69 (7,45)	55 60,29 (8,79)	51 60,59 (7,99)	44 59,91 (8,35)	44 62,34 (6,27)	40 62,28 (7,81)	37 61,46 (8,74)	-2,22 (0,55)	66 62,62 (9,16)	63 62,68 (9,11)	61 62,66 (8,66)	56 62,55 (8,71)	49 62,92 (7,10)	48 63,35 (6,73)	44 63,73 (6,86)	42 62,31 (7,29)	33 62,12 (6,57)	-0,34 (0,53)	-1,88 [-3,40;-0,35] 0,0164 -0,44 [-0,79;-0,08]
Region (p-Wert des Interaktionsterms: 0,1666)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	548 60,50 (8,26)	518 57,52 (9,37)	491 57,97 (9,18)	469 57,87 (9,18)	443 57,37 (9,50)	411 57,32 (9,73)	396 58,70 (9,07)	390 58,84 (8,73)	356 58,56 (8,93)	-2,61 (0,23)	528 59,66 (8,57)	492 58,90 (9,07)	489 58,35 (9,02)	453 58,18 (9,11)	435 58,00 (9,15)	417 58,21 (9,06)	383 58,22 (9,16)	386 58,31 (9,20)	344 57,99 (9,49)	-1,55 (0,24)	-1,06 [-1,72;-0,41] 0,0015 -0,19 [-0,31;-0,07]
Asien	195 63,02 (6,65)	194 60,91 (7,53)	188 59,97 (8,84)	187 59,58 (8,76)	182 59,46 (8,87)	171 59,05 (9,14)	171 60,95 (8,49)	168 60,97 (8,19)	157 61,15 (8,50)	-2,68 (0,40)	193 63,04 (6,76)	192 62,45 (7,42)	188 62,46 (7,27)	185 61,52 (8,21)	181 61,82 (7,47)	175 61,90 (7,81)	173 62,47 (7,27)	169 61,69 (7,80)	164 61,72 (7,82)	-1,02 (0,40)	-1,66 [-2,78;-0,54] 0,0038 -0,30 [-0,50;-0,10]
Andere	364 60,88 (8,06)	360 59,41 (8,28)	351 59,83 (8,57)	337 59,14 (8,82)	330 59,45 (8,50)	315 59,30 (8,54)	295 60,66 (8,01)	291 60,47 (8,29)	270 60,55 (8,86)	-0,81 (0,30)	389 60,62 (8,12)	383 60,30 (7,95)	382 59,78 (8,50)	373 59,79 (8,28)	350 59,88 (8,42)	326 59,78 (8,75)	304 60,03 (8,52)	291 59,82 (8,57)	269 59,94 (8,81)	-0,61 (0,29)	-0,20 [-1,02;0,61] 0,6206 -0,04 [-0,18;0,11]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3004)																					
< 20 mm	280 59,83 (8,61)	267 57,81 (9,25)	257 57,59 (9,69)	253 57,45 (9,67)	242 57,25 (9,59)	233 57,27 (10,01)	230 59,10 (9,04)	220 58,96 (8,60)	208 58,81 (9,20)	-2,17 (0,34)	297 60,45 (8,46)	286 59,91 (8,75)	283 60,15 (8,78)	269 59,71 (9,22)	260 59,47 (9,29)	240 59,59 (9,28)	231 59,93 (9,39)	222 59,43 (8,74)	207 58,40 (10,01)	-0,86 (0,33)	-1,31 [-2,24;-0,39] 0,0056 -0,23 [-0,40;-0,07]
≥ 20 bis < 50 mm	569 61,24 (7,96)	559 59,00 (8,72)	530 59,28 (9,11)	516 58,89 (8,96)	492 58,90 (8,97)	465 58,83 (9,25)	449 60,16 (8,78)	438 60,06 (8,81)	402 59,93 (9,16)	-1,86 (0,24)	572 60,55 (7,99)	552 60,09 (8,50)	548 59,71 (8,39)	526 59,27 (8,84)	503 59,47 (8,58)	492 59,33 (8,86)	446 59,68 (8,66)	451 59,77 (8,73)	420 59,97 (8,89)	-1,07 (0,24)	-0,79 [-1,46;-0,13] 0,0190 -0,14 [-0,26;-0,02]
≥ 50 mm	241 61,90 (7,25)	230 59,09 (8,51)	227 59,68 (7,68)	211 59,23 (8,15)	206 58,85 (8,86)	185 58,23 (8,32)	169 59,70 (7,84)	178 60,20 (7,73)	160 60,27 (7,75)	-2,16 (0,36)	230 60,60 (8,46)	218 59,80 (8,20)	218 58,39 (9,19)	205 59,02 (7,83)	195 58,93 (8,30)	177 59,40 (8,14)	174 59,33 (8,04)	164 58,65 (9,12)	142 59,23 (7,85)	-1,82 (0,37)	-0,34 [-1,36;0,67] 0,5048 -0,06 [-0,24;0,12]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,9704)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	368 60,43 (8,51)	358 57,79 (9,23)	343 58,39 (9,24)	323 58,48 (8,96)	320 58,07 (9,39)	297 57,92 (9,34)	286 59,06 (8,74)	282 59,28 (8,66)	259 59,62 (8,79)	-1,91 (0,29)	359 60,21 (8,07)	343 59,55 (8,33)	345 59,12 (8,31)	326 59,25 (8,33)	314 59,42 (8,25)	294 59,10 (8,32)	279 59,25 (8,56)	267 59,05 (9,28)	246 58,70 (8,81)	-1,09 (0,30)	-0,82 [-1,65;-0,00] 0,0494 -0,15 [-0,29;-0,00]
4-9	475 61,14 (7,89)	458 59,06 (8,69)	444 58,92 (9,08)	434 58,49 (9,19)	412 58,62 (9,12)	386 58,25 (9,65)	374 59,89 (8,82)	372 60,12 (8,57)	350 59,89 (9,12)	-2,12 (0,27)	487 60,54 (8,42)	469 60,02 (8,83)	469 59,59 (9,08)	446 59,39 (9,33)	430 59,20 (9,29)	418 59,52 (9,24)	387 59,94 (9,16)	386 59,91 (8,49)	359 59,80 (9,34)	-1,09 (0,26)	-1,02 [-1,76;-0,29] 0,0065 -0,18 [-0,30;-0,05]
≥ 10	264 61,83 (7,31)	256 59,60 (8,24)	243 59,87 (8,26)	236 59,06 (8,72)	223 58,83 (8,62)	214 59,12 (8,36)	202 60,74 (8,16)	195 60,02 (8,20)	174 59,74 (8,57)	-2,09 (0,33)	264 61,16 (7,98)	255 60,75 (8,04)	245 60,28 (8,32)	239 59,54 (8,10)	222 59,74 (8,18)	206 59,90 (8,67)	194 59,92 (8,06)	193 59,32 (8,75)	172 59,82 (8,66)	-1,37 (0,33)	-0,73 [-1,65;0,20] 0,1228 -0,13 [-0,31;0,04]
Tumorstadium (p-Wert des Interaktionsterms: 0,5990)																					
IIA	93 58,61 (8,99)	91 57,15 (9,30)	87 56,83 (9,68)	83 56,56 (10,11)	83 55,81 (9,96)	80 56,33 (10,01)	79 57,75 (9,43)	72 58,11 (9,08)	67 58,69 (8,85)	-1,56 (0,56)	95 59,22 (8,63)	92 59,00 (8,42)	89 58,95 (8,62)	87 59,60 (7,84)	81 59,48 (7,90)	81 58,86 (7,95)	78 58,87 (8,57)	73 58,22 (8,76)	66 58,09 (9,16)	-0,22 (0,55)	-1,34 [-2,89;0,21] 0,0896 -0,25 [-0,54;0,04]
IIB	133 61,01 (9,03)	129 58,26 (9,82)	122 59,42 (9,32)	120 59,14 (9,20)	118 59,23 (9,46)	109 58,26 (10,14)	103 59,81 (8,97)	104 59,84 (9,06)	97 60,22 (9,05)	-2,00 (0,51)	112 61,34 (7,40)	106 59,67 (8,88)	106 59,83 (7,67)	101 58,20 (9,60)	95 58,86 (8,31)	96 58,58 (8,83)	91 58,69 (9,03)	87 58,43 (9,73)	82 58,32 (9,40)	-2,56 (0,56)	0,55 [-0,94;2,04] 0,4671 0,09 [-0,16;0,34]
IIIA	430 60,95 (7,83)	417 58,92 (8,59)	402 58,80 (8,91)	390 58,24 (9,13)	368 58,47 (9,06)	343 58,21 (9,44)	329 59,55 (8,73)	338 59,45 (8,84)	310 59,52 (9,31)	-2,02 (0,28)	437 60,60 (7,96)	417 60,10 (8,22)	425 59,46 (8,86)	401 59,52 (8,55)	388 59,28 (8,67)	372 59,66 (8,70)	346 60,13 (8,68)	342 59,64 (8,27)	318 59,74 (8,75)	-1,03 (0,28)	-0,99 [-1,77;-0,21] 0,0128 -0,17 [-0,30;-0,04]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIIB	47 62,09 (9,12)	45 60,29 (9,86)	45 60,62 (10,17)	44 59,73 (9,43)	43 60,65 (8,86)	39 59,64 (10,68)	36 60,89 (9,49)	33 63,21 (6,29)	35 61,57 (8,40)	-1,64 (0,68)	41 61,98 (8,64)	40 61,68 (8,69)	40 61,03 (8,31)	36 62,36 (8,41)	35 61,66 (8,25)	33 61,52 (6,83)	31 62,65 (6,32)	29 62,90 (5,58)	28 62,68 (7,53)	-0,54 (0,73)	-1,10 [-3,08;0,88] 0,2740 -0,24 [-0,66;0,18]
IIIC	402 61,62 (7,28)	389 58,95 (8,37)	372 59,28 (8,53)	354 59,18 (8,40)	341 58,61 (8,75)	324 58,83 (8,32)	313 60,46 (8,13)	300 60,22 (7,92)	272 59,87 (8,39)	-2,23 (0,28)	423 60,52 (8,51)	410 60,16 (8,68)	397 59,68 (8,79)	384 59,25 (8,88)	365 59,43 (9,07)	334 59,45 (9,33)	313 59,49 (8,88)	313 59,64 (9,27)	281 59,46 (9,30)	-1,14 (0,27)	-1,09 [-1,85;-0,33] 0,0052 -0,20 [-0,33;-0,06]
Tumorgrading (p-Wert des Interaktionsterms: 0,8480)																					
G1	82 60,21 (7,96)	80 59,86 (8,31)	82 58,45 (9,90)	75 58,96 (8,88)	73 58,18 (9,86)	71 58,62 (8,36)	68 59,84 (8,53)	67 59,48 (9,02)	61 59,57 (9,06)	-1,36 (0,64)	84 62,08 (7,90)	83 62,01 (7,67)	81 61,46 (7,40)	75 60,57 (8,12)	77 60,73 (8,32)	71 61,25 (8,04)	66 60,95 (7,66)	67 60,97 (7,19)	59 60,31 (8,23)	-0,84 (0,63)	-0,52 [-2,29;1,25] 0,5627 -0,09 [-0,39;0,21]
G2	525 61,33 (7,78)	509 58,66 (8,86)	487 59,03 (8,94)	467 58,47 (9,00)	446 58,49 (8,88)	418 58,49 (9,20)	394 60,06 (8,58)	402 59,83 (8,64)	368 59,79 (8,87)	-2,20 (0,25)	533 59,92 (8,42)	508 59,54 (8,50)	507 58,72 (9,01)	491 58,68 (9,01)	463 58,62 (8,97)	441 58,82 (8,88)	412 59,31 (8,72)	409 58,99 (8,69)	380 59,09 (8,83)	-1,32 (0,24)	-0,88 [-1,57;-0,20] 0,0114 -0,16 [-0,28;-0,04]
G3	451 60,90 (8,30)	436 58,65 (8,88)	415 58,96 (8,78)	404 58,68 (8,89)	392 58,38 (9,20)	366 58,09 (9,44)	361 59,39 (8,94)	339 59,69 (8,45)	321 59,69 (8,87)	-1,94 (0,27)	435 60,66 (8,07)	418 59,83 (8,52)	414 59,74 (8,54)	391 59,55 (8,59)	375 59,65 (8,51)	359 59,40 (9,01)	338 59,67 (9,05)	326 59,57 (9,36)	301 59,49 (9,59)	-1,02 (0,28)	-0,91 [-1,68;-0,15] 0,0185 -0,16 [-0,29;-0,03]
GX	47 61,85 (6,67)	45 59,64 (7,63)	44 59,77 (9,01)	45 59,91 (9,51)	42 60,95 (8,04)	40 60,00 (8,36)	37 61,95 (6,14)	39 61,85 (6,76)	32 60,69 (9,23)	-1,79 (0,67)	54 64,35 (5,90)	54 63,39 (8,24)	53 64,17 (5,73)	50 63,16 (6,75)	48 62,65 (7,25)	44 63,41 (6,49)	42 61,76 (7,52)	41 61,59 (7,37)	34 61,35 (7,43)	-1,35 (0,63)	-0,44 [-2,28;1,40] 0,6376 -0,10 [-0,49;0,30]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,2550)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Negativ	137 61,07 (7,91)	134 58,66 (8,64)	127 58,64 (9,60)	124 58,10 (9,17)	117 58,78 (8,77)	105 58,48 (8,98)	98 60,35 (8,38)	102 59,99 (8,36)	90 59,06 (7,72)	-2,11 (0,43)	148 60,95 (7,90)	142 60,88 (8,55)	140 60,25 (8,21)	134 59,63 (8,58)	125 59,71 (8,88)	116 59,53 (8,64)	105 59,22 (8,53)	102 59,41 (8,12)	91 60,15 (8,50)	-1,11 (0,42)	-1,00 [-2,18;0,18] 0,0966 -0,20 [-0,43;0,04]
Positiv	939 60,96 (8,02)	907 58,63 (8,81)	872 58,84 (8,91)	844 58,53 (9,00)	814 58,32 (9,18)	767 58,15 (9,29)	738 59,61 (8,75)	723 59,72 (8,55)	672 59,76 (9,05)	-2,07 (0,19)	935 60,53 (8,25)	901 59,91 (8,45)	895 59,49 (8,73)	854 59,34 (8,72)	819 59,35 (8,67)	780 59,46 (8,86)	735 59,81 (8,75)	722 59,50 (8,90)	665 59,40 (9,05)	-1,16 (0,19)	-0,91 [-1,43;-0,39] 0,0006 -0,16 [-0,25;-0,07]
Unbekannt	9 63,44 (4,93)	9 59,44 (11,77)	9 63,44 (6,62)	7 66,86 (4,53)	5 66,60 (5,77)	7 64,86 (8,03)	8 66,00 (4,17)	7 65,43 (4,39)	5 67,40 (5,73)	1,50 (1,44)	7 61,00 (8,49)	6 66,00 (6,16)	6 61,00 (7,13)	6 65,00 (4,34)	6 63,67 (4,63)	6 62,50 (6,80)	5 62,80 (5,54)	6 64,67 (4,72)	5 63,40 (3,65)	2,96 (1,62)	-1,47 [-6,21;3,27] 0,5132 -0,32 [-1,26;0,62]
Ethnizität (p-Wert des Interaktionsterms: 0,1539)																					
Weiß	808 60,35 (8,23)	777 57,88 (8,94)	752 58,39 (8,85)	721 58,07 (8,93)	692 57,73 (9,06)	645 57,81 (9,16)	612 59,06 (8,67)	605 59,20 (8,44)	561 59,02 (8,78)	-2,05 (0,19)	818 60,04 (8,34)	778 59,44 (8,58)	776 58,93 (8,75)	733 58,59 (8,85)	699 58,64 (8,83)	667 58,81 (8,94)	613 58,83 (8,98)	610 58,75 (8,90)	546 58,56 (9,12)	-1,23 (0,19)	-0,82 [-1,35;-0,28] 0,0028 -0,15 [-0,25;-0,05]
Asiatisch	233 63,37 (6,83)	231 61,58 (7,65)	221 60,88 (8,87)	219 60,60 (8,75)	214 60,56 (8,84)	200 59,90 (9,12)	199 61,48 (8,29)	197 61,47 (8,12)	179 61,75 (8,38)	-2,16 (0,38)	222 62,69 (6,98)	220 62,44 (7,38)	216 62,56 (7,39)	214 61,85 (8,14)	206 62,13 (7,51)	194 62,01 (7,82)	192 62,49 (7,30)	186 61,74 (8,12)	182 61,86 (8,02)	-0,64 (0,39)	-1,53 [-2,60;-0,46] 0,0052 -0,26 [-0,45;-0,08]
Andere	54 62,26 (6,60)	52 60,55 (8,12)	48 59,69 (9,05)	45 59,31 (8,54)	43 60,95 (8,32)	42 60,07 (8,37)	44 62,86 (6,82)	39 61,13 (10,24)	35 62,46 (9,94)	-0,79 (0,88)	57 60,63 (9,31)	57 59,33 (9,97)	55 58,53 (9,89)	52 60,33 (8,13)	50 58,54 (9,89)	46 58,61 (9,23)	45 60,80 (8,39)	40 60,15 (8,85)	40 61,20 (9,91)	-2,01 (0,85)	1,23 [-1,20;3,65] 0,3183 0,19 [-0,18;0,56]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,6733)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Tamoxifen	104 58,54 (7,97)	101 56,11 (8,99)	100 56,27 (9,53)	98 56,10 (9,61)	97 55,21 (10,74)	95 54,91 (10,83)	90 56,61 (10,31)	89 56,63 (9,83)	90 57,26 (10,48)	-2,39 (0,60)	124 58,95 (8,15)	123 58,66 (8,24)	122 57,42 (8,84)	117 57,51 (9,25)	109 57,48 (7,96)	98 57,94 (9,38)	94 58,15 (8,48)	91 58,32 (8,69)	89 58,18 (10,37)	-1,06 (0,55)	-1,33 [-2,94;0,28] 0,1041 -0,22 [-0,48;0,04]
Aromatase-Inhibitor	1003 61,33 (7,94)	971 59,04 (8,73)	930 59,26 (8,85)	895 58,90 (8,89)	858 58,86 (8,82)	802 58,76 (8,97)	772 60,19 (8,37)	760 60,19 (8,27)	693 60,09 (8,61)	-2,00 (0,18)	986 60,79 (8,19)	944 60,22 (8,51)	937 59,88 (8,61)	894 59,63 (8,63)	857 59,64 (8,77)	820 59,65 (8,74)	766 59,90 (8,74)	755 59,65 (8,81)	688 59,62 (8,84)	-1,16 (0,18)	-0,84 [-1,33;-0,34] 0,0009 -0,15 [-0,24;-0,06]
ECOG-PS (p-Wert des Interaktionsterms: 0,7326)																					
ECOG-PS 0	933 61,06 (7,97)	903 58,83 (8,80)	869 58,81 (9,06)	846 58,43 (9,08)	813 58,41 (9,11)	768 58,42 (9,23)	736 59,79 (8,62)	729 59,89 (8,48)	677 59,71 (8,98)	-2,13 (0,18)	898 60,77 (8,05)	862 60,11 (8,38)	858 59,60 (8,60)	822 59,43 (8,59)	789 59,43 (8,71)	752 59,51 (8,88)	699 59,73 (8,82)	689 59,50 (8,76)	628 59,48 (9,01)	-1,29 (0,19)	-0,84 [-1,35;-0,33] 0,0012 -0,15 [-0,24;-0,06]
ECOG-PS 1	174 61,08 (8,04)	169 58,43 (8,76)	161 59,79 (8,39)	147 59,73 (8,43)	142 58,95 (9,03)	129 57,95 (9,40)	126 59,98 (8,91)	120 59,36 (8,73)	106 60,16 (8,23)	-1,45 (0,46)	212 59,79 (8,80)	205 59,74 (8,94)	201 59,58 (8,96)	189 59,19 (9,33)	177 59,24 (8,72)	166 59,29 (8,56)	161 59,66 (8,32)	157 59,54 (9,01)	149 59,36 (9,14)	-0,59 (0,41)	-0,86 [-2,08;0,36] 0,1644 -0,14 [-0,34;0,06]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des ESS 18 Score = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des ESS 18 Score haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; ESS: Endocrine symptom scale; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t114_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba

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Anhang 4-G3.4: Gesundheitsbezogene Lebensqualität anhand des FACT-B

Anhang 4-G3.4.1: Subgruppenanalysen nicht-interagierender Subgruppen

Tabelle 105.1.2: Subgruppen für die Veränderung des FACT-B (Gesamtscore) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,7327)																					
Neoadjuvante Chemotherapie	281 109,73 (16,89)	271 107,26 (19,24)	262 107,61 (20,20)	263 106,33 (20,49)	240 106,11 (20,34)	238 106,51 (21,22)	224 106,16 (21,46)	221 109,12 (20,54)	202 108,04 (21,34)	-2,89 (0,77)	267 106,54 (17,92)	257 105,75 (18,46)	253 107,76 (17,67)	230 108,24 (19,50)	220 107,92 (19,33)	202 108,62 (20,09)	186 108,68 (19,57)	184 107,46 (19,48)	170 107,18 (20,30)	-0,12 (0,80)	-2,76 [-4,94;-0,59] 0,0128 -0,21 [-0,38;-0,05]
Adjuvante Chemotherapie	404 106,65 (18,19)	397 106,20 (18,73)	386 107,15 (19,93)	380 107,31 (19,75)	370 106,46 (20,78)	359 106,92 (21,01)	340 106,87 (21,08)	343 107,64 (19,80)	314 107,99 (20,54)	0,09 (0,59)	378 106,81 (17,84)	372 107,64 (19,06)	358 108,70 (17,99)	352 109,20 (18,68)	330 109,69 (18,74)	319 108,99 (18,90)	319 110,11 (18,63)	319 109,38 (18,79)	295 109,31 (18,93)	1,94 (0,62)	-1,84 [-3,52;-0,16] 0,0315 -0,15 [-0,29;-0,01]
Keine Chemotherapie	7 111,14 (28,33)	7 107,29 (24,59)	6 101,67 (23,61)	6 104,83 (25,73)	6 106,00 (24,96)	6 97,83 (24,14)	6 104,00 (22,55)	5 103,00 (21,95)	4 118,00 (10,86)	-3,02 (2,86)	3 103,00 (15,39)	3 95,33 (18,61)	3 91,67 (12,06)	3 93,00 (15,39)	3 95,33 (13,65)	3 96,33 (14,57)	3 98,00 (14,53)	3 106,67 (21,55)	2 93,50 (13,44)	-7,00 (4,07)	3,98 [-7,42;15,39] 0,4469 0,48 [-0,76;1,72]
Region (p-Wert des Interaktionsterms: 0,7375)																					
Nordamerika / Europa	280 108,64 (16,47)	266 106,74 (18,14)	254 107,02 (19,62)	251 106,08 (19,22)	225 106,30 (19,18)	225 105,91 (20,78)	209 106,73 (19,82)	206 108,67 (19,02)	177 108,07 (20,21)	-1,89 (0,70)	256 107,32 (17,40)	244 105,90 (19,07)	228 107,97 (17,53)	209 108,05 (19,56)	193 109,13 (19,57)	188 108,57 (19,72)	178 108,70 (18,96)	180 108,27 (19,85)	164 108,30 (19,79)	-0,06 (0,74)	-1,83 [-3,84;0,18] 0,0740 -0,15 [-0,32;0,01]
Asien	232 107,88 (19,28)	231 106,22 (19,73)	227 106,87 (20,82)	226 106,86 (22,06)	222 106,09 (22,42)	216 106,28 (22,22)	215 106,73 (22,40)	212 108,19 (21,39)	210 108,27 (22,18)	-1,10 (0,79)	210 107,07 (17,95)	209 107,37 (18,60)	209 108,39 (18,46)	202 110,28 (18,39)	192 109,74 (18,42)	187 109,68 (19,86)	183 109,62 (20,16)	181 109,99 (18,98)	171 109,33 (20,08)	1,68 (0,84)	-2,77 [-5,04;-0,51] 0,0164 -0,23 [-0,42;-0,04]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	180 106,96 (17,99)	178 107,01 (19,28)	173 108,21 (19,71)	172 108,10 (18,57)	169 106,63 (20,09)	162 108,26 (20,04)	146 106,08 (21,46)	151 107,48 (19,73)	133 107,83 (19,40)	0,03 (0,98)	182 105,34 (18,34)	179 107,40 (18,81)	177 108,36 (17,65)	174 107,78 (19,03)	168 107,69 (18,96)	149 107,90 (18,24)	147 110,36 (17,46)	145 107,50 (18,08)	132 107,56 (18,20)	1,87 (0,98)	-1,84 [-4,56;0,88] 0,1848 -0,14 [-0,35;0,07]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,5785)																					
< 20 mm	179 107,98 (16,41)	176 106,56 (18,20)	167 106,80 (19,81)	169 106,22 (20,59)	160 105,91 (20,61)	158 106,09 (21,27)	152 105,97 (21,40)	154 107,60 (19,81)	148 107,49 (21,14)	-1,66 (0,90)	169 105,86 (19,09)	164 105,98 (19,60)	159 107,56 (17,20)	153 106,85 (19,17)	148 108,20 (18,68)	140 109,14 (18,91)	135 109,24 (19,24)	135 108,29 (20,25)	123 109,00 (19,52)	1,28 (0,93)	-2,94 [-5,48;-0,40] 0,0233 -0,24 [-0,46;-0,03]
≥ 20 bis < 50 mm	323 108,52 (18,57)	312 106,62 (20,14)	310 108,39 (20,41)	304 107,01 (20,22)	287 106,61 (21,20)	279 106,95 (21,36)	262 106,40 (21,48)	263 108,19 (21,01)	236 108,78 (21,20)	-1,33 (0,70)	314 106,10 (17,80)	307 106,20 (18,60)	301 108,79 (18,01)	289 109,45 (18,91)	270 109,53 (18,90)	260 108,49 (19,29)	252 109,55 (18,81)	246 108,52 (18,59)	235 108,27 (19,30)	1,59 (0,71)	-2,92 [-4,88;-0,96] 0,0036 -0,23 [-0,39;-0,08]
≥ 50 mm	172 106,40 (17,62)	169 106,09 (17,55)	162 104,93 (19,41)	160 106,53 (18,95)	153 105,45 (18,85)	152 106,05 (20,07)	142 106,78 (20,00)	139 108,10 (18,24)	122 106,89 (19,52)	-0,49 (0,90)	157 108,47 (16,13)	153 108,65 (18,38)	146 107,64 (18,17)	135 109,47 (18,91)	129 108,00 (19,35)	117 108,84 (20,14)	114 109,62 (18,86)	118 109,05 (18,24)	103 107,49 (19,60)	-0,11 (0,96)	-0,39 [-2,98;2,21] 0,7687 -0,03 [-0,25;0,18]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,5677)																					
0-3	238 108,49 (17,29)	231 106,95 (18,68)	218 106,96 (20,38)	220 106,26 (20,66)	201 106,25 (20,00)	199 106,78 (21,88)	192 105,41 (21,71)	187 108,75 (19,57)	169 107,39 (21,86)	-1,73 (0,84)	237 105,84 (17,14)	231 106,33 (18,80)	223 107,27 (18,20)	209 107,50 (18,72)	199 107,04 (18,45)	191 107,98 (19,35)	183 108,56 (18,46)	180 108,27 (18,97)	175 107,35 (20,62)	0,71 (0,84)	-2,43 [-4,77;-0,09] 0,0419 -0,19 [-0,37;-0,01]
4-9	314 106,17 (18,86)	305 104,10 (19,68)	301 105,92 (20,33)	297 105,60 (20,26)	287 104,48 (20,91)	284 105,26 (21,23)	262 105,08 (21,61)	262 106,62 (20,68)	243 107,09 (20,49)	-1,06 (0,69)	294 107,08 (18,49)	287 106,90 (18,92)	277 108,34 (17,96)	266 108,95 (19,31)	252 110,27 (18,89)	241 109,25 (19,33)	240 109,66 (19,51)	237 109,00 (18,89)	219 109,00 (18,25)	1,17 (0,71)	-2,23 [-4,18;-0,29] 0,0243 -0,18 [-0,34;-0,02]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 10	140 111,01 (15,91)	139 111,66 (16,84)	135 110,84 (18,52)	132 110,84 (18,23)	128 110,54 (20,44)	120 109,83 (19,24)	116 111,82 (18,63)	120 110,68 (19,45)	108 111,43 (19,58)	-0,31 (0,98)	117 107,37 (17,64)	114 107,57 (18,78)	114 109,83 (16,96)	110 110,60 (18,80)	102 109,19 (20,06)	92 109,18 (19,52)	85 111,15 (18,56)	89 108,57 (19,77)	73 109,55 (20,09)	1,64 (1,08)	-1,95 [-4,82;0,92] 0,1814 -0,17 [-0,41;0,08]
Tumorstadium (p-Wert des Interaktionsterms: 0,4302)																					
IIA	71 109,44 (16,10)	69 107,84 (19,23)	67 106,55 (20,61)	66 104,76 (21,09)	65 105,48 (20,70)	61 104,85 (21,45)	59 104,92 (21,85)	60 107,63 (20,75)	55 105,85 (21,95)	-3,49 (1,43)	69 107,58 (16,53)	67 108,03 (16,67)	66 109,50 (16,35)	60 107,00 (16,92)	57 110,96 (14,80)	56 110,16 (17,32)	56 111,80 (15,97)	51 111,59 (18,33)	50 111,62 (18,88)	2,13 (1,46)	-5,62 [-9,66;-1,57] 0,0069 -0,46 [-0,80;-0,13]
IIB	65 108,48 (16,02)	63 107,27 (18,80)	59 110,93 (17,89)	61 106,43 (20,34)	52 107,52 (18,28)	55 106,95 (20,75)	54 107,00 (18,51)	53 109,60 (17,02)	51 110,35 (20,10)	-0,76 (1,62)	85 105,91 (16,67)	83 107,05 (17,35)	82 107,73 (18,42)	76 107,79 (19,95)	76 105,61 (18,04)	72 107,96 (18,32)	67 108,96 (17,60)	70 108,20 (17,43)	68 108,15 (18,36)	-0,22 (1,42)	-0,54 [-4,80;3,71] 0,8017 -0,04 [-0,36;0,28]
IIIA	307 106,73 (19,38)	300 105,09 (19,43)	294 106,19 (20,36)	293 106,66 (19,81)	279 105,53 (20,74)	277 106,34 (21,37)	252 105,76 (21,59)	252 107,60 (20,80)	234 107,63 (20,89)	-0,51 (0,68)	267 106,49 (19,06)	259 106,54 (18,99)	248 107,92 (18,18)	244 108,37 (19,29)	226 108,75 (19,91)	215 109,06 (19,79)	214 109,12 (19,86)	214 109,34 (18,51)	200 108,28 (19,24)	0,91 (0,73)	-1,42 [-3,39;0,55] 0,1563 -0,12 [-0,28;0,05]
IIIB	18 99,39 (19,75)	18 98,06 (18,29)	16 93,19 (25,50)	17 91,76 (23,38)	13 88,77 (15,78)	14 91,64 (24,23)	14 88,36 (21,31)	14 89,57 (15,58)	14 92,71 (17,16)	-8,18 (2,84)	17 113,35 (15,85)	17 113,29 (18,83)	16 112,00 (17,48)	13 112,31 (23,24)	11 114,73 (18,78)	12 109,58 (21,36)	13 106,46 (20,34)	12 104,00 (18,78)	11 106,82 (18,46)	-0,44 (3,08)	-7,74 [-16,58;1,10] 0,0835 -0,61 [-1,27;0,05]
IIIC	227 109,54 (16,05)	221 108,76 (18,21)	214 108,92 (19,19)	208 109,07 (19,36)	203 108,54 (20,67)	193 108,59 (20,25)	188 109,27 (20,67)	188 109,96 (19,35)	163 109,93 (20,39)	-0,77 (0,83)	209 106,37 (17,31)	205 106,06 (19,90)	201 108,04 (17,89)	191 109,88 (18,71)	183 109,48 (19,32)	169 108,26 (19,86)	158 109,72 (19,28)	159 107,38 (20,65)	138 107,90 (20,65)	1,51 (0,87)	-2,28 [-4,66;0,09] 0,0595 -0,18 [-0,37;0,01]
Tumorgrading (p-Wert des Interaktionsterms: 0,9019)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
G1	59 108,42 (17,24)	57 107,02 (16,95)	54 107,31 (19,32)	54 106,07 (20,21)	55 106,64 (19,77)	53 106,23 (18,98)	51 107,84 (18,84)	53 107,32 (20,80)	46 107,52 (20,25)	-1,02 (1,49)	47 105,21 (17,30)	45 107,71 (15,99)	41 107,93 (15,29)	43 109,67 (18,19)	39 108,85 (18,92)	39 105,49 (20,53)	39 109,54 (20,19)	38 108,29 (20,42)	34 109,09 (19,13)	2,38 (1,68)	-3,40 [-7,86;1,05] 0,1323 -0,30 [-0,68;0,09]
G2	310 108,55 (17,91)	303 106,83 (19,32)	296 107,86 (19,69)	293 106,96 (19,84)	278 106,59 (20,43)	274 106,62 (20,87)	256 107,13 (21,10)	251 108,61 (19,40)	234 108,00 (19,82)	-1,52 (0,67)	283 107,69 (18,21)	276 107,39 (19,74)	268 109,47 (18,46)	254 109,39 (19,26)	235 109,91 (19,43)	233 110,00 (19,82)	222 109,87 (20,11)	224 108,77 (20,28)	203 108,27 (20,55)	0,56 (0,71)	-2,08 [-3,99;-0,17] 0,0330 -0,18 [-0,34;-0,01]
G3	278 106,41 (17,34)	272 105,74 (18,95)	262 105,76 (20,51)	259 105,95 (19,91)	242 105,07 (20,82)	235 106,03 (21,39)	223 104,48 (21,27)	226 106,96 (20,12)	200 107,17 (21,41)	-0,84 (0,78)	281 105,73 (17,47)	275 106,06 (18,22)	270 107,09 (17,51)	253 108,13 (18,43)	246 107,54 (18,79)	220 108,12 (18,41)	216 109,06 (17,26)	211 108,57 (17,65)	200 108,51 (18,54)	1,39 (0,78)	-2,24 [-4,40;-0,08] 0,0425 -0,17 [-0,34;-0,01]
GX	42 111,69 (20,69)	40 109,53 (19,41)	39 111,49 (20,28)	40 111,98 (22,38)	38 110,76 (21,33)	38 110,11 (23,68)	37 111,86 (23,48)	36 112,86 (22,96)	37 112,86 (23,58)	-0,41 (2,05)	35 107,40 (18,36)	34 106,47 (20,42)	33 107,76 (19,14)	33 106,73 (23,05)	31 112,06 (17,55)	30 108,37 (21,47)	29 110,17 (21,68)	31 109,42 (18,42)	28 108,61 (19,27)	0,93 (2,24)	-1,34 [-7,40;4,73] 0,6616 -0,10 [-0,55;0,35]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4094)																					
Negativ	63 104,95 (16,84)	60 103,10 (18,86)	58 103,93 (22,48)	60 102,30 (22,09)	57 101,59 (21,18)	53 101,09 (21,50)	50 97,68 (21,23)	50 102,62 (22,82)	50 104,40 (23,41)	-2,91 (1,65)	53 107,30 (16,34)	52 107,10 (18,64)	51 108,43 (15,95)	44 111,77 (14,92)	43 111,55 (14,56)	40 110,90 (16,62)	40 111,95 (15,95)	37 114,84 (13,62)	36 114,44 (13,21)	3,99 (1,83)	-6,90 [-11,79;-2,01] 0,0061 -0,52 [-0,89;-0,15]
Positiv	608 108,04 (18,10)	594 106,78 (19,11)	578 107,30 (19,84)	570 106,97 (19,91)	544 106,52 (20,56)	536 106,92 (21,07)	504 107,07 (21,13)	507 108,51 (19,80)	458 108,44 (20,65)	-1,09 (0,50)	578 106,62 (17,96)	565 106,78 (18,76)	549 108,29 (17,94)	527 108,35 (19,22)	496 108,39 (19,35)	469 108,61 (19,49)	457 109,28 (19,16)	455 108,29 (19,13)	419 107,97 (19,79)	0,79 (0,51)	-1,87 [-3,28;-0,46] 0,0092 -0,15 [-0,27;-0,04]

Subgruppe	Abemaciclib+ET[1] B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	ET[1] B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Abemaciclib+ET vs. ET[1] Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Unbekannt	6 116,50 (7,06)	6 109,67 (19,78)	6 125,00 (15,56)	4 130,00 (10,58)	4 128,25 (11,12)	4 127,25 (11,79)	4 127,00 (14,07)	3 121,33 (22,14)	3 126,33 (7,37)	6,25 (3,45)	8 100,13 (23,68)	7 98,86 (29,64)	8 103,13 (25,34)	6 106,00 (28,38)	6 116,33 (19,54)	8 100,75 (27,41)	4 104,25 (33,39)	8 98,38 (29,62)	7 101,43 (23,49)	1,71 (2,62)	4,53 [-5,17;14,24] 0,3370 0,54 [-0,47;1,55]
Ethnizität (p-Wert des Interaktionsterms: 0,7924)																					
Weiß	396 107,70 (16,83)	383 106,09 (18,21)	367 106,75 (19,16)	364 105,90 (18,47)	338 105,29 (19,34)	333 105,73 (20,34)	303 105,44 (19,96)	307 106,98 (19,02)	274 107,22 (19,09)	-1,68 (0,60)	381 106,56 (17,70)	367 106,04 (19,05)	352 107,82 (17,78)	337 107,34 (19,39)	319 107,97 (19,37)	301 108,00 (19,23)	288 108,89 (18,31)	289 107,72 (19,06)	267 107,27 (19,16)	0,12 (0,61)	-1,80 [-3,47;-0,12] 0,0358 -0,15 [-0,29;-0,01]
Asiatisch	259 107,89 (19,15)	257 106,95 (19,76)	253 107,72 (21,05)	251 108,40 (21,74)	245 107,49 (22,41)	239 107,59 (22,44)	236 107,72 (22,52)	235 109,17 (21,61)	223 108,80 (22,86)	-0,04 (0,80)	226 107,02 (18,09)	225 107,60 (18,52)	223 108,97 (18,37)	217 111,15 (18,52)	202 110,03 (18,59)	194 109,84 (19,95)	192 110,10 (20,06)	188 110,05 (18,77)	176 109,66 (20,06)	2,16 (0,86)	-2,20 [-4,51;0,12] 0,0629 -0,17 [-0,35;0,01]
Andere	26 111,15 (22,16)	25 111,56 (23,34)	25 110,20 (23,13)	25 106,52 (23,94)	24 108,71 (20,88)	22 111,18 (18,82)	22 110,41 (23,76)	20 112,60 (17,77)	18 112,61 (20,03)	-2,19 (2,63)	29 104,48 (20,21)	28 107,64 (20,00)	28 105,11 (16,85)	27 105,89 (16,99)	25 109,66 (18,15)	22 107,32 (16,45)	21 111,24 (19,60)	23 107,57 (21,72)	18 111,61 (18,78)	3,61 (2,52)	-5,81 [-13,20;1,59] 0,1208 -0,43 [-0,97;0,11]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,3849)																					
Tamoxifen	490 106,47 (17,09)	478 105,19 (18,11)	458 105,57 (19,37)	459 105,00 (19,12)	430 104,31 (19,27)	422 104,92 (20,04)	398 104,41 (20,12)	399 106,47 (19,20)	361 105,65 (19,49)	-1,35 (0,54)	476 105,88 (17,27)	463 106,17 (17,99)	447 107,51 (17,39)	426 108,06 (18,47)	399 108,11 (18,63)	386 107,63 (18,80)	371 108,40 (18,06)	375 107,50 (18,47)	346 107,44 (19,01)	1,02 (0,55)	-2,37 [-3,88;-0,85] 0,0022 -0,20 [-0,32;-0,07]
Aromatase-Inhibitor	202 111,53 (19,09)	197 110,14 (20,55)	196 111,30 (21,04)	190 111,45 (21,61)	186 110,96 (22,81)	181 110,75 (22,96)	172 111,53 (22,83)	170 112,19 (21,57)	159 113,63 (22,60)	-0,64 (0,92)	172 108,89 (19,20)	169 108,56 (20,90)	167 110,13 (18,98)	159 110,58 (20,31)	154 110,97 (19,76)	138 111,99 (20,52)	137 112,53 (20,98)	131 112,02 (20,29)	121 111,42 (20,40)	1,32 (1,01)	-1,95 [-4,64;0,73] 0,1530 -0,15 [-0,35;0,05]
ECOG-PS (p-Wert des Interaktionsterms: 0,4634)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
ECOG-PS 0	614 107,84 (17,78)	598 106,40 (18,82)	579 106,83 (20,06)	577 106,32 (19,89)	544 105,61 (20,58)	535 106,30 (20,81)	504 106,05 (21,07)	502 107,87 (20,00)	463 107,73 (20,68)	-1,55 (0,49)	575 107,77 (17,47)	560 107,68 (18,71)	544 108,97 (17,67)	521 109,45 (18,95)	492 109,62 (18,95)	467 109,81 (19,22)	455 110,18 (18,73)	446 109,57 (18,92)	417 109,28 (19,17)	0,79 (0,50)	-2,34 [-3,71;-0,96] 0,0009 -0,19 [-0,31;-0,08]
ECOG-PS 1	78 108,82 (18,32)	77 108,47 (20,16)	75 110,81 (19,72)	72 111,39 (21,14)	72 111,65 (20,24)	68 109,57 (23,28)	66 110,50 (22,00)	67 110,49 (20,77)	57 111,04 (21,68)	2,61 (1,62)	73 98,14 (18,55)	72 100,06 (18,49)	70 102,47 (18,42)	64 102,98 (18,63)	61 103,16 (18,40)	57 100,35 (18,36)	53 103,79 (20,13)	60 101,93 (18,69)	50 101,68 (20,53)	2,67 (1,69)	-0,06 [-4,76;4,65] 0,9809 -0,00 [-0,32;0,32]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B Gesamtscore = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B Gesamtscore haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t105_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 105.2.2: Subgruppen für die Veränderung des FACT-B (Gesamtscore) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,6314)																					
< 65 Jahre	803 108,26 (18,08)	777 107,24 (18,88)	753 107,22 (19,55)	717 106,68 (19,01)	696 106,77 (19,26)	664 106,10 (19,35)	631 106,81 (19,58)	630 107,07 (19,58)	587 107,58 (19,65)	-1,59 (0,43)	832 107,01 (18,06)	797 107,97 (17,90)	797 107,68 (17,99)	753 107,39 (18,53)	720 108,05 (18,73)	681 107,88 (18,97)	639 107,87 (19,37)	632 107,60 (19,13)	587 107,86 (19,04)	0,37 (0,43)	-1,96 [-3,16;-0,77] 0,0013 -0,16 [-0,26;-0,06]
≥ 65 Jahre	302 108,44 (18,54)	291 105,50 (19,09)	273 107,24 (17,56)	269 106,29 (18,82)	252 105,51 (20,02)	233 104,73 (19,68)	224 107,17 (18,90)	215 106,40 (19,10)	196 106,59 (19,54)	-3,27 (0,68)	279 109,92 (17,32)	268 109,35 (18,11)	259 109,97 (17,04)	253 109,71 (16,77)	245 108,05 (18,26)	238 107,78 (17,85)	220 107,37 (18,01)	216 106,81 (18,08)	190 106,29 (18,47)	-1,89 (0,70)	-1,38 [-3,29;0,53] 0,1557 -0,12 [-0,28;0,04]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,8677)																					
Neoadjuvante Chemotherapie	362 109,93 (17,94)	344 107,83 (19,30)	328 108,54 (19,29)	313 106,02 (19,83)	295 106,10 (20,35)	274 106,20 (20,24)	256 107,18 (20,61)	253 107,02 (18,92)	236 106,57 (20,66)	-3,48 (0,64)	365 106,77 (17,97)	350 107,21 (17,27)	342 106,54 (17,69)	320 106,08 (18,17)	305 106,32 (17,71)	281 106,53 (18,90)	267 106,91 (19,12)	264 105,64 (19,03)	234 105,50 (18,99)	-1,23 (0,64)	-2,25 [-4,03;-0,47] 0,0135 -0,18 [-0,33;-0,04]
Adjuvante Chemotherapie	683 107,45 (18,52)	667 106,51 (18,76)	645 106,76 (19,05)	618 107,25 (18,45)	602 106,78 (19,06)	579 105,89 (19,15)	555 107,00 (18,98)	552 106,92 (19,87)	510 107,77 (19,28)	-1,00 (0,47)	679 108,10 (17,75)	651 109,02 (18,10)	653 109,20 (17,82)	629 109,11 (17,92)	610 109,12 (18,97)	590 108,83 (18,48)	547 108,40 (19,02)	541 108,33 (18,64)	509 108,62 (18,70)	0,68 (0,46)	-1,68 [-2,97;-0,39] 0,0109 -0,14 [-0,24;-0,03]
Keine Chemotherapie	60 108,42 (15,40)	57 103,33 (18,66)	53 104,75 (16,94)	55 102,03 (18,91)	51 104,37 (19,17)	44 100,93 (17,79)	44 104,05 (17,48)	40 105,95 (17,09)	37 106,27 (17,61)	-5,80 (1,42)	67 109,30 (19,25)	64 107,31 (20,04)	61 107,59 (17,43)	57 106,04 (19,30)	50 105,58 (18,80)	48 103,60 (19,10)	45 104,73 (18,31)	43 106,44 (20,09)	34 104,03 (20,40)	-3,61 (1,36)	-2,18 [-6,09;1,72] 0,2703 -0,20 [-0,55;0,15]
Region (p-Wert des Interaktionsterms: 0,2249)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	548 109,82 (18,66)	516 107,57 (19,78)	489 108,14 (19,62)	466 107,46 (19,32)	438 108,13 (19,45)	412 106,70 (19,99)	391 108,47 (19,64)	387 109,02 (19,49)	357 107,60 (19,53)	-2,89 (0,48)	530 108,94 (18,03)	491 109,88 (18,13)	489 109,56 (17,81)	449 109,34 (18,62)	436 109,05 (18,95)	419 109,59 (18,97)	381 109,03 (19,43)	388 108,54 (19,33)	344 108,73 (18,32)	-0,43 (0,49)	-2,46 [-3,81;-1,10] 0,0004 -0,22 [-0,34;-0,10]
Asien	195 107,09 (18,48)	194 105,70 (19,84)	188 105,24 (20,57)	186 105,20 (20,18)	182 104,32 (21,16)	171 104,10 (21,62)	171 103,47 (21,29)	168 102,87 (20,94)	157 105,50 (21,44)	-2,23 (0,92)	192 106,82 (18,31)	191 106,17 (18,70)	187 106,34 (18,63)	184 107,03 (18,81)	179 106,78 (19,89)	174 106,06 (19,52)	172 106,40 (19,10)	168 105,64 (18,99)	163 107,18 (19,72)	-0,54 (0,92)	-1,69 [-4,25;0,86] 0,1933 -0,13 [-0,33;0,07]
Andere	362 106,69 (17,18)	358 106,19 (17,13)	349 107,01 (17,21)	334 106,09 (17,65)	328 105,35 (18,34)	314 105,38 (17,32)	293 106,81 (17,65)	290 106,41 (18,11)	269 108,05 (18,61)	-0,70 (0,66)	389 106,55 (17,50)	383 107,38 (17,22)	380 107,48 (17,24)	373 106,79 (17,08)	350 107,45 (17,44)	326 106,57 (17,68)	306 106,90 (18,40)	292 106,89 (18,09)	270 106,06 (19,09)	0,24 (0,63)	-0,94 [-2,73;0,84] 0,3001 -0,08 [-0,22;0,07]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3267)																					
< 20 mm	279 108,84 (18,54)	266 107,48 (19,01)	256 108,33 (19,34)	252 106,67 (19,57)	238 105,79 (20,39)	232 104,97 (20,95)	227 107,51 (20,34)	219 106,42 (20,19)	208 106,88 (20,34)	-2,54 (0,72)	298 108,55 (17,29)	284 108,47 (17,73)	283 109,40 (17,09)	267 108,48 (17,96)	259 108,25 (17,81)	241 108,14 (18,02)	230 108,20 (18,18)	223 107,58 (17,95)	207 107,23 (17,87)	-0,75 (0,70)	-1,79 [-3,76;0,17] 0,0740 -0,15 [-0,31;0,01]
≥ 20 bis < 50 mm	568 107,91 (18,58)	556 106,65 (19,16)	528 107,42 (19,05)	512 107,02 (18,75)	489 106,77 (19,50)	464 106,84 (18,78)	446 107,75 (19,03)	435 107,74 (19,02)	402 107,95 (18,89)	-1,29 (0,52)	572 107,80 (18,08)	552 108,28 (17,99)	547 108,19 (17,77)	523 107,82 (18,49)	502 108,34 (18,79)	492 107,93 (18,93)	446 107,90 (19,65)	450 107,54 (18,96)	421 107,70 (19,45)	-0,16 (0,51)	-1,13 [-2,56;0,30] 0,1222 -0,09 [-0,21;0,02]
≥ 50 mm	241 108,76 (16,98)	230 106,20 (18,55)	226 105,78 (18,57)	209 105,59 (18,72)	206 106,83 (18,17)	187 104,57 (18,70)	168 104,35 (19,03)	178 105,66 (19,79)	160 106,37 (20,46)	-2,92 (0,78)	230 106,22 (18,58)	218 107,86 (18,45)	216 106,40 (18,86)	205 107,32 (17,70)	196 106,79 (19,40)	177 106,92 (19,16)	174 106,46 (18,78)	166 106,39 (20,03)	141 106,80 (19,18)	0,18 (0,79)	-3,10 [-5,28;-0,92] 0,0055 -0,26 [-0,44;-0,08]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,8569)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	366 108,28 (19,19)	357 106,71 (19,34)	340 107,57 (19,84)	320 106,58 (19,39)	315 106,53 (20,14)	297 105,32 (20,50)	281 106,65 (20,22)	279 106,93 (20,57)	258 107,29 (20,79)	-1,96 (0,64)	360 107,68 (17,59)	341 107,79 (17,28)	346 108,16 (16,61)	322 107,40 (17,69)	314 108,58 (17,55)	295 107,57 (18,42)	280 107,91 (18,34)	268 106,44 (19,31)	246 106,77 (18,10)	-0,28 (0,65)	-1,68 [-3,47;0,11] 0,0661 -0,14 [-0,28;0,01]
4-9	475 107,99 (17,32)	455 106,56 (18,39)	444 106,74 (18,62)	431 105,84 (18,67)	412 105,86 (19,11)	386 106,14 (18,57)	373 107,10 (19,01)	371 106,63 (18,23)	351 107,56 (19,29)	-1,92 (0,55)	486 107,63 (18,34)	468 108,68 (18,58)	466 108,45 (18,18)	443 108,14 (19,03)	429 107,70 (19,64)	418 107,73 (19,02)	385 107,52 (19,63)	385 108,02 (18,51)	359 107,81 (19,52)	-0,09 (0,54)	-1,82 [-3,34;-0,31] 0,0182 -0,15 [-0,28;-0,03]
≥ 10	264 108,95 (18,38)	256 107,22 (19,41)	242 107,62 (18,67)	235 107,89 (18,85)	221 107,37 (19,18)	214 105,61 (19,51)	201 106,89 (19,02)	195 107,39 (20,13)	174 106,94 (18,57)	-2,28 (0,76)	265 108,02 (17,61)	256 108,36 (17,75)	244 107,96 (18,69)	241 108,42 (17,00)	222 107,96 (18,05)	206 108,50 (18,41)	194 107,95 (18,84)	195 107,47 (18,95)	172 107,79 (18,80)	-0,38 (0,76)	-1,90 [-4,02;0,22] 0,0790 -0,15 [-0,32;0,02]
Tumorgrading (p-Wert des Interaktionsterms: 0,9795)																					
G1	81 108,06 (18,29)	78 108,45 (19,15)	81 106,88 (20,19)	74 107,61 (19,18)	70 107,46 (20,28)	68 107,03 (17,09)	68 108,37 (18,84)	67 108,61 (18,60)	62 109,00 (19,08)	-0,70 (1,35)	84 110,05 (17,57)	83 111,23 (18,32)	80 111,06 (17,24)	75 111,80 (15,59)	78 108,30 (20,29)	72 110,46 (18,97)	66 110,06 (19,40)	67 110,67 (17,02)	59 109,61 (18,33)	0,66 (1,32)	-1,36 [-5,09;2,37] 0,4723 -0,11 [-0,42;0,19]
G2	526 108,61 (17,71)	509 106,46 (19,38)	488 106,82 (19,24)	466 106,32 (19,49)	448 106,02 (19,78)	420 105,16 (19,89)	392 106,93 (19,59)	401 105,98 (19,71)	367 106,90 (20,05)	-2,76 (0,53)	534 107,43 (18,10)	509 107,78 (18,06)	507 107,65 (18,08)	488 107,32 (18,40)	463 106,66 (19,19)	441 107,17 (18,76)	414 106,75 (19,33)	412 106,93 (18,69)	379 106,73 (18,90)	-0,85 (0,52)	-1,90 [-3,36;-0,44] 0,0106 -0,16 [-0,28;-0,04]
G3	449 108,03 (18,95)	434 106,90 (18,65)	411 108,05 (18,76)	400 106,84 (18,29)	386 106,98 (19,14)	367 106,12 (19,32)	356 106,72 (19,47)	336 107,38 (19,54)	321 107,52 (19,60)	-1,32 (0,58)	436 107,43 (17,97)	416 108,39 (17,86)	413 108,27 (17,69)	389 108,14 (18,32)	374 109,61 (17,22)	360 108,44 (18,70)	336 108,79 (18,76)	326 107,63 (19,31)	303 108,19 (18,93)	0,68 (0,58)	-2,01 [-3,62;-0,39] 0,0149 -0,16 [-0,30;-0,03]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
GX	47 107,94 (16,72)	45 105,84 (16,97)	44 104,52 (17,47)	44 104,99 (19,33)	42 104,95 (18,20)	40 106,33 (19,94)	37 106,00 (18,49)	39 108,95 (17,93)	32 107,38 (16,58)	-2,91 (1,84)	53 109,42 (15,28)	53 107,89 (16,81)	52 109,00 (16,24)	50 106,88 (16,29)	47 108,24 (20,12)	43 104,53 (16,38)	41 104,49 (16,84)	40 103,78 (19,13)	33 105,06 (20,05)	-2,49 (1,74)	-0,42 [-5,44;4,61] 0,8701 -0,03 [-0,43;0,36]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9022)																					
Negativ	137 104,73 (17,35)	133 103,06 (19,85)	126 103,11 (20,43)	124 103,59 (19,66)	115 102,37 (20,70)	104 101,46 (19,89)	98 103,37 (19,10)	101 101,86 (18,98)	89 102,80 (19,62)	-2,63 (1,03)	149 106,64 (17,46)	143 106,96 (18,00)	140 107,44 (17,94)	133 107,17 (18,56)	125 107,50 (18,29)	117 106,51 (19,89)	105 104,36 (20,03)	104 105,72 (16,72)	91 106,56 (18,09)	-0,30 (0,99)	-2,34 [-5,16;0,48] 0,1040 -0,19 [-0,43;0,04]
Positiv	937 108,54 (18,24)	904 106,87 (18,71)	870 107,38 (18,73)	837 106,56 (18,67)	811 106,68 (19,10)	770 105,89 (19,20)	731 106,93 (19,32)	721 107,27 (19,37)	673 107,56 (19,58)	-2,06 (0,40)	935 107,61 (17,92)	899 108,32 (17,90)	893 108,08 (17,76)	850 107,84 (17,99)	818 107,86 (18,67)	780 107,81 (18,53)	735 108,00 (18,84)	722 107,41 (19,09)	665 107,38 (19,04)	-0,16 (0,40)	-1,90 [-3,00;-0,80] 0,0007 -0,16 [-0,25;-0,07]
Unbekannt	9 112,00 (22,72)	9 114,78 (15,72)	9 123,22 (12,27)	7 127,00 (18,48)	3 139,33 (3,06)	7 122,86 (21,29)	8 123,13 (19,74)	7 123,86 (17,42)	5 128,40 (14,98)	6,91 (4,02)	7 118,29 (18,16)	6 122,67 (10,63)	6 119,17 (10,78)	6 125,83 (8,33)	6 120,00 (10,14)	6 119,33 (11,84)	5 121,20 (14,45)	6 128,33 (9,93)	5 123,20 (9,96)	8,57 (4,50)	-1,66 [-14,79;11,46] 0,7879 -0,13 [-1,07;0,80]
Ethnizität (p-Wert des Interaktionsterms: 0,4736)																					
Weiß	806 108,23 (18,05)	773 106,79 (18,47)	750 107,31 (18,33)	717 106,20 (18,47)	684 106,31 (19,06)	646 105,57 (18,67)	605 107,08 (18,71)	603 107,29 (18,74)	561 106,84 (19,11)	-2,37 (0,42)	820 108,10 (17,72)	778 108,83 (17,73)	774 108,89 (17,36)	730 107,90 (18,02)	700 108,24 (18,39)	669 108,23 (18,29)	613 107,92 (18,78)	612 107,54 (18,82)	547 107,39 (18,72)	-0,39 (0,41)	-1,99 [-3,13;-0,84] 0,0007 -0,17 [-0,27;-0,07]
Asiatisch	233 108,27 (18,82)	231 106,87 (20,04)	221 107,09 (20,58)	218 107,44 (20,52)	213 106,90 (21,23)	200 106,26 (21,57)	199 105,52 (21,31)	197 105,41 (21,42)	179 108,11 (21,70)	-0,94 (0,89)	221 106,56 (18,59)	218 106,86 (18,76)	215 106,51 (19,03)	213 108,28 (18,96)	204 107,90 (20,01)	193 106,67 (19,57)	191 107,11 (19,44)	185 106,66 (19,38)	181 108,01 (19,82)	0,46 (0,91)	-1,40 [-3,90;1,10] 0,2708 -0,10 [-0,29;0,08]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	54 109,61 (17,43)	52 106,55 (20,59)	47 107,30 (21,00)	43 108,19 (18,45)	43 105,33 (17,66)	42 106,93 (21,07)	44 109,41 (20,17)	38 107,39 (19,77)	35 110,86 (16,73)	-1,60 (1,69)	57 108,77 (17,84)	57 107,25 (18,53)	55 107,96 (16,56)	51 107,59 (17,17)	50 105,53 (16,61)	46 108,41 (19,88)	45 110,56 (20,22)	40 108,40 (18,47)	40 107,18 (19,28)	-1,49 (1,63)	-0,12 [-4,77;4,54] 0,9607 -0,01 [-0,38;0,36]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,2864)																					
Tamoxifen	103 106,28 (17,10)	99 105,83 (17,49)	100 105,43 (19,32)	97 105,62 (17,30)	96 105,80 (18,86)	95 105,92 (18,26)	90 105,99 (19,31)	89 106,64 (19,74)	90 107,49 (19,22)	-0,25 (1,14)	124 105,38 (16,61)	123 105,77 (16,32)	123 106,00 (17,19)	116 106,15 (16,50)	109 104,67 (17,36)	98 106,60 (17,81)	94 106,27 (16,09)	91 105,79 (17,49)	89 107,73 (16,36)	0,09 (1,05)	-0,34 [-3,40;2,72] 0,8257 -0,03 [-0,29;0,23]
Aromatase-Inhibitor	1002 108,52 (18,30)	969 106,86 (19,09)	926 107,42 (19,00)	889 106,67 (19,12)	852 106,51 (19,54)	802 105,72 (19,58)	765 107,01 (19,42)	756 106,93 (19,43)	693 107,31 (19,68)	-2,23 (0,39)	987 108,03 (18,06)	942 108,65 (18,14)	933 108,54 (17,85)	890 108,21 (18,32)	856 108,48 (18,72)	821 108,00 (18,78)	765 107,93 (19,35)	757 107,59 (19,02)	688 107,45 (19,22)	-0,25 (0,39)	-1,97 [-3,05;-0,90] 0,0003 -0,16 [-0,25;-0,07]
ECOG-PS (p-Wert des Interaktionsterms: 0,4652)																					
ECOG-PS 0	931 109,24 (17,76)	899 107,65 (18,72)	865 107,98 (18,91)	841 107,06 (18,79)	807 107,19 (19,18)	769 106,31 (19,32)	730 107,63 (18,92)	725 107,60 (19,03)	677 107,89 (19,25)	-2,10 (0,39)	899 108,54 (17,74)	861 109,08 (17,79)	855 108,86 (17,41)	819 108,47 (17,72)	788 108,46 (18,66)	753 108,07 (18,46)	699 107,80 (18,99)	691 107,55 (18,64)	628 107,96 (18,93)	-0,58 (0,40)	-1,52 [-2,62;-0,43] 0,0065 -0,13 [-0,22;-0,04]
ECOG-PS 1	174 103,37 (19,73)	169 102,09 (19,46)	161 103,17 (19,20)	145 103,73 (19,68)	141 102,12 (20,54)	128 102,30 (19,84)	125 102,63 (21,56)	120 102,68 (21,41)	106 103,81 (21,60)	-1,65 (1,01)	212 104,33 (18,30)	204 105,10 (18,35)	201 105,60 (19,13)	187 105,79 (19,70)	177 106,23 (18,30)	166 106,84 (19,65)	160 107,49 (19,19)	157 106,71 (19,85)	149 105,43 (18,72)	1,59 (0,90)	-3,24 [-5,90;-0,58] 0,0170 -0,25 [-0,45;-0,04]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Datenschnitt: 01.07.2022 Safety-Population 1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B Gesamtscore = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B Gesamtscore haben. Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.																				

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t105_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
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Tabelle 106.1.2: Subgruppen für die Veränderung der FACT-B-Subskala: BCS aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Region (p-Wert des Interaktionsterms: 0,7210)																					
Nordamerika / Europa	280 23,76 (5,31)	267 24,17 (5,50)	254 24,13 (5,40)	252 23,78 (5,43)	225 23,95 (5,54)	225 23,48 (5,61)	209 23,27 (5,89)	208 23,83 (5,50)	178 23,65 (5,76)	0,07 (0,20)	256 23,25 (5,94)	244 23,80 (5,80)	233 24,07 (5,75)	210 24,32 (5,55)	195 24,66 (5,52)	188 24,29 (5,41)	178 24,40 (5,20)	180 24,37 (5,33)	165 24,39 (5,49)	0,83 (0,22)	-0,75 [-1,34;-0,17] 0,0118 -0,22 [-0,39;-0,05]
Asien	233 24,06 (6,25)	232 24,90 (6,11)	228 24,81 (6,46)	227 24,51 (6,87)	223 24,01 (6,97)	217 23,89 (7,08)	216 24,06 (7,17)	212 23,90 (7,40)	210 24,03 (7,06)	0,23 (0,25)	211 24,04 (5,59)	210 24,58 (5,94)	209 24,81 (6,02)	203 24,81 (6,13)	193 24,58 (6,06)	187 24,58 (6,50)	183 25,20 (6,32)	181 24,85 (6,13)	171 24,18 (6,18)	0,64 (0,26)	-0,41 [-1,12;0,30] 0,2526 -0,11 [-0,30;0,08]
Andere	180 23,18 (5,81)	179 24,09 (5,64)	174 24,89 (5,88)	172 24,37 (5,69)	169 24,23 (6,35)	162 24,54 (6,11)	146 23,55 (6,30)	151 23,95 (6,17)	133 24,19 (5,87)	0,96 (0,29)	182 22,82 (5,59)	179 23,91 (5,66)	177 24,30 (5,28)	174 24,20 (5,49)	168 24,23 (5,32)	149 23,95 (5,69)	148 25,07 (5,59)	145 24,43 (5,49)	132 24,09 (5,50)	1,28 (0,29)	-0,32 [-1,12;0,48] 0,4332 -0,08 [-0,29;0,12]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,8049)																					
< 20 mm	179 23,59 (5,52)	176 24,38 (5,33)	167 24,31 (5,74)	169 24,09 (6,10)	160 23,58 (6,04)	158 23,56 (6,29)	152 23,26 (6,53)	155 23,28 (6,44)	148 23,85 (6,35)	0,28 (0,28)	169 22,86 (6,32)	164 23,52 (6,28)	161 24,02 (5,93)	153 23,54 (5,62)	150 23,75 (5,70)	140 24,19 (5,74)	135 24,58 (5,81)	135 24,41 (5,90)	123 24,53 (5,71)	0,93 (0,29)	-0,65 [-1,43;0,14] 0,1072 -0,17 [-0,38;0,04]
≥ 20 bis < 50 mm	324 23,95 (5,85)	315 24,78 (6,01)	312 25,02 (6,11)	306 24,35 (6,02)	288 24,48 (6,50)	280 24,29 (6,49)	263 24,02 (6,63)	264 24,41 (6,57)	237 24,40 (6,45)	0,47 (0,21)	314 23,29 (5,69)	307 24,01 (5,55)	303 24,48 (5,61)	290 24,66 (5,88)	270 24,74 (5,62)	260 24,27 (6,03)	253 24,92 (5,66)	246 24,46 (5,56)	236 24,03 (5,64)	0,96 (0,21)	-0,49 [-1,07;0,10] 0,1044 -0,13 [-0,28;0,03]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 50 mm	172 23,17 (5,60)	169 23,70 (5,36)	162 23,81 (5,44)	160 23,76 (5,62)	153 23,46 (5,92)	152 23,39 (5,83)	142 23,15 (5,90)	139 23,29 (5,83)	122 22,89 (5,93)	0,20 (0,27)	158 23,97 (5,05)	154 24,77 (5,56)	147 24,45 (5,63)	136 24,92 (5,34)	130 24,75 (5,46)	117 24,33 (5,69)	114 24,97 (5,68)	118 24,64 (5,49)	103 24,00 (5,82)	0,68 (0,28)	-0,48 [-1,24;0,29] 0,2196 -0,14 [-0,35;0,08]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,3768)																					
0-3	238 23,71 (5,75)	231 24,07 (5,68)	218 24,23 (5,83)	221 23,79 (5,93)	201 23,90 (5,74)	199 23,58 (5,90)	192 22,99 (6,10)	187 23,70 (5,84)	169 23,46 (6,20)	0,08 (0,24)	237 23,13 (5,41)	231 23,93 (5,45)	224 24,24 (5,47)	210 24,23 (5,32)	200 23,97 (5,29)	191 24,11 (5,60)	183 24,35 (5,42)	180 24,32 (5,50)	176 23,91 (5,75)	0,84 (0,24)	-0,76 [-1,43;-0,09] 0,0272 -0,20 [-0,38;-0,02]
4-9	315 23,42 (5,96)	308 24,14 (5,85)	303 24,49 (6,02)	298 23,94 (6,10)	288 23,74 (6,48)	285 23,79 (6,60)	263 23,53 (6,78)	264 23,66 (6,65)	243 23,97 (6,37)	0,42 (0,21)	294 23,46 (5,97)	287 24,02 (6,03)	281 24,42 (5,98)	266 24,42 (6,04)	254 24,85 (5,89)	241 24,55 (6,12)	240 25,13 (5,96)	237 24,76 (5,93)	219 24,37 (5,69)	0,98 (0,22)	-0,56 [-1,16;0,04] 0,0678 -0,15 [-0,31;0,01]
≥ 10	140 24,37 (5,35)	139 25,53 (5,56)	135 25,30 (5,80)	132 25,45 (5,96)	128 24,98 (6,68)	120 24,76 (6,23)	116 24,97 (6,34)	120 24,68 (6,79)	109 24,62 (6,47)	0,63 (0,29)	118 23,72 (5,85)	115 24,59 (5,96)	114 24,58 (5,53)	111 24,95 (5,78)	102 24,68 (5,69)	92 24,02 (5,91)	86 25,35 (5,72)	89 24,52 (5,30)	73 24,59 (5,95)	0,77 (0,32)	-0,14 [-1,00;0,72] 0,7524 -0,04 [-0,28;0,21]
Tumorstadium (p-Wert des Interaktionsterms: 0,1150)																					
IIA	71 24,17 (5,63)	69 24,59 (5,52)	67 24,55 (5,58)	67 23,73 (6,25)	65 23,55 (5,92)	61 22,97 (5,64)	59 22,86 (6,05)	60 23,38 (6,22)	55 23,44 (6,43)	-0,23 (0,43)	69 23,22 (5,94)	67 24,09 (5,61)	66 24,97 (5,07)	60 24,00 (5,18)	57 24,54 (5,42)	56 24,66 (5,91)	56 25,13 (5,34)	51 25,12 (5,39)	50 25,00 (5,45)	1,28 (0,44)	-1,51 [-2,72;-0,30] 0,0151 -0,42 [-0,75;-0,08]
IIB	65 23,40 (5,08)	63 24,30 (5,90)	59 25,31 (5,89)	61 23,74 (6,26)	52 24,56 (5,87)	55 23,76 (6,32)	54 23,74 (5,76)	53 24,04 (5,84)	51 24,06 (6,04)	0,26 (0,50)	85 23,20 (5,13)	83 24,41 (4,50)	83 23,83 (5,37)	77 24,40 (5,83)	76 23,62 (5,01)	72 24,03 (5,40)	67 24,22 (5,24)	70 24,20 (5,49)	69 23,86 (5,34)	0,37 (0,43)	-0,11 [-1,42;1,19] 0,8645 -0,03 [-0,35;0,29]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIIA	308 23,59 (6,06)	302 24,21 (5,71)	296 24,47 (6,01)	294 24,01 (5,98)	280 23,93 (6,38)	278 23,85 (6,64)	253 23,56 (6,69)	254 23,73 (6,64)	234 23,90 (6,47)	0,36 (0,22)	267 23,55 (5,97)	259 23,87 (6,01)	252 24,22 (6,14)	244 24,31 (6,02)	228 24,53 (6,00)	215 24,37 (6,23)	214 25,05 (6,13)	214 24,84 (5,96)	200 24,24 (5,85)	0,71 (0,23)	-0,34 [-0,97;0,28] 0,2804 -0,09 [-0,25;0,07]
IIIB	18 21,56 (7,19)	18 22,44 (6,18)	16 20,94 (6,96)	17 21,71 (5,64)	13 20,69 (4,63)	14 20,71 (5,77)	14 19,50 (7,25)	14 20,00 (6,09)	14 22,64 (5,39)	-0,25 (0,79)	17 24,82 (4,26)	17 27,53 (4,57)	16 26,38 (4,66)	13 27,54 (4,54)	12 27,58 (3,20)	12 26,17 (4,51)	13 25,38 (4,86)	12 24,42 (3,42)	11 24,45 (4,41)	1,53 (0,86)	-1,78 [-4,20;0,65] 0,1443 -0,51 [-1,16;0,15]
IIIC	227 23,92 (5,33)	222 24,78 (5,78)	214 24,72 (5,76)	208 24,85 (5,95)	203 24,45 (6,47)	193 24,55 (6,01)	188 24,22 (6,47)	188 24,45 (6,31)	164 24,16 (6,31)	0,61 (0,23)	210 23,16 (5,73)	206 23,91 (6,11)	201 24,44 (5,56)	192 24,56 (5,56)	183 24,63 (5,61)	169 24,07 (5,75)	159 24,81 (5,62)	159 24,17 (5,58)	138 24,10 (6,03)	1,11 (0,24)	-0,50 [-1,16;0,15] 0,1336 -0,14 [-0,33;0,04]
Tumorgrading (p-Wert des Interaktionsterms: 0,6251)																					
G1	59 24,00 (5,52)	58 24,40 (5,46)	54 24,50 (5,52)	54 24,30 (5,29)	55 24,36 (5,61)	53 23,58 (5,46)	51 24,18 (5,83)	53 23,96 (6,24)	47 23,53 (6,09)	0,67 (0,47)	47 21,32 (5,82)	45 22,93 (5,54)	43 22,95 (6,11)	43 23,60 (5,67)	41 24,12 (5,47)	39 22,59 (6,20)	39 24,13 (6,25)	38 23,42 (6,27)	34 23,35 (6,00)	1,34 (0,53)	-0,68 [-2,10;0,74] 0,3464 -0,19 [-0,57;0,20]
G2	310 24,14 (5,54)	303 24,67 (5,64)	296 24,90 (5,74)	293 24,25 (5,99)	278 24,27 (6,22)	274 24,07 (6,44)	256 24,14 (6,28)	253 24,24 (6,34)	234 23,81 (6,20)	0,11 (0,21)	283 24,04 (5,69)	276 24,53 (5,97)	270 24,91 (5,86)	255 24,82 (5,80)	236 24,99 (5,74)	233 24,78 (5,96)	223 25,30 (5,87)	224 24,83 (5,78)	204 24,39 (5,92)	0,61 (0,22)	-0,50 [-1,10;0,09] 0,0949 -0,14 [-0,30;0,02]
G3	279 22,92 (5,86)	273 23,85 (5,85)	264 23,97 (6,04)	261 23,69 (5,94)	243 23,47 (6,38)	236 23,42 (6,09)	224 22,56 (6,46)	226 23,04 (6,22)	200 23,65 (6,28)	0,51 (0,23)	281 23,01 (5,65)	275 23,90 (5,50)	271 24,05 (5,37)	253 24,42 (5,45)	246 24,13 (5,44)	220 24,07 (5,58)	216 24,55 (5,42)	211 24,36 (5,45)	200 24,13 (5,57)	1,19 (0,23)	-0,69 [-1,32;-0,06] 0,0325 -0,18 [-0,35;-0,02]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
GX	42 25,12 (6,75)	41 25,73 (6,20)	39 25,87 (6,78)	40 26,38 (7,39)	38 25,37 (7,13)	38 25,74 (7,30)	37 25,49 (7,87)	36 26,17 (7,74)	37 26,41 (7,19)	0,53 (0,59)	36 23,53 (5,70)	35 23,39 (6,89)	33 24,58 (6,50)	34 22,79 (7,18)	31 24,19 (6,69)	30 24,33 (7,00)	29 25,10 (6,32)	31 25,32 (5,39)	28 24,57 (5,33)	0,53 (0,64)	0,01 [-1,73;1,74] 0,9953 0,00 [-0,44;0,45]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4032)																					
Negativ	63 21,97 (5,40)	60 23,27 (5,54)	58 23,16 (6,01)	60 22,46 (6,64)	57 22,39 (6,66)	53 21,45 (6,49)	50 20,06 (6,35)	50 21,98 (6,57)	50 23,02 (6,52)	0,27 (0,52)	53 23,09 (5,14)	52 23,73 (5,61)	51 24,04 (5,01)	44 24,59 (5,50)	43 24,16 (5,24)	40 24,53 (5,16)	40 24,95 (5,22)	37 25,27 (4,77)	36 25,00 (5,35)	2,03 (0,58)	-1,77 [-3,31;-0,22] 0,0254 -0,42 [-0,79;-0,05]
Positiv	609 23,78 (5,81)	597 24,47 (5,79)	580 24,65 (5,93)	572 24,29 (5,98)	545 24,15 (6,25)	537 24,05 (6,27)	505 23,88 (6,44)	508 23,97 (6,41)	459 24,00 (6,36)	0,37 (0,15)	579 23,37 (5,81)	566 24,10 (5,82)	554 24,37 (5,78)	529 24,39 (5,72)	498 24,47 (5,72)	469 24,25 (5,98)	458 24,86 (5,82)	455 24,48 (5,75)	420 24,13 (5,81)	0,81 (0,15)	-0,45 [-0,87;-0,02] 0,0382 -0,12 [-0,23;-0,01]
Unbekannt	6 28,50 (3,73)	6 27,33 (6,15)	6 29,33 (3,14)	4 31,25 (2,50)	4 32,25 (3,10)	4 31,75 (2,06)	4 32,00 (2,83)	3 31,00 (3,61)	3 31,33 (2,08)	2,07 (0,92)	8 24,13 (6,71)	7 22,43 (8,22)	8 25,38 (6,37)	6 25,17 (9,26)	6 26,17 (4,88)	8 23,88 (5,91)	4 25,00 (5,94)	8 24,38 (6,32)	7 24,29 (5,19)	-0,41 (0,70)	2,48 [-0,14;5,09] 0,0619 1,10 [0,03;2,18]
Ethnizität (p-Wert des Interaktionsterms: 0,4420)																					
Weiß	396 23,43 (5,45)	385 23,95 (5,44)	368 24,22 (5,47)	365 23,73 (5,40)	338 23,78 (5,78)	333 23,68 (5,76)	303 23,05 (5,91)	309 23,53 (5,63)	275 23,76 (5,68)	0,29 (0,18)	381 23,09 (5,80)	367 23,70 (5,83)	357 24,09 (5,60)	337 24,18 (5,61)	321 24,41 (5,47)	301 24,15 (5,42)	288 24,60 (5,19)	289 24,53 (5,27)	267 24,21 (5,37)	0,96 (0,18)	-0,67 [-1,18;-0,17] 0,0093 -0,19 [-0,33;-0,05]
Asiatisch	260 24,13 (6,10)	258 25,00 (6,04)	254 25,08 (6,35)	252 24,89 (6,72)	246 24,41 (7,00)	240 24,18 (7,08)	237 24,39 (7,12)	235 24,29 (7,37)	223 24,16 (7,12)	0,49 (0,24)	227 24,03 (5,57)	226 24,58 (5,84)	223 24,98 (6,02)	218 24,99 (6,09)	203 24,68 (6,02)	194 24,61 (6,54)	192 25,28 (6,35)	188 24,80 (6,04)	176 24,25 (6,16)	0,72 (0,26)	-0,23 [-0,92;0,46] 0,5115 -0,06 [-0,24;0,12]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	26 24,04 (7,42)	25 25,20 (7,14)	25 24,64 (7,34)	25 23,80 (7,21)	24 24,04 (5,92)	22 24,23 (5,78)	22 24,18 (7,05)	20 24,45 (6,09)	18 24,33 (6,10)	0,13 (0,74)	29 22,52 (5,65)	28 24,71 (5,73)	28 23,36 (4,64)	27 23,30 (4,15)	25 23,94 (5,55)	22 22,82 (6,03)	22 25,23 (6,83)	23 23,04 (7,27)	18 23,67 (7,08)	1,42 (0,71)	-1,29 [-3,36;0,78] 0,2166 -0,34 [-0,87;0,19]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,6132)																					
Tamoxifen	491 23,14 (5,47)	481 23,71 (5,43)	460 23,84 (5,59)	461 23,40 (5,61)	431 23,09 (5,80)	423 23,11 (5,72)	399 22,72 (5,81)	401 23,00 (5,91)	362 22,98 (5,84)	0,18 (0,16)	477 23,01 (5,42)	464 23,57 (5,46)	450 23,99 (5,47)	428 23,96 (5,45)	402 23,92 (5,41)	386 23,68 (5,51)	372 24,24 (5,28)	375 24,01 (5,24)	347 23,68 (5,45)	0,78 (0,16)	-0,60 [-1,05;-0,15] 0,0095 -0,17 [-0,29;-0,04]
Aromatase-Inhibitor	202 25,10 (6,24)	197 26,08 (6,18)	196 26,29 (6,31)	190 26,12 (6,59)	186 26,27 (6,85)	181 25,80 (7,18)	172 25,79 (7,46)	170 25,98 (7,10)	159 26,14 (6,87)	0,73 (0,28)	172 24,41 (6,47)	169 25,51 (6,47)	169 25,45 (6,20)	159 25,77 (6,28)	154 26,04 (5,98)	138 26,01 (6,57)	137 26,64 (6,52)	131 26,12 (6,51)	121 25,81 (6,27)	1,26 (0,30)	-0,53 [-1,33;0,27] 0,1949 -0,13 [-0,34;0,07]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B BCS = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B BCS haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; BCS: Mammakarzinomspezifische Subskala; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t106_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 106.2.2: Subgruppen für die Veränderung der FACT-B-Subskala: BCS aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,4543)																					
< 65 Jahre	804 23,74 (5,65)	778 24,41 (5,53)	756 24,49 (5,64)	719 24,08 (5,65)	700 24,02 (5,87)	668 23,88 (5,75)	634 23,95 (5,75)	631 23,90 (5,76)	587 24,10 (5,70)	0,39 (0,13)	833 23,36 (5,63)	797 24,28 (5,40)	798 24,19 (5,35)	758 24,18 (5,47)	723 24,42 (5,55)	684 24,22 (5,62)	641 24,37 (5,75)	636 24,22 (5,73)	588 24,02 (5,82)	0,82 (0,13)	-0,43 [-0,78;-0,08] 0,0163 -0,12 [-0,22;-0,02]
≥ 65 Jahre	303 24,44 (5,09)	293 24,93 (5,17)	276 24,95 (5,12)	273 23,91 (5,33)	253 24,15 (5,52)	237 23,93 (5,21)	225 24,29 (5,06)	217 24,64 (5,08)	199 24,34 (5,41)	-0,32 (0,20)	279 24,96 (5,52)	268 24,59 (5,29)	262 25,43 (4,97)	253 25,21 (5,11)	245 24,69 (5,30)	238 24,78 (5,14)	221 24,57 (5,67)	217 24,72 (5,33)	193 24,80 (5,22)	-0,11 (0,21)	-0,21 [-0,78;0,36] 0,4740 -0,06 [-0,22;0,10]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,8948)																					
Neoadjuvante Chemotherapie	362 24,48 (5,53)	344 24,90 (5,68)	329 24,81 (5,73)	315 23,81 (5,62)	297 24,04 (6,01)	274 23,90 (5,72)	257 24,01 (5,78)	253 24,02 (5,57)	236 23,93 (5,89)	-0,29 (0,19)	365 23,75 (5,61)	350 24,41 (5,17)	343 24,20 (5,29)	322 23,98 (5,24)	306 24,22 (5,14)	281 24,20 (5,30)	268 24,41 (5,34)	266 23,96 (5,74)	235 23,71 (5,52)	0,21 (0,19)	-0,50 [-1,02;0,02] 0,0604 -0,14 [-0,29;0,01]
Adjuvante Chemotherapie	685 23,52 (5,58)	670 24,33 (5,36)	650 24,46 (5,47)	622 24,18 (5,60)	605 24,07 (5,77)	585 23,94 (5,65)	558 24,03 (5,59)	554 24,07 (5,72)	513 24,22 (5,60)	0,57 (0,14)	680 23,63 (5,70)	651 24,31 (5,47)	656 24,53 (5,37)	632 24,58 (5,52)	612 24,55 (5,67)	592 24,42 (5,67)	549 24,38 (5,94)	544 24,42 (5,58)	512 24,37 (5,78)	0,84 (0,14)	-0,27 [-0,66;0,12] 0,1695 -0,07 [-0,18;0,03]
Keine Chemotherapie	60 25,28 (3,95)	57 25,14 (4,82)	53 25,26 (4,50)	55 23,63 (4,78)	51 23,92 (4,24)	46 23,28 (4,50)	44 24,34 (4,11)	41 24,80 (4,03)	37 24,73 (4,17)	-1,11 (0,43)	67 25,25 (5,11)	64 24,50 (5,47)	61 25,80 (4,14)	57 25,52 (4,81)	50 25,38 (5,23)	49 24,57 (4,54)	45 24,84 (5,38)	43 25,88 (5,50)	34 25,38 (5,19)	-0,34 (0,41)	-0,77 [-1,95;0,41] 0,1968 -0,23 [-0,58;0,12]
Region (p-Wert des Interaktionsterms: 0,3902)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	548 24,22 (5,67)	517 24,64 (5,58)	493 24,76 (5,50)	468 24,02 (5,51)	441 24,29 (5,78)	418 23,92 (5,75)	393 24,17 (5,53)	388 24,21 (5,60)	359 23,90 (5,54)	-0,16 (0,15)	530 23,85 (5,74)	491 24,42 (5,53)	490 24,50 (5,31)	452 24,61 (5,51)	437 24,49 (5,49)	421 24,53 (5,52)	383 24,36 (5,92)	392 24,67 (5,76)	347 24,41 (5,58)	0,46 (0,15)	-0,62 [-1,03;-0,21] 0,0031 -0,18 [-0,30;-0,06]
Asien	195 24,25 (5,55)	194 24,69 (5,70)	188 24,13 (6,19)	187 24,07 (6,10)	182 23,79 (6,12)	171 23,46 (6,17)	171 23,68 (6,14)	168 23,43 (5,82)	157 24,03 (5,86)	-0,11 (0,26)	192 23,85 (6,02)	191 24,10 (5,57)	187 24,36 (5,70)	184 24,39 (5,87)	180 24,42 (5,90)	174 23,91 (6,17)	172 24,42 (5,76)	168 23,76 (5,78)	163 23,94 (6,09)	0,29 (0,27)	-0,40 [-1,14;0,33] 0,2816 -0,11 [-0,31;0,09]
Andere	364 23,33 (5,20)	360 24,36 (5,09)	351 24,67 (5,12)	337 24,02 (5,32)	330 23,88 (5,57)	316 24,09 (5,09)	295 24,06 (5,31)	292 24,30 (5,47)	270 24,58 (5,60)	0,87 (0,19)	390 23,61 (5,33)	383 24,41 (5,06)	383 24,56 (5,06)	375 24,26 (5,01)	351 24,52 (5,27)	327 24,39 (5,10)	307 24,48 (5,48)	293 24,26 (5,36)	271 24,12 (5,57)	0,90 (0,19)	-0,04 [-0,56;0,49] 0,8934 -0,01 [-0,15;0,13]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,1768)																					
< 20 mm	280 23,78 (5,68)	267 24,37 (5,83)	258 24,78 (5,86)	253 24,22 (5,59)	240 23,71 (6,05)	235 23,60 (6,05)	229 24,17 (5,70)	221 23,84 (5,83)	209 23,87 (5,82)	0,23 (0,22)	298 23,76 (5,42)	284 24,21 (5,41)	284 24,53 (5,20)	269 24,18 (5,59)	260 24,19 (5,63)	241 24,11 (5,59)	231 24,42 (5,68)	223 24,04 (5,66)	208 23,79 (5,64)	0,46 (0,21)	-0,24 [-0,83;0,36] 0,4346 -0,07 [-0,23;0,10]
≥ 20 bis < 50 mm	568 23,90 (5,57)	557 24,63 (5,38)	531 24,68 (5,43)	514 24,15 (5,64)	490 24,22 (5,77)	466 24,26 (5,53)	447 24,25 (5,68)	435 24,39 (5,62)	403 24,32 (5,59)	0,36 (0,15)	573 23,85 (5,72)	552 24,33 (5,37)	549 24,49 (5,34)	525 24,57 (5,33)	504 24,70 (5,45)	494 24,45 (5,58)	448 24,42 (5,91)	455 24,44 (5,56)	423 24,36 (5,67)	0,53 (0,15)	-0,16 [-0,59;0,26] 0,4424 -0,05 [-0,16;0,07]
≥ 50 mm	242 24,17 (5,19)	231 24,54 (5,12)	227 24,32 (5,24)	212 23,64 (5,31)	208 24,17 (5,35)	190 23,49 (5,21)	169 23,46 (5,12)	179 23,74 (5,30)	161 24,07 (5,40)	-0,07 (0,23)	230 23,47 (5,80)	218 24,55 (5,33)	217 24,39 (5,33)	206 24,40 (5,42)	196 24,24 (5,43)	178 24,35 (5,25)	174 24,32 (5,42)	166 24,42 (5,81)	142 24,38 (5,87)	0,84 (0,23)	-0,91 [-1,55;-0,26] 0,0061 -0,25 [-0,44;-0,07]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7484)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	368 23,83 (5,59)	359 24,45 (5,57)	344 24,77 (5,39)	323 24,16 (5,46)	318 24,27 (5,82)	301 23,84 (5,77)	285 24,10 (5,56)	281 24,20 (5,92)	260 24,23 (5,77)	0,48 (0,19)	360 23,80 (5,30)	341 24,39 (5,10)	346 24,56 (5,01)	324 24,48 (5,39)	315 24,94 (4,86)	296 24,44 (5,14)	280 24,62 (5,36)	269 24,35 (5,66)	247 24,22 (5,54)	0,68 (0,19)	-0,20 [-0,72;0,33] 0,4600 -0,05 [-0,20;0,09]
4-9	475 23,84 (5,51)	456 24,40 (5,35)	444 24,35 (5,59)	434 23,75 (5,57)	413 23,85 (5,69)	389 23,94 (5,38)	373 23,92 (5,54)	372 23,84 (5,49)	351 24,12 (5,73)	0,07 (0,16)	486 23,84 (5,80)	468 24,33 (5,45)	467 24,62 (5,28)	445 24,66 (5,42)	430 24,32 (5,82)	418 24,37 (5,65)	386 24,35 (5,97)	386 24,51 (5,51)	360 24,28 (5,66)	0,55 (0,16)	-0,47 [-0,92;-0,02] 0,0407 -0,13 [-0,26;-0,01]
≥ 10	264 24,25 (5,41)	256 24,98 (5,41)	244 24,87 (5,53)	235 24,39 (5,68)	222 24,13 (5,87)	215 23,88 (5,82)	201 24,17 (5,70)	195 24,39 (5,34)	175 24,14 (5,21)	0,09 (0,23)	266 23,59 (5,82)	256 24,36 (5,59)	247 24,17 (5,66)	242 23,98 (5,36)	223 24,17 (5,63)	208 24,25 (5,72)	196 24,25 (5,76)	198 24,04 (5,85)	174 24,06 (5,96)	0,48 (0,23)	-0,40 [-1,03;0,24] 0,2193 -0,11 [-0,28;0,06]
Tumorstadium (p-Wert des Interaktionsterms: 0,1029)																					
IIA	93 23,88 (5,98)	91 24,34 (6,07)	87 24,87 (5,47)	84 24,43 (5,40)	83 23,83 (5,92)	81 24,36 (5,73)	79 24,54 (6,05)	72 24,13 (6,51)	67 24,48 (6,08)	0,52 (0,33)	95 23,28 (5,04)	90 23,53 (5,34)	90 23,80 (4,64)	87 23,24 (5,33)	83 24,06 (5,08)	82 23,00 (5,51)	78 23,56 (5,25)	73 23,23 (5,34)	66 23,15 (5,31)	0,20 (0,33)	0,32 [-0,61;1,25] 0,4994 0,10 [-0,19;0,38]
IIB	133 23,64 (5,79)	130 24,91 (5,76)	123 24,86 (5,26)	120 24,38 (5,48)	118 24,47 (5,76)	110 23,63 (5,68)	102 24,33 (5,33)	103 24,58 (5,73)	97 24,27 (5,68)	0,70 (0,33)	113 24,33 (5,49)	107 24,40 (5,09)	107 24,48 (4,89)	101 24,47 (5,54)	96 25,37 (4,91)	97 24,58 (5,05)	92 24,77 (5,63)	89 24,27 (5,82)	83 24,13 (6,01)	0,26 (0,35)	0,44 [-0,50;1,39] 0,3565 0,12 [-0,13;0,37]
IIIA	429 23,93 (5,34)	414 24,36 (5,12)	401 24,41 (5,31)	389 23,53 (5,49)	368 23,79 (5,64)	347 23,88 (5,40)	329 23,76 (5,38)	337 23,60 (5,58)	312 23,90 (5,75)	-0,07 (0,17)	437 23,81 (5,66)	417 24,38 (5,32)	423 24,70 (5,20)	399 24,71 (5,25)	390 24,35 (5,75)	373 24,50 (5,53)	345 24,64 (5,79)	342 24,63 (5,55)	320 24,28 (5,70)	0,68 (0,17)	-0,75 [-1,22;-0,27] 0,0020 -0,21 [-0,34;-0,08]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIIB	47 23,53 (6,11)	45 24,20 (6,52)	45 24,69 (6,49)	44 24,00 (6,77)	43 25,02 (6,42)	39 23,49 (5,59)	36 24,08 (6,29)	33 24,58 (5,99)	35 24,60 (5,98)	0,63 (0,52)	41 24,98 (6,19)	40 25,98 (5,69)	40 26,05 (5,79)	37 26,86 (5,48)	35 25,91 (5,63)	33 25,24 (5,79)	32 24,84 (6,45)	29 25,79 (5,47)	28 26,21 (5,01)	1,07 (0,56)	-0,44 [-1,97;1,09] 0,5659 -0,12 [-0,54;0,30]
IIIC	403 24,10 (5,44)	390 24,74 (5,39)	374 24,71 (5,68)	353 24,40 (5,54)	339 24,15 (5,78)	326 23,95 (5,81)	311 24,15 (5,66)	301 24,45 (5,29)	273 24,32 (5,32)	0,25 (0,18)	424 23,56 (5,75)	409 24,34 (5,46)	398 24,28 (5,54)	385 24,19 (5,47)	362 24,36 (5,42)	335 24,39 (5,57)	314 24,25 (5,74)	318 24,19 (5,73)	282 24,22 (5,70)	0,59 (0,18)	-0,35 [-0,85;0,16] 0,1807 -0,09 [-0,23;0,04]
Tumorgrading (p-Wert des Interaktionsterms: 0,7381)																					
G1	82 23,07 (5,75)	79 24,57 (5,17)	82 24,38 (5,71)	75 23,56 (5,39)	72 23,09 (6,54)	72 23,44 (5,73)	69 23,10 (6,25)	68 23,43 (6,09)	62 23,58 (5,86)	0,38 (0,40)	84 24,68 (5,26)	83 25,37 (5,55)	80 25,24 (5,06)	76 25,17 (5,15)	78 24,23 (5,74)	73 24,88 (5,29)	66 25,02 (5,51)	67 24,99 (5,46)	59 24,39 (5,77)	0,35 (0,39)	0,02 [-1,09;1,13] 0,9706 0,01 [-0,30;0,31]
G2	526 24,15 (5,49)	510 24,68 (5,49)	489 24,65 (5,63)	467 23,99 (5,74)	449 24,08 (5,86)	422 23,94 (5,70)	392 24,20 (5,51)	402 23,94 (5,60)	369 24,22 (5,61)	0,02 (0,16)	535 23,68 (5,86)	509 24,20 (5,38)	509 24,38 (5,41)	491 24,35 (5,52)	464 24,22 (5,68)	443 24,19 (5,65)	415 24,10 (5,91)	414 24,18 (5,65)	383 24,29 (5,72)	0,42 (0,15)	-0,40 [-0,83;0,03] 0,0678 -0,11 [-0,23;0,01]
G3	450 23,88 (5,50)	435 24,47 (5,52)	415 24,67 (5,41)	403 24,19 (5,38)	388 24,25 (5,58)	369 23,93 (5,45)	359 24,07 (5,52)	337 24,33 (5,54)	322 24,25 (5,69)	0,43 (0,17)	436 23,52 (5,48)	416 24,35 (5,27)	415 24,43 (5,20)	390 24,30 (5,33)	376 24,85 (5,10)	360 24,53 (5,40)	338 24,72 (5,66)	329 24,45 (5,58)	303 24,14 (5,60)	0,88 (0,18)	-0,45 [-0,94;0,04] 0,0696 -0,12 [-0,25;0,01]
GX	47 23,43 (5,46)	45 23,98 (4,67)	44 24,11 (4,85)	45 23,73 (5,76)	42 23,76 (5,29)	40 23,98 (6,10)	37 23,92 (5,68)	39 24,72 (5,44)	32 23,69 (4,93)	0,32 (0,50)	53 24,77 (4,88)	53 23,92 (5,36)	52 24,63 (4,90)	50 24,92 (5,07)	47 24,33 (5,99)	43 23,60 (4,84)	41 23,73 (4,51)	40 23,75 (5,86)	33 23,33 (6,06)	-0,18 (0,47)	0,49 [-0,87;1,86] 0,4738 0,14 [-0,25;0,54]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,8154)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Negativ	137 23,30 (5,66)	133 23,62 (5,76)	127 24,11 (5,51)	124 23,60 (5,38)	115 23,59 (6,04)	105 23,25 (5,62)	98 23,93 (5,46)	101 23,34 (5,68)	90 23,38 (5,48)	0,30 (0,30)	149 23,50 (5,51)	143 24,16 (5,25)	141 24,74 (5,08)	134 24,19 (5,49)	126 23,88 (5,23)	117 24,32 (5,33)	105 23,66 (5,38)	104 24,03 (4,78)	92 23,88 (5,06)	0,66 (0,29)	-0,36 [-1,18;0,46] 0,3848 -0,10 [-0,34;0,13]
Positiv	939 23,95 (5,49)	907 24,61 (5,39)	875 24,57 (5,51)	842 23,99 (5,58)	815 24,02 (5,71)	776 23,87 (5,60)	735 23,94 (5,58)	724 24,12 (5,60)	675 24,17 (5,66)	0,17 (0,12)	936 23,71 (5,65)	899 24,30 (5,38)	895 24,37 (5,33)	854 24,40 (5,37)	819 24,48 (5,53)	783 24,30 (5,55)	737 24,43 (5,78)	727 24,29 (5,75)	668 24,16 (5,78)	0,56 (0,12)	-0,39 [-0,72;-0,06] 0,0198 -0,11 [-0,20;-0,02]
Unbekannt	9 25,22 (6,48)	9 25,33 (4,53)	9 28,56 (4,80)	7 29,71 (4,42)	4 32,75 (3,77)	7 28,14 (5,87)	8 29,00 (4,96)	7 27,86 (5,18)	5 30,00 (4,30)	2,60 (1,47)	7 26,57 (5,47)	6 28,67 (1,86)	6 27,00 (2,10)	6 30,33 (2,94)	6 27,00 (4,00)	6 28,83 (3,71)	5 29,00 (3,39)	6 29,67 (4,03)	5 30,00 (3,54)	3,48 (1,66)	-0,88 [-5,90;4,14] 0,7016 -0,19 [-1,12;0,75]
Ethnizität (p-Wert des Interaktionsterms: 0,6061)																					
Weiß	808 23,66 (5,50)	776 24,36 (5,29)	753 24,56 (5,28)	721 23,74 (5,27)	688 23,77 (5,60)	654 23,69 (5,37)	609 23,82 (5,39)	606 24,00 (5,47)	564 23,88 (5,49)	0,13 (0,12)	820 23,75 (5,52)	778 24,37 (5,30)	777 24,52 (5,17)	733 24,31 (5,27)	701 24,39 (5,36)	671 24,41 (5,31)	615 24,28 (5,61)	615 24,47 (5,54)	550 24,18 (5,54)	0,59 (0,12)	-0,45 [-0,79;-0,11] 0,0090 -0,13 [-0,23;-0,03]
Asiatisch	233 24,68 (5,58)	231 25,06 (5,63)	221 24,82 (6,19)	219 24,91 (6,31)	214 24,74 (6,29)	200 24,21 (6,24)	199 24,32 (6,10)	197 24,13 (5,98)	179 24,74 (5,99)	0,31 (0,26)	221 23,87 (5,99)	218 24,26 (5,61)	215 24,56 (5,69)	213 24,72 (5,91)	205 24,80 (6,03)	193 24,13 (6,17)	191 24,61 (5,91)	185 24,01 (5,96)	181 24,26 (6,22)	0,51 (0,26)	-0,19 [-0,92;0,53] 0,5951 -0,05 [-0,23;0,13]
Andere	54 24,67 (4,93)	52 25,24 (6,41)	48 24,42 (5,78)	44 24,43 (5,92)	43 24,77 (5,85)	42 26,19 (5,82)	44 25,86 (5,70)	38 25,00 (5,84)	35 25,31 (5,72)	0,69 (0,54)	58 24,47 (5,56)	57 24,96 (5,28)	56 24,34 (5,44)	53 25,34 (5,33)	51 24,51 (5,16)	47 24,89 (5,39)	46 25,89 (6,17)	41 24,27 (5,90)	41 25,10 (5,37)	0,36 (0,52)	0,33 [-1,16;1,81] 0,6629 0,08 [-0,29;0,45]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,2655)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Tamoxifen	103 22,50 (5,20)	99 23,35 (4,87)	100 23,65 (5,25)	97 23,24 (5,55)	96 23,88 (6,04)	95 23,74 (5,81)	90 23,59 (5,63)	89 23,16 (5,79)	90 23,73 (5,55)	0,84 (0,32)	124 23,37 (5,34)	123 23,93 (4,87)	123 23,68 (4,88)	116 23,81 (5,20)	109 23,02 (5,09)	98 23,76 (5,02)	94 23,85 (4,58)	91 23,42 (5,00)	89 23,03 (5,02)	0,43 (0,29)	0,41 [-0,45;1,26] 0,3491 0,13 [-0,14;0,39]
Aromatase-Inhibitor	1004 24,08 (5,52)	972 24,68 (5,48)	932 24,72 (5,53)	895 24,12 (5,56)	857 24,07 (5,74)	810 23,91 (5,59)	769 24,09 (5,57)	759 24,20 (5,57)	696 24,21 (5,64)	0,14 (0,12)	988 23,82 (5,68)	942 24,41 (5,43)	937 24,60 (5,33)	895 24,52 (5,42)	859 24,67 (5,51)	824 24,43 (5,56)	768 24,49 (5,85)	762 24,46 (5,70)	692 24,36 (5,75)	0,59 (0,12)	-0,45 [-0,77;-0,13] 0,0056 -0,12 [-0,21;-0,04]
ECOG-PS (p-Wert des Interaktionsterms: 0,5633)																					
ECOG-PS 0	932 24,11 (5,47)	901 24,65 (5,40)	870 24,74 (5,53)	845 24,16 (5,55)	811 24,17 (5,78)	776 24,00 (5,62)	733 24,20 (5,54)	727 24,24 (5,57)	679 24,32 (5,58)	0,22 (0,12)	899 23,85 (5,63)	861 24,47 (5,34)	858 24,56 (5,19)	823 24,42 (5,35)	790 24,47 (5,56)	755 24,33 (5,53)	700 24,43 (5,78)	694 24,31 (5,65)	630 24,30 (5,71)	0,49 (0,12)	-0,27 [-0,60;0,05] 0,1019 -0,08 [-0,17;0,02]
ECOG-PS 1	175 22,98 (5,66)	170 24,04 (5,61)	162 23,94 (5,36)	147 23,32 (5,58)	142 23,38 (5,73)	129 23,23 (5,51)	126 23,10 (5,73)	121 23,19 (5,70)	107 23,15 (5,85)	0,13 (0,29)	213 23,39 (5,68)	204 23,87 (5,49)	202 24,22 (5,67)	188 24,52 (5,62)	178 24,58 (5,16)	167 24,53 (5,41)	162 24,34 (5,51)	159 24,52 (5,57)	151 23,85 (5,59)	1,00 (0,26)	-0,87 [-1,64;-0,10] 0,0271 -0,23 [-0,43;-0,03]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B BCS = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B BCS haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; BCS: Mammakarzinomspezifische Subskala; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t106_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba

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Tabelle 107.1.2: Subgruppen für die Veränderung der FACT-B-Subskala: PWB aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9779)																					
Neoadjuvante Chemotherapie	281 23,90 (3,77)	272 22,55 (4,71)	262 23,06 (4,50)	264 22,95 (4,67)	241 22,89 (4,70)	239 23,06 (5,03)	225 23,64 (4,72)	224 24,01 (4,65)	202 23,81 (4,84)	-0,75 (0,20)	267 23,18 (4,33)	258 22,90 (4,47)	255 23,31 (4,10)	231 23,47 (4,38)	221 23,41 (4,37)	203 23,52 (4,48)	187 23,60 (4,23)	184 23,41 (4,64)	171 23,65 (4,32)	-0,21 (0,21)	-0,54 [-1,10;0,03] 0,0613 -0,16 [-0,33;0,01]
Adjuvante Chemotherapie	407 23,27 (4,38)	401 22,36 (4,80)	391 22,77 (4,82)	385 22,99 (4,62)	373 22,86 (4,62)	362 23,08 (4,69)	343 23,53 (4,39)	347 23,80 (4,23)	317 23,85 (4,39)	-0,21 (0,14)	379 23,32 (4,02)	373 23,32 (4,22)	363 23,62 (4,23)	353 23,68 (4,25)	334 23,76 (4,35)	321 23,69 (4,33)	321 24,04 (4,14)	320 23,83 (4,36)	295 23,86 (4,51)	0,30 (0,15)	-0,50 [-0,91;-0,10] 0,0140 -0,18 [-0,32;-0,04]
Keine Chemotherapie	7 25,00 (3,61)	7 23,00 (4,40)	6 21,83 (4,45)	6 22,83 (4,54)	6 22,50 (5,86)	6 22,33 (5,39)	6 23,33 (5,50)	5 23,60 (4,51)	4 26,25 (1,50)	-1,62 (0,57)	3 20,67 (4,16)	3 17,67 (5,51)	3 19,33 (2,31)	3 21,00 (2,65)	3 22,33 (3,06)	3 23,00 (3,46)	3 21,67 (2,08)	3 25,67 (4,04)	2 22,00 (7,07)	1,13 (0,84)	-2,76 [-5,06;-0,45] 0,0233 -1,66 [-3,08;-0,24]
Region (p-Wert des Interaktionsterms: 0,8610)																					
Nordamerika / Europa	282 23,44 (3,99)	269 21,87 (4,75)	257 22,20 (4,99)	256 22,38 (4,81)	228 22,46 (4,62)	228 22,31 (5,14)	212 23,25 (4,53)	213 23,51 (4,41)	180 23,27 (4,89)	-0,80 (0,19)	256 23,05 (4,29)	245 22,58 (4,78)	235 22,89 (4,47)	210 22,87 (4,74)	197 23,21 (4,83)	191 22,99 (5,09)	180 23,43 (4,57)	181 22,98 (5,19)	165 23,09 (5,02)	-0,25 (0,20)	-0,55 [-1,09;-0,00] 0,0492 -0,17 [-0,34;-0,00]
Asien	233 23,89 (4,06)	232 22,89 (4,62)	228 23,49 (4,20)	227 23,66 (4,18)	223 23,43 (4,59)	217 23,77 (4,37)	216 24,13 (4,18)	212 24,53 (4,11)	210 24,42 (4,34)	-0,08 (0,18)	211 23,50 (3,53)	210 23,63 (3,70)	209 23,98 (3,80)	203 24,34 (3,60)	193 24,31 (3,63)	187 24,45 (3,55)	183 24,19 (4,08)	181 24,63 (3,75)	171 24,52 (3,78)	0,56 (0,19)	-0,64 [-1,15;-0,13] 0,0135 -0,24 [-0,42;-0,05]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	180 23,25 (4,46)	179 22,73 (4,86)	174 23,09 (4,73)	172 22,95 (4,82)	169 22,67 (4,74)	162 23,19 (4,82)	146 23,20 (4,94)	151 23,51 (4,67)	133 23,74 (4,34)	-0,32 (0,24)	182 23,24 (4,59)	179 23,26 (4,37)	177 23,64 (4,12)	174 23,56 (4,34)	168 23,29 (4,45)	149 23,38 (4,21)	148 24,01 (3,72)	145 23,40 (4,10)	132 23,67 (4,35)	0,05 (0,23)	-0,37 [-1,02;0,28] 0,2664 -0,12 [-0,32;0,09]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3796)																					
< 20 mm	179 23,47 (3,83)	176 22,45 (4,41)	167 22,60 (4,51)	171 22,70 (4,73)	160 22,76 (4,59)	159 22,82 (4,86)	153 23,57 (4,32)	157 23,69 (4,62)	148 23,42 (4,63)	-0,41 (0,22)	169 22,49 (4,51)	164 22,60 (4,14)	162 23,02 (4,02)	153 23,32 (3,95)	151 23,41 (4,11)	142 23,30 (4,17)	136 23,76 (3,88)	135 23,21 (4,48)	123 23,76 (4,26)	0,34 (0,22)	-0,75 [-1,36;-0,13] 0,0177 -0,26 [-0,47;-0,05]
≥ 20 bis < 50 mm	326 23,72 (4,14)	317 22,43 (5,16)	315 23,15 (4,69)	308 23,00 (4,71)	290 22,90 (4,74)	282 23,05 (4,92)	265 23,48 (4,63)	266 23,88 (4,51)	239 24,11 (4,67)	-0,56 (0,18)	314 23,32 (4,02)	308 23,11 (4,54)	304 23,70 (4,19)	290 23,78 (4,44)	272 23,66 (4,55)	261 23,72 (4,53)	254 23,88 (4,34)	246 23,83 (4,43)	236 23,87 (4,43)	0,17 (0,18)	-0,73 [-1,23;-0,23] 0,0040 -0,23 [-0,38;-0,07]
≥ 50 mm	172 23,19 (4,53)	169 22,28 (4,45)	162 22,44 (4,90)	160 22,99 (4,42)	154 22,81 (4,55)	152 23,14 (4,69)	142 23,61 (4,58)	140 23,94 (3,96)	122 23,70 (4,30)	-0,34 (0,23)	158 23,89 (3,89)	154 23,60 (4,16)	147 23,41 (4,33)	136 23,39 (4,37)	129 23,72 (4,26)	117 23,71 (4,40)	114 23,97 (4,12)	119 23,87 (4,57)	103 23,43 (4,74)	-0,26 (0,24)	-0,08 [-0,73;0,57] 0,8074 -0,03 [-0,24;0,19]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,2266)																					
0-3	238 23,65 (4,01)	231 22,39 (4,57)	218 22,76 (4,67)	222 22,85 (4,58)	202 22,88 (4,41)	200 23,10 (4,79)	192 23,46 (4,80)	188 24,08 (4,18)	169 23,76 (4,99)	-0,54 (0,20)	237 23,00 (4,01)	231 22,88 (4,31)	224 23,15 (4,54)	210 23,35 (3,98)	200 23,23 (4,41)	191 23,36 (4,41)	183 23,68 (3,93)	180 23,61 (4,32)	176 23,36 (4,87)	-0,04 (0,21)	-0,50 [-1,07;0,07] 0,0869 -0,16 [-0,34;0,02]
4-9	317 23,25 (4,27)	310 22,00 (5,04)	306 22,66 (4,70)	301 22,88 (4,57)	290 22,48 (4,71)	287 22,72 (4,82)	266 23,28 (4,40)	268 23,53 (4,47)	245 23,62 (4,36)	-0,44 (0,16)	294 23,33 (4,27)	288 23,17 (4,29)	283 23,63 (3,92)	266 23,68 (4,37)	256 23,98 (4,19)	244 23,86 (4,21)	242 24,01 (4,16)	238 23,82 (4,43)	219 24,10 (4,12)	0,33 (0,17)	-0,78 [-1,24;-0,32] 0,0010 -0,27 [-0,43;-0,11]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 10	140 24,03 (4,06)	139 23,52 (4,24)	135 23,59 (4,66)	132 23,40 (4,86)	128 23,73 (4,83)	120 23,82 (4,85)	116 24,42 (4,28)	120 24,37 (4,52)	109 24,51 (4,24)	-0,24 (0,28)	118 23,55 (4,13)	115 23,46 (4,55)	114 23,70 (4,05)	111 23,78 (4,69)	102 23,46 (4,61)	92 23,52 (4,77)	86 23,87 (4,68)	89 23,51 (4,85)	73 23,82 (4,24)	-0,17 (0,30)	-0,06 [-0,87;0,75] 0,8765 -0,02 [-0,26;0,23]
Tumorgrading (p-Wert des Interaktionsterms: 0,4849)																					
G1	59 24,02 (3,66)	58 22,43 (3,96)	54 22,94 (4,52)	54 23,46 (4,12)	55 22,96 (4,28)	53 22,83 (5,22)	51 23,33 (4,59)	53 23,66 (4,46)	47 23,79 (4,53)	-0,64 (0,40)	47 23,17 (4,91)	45 23,51 (4,09)	43 23,47 (4,04)	43 23,67 (4,08)	41 23,61 (4,53)	39 23,05 (4,89)	39 23,72 (4,57)	38 23,58 (4,82)	34 23,65 (4,21)	0,34 (0,45)	-0,98 [-2,18;0,21] 0,1065 -0,32 [-0,70;0,07]
G2	311 23,54 (4,29)	304 22,26 (4,97)	298 22,87 (4,74)	295 22,87 (4,77)	280 22,91 (4,59)	275 23,05 (4,77)	258 23,71 (4,36)	257 24,02 (4,41)	234 23,75 (4,62)	-0,46 (0,17)	283 23,37 (4,23)	276 23,46 (4,41)	271 23,77 (4,26)	255 23,78 (4,41)	237 23,95 (4,26)	234 23,83 (4,50)	223 23,89 (4,53)	225 23,68 (4,95)	204 23,75 (4,68)	0,17 (0,18)	-0,63 [-1,12;-0,14] 0,0121 -0,21 [-0,37;-0,05]
G3	280 23,30 (4,13)	274 22,45 (4,74)	265 22,67 (4,78)	263 22,76 (4,59)	244 22,57 (4,82)	238 22,92 (4,84)	225 23,26 (4,76)	227 23,57 (4,44)	202 23,75 (4,60)	-0,42 (0,19)	281 23,07 (3,93)	276 22,66 (4,30)	272 23,08 (4,21)	253 23,36 (4,06)	247 23,13 (4,52)	221 23,35 (4,29)	217 23,77 (3,74)	211 23,54 (3,89)	200 23,71 (4,36)	-0,02 (0,19)	-0,40 [-0,92;0,12] 0,1286 -0,13 [-0,29;0,04]
GX	42 24,21 (3,75)	41 23,71 (4,34)	39 23,95 (3,87)	40 24,33 (4,45)	38 24,13 (4,59)	38 24,26 (4,59)	37 24,68 (4,16)	36 25,22 (3,69)	37 25,05 (3,87)	0,14 (0,45)	36 23,64 (4,26)	35 23,29 (4,32)	33 24,21 (3,15)	34 23,50 (5,41)	31 24,97 (3,09)	31 24,65 (3,43)	30 24,57 (4,02)	31 24,90 (4,04)	28 24,61 (3,70)	0,41 (0,49)	-0,27 [-1,59;1,05] 0,6856 -0,09 [-0,54;0,35]
Ethnizität (p-Wert des Interaktionsterms: 0,7372)																					
Weiß	398 23,38 (4,18)	387 22,13 (4,80)	371 22,47 (4,89)	369 22,52 (4,82)	341 22,42 (4,70)	336 22,61 (4,95)	305 23,21 (4,57)	313 23,34 (4,45)	277 23,40 (4,57)	-0,68 (0,16)	381 23,08 (4,36)	368 22,74 (4,65)	359 23,08 (4,42)	337 23,02 (4,67)	323 23,22 (4,66)	304 23,11 (4,78)	290 23,59 (4,25)	290 23,07 (4,85)	267 23,14 (4,87)	-0,21 (0,16)	-0,47 [-0,92;-0,02] 0,0397 -0,15 [-0,29;-0,01]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Asiatisch	260 23,80 (4,14)	258 22,89 (4,65)	254 23,56 (4,31)	252 23,77 (4,09)	246 23,46 (4,62)	240 23,75 (4,50)	237 24,13 (4,27)	236 24,50 (4,25)	223 24,39 (4,51)	0,01 (0,17)	227 23,47 (3,56)	226 23,67 (3,81)	223 24,05 (3,77)	218 24,41 (3,59)	203 24,29 (3,69)	194 24,40 (3,62)	192 24,20 (4,06)	188 24,63 (3,70)	176 24,55 (3,75)	0,63 (0,18)	-0,62 [-1,10;-0,13] 0,0133 -0,23 [-0,40;-0,05]
Andere	26 23,65 (4,22)	25 22,72 (5,30)	25 22,36 (5,10)	25 21,84 (6,22)	24 23,48 (4,73)	22 23,41 (5,76)	23 23,61 (5,34)	20 24,80 (4,50)	18 24,56 (4,20)	-0,67 (0,77)	29 22,97 (5,74)	28 23,14 (4,20)	28 23,46 (4,03)	27 23,63 (3,81)	25 23,26 (4,64)	22 23,45 (4,30)	22 24,09 (4,28)	23 23,39 (4,25)	18 25,22 (3,21)	0,19 (0,74)	-0,86 [-3,01;1,29] 0,4263 -0,22 [-0,75;0,31]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,6866)																					
Tamoxifen	492 23,41 (4,24)	482 22,44 (4,68)	462 22,67 (4,75)	463 22,65 (4,72)	433 22,56 (4,62)	425 22,82 (4,78)	401 23,35 (4,52)	405 23,63 (4,45)	363 23,52 (4,60)	-0,52 (0,14)	477 23,24 (4,26)	464 23,23 (4,31)	451 23,48 (4,18)	428 23,56 (4,42)	404 23,51 (4,52)	388 23,45 (4,58)	373 23,66 (4,33)	376 23,51 (4,53)	347 23,51 (4,63)	0,04 (0,14)	-0,56 [-0,95;-0,17] 0,0049 -0,18 [-0,31;-0,05]
Aromatase-Inhibitor	203 23,86 (3,89)	198 22,46 (4,93)	197 23,38 (4,50)	192 23,76 (4,32)	187 23,56 (4,69)	182 23,64 (4,88)	173 24,09 (4,51)	171 24,49 (4,22)	160 24,61 (4,37)	-0,24 (0,21)	172 23,27 (3,83)	170 22,81 (4,45)	170 23,43 (4,19)	159 23,64 (3,96)	154 23,90 (3,89)	139 24,09 (3,73)	138 24,42 (3,64)	131 24,21 (4,23)	121 24,53 (3,77)	0,29 (0,23)	-0,53 [-1,14;0,08] 0,0907 -0,18 [-0,38;0,03]
ECOG-PS (p-Wert des Interaktionsterms: 0,7901)																					
ECOG-PS 0	617 23,56 (4,18)	603 22,48 (4,72)	584 22,82 (4,74)	583 22,96 (4,60)	548 22,79 (4,65)	539 23,10 (4,71)	508 23,56 (4,56)	509 23,89 (4,37)	466 23,81 (4,56)	-0,48 (0,12)	576 23,41 (4,02)	562 23,26 (4,25)	549 23,58 (4,07)	523 23,70 (4,20)	497 23,71 (4,33)	470 23,86 (4,17)	457 23,98 (4,04)	447 23,78 (4,46)	418 23,94 (4,34)	0,08 (0,12)	-0,55 [-0,89;-0,22] 0,0013 -0,19 [-0,30;-0,07]
ECOG-PS 1	78 23,41 (3,89)	77 22,17 (5,08)	75 23,36 (4,25)	72 23,10 (4,91)	72 23,40 (4,71)	68 22,81 (5,69)	66 23,64 (4,31)	67 23,82 (4,60)	57 24,21 (4,56)	-0,02 (0,42)	73 21,96 (4,87)	72 22,04 (4,95)	72 22,58 (4,82)	64 22,63 (4,91)	61 22,84 (4,48)	57 21,65 (5,49)	54 22,93 (5,07)	60 22,98 (4,46)	50 22,42 (5,02)	0,25 (0,44)	-0,27 [-1,48;0,95] 0,6649 -0,07 [-0,39;0,25]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Datenschnitt: 01.07.2022 Safety-Population 1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3:6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B PWB = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B PWB haben. Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; PWB: körperliches Wohlbefinden; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.																				

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t107_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 107.2.2: Subgruppen für die Veränderung der FACT-B-Subskala: PWB aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,1155)																					
< 65 Jahre	805 23,39 (4,22)	781 22,37 (4,80)	756 22,47 (4,65)	723 22,66 (4,47)	705 22,55 (4,67)	669 22,54 (4,85)	639 23,24 (4,51)	633 23,25 (4,67)	588 23,59 (4,31)	-0,66 (0,11)	833 23,07 (4,24)	798 23,07 (4,24)	799 23,14 (4,20)	757 23,03 (4,34)	725 23,21 (4,33)	684 23,34 (4,32)	642 23,50 (4,29)	636 23,51 (4,30)	588 23,54 (4,31)	-0,02 (0,11)	-0,63 [-0,94;-0,33] <,0001 -0,20 [-0,30;-0,11]
≥ 65 Jahre	304 23,58 (4,22)	294 22,13 (4,60)	277 22,67 (4,31)	274 22,55 (4,86)	256 22,13 (4,84)	240 22,48 (4,43)	225 23,22 (4,32)	218 23,07 (4,83)	201 23,22 (4,65)	-1,17 (0,18)	279 23,35 (4,17)	270 23,42 (4,30)	264 23,60 (4,07)	255 23,60 (3,79)	246 23,38 (4,10)	238 23,23 (4,53)	221 23,29 (4,05)	217 22,92 (4,62)	193 23,10 (4,72)	-0,19 (0,18)	-0,99 [-1,48;-0,49] 0,0001 -0,32 [-0,49;-0,16]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,3073)																					
Neoadjuvante Chemotherapie	363 23,71 (4,04)	345 22,35 (4,91)	329 22,69 (4,51)	316 22,51 (4,73)	299 22,32 (5,14)	276 22,53 (4,87)	260 23,13 (4,56)	254 23,26 (4,82)	236 23,44 (4,81)	-1,05 (0,17)	365 22,87 (4,32)	352 23,03 (4,23)	344 22,84 (4,19)	322 22,83 (4,40)	307 22,95 (4,31)	281 22,86 (4,70)	268 23,07 (4,54)	266 23,19 (4,28)	235 23,07 (4,56)	-0,28 (0,17)	-0,77 [-1,24;-0,30] 0,0015 -0,24 [-0,38;-0,09]
Adjuvante Chemotherapie	686 23,28 (4,31)	673 22,31 (4,68)	651 22,48 (4,62)	626 22,75 (4,45)	611 22,51 (4,50)	587 22,59 (4,70)	560 23,28 (4,44)	556 23,16 (4,72)	515 23,50 (4,27)	-0,57 (0,12)	680 23,21 (4,17)	652 23,17 (4,18)	657 23,38 (4,21)	632 23,32 (4,06)	614 23,41 (4,29)	592 23,55 (4,17)	550 23,60 (4,13)	544 23,46 (4,41)	512 23,59 (4,34)	0,10 (0,12)	-0,68 [-1,00;-0,36] <,0001 -0,22 [-0,33;-0,12]
Keine Chemotherapie	60 23,60 (4,17)	57 21,87 (4,57)	53 22,02 (4,10)	55 21,97 (5,15)	51 22,24 (4,70)	46 21,65 (4,47)	44 23,16 (4,08)	41 23,46 (3,87)	38 23,84 (3,57)	-1,99 (0,41)	67 23,84 (4,12)	64 23,75 (5,12)	62 24,19 (3,40)	58 23,53 (4,61)	50 23,26 (3,66)	49 23,06 (4,67)	45 23,89 (3,37)	43 23,14 (4,76)	34 23,44 (4,40)	-0,71 (0,39)	-1,29 [-2,41;-0,16] 0,0250 -0,40 [-0,76;-0,05]
Region (p-Wert des Interaktionsterms: 0,0583)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	550 23,38 (4,35)	521 21,88 (5,20)	494 22,10 (4,94)	473 22,40 (4,88)	449 22,32 (4,88)	422 22,32 (4,93)	397 23,18 (4,50)	391 23,21 (4,80)	362 23,19 (4,52)	-1,02 (0,13)	530 22,85 (4,42)	493 22,92 (4,49)	493 22,97 (4,26)	453 23,08 (4,36)	439 23,06 (4,41)	421 23,10 (4,52)	384 23,15 (4,39)	392 23,13 (4,53)	347 23,27 (4,29)	-0,03 (0,14)	-0,99 [-1,36;-0,62] <,0001 -0,32 [-0,44;-0,20]
Asien	195 23,90 (3,86)	194 22,92 (4,08)	188 23,23 (3,94)	187 23,17 (4,14)	182 23,02 (4,33)	171 23,18 (4,29)	171 23,29 (4,32)	168 23,17 (4,82)	157 23,97 (3,97)	-0,70 (0,22)	192 23,83 (3,65)	191 23,44 (4,15)	187 23,52 (4,18)	184 23,53 (3,97)	180 23,79 (4,15)	174 23,80 (4,25)	172 23,94 (3,81)	168 23,88 (4,18)	163 24,08 (4,20)	-0,19 (0,22)	-0,51 [-1,12;0,10] 0,0995 -0,17 [-0,37;0,03]
Andere	364 23,28 (4,18)	360 22,58 (4,32)	351 22,75 (4,26)	337 22,66 (4,36)	330 22,27 (4,68)	316 22,44 (4,70)	296 23,26 (4,48)	292 23,22 (4,53)	270 23,63 (4,46)	-0,52 (0,16)	390 23,19 (4,18)	384 23,32 (3,99)	383 23,49 (4,04)	375 23,13 (4,14)	352 23,23 (4,14)	327 23,32 (4,24)	307 23,54 (4,23)	293 23,36 (4,30)	271 23,23 (4,67)	-0,02 (0,15)	-0,49 [-0,93;-0,06] 0,0259 -0,16 [-0,31;-0,02]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,5380)																					
< 20 mm	280 23,07 (4,52)	267 22,11 (4,59)	258 22,27 (4,60)	253 21,99 (4,89)	243 21,82 (5,10)	235 22,10 (5,01)	230 22,90 (4,72)	221 22,83 (5,21)	210 23,11 (4,83)	-0,83 (0,19)	298 22,94 (4,30)	286 23,11 (4,21)	285 23,31 (3,98)	269 23,31 (4,23)	263 23,75 (3,86)	241 23,46 (4,28)	231 23,45 (4,26)	223 23,43 (4,12)	208 23,26 (4,35)	0,19 (0,19)	-1,03 [-1,55;-0,50] 0,0001 -0,32 [-0,49;-0,16]
≥ 20 bis < 50 mm	569 23,68 (4,11)	560 22,46 (4,80)	530 22,70 (4,54)	517 22,99 (4,34)	494 22,69 (4,61)	469 22,86 (4,48)	449 23,53 (4,31)	437 23,41 (4,46)	404 23,64 (4,11)	-0,75 (0,13)	573 23,24 (4,23)	552 23,18 (4,33)	550 23,40 (4,13)	526 23,12 (4,27)	504 23,12 (4,35)	494 23,26 (4,48)	449 23,40 (4,30)	455 23,35 (4,47)	423 23,43 (4,59)	-0,19 (0,13)	-0,56 [-0,92;-0,20] 0,0022 -0,18 [-0,30;-0,07]
≥ 50 mm	243 23,28 (4,11)	232 22,01 (4,86)	229 22,45 (4,54)	214 22,59 (4,67)	209 22,59 (4,29)	191 22,37 (4,86)	171 22,94 (4,43)	180 23,16 (4,65)	162 23,60 (4,55)	-0,82 (0,20)	230 23,05 (4,14)	219 23,07 (4,22)	218 22,69 (4,50)	206 23,00 (4,09)	196 22,85 (4,55)	178 23,13 (4,25)	174 23,44 (4,05)	166 23,14 (4,57)	142 23,55 (4,07)	-0,16 (0,20)	-0,65 [-1,20;-0,10] 0,0204 -0,21 [-0,39;-0,03]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,8065)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	369 23,35 (4,18)	360 22,20 (4,93)	344 22,54 (4,54)	324 22,58 (4,34)	321 22,59 (4,52)	302 22,54 (4,72)	287 23,24 (4,49)	282 23,11 (4,69)	260 23,50 (4,49)	-0,75 (0,16)	360 23,20 (3,98)	344 23,04 (4,19)	347 23,19 (3,92)	325 23,13 (4,02)	317 23,22 (4,12)	296 23,16 (4,54)	280 23,41 (4,10)	269 23,40 (4,20)	247 23,19 (4,26)	-0,12 (0,16)	-0,63 [-1,07;-0,19] 0,0051 -0,21 [-0,35;-0,06]
4-9	476 23,43 (4,22)	459 22,40 (4,66)	446 22,52 (4,64)	436 22,58 (4,80)	416 22,26 (4,84)	391 22,54 (4,73)	375 23,32 (4,41)	374 23,33 (4,53)	354 23,51 (4,45)	-0,78 (0,14)	486 23,03 (4,46)	468 23,22 (4,40)	468 23,41 (4,23)	445 23,10 (4,51)	431 23,33 (4,39)	418 23,21 (4,52)	387 23,47 (4,46)	386 23,33 (4,61)	360 23,38 (4,66)	-0,01 (0,14)	-0,77 [-1,17;-0,37] 0,0002 -0,25 [-0,37;-0,12]
≥ 10	264 23,58 (4,28)	256 22,28 (4,64)	243 22,52 (4,45)	237 22,80 (4,51)	224 22,54 (4,77)	216 22,48 (4,81)	202 23,06 (4,50)	195 23,11 (5,08)	175 23,47 (4,20)	-0,89 (0,19)	266 23,25 (4,10)	256 23,20 (4,09)	248 23,06 (4,40)	242 23,38 (3,88)	223 23,17 (4,25)	208 23,73 (3,79)	196 23,46 (3,96)	198 23,34 (4,22)	174 23,86 (4,09)	-0,09 (0,19)	-0,80 [-1,34;-0,26] 0,0036 -0,25 [-0,43;-0,08]
Tumorstadium (p-Wert des Interaktionsterms: 0,1911)																					
IIA	93 23,25 (4,24)	91 22,36 (4,41)	87 22,54 (4,38)	84 21,90 (4,55)	84 22,11 (5,11)	81 22,57 (4,81)	79 22,70 (5,29)	72 22,19 (5,67)	67 23,19 (4,92)	-0,71 (0,34)	95 22,55 (4,53)	92 23,08 (4,25)	90 22,59 (4,31)	87 23,07 (4,41)	83 23,51 (3,68)	82 23,02 (4,34)	78 23,14 (4,23)	73 23,01 (4,39)	66 22,73 (4,17)	0,12 (0,33)	-0,82 [-1,76;0,11] 0,0843 -0,25 [-0,54;0,03]
IIB	133 23,97 (3,78)	130 22,96 (4,82)	122 23,14 (4,13)	120 23,24 (3,98)	118 23,38 (3,95)	110 22,76 (4,81)	103 23,89 (3,93)	104 24,00 (3,48)	97 24,06 (3,81)	-0,78 (0,25)	113 23,76 (3,62)	107 22,98 (4,37)	107 23,55 (4,06)	102 22,76 (4,17)	96 22,44 (4,69)	97 22,99 (5,02)	92 23,05 (4,44)	89 22,71 (4,80)	83 22,61 (4,94)	-0,88 (0,27)	0,10 [-0,61;0,82] 0,7797 0,04 [-0,21;0,29]
IIIA	431 23,21 (4,07)	418 22,01 (4,77)	404 22,30 (4,67)	392 22,18 (4,90)	372 21,98 (4,79)	350 22,32 (4,73)	331 23,06 (4,43)	339 22,99 (4,75)	314 23,38 (4,46)	-0,89 (0,15)	437 23,04 (4,38)	417 23,20 (4,24)	425 23,40 (4,18)	400 23,34 (4,02)	390 23,34 (4,28)	373 23,28 (4,45)	346 23,72 (4,18)	342 23,45 (4,43)	320 23,43 (4,51)	0,10 (0,15)	-0,99 [-1,41;-0,57] <,0001 -0,31 [-0,45;-0,18]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIIB	47 23,70 (4,35)	45 22,78 (5,30)	45 23,13 (5,05)	44 23,07 (4,60)	43 22,77 (5,11)	39 23,26 (4,76)	36 23,89 (4,38)	33 24,12 (4,57)	35 23,40 (4,65)	-0,59 (0,38)	41 23,61 (4,64)	40 24,25 (3,48)	40 23,90 (3,34)	37 23,62 (4,71)	35 24,71 (3,25)	33 24,03 (4,38)	32 23,47 (5,08)	29 23,72 (5,24)	28 24,14 (4,73)	0,27 (0,41)	-0,86 [-1,97;0,25] 0,1276 -0,33 [-0,75;0,09]
IIIC	403 23,54 (4,47)	390 22,33 (4,71)	373 22,50 (4,56)	355 23,06 (4,36)	342 22,67 (4,66)	327 22,59 (4,72)	313 23,25 (4,43)	301 23,30 (4,76)	274 23,51 (4,39)	-0,74 (0,15)	424 23,15 (4,08)	410 23,08 (4,33)	399 23,09 (4,23)	384 23,10 (4,33)	365 23,18 (4,33)	335 23,43 (4,11)	314 23,34 (4,14)	318 23,47 (4,15)	282 23,76 (4,15)	-0,11 (0,15)	-0,63 [-1,06;-0,21] 0,0036 -0,20 [-0,34;-0,07]
Tumorgrading (p-Wert des Interaktionsterms: 0,7554)																					
G1	83 22,73 (4,70)	81 22,68 (4,30)	83 22,28 (4,96)	76 23,03 (4,25)	74 22,70 (4,57)	73 22,90 (4,78)	69 23,49 (4,28)	68 23,82 (3,87)	63 23,56 (4,59)	0,05 (0,35)	84 23,32 (4,72)	83 23,63 (4,26)	81 23,62 (3,99)	76 23,75 (4,11)	78 23,44 (4,85)	73 23,70 (4,17)	66 24,26 (3,90)	67 23,69 (4,09)	59 23,95 (4,10)	0,52 (0,35)	-0,47 [-1,44;0,50] 0,3412 -0,15 [-0,45;0,16]
G2	526 23,39 (4,36)	511 22,16 (4,99)	489 22,37 (4,77)	469 22,44 (4,78)	451 22,20 (4,80)	424 22,35 (4,66)	395 23,18 (4,31)	403 23,06 (4,75)	370 23,47 (4,36)	-0,94 (0,14)	535 23,01 (4,22)	509 22,99 (4,18)	511 23,14 (4,16)	490 22,98 (4,19)	465 23,09 (4,30)	443 23,11 (4,44)	415 23,25 (4,16)	414 23,24 (4,41)	383 23,30 (4,35)	-0,16 (0,14)	-0,77 [-1,15;-0,39] <,0001 -0,25 [-0,37;-0,12]
G3	451 23,57 (4,00)	436 22,40 (4,58)	415 22,80 (4,21)	405 22,73 (4,45)	392 22,69 (4,56)	370 22,65 (4,79)	361 23,25 (4,66)	339 23,17 (4,88)	323 23,50 (4,47)	-0,75 (0,15)	436 23,15 (4,18)	419 23,17 (4,30)	415 23,18 (4,24)	392 23,26 (4,24)	378 23,26 (4,17)	360 23,36 (4,43)	339 23,44 (4,43)	329 23,43 (4,36)	303 23,39 (4,58)	-0,03 (0,15)	-0,72 [-1,13;-0,31] 0,0005 -0,23 [-0,37;-0,10]
GX	47 24,15 (3,18)	45 22,49 (4,33)	44 22,09 (4,63)	45 23,26 (4,14)	42 22,52 (5,24)	40 22,80 (4,85)	37 23,35 (4,32)	39 23,95 (4,11)	32 23,56 (4,08)	-1,32 (0,40)	53 24,15 (3,48)	53 23,94 (4,63)	52 24,56 (3,61)	50 23,64 (3,93)	47 24,33 (3,69)	43 24,09 (3,55)	41 24,02 (3,73)	40 23,33 (5,05)	33 24,18 (4,30)	-0,25 (0,38)	-1,07 [-2,16;0,01] 0,0523 -0,39 [-0,79;0,00]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4694)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Negativ	137 22,75 (4,58)	134 21,58 (5,02)	126 21,90 (5,19)	124 22,38 (4,57)	117 22,32 (4,62)	105 22,11 (4,72)	98 23,19 (4,41)	101 22,96 (4,19)	90 23,07 (4,33)	-0,79 (0,27)	149 23,34 (4,11)	143 22,97 (4,56)	141 22,93 (4,81)	135 22,85 (4,56)	126 23,13 (4,53)	117 22,76 (5,00)	106 23,11 (4,84)	104 23,12 (3,96)	92 23,37 (4,35)	-0,50 (0,26)	-0,29 [-1,02;0,44] 0,4385 -0,09 [-0,32;0,14]
Positiv	941 23,50 (4,17)	910 22,35 (4,69)	876 22,56 (4,48)	847 22,59 (4,60)	820 22,42 (4,74)	779 22,51 (4,77)	740 23,18 (4,49)	726 23,21 (4,80)	678 23,52 (4,44)	-0,81 (0,10)	936 23,08 (4,25)	901 23,16 (4,23)	898 23,29 (4,08)	854 23,21 (4,16)	822 23,24 (4,26)	783 23,36 (4,28)	737 23,49 (4,13)	727 23,36 (4,46)	668 23,41 (4,46)	0,00 (0,10)	-0,82 [-1,10;-0,54] <,0001 -0,26 [-0,35;-0,17]
Unbekannt	9 24,78 (3,63)	9 21,78 (6,22)	9 24,67 (2,92)	7 25,57 (3,21)	5 26,80 (1,30)	7 25,00 (3,11)	8 25,25 (2,92)	7 25,14 (3,48)	5 26,40 (2,07)	0,07 (0,64)	7 24,43 (2,99)	6 25,67 (2,25)	6 24,83 (1,72)	6 26,17 (0,98)	6 25,00 (2,10)	6 25,67 (2,16)	5 26,20 (2,05)	6 26,83 (0,98)	5 24,80 (1,92)	1,49 (0,74)	-1,42 [-3,51;0,68] 0,1689 -0,69 [-1,66;0,27]
Ethnizität (p-Wert des Interaktionsterms: 0,1448)																					
Weiß	810 23,28 (4,32)	780 22,12 (4,80)	755 22,26 (4,64)	724 22,35 (4,72)	696 22,14 (4,83)	657 22,25 (4,82)	614 23,06 (4,46)	609 23,08 (4,67)	567 23,19 (4,55)	-0,91 (0,11)	820 23,05 (4,27)	780 23,12 (4,29)	780 23,24 (4,05)	734 23,02 (4,33)	704 23,14 (4,32)	671 23,22 (4,39)	616 23,30 (4,32)	615 23,22 (4,45)	550 23,22 (4,43)	-0,07 (0,11)	-0,84 [-1,14;-0,53] <,0001 -0,27 [-0,36;-0,17]
Asiatisch	233 23,96 (3,75)	231 23,05 (4,15)	221 23,50 (3,86)	220 23,41 (4,01)	214 23,32 (4,19)	200 23,41 (4,28)	199 23,60 (4,29)	197 23,47 (4,74)	179 24,31 (3,91)	-0,44 (0,20)	221 23,61 (3,81)	219 23,42 (4,12)	215 23,47 (4,25)	213 23,62 (3,89)	205 23,70 (4,13)	193 23,77 (4,16)	191 23,91 (3,90)	185 23,81 (4,19)	181 24,03 (4,21)	-0,07 (0,20)	-0,36 [-0,92;0,19] 0,2006 -0,12 [-0,30;0,06]
Andere	54 23,96 (3,90)	52 22,41 (5,39)	47 22,57 (5,44)	44 23,36 (3,95)	43 22,65 (4,93)	42 22,74 (4,92)	44 23,84 (5,09)	38 23,63 (5,19)	35 24,51 (3,69)	-0,74 (0,42)	58 23,21 (4,61)	57 23,05 (4,39)	56 23,55 (4,28)	53 23,75 (3,72)	51 23,10 (4,22)	47 23,28 (4,36)	46 24,37 (3,84)	41 23,49 (4,62)	41 23,85 (5,07)	-0,04 (0,40)	-0,70 [-1,86;0,46] 0,2322 -0,23 [-0,60;0,14]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,7413)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Tamoxifen	104 23,36 (3,63)	101 22,84 (4,17)	101 22,45 (4,86)	98 23,05 (4,10)	97 22,22 (4,91)	96 22,57 (4,38)	90 23,14 (4,23)	89 23,21 (4,76)	90 23,57 (4,28)	-0,41 (0,31)	124 23,06 (3,75)	123 23,32 (3,95)	123 23,40 (4,04)	117 23,56 (4,10)	109 23,63 (3,99)	98 23,89 (4,38)	94 24,02 (3,82)	91 23,98 (4,31)	89 24,11 (3,75)	0,32 (0,29)	-0,74 [-1,58;0,10] 0,0843 -0,23 [-0,49;0,03]
Aromatase-Inhibitor	1005 23,45 (4,27)	974 22,25 (4,80)	932 22,53 (4,53)	899 22,59 (4,63)	864 22,46 (4,69)	813 22,52 (4,78)	774 23,24 (4,48)	762 23,20 (4,71)	699 23,49 (4,42)	-0,84 (0,10)	988 23,15 (4,28)	945 23,14 (4,30)	940 23,24 (4,19)	895 23,13 (4,22)	862 23,21 (4,30)	824 23,24 (4,37)	769 23,38 (4,27)	762 23,28 (4,39)	692 23,34 (4,49)	-0,12 (0,10)	-0,72 [-0,99;-0,45] <,0001 -0,23 [-0,32;-0,15]
ECOG-PS (p-Wert des Interaktionsterms: 0,9681)																					
ECOG-PS 0	934 23,68 (4,06)	905 22,48 (4,72)	871 22,65 (4,53)	850 22,76 (4,54)	818 22,58 (4,64)	779 22,65 (4,67)	737 23,35 (4,37)	730 23,35 (4,61)	681 23,55 (4,35)	-0,87 (0,10)	899 23,40 (4,10)	863 23,33 (4,10)	861 23,45 (4,03)	822 23,38 (4,06)	792 23,35 (4,17)	755 23,47 (4,28)	701 23,57 (4,11)	694 23,43 (4,29)	630 23,57 (4,25)	-0,16 (0,10)	-0,70 [-0,98;-0,42] <,0001 -0,23 [-0,32;-0,14]
ECOG-PS 1	175 22,15 (4,79)	170 21,34 (4,79)	162 21,87 (4,66)	147 21,90 (4,75)	143 21,64 (5,05)	130 21,76 (5,08)	127 22,56 (4,88)	121 22,32 (5,21)	108 23,14 (4,75)	-0,46 (0,26)	213 22,03 (4,54)	205 22,44 (4,82)	202 22,42 (4,64)	190 22,31 (4,71)	179 22,84 (4,66)	167 22,60 (4,74)	162 22,93 (4,70)	159 23,05 (4,77)	151 22,83 (5,01)	0,43 (0,23)	-0,89 [-1,57;-0,22] 0,0095 -0,27 [-0,47;-0,07]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3:6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B PWB = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B PWB haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; PWB: körperliches Wohlbefinden; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t107_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba

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Tabelle 108.1.2: Subgruppen für die Veränderung der FACT-B-Subskala: SWB aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,5302)																					
Neoadjuvante Chemotherapie	281 23,15 (4,41)	272 22,24 (4,77)	262 21,71 (5,37)	264 21,65 (5,41)	241 21,59 (5,36)	239 21,52 (5,32)	225 21,25 (5,06)	224 21,77 (4,82)	202 21,72 (5,37)	-1,43 (0,20)	267 22,40 (4,90)	258 21,40 (5,36)	255 21,59 (5,57)	231 21,68 (5,52)	221 21,55 (5,30)	203 21,73 (5,46)	187 21,80 (5,24)	184 21,47 (5,44)	171 21,23 (5,90)	-1,05 (0,21)	-0,39 [-0,97;0,19] 0,1897 -0,11 [-0,28;0,06]
Adjuvante Chemotherapie	406 22,47 (5,03)	400 21,90 (4,83)	390 21,77 (5,49)	384 21,54 (5,49)	372 21,38 (5,37)	361 21,51 (5,45)	342 20,99 (5,73)	347 21,29 (5,34)	317 21,19 (5,54)	-0,93 (0,17)	379 22,26 (5,08)	373 21,73 (5,22)	362 21,64 (5,06)	353 21,83 (4,90)	334 21,78 (4,89)	321 21,68 (4,86)	321 21,50 (4,94)	320 21,77 (5,04)	295 21,59 (5,02)	-0,59 (0,18)	-0,33 [-0,81;0,15] 0,1744 -0,10 [-0,24;0,04]
Keine Chemotherapie	7 21,57 (5,94)	7 21,14 (6,31)	6 18,83 (6,79)	6 20,83 (6,62)	6 18,17 (8,82)	6 16,50 (12,63)	6 20,00 (8,51)	5 19,20 (9,09)	4 23,50 (6,14)	-1,36 (1,12)	3 24,67 (2,52)	3 20,67 (5,51)	3 21,67 (6,03)	3 19,67 (5,51)	3 21,33 (6,03)	3 19,67 (4,62)	3 21,00 (5,57)	3 18,33 (7,57)	2 20,00 (2,83)	-4,36 (1,60)	3,01 [-1,42;7,43] 0,1608 0,93 [-0,36;2,22]
Region (p-Wert des Interaktionsterms: 0,8609)																					
Nordamerika / Europa	282 23,71 (4,44)	269 22,93 (4,42)	257 22,63 (5,28)	256 22,34 (5,20)	228 22,23 (5,03)	228 22,14 (5,12)	212 21,87 (5,09)	213 22,15 (5,18)	180 22,22 (5,20)	-1,39 (0,19)	256 23,24 (4,08)	245 22,29 (4,78)	234 22,47 (4,66)	210 22,49 (4,75)	197 22,27 (4,76)	191 22,37 (4,57)	180 22,12 (4,91)	181 22,17 (4,77)	165 22,03 (4,93)	-1,06 (0,20)	-0,34 [-0,88;0,20] 0,2207 -0,11 [-0,28;0,06]
Asien	232 21,69 (5,05)	231 20,87 (5,36)	227 20,70 (5,57)	226 20,40 (5,97)	222 20,48 (5,93)	216 20,54 (5,87)	215 20,31 (5,83)	212 20,64 (5,32)	210 20,70 (5,64)	-1,13 (0,24)	211 21,34 (5,39)	210 20,64 (5,58)	209 20,66 (5,73)	203 21,16 (5,54)	193 21,10 (5,27)	187 20,98 (5,53)	183 20,83 (5,30)	181 20,97 (5,28)	171 20,75 (5,70)	-0,63 (0,25)	-0,50 [-1,19;0,18] 0,1508 -0,14 [-0,32;0,05]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	180 22,55 (4,75)	179 22,16 (4,36)	174 21,71 (5,35)	172 21,98 (4,88)	169 21,61 (5,00)	162 21,75 (5,40)	146 21,08 (5,47)	151 21,64 (4,84)	133 21,44 (5,48)	-0,82 (0,25)	182 22,20 (5,46)	179 21,74 (5,40)	177 21,61 (5,31)	174 21,58 (5,07)	168 21,67 (5,10)	149 21,69 (5,06)	148 21,93 (4,81)	145 21,82 (5,53)	132 21,64 (5,32)	-0,70 (0,25)	-0,12 [-0,83;0,58] 0,7326 -0,04 [-0,24;0,17]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,8293)																					
< 20 mm	179 23,06 (4,30)	176 22,25 (4,79)	167 21,82 (5,39)	171 21,33 (5,82)	160 21,34 (5,46)	159 21,42 (5,43)	153 21,04 (5,63)	157 21,43 (4,84)	148 21,45 (5,27)	-1,53 (0,24)	169 22,62 (5,04)	164 21,80 (5,34)	161 21,68 (5,51)	153 21,67 (5,31)	151 22,21 (4,61)	142 21,94 (4,77)	136 21,85 (4,83)	135 22,02 (5,07)	123 21,63 (5,74)	-0,82 (0,25)	-0,70 [-1,38;-0,03] 0,0406 -0,22 [-0,43;-0,01]
≥ 20 bis < 50 mm	325 22,64 (5,05)	316 21,92 (4,89)	314 21,87 (5,34)	307 21,71 (5,48)	289 21,46 (5,25)	281 21,62 (5,32)	264 21,09 (5,46)	266 21,43 (5,23)	239 21,57 (5,53)	-0,92 (0,19)	314 22,11 (4,90)	308 21,39 (5,17)	304 21,60 (5,15)	290 21,76 (5,01)	272 21,77 (5,00)	261 21,51 (5,11)	254 21,58 (5,06)	246 21,50 (5,30)	236 21,39 (5,20)	-0,66 (0,19)	-0,25 [-0,78;0,28] 0,3494 -0,07 [-0,23;0,08]
≥ 50 mm	172 22,60 (4,83)	169 21,91 (4,74)	162 21,30 (5,71)	160 21,52 (4,96)	154 21,39 (5,55)	152 21,26 (5,87)	142 21,08 (5,39)	140 21,61 (5,38)	122 21,16 (5,55)	-1,27 (0,29)	158 22,46 (5,18)	154 21,78 (5,47)	147 21,61 (5,33)	136 21,98 (5,34)	129 20,82 (5,58)	117 21,78 (5,43)	114 21,40 (5,31)	119 21,56 (4,98)	103 21,17 (5,29)	-1,03 (0,30)	-0,24 [-1,06;0,57] 0,5596 -0,06 [-0,28;0,15]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7858)																					
0-3	238 22,87 (5,04)	231 22,28 (4,65)	218 21,77 (5,51)	222 21,73 (5,12)	202 21,62 (5,19)	200 21,69 (5,60)	192 20,85 (5,83)	188 21,77 (5,36)	169 21,59 (5,85)	-1,11 (0,24)	237 22,24 (4,94)	231 21,57 (5,14)	224 21,58 (5,49)	210 21,68 (5,40)	200 21,31 (5,26)	191 21,57 (5,41)	183 21,46 (5,21)	180 21,48 (5,47)	176 21,26 (5,49)	-0,86 (0,24)	-0,25 [-0,92;0,42] 0,4590 -0,07 [-0,25;0,11]
4-9	316 22,49 (4,89)	309 21,58 (5,03)	305 21,47 (5,47)	300 21,29 (5,69)	289 21,03 (5,47)	286 21,25 (5,39)	265 20,90 (5,58)	268 21,13 (5,01)	245 21,18 (5,26)	-1,25 (0,19)	294 22,46 (4,83)	288 21,67 (5,05)	282 21,50 (5,34)	266 21,82 (4,82)	256 21,86 (5,01)	244 21,68 (4,96)	242 21,61 (5,01)	238 21,72 (5,04)	219 21,39 (5,21)	-0,88 (0,19)	-0,37 [-0,90;0,15] 0,1647 -0,11 [-0,27;0,05]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 10	140 23,04 (4,16)	139 22,60 (4,54)	135 22,20 (5,34)	132 21,97 (5,49)	128 22,03 (5,56)	120 21,62 (5,65)	116 21,88 (4,68)	120 21,71 (5,26)	109 21,65 (5,39)	-0,92 (0,27)	118 22,17 (5,53)	115 21,41 (6,06)	114 21,98 (4,67)	111 21,77 (5,48)	102 21,97 (4,76)	92 21,96 (4,76)	86 21,88 (4,87)	89 21,75 (5,09)	73 22,10 (5,44)	-0,44 (0,30)	-0,47 [-1,28;0,33] 0,2486 -0,14 [-0,39;0,10]
Tumorstadium (p-Wert des Interaktionsterms: 0,7000)																					
IIA	71 23,34 (4,03)	69 22,49 (4,89)	67 21,30 (5,97)	68 21,25 (5,40)	65 21,21 (5,68)	62 21,05 (5,74)	59 20,47 (6,09)	60 21,52 (5,44)	55 21,00 (6,55)	-2,09 (0,37)	69 22,94 (4,09)	67 22,13 (3,94)	66 21,83 (5,45)	60 20,94 (5,31)	58 22,23 (4,22)	56 22,00 (4,35)	56 21,98 (4,29)	51 22,65 (4,62)	50 22,04 (4,95)	-0,92 (0,38)	-1,17 [-2,23;-0,11] 0,0309 -0,37 [-0,70;-0,03]
IIB	65 22,46 (5,47)	63 22,32 (4,55)	59 22,19 (4,91)	61 21,80 (4,85)	52 21,71 (4,71)	55 21,73 (5,65)	54 20,72 (5,96)	53 22,13 (4,23)	51 22,25 (4,96)	-0,28 (0,42)	85 21,73 (5,48)	83 21,27 (5,64)	83 21,87 (5,08)	77 21,81 (5,12)	76 21,09 (5,04)	72 21,18 (5,54)	67 21,31 (5,23)	70 20,60 (5,81)	69 21,25 (5,30)	-0,59 (0,37)	0,30 [-0,80;1,41] 0,5872 0,09 [-0,23;0,41]
IIIA	309 22,35 (5,08)	303 21,46 (5,14)	298 21,42 (5,52)	295 21,41 (5,47)	282 21,15 (5,40)	279 21,44 (5,55)	254 21,16 (5,55)	258 21,28 (5,14)	235 21,30 (5,40)	-1,02 (0,19)	267 22,34 (4,93)	260 21,69 (5,09)	253 21,52 (5,37)	244 21,76 (4,98)	229 21,59 (5,39)	217 21,67 (5,13)	215 21,56 (5,20)	214 21,89 (5,08)	200 21,32 (5,27)	-0,82 (0,20)	-0,20 [-0,75;0,34] 0,4655 -0,06 [-0,22;0,10]
IIIB	18 22,78 (4,22)	18 22,39 (4,23)	16 21,56 (3,46)	17 20,00 (6,02)	13 19,54 (5,22)	14 20,00 (4,04)	14 18,50 (4,65)	14 18,07 (5,34)	14 17,93 (4,75)	-3,08 (1,22)	17 24,00 (4,08)	17 20,41 (7,83)	16 21,31 (7,05)	13 21,08 (7,91)	12 21,83 (7,96)	12 20,67 (8,18)	13 20,38 (6,29)	12 20,25 (6,93)	11 20,55 (6,76)	-1,89 (1,27)	-1,19 [-4,80;2,41] 0,5046 -0,22 [-0,87;0,43]
IIIC	227 23,11 (4,47)	222 22,50 (4,43)	214 22,12 (5,47)	209 21,95 (5,60)	203 21,92 (5,49)	193 21,65 (5,48)	189 21,48 (5,15)	189 21,73 (5,31)	165 21,73 (5,39)	-1,09 (0,23)	210 22,22 (5,21)	206 21,51 (5,50)	201 21,58 (5,06)	192 22,06 (5,15)	183 21,87 (4,66)	170 21,89 (4,83)	160 21,75 (4,95)	160 21,55 (5,06)	138 21,61 (5,55)	-0,68 (0,24)	-0,41 [-1,08;0,25] 0,2228 -0,12 [-0,30;0,07]
Tumorgrading (p-Wert des Interaktionsterms: 0,9212)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
G1	59 22,32 (4,78)	58 21,72 (5,08)	54 21,65 (5,80)	54 20,61 (7,02)	55 21,20 (5,71)	53 21,83 (5,77)	51 21,57 (5,44)	53 21,15 (5,45)	47 20,83 (5,98)	-1,14 (0,41)	47 22,79 (5,06)	45 22,02 (5,41)	42 21,88 (5,94)	43 22,70 (4,27)	41 22,00 (5,19)	39 22,38 (4,57)	39 22,72 (4,48)	38 22,55 (4,36)	34 22,35 (4,59)	-0,29 (0,46)	-0,85 [-2,07;0,37] 0,1689 -0,27 [-0,66;0,11]
G2	311 22,79 (4,68)	304 22,11 (4,83)	298 21,67 (5,42)	295 21,70 (5,23)	280 21,51 (5,31)	275 21,48 (5,53)	258 21,21 (5,40)	257 21,35 (5,08)	234 21,52 (5,06)	-1,18 (0,19)	283 22,45 (4,80)	276 21,50 (5,67)	271 21,85 (5,15)	255 21,85 (5,06)	237 21,80 (5,13)	234 21,73 (5,10)	223 21,55 (5,31)	225 21,68 (5,40)	204 21,28 (5,67)	-0,88 (0,20)	-0,31 [-0,85;0,24] 0,2705 -0,09 [-0,25;0,07]
G3	279 22,67 (4,94)	273 22,01 (4,72)	264 21,68 (5,38)	262 21,70 (5,27)	243 21,35 (5,43)	237 21,43 (5,30)	224 20,76 (5,56)	227 21,60 (5,17)	202 21,41 (5,73)	-1,07 (0,22)	281 22,17 (5,19)	276 21,70 (4,82)	272 21,45 (5,31)	253 21,60 (5,45)	247 21,40 (5,11)	221 21,62 (5,18)	217 21,49 (4,86)	211 21,66 (5,16)	200 21,52 (5,11)	-0,74 (0,22)	-0,32 [-0,92;0,28] 0,2916 -0,09 [-0,25;0,08]
GX	42 23,02 (5,02)	41 21,63 (5,21)	39 22,03 (5,92)	40 20,80 (5,92)	38 21,47 (5,68)	38 20,76 (6,39)	37 21,11 (6,06)	36 21,36 (5,70)	37 21,08 (6,10)	-1,34 (0,47)	36 22,03 (5,08)	35 20,90 (5,51)	33 20,76 (5,29)	34 21,21 (4,74)	31 22,68 (3,94)	31 21,03 (5,18)	30 21,43 (5,32)	31 20,35 (4,86)	28 21,00 (5,70)	-1,08 (0,51)	-0,26 [-1,64;1,11] 0,7052 -0,09 [-0,53;0,36]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,0784)																					
Negativ	63 23,49 (3,93)	60 22,03 (4,74)	58 21,59 (5,07)	60 21,10 (4,89)	57 20,73 (5,58)	54 20,83 (5,11)	50 19,72 (5,05)	51 20,76 (5,11)	50 21,26 (5,01)	-2,17 (0,38)	53 22,53 (4,49)	52 22,19 (5,11)	51 21,94 (5,52)	44 22,73 (4,52)	43 22,26 (4,02)	40 22,08 (4,27)	40 22,20 (4,40)	37 23,30 (3,68)	36 23,22 (3,16)	-0,43 (0,43)	-1,75 [-2,89;-0,60] 0,0031 -0,57 [-0,94;-0,19]
Positiv	609 22,61 (4,91)	597 21,95 (4,85)	581 21,64 (5,50)	574 21,53 (5,54)	546 21,41 (5,40)	537 21,45 (5,56)	506 21,11 (5,54)	510 21,50 (5,17)	461 21,40 (5,56)	-1,08 (0,14)	579 22,32 (5,05)	567 21,48 (5,30)	555 21,57 (5,27)	529 21,63 (5,23)	500 21,56 (5,15)	472 21,62 (5,15)	460 21,52 (5,11)	456 21,48 (5,28)	420 21,30 (5,50)	-0,87 (0,15)	-0,22 [-0,62;0,18] 0,2828 -0,06 [-0,18;0,05]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Unbekannt	6 23,17 (4,75)	6 21,50 (5,13)	6 23,67 (6,53)	5 23,60 (5,73)	4 24,00 (4,55)	4 24,25 (5,19)	4 23,00 (7,07)	3 22,00 (10,39)	3 24,00 (6,08)	0,50 (1,06)	8 20,75 (5,23)	7 23,86 (2,97)	8 22,50 (3,25)	6 23,33 (3,78)	6 23,67 (3,83)	8 21,38 (6,00)	4 21,50 (5,92)	8 21,13 (6,73)	7 20,57 (4,86)	1,19 (0,80)	-0,69 [-3,59;2,21] 0,6163 -0,27 [-1,26;0,73]
Ethnizität (p-Wert des Interaktionsterms: 0,9308)																					
Weiß	398 23,34 (4,42)	387 22,56 (4,43)	371 22,17 (5,21)	369 22,04 (5,02)	341 21,72 (5,07)	336 21,75 (5,27)	305 21,46 (5,19)	313 21,75 (4,96)	277 21,71 (5,20)	-1,34 (0,15)	381 22,89 (4,53)	368 22,07 (4,94)	358 22,13 (4,83)	337 22,04 (4,76)	323 21,84 (5,01)	304 22,06 (4,88)	290 21,87 (4,97)	290 21,96 (5,14)	267 21,69 (5,18)	-1,06 (0,16)	-0,28 [-0,72;0,15] 0,2066 -0,09 [-0,23;0,05]
Asiatisch	259 21,67 (5,24)	257 21,15 (5,28)	253 20,83 (5,77)	251 20,79 (6,01)	245 20,89 (5,87)	239 20,95 (5,87)	236 20,47 (5,91)	236 20,89 (5,43)	223 20,87 (5,77)	-0,89 (0,24)	227 21,45 (5,62)	226 20,69 (5,68)	223 20,78 (5,81)	218 21,41 (5,58)	203 21,26 (5,30)	194 21,12 (5,52)	192 20,99 (5,25)	188 21,03 (5,30)	176 20,87 (5,73)	-0,57 (0,26)	-0,32 [-1,02;0,39] 0,3785 -0,08 [-0,26;0,10]
Andere	26 23,35 (4,96)	25 22,72 (4,96)	25 23,28 (4,47)	25 22,64 (5,02)	24 22,92 (4,87)	22 22,91 (4,49)	23 22,35 (4,80)	20 23,30 (4,87)	18 23,33 (5,50)	-0,29 (0,57)	29 21,45 (5,47)	28 21,75 (5,78)	28 21,09 (6,04)	27 20,52 (6,10)	25 22,56 (3,65)	22 20,86 (3,86)	22 22,77 (4,15)	23 22,30 (4,99)	18 22,78 (4,17)	0,09 (0,55)	-0,37 [-1,99;1,24] 0,6441 -0,13 [-0,66;0,40]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,2594)																					
Tamoxifen	491 22,34 (4,93)	481 21,67 (4,85)	461 21,37 (5,59)	462 21,29 (5,50)	432 21,05 (5,38)	424 21,23 (5,45)	400 20,73 (5,45)	405 21,26 (5,10)	363 20,96 (5,43)	-1,05 (0,16)	477 22,14 (5,09)	464 21,51 (5,30)	450 21,55 (5,30)	428 21,73 (5,02)	404 21,67 (4,94)	388 21,52 (5,04)	373 21,56 (4,92)	376 21,56 (5,17)	347 21,45 (5,04)	-0,62 (0,16)	-0,43 [-0,87;0,00] 0,0521 -0,13 [-0,25;0,00]
Aromatase-Inhibitor	203 23,68 (4,35)	198 22,88 (4,64)	197 22,54 (5,04)	192 22,27 (5,31)	187 22,33 (5,38)	182 22,02 (5,61)	173 21,90 (5,55)	171 21,92 (5,34)	160 22,43 (5,48)	-1,38 (0,24)	172 22,84 (4,69)	170 21,80 (5,19)	170 21,79 (5,20)	159 21,84 (5,51)	154 21,72 (5,37)	139 22,15 (5,20)	138 21,71 (5,41)	131 21,86 (5,27)	121 21,45 (6,16)	-1,21 (0,26)	-0,18 [-0,87;0,52] 0,6185 -0,05 [-0,25;0,15]
ECOG-PS (p-Wert des Interaktionsterms: 0,6077)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
ECOG-PS 0	616 22,77 (4,69)	602 21,97 (4,88)	583 21,68 (5,46)	582 21,44 (5,47)	547 21,35 (5,41)	538 21,44 (5,44)	507 21,06 (5,42)	509 21,50 (5,12)	466 21,48 (5,34)	-1,23 (0,13)	576 22,57 (4,82)	562 21,73 (5,29)	548 21,80 (5,15)	523 21,92 (5,05)	497 21,80 (5,06)	470 21,90 (5,00)	457 21,74 (5,02)	447 21,87 (5,13)	418 21,55 (5,30)	-0,88 (0,14)	-0,36 [-0,74;0,03] 0,0674 -0,11 [-0,22;0,01]
ECOG-PS 1	78 22,45 (5,63)	77 22,45 (4,33)	75 22,03 (5,41)	72 22,67 (5,32)	72 22,07 (5,38)	68 21,63 (6,04)	66 21,26 (6,16)	67 21,16 (5,61)	57 20,88 (6,51)	-0,22 (0,45)	73 20,45 (5,93)	72 20,49 (5,02)	72 20,24 (5,98)	64 20,47 (5,81)	61 20,75 (5,01)	57 19,96 (5,55)	54 20,48 (5,21)	60 19,97 (5,40)	50 20,62 (5,71)	-0,27 (0,47)	0,05 [-1,25;1,35] 0,9352 0,01 [-0,31;0,33]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B SWB = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B SWB haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SWB: soziales und familiäres Wohlbefinden.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t108_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 108.2.2: Subgruppen für die Veränderung der FACT-B-Subskala: SWB aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,8788)																					
< 65 Jahre	805 22,63 (5,12)	781 22,40 (5,12)	756 22,00 (5,12)	723 21,88 (5,33)	705 21,85 (5,19)	669 21,60 (5,30)	638 21,55 (5,55)	633 21,62 (5,53)	588 21,61 (5,46)	-0,77 (0,12)	833 22,64 (4,95)	798 22,11 (5,28)	799 22,14 (5,17)	757 21,88 (5,19)	725 21,90 (5,07)	683 21,75 (5,40)	642 21,61 (5,45)	636 21,49 (5,32)	588 21,70 (5,32)	-0,72 (0,12)	-0,06 [-0,40;0,29] 0,7492 -0,02 [-0,11;0,08]
≥ 65 Jahre	304 22,57 (5,35)	294 21,71 (6,19)	278 21,78 (5,94)	273 22,16 (5,49)	256 21,75 (5,85)	240 21,63 (6,07)	225 22,04 (5,90)	218 21,46 (5,82)	201 21,57 (5,87)	-0,74 (0,21)	279 22,73 (5,33)	270 22,20 (5,52)	262 22,12 (5,55)	255 22,08 (5,45)	246 21,45 (5,89)	238 21,55 (5,53)	221 21,69 (5,33)	217 21,47 (5,72)	192 21,14 (5,70)	-0,91 (0,21)	0,17 [-0,41;0,75] 0,5737 0,05 [-0,12;0,21]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,4384)																					
Neoadjuvante Chemotherapie	363 22,82 (5,13)	345 22,31 (5,18)	330 22,29 (5,12)	315 22,10 (5,41)	299 21,66 (5,68)	276 21,78 (5,46)	259 22,07 (5,66)	254 21,59 (5,59)	236 21,50 (5,78)	-0,86 (0,19)	365 22,38 (4,94)	352 21,60 (5,49)	344 21,65 (5,33)	322 21,53 (5,24)	307 21,31 (5,43)	281 21,22 (5,67)	268 21,49 (5,58)	266 20,82 (5,68)	235 21,00 (5,82)	-1,01 (0,18)	0,15 [-0,36;0,67] 0,5553 0,04 [-0,10;0,19]
Adjuvante Chemotherapie	686 22,55 (5,15)	673 22,29 (5,41)	651 21,85 (5,39)	626 21,98 (5,26)	611 21,98 (5,10)	587 21,61 (5,44)	560 21,62 (5,60)	556 21,61 (5,59)	515 21,71 (5,42)	-0,70 (0,13)	680 22,81 (5,11)	652 22,45 (5,17)	655 22,51 (5,06)	632 22,22 (5,09)	614 22,17 (5,12)	591 22,09 (5,14)	550 21,83 (5,24)	544 21,85 (5,20)	511 21,92 (5,13)	-0,56 (0,13)	-0,14 [-0,52;0,23] 0,4468 -0,04 [-0,15;0,06]
Keine Chemotherapie	60 22,03 (5,81)	57 20,67 (6,95)	53 20,94 (6,22)	55 20,90 (6,33)	51 21,02 (6,56)	46 20,52 (6,61)	44 20,20 (6,06)	41 20,98 (5,88)	38 20,71 (6,20)	-1,05 (0,46)	67 22,69 (5,03)	64 21,88 (6,03)	62 20,85 (6,56)	58 20,91 (6,78)	50 20,00 (6,02)	49 19,63 (6,73)	45 20,07 (6,29)	43 20,91 (6,15)	34 20,09 (6,35)	-1,56 (0,44)	0,51 [-0,76;1,77] 0,4285 0,14 [-0,21;0,49]
Region (p-Wert des Interaktionsterms: 0,9948)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	550 23,59 (4,59)	521 23,37 (4,57)	495 22,98 (4,87)	473 23,14 (4,76)	449 23,05 (4,50)	422 22,67 (5,06)	396 22,96 (4,93)	391 22,82 (4,85)	362 22,62 (4,99)	-0,70 (0,13)	530 23,57 (4,47)	493 23,39 (4,65)	493 23,30 (4,73)	453 22,82 (4,99)	439 22,77 (4,92)	420 23,04 (4,86)	384 22,95 (4,74)	392 22,36 (5,16)	346 22,51 (5,04)	-0,71 (0,14)	0,01 [-0,36;0,39] 0,9508 0,00 [-0,12;0,12]
Asien	195 20,59 (6,33)	194 20,27 (6,55)	188 19,91 (6,16)	186 19,80 (6,26)	182 19,45 (6,60)	171 19,56 (6,38)	171 18,97 (6,82)	168 19,14 (6,75)	157 19,29 (6,84)	-0,94 (0,28)	192 20,96 (5,68)	191 20,18 (6,21)	187 20,36 (5,95)	184 20,32 (5,63)	180 19,71 (5,95)	174 19,53 (5,96)	172 19,60 (5,80)	168 19,53 (5,91)	163 20,04 (5,93)	-0,90 (0,28)	-0,04 [-0,83;0,74] 0,9136 -0,01 [-0,21;0,19]
Andere	364 22,21 (4,99)	360 21,58 (5,56)	351 21,57 (5,19)	337 21,49 (5,23)	330 21,47 (5,22)	316 21,29 (5,23)	296 21,53 (5,22)	292 21,31 (5,32)	270 21,57 (5,06)	-0,82 (0,19)	390 22,26 (5,20)	384 21,49 (5,32)	381 21,51 (5,23)	375 21,64 (5,17)	352 21,61 (5,07)	327 21,12 (5,37)	307 21,12 (5,56)	293 21,43 (5,19)	271 21,27 (5,35)	-0,83 (0,18)	0,01 [-0,51;0,53] 0,9816 0,00 [-0,14;0,14]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,5528)																					
< 20 mm	280 23,09 (4,50)	267 22,64 (4,56)	258 22,34 (4,60)	253 22,44 (4,78)	243 22,18 (4,84)	235 21,70 (5,40)	229 22,28 (4,96)	221 21,77 (5,32)	210 21,93 (5,20)	-0,94 (0,20)	298 23,24 (4,71)	286 22,29 (5,71)	285 22,45 (5,21)	269 22,30 (5,19)	263 21,78 (5,51)	241 21,75 (5,44)	231 21,92 (5,39)	223 21,54 (5,50)	207 21,50 (5,63)	-1,17 (0,19)	0,23 [-0,31;0,78] 0,4028 0,07 [-0,09;0,23]
≥ 20 bis < 50 mm	569 22,27 (5,56)	560 21,92 (5,94)	531 21,85 (5,59)	516 21,72 (5,51)	494 21,64 (5,73)	469 21,64 (5,62)	449 21,57 (5,85)	437 21,58 (5,66)	404 21,51 (5,69)	-0,61 (0,15)	573 22,49 (5,09)	552 21,99 (5,14)	549 22,07 (5,12)	526 21,71 (5,46)	504 21,81 (5,17)	493 21,67 (5,40)	449 21,64 (5,38)	455 21,50 (5,40)	423 21,68 (5,28)	-0,63 (0,15)	0,03 [-0,39;0,45] 0,8944 0,01 [-0,11;0,12]
≥ 50 mm	243 22,87 (4,98)	232 22,46 (5,09)	229 21,70 (5,55)	214 22,05 (5,73)	209 22,04 (4,96)	191 21,57 (5,40)	171 21,25 (5,96)	180 21,34 (5,79)	162 21,46 (5,73)	-0,88 (0,23)	230 22,30 (5,42)	219 22,23 (5,44)	217 21,82 (5,74)	206 21,95 (4,80)	196 21,76 (5,33)	178 21,61 (5,61)	174 21,22 (5,64)	166 21,22 (5,47)	142 21,15 (5,60)	-0,65 (0,24)	-0,23 [-0,89;0,42] 0,4847 -0,06 [-0,24;0,12]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,5939)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	369 22,82 (5,06)	360 22,21 (5,26)	345 21,99 (5,40)	323 21,79 (5,44)	321 21,63 (5,52)	302 21,33 (5,83)	286 21,50 (5,78)	282 21,35 (5,77)	260 21,60 (5,63)	-1,03 (0,19)	360 22,69 (5,04)	344 21,77 (5,53)	347 21,78 (5,35)	325 21,57 (5,39)	317 21,72 (5,30)	296 21,60 (5,33)	280 21,41 (5,65)	269 21,02 (5,67)	247 21,20 (5,55)	-1,05 (0,19)	0,02 [-0,50;0,53] 0,9534 0,00 [-0,14;0,15]
4-9	476 22,38 (5,17)	459 21,94 (5,62)	446 21,75 (5,38)	436 21,83 (5,41)	416 21,74 (5,41)	391 21,82 (5,40)	375 21,77 (5,59)	374 21,58 (5,43)	354 21,72 (5,53)	-0,63 (0,16)	486 22,59 (5,20)	468 22,41 (5,42)	468 22,10 (5,35)	445 22,04 (5,29)	431 21,71 (5,37)	418 21,74 (5,55)	387 21,62 (5,35)	386 21,63 (5,34)	360 21,79 (5,45)	-0,61 (0,16)	-0,02 [-0,46;0,43] 0,9438 -0,00 [-0,13;0,12]
≥ 10	264 22,73 (5,36)	256 22,70 (5,35)	243 22,23 (5,23)	237 22,42 (5,21)	224 22,27 (5,07)	216 21,62 (5,25)	202 21,77 (5,57)	195 21,89 (5,69)	175 21,35 (5,55)	-0,64 (0,22)	266 22,74 (4,78)	256 22,12 (4,92)	246 22,70 (4,94)	242 22,22 (5,00)	223 22,02 (5,14)	207 21,74 (5,34)	196 21,98 (5,20)	198 21,82 (5,22)	173 21,61 (5,17)	-0,65 (0,22)	0,01 [-0,59;0,61] 0,9843 0,00 [-0,17;0,17]
Tumorstadium (p-Wert des Interaktionsterms: 0,5917)																					
IIA	93 23,46 (4,22)	91 22,54 (4,54)	87 22,47 (4,49)	84 22,37 (4,63)	84 22,26 (4,66)	81 21,46 (5,19)	78 22,06 (4,75)	72 21,42 (5,33)	67 22,16 (4,92)	-1,07 (0,30)	95 22,82 (4,85)	92 21,69 (5,58)	90 21,98 (5,09)	87 21,74 (5,19)	83 21,90 (4,71)	82 21,72 (5,14)	78 21,85 (4,89)	73 20,36 (5,41)	66 20,67 (5,69)	-1,20 (0,30)	0,13 [-0,72;0,97] 0,7685 0,04 [-0,24;0,33]
IIB	133 22,35 (5,65)	130 22,22 (5,56)	123 21,95 (5,62)	120 21,68 (5,65)	118 21,38 (5,79)	110 21,82 (5,79)	103 21,14 (6,53)	104 21,63 (5,98)	97 21,67 (5,90)	-0,75 (0,31)	113 23,04 (4,53)	107 22,24 (4,63)	107 21,82 (4,99)	102 21,30 (5,77)	96 21,61 (5,07)	97 21,21 (5,30)	92 20,92 (5,78)	89 21,19 (5,59)	83 21,45 (4,77)	-1,33 (0,34)	0,58 [-0,32;1,48] 0,2038 0,16 [-0,09;0,41]
IIIA	431 22,63 (4,98)	418 22,07 (5,31)	404 21,85 (5,35)	392 21,95 (5,25)	372 21,86 (5,23)	350 22,01 (5,15)	331 21,82 (5,46)	339 21,67 (5,32)	314 21,82 (5,21)	-0,71 (0,17)	437 22,41 (5,53)	417 22,30 (5,59)	425 21,84 (5,54)	400 21,84 (5,44)	390 21,69 (5,44)	373 21,60 (5,72)	346 21,40 (5,54)	342 21,53 (5,56)	320 21,78 (5,70)	-0,68 (0,17)	-0,03 [-0,50;0,45] 0,9089 -0,01 [-0,14;0,13]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIIB	47 21,70 (5,66)	45 20,58 (7,12)	45 21,22 (6,36)	43 20,98 (7,09)	43 20,07 (7,17)	39 19,74 (7,59)	36 20,81 (6,15)	33 20,09 (7,08)	35 21,34 (6,22)	-1,09 (0,60)	41 22,93 (4,90)	40 22,55 (4,96)	40 22,18 (4,83)	37 22,05 (5,03)	35 20,91 (5,58)	33 21,12 (5,86)	32 21,38 (6,35)	29 21,69 (4,73)	28 20,64 (6,45)	-0,65 (0,65)	-0,44 [-2,20;1,32] 0,6188 -0,11 [-0,53;0,31]
IIIC	403 22,62 (5,32)	390 22,50 (5,44)	373 22,05 (5,28)	355 22,12 (5,33)	342 22,10 (5,22)	327 21,40 (5,53)	313 21,74 (5,67)	301 21,69 (5,66)	274 21,23 (5,91)	-0,71 (0,18)	424 22,76 (4,73)	410 22,01 (5,27)	397 22,57 (5,12)	384 22,23 (4,93)	365 22,02 (5,28)	334 21,99 (5,18)	314 22,09 (5,17)	318 21,76 (5,28)	281 21,65 (5,11)	-0,63 (0,17)	-0,08 [-0,57;0,41] 0,7425 -0,02 [-0,16;0,11]
Tumorgrading (p-Wert des Interaktionsterms: 0,6608)																					
G1	83 23,22 (4,29)	81 22,00 (6,22)	83 21,80 (5,74)	76 22,37 (4,87)	74 22,81 (4,75)	73 22,26 (5,52)	69 22,64 (4,70)	68 22,60 (5,12)	63 22,59 (5,16)	-0,93 (0,37)	84 22,77 (5,15)	83 22,35 (5,18)	81 22,74 (4,89)	76 22,80 (5,05)	78 21,90 (5,65)	72 22,47 (5,15)	66 21,76 (5,36)	67 22,37 (4,32)	59 21,93 (4,64)	-0,46 (0,36)	-0,47 [-1,49;0,56] 0,3700 -0,14 [-0,44;0,16]
G2	526 22,62 (5,04)	511 22,28 (5,28)	490 21,93 (5,38)	468 21,89 (5,59)	451 21,68 (5,47)	424 21,48 (5,60)	395 21,72 (5,62)	403 21,38 (5,63)	370 21,28 (5,67)	-0,83 (0,16)	535 22,61 (5,02)	509 22,10 (5,43)	511 22,05 (5,29)	490 21,91 (5,11)	465 21,54 (5,42)	443 21,60 (5,40)	415 21,54 (5,38)	414 21,40 (5,46)	382 21,46 (5,54)	-0,83 (0,16)	-0,00 [-0,44;0,44] 0,9934 -0,00 [-0,12;0,12]
G3	451 22,54 (5,46)	436 22,16 (5,52)	415 22,10 (5,28)	405 22,01 (5,15)	392 21,88 (5,30)	370 21,57 (5,43)	360 21,55 (5,73)	339 21,56 (5,70)	323 21,74 (5,55)	-0,69 (0,16)	436 22,82 (4,96)	419 22,18 (5,31)	413 22,20 (5,21)	392 21,88 (5,38)	378 22,19 (4,93)	360 21,90 (5,41)	339 21,97 (5,28)	329 21,62 (5,40)	303 21,77 (5,27)	-0,72 (0,16)	0,03 [-0,41;0,47] 0,8976 0,01 [-0,12;0,14]
GX	47 21,96 (5,47)	45 22,11 (5,14)	44 20,80 (5,10)	45 21,48 (6,11)	42 21,17 (5,99)	40 21,95 (5,33)	37 20,70 (6,78)	39 21,87 (5,37)	32 21,91 (5,32)	-0,52 (0,62)	53 21,57 (5,89)	53 21,81 (5,21)	52 21,21 (6,01)	50 20,96 (6,02)	47 20,80 (6,25)	43 19,53 (6,09)	41 19,54 (6,66)	40 19,60 (6,59)	33 20,12 (6,67)	-0,93 (0,58)	0,42 [-1,27;2,10] 0,6248 0,10 [-0,29;0,49]
Ethnizität (p-Wert des Interaktionsterms: 0,4616)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Weiß	810 23,13 (4,73)	780 22,69 (4,97)	755 22,43 (4,96)	724 22,47 (4,96)	696 22,43 (4,82)	657 22,15 (5,14)	613 22,43 (5,01)	609 22,23 (5,00)	567 22,11 (5,01)	-0,79 (0,12)	820 23,10 (4,80)	780 22,58 (5,10)	778 22,61 (4,96)	734 22,38 (4,96)	704 22,32 (4,95)	670 22,27 (5,11)	616 22,21 (5,09)	615 21,93 (5,16)	549 22,06 (5,11)	-0,78 (0,12)	-0,01 [-0,33;0,31] 0,9589 -0,00 [-0,10;0,09]
Asiatisch	233 20,98 (6,35)	231 20,64 (6,75)	221 20,38 (6,32)	219 20,32 (6,42)	214 20,07 (6,65)	200 20,04 (6,37)	199 19,39 (6,92)	197 19,79 (6,85)	179 19,87 (6,96)	-0,75 (0,28)	221 21,04 (5,79)	219 20,66 (6,08)	215 20,49 (6,00)	213 20,71 (5,78)	205 20,15 (6,12)	193 19,75 (6,13)	191 19,85 (6,03)	185 19,89 (6,11)	181 20,25 (6,23)	-0,70 (0,28)	-0,05 [-0,83;0,72] 0,8949 -0,01 [-0,20;0,17]
Andere	54 21,70 (4,81)	52 21,67 (4,62)	48 21,56 (5,18)	44 21,50 (4,89)	43 20,63 (5,06)	42 20,12 (5,60)	44 21,16 (5,08)	38 20,29 (5,65)	35 21,74 (4,92)	-0,67 (0,47)	58 22,57 (4,62)	57 21,51 (4,92)	56 21,70 (5,19)	53 20,28 (6,14)	51 20,52 (5,06)	47 21,34 (5,37)	46 21,41 (5,60)	41 21,80 (4,64)	41 20,39 (4,91)	-1,14 (0,44)	0,47 [-0,81;1,74] 0,4717 0,14 [-0,23;0,51]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,3843)																					
Tamoxifen	104 22,28 (4,99)	101 21,91 (5,23)	101 21,82 (5,57)	98 21,78 (5,32)	97 21,52 (5,51)	96 21,70 (5,44)	90 21,24 (6,20)	89 21,83 (5,38)	90 21,46 (5,66)	-0,45 (0,30)	124 21,46 (5,22)	123 20,98 (5,22)	123 21,41 (5,13)	117 20,97 (5,14)	109 20,53 (5,48)	98 20,42 (5,24)	94 20,41 (5,19)	91 20,20 (5,38)	89 21,26 (4,96)	-0,79 (0,28)	0,34 [-0,47;1,16] 0,4090 0,11 [-0,15;0,37]
Aromatase-Inhibitor	1005 22,64 (5,20)	974 22,24 (5,46)	933 21,96 (5,33)	898 21,98 (5,38)	864 21,86 (5,36)	813 21,60 (5,52)	773 21,73 (5,58)	762 21,55 (5,63)	699 21,62 (5,55)	-0,81 (0,11)	988 22,81 (5,01)	945 22,29 (5,34)	938 22,23 (5,28)	895 22,05 (5,26)	862 21,94 (5,25)	823 21,85 (5,44)	769 21,78 (5,43)	762 21,64 (5,41)	691 21,60 (5,48)	-0,76 (0,11)	-0,05 [-0,37;0,26] 0,7367 -0,02 [-0,10;0,07]
ECOG-PS (p-Wert des Interaktionsterms: 0,1375)																					
ECOG-PS 0	934 22,81 (5,08)	905 22,42 (5,35)	872 22,13 (5,29)	849 22,13 (5,26)	818 22,08 (5,22)	779 21,81 (5,41)	736 21,92 (5,48)	730 21,77 (5,51)	681 21,75 (5,50)	-0,77 (0,11)	899 22,83 (4,92)	863 22,29 (5,34)	859 22,18 (5,27)	822 21,97 (5,24)	792 21,88 (5,25)	754 21,67 (5,39)	701 21,57 (5,39)	694 21,48 (5,44)	629 21,61 (5,40)	-0,89 (0,12)	0,13 [-0,19;0,45] 0,4284 0,04 [-0,05;0,13]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
ECOG-PS 1	175 21,54 (5,60)	170 21,11 (5,79)	162 20,96 (5,61)	147 20,99 (5,92)	143 20,40 (6,00)	130 20,42 (5,95)	127 20,29 (6,38)	121 20,43 (6,00)	108 20,65 (5,88)	-0,81 (0,29)	213 21,94 (5,52)	205 21,48 (5,33)	202 21,94 (5,27)	190 21,74 (5,33)	179 21,37 (5,49)	167 21,82 (5,64)	162 21,90 (5,55)	159 21,48 (5,36)	151 21,38 (5,54)	-0,16 (0,26)	-0,66 [-1,42;0,10] 0,0907 -0,17 [-0,37;0,03]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B SWB = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B SWB haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SWB: soziales und familiäres Wohlbefinden.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t108_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 109.1.2: Subgruppen für die Veränderung der FACT-B-Subskala: EWB aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Region (p-Wert des Interaktionsterms: 0,3214)																					
Nordamerika / Europa	282 18,09 (3,86)	269 18,32 (4,03)	256 18,22 (4,26)	255 18,00 (4,16)	228 18,07 (3,88)	228 18,17 (4,12)	211 18,22 (4,06)	210 18,35 (3,79)	178 18,46 (4,13)	0,07 (0,16)	256 18,14 (4,04)	245 17,78 (4,35)	231 18,34 (4,01)	209 18,09 (4,32)	197 18,27 (4,19)	191 18,28 (4,22)	180 18,17 (4,27)	181 18,08 (4,15)	164 18,21 (4,31)	-0,12 (0,17)	0,19 [-0,27;0,64] 0,4232 0,07 [-0,10;0,24]
Asien	233 18,28 (4,22)	232 18,11 (4,16)	228 18,22 (4,10)	227 18,09 (4,52)	223 17,99 (4,24)	217 18,18 (4,10)	216 18,21 (4,39)	212 18,39 (4,20)	210 18,30 (4,50)	-0,14 (0,18)	211 18,22 (4,14)	210 18,28 (4,15)	209 18,48 (3,83)	203 18,63 (3,77)	192 18,54 (3,82)	187 18,34 (4,14)	183 18,61 (4,10)	181 18,44 (4,10)	171 18,73 (3,97)	0,14 (0,19)	-0,28 [-0,79;0,22] 0,2678 -0,11 [-0,29;0,08]
Andere	180 17,98 (4,30)	178 18,40 (4,19)	173 18,61 (3,82)	172 18,65 (3,90)	169 18,17 (4,20)	162 18,49 (3,80)	146 18,28 (4,50)	151 18,27 (4,20)	133 18,32 (4,00)	0,34 (0,21)	182 17,57 (4,42)	179 18,09 (4,44)	177 18,14 (4,06)	174 18,08 (4,20)	168 18,32 (4,09)	149 18,49 (3,81)	148 18,74 (3,76)	145 18,03 (3,94)	132 17,95 (4,12)	0,49 (0,21)	-0,15 [-0,74;0,44] 0,6166 -0,05 [-0,26;0,15]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,7394)																					
< 20 mm	179 17,84 (4,08)	176 18,05 (4,09)	167 18,17 (4,13)	171 18,13 (4,31)	160 18,07 (4,02)	159 18,14 (4,05)	152 18,04 (4,12)	155 18,43 (3,91)	148 18,18 (4,50)	0,09 (0,20)	169 18,11 (4,23)	164 18,29 (4,18)	161 18,31 (3,66)	153 18,33 (4,15)	149 18,25 (4,09)	142 18,60 (4,05)	136 18,40 (4,37)	135 18,07 (4,29)	123 18,35 (3,92)	0,16 (0,20)	-0,07 [-0,62;0,49] 0,8087 -0,03 [-0,24;0,18]
≥ 20 bis < 50 mm	326 18,43 (4,03)	316 18,30 (4,28)	313 18,52 (4,18)	307 18,25 (4,13)	290 18,11 (4,19)	282 18,37 (4,06)	265 18,12 (4,48)	265 18,17 (4,16)	237 18,44 (4,07)	-0,10 (0,15)	314 17,87 (4,11)	308 17,73 (4,39)	302 18,47 (3,95)	289 18,24 (4,07)	272 18,43 (4,00)	261 18,31 (3,99)	254 18,52 (3,91)	246 18,28 (3,82)	235 18,18 (4,27)	0,17 (0,16)	-0,26 [-0,69;0,16] 0,2249 -0,10 [-0,25;0,06]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 50 mm	172 17,77 (4,17)	169 18,34 (3,85)	162 17,96 (3,96)	160 18,19 (4,21)	154 17,98 (3,78)	152 18,09 (3,85)	142 18,50 (4,11)	140 18,44 (3,92)	122 18,34 (4,33)	0,35 (0,21)	158 18,13 (4,30)	154 18,34 (4,30)	146 18,10 (4,34)	136 18,31 (4,19)	130 18,34 (4,06)	117 18,30 (4,25)	114 18,59 (4,03)	119 18,10 (4,29)	103 18,64 (4,08)	0,15 (0,22)	0,20 [-0,40;0,80] 0,5096 0,07 [-0,14;0,29]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,5166)																					
0-3	238 18,14 (3,95)	231 18,44 (3,88)	218 18,33 (4,03)	221 18,24 (4,31)	202 17,90 (4,19)	200 18,11 (4,09)	192 18,19 (4,31)	188 18,45 (3,90)	169 18,13 (4,60)	0,02 (0,18)	237 18,11 (4,11)	231 18,26 (4,33)	223 18,26 (4,08)	209 18,12 (4,11)	201 18,41 (4,01)	191 18,50 (3,98)	183 18,60 (3,88)	180 18,43 (4,17)	175 18,20 (4,36)	0,08 (0,19)	-0,06 [-0,57;0,46] 0,8292 -0,02 [-0,20;0,16]
4-9	317 17,79 (4,27)	309 17,80 (4,34)	304 18,06 (4,25)	301 17,90 (4,32)	290 17,78 (4,12)	287 18,17 (3,98)	265 17,93 (4,32)	265 18,25 (4,12)	244 18,25 (4,18)	0,11 (0,15)	294 17,78 (4,42)	288 17,78 (4,39)	280 18,30 (3,92)	266 18,25 (4,13)	254 18,43 (3,95)	244 18,24 (4,13)	242 18,28 (4,31)	238 18,05 (4,07)	219 18,42 (4,09)	0,30 (0,16)	-0,19 [-0,62;0,24] 0,3855 -0,07 [-0,23;0,09]
≥ 10	140 18,87 (3,85)	139 19,04 (3,87)	135 18,89 (3,79)	132 18,84 (3,80)	128 19,00 (3,76)	120 18,73 (4,02)	116 18,98 (4,15)	120 18,40 (4,13)	108 18,97 (3,75)	0,00 (0,22)	118 18,36 (3,69)	115 18,22 (4,03)	114 18,54 (3,84)	111 18,60 (4,02)	102 18,19 (4,29)	92 18,39 (4,15)	86 18,84 (3,71)	89 18,10 (3,86)	73 18,33 (3,76)	-0,11 (0,24)	0,12 [-0,52;0,75] 0,7222 0,04 [-0,20;0,29]
Tumorstadium (p-Wert des Interaktionsterms: 0,7347)																					
IIA	71 17,48 (4,03)	69 18,17 (3,82)	67 18,12 (4,18)	67 18,15 (4,02)	65 17,76 (4,32)	62 17,98 (4,20)	59 17,86 (3,93)	60 18,48 (3,89)	55 17,27 (4,86)	0,13 (0,32)	69 18,71 (3,61)	67 19,03 (3,65)	66 18,76 (3,53)	60 18,77 (3,58)	58 19,14 (3,49)	56 19,00 (3,70)	56 19,50 (3,44)	51 19,04 (4,00)	50 19,20 (3,49)	0,44 (0,32)	-0,32 [-1,21;0,58] 0,4882 -0,12 [-0,45;0,21]
IIB	65 18,57 (3,60)	63 18,52 (4,16)	59 19,27 (3,35)	61 18,21 (4,03)	52 18,13 (4,15)	55 18,24 (4,01)	54 18,93 (3,64)	53 18,08 (4,05)	51 18,75 (3,92)	-0,06 (0,33)	85 18,06 (3,87)	83 18,14 (4,20)	82 18,50 (4,13)	76 17,78 (4,47)	76 18,22 (4,12)	72 18,64 (3,65)	67 18,66 (3,57)	70 18,89 (3,46)	68 18,22 (4,24)	0,00 (0,29)	-0,06 [-0,92;0,80] 0,8911 -0,02 [-0,35;0,30]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIIA	310 17,92 (4,34)	304 18,09 (4,10)	297 18,11 (4,20)	296 18,14 (4,25)	283 17,98 (4,02)	280 18,25 (3,86)	255 17,96 (4,40)	255 18,37 (4,19)	235 18,42 (4,29)	0,23 (0,15)	267 17,69 (4,60)	260 17,82 (4,36)	251 18,21 (4,05)	244 18,09 (4,16)	229 18,22 (4,11)	217 18,24 (4,21)	215 18,17 (4,37)	214 18,03 (4,23)	200 18,32 (4,18)	0,21 (0,17)	0,03 [-0,42;0,47] 0,9116 0,01 [-0,15;0,17]
IIIB	18 15,72 (4,84)	18 16,39 (5,21)	16 14,94 (6,29)	17 15,00 (5,39)	13 14,38 (3,75)	14 15,07 (5,44)	14 15,07 (5,53)	14 15,86 (3,46)	14 15,71 (5,03)	-1,09 (0,69)	17 19,82 (2,58)	17 19,35 (3,66)	16 19,00 (2,61)	13 19,23 (4,15)	11 19,45 (3,21)	12 19,33 (3,70)	13 18,92 (2,99)	12 18,17 (1,95)	11 18,82 (3,19)	0,78 (0,75)	-1,87 [-4,07;0,33] 0,0928 -0,61 [-1,27;0,05]
IIIC	227 18,70 (3,72)	221 18,65 (4,11)	214 18,69 (3,78)	209 18,63 (4,02)	203 18,58 (3,94)	193 18,61 (4,03)	188 18,76 (4,23)	189 18,49 (3,91)	163 18,74 (3,89)	-0,07 (0,19)	210 18,01 (3,99)	206 17,81 (4,50)	201 18,23 (4,02)	192 18,50 (4,03)	183 18,33 (4,10)	170 18,11 (4,21)	160 18,46 (4,09)	160 17,85 (4,19)	138 18,04 (4,31)	-0,05 (0,20)	-0,02 [-0,55;0,51] 0,9362 -0,01 [-0,20;0,18]
Tumorgrading (p-Wert des Interaktionsterms: 0,5109)																					
G1	59 18,14 (3,96)	58 18,64 (4,30)	54 18,80 (3,75)	54 18,50 (4,57)	55 18,22 (4,19)	53 18,17 (3,33)	51 18,35 (3,88)	53 18,04 (4,19)	46 18,43 (3,94)	0,31 (0,36)	47 17,98 (4,09)	45 18,13 (3,96)	42 17,83 (4,22)	43 18,74 (3,86)	39 17,85 (4,27)	39 17,31 (4,68)	39 18,13 (4,81)	38 17,58 (4,28)	34 18,15 (3,95)	-0,35 (0,41)	0,66 [-0,41;1,74] 0,2253 0,24 [-0,15;0,62]
G2	311 18,25 (3,98)	304 18,26 (3,95)	297 18,28 (4,11)	295 18,09 (4,11)	280 18,15 (3,84)	275 18,27 (3,93)	257 18,19 (4,24)	254 18,42 (4,00)	234 18,48 (3,98)	-0,01 (0,15)	283 18,04 (4,26)	276 17,93 (4,50)	269 18,58 (3,86)	254 18,27 (4,15)	238 18,39 (4,05)	234 18,53 (4,05)	223 18,52 (4,02)	225 18,24 (4,29)	203 18,42 (4,21)	0,14 (0,16)	-0,15 [-0,59;0,29] 0,5014 -0,06 [-0,22;0,11]
G3	280 17,93 (4,08)	274 18,16 (4,22)	264 18,13 (4,22)	262 18,18 (4,25)	244 17,86 (4,29)	238 18,21 (4,29)	225 18,12 (4,48)	227 18,23 (4,04)	201 18,08 (4,49)	0,07 (0,17)	281 17,93 (4,11)	276 18,08 (4,24)	271 18,17 (3,97)	253 18,23 (4,08)	247 18,41 (4,03)	221 18,47 (3,89)	217 18,55 (3,95)	211 18,33 (3,87)	200 18,33 (4,08)	0,26 (0,17)	-0,18 [-0,65;0,28] 0,4399 -0,07 [-0,23;0,10]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
GX	42 18,24 (5,19)	40 18,28 (4,47)	39 19,13 (3,56)	40 18,63 (4,59)	38 18,47 (4,58)	38 18,53 (4,12)	37 18,78 (4,28)	36 18,78 (4,41)	37 18,81 (4,93)	0,17 (0,39)	36 18,33 (4,36)	35 18,26 (3,89)	33 18,45 (4,38)	34 18,00 (4,39)	31 18,74 (3,65)	31 17,71 (4,72)	30 18,37 (4,44)	31 17,87 (3,50)	28 18,04 (4,56)	-0,06 (0,43)	0,23 [-0,92;1,39] 0,6904 0,09 [-0,35;0,54]
Ethnizität (p-Wert des Interaktionsterms: 0,5536)																					
Weiß	398 17,92 (4,06)	386 18,18 (4,09)	369 18,22 (4,12)	368 18,07 (4,08)	341 17,92 (3,98)	336 18,10 (4,01)	305 18,03 (4,16)	310 18,10 (4,00)	275 18,22 (3,94)	0,10 (0,14)	381 17,86 (4,18)	368 17,78 (4,35)	355 18,16 (4,00)	337 17,92 (4,27)	323 18,12 (4,19)	304 18,26 (4,10)	290 18,30 (4,08)	290 17,94 (4,05)	267 17,91 (4,26)	0,00 (0,14)	0,09 [-0,29;0,47] 0,6303 0,03 [-0,11;0,18]
Asiatisch	260 18,34 (4,13)	258 18,30 (4,17)	254 18,45 (4,07)	252 18,40 (4,48)	246 18,27 (4,26)	240 18,42 (4,12)	237 18,50 (4,37)	236 18,61 (4,15)	223 18,46 (4,61)	0,07 (0,17)	227 18,19 (4,14)	226 18,32 (4,11)	223 18,58 (3,90)	218 18,80 (3,82)	202 18,63 (3,82)	194 18,39 (4,14)	192 18,73 (4,08)	188 18,49 (4,07)	176 18,79 (3,96)	0,28 (0,19)	-0,20 [-0,70;0,30] 0,4285 -0,07 [-0,25;0,11]
Andere	26 18,62 (4,62)	25 19,16 (4,12)	25 18,44 (4,24)	25 18,32 (3,85)	24 17,94 (4,65)	22 18,55 (3,58)	22 17,73 (5,40)	20 18,15 (3,95)	18 18,83 (4,13)	-0,25 (0,59)	29 18,48 (4,68)	28 18,54 (5,16)	28 17,88 (4,20)	27 18,56 (4,03)	25 19,16 (3,65)	22 19,18 (3,57)	22 18,86 (4,44)	23 18,57 (4,44)	18 19,28 (3,82)	0,52 (0,57)	-0,77 [-2,42;0,88] 0,3538 -0,25 [-0,78;0,28]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,2674)																					
Tamoxifen	492 18,00 (4,10)	481 18,04 (4,18)	460 18,14 (4,14)	462 17,99 (4,16)	433 17,89 (4,15)	425 18,02 (4,09)	400 17,94 (4,36)	402 18,07 (4,05)	361 18,00 (4,26)	-0,02 (0,13)	477 17,80 (4,18)	464 17,91 (4,23)	449 18,21 (3,96)	427 18,10 (4,01)	403 18,26 (4,02)	388 18,14 (4,06)	373 18,32 (3,91)	376 18,00 (4,17)	346 18,12 (4,26)	0,14 (0,13)	-0,16 [-0,51;0,19] 0,3775 -0,06 [-0,18;0,07]
Aromatase-Inhibitor	203 18,45 (4,08)	198 18,82 (3,91)	197 18,75 (3,96)	192 18,71 (4,36)	187 18,49 (3,95)	182 18,84 (3,82)	173 18,91 (4,06)	171 18,99 (3,97)	160 19,18 (4,11)	0,26 (0,18)	172 18,58 (4,15)	170 18,38 (4,51)	168 18,65 (3,95)	159 18,73 (4,30)	154 18,69 (4,04)	139 18,98 (4,06)	138 18,96 (4,45)	131 18,76 (3,73)	121 18,92 (3,75)	0,15 (0,20)	0,11 [-0,42;0,63] 0,6866 0,04 [-0,16;0,25]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Datenschnitt: 01.07.2022 Safety-Population 1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B EWB = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B EWB haben. Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Abkürzungen: B: Baseline; ET: Endokrine Therapie; EWB: emotionales Wohlbefinden; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.																				

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t109_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 109.2.2: Subgruppen für die Veränderung der FACT-B-Subskala: EWB aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,6775)																					
< 65 Jahre	804 18,53 (3,99)	780 18,64 (4,04)	755 18,75 (4,10)	720 18,60 (4,12)	699 18,73 (3,78)	665 18,50 (4,10)	637 18,53 (4,12)	632 18,70 (4,00)	588 18,67 (3,94)	0,04 (0,09)	832 18,31 (4,22)	798 18,57 (4,13)	798 18,55 (3,95)	757 18,49 (4,01)	722 18,56 (4,17)	682 18,55 (3,97)	639 18,49 (4,08)	632 18,48 (4,10)	587 18,34 (4,22)	0,08 (0,09)	-0,05 [-0,30;0,21] 0,7232 -0,02 [-0,11;0,08]
≥ 65 Jahre	303 18,59 (4,01)	292 18,61 (3,98)	276 18,95 (3,62)	271 18,71 (4,00)	255 18,68 (3,88)	236 18,61 (3,73)	224 18,76 (3,96)	216 18,95 (3,76)	198 18,78 (3,79)	-0,09 (0,14)	279 19,19 (3,88)	269 19,32 (3,87)	262 19,36 (3,72)	254 19,34 (3,62)	246 19,17 (3,80)	238 19,04 (3,70)	220 18,94 (3,68)	216 18,70 (3,89)	191 18,57 (4,09)	-0,08 (0,15)	-0,01 [-0,41;0,39] 0,9749 -0,00 [-0,17;0,16]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,6919)																					
Neoadjuvante Chemotherapie	363 18,90 (3,98)	345 18,88 (4,13)	330 19,13 (3,98)	315 18,48 (4,23)	297 18,70 (3,88)	276 18,57 (4,22)	260 18,45 (4,33)	254 18,78 (4,07)	236 18,46 (4,28)	-0,26 (0,14)	365 18,30 (4,30)	352 18,42 (4,20)	342 18,38 (3,86)	322 18,35 (3,94)	306 18,33 (4,11)	281 18,39 (3,93)	267 18,36 (3,99)	264 18,11 (4,12)	234 17,97 (4,32)	-0,23 (0,14)	-0,02 [-0,42;0,38] 0,9065 -0,01 [-0,15;0,14]
Adjuvante Chemotherapie	684 18,35 (4,02)	670 18,50 (4,00)	648 18,62 (4,05)	621 18,75 (4,00)	606 18,73 (3,79)	581 18,53 (3,96)	557 18,66 (4,01)	554 18,75 (3,92)	512 18,78 (3,75)	0,14 (0,10)	679 18,67 (3,98)	651 19,00 (3,93)	656 18,92 (3,95)	631 18,87 (3,87)	612 18,92 (4,10)	591 18,83 (3,91)	547 18,72 (4,01)	541 18,74 (3,97)	510 18,63 (4,14)	0,18 (0,10)	-0,04 [-0,31;0,23] 0,7859 -0,01 [-0,12;0,09]
Keine Chemotherapie	60 18,67 (3,63)	57 18,60 (3,57)	53 18,91 (2,88)	55 18,15 (4,17)	51 18,75 (3,69)	44 18,23 (3,26)	44 18,55 (3,43)	40 18,90 (3,22)	38 19,16 (3,42)	-0,18 (0,32)	67 18,40 (4,93)	64 18,14 (4,65)	62 18,98 (3,67)	58 18,85 (4,40)	50 18,60 (3,73)	48 18,58 (3,71)	45 18,62 (3,50)	43 18,58 (4,38)	34 17,85 (3,83)	0,01 (0,31)	-0,19 [-1,08;0,69] 0,6633 -0,08 [-0,43;0,27]
Region (p-Wert des Interaktionsterms: 0,2981)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	550 18,51 (4,23)	520 18,44 (4,32)	494 18,68 (4,12)	470 18,28 (4,34)	444 18,61 (3,99)	416 18,38 (4,12)	396 18,38 (4,33)	390 18,83 (3,95)	360 18,43 (3,99)	-0,19 (0,11)	530 18,59 (4,24)	493 18,86 (4,04)	491 18,73 (3,93)	453 18,67 (3,97)	438 18,84 (4,11)	420 18,72 (4,04)	381 18,59 (4,01)	388 18,46 (4,10)	345 18,39 (4,23)	-0,06 (0,11)	-0,13 [-0,44;0,17] 0,3995 -0,05 [-0,17;0,07]
Asien	195 18,91 (3,53)	194 18,98 (3,55)	188 18,90 (3,87)	187 18,89 (3,81)	182 18,91 (3,69)	171 18,84 (3,80)	171 18,61 (3,81)	168 18,63 (3,73)	157 18,93 (3,85)	-0,00 (0,18)	192 18,58 (3,96)	191 18,63 (3,96)	187 18,85 (3,81)	184 19,01 (3,73)	179 19,00 (3,82)	174 18,83 (3,73)	172 18,93 (3,87)	168 18,77 (3,87)	163 18,76 (4,08)	0,16 (0,18)	-0,17 [-0,66;0,32] 0,5051 -0,07 [-0,27;0,13]
Andere	362 18,41 (3,86)	358 18,72 (3,79)	349 18,92 (3,83)	334 18,99 (3,82)	328 18,76 (3,63)	314 18,54 (3,97)	294 18,86 (3,87)	290 18,77 (4,04)	269 18,93 (3,81)	0,31 (0,14)	389 18,42 (4,13)	383 18,69 (4,18)	382 18,71 (3,93)	374 18,60 (3,98)	351 18,41 (4,18)	326 18,55 (3,84)	306 18,43 (4,01)	292 18,50 (4,07)	270 18,20 (4,19)	0,08 (0,14)	0,22 [-0,16;0,61] 0,2585 0,08 [-0,06;0,23]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,8885)																					
< 20 mm	279 18,81 (3,92)	266 18,92 (3,94)	256 19,03 (3,75)	252 18,50 (4,29)	241 18,72 (3,68)	232 18,43 (4,22)	229 18,66 (4,06)	219 18,69 (3,82)	209 18,65 (3,66)	-0,19 (0,15)	298 18,69 (3,89)	286 18,91 (4,00)	284 19,07 (3,67)	268 18,70 (4,06)	262 18,58 (4,02)	241 18,74 (3,64)	230 18,43 (3,85)	223 18,53 (3,80)	208 18,50 (4,14)	-0,10 (0,15)	-0,09 [-0,51;0,32] 0,6578 -0,04 [-0,20;0,13]
≥ 20 bis < 50 mm	569 18,50 (4,02)	559 18,57 (4,03)	531 18,79 (4,08)	516 18,88 (3,97)	491 18,81 (3,83)	467 18,83 (3,82)	448 18,80 (4,02)	437 19,00 (3,87)	403 18,94 (3,75)	0,16 (0,11)	572 18,57 (4,23)	552 18,79 (4,10)	548 18,71 (3,91)	525 18,81 (3,83)	502 18,84 (4,06)	493 18,75 (4,01)	446 18,79 (4,01)	450 18,67 (3,96)	421 18,43 (4,12)	0,10 (0,11)	0,06 [-0,24;0,36] 0,6861 0,02 [-0,09;0,14]
≥ 50 mm	242 18,38 (4,05)	231 18,48 (4,08)	228 18,64 (3,89)	210 18,17 (4,14)	207 18,58 (3,89)	188 18,03 (4,02)	170 17,96 (4,19)	179 18,36 (4,20)	161 18,19 (4,39)	-0,09 (0,17)	230 18,20 (4,35)	218 18,48 (4,13)	218 18,40 (4,23)	207 18,46 (4,00)	196 18,56 (4,27)	177 18,44 (3,95)	174 18,34 (4,04)	166 18,22 (4,54)	141 18,17 (4,52)	0,06 (0,18)	-0,15 [-0,64;0,34] 0,5398 -0,06 [-0,24;0,12]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,0860)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	367 18,59 (3,96)	358 18,73 (3,93)	342 18,79 (4,38)	322 18,60 (4,23)	317 18,77 (3,87)	298 18,38 (4,22)	284 18,35 (4,14)	280 18,93 (4,05)	258 18,73 (4,17)	-0,07 (0,14)	360 18,47 (4,33)	343 18,79 (4,04)	347 18,93 (3,84)	325 18,76 (3,90)	316 18,97 (3,89)	295 18,80 (3,80)	280 18,81 (3,73)	268 18,41 (4,31)	246 18,44 (4,07)	0,13 (0,14)	-0,20 [-0,58;0,18] 0,2956 -0,08 [-0,22;0,07]
4-9	476 18,55 (3,98)	458 18,71 (3,98)	446 18,89 (3,66)	433 18,75 (3,87)	414 18,71 (3,72)	388 18,62 (3,88)	375 18,76 (4,04)	373 18,80 (3,72)	354 18,82 (3,73)	0,11 (0,12)	486 18,50 (4,17)	468 18,56 (4,14)	467 18,65 (3,83)	445 18,51 (4,00)	430 18,39 (4,28)	418 18,48 (4,04)	385 18,41 (4,18)	385 18,66 (3,83)	359 18,17 (4,36)	-0,10 (0,12)	0,21 [-0,12;0,54] 0,2160 0,08 [-0,05;0,21]
≥ 10	264 18,50 (4,07)	256 18,35 (4,22)	243 18,64 (3,96)	236 18,47 (4,28)	223 18,66 (3,90)	215 18,56 (3,95)	202 18,61 (4,08)	195 18,47 (4,17)	174 18,42 (3,85)	-0,08 (0,16)	265 18,67 (3,87)	256 19,08 (4,01)	246 18,68 (4,16)	241 18,99 (3,84)	222 18,99 (3,94)	207 18,90 (3,78)	194 18,68 (3,94)	195 18,45 (4,08)	173 18,82 (3,97)	0,14 (0,16)	-0,22 [-0,67;0,23] 0,3398 -0,08 [-0,25;0,09]
Tumorstadium (p-Wert des Interaktionsterms: 0,6226)																					
IIA	92 18,73 (4,08)	90 18,79 (3,74)	85 18,80 (4,19)	83 18,40 (4,23)	82 18,45 (3,66)	80 18,31 (4,17)	78 17,90 (4,60)	71 18,76 (4,01)	66 18,76 (4,09)	-0,30 (0,25)	95 18,16 (4,95)	92 18,38 (4,66)	90 18,82 (3,86)	86 18,28 (4,12)	82 18,50 (3,66)	82 18,22 (3,74)	78 18,17 (3,71)	73 17,84 (3,89)	65 18,20 (4,10)	-0,04 (0,25)	-0,27 [-0,97;0,44] 0,4599 -0,11 [-0,40;0,18]
IIB	133 18,86 (3,79)	130 19,07 (3,83)	123 19,33 (4,17)	120 18,88 (4,27)	118 19,19 (3,76)	110 19,29 (3,79)	102 19,03 (3,73)	104 19,48 (3,51)	97 19,45 (3,64)	0,10 (0,22)	113 19,11 (4,14)	107 19,51 (3,43)	107 19,15 (3,74)	102 19,01 (3,72)	96 19,34 (4,03)	97 19,29 (4,13)	92 19,28 (3,98)	88 18,69 (4,90)	83 18,53 (4,26)	-0,07 (0,24)	0,17 [-0,47;0,81] 0,6104 0,07 [-0,19;0,32]
IIIA	431 18,55 (3,91)	417 18,70 (3,92)	404 18,85 (3,67)	389 18,63 (3,85)	370 18,59 (3,76)	346 18,50 (3,87)	331 18,64 (4,05)	339 18,54 (3,90)	313 18,71 (3,93)	0,01 (0,13)	437 18,53 (4,25)	417 18,49 (4,08)	424 18,71 (3,89)	400 18,58 (4,03)	389 18,44 (4,36)	372 18,52 (4,00)	344 18,42 (4,07)	341 18,74 (3,84)	319 18,24 (4,40)	-0,04 (0,12)	0,05 [-0,30;0,40] 0,7684 0,02 [-0,11;0,15]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIIB	47 17,34 (4,52)	45 17,53 (4,67)	45 18,40 (4,63)	44 17,95 (4,62)	43 18,23 (3,74)	39 17,72 (4,67)	36 18,25 (4,33)	33 19,03 (3,95)	35 18,20 (4,16)	0,36 (0,39)	41 18,63 (4,03)	40 19,30 (3,91)	40 19,13 (3,68)	37 19,41 (4,00)	35 19,09 (4,29)	33 18,97 (3,68)	32 18,56 (4,54)	29 18,69 (4,21)	28 18,43 (3,81)	0,66 (0,42)	-0,30 [-1,45;0,85] 0,6061 -0,11 [-0,53;0,31]
IIIC	402 18,56 (4,05)	389 18,50 (4,17)	372 18,62 (4,12)	353 18,70 (4,19)	339 18,83 (3,93)	324 18,46 (4,09)	312 18,61 (4,06)	299 18,75 (4,09)	273 18,51 (3,81)	-0,01 (0,13)	423 18,45 (3,88)	409 18,89 (4,06)	397 18,62 (4,02)	384 18,78 (3,84)	364 18,86 (3,87)	334 18,76 (3,80)	312 18,72 (3,89)	315 18,42 (4,03)	281 18,58 (4,00)	0,11 (0,13)	-0,12 [-0,48;0,24] 0,5204 -0,04 [-0,18;0,09]
Tumorgrading (p-Wert des Interaktionsterms: 0,3303)																					
G1	82 18,99 (4,06)	80 19,30 (3,18)	82 18,76 (4,04)	75 18,73 (4,67)	72 19,00 (3,76)	69 18,43 (3,81)	68 18,65 (3,94)	67 18,57 (4,06)	63 18,87 (3,77)	-0,14 (0,27)	84 18,93 (4,00)	83 19,12 (4,03)	81 18,71 (4,58)	76 19,34 (3,72)	78 18,79 (4,24)	73 19,34 (3,87)	66 18,73 (4,68)	67 19,24 (3,90)	59 18,88 (3,97)	0,08 (0,27)	-0,22 [-0,98;0,54] 0,5650 -0,09 [-0,39;0,21]
G2	526 18,59 (4,00)	510 18,57 (4,15)	490 18,81 (3,87)	469 18,67 (4,08)	450 18,70 (3,87)	422 18,50 (4,02)	395 18,63 (4,17)	402 18,57 (4,10)	368 18,70 (3,91)	-0,06 (0,11)	534 18,55 (4,17)	509 18,56 (4,14)	508 18,57 (3,92)	491 18,44 (3,97)	464 18,34 (4,30)	441 18,53 (3,92)	414 18,33 (4,01)	412 18,53 (3,90)	380 18,19 (4,07)	-0,20 (0,11)	0,15 [-0,17;0,46] 0,3534 0,06 [-0,06;0,18]
G3	450 18,45 (3,98)	435 18,57 (4,01)	413 18,82 (4,10)	401 18,57 (3,99)	388 18,73 (3,76)	368 18,61 (4,06)	359 18,54 (4,07)	338 19,00 (3,74)	322 18,70 (3,96)	0,11 (0,12)	436 18,38 (4,24)	418 18,97 (3,97)	415 18,91 (3,87)	390 18,92 (3,90)	376 19,16 (3,78)	360 18,78 (3,99)	336 18,88 (3,88)	326 18,40 (4,26)	303 18,60 (4,35)	0,33 (0,13)	-0,22 [-0,57;0,12] 0,2077 -0,08 [-0,22;0,05]
GX	47 18,21 (4,05)	45 18,58 (4,00)	44 18,57 (4,09)	44 18,53 (4,13)	42 18,36 (3,82)	40 18,23 (3,96)	37 18,43 (3,57)	39 19,05 (3,67)	32 18,41 (3,71)	0,01 (0,34)	53 19,00 (3,55)	53 18,28 (4,39)	52 19,29 (2,97)	50 18,76 (3,73)	47 18,61 (3,77)	43 18,14 (2,86)	41 18,61 (3,11)	40 18,40 (3,94)	33 18,06 (4,41)	-0,14 (0,32)	0,15 [-0,78;1,08] 0,7528 0,06 [-0,33;0,46]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9091)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Negativ	137 18,05 (3,58)	134 18,02 (4,09)	127 18,10 (4,05)	124 18,38 (3,91)	116 17,94 (3,86)	104 17,50 (4,03)	98 17,98 (3,67)	101 18,04 (3,98)	89 17,94 (4,00)	-0,22 (0,23)	149 18,33 (3,96)	143 18,38 (4,18)	140 18,33 (4,00)	134 18,32 (4,12)	125 18,67 (3,83)	117 18,37 (4,00)	105 17,88 (4,53)	104 18,18 (3,76)	92 18,33 (3,94)	-0,02 (0,22)	-0,20 [-0,82;0,42] 0,5273 -0,07 [-0,31;0,16]
Positiv	939 18,60 (4,06)	907 18,67 (4,02)	873 18,86 (3,97)	842 18,60 (4,12)	816 18,78 (3,79)	773 18,61 (3,99)	737 18,60 (4,13)	723 18,82 (3,90)	676 18,74 (3,88)	0,02 (0,08)	935 18,49 (4,17)	900 18,79 (4,07)	896 18,76 (3,90)	854 18,73 (3,90)	821 18,67 (4,14)	781 18,69 (3,91)	735 18,67 (3,90)	722 18,55 (4,09)	665 18,37 (4,24)	0,07 (0,08)	-0,05 [-0,29;0,18] 0,6488 -0,02 [-0,11;0,07]
Unbekannt	9 18,00 (4,24)	9 19,33 (3,84)	9 19,89 (3,66)	7 21,00 (3,42)	3 22,33 (2,08)	7 20,29 (4,42)	8 19,63 (4,81)	7 19,43 (6,32)	5 22,00 (2,83)	0,89 (0,91)	7 20,86 (3,89)	6 20,00 (4,34)	6 20,67 (3,44)	6 21,00 (1,41)	6 21,17 (2,14)	6 20,00 (2,10)	5 20,80 (0,84)	6 22,00 (1,90)	5 20,80 (1,64)	0,85 (1,00)	0,05 [-2,92;3,01] 0,9737 0,02 [-0,92;0,95]
Ethnizität (p-Wert des Interaktionsterms: 0,8289)																					
Weiß	808 18,40 (4,11)	777 18,48 (4,10)	754 18,70 (3,99)	720 18,43 (4,19)	690 18,57 (3,89)	649 18,33 (4,07)	611 18,41 (4,17)	606 18,63 (3,99)	564 18,45 (3,96)	-0,06 (0,09)	820 18,50 (4,18)	779 18,76 (4,08)	778 18,74 (3,82)	734 18,53 (3,99)	703 18,59 (4,18)	670 18,59 (3,95)	613 18,48 (4,00)	612 18,35 (4,12)	548 18,22 (4,29)	-0,03 (0,09)	-0,03 [-0,29;0,23] 0,8139 -0,01 [-0,11;0,09]
Asiatisch	233 18,98 (3,50)	231 19,13 (3,59)	221 19,14 (3,83)	219 19,16 (3,77)	213 19,17 (3,62)	200 19,16 (3,74)	199 18,92 (3,77)	197 19,06 (3,81)	179 19,30 (3,85)	0,26 (0,17)	221 18,53 (4,01)	219 18,67 (4,00)	215 18,79 (4,01)	213 19,22 (3,74)	204 19,19 (3,87)	193 18,93 (3,74)	191 19,01 (3,91)	185 19,01 (3,90)	181 18,91 (4,00)	0,31 (0,17)	-0,05 [-0,51;0,42] 0,8448 -0,02 [-0,20;0,17]
Andere	54 19,00 (3,97)	52 18,65 (4,56)	48 19,02 (4,35)	43 19,28 (3,50)	43 18,60 (3,35)	42 18,67 (4,30)	44 19,14 (4,14)	38 19,24 (3,78)	35 19,31 (3,10)	-0,19 (0,35)	57 19,09 (4,10)	57 18,82 (4,60)	55 18,95 (4,03)	52 18,92 (3,83)	50 18,47 (3,78)	46 19,04 (4,07)	45 18,89 (4,02)	40 19,18 (3,75)	40 18,65 (3,59)	-0,28 (0,33)	0,09 [-0,86;1,05] 0,8448 0,04 [-0,33;0,41]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,7543)																					

Subgruppe	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Tamoxifen	104 18,47 (4,04)	101 18,06 (4,41)	101 18,07 (4,38)	98 17,78 (4,21)	97 18,45 (3,81)	96 18,22 (3,92)	90 18,28 (4,06)	89 18,07 (4,53)	90 18,62 (4,07)	-0,17 (0,24)	124 17,87 (4,13)	123 18,14 (4,08)	123 17,83 (4,35)	117 17,88 (3,92)	109 17,85 (3,94)	98 18,06 (3,99)	94 18,12 (3,70)	91 17,85 (4,09)	89 18,17 (3,68)	-0,01 (0,22)	-0,16 [-0,81;0,49] 0,6255 -0,06 [-0,33;0,20]
Aromatase-Inhibitor	1003 18,56 (3,99)	971 18,69 (3,98)	930 18,88 (3,93)	893 18,73 (4,06)	857 18,75 (3,81)	805 18,56 (4,02)	771 18,63 (4,08)	759 18,85 (3,85)	696 18,71 (3,88)	0,02 (0,08)	987 18,61 (4,15)	944 18,84 (4,07)	937 18,87 (3,83)	894 18,81 (3,92)	859 18,83 (4,09)	822 18,75 (3,89)	765 18,66 (4,01)	757 18,62 (4,03)	689 18,43 (4,25)	0,04 (0,08)	-0,03 [-0,26;0,20] 0,8170 -0,01 [-0,10;0,08]
ECOG-PS (p-Wert des Interaktionsterms: 0,5338)																					
ECOG-PS 0	933 18,67 (3,89)	903 18,77 (3,95)	870 18,88 (3,94)	846 18,66 (4,06)	812 18,81 (3,76)	772 18,54 (4,03)	735 18,62 (4,05)	728 18,85 (3,89)	679 18,75 (3,82)	0,00 (0,08)	899 18,58 (4,12)	862 18,80 (4,05)	859 18,84 (3,81)	823 18,77 (3,88)	790 18,71 (4,09)	754 18,67 (3,88)	699 18,54 (4,05)	691 18,51 (4,02)	629 18,44 (4,18)	-0,00 (0,09)	0,00 [-0,23;0,24] 0,9746 0,00 [-0,09;0,09]
ECOG-PS 1	174 17,92 (4,45)	169 17,87 (4,29)	161 18,39 (4,16)	145 18,48 (4,25)	142 18,19 (4,03)	129 18,43 (3,87)	126 18,41 (4,27)	120 18,29 (4,17)	107 18,41 (4,40)	0,01 (0,21)	212 18,33 (4,30)	205 18,56 (4,19)	201 18,37 (4,30)	188 18,42 (4,15)	178 18,72 (4,07)	166 18,72 (4,02)	160 18,87 (3,69)	157 18,66 (4,14)	149 18,25 (4,21)	0,21 (0,18)	-0,20 [-0,75;0,35] 0,4726 -0,07 [-0,27;0,13]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B EWB = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B EWB haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; EWB: emotionales Wohlbefinden; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t109_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba

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Tabelle 110.1.2: Subgruppen für die Veränderung der FACT-B-Subskala: FWB aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,1810)																					
Neoadjuvante Chemotherapie	281 20,24 (5,00)	271 19,65 (5,56)	262 19,90 (5,67)	264 19,89 (5,58)	241 19,78 (5,60)	239 19,95 (6,08)	224 19,83 (5,74)	223 20,66 (5,38)	202 20,48 (5,69)	-0,32 (0,21)	267 19,53 (5,16)	258 19,86 (5,33)	254 20,17 (5,14)	230 20,50 (5,38)	221 20,31 (5,58)	203 20,67 (5,61)	187 20,45 (5,41)	184 20,35 (5,54)	170 20,06 (5,94)	0,36 (0,22)	-0,68 [-1,28;-0,08] 0,0273 -0,19 [-0,36;-0,02]
Adjuvante Chemotherapie	406 19,65 (5,31)	399 19,52 (5,15)	388 19,75 (5,72)	382 20,02 (5,38)	372 20,11 (5,60)	361 20,09 (5,66)	342 20,27 (5,63)	345 20,56 (5,22)	315 20,55 (5,33)	0,40 (0,17)	378 19,80 (5,37)	372 19,95 (5,43)	360 20,60 (5,33)	352 20,75 (5,26)	333 21,11 (4,99)	321 20,92 (5,07)	320 20,96 (4,97)	320 20,78 (5,19)	295 21,07 (4,93)	0,85 (0,18)	-0,45 [-0,94;0,03] 0,0666 -0,13 [-0,27;0,01]
Keine Chemotherapie	7 18,71 (7,95)	7 19,00 (6,53)	6 18,67 (7,20)	6 19,17 (6,97)	6 19,83 (6,74)	6 18,33 (7,09)	6 19,33 (5,20)	5 19,60 (6,11)	4 23,00 (2,16)	0,99 (1,45)	3 19,33 (2,52)	3 17,67 (4,16)	3 17,67 (4,93)	3 14,67 (4,04)	3 16,00 (3,00)	3 17,00 (3,00)	3 16,00 (4,00)	3 19,33 (7,02)	2 16,50 (2,12)	-2,04 (2,07)	3,04 [-3,09;9,16] 0,2735 0,73 [-0,54;1,99]
Region (p-Wert des Interaktionsterms: 0,3022)																					
Nordamerika / Europa	282 19,68 (5,23)	268 19,50 (5,10)	256 19,78 (5,32)	254 19,64 (5,33)	228 19,79 (5,43)	228 19,87 (5,73)	211 20,18 (5,43)	210 20,80 (5,13)	178 20,52 (5,31)	0,23 (0,20)	256 19,64 (4,95)	245 19,36 (5,53)	231 20,15 (5,10)	209 20,26 (5,49)	197 20,81 (5,42)	191 20,60 (5,37)	180 20,72 (5,26)	181 20,75 (5,49)	164 20,57 (5,54)	0,50 (0,22)	-0,27 [-0,86;0,31] 0,3584 -0,08 [-0,25;0,09]
Asien	232 20,02 (5,28)	231 19,52 (5,58)	227 19,70 (5,99)	226 20,17 (5,84)	222 20,21 (5,84)	216 19,96 (6,06)	215 20,07 (5,76)	212 20,73 (5,43)	210 20,81 (5,72)	0,10 (0,23)	210 19,90 (5,39)	209 20,13 (5,45)	209 20,46 (5,29)	202 21,21 (5,24)	192 21,23 (5,05)	187 21,33 (5,53)	183 20,80 (5,46)	181 21,11 (5,30)	171 21,15 (5,48)	0,85 (0,24)	-0,75 [-1,39;-0,10] 0,0233 -0,22 [-0,40;-0,03]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	180 20,00 (5,12)	178 19,72 (5,36)	173 19,97 (5,90)	172 20,15 (5,16)	169 19,94 (5,55)	162 20,29 (5,71)	146 19,98 (5,88)	151 20,12 (5,28)	133 20,14 (5,23)	0,02 (0,27)	182 19,51 (5,58)	179 20,39 (5,04)	177 20,68 (5,42)	174 20,36 (5,15)	168 20,18 (5,21)	149 20,40 (4,80)	147 20,71 (4,58)	145 19,82 (5,07)	132 20,22 (4,85)	0,57 (0,27)	-0,55 [-1,30;0,20] 0,1522 -0,15 [-0,36;0,06]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,2678)																					
< 20 mm	179 20,02 (4,88)	176 19,42 (5,08)	167 19,90 (5,38)	171 19,95 (5,39)	160 20,16 (5,33)	159 20,08 (5,80)	152 20,04 (5,64)	155 20,76 (4,88)	148 20,59 (5,29)	0,04 (0,26)	169 19,80 (5,21)	164 19,77 (5,53)	161 20,57 (4,86)	153 19,99 (5,74)	149 20,75 (5,41)	142 20,94 (5,52)	136 20,71 (5,42)	135 20,58 (5,78)	123 20,73 (5,77)	0,48 (0,27)	-0,43 [-1,18;0,31] 0,2546 -0,12 [-0,33;0,09]
≥ 20 bis < 50 mm	325 19,86 (5,51)	314 19,35 (5,77)	312 19,83 (5,78)	305 19,76 (5,64)	289 19,78 (5,93)	281 19,78 (5,92)	264 19,83 (5,86)	265 20,31 (5,72)	237 20,28 (5,71)	-0,04 (0,20)	314 19,51 (5,28)	308 19,89 (5,22)	302 20,42 (5,47)	289 20,99 (5,03)	272 20,88 (5,06)	261 20,75 (5,06)	253 20,79 (5,00)	246 20,44 (5,11)	235 20,78 (5,22)	0,81 (0,20)	-0,85 [-1,41;-0,30] 0,0027 -0,24 [-0,39;-0,08]
≥ 50 mm	172 19,67 (5,08)	169 19,86 (4,78)	162 19,41 (5,94)	160 20,08 (5,19)	154 19,96 (5,24)	152 20,16 (5,74)	142 20,44 (5,29)	140 20,79 (4,85)	122 20,80 (5,15)	0,39 (0,25)	157 19,91 (5,32)	153 20,00 (5,62)	146 20,19 (5,22)	135 20,67 (5,34)	130 20,44 (5,47)	117 20,72 (5,52)	114 20,68 (5,22)	119 21,01 (5,16)	103 20,25 (5,13)	0,48 (0,27)	-0,09 [-0,81;0,63] 0,8062 -0,03 [-0,24;0,19]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,7236)																					
0-3	238 20,12 (5,27)	231 19,77 (5,27)	218 19,87 (5,88)	221 19,74 (5,76)	202 20,06 (5,61)	200 20,25 (6,22)	192 19,91 (6,21)	188 20,74 (5,32)	169 20,45 (5,81)	-0,02 (0,23)	237 19,35 (5,22)	231 19,69 (5,48)	223 20,13 (5,45)	209 20,15 (5,52)	201 20,26 (5,38)	191 20,46 (5,38)	183 20,47 (5,19)	180 20,43 (5,37)	175 20,62 (5,48)	0,51 (0,23)	-0,53 [-1,18;0,11] 0,1061 -0,15 [-0,33;0,03]
4-9	316 19,33 (5,36)	307 18,78 (5,47)	303 19,27 (5,71)	299 19,58 (5,39)	289 19,57 (5,56)	286 19,48 (5,64)	264 19,56 (5,38)	265 20,06 (5,28)	244 20,15 (5,32)	0,05 (0,20)	294 20,06 (5,14)	288 20,17 (5,11)	280 20,37 (5,31)	266 20,76 (5,22)	254 21,11 (5,06)	244 20,89 (5,24)	242 20,74 (5,20)	238 20,71 (5,18)	219 20,73 (5,08)	0,53 (0,20)	-0,48 [-1,04;0,08] 0,0920 -0,14 [-0,30;0,02]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 10	140 20,70 (4,66)	139 20,97 (4,77)	135 20,87 (5,30)	132 21,17 (5,00)	128 20,80 (5,64)	120 20,90 (5,54)	116 21,56 (5,11)	120 21,53 (5,12)	108 21,56 (5,08)	0,49 (0,29)	117 19,43 (5,67)	114 19,68 (5,84)	114 21,03 (4,67)	110 21,17 (5,10)	102 20,89 (5,40)	92 21,29 (5,20)	85 21,38 (4,88)	89 20,70 (5,67)	73 20,71 (5,77)	1,17 (0,32)	-0,67 [-1,53;0,18] 0,1200 -0,20 [-0,44;0,05]
Tumorstadium (p-Wert des Interaktionsterms: 0,4816)																					
IIA	71 20,32 (4,83)	69 19,48 (5,69)	67 19,60 (5,80)	67 19,21 (5,61)	65 19,88 (5,62)	62 20,05 (5,80)	59 20,02 (6,03)	60 20,68 (4,87)	55 20,49 (5,67)	-0,41 (0,39)	69 19,87 (4,89)	67 20,16 (4,53)	66 20,98 (4,51)	60 20,13 (5,50)	58 21,71 (4,31)	56 21,09 (5,04)	56 21,20 (4,86)	51 21,12 (5,39)	50 21,48 (5,53)	0,93 (0,40)	-1,34 [-2,44;-0,23] 0,0180 -0,41 [-0,74;-0,07]
IIB	65 20,23 (4,96)	63 19,81 (5,25)	59 20,53 (5,11)	61 19,74 (5,56)	52 19,83 (5,29)	55 19,95 (6,20)	54 19,70 (6,05)	53 20,87 (4,79)	51 20,88 (5,03)	-0,17 (0,41)	85 19,65 (4,70)	83 20,02 (4,72)	82 20,55 (5,88)	76 20,59 (4,90)	76 20,07 (5,10)	72 20,50 (4,80)	67 20,91 (4,62)	70 20,73 (4,25)	68 21,07 (4,50)	0,38 (0,36)	-0,54 [-1,63;0,55] 0,3275 -0,16 [-0,49;0,16]
IIIA	309 19,65 (5,47)	302 19,35 (5,34)	296 19,42 (5,78)	295 19,94 (5,28)	282 19,99 (5,56)	279 19,84 (5,75)	254 19,81 (5,37)	255 20,48 (5,31)	235 20,39 (5,39)	0,22 (0,19)	267 19,77 (5,35)	260 19,99 (5,31)	251 20,30 (5,31)	244 20,60 (5,24)	229 20,69 (5,25)	217 20,92 (5,26)	215 20,60 (5,20)	214 20,69 (5,23)	200 20,68 (5,06)	0,55 (0,21)	-0,33 [-0,89;0,24] 0,2553 -0,10 [-0,26;0,07]
IIIB	18 17,94 (5,55)	18 17,56 (5,01)	16 16,81 (6,75)	17 15,94 (5,46)	13 15,15 (3,93)	14 16,21 (6,92)	14 15,43 (6,48)	14 15,21 (5,74)	14 15,50 (5,85)	-1,92 (0,86)	17 20,24 (7,33)	17 20,41 (7,46)	16 20,06 (6,89)	13 18,92 (9,14)	11 20,09 (8,17)	12 18,67 (8,33)	13 17,54 (8,39)	12 17,08 (8,60)	11 18,55 (7,43)	-0,94 (0,94)	-0,98 [-3,60;1,65] 0,4518 -0,25 [-0,90;0,40]
IIIC	227 20,07 (5,00)	221 19,94 (5,28)	214 20,36 (5,60)	208 20,56 (5,56)	203 20,36 (5,71)	193 20,51 (5,76)	188 20,89 (5,62)	189 21,02 (5,28)	163 21,06 (5,43)	0,42 (0,24)	209 19,50 (5,37)	205 19,62 (5,82)	201 20,32 (5,04)	191 20,93 (5,20)	183 20,88 (5,35)	170 20,84 (5,35)	159 20,97 (5,00)	160 20,56 (5,52)	138 20,38 (5,82)	0,86 (0,26)	-0,43 [-1,13;0,26] 0,2203 -0,12 [-0,31;0,07]
Tumorgrading (p-Wert des Interaktionsterms: 0,5721)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
G1	59 19,95 (5,03)	57 19,88 (4,58)	54 19,43 (6,22)	54 19,20 (5,05)	55 19,89 (5,33)	53 19,81 (5,95)	51 20,41 (4,85)	53 20,51 (5,19)	46 20,76 (5,26)	-0,00 (0,41)	47 19,96 (5,46)	45 21,11 (4,68)	42 21,60 (3,98)	43 20,95 (5,24)	39 21,44 (5,09)	39 20,15 (5,30)	39 20,85 (5,77)	38 21,16 (5,40)	34 21,59 (4,49)	1,26 (0,47)	-1,26 [-2,49;-0,03] 0,0451 -0,40 [-0,78;-0,01]
G2	311 19,86 (5,19)	304 19,59 (5,49)	297 20,11 (5,59)	294 20,03 (5,48)	280 19,88 (5,63)	275 19,80 (5,67)	257 19,90 (5,74)	254 20,54 (5,11)	234 20,44 (5,21)	0,10 (0,20)	283 19,80 (5,41)	276 19,96 (5,64)	269 20,38 (5,39)	254 20,66 (5,45)	238 20,76 (5,41)	234 21,03 (5,50)	222 20,67 (5,54)	225 20,40 (5,79)	203 20,42 (5,82)	0,47 (0,21)	-0,37 [-0,92;0,19] 0,1992 -0,11 [-0,27;0,06]
G3	279 19,67 (5,30)	273 19,32 (5,35)	263 19,37 (5,66)	261 19,70 (5,57)	243 19,88 (5,59)	237 20,13 (5,92)	224 19,88 (5,79)	227 20,52 (5,41)	201 20,36 (5,76)	0,12 (0,21)	281 19,55 (5,12)	276 19,64 (5,25)	271 20,32 (5,21)	253 20,52 (5,20)	247 20,55 (5,16)	221 20,69 (5,06)	217 20,79 (4,67)	211 20,69 (4,93)	200 20,83 (4,92)	0,65 (0,21)	-0,53 [-1,12;0,06] 0,0805 -0,15 [-0,31;0,02]
GX	42 21,10 (5,21)	40 20,50 (5,01)	39 20,51 (6,17)	40 21,85 (5,04)	38 21,32 (5,91)	38 20,82 (6,40)	37 21,81 (5,21)	36 21,33 (5,78)	37 21,51 (5,60)	0,48 (0,61)	35 19,43 (5,39)	34 19,97 (5,21)	33 19,76 (6,03)	33 20,48 (5,51)	31 21,48 (4,95)	31 20,71 (5,48)	30 20,90 (4,86)	31 20,97 (4,59)	28 20,39 (5,69)	0,84 (0,67)	-0,37 [-2,18;1,44] 0,6862 -0,09 [-0,54;0,36]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,7854)																					
Negativ	63 18,89 (5,35)	60 18,63 (5,53)	58 19,55 (5,59)	60 18,95 (5,48)	57 18,82 (5,61)	54 18,87 (6,17)	50 18,88 (5,90)	50 19,42 (5,65)	50 19,76 (5,91)	0,17 (0,42)	53 20,09 (4,95)	52 19,77 (5,39)	51 19,76 (5,55)	44 21,23 (4,79)	43 21,79 (3,97)	40 21,23 (4,97)	40 21,23 (4,45)	37 21,24 (4,60)	36 21,67 (4,04)	0,91 (0,47)	-0,74 [-1,99;0,50] 0,2385 -0,22 [-0,59;0,14]
Positiv	609 19,93 (5,23)	595 19,60 (5,33)	580 19,75 (5,74)	573 19,98 (5,45)	546 20,04 (5,61)	537 20,06 (5,79)	505 20,14 (5,67)	509 20,65 (5,24)	459 20,63 (5,42)	0,07 (0,14)	578 19,70 (5,29)	566 19,96 (5,36)	552 20,52 (5,18)	527 20,56 (5,36)	500 20,61 (5,33)	472 20,79 (5,29)	459 20,71 (5,16)	456 20,62 (5,32)	419 20,63 (5,39)	0,60 (0,15)	-0,53 [-0,93;-0,13] 0,0101 -0,15 [-0,26;-0,04]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Unbekannt	6 22,33 (2,34)	6 20,50 (6,19)	6 24,50 (5,09)	4 26,25 (3,50)	4 23,50 (5,07)	4 24,75 (3,77)	4 23,25 (3,59)	3 23,00 (6,24)	3 23,33 (2,31)	1,72 (1,61)	8 16,00 (6,68)	7 16,57 (7,70)	8 17,75 (7,17)	6 18,17 (5,56)	6 22,83 (6,05)	8 18,00 (7,29)	4 18,25 (10,72)	8 17,38 (7,65)	7 17,29 (7,78)	1,85 (1,18)	-0,13 [-4,60;4,35] 0,9519 -0,03 [-1,02;0,96]
Ethnizität (p-Wert des Interaktionsterms: 0,7276)																					
Weiß	398 19,66 (5,06)	385 19,34 (5,14)	369 19,66 (5,34)	367 19,60 (5,15)	341 19,59 (5,43)	336 19,63 (5,73)	305 19,76 (5,49)	310 20,25 (5,07)	275 20,15 (5,12)	0,04 (0,17)	381 19,64 (5,12)	368 19,69 (5,34)	355 20,33 (5,29)	337 20,15 (5,29)	323 20,45 (5,32)	304 20,41 (5,19)	290 20,62 (5,08)	290 20,28 (5,38)	267 20,31 (5,34)	0,39 (0,18)	-0,36 [-0,84;0,13] 0,1472 -0,10 [-0,24;0,04]
Asiatisch	259 20,02 (5,43)	257 19,67 (5,53)	253 19,84 (6,18)	251 20,53 (5,73)	245 20,49 (5,81)	239 20,35 (6,05)	236 20,28 (5,92)	236 20,86 (5,62)	223 20,91 (5,90)	0,32 (0,23)	226 19,81 (5,64)	225 20,23 (5,44)	223 20,59 (5,25)	217 21,41 (5,24)	202 21,19 (5,10)	194 21,32 (5,50)	192 20,90 (5,39)	188 21,10 (5,22)	176 21,20 (5,42)	0,98 (0,24)	-0,66 [-1,32;-0,01] 0,0474 -0,18 [-0,36;-0,00]
Andere	26 21,50 (5,95)	25 21,76 (6,37)	25 21,48 (6,17)	25 19,92 (6,53)	24 20,33 (6,23)	22 22,09 (5,37)	22 22,27 (5,26)	20 21,90 (4,60)	18 21,56 (5,09)	-0,53 (0,70)	29 19,07 (4,91)	28 19,50 (6,16)	28 19,32 (5,46)	27 19,89 (5,74)	25 20,74 (5,66)	22 21,00 (4,61)	21 20,90 (4,25)	23 20,26 (5,50)	18 20,67 (4,74)	1,02 (0,67)	-1,54 [-3,53;0,44] 0,1234 -0,43 [-0,97;0,11]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,9209)																					
Tamoxifen	491 19,64 (5,13)	479 19,44 (5,19)	459 19,59 (5,50)	461 19,68 (5,27)	432 19,83 (5,34)	424 19,80 (5,60)	399 19,74 (5,50)	402 20,50 (5,11)	361 20,20 (5,28)	0,09 (0,15)	476 19,65 (5,26)	463 19,90 (5,36)	449 20,37 (5,22)	426 20,63 (5,28)	403 20,82 (5,23)	388 20,78 (5,18)	372 20,68 (5,00)	376 20,45 (5,29)	346 20,67 (5,08)	0,64 (0,16)	-0,54 [-0,98;-0,11] 0,0136 -0,16 [-0,29;-0,03]
Aromatase-Inhibitor	203 20,44 (5,39)	198 19,87 (5,65)	197 20,29 (6,14)	191 20,63 (5,88)	187 20,34 (6,18)	182 20,51 (6,34)	173 20,87 (5,97)	171 20,81 (5,67)	160 21,30 (5,78)	0,16 (0,26)	172 19,79 (5,33)	170 19,92 (5,44)	168 20,50 (5,34)	159 20,59 (5,42)	154 20,63 (5,28)	139 20,86 (5,57)	138 20,93 (5,52)	131 21,07 (5,42)	121 20,71 (6,03)	0,65 (0,29)	-0,50 [-1,26;0,26] 0,1993 -0,13 [-0,34;0,07]
ECOG-PS (p-Wert des Interaktionsterms: 0,8670)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
ECOG-PS 0	616 19,86 (5,19)	600 19,58 (5,26)	581 19,79 (5,66)	580 19,95 (5,42)	547 19,91 (5,59)	538 19,97 (5,77)	506 19,99 (5,49)	506 20,62 (5,21)	464 20,58 (5,34)	0,06 (0,14)	575 20,11 (5,06)	561 20,23 (5,26)	547 20,74 (5,11)	521 20,84 (5,22)	496 21,00 (5,25)	470 21,01 (5,25)	457 20,98 (5,11)	447 20,93 (5,20)	417 20,93 (5,26)	0,54 (0,14)	-0,48 [-0,87;-0,09] 0,0163 -0,14 [-0,25;-0,03]
ECOG-PS 1	78 20,03 (5,44)	77 19,44 (5,83)	75 19,88 (6,14)	72 20,00 (5,92)	72 20,51 (5,76)	68 20,37 (6,37)	66 20,79 (6,87)	67 20,37 (5,80)	57 20,19 (6,32)	0,75 (0,46)	73 16,34 (5,76)	72 17,39 (5,68)	70 17,79 (5,64)	64 18,83 (5,76)	61 18,84 (4,79)	57 19,12 (5,27)	53 18,70 (4,98)	60 18,23 (5,64)	50 18,66 (5,52)	1,22 (0,48)	-0,47 [-1,81;0,87] 0,4932 -0,11 [-0,43;0,20]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B FWB = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B FWB haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FWB: funktionales Wohlbefinden; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t110_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 110.2.2: Subgruppen für die Veränderung der FACT-B-Subskala: FWB aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,4980)																					
< 65 Jahre	804 19,94 (5,45)	780 19,40 (5,66)	755 19,49 (5,49)	720 19,48 (5,61)	699 19,63 (5,28)	665 19,49 (5,46)	637 19,58 (5,55)	631 19,54 (5,69)	588 19,60 (5,91)	-0,44 (0,13)	832 19,64 (5,65)	798 19,96 (5,22)	798 19,67 (5,35)	756 19,86 (5,45)	722 20,01 (5,42)	682 20,05 (5,47)	640 19,90 (5,38)	633 19,89 (5,55)	587 20,28 (5,60)	0,17 (0,13)	-0,61 [-0,96;-0,26] 0,0007 -0,17 [-0,26;-0,07]
≥ 65 Jahre	303 19,26 (6,21)	292 18,09 (6,06)	276 19,00 (5,93)	271 18,91 (5,46)	255 18,66 (5,97)	236 18,33 (6,13)	224 18,79 (5,97)	216 18,19 (5,95)	198 18,62 (5,83)	-1,09 (0,21)	279 19,69 (5,66)	269 19,91 (5,32)	263 19,40 (5,69)	254 19,52 (5,49)	246 19,34 (5,58)	238 19,18 (5,29)	220 18,89 (5,69)	216 18,94 (5,35)	191 18,79 (5,33)	-0,53 (0,22)	-0,57 [-1,16;0,03] 0,0607 -0,16 [-0,32;0,01]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9101)																					
Neoadjuvante Chemotherapie	363 20,05 (5,70)	345 19,41 (5,62)	330 19,68 (5,40)	315 19,23 (5,86)	297 19,45 (5,72)	276 19,53 (5,78)	260 19,66 (6,06)	253 19,37 (5,65)	236 19,24 (6,29)	-0,73 (0,19)	365 19,48 (5,54)	352 19,86 (5,20)	343 19,46 (5,36)	322 19,42 (5,54)	306 19,60 (5,40)	281 19,86 (5,44)	268 19,50 (5,44)	265 19,43 (5,44)	234 19,75 (5,72)	-0,11 (0,19)	-0,62 [-1,14;-0,09] 0,0210 -0,17 [-0,32;-0,03]
Adjuvante Chemotherapie	684 19,68 (5,65)	670 19,03 (5,84)	648 19,34 (5,60)	621 19,55 (5,36)	606 19,41 (5,33)	581 19,17 (5,54)	557 19,36 (5,44)	554 19,21 (5,85)	512 19,51 (5,71)	-0,50 (0,14)	679 19,80 (5,64)	651 20,08 (5,27)	656 19,85 (5,41)	630 20,17 (5,29)	612 20,07 (5,50)	591 19,97 (5,34)	547 19,90 (5,34)	541 19,89 (5,52)	510 20,16 (5,45)	0,16 (0,14)	-0,66 [-1,05;-0,27] 0,0009 -0,18 [-0,29;-0,07]
Keine Chemotherapie	60 18,83 (5,63)	57 17,06 (6,14)	53 17,62 (6,78)	55 17,37 (5,99)	51 18,45 (5,90)	44 17,25 (6,15)	44 17,80 (5,96)	40 17,98 (5,70)	38 18,03 (5,91)	-1,48 (0,50)	67 19,12 (6,28)	64 19,05 (5,24)	62 17,76 (5,82)	58 17,43 (6,22)	50 18,34 (5,24)	48 17,81 (6,24)	45 17,31 (6,61)	43 17,93 (5,70)	34 17,26 (5,85)	-1,11 (0,47)	-0,37 [-1,73;0,98] 0,5861 -0,10 [-0,45;0,25]
Region (p-Wert des Interaktionsterms: 0,9030)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	550 20,11 (5,64)	520 19,24 (5,81)	494 19,71 (5,55)	470 19,62 (5,83)	444 19,81 (5,36)	416 19,47 (5,82)	396 19,86 (5,68)	389 19,88 (5,62)	360 19,44 (6,02)	-0,76 (0,15)	530 20,08 (5,36)	493 20,35 (5,27)	492 19,97 (5,34)	453 20,22 (5,59)	438 19,97 (5,48)	420 20,24 (5,51)	382 19,93 (5,38)	389 19,83 (5,63)	345 20,19 (5,26)	-0,14 (0,15)	-0,61 [-1,03;-0,20] 0,0039 -0,18 [-0,30;-0,06]
Asien	195 19,43 (6,23)	194 18,83 (6,40)	188 19,06 (6,21)	187 19,29 (5,75)	182 19,15 (6,04)	171 19,06 (6,26)	171 18,91 (6,21)	168 18,51 (6,50)	157 19,28 (6,53)	-0,45 (0,29)	192 19,59 (6,20)	191 19,82 (5,65)	187 19,25 (6,06)	184 19,78 (5,95)	179 19,84 (6,30)	174 19,98 (5,83)	172 19,51 (6,02)	168 19,70 (5,95)	163 20,36 (6,19)	0,10 (0,30)	-0,55 [-1,37;0,27] 0,1897 -0,13 [-0,33;0,07]
Andere	362 19,39 (5,38)	358 18,88 (5,44)	349 19,02 (5,35)	334 18,92 (5,07)	328 18,91 (5,30)	314 18,87 (5,07)	294 18,99 (5,28)	290 18,68 (5,48)	269 19,28 (5,35)	-0,52 (0,19)	389 19,10 (5,71)	383 19,49 (4,97)	382 19,29 (5,20)	373 19,23 (4,99)	351 19,66 (4,98)	326 19,20 (5,06)	306 19,35 (5,26)	292 19,38 (5,09)	270 19,28 (5,54)	0,10 (0,18)	-0,62 [-1,12;-0,11] 0,0167 -0,18 [-0,32;-0,03]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3815)																					
< 20 mm	279 20,05 (5,48)	266 19,36 (5,74)	256 19,79 (5,51)	252 19,47 (5,68)	241 19,28 (5,78)	232 19,21 (5,94)	229 19,46 (5,92)	219 19,25 (5,60)	209 19,28 (5,70)	-0,76 (0,21)	298 19,93 (5,47)	286 20,08 (5,33)	285 19,91 (5,54)	267 19,99 (5,39)	262 20,09 (5,28)	241 20,08 (5,17)	231 19,90 (5,16)	223 20,03 (5,30)	208 20,25 (5,24)	-0,08 (0,21)	-0,69 [-1,28;-0,10] 0,0219 -0,19 [-0,36;-0,03]
≥ 20 bis < 50 mm	569 19,53 (5,97)	559 19,06 (5,84)	531 19,45 (5,64)	516 19,33 (5,57)	491 19,39 (5,53)	467 19,32 (5,62)	448 19,58 (5,53)	437 19,31 (5,97)	403 19,47 (6,10)	-0,42 (0,16)	572 19,67 (5,75)	552 19,99 (5,16)	548 19,56 (5,34)	525 19,66 (5,52)	502 19,86 (5,44)	493 19,84 (5,46)	446 19,70 (5,57)	451 19,54 (5,65)	421 19,82 (5,68)	-0,00 (0,15)	-0,42 [-0,85;0,01] 0,0551 -0,11 [-0,23;0,00]
≥ 50 mm	242 20,05 (5,13)	231 18,71 (5,82)	228 18,79 (5,70)	210 19,16 (5,53)	207 19,43 (5,10)	188 18,89 (5,46)	170 18,87 (5,69)	178 18,92 (5,69)	161 19,12 (5,73)	-0,91 (0,24)	230 19,20 (5,69)	218 19,56 (5,40)	218 19,17 (5,58)	207 19,64 (5,49)	196 19,38 (5,85)	177 19,40 (5,79)	174 19,14 (5,70)	166 19,38 (5,52)	141 19,57 (5,83)	-0,05 (0,24)	-0,86 [-1,53;-0,20] 0,0113 -0,23 [-0,42;-0,05]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,6308)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	367 19,64 (5,77)	358 19,07 (5,75)	342 19,46 (5,84)	322 19,43 (5,53)	317 19,17 (5,61)	298 19,07 (5,98)	284 19,46 (5,79)	280 19,15 (6,12)	258 19,23 (6,27)	-0,52 (0,20)	360 19,51 (5,74)	343 19,93 (5,27)	347 19,71 (5,19)	325 19,53 (5,67)	316 19,87 (5,38)	295 19,57 (5,65)	280 19,66 (5,66)	268 19,22 (5,74)	246 19,73 (5,39)	0,08 (0,20)	-0,60 [-1,15;-0,04] 0,0367 -0,16 [-0,30;-0,01]
4-9	476 19,77 (5,45)	458 19,10 (5,68)	446 19,25 (5,55)	433 18,95 (5,62)	414 19,36 (5,43)	388 19,26 (5,34)	375 19,32 (5,69)	372 19,06 (5,43)	354 19,38 (5,70)	-0,68 (0,16)	486 19,67 (5,76)	468 20,15 (5,24)	468 19,59 (5,56)	444 19,90 (5,50)	430 19,93 (5,55)	418 19,93 (5,29)	386 19,64 (5,43)	385 19,81 (5,28)	359 20,19 (5,49)	0,06 (0,16)	-0,73 [-1,18;-0,29] 0,0013 -0,21 [-0,33;-0,08]
≥ 10	264 19,88 (5,93)	256 18,91 (6,10)	243 19,42 (5,42)	236 19,85 (5,51)	223 19,69 (5,43)	215 19,21 (5,79)	202 19,35 (5,49)	195 19,52 (5,97)	174 19,48 (5,78)	-0,66 (0,23)	265 19,80 (5,32)	256 19,60 (5,21)	246 19,47 (5,54)	241 19,86 (5,10)	222 19,61 (5,46)	207 19,98 (5,42)	194 19,63 (5,32)	196 19,91 (5,65)	173 19,58 (5,99)	-0,28 (0,23)	-0,38 [-1,01;0,24] 0,2319 -0,10 [-0,27;0,07]
Tumorgrading (p-Wert des Interaktionsterms: 0,7317)																					
G1	82 20,02 (5,28)	80 19,88 (6,42)	82 19,74 (6,34)	75 19,93 (5,26)	72 20,05 (5,44)	69 19,67 (5,32)	68 20,18 (5,49)	67 19,81 (5,49)	63 20,46 (5,60)	-0,14 (0,39)	84 20,35 (5,61)	83 20,76 (4,86)	81 20,37 (5,24)	75 20,95 (4,33)	78 19,94 (6,09)	73 20,29 (5,59)	66 20,30 (5,71)	67 20,39 (5,54)	59 20,46 (5,81)	0,25 (0,39)	-0,39 [-1,48;0,70] 0,4767 -0,11 [-0,42;0,19]
G2	526 19,86 (5,55)	510 18,80 (5,86)	490 19,13 (5,62)	469 19,37 (5,49)	450 19,35 (5,40)	422 18,97 (5,77)	395 19,30 (5,74)	401 19,06 (5,67)	368 19,21 (5,94)	-0,83 (0,16)	534 19,58 (5,63)	509 19,93 (5,18)	509 19,51 (5,39)	491 19,72 (5,42)	464 19,45 (5,49)	441 19,76 (5,23)	414 19,55 (5,26)	412 19,56 (5,33)	380 19,57 (5,62)	-0,15 (0,15)	-0,68 [-1,11;-0,25] 0,0019 -0,19 [-0,31;-0,07]
G3	450 19,54 (5,94)	435 19,21 (5,67)	413 19,60 (5,51)	401 19,27 (5,70)	388 19,32 (5,65)	368 19,30 (5,64)	359 19,28 (5,64)	338 19,22 (6,07)	322 19,26 (6,01)	-0,38 (0,18)	436 19,56 (5,70)	418 19,82 (5,47)	415 19,60 (5,52)	390 19,77 (5,61)	376 20,24 (5,29)	360 19,87 (5,60)	337 19,73 (5,57)	327 19,71 (5,63)	303 20,29 (5,36)	0,21 (0,18)	-0,60 [-1,09;-0,10] 0,0177 -0,16 [-0,29;-0,03]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
GX	47 20,19 (5,15)	45 18,69 (5,41)	44 18,95 (5,31)	44 18,34 (5,89)	42 19,14 (5,21)	40 19,38 (5,29)	37 19,59 (5,67)	39 19,36 (5,17)	32 19,81 (5,07)	-1,39 (0,62)	53 19,92 (5,39)	53 19,92 (4,54)	52 19,31 (5,44)	50 18,60 (6,00)	47 20,18 (5,60)	43 19,16 (5,90)	41 18,59 (6,48)	40 18,70 (6,38)	33 19,36 (6,51)	-0,87 (0,58)	-0,51 [-2,21;1,18] 0,5476 -0,12 [-0,51;0,27]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4548)																					
Negativ	137 18,79 (5,81)	134 18,33 (5,99)	127 18,44 (5,97)	124 18,20 (6,23)	116 18,14 (5,86)	104 18,07 (6,06)	98 18,07 (6,39)	101 17,57 (6,55)	89 18,39 (6,07)	-0,88 (0,34)	149 19,17 (6,02)	143 19,60 (5,09)	141 19,48 (5,56)	134 19,81 (5,66)	125 20,00 (5,40)	117 19,88 (5,59)	105 19,02 (5,49)	104 19,46 (5,55)	92 19,95 (6,02)	0,36 (0,33)	-1,24 [-2,19;-0,30] 0,0097 -0,31 [-0,54;-0,08]
Positiv	939 19,80 (5,63)	907 19,01 (5,76)	873 19,38 (5,53)	842 19,37 (5,42)	816 19,47 (5,39)	773 19,22 (5,57)	737 19,43 (5,53)	723 19,34 (5,64)	676 19,39 (5,90)	-0,62 (0,12)	935 19,66 (5,58)	900 19,94 (5,23)	896 19,54 (5,41)	853 19,70 (5,42)	821 19,75 (5,49)	781 19,78 (5,36)	736 19,68 (5,47)	723 19,66 (5,48)	665 19,85 (5,52)	-0,07 (0,12)	-0,55 [-0,87;-0,22] 0,0010 -0,15 [-0,24;-0,06]
Unbekannt	9 21,78 (6,89)	9 22,78 (3,73)	9 23,44 (5,96)	7 25,29 (3,99)	3 27,67 (0,58)	7 24,29 (5,99)	8 24,75 (4,74)	7 24,71 (2,87)	5 24,40 (3,51)	2,58 (0,94)	7 21,71 (7,32)	6 24,67 (4,18)	6 23,67 (4,23)	6 24,17 (4,71)	6 24,00 (3,69)	6 20,17 (10,65)	5 24,00 (3,32)	6 25,33 (3,08)	5 23,60 (3,85)	2,58 (1,04)	-0,00 [-3,00;3,00] 0,9996 -0,00 [-0,93;0,93]
Ethnizität (p-Wert des Interaktionsterms: 0,8122)																					
Weiß	808 19,74 (5,49)	777 19,10 (5,58)	754 19,36 (5,34)	720 19,17 (5,48)	690 19,34 (5,32)	649 19,10 (5,47)	611 19,38 (5,48)	605 19,25 (5,47)	564 19,16 (5,66)	-0,72 (0,12)	820 19,71 (5,44)	779 20,02 (5,07)	779 19,75 (5,21)	734 19,70 (5,37)	703 19,84 (5,27)	670 19,76 (5,26)	614 19,63 (5,26)	613 19,53 (5,33)	548 19,74 (5,34)	-0,08 (0,12)	-0,64 [-0,98;-0,30] 0,0002 -0,18 [-0,28;-0,09]
Asiatisch	233 19,67 (6,23)	231 18,98 (6,53)	221 19,26 (6,30)	219 19,70 (5,72)	213 19,66 (5,98)	200 19,45 (6,14)	199 19,29 (6,20)	197 18,97 (6,55)	179 19,89 (6,44)	-0,25 (0,28)	221 19,51 (6,28)	219 19,95 (5,65)	215 19,21 (6,26)	213 20,01 (5,82)	204 20,03 (6,20)	193 20,09 (5,80)	191 19,73 (5,96)	185 19,95 (6,04)	181 20,55 (6,18)	0,27 (0,28)	-0,53 [-1,30;0,25] 0,1822 -0,13 [-0,31;0,06]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	54 20,28 (5,86)	52 18,57 (5,49)	48 20,06 (5,87)	43 19,95 (5,19)	43 18,67 (5,58)	42 19,21 (5,99)	44 19,41 (5,89)	38 19,24 (6,31)	35 19,97 (6,28)	-0,57 (0,52)	57 19,60 (6,35)	57 18,89 (5,94)	55 19,55 (4,81)	51 19,76 (5,41)	50 18,97 (5,13)	46 19,93 (5,80)	45 20,18 (5,91)	40 20,00 (5,85)	40 19,40 (6,05)	-0,28 (0,50)	-0,30 [-1,74;1,14] 0,6815 -0,08 [-0,45;0,29]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,0977)																					
Tamoxifen	104 19,83 (5,45)	101 19,87 (5,25)	101 19,55 (5,74)	98 19,88 (5,01)	97 19,82 (5,04)	96 19,79 (5,33)	90 19,73 (5,74)	89 20,37 (5,43)	90 20,11 (5,90)	0,05 (0,32)	124 19,61 (5,51)	123 19,41 (5,03)	123 19,67 (4,87)	117 20,08 (5,12)	109 19,64 (5,55)	98 20,48 (5,34)	94 19,86 (4,87)	91 20,35 (5,49)	89 21,16 (5,37)	0,23 (0,30)	-0,18 [-1,05;0,69] 0,6868 -0,05 [-0,31;0,21]
Aromatase-Inhibitor	1003 19,75 (5,69)	971 18,96 (5,85)	930 19,34 (5,60)	893 19,26 (5,63)	857 19,32 (5,54)	805 19,11 (5,70)	771 19,33 (5,66)	758 19,06 (5,81)	696 19,26 (5,90)	-0,69 (0,12)	987 19,65 (5,67)	944 20,02 (5,27)	938 19,59 (5,51)	893 19,73 (5,51)	859 19,86 (5,46)	822 19,75 (5,44)	766 19,61 (5,54)	758 19,56 (5,52)	689 19,75 (5,58)	-0,04 (0,12)	-0,65 [-0,98;-0,33] <,0001 -0,18 [-0,26;-0,09]
ECOG-PS (p-Wert des Interaktionsterms: 0,5568)																					
ECOG-PS 0	933 19,95 (5,61)	903 19,30 (5,76)	870 19,61 (5,48)	846 19,40 (5,58)	812 19,57 (5,42)	772 19,32 (5,70)	735 19,56 (5,58)	727 19,35 (5,72)	679 19,46 (5,86)	-0,61 (0,12)	899 19,88 (5,63)	862 20,21 (5,16)	860 19,81 (5,37)	822 19,96 (5,37)	790 20,09 (5,42)	754 19,96 (5,42)	699 19,70 (5,40)	691 19,79 (5,42)	629 20,08 (5,59)	-0,03 (0,12)	-0,58 [-0,91;-0,25] 0,0006 -0,16 [-0,25;-0,07]
ECOG-PS 1	174 18,69 (5,91)	169 17,71 (5,87)	161 17,99 (6,13)	145 18,86 (5,55)	142 18,24 (5,75)	129 18,40 (5,38)	126 18,32 (6,08)	120 18,26 (6,10)	107 18,70 (6,18)	-0,68 (0,30)	212 18,69 (5,62)	205 18,85 (5,45)	201 18,70 (5,61)	188 18,96 (5,79)	178 18,71 (5,57)	166 19,20 (5,47)	161 19,40 (5,77)	158 19,02 (5,91)	149 19,21 (5,48)	0,14 (0,27)	-0,82 [-1,60;-0,03] 0,0414 -0,21 [-0,41;-0,01]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Datenschnitt: 01.07.2022 Safety-Population 1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B FWB = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B FWB haben. Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FWB: funktionales Wohlbefinden; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.																				

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t110_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
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Tabelle 111.1.2: Subgruppen für die Veränderung des FACT-G (Gesamtscore) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,3525)																					
Neoadjuvante Chemotherapie	281 85,78 (12,80)	271 82,85 (14,92)	262 83,15 (15,64)	264 82,59 (15,43)	241 82,38 (15,50)	239 82,84 (16,39)	224 82,99 (16,36)	223 85,01 (15,58)	202 84,38 (16,60)	-2,82 (0,61)	267 83,09 (13,83)	258 82,06 (14,69)	254 83,30 (14,19)	230 83,73 (15,34)	220 83,51 (15,42)	203 84,33 (15,91)	187 84,14 (15,29)	184 83,30 (15,33)	170 83,01 (15,98)	-0,85 (0,63)	-1,97 [-3,70;-0,23] 0,0261 -0,19 [-0,36;-0,02]
Adjuvante Chemotherapie	406 83,24 (14,04)	399 81,92 (14,74)	388 82,49 (15,56)	382 82,79 (15,45)	372 82,35 (15,64)	361 82,89 (16,11)	342 82,96 (16,20)	345 83,84 (14,89)	315 83,91 (15,69)	-0,56 (0,48)	378 83,43 (14,11)	372 83,21 (14,89)	359 84,35 (14,06)	352 84,72 (14,59)	333 85,10 (14,66)	321 84,64 (14,38)	320 85,12 (14,46)	320 84,65 (14,87)	295 85,04 (14,88)	0,91 (0,49)	-1,48 [-2,82;-0,13] 0,0316 -0,15 [-0,29;-0,01]
Keine Chemotherapie	7 82,86 (22,63)	7 81,71 (19,83)	6 76,83 (18,76)	6 80,17 (21,48)	6 80,50 (22,09)	6 75,00 (21,37)	6 82,33 (20,28)	5 80,80 (20,91)	4 92,75 (8,88)	-0,21 (2,02)	3 82,67 (10,21)	3 71,00 (13,53)	3 70,67 (10,97)	3 71,67 (13,20)	3 74,33 (9,71)	3 75,33 (11,37)	3 75,00 (14,00)	3 80,67 (19,01)	2 71,50 (13,44)	-8,05 (2,86)	7,84 [-0,08;15,77] 0,0519 1,35 [-0,01;2,71]
Region (p-Wert des Interaktionsterms: 0,4374)																					
Nordamerika / Europa	282 84,91 (12,81)	268 82,65 (14,22)	256 82,81 (15,51)	254 82,29 (15,15)	228 82,55 (14,93)	228 82,49 (16,33)	211 83,55 (15,37)	210 84,78 (14,74)	178 84,45 (15,84)	-1,92 (0,57)	256 84,07 (13,03)	245 82,01 (15,06)	230 83,93 (13,78)	209 83,70 (15,55)	196 84,50 (15,71)	191 84,25 (15,75)	180 84,44 (15,27)	181 83,98 (15,97)	164 83,91 (15,71)	-0,90 (0,60)	-1,01 [-2,65;0,62] 0,2238 -0,11 [-0,27;0,06]
Asien	232 83,84 (14,58)	231 81,34 (15,39)	227 82,09 (15,91)	226 82,33 (16,73)	222 82,09 (16,88)	216 82,42 (16,77)	215 82,68 (16,86)	212 84,29 (15,71)	210 84,24 (16,75)	-1,32 (0,63)	210 83,01 (14,18)	209 82,78 (14,37)	209 83,58 (14,36)	202 85,44 (14,06)	192 85,17 (14,17)	187 85,11 (15,00)	183 84,43 (15,45)	181 85,15 (14,63)	171 85,15 (15,59)	1,02 (0,66)	-2,34 [-4,13;-0,55] 0,0107 -0,24 [-0,43;-0,06]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	180 83,78 (13,86)	178 82,97 (15,10)	173 83,34 (15,42)	172 83,73 (14,24)	169 82,39 (14,90)	162 83,72 (15,55)	146 82,53 (16,74)	151 83,54 (15,20)	133 83,65 (15,10)	-0,88 (0,77)	182 82,52 (14,98)	179 83,49 (15,01)	177 84,06 (14,34)	174 83,58 (15,03)	168 83,46 (14,98)	149 83,95 (13,93)	147 85,36 (13,25)	145 83,07 (14,37)	132 83,47 (14,44)	0,53 (0,77)	-1,41 [-3,56;0,74] 0,1969 -0,14 [-0,34;0,07]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,3748)																					
< 20 mm	179 84,39 (12,67)	176 82,18 (14,31)	167 82,50 (15,32)	171 82,11 (15,78)	160 82,33 (15,70)	159 82,45 (16,41)	152 82,72 (16,22)	155 84,26 (14,78)	148 83,64 (16,18)	-1,90 (0,71)	169 83,01 (14,62)	164 82,46 (15,17)	160 83,59 (13,35)	153 83,31 (15,18)	149 84,57 (14,74)	142 84,78 (14,96)	136 84,71 (14,83)	135 83,87 (16,01)	123 84,47 (15,59)	0,29 (0,74)	-2,19 [-4,21;-0,17] 0,0336 -0,23 [-0,44;-0,02]
≥ 20 bis < 50 mm	325 84,62 (14,27)	314 81,96 (15,79)	312 83,33 (15,82)	305 82,66 (15,59)	289 82,23 (16,02)	281 82,78 (16,25)	264 82,48 (16,42)	265 83,79 (15,95)	237 84,40 (16,32)	-1,73 (0,56)	314 82,81 (13,97)	308 82,12 (14,74)	302 84,27 (14,40)	289 84,76 (14,68)	272 84,74 (14,86)	261 84,28 (14,74)	253 84,75 (14,75)	246 84,06 (14,72)	235 84,24 (15,33)	0,58 (0,57)	-2,31 [-3,88;-0,75] 0,0039 -0,23 [-0,39;-0,07]
≥ 50 mm	172 83,23 (13,71)	169 82,40 (13,86)	162 81,12 (15,56)	160 82,78 (14,94)	154 82,14 (14,43)	152 82,66 (15,91)	142 83,63 (15,84)	140 84,79 (14,04)	122 84,00 (15,25)	-0,76 (0,73)	157 84,47 (13,07)	153 83,88 (14,73)	146 83,26 (14,40)	135 84,50 (15,12)	129 83,26 (15,47)	117 84,50 (15,75)	114 84,65 (14,77)	119 84,54 (14,36)	103 83,49 (15,07)	-0,76 (0,77)	-0,01 [-2,10;2,09] 0,9941 -0,00 [-0,22;0,22]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,5417)																					
0-3	238 84,78 (13,49)	231 82,88 (14,70)	218 82,73 (15,98)	221 82,52 (16,10)	202 82,46 (15,49)	200 83,14 (17,24)	192 82,42 (17,21)	188 85,04 (15,24)	169 83,93 (17,25)	-1,76 (0,68)	237 82,71 (13,63)	231 82,40 (15,10)	223 83,08 (14,53)	209 83,28 (15,07)	200 83,18 (15,00)	191 83,87 (15,35)	183 84,21 (14,70)	180 83,95 (15,02)	175 83,45 (16,39)	-0,18 (0,68)	-1,58 [-3,47;0,30] 0,0999 -0,15 [-0,33;0,03]
4-9	316 82,82 (14,37)	307 80,10 (15,50)	303 81,41 (15,81)	299 81,61 (15,61)	289 80,84 (15,81)	286 81,59 (16,07)	264 81,66 (16,27)	265 82,94 (15,48)	244 83,16 (15,61)	-1,48 (0,54)	294 83,63 (14,42)	288 82,80 (14,66)	279 83,90 (14,21)	266 84,52 (14,79)	254 85,35 (14,57)	244 84,68 (14,77)	242 84,64 (15,01)	238 84,31 (14,65)	219 84,63 (14,29)	0,22 (0,56)	-1,70 [-3,23;-0,16] 0,0300 -0,18 [-0,34;-0,02]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 10	140 86,64 (12,03)	139 86,13 (12,72)	135 85,54 (14,22)	132 85,39 (13,83)	128 85,56 (15,03)	120 85,07 (14,88)	116 86,84 (14,05)	120 86,01 (14,38)	108 86,78 (14,67)	-0,86 (0,79)	117 83,62 (13,55)	114 82,97 (14,71)	114 85,25 (13,05)	110 85,51 (14,84)	102 84,50 (15,81)	92 85,16 (14,80)	85 85,93 (14,28)	89 84,06 (16,26)	73 84,96 (15,68)	0,72 (0,87)	-1,58 [-3,90;0,75] 0,1831 -0,17 [-0,41;0,08]
Tumorstadium (p-Wert des Interaktionsterms: 0,6172)																					
IIA	71 85,27 (12,18)	69 83,25 (15,03)	67 82,00 (16,08)	67 81,22 (15,91)	65 81,93 (15,74)	62 81,71 (16,68)	59 82,05 (16,72)	60 84,25 (15,55)	55 82,42 (16,81)	-3,17 (1,13)	69 84,36 (12,35)	67 83,94 (12,55)	66 84,53 (12,77)	60 83,00 (13,56)	58 86,70 (11,65)	56 85,50 (13,48)	56 86,68 (12,50)	51 86,47 (14,43)	50 86,62 (14,79)	0,76 (1,15)	-3,93 [-7,12;-0,74] 0,0163 -0,41 [-0,75;-0,08]
IIB	65 85,08 (12,63)	63 82,97 (14,67)	59 85,63 (13,61)	61 82,69 (15,38)	52 82,96 (13,95)	55 83,18 (16,18)	54 83,26 (14,94)	53 85,57 (12,87)	51 86,29 (15,50)	-1,02 (1,28)	85 82,71 (13,66)	83 82,64 (14,39)	82 84,04 (15,09)	76 83,41 (15,70)	76 81,99 (14,87)	72 83,93 (14,22)	67 84,73 (13,75)	70 84,00 (13,52)	68 84,29 (14,54)	-0,58 (1,12)	-0,44 [-3,81;2,92] 0,7950 -0,04 [-0,37;0,28]
IIIA	309 83,20 (14,83)	302 80,98 (15,39)	296 81,69 (15,87)	295 82,60 (15,27)	282 81,78 (15,69)	279 82,61 (16,24)	254 82,31 (16,36)	255 83,84 (15,70)	235 83,76 (15,96)	-0,86 (0,54)	267 82,94 (15,04)	260 82,57 (14,91)	250 83,69 (14,41)	244 84,06 (14,79)	228 84,18 (15,54)	217 84,59 (15,06)	215 84,10 (15,25)	214 84,50 (14,30)	200 84,04 (14,86)	0,21 (0,58)	-1,07 [-2,62;0,48] 0,1759 -0,11 [-0,28;0,05]
IIIB	18 77,83 (14,73)	18 75,61 (14,28)	16 72,25 (18,95)	17 70,06 (18,25)	13 68,08 (12,37)	14 70,93 (19,35)	14 68,86 (16,28)	14 69,57 (11,93)	14 70,07 (13,64)	-7,93 (2,33)	17 88,53 (13,12)	17 85,76 (15,67)	16 85,63 (15,03)	13 84,77 (19,57)	11 86,91 (16,88)	12 83,42 (18,98)	13 81,08 (17,51)	12 79,58 (16,95)	11 82,36 (16,55)	-1,71 (2,50)	-6,22 [-13,44;0,99] 0,0882 -0,60 [-1,27;0,06]
IIIC	227 85,62 (12,45)	221 84,01 (14,03)	214 84,20 (15,09)	208 84,22 (15,11)	203 84,10 (15,60)	193 84,04 (15,80)	188 85,05 (15,97)	189 85,49 (14,74)	163 85,76 (15,71)	-1,32 (0,68)	209 83,20 (13,27)	205 82,15 (15,56)	201 83,60 (13,85)	191 85,24 (14,90)	183 84,84 (15,08)	170 84,29 (15,47)	159 85,09 (15,08)	160 83,31 (16,65)	138 83,80 (16,48)	0,32 (0,71)	-1,64 [-3,58;0,30] 0,0979 -0,16 [-0,35;0,03]
Tumorgrading (p-Wert des Interaktionsterms: 0,9450)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
G1	59 84,42 (13,18)	57 82,77 (12,97)	54 82,81 (15,12)	54 81,78 (16,35)	55 82,27 (15,21)	53 82,64 (15,58)	51 83,67 (14,58)	53 83,36 (15,71)	46 83,96 (15,65)	-1,54 (1,19)	47 83,89 (13,69)	45 84,78 (12,56)	41 84,88 (11,97)	43 86,07 (14,12)	39 84,69 (15,03)	39 82,90 (15,69)	39 85,41 (15,44)	38 84,87 (15,57)	34 85,74 (14,24)	0,94 (1,34)	-2,48 [-6,04;1,08] 0,1699 -0,27 [-0,66;0,11]
G2	311 84,44 (13,85)	304 82,21 (15,29)	297 82,92 (15,60)	294 82,65 (15,48)	280 82,45 (15,66)	275 82,60 (15,91)	257 83,04 (16,32)	254 84,31 (14,61)	234 84,19 (15,29)	-1,62 (0,54)	283 83,65 (14,14)	276 82,86 (15,50)	269 84,60 (14,43)	254 84,55 (14,96)	237 84,88 (15,21)	234 85,12 (15,39)	222 84,61 (15,71)	225 84,01 (16,19)	203 83,88 (16,27)	-0,06 (0,57)	-1,55 [-3,09;-0,02] 0,0477 -0,16 [-0,32;-0,00]
G3	279 83,52 (13,32)	273 81,90 (14,84)	263 81,80 (15,79)	261 82,30 (15,25)	243 81,65 (15,71)	237 82,65 (16,68)	224 81,99 (16,50)	227 83,93 (15,56)	201 83,55 (16,69)	-1,34 (0,62)	281 82,72 (13,82)	276 82,08 (14,43)	271 83,04 (14,07)	253 83,71 (14,77)	247 83,49 (15,05)	221 84,13 (14,35)	217 84,60 (13,54)	211 84,21 (13,87)	200 84,38 (14,56)	0,19 (0,62)	-1,53 [-3,26;0,19] 0,0814 -0,15 [-0,31;0,02]
GX	42 86,57 (15,47)	40 83,98 (14,51)	39 85,62 (15,09)	40 85,60 (15,91)	38 85,39 (15,25)	38 84,37 (17,52)	37 86,38 (16,74)	36 86,69 (16,45)	37 86,46 (17,32)	-0,82 (1,60)	35 83,77 (14,60)	34 83,09 (15,56)	33 83,18 (14,93)	33 83,79 (17,06)	31 87,87 (12,49)	31 84,10 (16,07)	30 85,27 (16,31)	31 84,10 (14,45)	28 84,04 (15,70)	0,48 (1,75)	-1,30 [-6,03;3,43] 0,5856 -0,13 [-0,57;0,32]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,3281)																					
Negativ	63 82,98 (13,17)	60 79,83 (14,96)	58 80,78 (17,41)	60 79,84 (16,91)	57 79,20 (15,67)	54 79,48 (16,07)	50 77,62 (16,60)	50 80,64 (17,54)	50 81,38 (18,13)	-3,18 (1,27)	53 84,21 (13,79)	52 83,37 (15,53)	51 84,39 (13,42)	44 87,18 (11,93)	43 87,38 (11,29)	40 86,38 (13,65)	40 87,00 (12,57)	37 89,57 (11,16)	36 89,44 (9,68)	2,12 (1,41)	-5,30 [-9,05;-1,55] 0,0061 -0,52 [-0,89;-0,15]
Positiv	609 84,27 (13,90)	595 82,35 (14,95)	580 82,63 (15,46)	573 82,67 (15,39)	546 82,43 (15,66)	537 82,91 (16,32)	505 83,22 (16,27)	509 84,52 (15,00)	459 84,45 (15,89)	-1,42 (0,40)	578 83,24 (13,98)	566 82,63 (14,70)	551 83,93 (14,09)	527 83,93 (15,08)	499 83,94 (15,24)	472 84,35 (15,00)	459 84,50 (14,85)	456 83,84 (15,04)	419 83,84 (15,60)	-0,05 (0,41)	-1,37 [-2,50;-0,24] 0,0172 -0,14 [-0,25;-0,02]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Unbekannt	6 88,00 (4,86)	6 82,33 (15,07)	6 95,67 (15,03)	4 98,75 (9,50)	4 96,00 (9,20)	4 95,50 (9,75)	4 95,00 (11,46)	3 90,33 (18,58)	3 95,00 (5,57)	4,84 (2,88)	8 76,00 (17,31)	7 76,43 (21,85)	8 77,75 (19,20)	6 80,83 (19,21)	6 90,17 (16,07)	8 76,88 (21,92)	4 79,25 (28,29)	8 74,00 (23,97)	7 77,14 (18,45)	1,72 (2,20)	3,12 [-4,92;11,16] 0,4221 0,44 [-0,56;1,45]
Ethnizität (p-Wert des Interaktionsterms: 0,6715)																					
Weiß	398 84,30 (12,99)	385 82,21 (14,39)	369 82,50 (15,11)	367 82,17 (14,53)	341 81,65 (14,83)	336 82,10 (15,98)	305 82,46 (15,62)	310 83,43 (14,78)	275 83,47 (14,90)	-1,93 (0,48)	381 83,47 (13,70)	368 82,27 (15,05)	354 83,75 (14,15)	337 83,14 (15,26)	322 83,59 (15,46)	304 83,84 (15,22)	290 84,38 (14,60)	290 83,25 (15,35)	267 83,06 (15,28)	-0,85 (0,49)	-1,08 [-2,41;0,26] 0,1136 -0,11 [-0,25;0,03]
Asiatisch	259 83,79 (14,69)	257 81,97 (15,43)	253 82,66 (16,28)	251 83,49 (16,52)	245 83,09 (16,81)	239 83,44 (16,93)	236 83,35 (17,02)	236 84,86 (15,93)	223 84,64 (17,42)	-0,53 (0,64)	226 82,98 (14,48)	225 83,01 (14,43)	223 83,99 (14,27)	217 86,12 (14,27)	202 85,35 (14,34)	194 85,23 (15,02)	192 84,82 (15,33)	188 85,25 (14,50)	176 85,41 (15,56)	1,42 (0,69)	-1,94 [-3,79;-0,10] 0,0391 -0,19 [-0,37;-0,01]
Andere	26 87,12 (16,19)	25 86,36 (17,26)	25 85,56 (16,60)	25 82,72 (17,57)	24 84,67 (16,15)	22 86,95 (14,43)	22 86,23 (17,47)	20 88,15 (13,26)	18 88,28 (14,93)	-2,02 (2,11)	29 81,97 (15,81)	28 82,93 (16,01)	28 81,75 (14,31)	27 82,59 (14,81)	25 85,72 (13,91)	22 84,50 (11,86)	21 86,52 (13,75)	23 84,52 (16,05)	18 87,94 (13,75)	2,06 (2,02)	-4,08 [-10,01;1,85] 0,1724 -0,38 [-0,91;0,16]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,3531)																					
Tamoxifen	491 83,36 (13,40)	479 81,56 (14,44)	459 81,73 (15,25)	461 81,59 (15,07)	432 81,32 (14,89)	424 81,84 (15,75)	399 81,75 (15,92)	402 83,45 (14,80)	361 82,67 (15,35)	-1,53 (0,44)	476 82,86 (13,78)	463 82,60 (14,35)	448 83,60 (13,95)	426 84,06 (14,72)	402 84,22 (14,83)	388 83,89 (14,87)	372 84,21 (14,33)	376 83,52 (14,93)	346 83,76 (15,05)	0,23 (0,45)	-1,76 [-2,98;-0,53] 0,0049 -0,18 [-0,31;-0,06]
Aromatase-Inhibitor	203 86,43 (14,16)	198 84,04 (15,71)	197 84,96 (16,24)	191 85,32 (16,15)	187 84,71 (17,01)	182 85,01 (17,26)	173 85,77 (16,77)	171 86,21 (15,98)	160 87,51 (16,96)	-1,32 (0,72)	172 84,48 (14,46)	170 82,91 (16,05)	168 84,51 (14,58)	159 84,81 (15,39)	154 84,93 (15,33)	139 86,08 (15,18)	138 86,01 (15,85)	131 85,89 (15,27)	121 85,61 (16,00)	0,01 (0,79)	-1,33 [-3,44;0,78] 0,2169 -0,13 [-0,33;0,07]
ECOG-PS (p-Wert des Interaktionsterms: 0,7635)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
ECOG-PS 0	616 84,23 (13,66)	600 82,19 (14,85)	581 82,47 (15,65)	580 82,40 (15,37)	547 81,99 (15,65)	538 82,64 (16,04)	506 82,71 (16,17)	506 84,24 (15,16)	464 84,07 (15,87)	-1,70 (0,39)	575 84,24 (13,51)	561 83,41 (14,61)	546 84,56 (13,81)	521 84,86 (14,71)	495 84,99 (14,92)	470 85,25 (14,88)	457 85,28 (14,61)	447 84,95 (14,97)	417 84,95 (15,09)	-0,10 (0,40)	-1,60 [-2,70;-0,50] 0,0044 -0,17 [-0,28;-0,05]
ECOG-PS 1	78 84,54 (14,00)	77 83,03 (14,95)	75 84,45 (15,23)	72 84,99 (16,24)	72 85,06 (15,26)	68 84,01 (18,05)	66 84,95 (17,04)	67 84,54 (15,67)	57 84,86 (17,20)	1,03 (1,29)	73 75,81 (15,29)	72 77,04 (15,27)	70 78,34 (15,36)	64 79,41 (15,65)	61 79,77 (14,58)	57 78,07 (14,28)	53 79,74 (15,24)	60 78,08 (14,25)	50 78,30 (15,90)	1,57 (1,35)	-0,54 [-4,30;3,22] 0,7763 -0,05 [-0,37;0,27]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-G Gesamtscore = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-G Gesamtscore haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-G: Functional Assessment of Cancer Therapy - General; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t111_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 111.2.2: Subgruppen für die Veränderung des FACT-G (Gesamtscore) aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,3369)																					
< 65 Jahre	804 84,51 (14,08)	780 82,81 (15,04)	754 82,73 (15,42)	720 82,61 (14,91)	699 82,75 (14,87)	665 82,18 (15,11)	636 82,92 (15,26)	631 83,14 (15,38)	588 83,47 (15,39)	-1,92 (0,35)	832 83,65 (14,22)	798 83,71 (14,08)	798 83,48 (14,23)	754 83,24 (14,71)	722 83,66 (14,64)	681 83,66 (14,92)	639 83,51 (14,98)	632 83,37 (15,02)	587 83,85 (14,83)	-0,47 (0,34)	-1,46 [-2,41;-0,50] 0,0028 -0,15 [-0,25;-0,05]
≥ 65 Jahre	303 84,03 (15,15)	292 80,57 (15,52)	275 82,39 (14,36)	270 82,37 (15,02)	255 81,26 (16,08)	236 80,99 (16,01)	224 82,83 (15,70)	216 81,67 (15,67)	198 82,25 (15,67)	-3,00 (0,54)	279 84,95 (13,97)	269 84,83 (14,50)	260 84,43 (14,02)	254 84,53 (13,43)	246 83,34 (14,96)	238 83,00 (14,38)	220 82,80 (14,15)	216 82,07 (14,32)	190 81,51 (14,77)	-1,74 (0,56)	-1,26 [-2,80;0,27] 0,1068 -0,13 [-0,30;0,03]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,8015)																					
Neoadjuvante Chemotherapie	363 85,48 (14,21)	345 82,96 (15,35)	329 83,76 (15,07)	314 82,25 (15,59)	297 82,07 (15,75)	276 82,41 (15,93)	259 83,32 (16,24)	253 83,01 (14,93)	236 82,64 (16,25)	-3,07 (0,52)	365 83,02 (14,43)	352 82,90 (13,90)	342 82,33 (13,99)	321 82,16 (14,55)	306 82,16 (14,34)	281 82,33 (15,32)	267 82,49 (15,22)	264 81,63 (15,04)	234 81,80 (15,14)	-1,52 (0,51)	-1,56 [-2,99;-0,13] 0,0328 -0,16 [-0,30;-0,01]
Adjuvante Chemotherapie	684 83,90 (14,55)	670 82,15 (15,06)	647 82,32 (15,16)	621 83,06 (14,42)	606 82,65 (14,81)	581 81,93 (15,07)	557 82,95 (14,96)	554 82,78 (15,75)	512 83,51 (15,11)	-1,58 (0,37)	679 84,48 (13,78)	651 84,70 (14,15)	654 84,62 (14,15)	629 84,54 (14,07)	612 84,56 (14,76)	590 84,41 (14,30)	547 84,02 (14,46)	541 83,93 (14,61)	509 84,26 (14,49)	-0,15 (0,37)	-1,43 [-2,46;-0,40] 0,0067 -0,15 [-0,25;-0,04]
Keine Chemotherapie	60 83,13 (13,17)	57 78,19 (15,66)	53 79,49 (14,98)	55 78,40 (16,42)	51 80,45 (16,74)	44 77,70 (15,10)	44 79,70 (15,24)	40 81,03 (15,00)	38 81,74 (15,35)	-4,71 (1,19)	67 84,04 (16,27)	64 82,81 (15,90)	62 81,79 (14,84)	58 80,72 (16,22)	50 80,20 (15,48)	48 78,98 (16,23)	45 79,89 (15,25)	43 80,56 (16,06)	34 78,65 (16,58)	-3,24 (1,14)	-1,48 [-4,75;1,79] 0,3718 -0,16 [-0,51;0,19]
Region (p-Wert des Interaktionsterms: 0,2819)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	550 85,60 (14,43)	520 82,92 (15,57)	492 83,44 (15,50)	470 83,45 (15,25)	444 83,76 (15,06)	416 82,83 (15,64)	395 84,38 (15,51)	389 84,73 (15,22)	360 83,69 (15,45)	-2,69 (0,39)	530 85,09 (13,92)	493 85,53 (14,00)	491 84,98 (14,10)	451 84,78 (14,66)	438 84,63 (14,95)	419 85,07 (14,98)	381 84,66 (14,81)	388 83,84 (15,15)	344 84,33 (14,34)	-0,91 (0,40)	-1,77 [-2,87;-0,68] 0,0015 -0,19 [-0,31;-0,07]
Asien	195 82,84 (14,95)	194 81,01 (16,09)	188 81,10 (16,30)	186 81,11 (15,80)	182 80,53 (16,54)	171 80,64 (16,87)	171 79,79 (16,65)	168 79,44 (16,87)	157 81,48 (16,97)	-2,09 (0,75)	192 82,97 (14,55)	191 82,07 (14,96)	187 81,98 (14,98)	184 82,64 (14,84)	179 82,35 (15,83)	174 82,15 (15,17)	172 81,98 (15,11)	168 81,88 (15,23)	163 83,24 (15,49)	-0,84 (0,75)	-1,26 [-3,34;0,82] 0,2350 -0,12 [-0,32;0,08]
Andere	362 83,35 (13,85)	358 81,81 (14,11)	349 82,33 (13,90)	334 82,07 (13,93)	328 81,45 (14,49)	314 81,27 (14,01)	294 82,71 (14,13)	290 82,06 (14,56)	269 83,44 (14,52)	-1,58 (0,52)	389 82,95 (14,20)	383 82,98 (13,86)	380 82,93 (13,75)	373 82,54 (13,77)	351 82,89 (13,75)	326 82,17 (14,14)	306 82,42 (14,42)	292 82,65 (14,21)	270 81,95 (15,03)	-0,66 (0,50)	-0,92 [-2,33;0,49] 0,2020 -0,09 [-0,24;0,05]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,5822)																					
< 20 mm	279 85,04 (14,34)	266 83,09 (14,80)	256 83,50 (14,96)	252 82,44 (15,42)	241 82,00 (15,72)	232 81,41 (16,46)	228 83,34 (15,90)	219 82,54 (15,83)	209 83,00 (15,70)	-2,73 (0,57)	298 84,80 (13,70)	286 84,39 (14,14)	284 84,75 (13,70)	267 84,30 (14,08)	262 84,15 (14,08)	241 84,03 (14,20)	230 83,77 (14,22)	223 83,53 (14,20)	207 83,45 (14,14)	-1,16 (0,56)	-1,57 [-3,14;0,00] 0,0503 -0,16 [-0,33;0,00]
≥ 20 bis < 50 mm	569 83,98 (14,75)	559 82,00 (15,51)	529 82,76 (15,20)	515 82,88 (14,67)	491 82,51 (15,33)	467 82,60 (14,81)	448 83,47 (14,93)	437 83,30 (15,05)	403 83,59 (14,95)	-1,64 (0,41)	572 83,95 (14,29)	552 83,95 (14,08)	547 83,70 (14,05)	524 83,27 (14,79)	502 83,62 (14,77)	492 83,48 (14,90)	446 83,48 (15,10)	450 83,08 (14,96)	421 83,35 (15,27)	-0,70 (0,41)	-0,94 [-2,08;0,21] 0,1087 -0,10 [-0,21;0,02]
≥ 50 mm	242 84,65 (13,56)	231 81,70 (15,07)	228 81,61 (15,23)	210 81,98 (15,08)	207 82,67 (14,31)	188 81,10 (14,99)	170 81,10 (15,78)	178 81,87 (16,16)	161 82,35 (16,45)	-2,79 (0,63)	230 82,75 (14,65)	218 83,32 (14,75)	217 82,02 (15,15)	206 83,03 (14,00)	196 82,56 (15,57)	177 82,56 (15,44)	174 82,14 (14,80)	166 81,97 (15,64)	141 82,41 (14,92)	-0,73 (0,64)	-2,06 [-3,83;-0,29] 0,0224 -0,21 [-0,39;-0,03]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,9316)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	367 84,47 (14,95)	358 82,27 (15,45)	341 82,81 (16,06)	321 82,42 (15,37)	317 82,16 (15,73)	298 81,48 (16,22)	283 82,61 (15,96)	280 82,63 (16,17)	258 83,07 (16,45)	-2,43 (0,52)	360 83,88 (14,34)	343 83,51 (14,00)	347 83,60 (13,46)	324 83,01 (14,11)	316 83,74 (14,29)	295 83,12 (15,04)	280 83,29 (14,63)	268 82,09 (15,51)	246 82,56 (14,31)	-0,94 (0,52)	-1,50 [-2,94;-0,05] 0,0420 -0,15 [-0,30;-0,01]
4-9	476 84,12 (13,69)	458 82,13 (14,89)	446 82,42 (14,68)	433 82,12 (14,72)	414 82,05 (15,02)	388 82,19 (14,71)	375 83,17 (15,08)	372 82,75 (14,40)	354 83,43 (14,95)	-1,97 (0,44)	486 83,79 (14,39)	468 84,35 (14,60)	467 83,75 (14,45)	443 83,49 (15,07)	430 83,36 (15,31)	418 83,36 (14,95)	385 83,16 (15,08)	385 83,49 (14,48)	359 83,53 (15,35)	-0,64 (0,43)	-1,34 [-2,55;-0,12] 0,0310 -0,14 [-0,27;-0,01]
≥ 10	264 84,69 (14,81)	256 82,24 (15,47)	242 82,80 (14,68)	236 83,50 (14,75)	223 83,17 (14,85)	215 81,83 (15,31)	202 82,79 (15,12)	195 82,99 (16,43)	174 82,77 (15,05)	-2,31 (0,61)	265 84,44 (13,50)	256 84,00 (13,72)	244 83,81 (14,68)	241 84,43 (13,52)	222 83,76 (14,20)	206 84,27 (14,06)	194 83,70 (14,38)	195 83,47 (14,65)	172 83,76 (14,57)	-0,90 (0,61)	-1,41 [-3,10;0,28] 0,1018 -0,14 [-0,31;0,03]
Tumorstadium (p-Wert des Interaktionsterms: 0,0924)																					
IIA	92 85,85 (14,81)	90 83,86 (14,14)	85 84,44 (14,89)	83 82,78 (15,07)	82 82,34 (15,89)	80 82,33 (16,91)	77 82,29 (18,35)	71 81,72 (17,79)	66 83,53 (16,41)	-2,62 (1,00)	95 83,36 (15,39)	92 83,15 (14,07)	90 83,32 (13,31)	86 82,87 (14,01)	82 83,82 (11,97)	82 82,61 (14,02)	78 83,23 (13,72)	73 80,18 (14,55)	65 81,12 (13,47)	-1,33 (0,98)	-1,29 [-4,06;1,48] 0,3587 -0,13 [-0,42;0,15]
IIB	133 84,70 (15,32)	130 83,80 (14,87)	122 84,54 (15,04)	120 83,25 (15,28)	118 83,65 (15,50)	110 83,09 (15,98)	102 83,91 (14,38)	104 84,84 (14,13)	97 85,41 (15,25)	-1,63 (0,84)	113 86,65 (13,60)	107 85,03 (13,02)	107 84,45 (12,99)	102 82,23 (14,49)	96 83,24 (15,39)	97 83,22 (16,23)	92 82,89 (15,62)	88 82,10 (16,57)	83 82,20 (15,43)	-3,00 (0,91)	1,37 [-1,06;3,80] 0,2686 0,14 [-0,11;0,39]
IIIA	431 84,09 (13,34)	417 81,58 (14,76)	404 82,09 (14,88)	389 81,54 (14,62)	370 81,43 (15,16)	346 82,06 (14,60)	331 82,84 (15,15)	338 81,98 (15,17)	313 83,36 (15,24)	-2,32 (0,48)	437 83,45 (14,68)	417 84,06 (14,61)	424 83,61 (14,56)	398 83,61 (14,72)	389 83,42 (15,81)	372 83,32 (15,32)	344 83,22 (15,00)	341 83,67 (14,65)	319 83,62 (15,58)	-0,32 (0,47)	-2,00 [-3,31;-0,68] 0,0031 -0,20 [-0,33;-0,07]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
IIIB	47 82,47 (14,43)	45 79,53 (17,54)	45 80,82 (16,86)	43 81,30 (17,21)	43 79,63 (15,77)	39 78,79 (17,32)	36 82,06 (15,34)	33 83,12 (15,33)	35 81,80 (15,63)	-2,31 (1,33)	41 85,59 (14,80)	40 87,38 (13,23)	40 85,53 (12,44)	37 86,19 (15,06)	35 85,86 (13,26)	33 84,09 (15,79)	32 83,31 (17,49)	29 84,03 (16,14)	28 82,96 (15,83)	0,48 (1,42)	-2,78 [-6,66;1,10] 0,1574 -0,31 [-0,73;0,12]
IIIC	402 84,55 (15,02)	389 82,31 (15,70)	371 82,49 (15,29)	353 83,57 (14,86)	339 83,32 (14,91)	324 81,57 (15,32)	312 82,90 (15,24)	299 83,17 (15,72)	273 82,27 (15,59)	-2,12 (0,49)	423 83,76 (13,39)	409 83,55 (14,19)	395 83,51 (14,49)	383 83,77 (14,10)	364 83,61 (14,07)	333 83,90 (13,87)	312 83,63 (14,29)	315 83,20 (14,55)	280 83,73 (14,07)	-0,69 (0,47)	-1,43 [-2,77;-0,10] 0,0355 -0,15 [-0,28;-0,01]
Tumorgrading (p-Wert des Interaktionsterms: 0,9984)																					
G1	82 85,18 (13,97)	80 83,95 (15,77)	82 82,67 (16,25)	75 84,13 (15,39)	72 84,53 (14,88)	69 83,70 (13,45)	68 85,18 (14,19)	67 85,06 (14,46)	63 85,48 (14,87)	-1,17 (1,06)	84 85,37 (13,96)	83 85,86 (13,98)	81 85,44 (13,95)	75 86,69 (12,20)	78 84,07 (16,28)	72 85,64 (14,90)	66 85,05 (15,20)	67 85,69 (12,79)	59 85,22 (14,02)	0,33 (1,04)	-1,50 [-4,43;1,43] 0,3128 -0,16 [-0,46;0,15]
G2	526 84,46 (14,04)	510 81,80 (15,56)	489 82,21 (15,36)	468 82,36 (15,30)	450 81,93 (15,43)	422 81,28 (15,70)	395 82,83 (15,69)	401 82,03 (15,85)	368 82,68 (15,80)	-2,72 (0,43)	534 83,75 (14,15)	509 83,58 (14,33)	508 83,26 (14,29)	489 83,02 (14,44)	464 82,41 (15,12)	441 82,98 (14,74)	414 82,65 (14,86)	412 82,75 (14,62)	379 82,46 (14,83)	-1,31 (0,42)	-1,40 [-2,58;-0,22] 0,0201 -0,14 [-0,26;-0,02]
G3	450 84,11 (15,02)	435 82,36 (14,84)	412 83,36 (14,79)	401 82,61 (14,41)	388 82,62 (15,10)	368 82,14 (15,33)	358 82,63 (15,35)	338 82,97 (15,42)	322 83,23 (15,45)	-1,71 (0,45)	436 83,91 (14,39)	418 84,12 (14,21)	413 83,86 (14,23)	390 83,85 (14,75)	376 84,83 (13,72)	360 83,91 (14,94)	336 84,06 (14,59)	326 83,17 (15,37)	303 84,06 (14,87)	-0,19 (0,46)	-1,52 [-2,79;-0,25] 0,0192 -0,16 [-0,29;-0,03]
GX	47 84,51 (12,92)	45 81,87 (13,97)	44 80,41 (14,21)	44 81,40 (15,51)	42 81,19 (14,64)	40 82,35 (15,10)	37 82,08 (14,62)	39 84,23 (13,69)	32 83,69 (12,93)	-3,28 (1,55)	53 84,64 (12,41)	53 83,96 (13,08)	52 84,37 (12,96)	50 81,96 (13,32)	47 83,91 (15,50)	43 80,93 (13,44)	41 80,76 (14,47)	40 80,03 (15,87)	33 81,73 (16,24)	-2,29 (1,47)	-0,99 [-5,24;3,25] 0,6428 -0,09 [-0,49;0,30]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,8518)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Negativ	137 81,43 (13,86)	134 79,56 (15,79)	126 79,02 (16,52)	124 79,99 (15,97)	116 78,94 (16,22)	104 78,23 (15,72)	98 79,44 (15,26)	101 78,52 (15,17)	89 79,36 (15,65)	-2,93 (0,85)	149 83,14 (14,26)	143 82,79 (14,22)	140 82,68 (14,46)	134 83,00 (14,71)	125 83,60 (14,81)	117 82,20 (16,02)	105 80,70 (15,69)	104 81,69 (13,99)	91 82,73 (14,66)	-0,91 (0,82)	-2,03 [-4,35;0,29] 0,0867 -0,20 [-0,44;0,03]
Positiv	939 84,58 (14,38)	907 82,24 (15,06)	872 82,82 (14,86)	841 82,58 (14,65)	816 82,59 (14,93)	773 82,04 (15,20)	736 83,02 (15,30)	723 83,09 (15,37)	676 83,38 (15,41)	-2,20 (0,32)	935 83,90 (14,13)	900 84,04 (14,15)	895 83,68 (14,12)	851 83,48 (14,33)	821 83,40 (14,74)	780 83,51 (14,60)	735 83,57 (14,61)	722 83,11 (14,88)	665 83,22 (14,89)	-0,74 (0,32)	-1,46 [-2,34;-0,58] 0,0011 -0,15 [-0,24;-0,06]
Unbekannt	9 86,78 (18,40)	9 89,44 (12,61)	9 94,67 (9,75)	7 97,29 (15,07)	3 105,00 (2,65)	7 94,71 (16,08)	8 94,13 (15,32)	7 96,00 (12,99)	5 98,40 (10,90)	5,50 (2,67)	7 91,71 (13,31)	6 94,00 (9,34)	6 92,17 (9,20)	6 95,50 (7,15)	6 93,00 (6,54)	6 90,50 (11,29)	5 92,20 (11,37)	6 98,67 (6,12)	5 93,20 (7,79)	4,97 (3,01)	0,53 [-8,10;9,15] 0,8977 0,06 [-0,87;1,00]
Ethnizität (p-Wert des Interaktionsterms: 0,4597)																					
Weiß	808 84,57 (14,19)	777 82,41 (14,81)	753 82,78 (14,60)	720 82,45 (14,69)	690 82,49 (14,92)	649 81,88 (14,84)	610 83,30 (14,89)	605 83,22 (14,89)	564 82,95 (15,12)	-2,50 (0,33)	820 84,35 (13,99)	779 84,48 (13,99)	776 84,34 (13,72)	732 83,63 (14,37)	703 83,88 (14,55)	669 83,82 (14,53)	613 83,63 (14,57)	612 83,05 (14,77)	547 83,22 (14,74)	-0,96 (0,33)	-1,54 [-2,46;-0,62] 0,0011 -0,16 [-0,26;-0,07]
Asiatisch	233 83,59 (15,12)	231 81,81 (16,31)	221 82,27 (16,23)	218 82,51 (15,88)	213 82,18 (16,47)	200 82,05 (16,68)	199 81,20 (16,70)	197 81,28 (17,06)	179 83,37 (17,02)	-1,21 (0,71)	221 82,69 (14,74)	219 82,69 (14,91)	215 81,96 (15,37)	213 83,56 (14,83)	204 83,08 (15,78)	193 82,53 (15,17)	191 82,50 (15,29)	185 82,65 (15,36)	181 83,75 (15,51)	-0,10 (0,73)	-1,10 [-3,11;0,91] 0,2809 -0,10 [-0,29;0,08]
Andere	54 84,94 (13,56)	52 81,31 (15,73)	47 82,94 (16,80)	43 83,88 (13,85)	43 80,56 (13,81)	42 80,74 (16,95)	44 83,55 (15,81)	38 82,39 (15,28)	35 85,54 (12,91)	-2,24 (1,29)	57 84,35 (14,43)	57 82,28 (14,56)	55 83,58 (13,13)	51 82,27 (13,55)	50 80,89 (13,13)	46 83,48 (15,65)	45 84,64 (14,99)	40 84,28 (14,61)	40 82,10 (15,04)	-1,86 (1,24)	-0,39 [-3,93;3,15] 0,8286 -0,04 [-0,41;0,33]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,3876)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Tamoxifen	104 83,93 (13,62)	101 82,68 (14,39)	101 81,89 (15,79)	98 82,48 (13,36)	97 82,01 (14,39)	96 82,28 (14,26)	90 82,40 (15,30)	89 83,48 (15,49)	90 83,76 (15,26)	-1,14 (0,93)	124 82,01 (13,14)	123 81,84 (13,35)	123 82,31 (13,82)	117 82,49 (13,15)	109 81,64 (14,33)	98 82,85 (14,22)	94 82,41 (12,84)	91 82,37 (14,35)	89 84,70 (12,98)	-0,28 (0,86)	-0,86 [-3,36;1,63] 0,4967 -0,09 [-0,35;0,17]
Aromatase-Inhibitor	1003 84,42 (14,46)	971 82,15 (15,29)	928 82,72 (15,07)	892 82,55 (15,11)	857 82,39 (15,31)	805 81,82 (15,49)	770 82,95 (15,39)	758 82,68 (15,47)	696 83,09 (15,50)	-2,34 (0,31)	987 84,22 (14,27)	944 84,27 (14,28)	935 83,90 (14,22)	891 83,70 (14,56)	859 83,82 (14,75)	821 83,57 (14,85)	765 83,44 (14,99)	757 83,12 (14,92)	688 83,09 (15,07)	-0,86 (0,31)	-1,48 [-2,34;-0,62] 0,0008 -0,15 [-0,24;-0,06]
ECOG-PS (p-Wert des Interaktionsterms: 0,3984)																					
ECOG-PS 0	933 85,12 (13,99)	903 82,98 (14,99)	868 83,27 (14,98)	845 82,92 (14,76)	812 83,03 (14,86)	772 82,31 (15,28)	734 83,45 (14,95)	727 83,32 (15,13)	679 83,53 (15,19)	-2,29 (0,32)	899 84,69 (13,91)	862 84,63 (14,05)	857 84,27 (13,81)	820 84,07 (14,07)	790 84,02 (14,62)	753 83,75 (14,54)	699 83,37 (14,68)	691 83,24 (14,61)	628 83,68 (14,83)	-1,08 (0,32)	-1,21 [-2,09;-0,33] 0,0073 -0,13 [-0,22;-0,03]
ECOG-PS 1	174 80,39 (15,73)	169 78,05 (15,71)	161 79,25 (15,59)	145 80,34 (15,77)	142 78,48 (16,59)	129 79,21 (15,59)	126 79,67 (17,34)	120 79,42 (17,03)	107 80,84 (16,99)	-1,82 (0,80)	212 80,96 (14,81)	205 81,34 (14,49)	201 81,37 (15,45)	188 81,35 (15,60)	178 81,60 (15,01)	166 82,31 (15,81)	160 83,14 (15,18)	157 82,17 (15,89)	149 81,58 (14,81)	0,61 (0,71)	-2,43 [-4,54;-0,33] 0,0235 -0,23 [-0,43;-0,03]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-G Gesamtscore = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-G Gesamtscore haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-G: Functional Assessment of Cancer Therapy - General; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t111_mmrm_saf3c1_posmp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba

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Tabelle 112.1.2: Subgruppen für die Veränderung des TOI aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Prämenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,9795)																					
Neoadjuvante Chemotherapie	281 68,10 (11,78)	271 66,60 (13,57)	262 67,42 (13,72)	263 66,59 (14,35)	240 66,45 (14,01)	238 66,66 (14,82)	224 66,64 (14,63)	221 68,75 (14,03)	202 67,96 (14,46)	-1,19 (0,53)	267 66,16 (12,42)	257 66,40 (12,47)	253 68,00 (11,63)	230 68,46 (12,91)	220 68,11 (12,99)	202 68,49 (13,05)	186 68,61 (12,61)	184 67,91 (13,13)	170 67,88 (13,54)	0,94 (0,55)	-2,12 [-3,62;-0,63] 0,0055 -0,24 [-0,41;-0,07]
Adjuvante Chemotherapie	404 66,32 (12,75)	397 66,17 (13,07)	386 67,19 (13,78)	380 67,52 (13,42)	370 67,11 (14,39)	359 67,21 (14,42)	340 67,72 (14,04)	343 68,18 (13,45)	314 68,50 (13,63)	0,87 (0,40)	378 66,48 (12,33)	372 67,70 (12,91)	359 68,62 (12,52)	352 68,93 (12,73)	330 69,49 (12,64)	319 68,97 (13,07)	319 70,02 (12,52)	319 69,36 (12,56)	295 69,21 (12,73)	2,18 (0,41)	-1,30 [-2,43;-0,18] 0,0231 -0,16 [-0,30;-0,02]
Keine Chemotherapie	7 72,00 (17,10)	7 67,57 (15,33)	6 65,33 (16,46)	6 66,67 (16,31)	6 67,83 (15,89)	6 63,50 (16,34)	6 64,33 (12,27)	5 65,40 (11,13)	4 74,50 (5,74)	-3,21 (2,23)	3 60,33 (11,24)	3 59,67 (12,86)	3 58,00 (8,89)	3 57,00 (8,19)	3 59,33 (9,45)	3 61,00 (7,21)	3 60,67 (6,66)	3 71,00 (13,11)	2 60,50 (9,19)	-0,21 (3,23)	-3,00 [-12,41;6,41] 0,4808 -0,46 [-1,70;0,77]
Region (p-Wert des Interaktionsterms: 0,9094)																					
Nordamerika / Europa	280 66,85 (11,84)	266 65,50 (12,99)	254 66,21 (13,62)	251 65,79 (13,53)	225 66,11 (13,54)	225 65,60 (14,43)	209 66,65 (13,66)	206 68,16 (13,04)	177 67,42 (13,78)	-0,52 (0,49)	256 65,94 (12,72)	244 65,78 (13,36)	229 67,22 (12,43)	209 67,44 (13,46)	193 68,69 (13,50)	188 67,94 (13,54)	178 68,48 (12,69)	180 68,04 (13,83)	164 68,04 (13,80)	1,10 (0,52)	-1,62 [-3,03;-0,21] 0,0243 -0,20 [-0,37;-0,03]
Asien	232 67,93 (12,75)	231 67,26 (13,17)	227 67,96 (13,80)	226 68,38 (14,37)	222 67,63 (14,84)	216 67,57 (14,94)	215 68,22 (14,64)	212 69,16 (14,28)	210 69,27 (14,61)	0,21 (0,53)	210 67,44 (11,59)	209 68,36 (12,06)	209 69,25 (11,97)	202 70,45 (12,02)	192 70,11 (11,82)	187 70,36 (12,86)	183 70,19 (13,10)	181 70,59 (12,08)	171 69,85 (12,86)	2,12 (0,56)	-1,92 [-3,42;-0,41] 0,0126 -0,24 [-0,43;-0,05]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	180 66,43 (12,92)	178 66,47 (13,83)	173 67,91 (13,89)	172 67,47 (13,36)	169 66,84 (14,36)	162 68,02 (14,23)	146 66,73 (14,50)	151 67,58 (13,58)	133 68,07 (12,93)	0,59 (0,66)	182 65,57 (12,66)	179 67,56 (12,53)	177 68,62 (11,96)	174 68,12 (12,71)	168 67,70 (12,95)	149 67,72 (12,47)	147 69,71 (11,64)	145 67,66 (12,06)	132 67,98 (12,21)	1,97 (0,66)	-1,38 [-3,21;0,45] 0,1385 -0,16 [-0,36;0,05]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,6069)																					
< 20 mm	179 67,08 (11,68)	176 66,26 (12,54)	167 66,81 (13,44)	169 66,79 (14,00)	160 66,50 (13,90)	158 66,50 (14,74)	152 66,87 (14,42)	154 67,71 (13,78)	148 67,86 (13,96)	-0,18 (0,62)	169 65,14 (13,21)	164 65,89 (13,16)	160 67,71 (11,80)	153 66,85 (12,77)	148 67,85 (12,68)	140 68,56 (12,72)	135 69,02 (12,65)	135 68,20 (13,61)	123 69,02 (13,12)	1,86 (0,64)	-2,03 [-3,78;-0,28] 0,0228 -0,25 [-0,46;-0,03]
≥ 20 bis < 50 mm	323 67,47 (12,81)	312 66,45 (14,26)	310 68,05 (13,99)	304 67,11 (14,09)	287 67,10 (14,72)	279 67,00 (14,88)	262 67,24 (14,42)	263 68,60 (14,23)	236 68,80 (14,26)	-0,19 (0,48)	314 66,12 (12,29)	307 67,04 (12,67)	301 68,69 (12,16)	289 69,44 (12,85)	270 69,33 (12,77)	260 68,71 (13,17)	252 69,50 (12,49)	246 68,74 (12,53)	235 68,68 (12,77)	1,99 (0,49)	-2,18 [-3,53;-0,84] 0,0015 -0,25 [-0,41;-0,10]
≥ 50 mm	172 66,03 (12,32)	169 65,85 (12,11)	162 65,67 (13,52)	160 66,83 (12,74)	153 66,16 (13,30)	152 66,70 (13,76)	142 67,20 (13,40)	139 68,07 (12,16)	122 67,39 (13,13)	0,34 (0,59)	157 67,78 (11,21)	153 68,40 (12,33)	146 67,97 (12,46)	135 69,12 (12,47)	129 68,88 (12,83)	117 68,76 (13,20)	114 69,63 (12,50)	118 69,44 (12,20)	103 67,68 (13,43)	0,87 (0,63)	-0,53 [-2,24;1,17] 0,5398 -0,07 [-0,28;0,15]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,4970)																					
0-3	238 67,48 (12,06)	231 66,23 (13,06)	218 66,86 (13,89)	220 66,33 (14,19)	201 66,79 (13,71)	199 66,96 (14,87)	192 66,36 (14,55)	187 68,56 (13,03)	169 67,67 (14,48)	-0,56 (0,56)	237 65,49 (11,70)	231 66,50 (12,49)	223 67,46 (12,52)	209 67,70 (12,12)	199 67,39 (12,23)	191 67,92 (12,80)	183 68,50 (11,80)	180 68,36 (12,38)	175 67,87 (13,56)	1,38 (0,57)	-1,94 [-3,51;-0,36] 0,0158 -0,22 [-0,40;-0,04]
4-9	314 65,92 (13,08)	305 64,79 (13,74)	301 66,45 (13,93)	297 66,45 (13,69)	287 65,72 (14,45)	284 65,88 (14,81)	262 66,29 (14,36)	262 67,24 (14,09)	243 67,70 (13,72)	0,08 (0,46)	294 66,84 (12,67)	287 67,40 (12,74)	278 68,58 (12,00)	266 68,87 (13,20)	252 70,01 (12,78)	241 69,35 (13,09)	240 69,82 (13,03)	237 69,25 (12,86)	219 69,19 (12,24)	1,78 (0,48)	-1,70 [-3,02;-0,38] 0,0115 -0,21 [-0,37;-0,05]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
≥ 10	140 69,10 (11,31)	139 70,02 (11,91)	135 69,76 (12,94)	132 70,02 (13,15)	128 69,51 (14,33)	120 69,48 (13,28)	116 70,96 (12,94)	120 70,58 (13,44)	108 70,80 (13,27)	0,75 (0,68)	117 66,69 (12,86)	114 67,76 (13,28)	114 69,31 (11,78)	110 70,11 (13,02)	102 69,03 (13,66)	92 68,84 (13,41)	85 70,45 (12,73)	89 68,72 (13,40)	73 69,12 (14,04)	2,03 (0,76)	-1,28 [-3,29;0,73] 0,2116 -0,16 [-0,40;0,09]
Tumorstadium (p-Wert des Interaktionsterms: 0,0732)																					
IIA	71 68,62 (11,57)	69 67,19 (13,38)	67 67,13 (13,52)	66 65,55 (14,41)	65 66,52 (13,54)	61 65,74 (13,97)	59 66,58 (14,31)	60 67,63 (13,64)	55 67,58 (13,75)	-1,60 (0,96)	69 65,93 (11,70)	67 66,87 (11,52)	66 68,91 (11,56)	60 67,29 (11,28)	57 69,74 (10,41)	56 69,16 (11,86)	56 70,32 (10,62)	51 69,90 (12,45)	50 70,38 (12,88)	2,54 (0,98)	-4,15 [-6,86;-1,43] 0,0030 -0,51 [-0,85;-0,18]
IIB	65 67,45 (10,87)	63 66,43 (12,97)	59 69,47 (12,42)	61 66,41 (14,74)	52 67,67 (12,63)	55 66,98 (14,43)	54 67,35 (12,09)	53 69,40 (11,82)	51 69,35 (13,77)	-0,35 (1,13)	85 66,12 (10,96)	83 67,64 (11,15)	82 67,44 (12,79)	76 68,21 (13,09)	76 66,30 (12,25)	72 68,14 (12,37)	67 68,99 (11,28)	70 68,71 (11,12)	68 68,63 (11,61)	0,26 (0,99)	-0,61 [-3,58;2,37] 0,6873 -0,07 [-0,39;0,26]
IIIA	307 66,50 (13,15)	300 65,58 (13,47)	294 66,72 (13,84)	293 67,13 (13,43)	279 66,51 (14,40)	277 66,69 (14,88)	252 66,70 (14,32)	252 67,94 (14,04)	234 67,92 (13,92)	0,31 (0,47)	267 66,46 (13,00)	259 66,98 (12,78)	249 68,24 (12,07)	244 68,53 (13,06)	226 69,00 (13,11)	215 69,13 (13,38)	214 69,41 (13,32)	214 69,43 (12,44)	200 68,65 (12,90)	1,54 (0,50)	-1,23 [-2,58;0,12] 0,0736 -0,15 [-0,31;0,01]
IIIB	18 60,89 (16,66)	18 59,28 (14,46)	16 56,69 (18,42)	17 56,76 (14,67)	13 54,85 (12,25)	14 56,57 (18,19)	14 54,79 (16,56)	14 55,64 (11,71)	14 59,07 (13,29)	-4,57 (1,64)	17 69,53 (11,71)	17 73,53 (11,63)	16 71,69 (10,65)	13 72,00 (14,11)	11 73,64 (10,02)	12 69,58 (12,18)	13 67,15 (13,44)	12 65,58 (12,93)	11 67,45 (10,96)	1,90 (1,78)	-6,47 [-11,53;-1,41] 0,0143 -0,88 [-1,56;-0,20]
IIIC	227 67,73 (11,43)	221 67,62 (12,87)	214 68,11 (13,41)	208 68,51 (13,51)	203 68,05 (14,34)	193 68,33 (13,93)	188 69,01 (14,17)	188 69,76 (13,29)	163 69,50 (13,89)	0,59 (0,56)	209 66,06 (12,39)	205 66,64 (13,69)	201 68,23 (12,36)	191 69,25 (12,80)	183 69,27 (13,34)	169 68,31 (13,40)	158 69,58 (12,66)	159 68,02 (13,99)	138 68,25 (14,13)	2,05 (0,58)	-1,46 [-3,05;0,13] 0,0717 -0,17 [-0,36;0,01]
Tumorgrading (p-Wert des Interaktionsterms: 0,6371)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
G1	59 67,97 (12,00)	57 66,63 (11,81)	54 66,87 (13,22)	54 66,96 (12,43)	55 67,22 (13,25)	53 66,23 (13,78)	51 67,92 (12,81)	53 68,13 (13,85)	46 68,26 (13,75)	-0,13 (1,05)	47 64,45 (13,04)	45 67,56 (11,31)	42 68,55 (10,43)	43 68,23 (12,58)	39 69,15 (13,08)	39 65,79 (14,22)	39 68,69 (14,10)	38 68,16 (14,42)	34 68,59 (13,12)	3,04 (1,18)	-3,17 [-6,32;-0,03] 0,0482 -0,39 [-0,78;-0,01]
G2	310 67,52 (12,38)	303 66,48 (13,58)	296 67,96 (13,51)	293 67,19 (13,71)	278 67,01 (14,09)	274 66,88 (14,56)	256 67,74 (14,16)	251 68,82 (13,36)	234 68,01 (13,60)	-0,26 (0,46)	283 67,21 (12,62)	276 67,95 (13,22)	268 69,03 (12,67)	254 69,26 (13,07)	235 69,75 (12,99)	233 69,72 (13,36)	222 69,81 (13,47)	224 68,88 (13,73)	203 68,55 (14,00)	1,27 (0,48)	-1,53 [-2,84;-0,22] 0,0225 -0,19 [-0,35;-0,03]
G3	278 65,83 (12,36)	272 65,58 (13,22)	262 65,96 (14,09)	259 66,13 (13,86)	242 65,89 (14,46)	235 66,40 (14,49)	223 65,62 (14,19)	226 67,14 (13,53)	200 67,72 (13,94)	0,20 (0,52)	281 65,63 (11,96)	275 66,24 (12,37)	270 67,51 (11,94)	253 68,30 (12,19)	246 67,78 (12,61)	220 68,07 (12,36)	216 69,06 (11,27)	211 68,58 (11,59)	200 68,67 (12,24)	1,83 (0,52)	-1,63 [-3,08;-0,18] 0,0275 -0,19 [-0,35;-0,02]
GX	42 70,43 (13,40)	40 69,73 (13,38)	39 70,33 (13,72)	40 72,55 (15,09)	38 70,82 (14,72)	38 70,82 (15,81)	37 71,97 (15,67)	36 72,72 (14,99)	37 72,97 (15,17)	0,82 (1,40)	35 66,57 (12,12)	34 66,74 (13,67)	33 68,55 (12,11)	33 67,27 (15,83)	31 70,65 (12,38)	30 69,70 (13,86)	29 70,48 (13,03)	31 71,19 (11,71)	28 69,57 (11,90)	2,14 (1,54)	-1,32 [-5,49;2,84] 0,5286 -0,15 [-0,59;0,30]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4975)																					
Negativ	63 64,16 (12,55)	60 63,77 (13,73)	58 64,79 (15,25)	60 63,69 (15,32)	57 63,39 (14,61)	53 62,60 (15,21)	50 61,42 (14,63)	50 64,08 (15,39)	50 65,28 (16,22)	-0,58 (1,09)	53 66,66 (10,64)	52 66,52 (12,57)	51 67,73 (10,76)	44 70,11 (10,79)	43 70,28 (9,74)	40 70,50 (10,71)	40 71,00 (9,68)	37 71,76 (8,89)	36 71,47 (9,59)	3,52 (1,22)	-4,10 [-7,36;-0,84] 0,0142 -0,47 [-0,84;-0,10]
Positiv	608 67,28 (12,51)	594 66,55 (13,31)	578 67,35 (13,65)	570 67,27 (13,65)	544 67,08 (14,20)	536 67,21 (14,53)	504 67,65 (14,17)	507 68,64 (13,47)	458 68,67 (13,71)	0,01 (0,34)	578 66,32 (12,45)	565 67,25 (12,66)	550 68,47 (12,18)	527 68,51 (12,84)	496 68,62 (13,05)	469 68,64 (13,12)	457 69,32 (12,74)	455 68,73 (12,82)	419 68,47 (13,17)	1,52 (0,35)	-1,51 [-2,47;-0,55] 0,0020 -0,18 [-0,29;-0,07]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Unbekannt	6 73,50 (5,47)	6 67,67 (15,00)	6 79,00 (7,72)	4 83,75 (4,92)	4 82,50 (6,66)	4 80,75 (6,24)	4 81,25 (6,08)	3 79,00 (11,14)	3 80,33 (4,04)	4,27 (2,85)	8 60,88 (18,76)	7 58,43 (21,13)	8 61,88 (19,19)	6 64,33 (22,98)	6 72,67 (13,92)	8 61,50 (19,22)	4 65,25 (22,94)	8 61,13 (20,67)	7 62,43 (19,19)	1,02 (2,16)	3,26 [-4,76;11,28] 0,4032 0,47 [-0,54;1,48]
Ethnizität (p-Wert des Interaktionsterms: 0,8116)																					
Weiß	396 66,44 (12,12)	383 65,36 (13,07)	367 66,40 (13,48)	364 65,84 (13,16)	338 65,73 (13,76)	333 65,88 (14,28)	303 65,99 (13,61)	307 67,11 (13,04)	274 67,31 (13,00)	-0,38 (0,42)	381 65,81 (12,71)	367 66,16 (13,22)	353 67,58 (12,46)	337 67,36 (13,28)	319 68,08 (13,27)	301 67,69 (13,06)	288 68,77 (12,18)	289 67,84 (13,09)	267 67,67 (13,21)	1,17 (0,43)	-1,55 [-2,72;-0,37] 0,0100 -0,19 [-0,33;-0,04]
Asiatisch	259 67,90 (12,74)	257 67,52 (13,22)	253 68,45 (13,83)	251 69,22 (14,08)	245 68,34 (14,86)	239 68,23 (15,06)	236 68,77 (14,72)	235 69,68 (14,44)	223 69,47 (14,99)	0,80 (0,52)	226 67,31 (11,69)	225 68,50 (11,95)	223 69,61 (11,94)	217 70,89 (12,02)	202 70,16 (11,93)	194 70,32 (12,96)	192 70,39 (13,02)	188 70,53 (11,88)	176 70,01 (12,79)	2,39 (0,56)	-1,60 [-3,09;-0,11] 0,0352 -0,19 [-0,37;-0,01]
Andere	26 69,19 (15,55)	25 69,68 (16,79)	25 68,48 (16,71)	25 65,56 (17,88)	24 67,85 (14,72)	22 69,73 (14,08)	22 70,09 (16,33)	20 71,15 (12,47)	18 70,44 (13,62)	-1,14 (1,89)	29 64,55 (13,77)	28 67,36 (13,06)	28 66,14 (10,60)	27 66,81 (10,66)	25 67,94 (13,62)	22 67,27 (12,84)	21 69,62 (13,76)	23 66,70 (15,03)	18 69,56 (13,03)	2,49 (1,81)	-3,63 [-8,94;1,67] 0,1749 -0,37 [-0,91;0,16]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,7407)																					
Tamoxifen	490 66,16 (11,91)	478 65,50 (12,59)	458 66,10 (13,24)	459 65,75 (13,12)	430 65,43 (13,16)	422 65,69 (13,69)	398 65,77 (13,27)	399 67,13 (12,99)	361 66,70 (13,00)	-0,24 (0,36)	476 65,91 (12,10)	463 66,71 (12,23)	448 67,81 (11,83)	426 68,19 (12,54)	399 68,24 (12,67)	386 67,96 (12,60)	371 68,54 (12,05)	375 67,95 (12,27)	346 67,86 (12,79)	1,48 (0,37)	-1,72 [-2,74;-0,70] 0,0010 -0,21 [-0,34;-0,09]
Aromatase-Inhibitor	202 69,39 (13,38)	197 68,43 (14,66)	196 70,00 (14,57)	190 70,50 (14,86)	186 70,16 (16,01)	181 69,91 (16,12)	172 70,73 (15,80)	170 71,29 (14,71)	159 72,03 (15,19)	0,57 (0,63)	172 67,47 (13,00)	169 68,31 (14,01)	167 69,66 (12,92)	159 70,00 (13,41)	154 70,56 (12,96)	138 70,91 (14,00)	137 71,92 (13,54)	131 71,40 (13,82)	121 71,05 (13,43)	2,30 (0,69)	-1,73 [-3,58;0,12] 0,0673 -0,19 [-0,39;0,01]
ECOG-PS (p-Wert des Interaktionsterms: 0,5789)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
ECOG-PS 0	614 67,02 (12,39)	598 66,27 (13,04)	579 66,97 (13,69)	577 66,84 (13,64)	544 66,37 (14,17)	535 66,73 (14,39)	504 66,91 (14,16)	502 68,14 (13,59)	463 68,06 (13,85)	-0,25 (0,33)	575 67,04 (12,15)	560 67,74 (12,67)	545 68,77 (12,10)	521 69,13 (12,82)	492 69,36 (12,81)	467 69,43 (12,85)	455 69,89 (12,39)	446 69,35 (12,69)	417 69,19 (12,80)	1,52 (0,34)	-1,76 [-2,70;-0,83] 0,0002 -0,22 [-0,33;-0,10]
ECOG-PS 1	78 67,72 (12,84)	77 67,05 (15,12)	75 69,60 (14,14)	72 69,50 (15,03)	72 70,51 (14,29)	68 68,74 (15,99)	66 69,97 (14,70)	67 70,15 (14,05)	57 70,58 (14,28)	2,20 (1,11)	73 60,63 (12,53)	72 62,44 (12,40)	70 64,70 (12,02)	64 65,03 (12,10)	61 65,07 (12,00)	57 63,05 (13,23)	53 65,62 (13,38)	60 65,07 (12,87)	50 64,46 (14,20)	2,68 (1,16)	-0,48 [-3,71;2,75] 0,7701 -0,05 [-0,37;0,27]

Datenschnitt: 01.07.2022
Safety-Population
1: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B TOI = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B TOI haben.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet.
Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; TOI: Trial Outcome Index.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/programs/primary/tfl/german_dossier/t_gba3c1_mmrm_qol_primgba_sub.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/output/shared/tfl/german_dossier/gba3c1/t112_mmrm_saf3c1_premp_pgba_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr4/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc9/data/analysis/shared/adamgba
29OCT2025 / 08:23

Tabelle 112.2.2: Subgruppen für die Veränderung des TOI aus RCT mit dem zu bewertenden Arzneimittel - Cohort 1 Population - Safety - Postmenopausale Patientinnen

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Alter (p-Wert des Interaktionsterms: 0,6736)																					
< 65 Jahre	803 67,08 (12,62)	777 66,19 (13,05)	753 66,47 (13,23)	717 66,20 (13,05)	696 66,18 (13,34)	664 65,95 (13,51)	632 66,76 (13,34)	630 66,73 (13,50)	587 67,30 (13,38)	-0,79 (0,30)	832 66,06 (12,52)	797 67,30 (12,20)	797 67,00 (12,31)	753 67,03 (12,55)	720 67,62 (12,80)	682 67,61 (12,86)	640 67,75 (13,03)	633 67,62 (12,91)	587 67,82 (13,22)	0,99 (0,30)	-1,77 [-2,60;-0,94] <,0001 -0,21 [-0,30;-0,11]
≥ 65 Jahre	302 67,30 (12,64)	291 65,20 (12,78)	273 66,57 (11,93)	270 65,44 (12,84)	252 65,06 (13,67)	233 64,59 (13,00)	224 66,37 (12,42)	215 66,01 (12,70)	196 66,27 (12,91)	-2,52 (0,47)	279 68,00 (11,96)	268 67,86 (12,19)	262 68,49 (11,37)	253 68,32 (11,42)	245 67,45 (12,05)	238 67,19 (12,17)	220 66,75 (12,22)	216 66,59 (12,67)	191 66,70 (12,74)	-0,83 (0,48)	-1,69 [-3,02;-0,36] 0,0126 -0,21 [-0,37;-0,04]
Vorherige Chemotherapie (p-Wert des Interaktionsterms: 0,7169)																					
Neoadjuvante Chemotherapie	362 68,22 (12,42)	344 66,64 (13,33)	328 67,15 (13,14)	314 65,48 (13,60)	295 65,74 (14,34)	274 65,89 (13,96)	257 66,73 (13,88)	253 66,65 (13,17)	236 66,61 (14,04)	-2,23 (0,45)	365 66,10 (12,33)	350 67,23 (11,66)	343 66,49 (12,12)	320 66,18 (12,39)	305 66,74 (12,07)	281 66,92 (12,67)	268 66,99 (12,67)	265 66,66 (12,71)	234 66,53 (13,04)	-0,09 (0,45)	-2,14 [-3,39;-0,90] 0,0008 -0,25 [-0,40;-0,10]
Adjuvante Chemotherapie	683 66,52 (12,88)	667 65,70 (12,87)	645 66,30 (12,88)	618 66,52 (12,68)	602 66,06 (13,10)	579 65,72 (13,20)	555 66,73 (12,84)	552 66,52 (13,54)	510 67,28 (13,08)	-0,48 (0,32)	679 66,63 (12,48)	651 67,56 (12,37)	655 67,79 (12,24)	629 68,03 (12,22)	610 68,05 (12,91)	591 67,94 (12,70)	547 67,86 (13,01)	541 67,74 (12,95)	510 68,11 (13,13)	1,10 (0,32)	-1,57 [-2,47;-0,68] 0,0006 -0,19 [-0,29;-0,08]
Keine Chemotherapie	60 67,72 (10,48)	57 64,07 (11,97)	53 64,91 (11,37)	55 62,97 (12,55)	51 64,61 (11,95)	44 62,07 (11,85)	44 65,30 (11,73)	40 66,25 (10,72)	37 66,54 (10,61)	-4,60 (1,03)	67 68,21 (12,16)	64 67,30 (13,33)	61 67,79 (10,19)	57 66,44 (11,98)	50 66,98 (11,94)	48 65,48 (12,52)	45 66,04 (11,38)	43 66,95 (12,65)	34 66,09 (13,00)	-2,12 (0,99)	-2,48 [-5,31;0,35] 0,0849 -0,31 [-0,66;0,04]
Region (p-Wert des Interaktionsterms: 0,1966)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Nordamerika / Europa	548 67,72 (13,10)	516 65,75 (14,05)	489 66,53 (13,61)	466 66,04 (13,53)	438 66,43 (13,65)	412 65,64 (14,07)	392 67,18 (13,30)	387 67,35 (13,65)	357 66,55 (13,43)	-1,99 (0,35)	530 66,78 (12,78)	491 67,65 (12,85)	490 67,49 (12,27)	449 67,85 (12,88)	436 67,48 (13,06)	420 67,87 (13,00)	382 67,44 (13,38)	389 67,66 (13,29)	345 67,88 (12,75)	0,34 (0,35)	-2,33 [-3,30;-1,36] <,0001 -0,29 [-0,41;-0,17]
Asien	195 67,58 (12,49)	194 66,44 (12,90)	188 66,42 (13,34)	187 66,54 (13,23)	182 65,96 (14,04)	171 65,70 (14,16)	171 65,89 (13,98)	168 65,11 (14,08)	157 67,28 (13,91)	-1,28 (0,63)	192 67,27 (12,16)	191 67,36 (12,29)	187 67,13 (12,50)	184 67,70 (12,48)	179 68,08 (13,29)	174 67,70 (13,33)	172 67,87 (12,58)	168 67,34 (12,61)	163 68,37 (13,44)	0,18 (0,64)	-1,46 [-3,23;0,31] 0,1050 -0,17 [-0,36;0,03]
Andere	362 66,03 (11,90)	358 65,86 (11,34)	349 66,50 (11,57)	334 65,62 (12,07)	328 65,11 (12,77)	314 65,48 (12,00)	293 66,40 (12,29)	290 66,30 (12,27)	269 67,55 (12,65)	-0,16 (0,44)	389 65,88 (12,00)	383 67,21 (11,27)	382 67,34 (11,69)	373 66,59 (11,42)	350 67,44 (11,67)	326 66,90 (11,91)	306 67,36 (12,27)	292 66,98 (12,42)	270 66,61 (13,33)	0,98 (0,43)	-1,14 [-2,35;0,06] 0,0625 -0,14 [-0,28;0,01]
Primärtumorgröße (p-Wert des Interaktionsterms: 0,2813)																					
< 20 mm	279 66,94 (13,17)	266 65,91 (13,33)	256 66,95 (13,48)	252 65,72 (13,46)	238 64,89 (14,50)	232 64,87 (14,49)	228 66,55 (13,96)	219 65,97 (14,17)	208 66,32 (13,98)	-1,37 (0,52)	298 66,62 (12,10)	284 67,32 (12,14)	284 67,81 (11,83)	267 67,48 (12,29)	259 68,00 (12,11)	241 67,65 (12,34)	231 67,76 (12,30)	223 67,50 (12,35)	208 67,31 (12,49)	0,54 (0,50)	-1,92 [-3,33;-0,50] 0,0080 -0,22 [-0,39;-0,06]
≥ 20 bis < 50 mm	568 67,13 (12,81)	556 66,16 (13,01)	528 66,79 (12,81)	513 66,43 (12,88)	489 66,30 (13,24)	464 66,42 (13,00)	446 67,39 (12,88)	435 67,14 (13,00)	402 67,48 (12,94)	-0,85 (0,36)	572 66,75 (12,49)	552 67,50 (12,26)	548 67,44 (12,07)	523 67,33 (12,46)	502 67,69 (12,69)	493 67,55 (12,89)	446 67,50 (13,33)	451 67,34 (13,04)	421 67,60 (13,54)	0,37 (0,35)	-1,22 [-2,21;-0,23] 0,0154 -0,14 [-0,26;-0,03]
≥ 50 mm	241 67,47 (11,59)	230 65,22 (12,63)	226 65,49 (12,32)	209 65,42 (12,69)	206 66,20 (12,34)	187 64,80 (12,72)	168 65,24 (12,44)	178 65,92 (13,15)	160 66,75 (13,16)	-1,85 (0,53)	230 65,72 (12,81)	218 67,16 (12,26)	217 66,26 (12,61)	205 66,93 (12,05)	196 66,47 (13,18)	177 66,89 (12,77)	174 66,90 (12,43)	166 66,95 (13,23)	141 67,50 (13,04)	0,70 (0,54)	-2,55 [-4,04;-1,06] 0,0008 -0,31 [-0,49;-0,13]
Anzahl betr. Lymphknoten (p-Wert des Interaktionsterms: 0,6764)																					

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
0-3	366 66,84 (13,16)	357 65,74 (13,52)	340 66,82 (13,02)	321 66,19 (12,96)	315 66,12 (13,51)	297 65,52 (13,81)	282 66,85 (13,65)	279 66,61 (14,03)	258 66,97 (13,74)	-0,82 (0,44)	360 66,51 (11,91)	341 67,28 (11,84)	346 67,46 (11,20)	322 67,09 (11,94)	314 67,97 (11,75)	295 67,17 (12,59)	280 67,69 (12,20)	268 66,98 (12,89)	246 67,14 (12,47)	0,62 (0,45)	-1,44 [-2,68;-0,20] 0,0230 -0,17 [-0,31;-0,02]
4-9	475 67,05 (12,19)	455 65,91 (12,51)	444 66,11 (12,90)	431 65,28 (13,01)	412 65,42 (13,37)	386 65,71 (12,88)	373 66,57 (12,80)	371 66,25 (12,52)	351 67,02 (13,31)	-1,40 (0,38)	486 66,54 (12,87)	468 67,71 (12,51)	467 67,66 (12,27)	443 67,62 (12,91)	429 67,61 (13,28)	418 67,50 (12,91)	386 67,45 (13,31)	385 67,71 (12,76)	359 67,85 (13,51)	0,62 (0,38)	-2,02 [-3,07;-0,96] 0,0002 -0,24 [-0,37;-0,12]
≥ 10	264 67,72 (12,65)	256 66,17 (13,08)	242 66,75 (12,73)	235 67,01 (12,97)	221 66,43 (13,47)	214 65,50 (13,75)	201 66,54 (12,92)	195 67,03 (13,70)	174 67,17 (12,49)	-1,54 (0,53)	265 66,62 (12,26)	256 67,16 (12,11)	246 66,70 (12,97)	241 67,22 (11,58)	222 66,96 (12,47)	207 67,95 (12,40)	194 67,31 (12,77)	196 67,19 (13,02)	173 67,47 (13,18)	0,15 (0,53)	-1,70 [-3,17;-0,22] 0,0245 -0,20 [-0,37;-0,03]
Tumorgrading (p-Wert des Interaktionsterms: 0,7330)																					
G1	81 65,74 (13,57)	78 66,99 (12,45)	81 66,36 (14,17)	74 66,46 (12,56)	70 65,76 (14,40)	68 66,09 (12,41)	68 66,97 (13,58)	67 67,30 (12,43)	62 67,60 (13,13)	0,37 (0,95)	84 68,35 (12,52)	83 69,76 (12,19)	80 69,45 (11,46)	75 69,79 (11,38)	78 67,62 (14,22)	73 68,86 (12,77)	66 69,58 (12,63)	67 69,06 (12,40)	59 68,80 (13,30)	1,10 (0,92)	-0,73 [-3,34;1,89] 0,5841 -0,09 [-0,39;0,22]
G2	526 67,40 (12,47)	509 65,63 (13,32)	488 66,11 (13,13)	467 65,77 (13,31)	448 65,63 (13,56)	420 65,20 (13,55)	392 66,63 (12,96)	401 66,05 (13,25)	367 66,92 (13,37)	-1,83 (0,37)	534 66,27 (12,61)	509 67,11 (12,00)	508 67,03 (12,21)	488 66,99 (12,49)	463 66,79 (12,75)	441 67,05 (12,67)	414 66,90 (12,89)	412 67,00 (12,72)	380 67,14 (13,01)	0,16 (0,36)	-1,99 [-3,00;-0,98] 0,0001 -0,24 [-0,36;-0,12]
G3	449 67,04 (12,80)	434 66,15 (12,88)	411 67,13 (12,44)	400 66,27 (12,83)	386 66,33 (13,15)	367 65,93 (13,36)	357 66,65 (13,27)	336 66,80 (13,71)	321 67,07 (13,38)	-0,73 (0,41)	436 66,23 (12,29)	416 67,27 (12,40)	415 67,21 (12,12)	389 67,34 (12,28)	374 68,31 (11,96)	360 67,76 (12,84)	337 67,89 (13,00)	327 67,56 (13,06)	303 67,82 (13,19)	1,07 (0,41)	-1,80 [-2,93;-0,66] 0,0019 -0,21 [-0,34;-0,08]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
GX	47 67,77 (11,11)	45 65,16 (11,41)	44 65,16 (12,23)	44 65,10 (12,22)	42 65,43 (13,17)	40 66,15 (13,72)	37 66,86 (12,50)	39 68,03 (12,05)	32 67,06 (11,74)	-2,32 (1,21)	53 68,85 (10,32)	53 67,79 (11,93)	52 68,50 (11,36)	50 67,16 (10,82)	47 68,84 (13,26)	43 66,86 (11,04)	41 66,34 (10,77)	40 65,78 (13,11)	33 66,88 (13,61)	-1,41 (1,14)	-0,91 [-4,22;2,39] 0,5843 -0,11 [-0,50;0,28]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6732)																					
Negativ	137 64,84 (12,77)	133 63,47 (14,07)	126 64,37 (13,99)	124 64,19 (13,43)	115 63,95 (14,01)	104 63,38 (13,74)	98 65,19 (13,00)	101 63,87 (12,82)	89 64,98 (13,16)	-1,36 (0,72)	149 66,00 (11,75)	143 66,73 (12,07)	141 67,15 (12,34)	133 66,90 (12,87)	125 67,04 (12,47)	117 66,96 (13,64)	105 65,74 (13,53)	104 66,61 (10,94)	92 67,20 (12,58)	0,46 (0,69)	-1,82 [-3,78;0,15] 0,0695 -0,22 [-0,45;0,02]
Positiv	937 67,27 (12,55)	904 66,00 (12,73)	870 66,52 (12,69)	838 65,97 (12,83)	811 65,95 (13,24)	770 65,60 (13,25)	732 66,56 (13,05)	721 66,73 (13,31)	673 67,09 (13,29)	-1,30 (0,28)	935 66,44 (12,46)	899 67,38 (12,15)	894 67,22 (12,07)	850 67,25 (12,13)	818 67,47 (12,65)	781 67,43 (12,56)	736 67,60 (12,71)	723 67,32 (13,11)	665 67,42 (13,22)	0,53 (0,28)	-1,82 [-2,59;-1,06] <,0001 -0,22 [-0,31;-0,12]
Unbekannt	9 71,78 (14,22)	9 69,89 (11,98)	9 76,67 (9,73)	7 80,57 (10,80)	3 89,67 (1,53)	7 77,43 (13,81)	8 79,00 (11,58)	7 77,71 (11,01)	5 80,80 (9,15)	4,62 (2,40)	7 72,71 (15,14)	6 79,00 (7,77)	6 75,50 (6,75)	6 80,67 (6,12)	6 76,00 (7,01)	6 74,67 (10,88)	5 79,20 (7,05)	6 81,83 (7,14)	5 78,40 (7,80)	7,22 (2,69)	-2,59 [-10,40;5,22] 0,4857 -0,34 [-1,28;0,60]
Ethnizität (p-Wert des Interaktionsterms: 0,4452)																					
Weiß	806 66,69 (12,56)	773 65,60 (12,79)	750 66,19 (12,57)	717 65,29 (12,75)	684 65,28 (13,24)	646 65,05 (13,01)	606 66,27 (12,75)	603 66,41 (12,92)	561 66,27 (12,94)	-1,51 (0,29)	820 66,51 (12,34)	778 67,49 (12,12)	777 67,54 (11,89)	730 66,99 (12,30)	700 67,37 (12,53)	670 67,40 (12,40)	614 67,21 (12,74)	613 67,23 (12,83)	548 67,14 (12,92)	0,44 (0,29)	-1,95 [-2,75;-1,15] <,0001 -0,24 [-0,33;-0,14]
Asiatisch	233 68,30 (12,61)	231 67,10 (12,98)	221 67,58 (13,32)	219 68,01 (13,43)	213 67,68 (14,02)	200 67,07 (14,19)	199 67,21 (13,92)	197 66,56 (14,31)	179 68,94 (14,06)	-0,42 (0,60)	221 66,98 (12,50)	218 67,57 (12,33)	215 67,24 (12,59)	213 68,35 (12,50)	204 68,56 (13,28)	193 67,99 (13,28)	191 68,25 (12,76)	185 67,77 (12,95)	181 68,85 (13,66)	0,75 (0,61)	-1,17 [-2,86;0,52] 0,1748 -0,13 [-0,31;0,06]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Andere	54 68,91 (12,62)	52 66,22 (14,62)	47 66,87 (14,60)	43 67,53 (13,03)	43 66,09 (13,41)	42 68,14 (14,14)	44 69,11 (14,20)	38 67,87 (13,91)	35 69,80 (12,59)	-0,83 (1,23)	57 67,18 (12,61)	57 66,91 (12,91)	55 67,44 (11,63)	51 68,75 (11,61)	50 66,61 (11,35)	46 68,07 (13,36)	45 70,38 (13,46)	40 67,55 (13,69)	40 68,23 (13,79)	0,04 (1,19)	-0,88 [-4,27;2,52] 0,6101 -0,10 [-0,47;0,28]
Endokrine Therapie zu Beginn (p-Wert des Interaktionsterms: 0,1508)																					
Tamoxifen	103 65,60 (11,07)	99 65,96 (11,13)	100 65,61 (12,41)	97 66,08 (11,75)	96 65,84 (12,92)	95 66,04 (12,47)	90 66,47 (12,74)	89 66,74 (12,88)	90 67,41 (12,34)	0,45 (0,80)	124 66,05 (11,49)	123 66,66 (10,67)	123 66,75 (11,20)	116 67,38 (11,75)	109 66,29 (11,73)	98 68,12 (12,18)	94 67,73 (10,70)	91 67,75 (12,10)	89 68,30 (11,33)	0,94 (0,73)	-0,49 [-2,63;1,65] 0,6537 -0,06 [-0,32;0,20]
Aromatase-Inhibitor	1002 67,30 (12,77)	969 65,91 (13,16)	926 66,59 (12,94)	890 65,98 (13,12)	852 65,89 (13,49)	802 65,54 (13,50)	766 66,68 (13,15)	756 66,52 (13,35)	693 66,99 (13,38)	-1,43 (0,27)	987 66,61 (12,52)	942 67,54 (12,38)	936 67,45 (12,21)	890 67,35 (12,36)	856 67,74 (12,71)	822 67,42 (12,75)	766 67,47 (13,07)	758 67,31 (12,95)	689 67,45 (13,32)	0,47 (0,27)	-1,89 [-2,64;-1,15] <,0001 -0,22 [-0,31;-0,14]
ECOG-PS (p-Wert des Interaktionsterms: 0,6622)																					
ECOG-PS 0	931 67,76 (12,37)	899 66,45 (12,86)	865 67,00 (12,78)	842 66,29 (12,97)	807 66,31 (13,35)	769 65,96 (13,35)	731 67,11 (12,89)	725 66,98 (12,98)	677 67,38 (13,03)	-1,31 (0,27)	899 67,13 (12,33)	861 67,99 (12,03)	858 67,85 (11,88)	819 67,73 (11,94)	788 67,89 (12,64)	754 67,76 (12,57)	699 67,70 (12,71)	691 67,55 (12,67)	629 67,95 (12,96)	0,31 (0,28)	-1,62 [-2,38;-0,86] <,0001 -0,19 [-0,29;-0,10]
ECOG-PS 1	174 63,83 (13,45)	169 63,07 (13,26)	161 63,80 (13,18)	145 64,28 (13,01)	141 63,45 (13,66)	128 63,41 (13,44)	125 63,98 (13,99)	120 63,89 (14,85)	106 64,84 (14,51)	-0,94 (0,70)	212 64,08 (12,49)	204 65,10 (12,64)	201 65,33 (12,82)	187 65,71 (13,61)	177 66,18 (12,41)	166 66,31 (13,15)	161 66,63 (13,30)	158 66,54 (13,62)	149 65,84 (13,63)	1,56 (0,62)	-2,50 [-4,34;-0,65] 0,0081 -0,27 [-0,47;-0,07]

	Abemaciclib+ET[1]										ET[1]										Abemaciclib+ET vs. ET[1]
Subgruppe	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	B N MW (SD)	M3 N MW (SD)	M6 N MW (SD)	M12 N MW (SD)	M18 N MW (SD)	M24 N MW (SD)	T30 FUP[2] N MW (SD)	M6 FUP[3] N MW (SD)	M12 FUP[3] N MW (SD)	PB LSM (SE)	Differenz Δ [95% KI] p-Wert[4] Hedges'g [95% KI]
Datenschnitt: 01.07.2022 Safety-Population 1: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: 30 Tage Follow-up; 3: 6 bzw. 12 Monate Follow-up; 4: p-Wert für Treatment Effekt aus dem MMRM Modell: Veränderung des FACT-B TOI = Baseline, Behandlung, Visite, Behandlung*Visite. Die Analyse berücksichtigt alle Visiten, an denen mindestens 25% aller Patienten beider Behandlungsgruppen Werte für die Veränderung des FACT-B TOI haben. Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Abkürzungen: B: Baseline; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSM: Least Squares Mean; M: Monat; mm: Millimeter; MW: Mittelwert; N: Anzahl der Patienten mit Werten in der jeweiligen Visite; PB: Post-Baseline; RCT: Randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; TOI: Trial Outcome Index.																				

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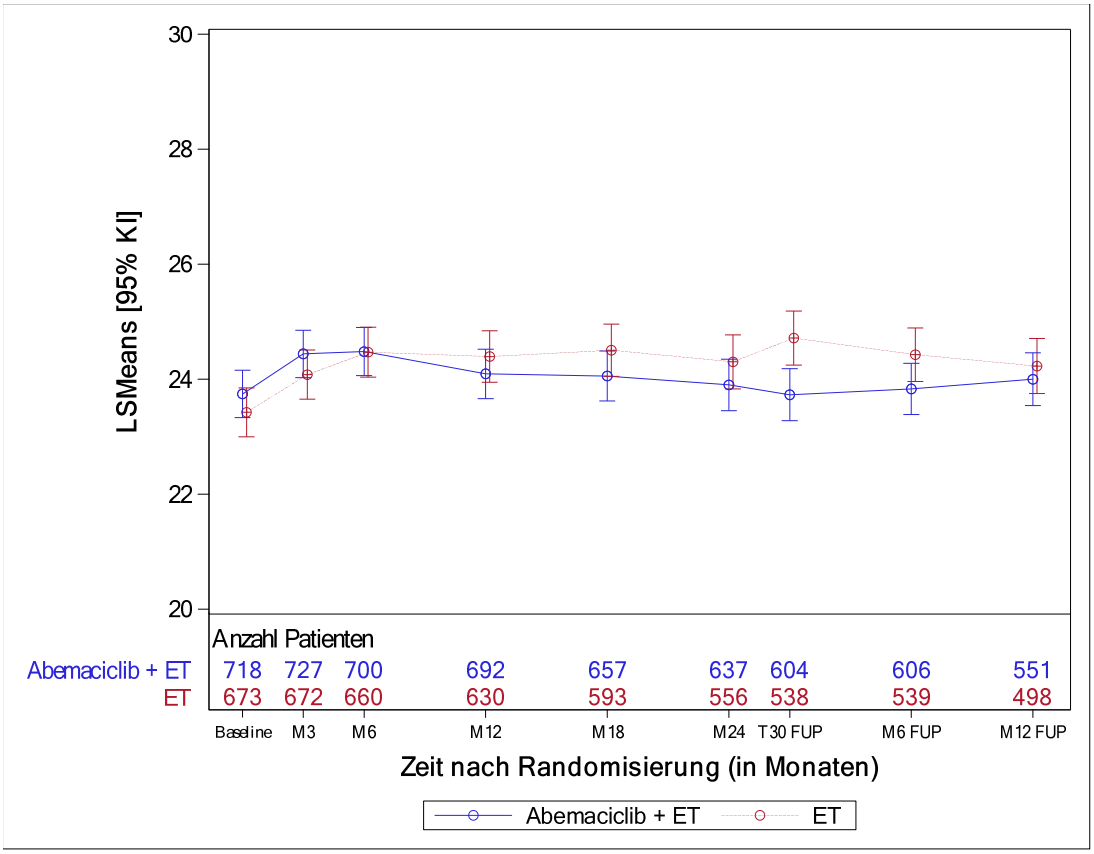
29OCT2025 / 08:23

Anhang 4-G3.4.2: Verlaufskurven der Subskalen des FACT-B

Verlaufskurven - FACT-B-Subskala: BCS
Kohorte 1 Population - Safety - Prämenopausal



Datenschnitt: 01.07.2022
Prämenopausal: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
LSMeans aus dem MMRM Modell: FACT-B BCS = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: BCS: Mammakarzinomspezifische Subskala; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FUP: Follow-up; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; T: Tag.
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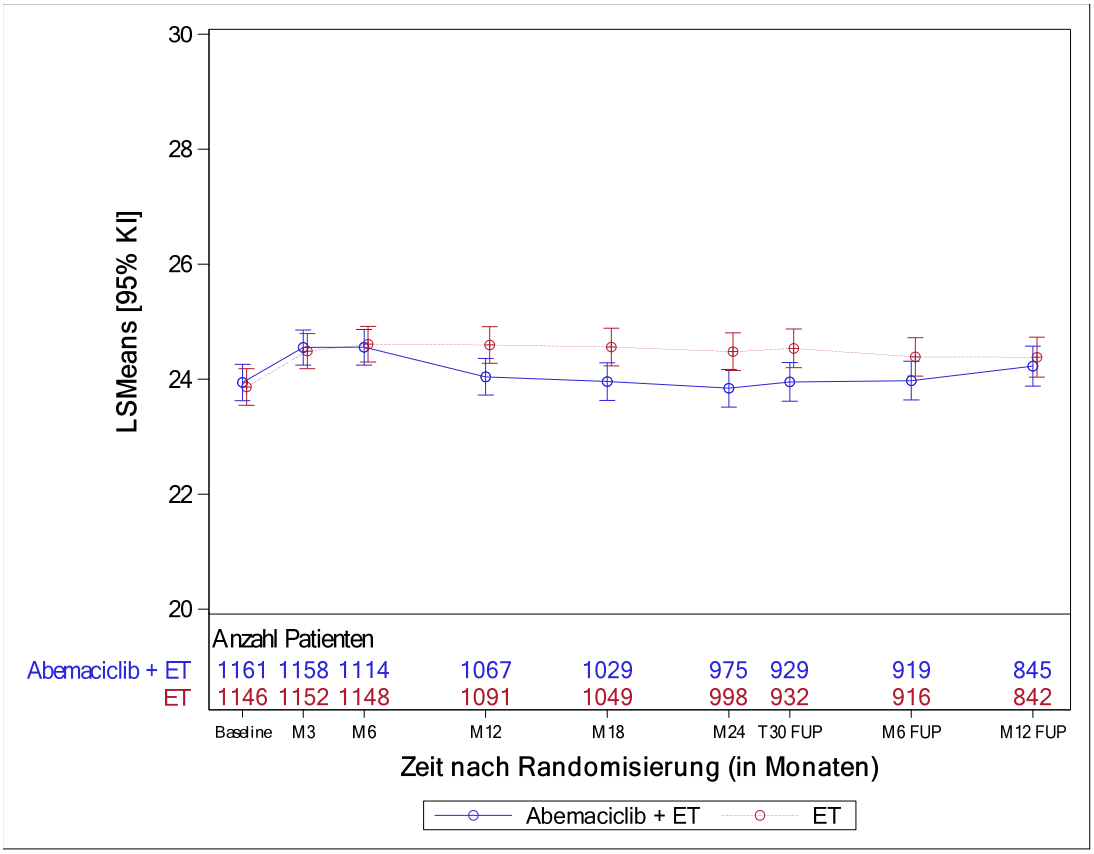
23OCT2025 / 02:27

Verlaufskurven - FACT-B-Subskala: BCS
Kohorte 1 Population - Safety - Postmenopausal



Datenschnitt: 01.07.2022
Postmenopausal: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
LSMeans aus dem MMRM Modell: FACT-B BCS = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: BCS: Mammakarzinomspezifische Subskala; ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FUP: Follow-up; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; T: Tag.
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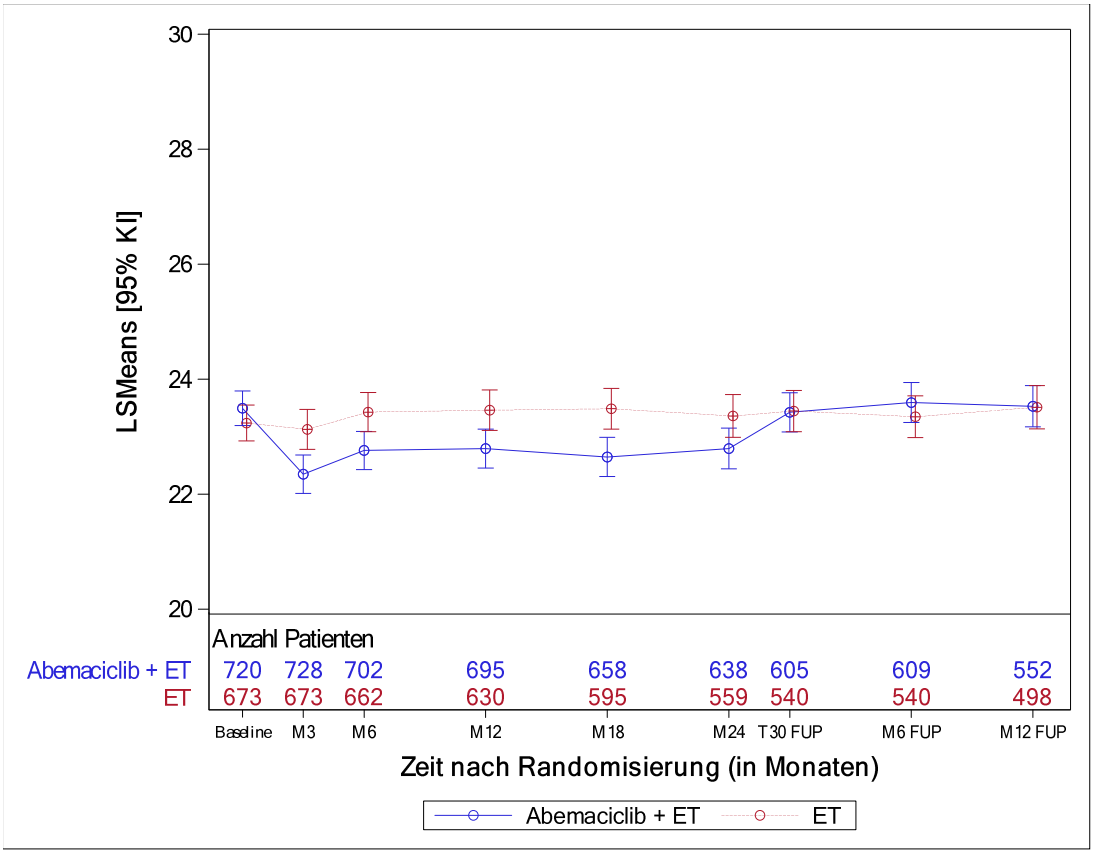
23OCT2025 / 02:27

Verlaufskurven - FACT-B-Subskala: PWB
Kohorte 1 Population - Safety - Prämenopausal



Datenschnitt: 01.07.2022
Prämenopausal: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
LSMeans aus dem MMRM Modell: FACT-B PWB = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FUP: Follow-up; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; PWB: körperliches Wohlbefinden; RCT: Randomisierte, kontrollierte Studie; T: Tag .
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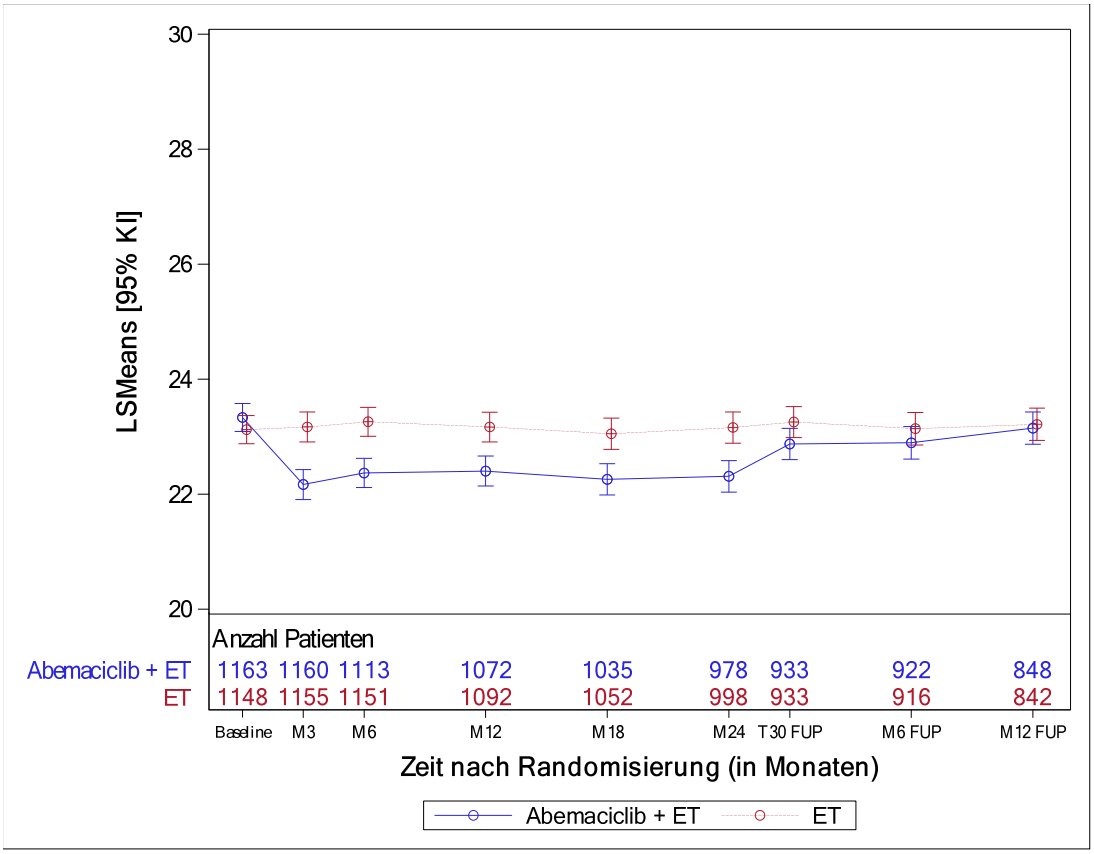
Verlaufskurven - FACT-B-Subskala: PWB
Kohorte 1 Population - Safety - Postmenopausal



Datenschnitt: 01.07.2022
Postmenopausal: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
LSMeans aus dem MMRM Modell: FACT-B PWB = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FUP: Follow-up; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; PWB: körperliches Wohlbefinden; RCT: Randomisierte, kontrollierte Studie; T: Tag .
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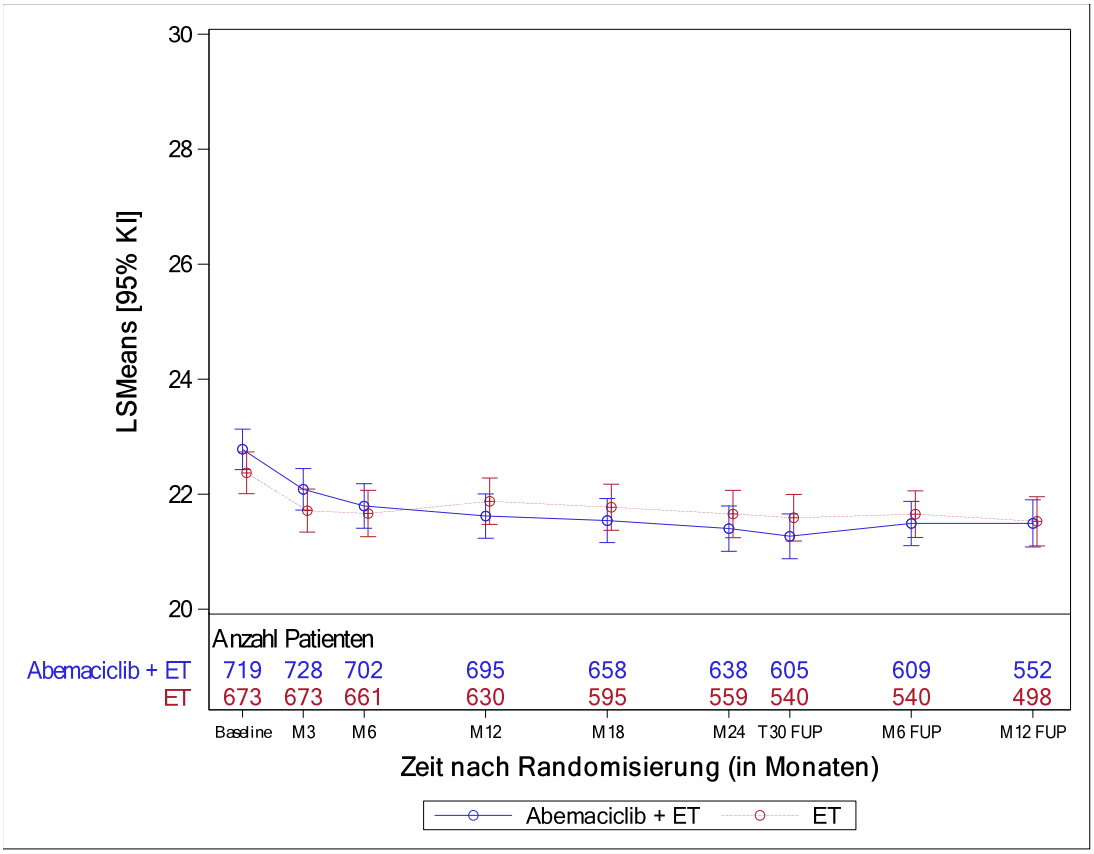
Verlaufskurven - FACT-B-Subskala: SWB
Kohorte 1 Population - Safety - Prämenopausal



Datenschnitt: 01.07.2022
Prämenopausal: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
LSMeans aus dem MMRM Modell: FACT-B SWB = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FUP: Follow-up; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; SWB: soziales und familiäres Wohlbefinden; T: Tag.
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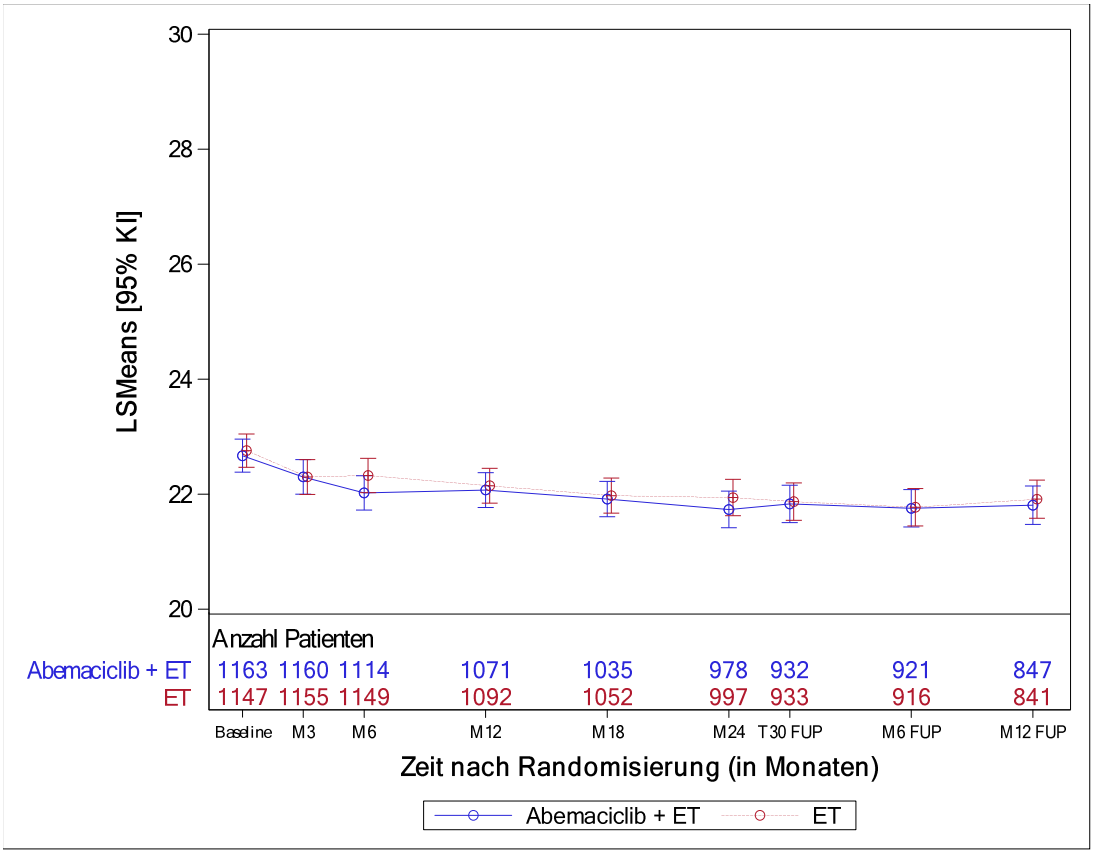
23OCT2025 / 02:27

Verlaufskurven - FACT-B-Subskala: SWB
Kohorte 1 Population - Safety - Postmenopausal



Datenschnitt: 01.07.2022
Postmenopausal: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
LSMeans aus dem MMRM Modell: FACT-B SWB = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FUP: Follow-up; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; SWB: soziales und familiäres Wohlbefinden; T: Tag.
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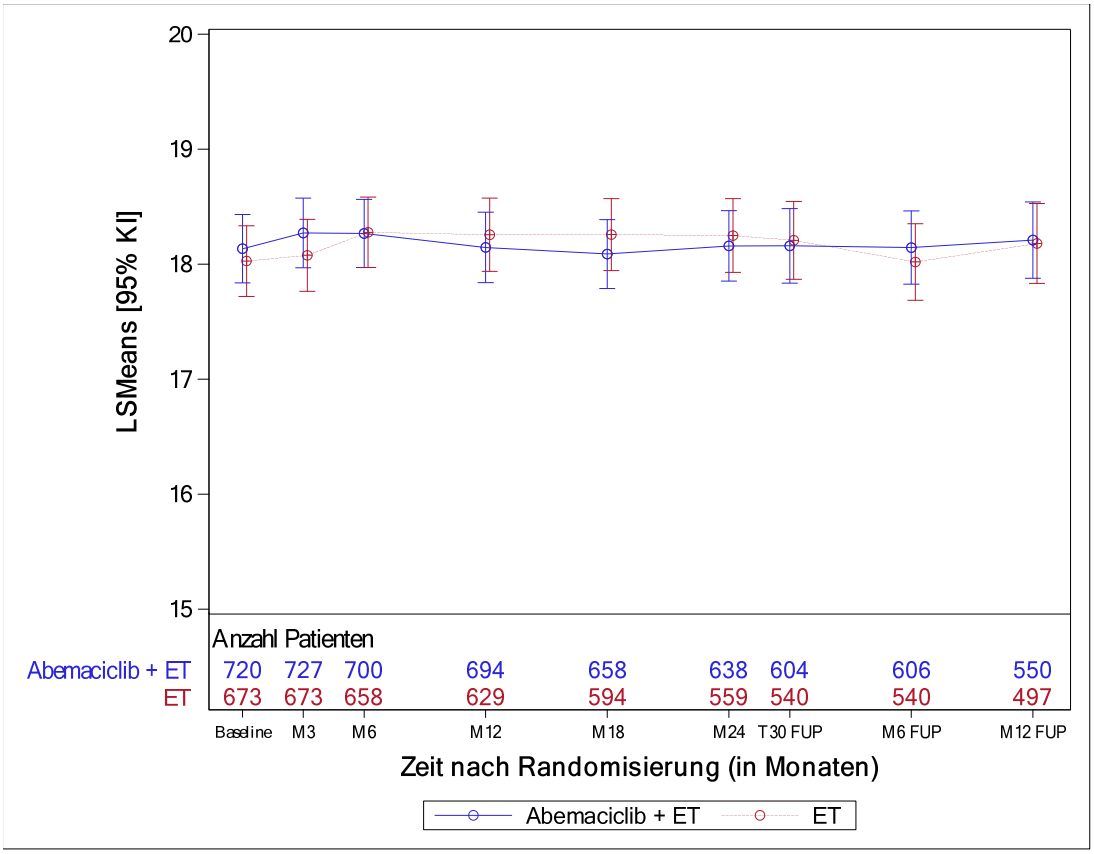
23OCT2025 / 02:27

Verlaufskurven - FACT-B-Subskala: EWB
Kohorte 1 Population - Safety - Prämenopausal



Datenschnitt: 01.07.2022
Prämenopausal: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
LSMeans aus dem MMRM Modell: FACT-B EWB = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; EWB: emotionales Wohlbefinden; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FUP: Follow-up; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; T: Tag.
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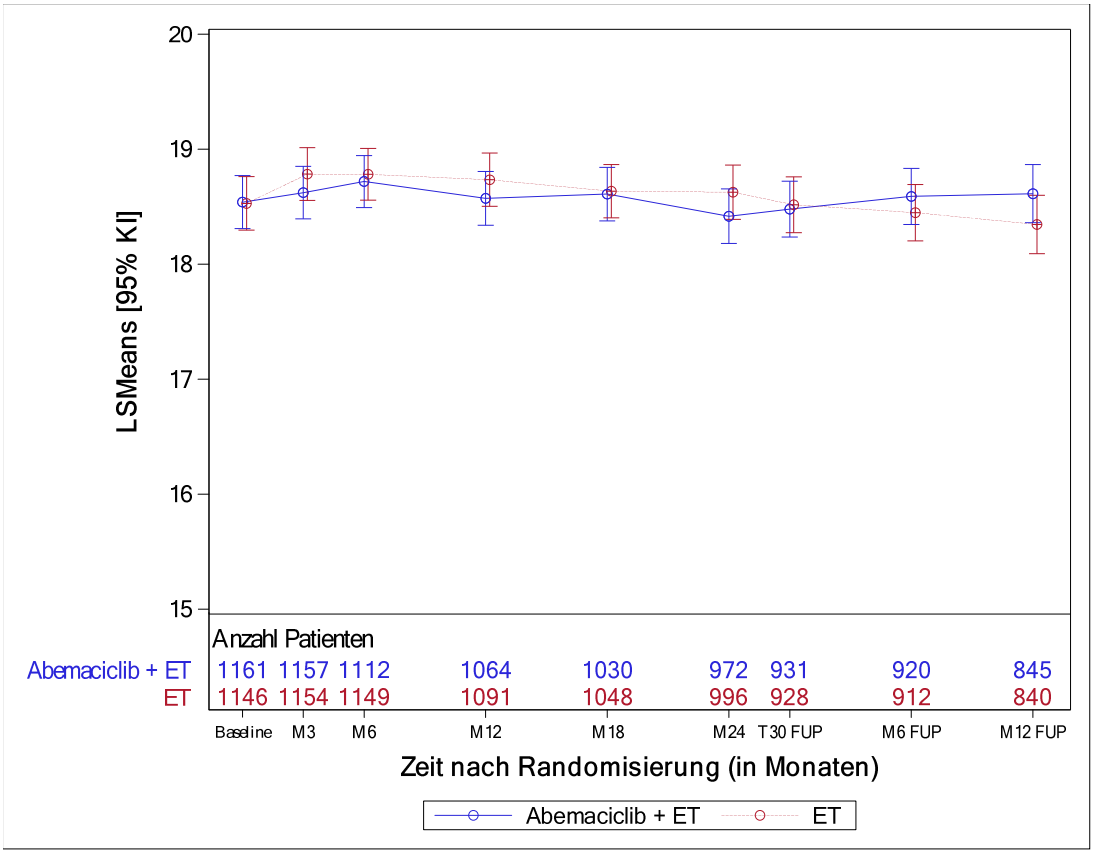
Verlaufskurven - FACT-B-Subskala: EWB
Kohorte 1 Population - Safety - Postmenopausal



Datenschnitt: 01.07.2022
Postmenopausal: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
LSMeans aus dem MMRM Modell: FACT-B EWB = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; EWB: emotionales Wohlbefinden; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FUP: Follow-up; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; T: Tag.
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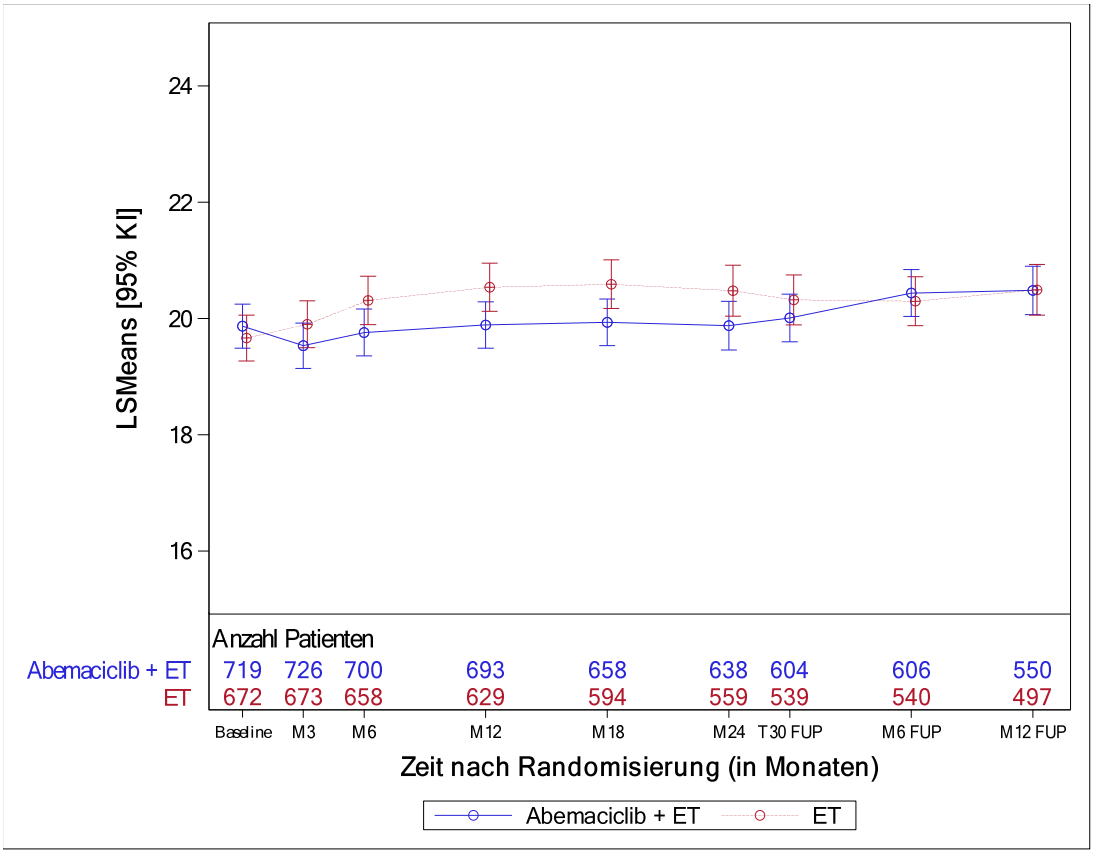
Verlaufskurven - FACT-B-Subskala: FWB
Kohorte 1 Population - Safety - Prämenopausal



Datenschnitt: 01.07.2022
Prämenopausal: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
LSMeans aus dem MMRM Modell: FACT-B FWB = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FWB: funktionales Wohlbefinden; FUP: Follow-up; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; T: Tag.
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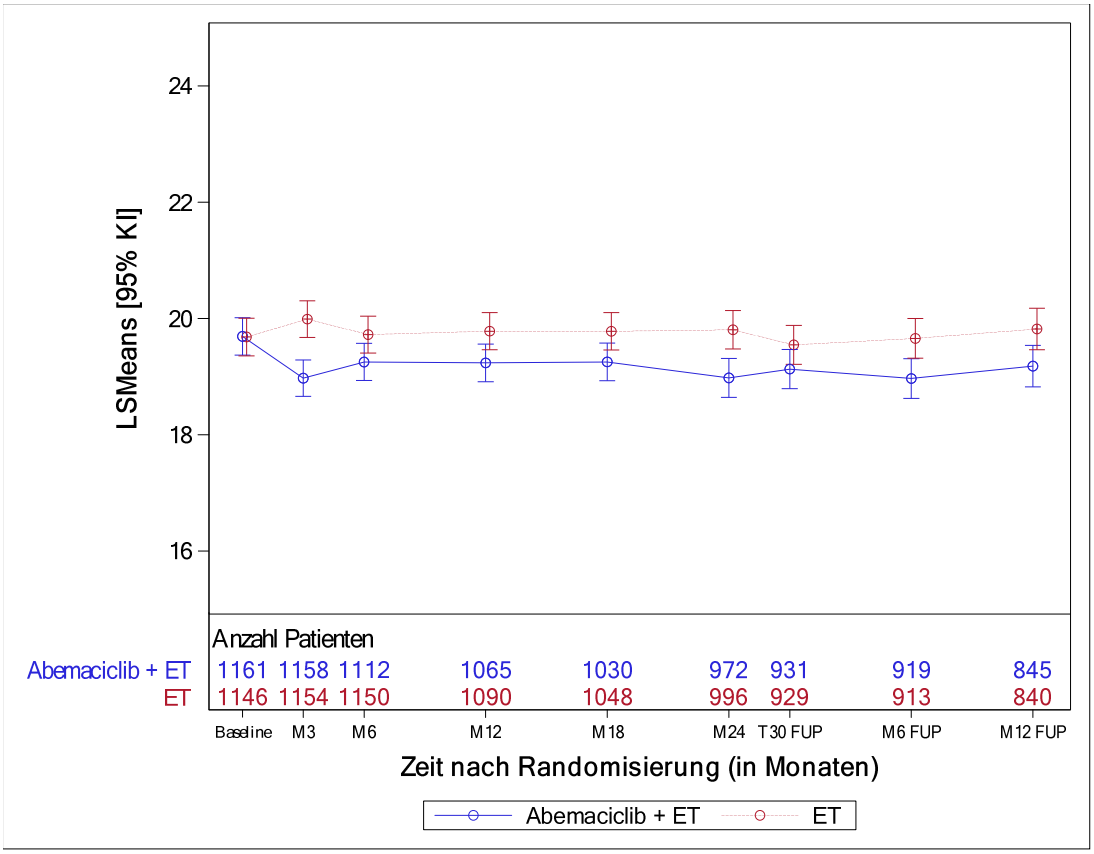
23OCT2025 / 02:27

Verlaufskurven - FACT-B-Subskala: FWB
Kohorte 1 Population - Safety - Postmenopausal



Datenschnitt: 01.07.2022
Postmenopausal: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
LSMeans aus dem MMRM Modell: FACT-B FWB = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FWB: funktionales Wohlbefinden; FUP: Follow-up; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; T: Tag.
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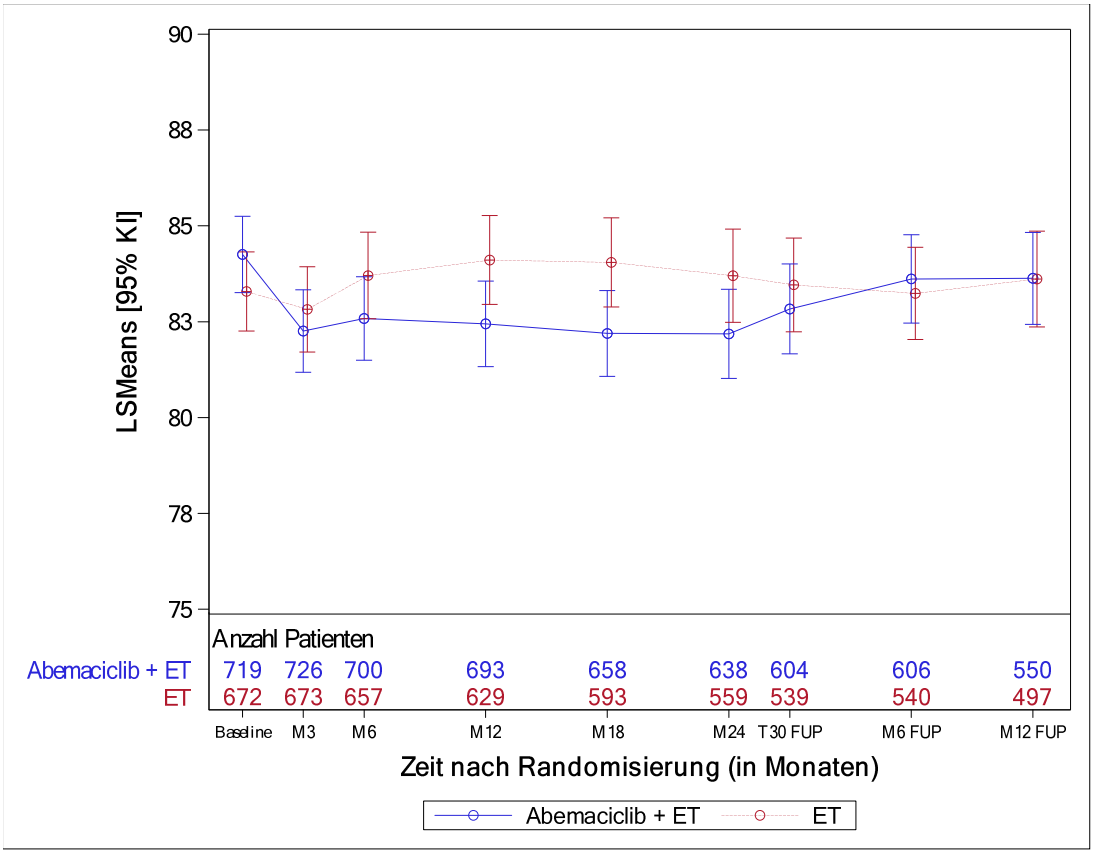
Verlaufskurven - FACT-G (Gesamtscore)
Kohorte 1 Population - Safety - Prämenopausal



Datenschnitt: 01.07.2022
Prämenopausal: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
LSMeans aus dem MMRM Modell: FACT-G Gesamtscore = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACT-G: Functional Assessment of Cancer Therapy - General; FUP: Follow-up; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; T: Tag.
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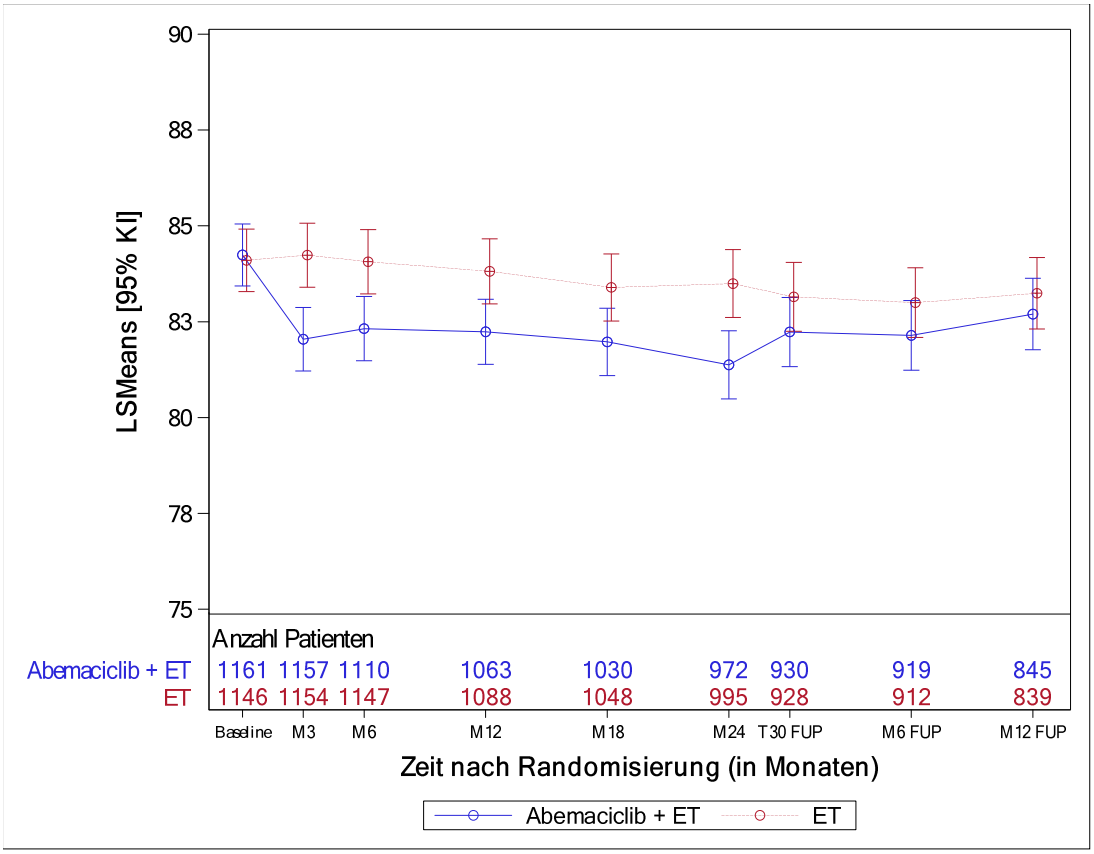
Verlaufskurven - FACT-G (Gesamtscore)
Kohorte 1 Population - Safety - Postmenopausal



Datenschnitt: 01.07.2022
Postmenopausal: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
LSMeans aus dem MMRM Modell: FACT-G Gesamtscore = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACT-G: Functional Assessment of Cancer Therapy - General; FUP: Follow-up; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; T: Tag.
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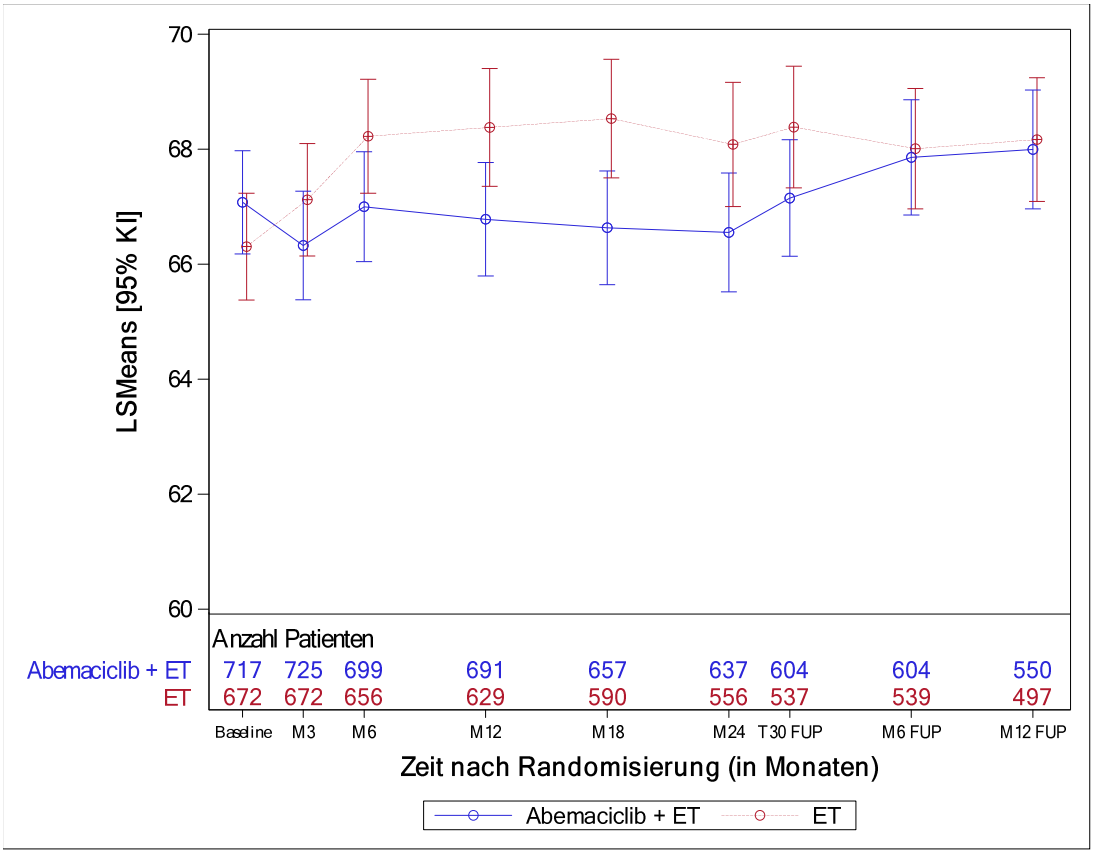
Verlaufskurven - FACT-B: TOI
Kohorte 1 Population - Safety - Prämenopausal



Datenschnitt: 01.07.2022
Prämenopausal: gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
LSMeans aus dem MMRM Modell: FACT-B TOI = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FUP: Follow-up; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; T: Tag; TOI: Trial Outcome Index.
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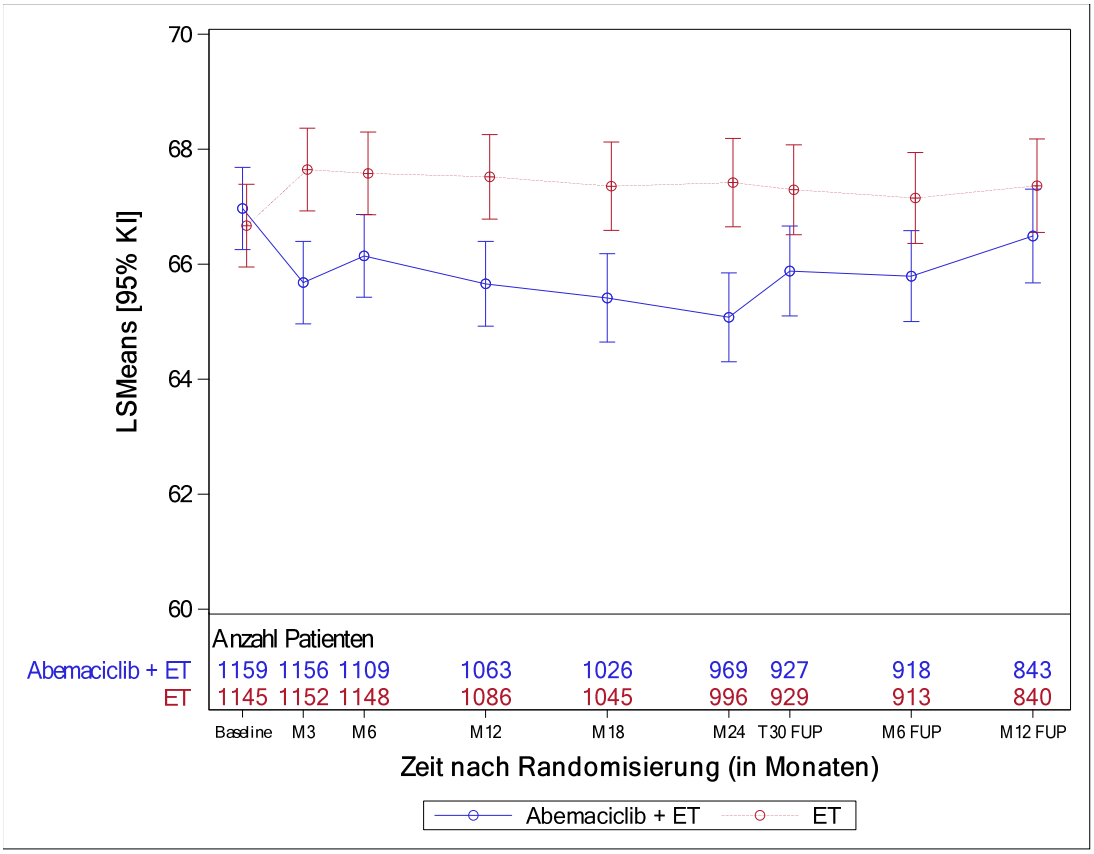
Verlaufskurven - FACT-B: TOI
Kohorte 1 Population - Safety - Postmenopausal



Datenschnitt: 01.07.2022
Postmenopausal: gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
LSMeans aus dem MMRM Modell: FACT-B TOI = Behandlung, Visite, Behandlung*Visite.
Die Follow-Up Beobachtungen für Patienten mit Therapieabbruch wurden der zeitlich entsprechenden Visite zugeordnet. Im Fall von mehreren Beobachtungen an einer Visite wurde der Mittelwert verwendet.
Nur Baseline-Werte, die vor Gabe der Studienmedikation erhoben wurden, gehen in die Analyse ein.
Abkürzungen: ET: Endokrine Therapie; FACT-B: Functional Assessment of Cancer Therapy - Breast Cancer; FUP: Follow-up; KI: Konfidenzintervall; LSMean: Least Squares Mean; M: Monat; RCT: Randomisierte, kontrollierte Studie; T: Tag; TOI: Trial Outcome Index.
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Anhang 4-G4: Ergänzende Ergebnisdarstellung des Datenschnitts vom 03.07.2023

Anhang 4-G4.1: Gesamtüberleben

Anhang 4-G4.1.1: Ergänzende Ergebnissdarstellung

Tabelle 001: Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Kohorte 1 Population - ITT

Population	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
Gesamtüberleben					
Prämenopausal	45/777 (5,8)	NE [NE; NE]	52/728 (7,1)	NE [NE; NE]	0,80 [0,54; 1,19] 0,2687
Postmenopausal	119/1284 (9,3)	NE [NE; NE]	145/1263 (11,5)	NE [NE; NE]	0,83 [0,65; 1,05] 0,1205

Datenschnitt: 03.07.2023
ITT-Population
1: Aus Log-rank-Test; 2: In Monaten; 3: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; n: Anzahl verstorbener Patienten; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte, kontrollierte Studie.

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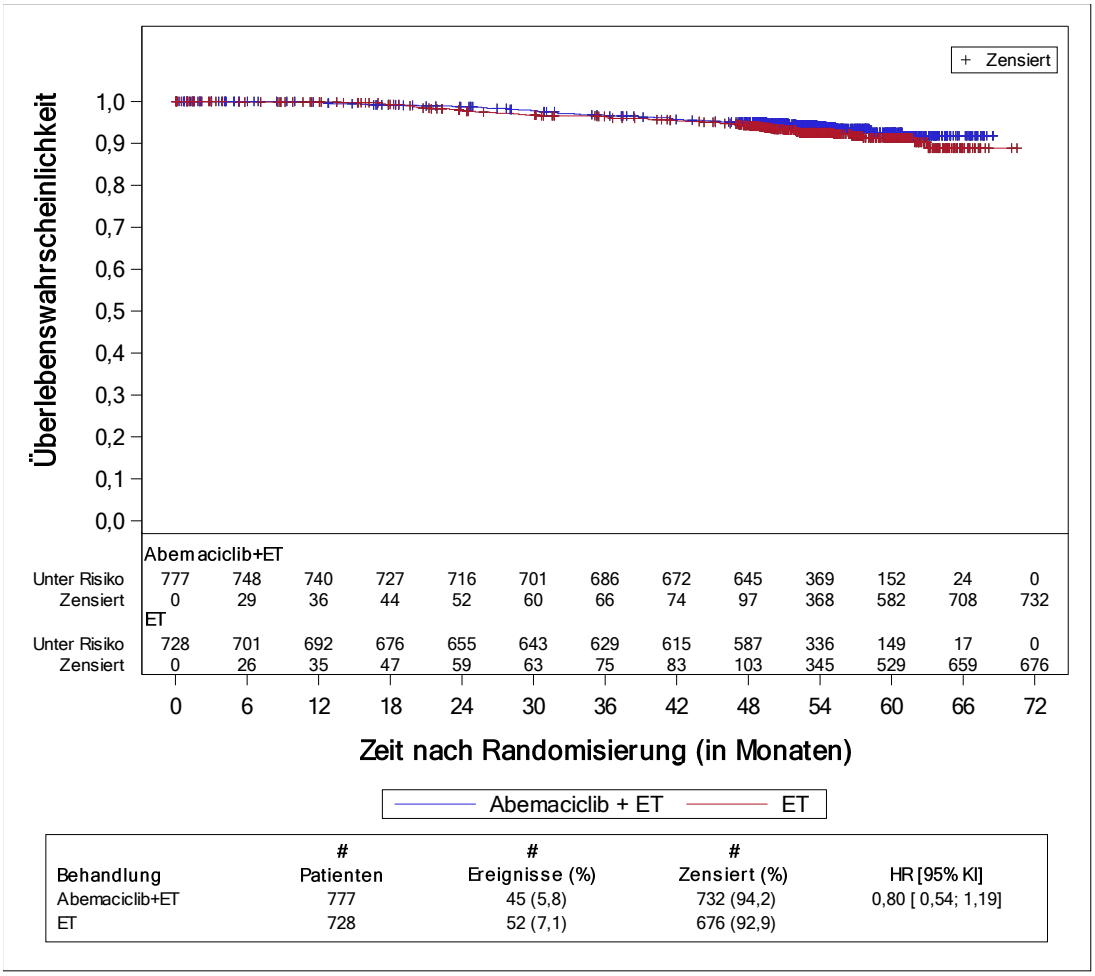
Anhang 4-G4.1.2: Kaplan-Meier-Kurven

Kaplan-Meier-Kurven - Gesamtüberleben
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	45 (5,8)	732 (94,2)	0,80 [0,54; 1,19]
ET	728	52 (7,1)	676 (92,9)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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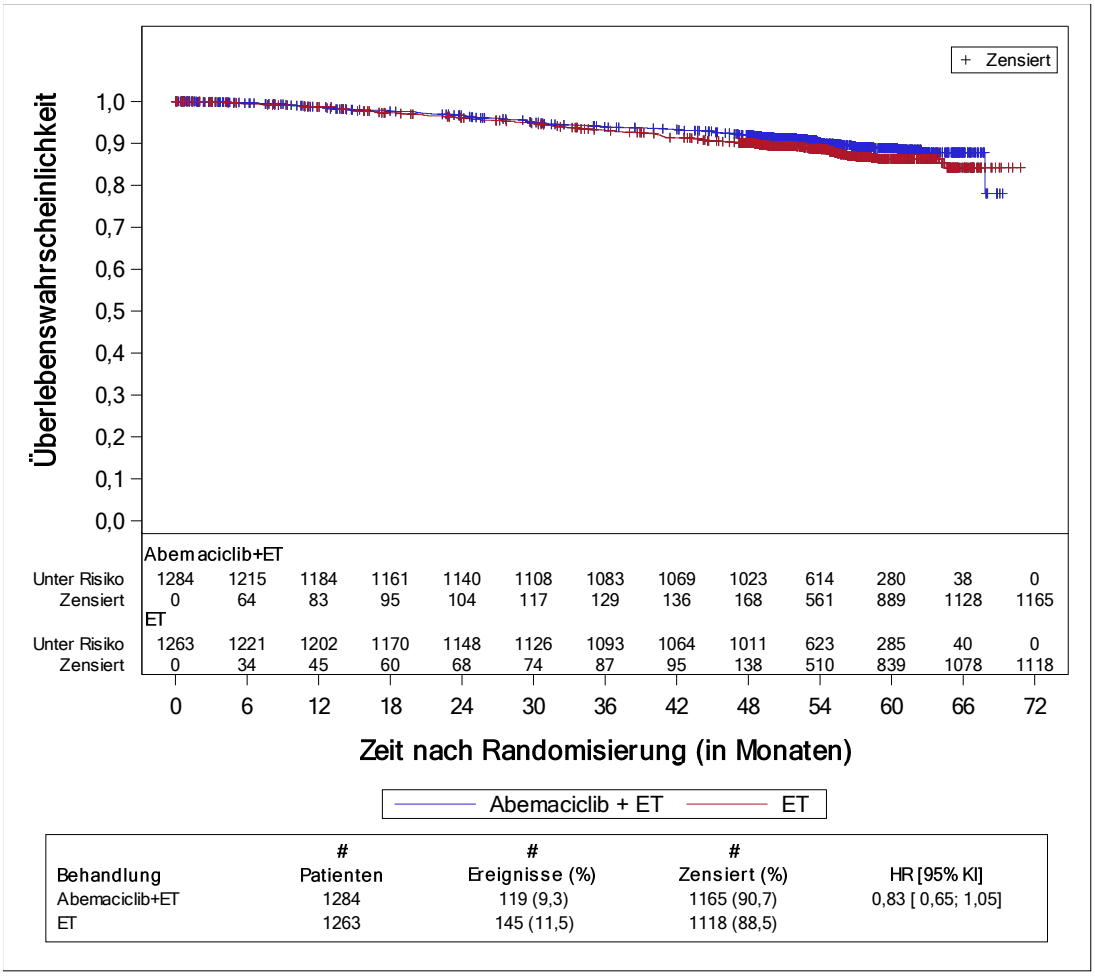
14OCT2025 / 07:36

Kaplan-Meier-Kurven - Gesamtüberleben
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	119 (9,3)	1165 (90,7)	0,83 [0,65; 1,05]
ET	1263	145 (11,5)	1118 (88,5)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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Anhang 4-G4.2: Invasives krankheitsfreies Überleben

Anhang 4-G4.2.1: Ergänzende Ergebnissdarstellung

Tabelle 002: Ergebnisse für IDFS aus RCT mit dem zu bewertenden Arzneimittel
Kohorte 1 Population - ITT

Population	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
IDFS					
Prämenopausal	96/777 (12,4)	NE [NE; NE]	174/728 (23,9)	NE [NE; NE]	0,48 [0,37; 0,61] <,0001
Postmenopausal	220/1284 (17,1)	NE [NE; NE]	302/1263 (23,9)	NE [NE; NE]	0,71 [0,60; 0,85] 0,0001
lokales Brustkrebsrezidiv					
Prämenopausal	7/777 (0,9)	NE [NE; NE]	16/728 (2,2)	NE [NE; NE]	0,38 [0,16; 0,93] 0,0270
Postmenopausal	23/1284 (1,8)	NE [NE; NE]	24/1263 (1,9)	NE [NE; NE]	0,94 [0,53; 1,66] 0,8309
regionäres invasives Brustkrebsrezidiv					
Prämenopausal	5/777 (0,6)	NE [NE; NE]	7/728 (1,0)	NE [NE; NE]	0,61 [0,19; 1,93] 0,3961
Postmenopausal	12/1284 (0,9)	NE [NE; NE]	16/1263 (1,3)	NE [NE; NE]	0,74 [0,35; 1,57] 0,4320
Fernrezidiv					
Prämenopausal	73/777 (9,4)	NE [NE; NE]	139/728 (19,1)	NE [NE; NE]	0,45 [0,34; 0,60] <,0001
Postmenopausal	133/1284 (10,4)	NE [NE; NE]	214/1263 (16,9)	NE [NE; NE]	0,61 [0,49; 0,76] <,0001
Tod jeglicher Ursache					
Prämenopausal	1/777 (0,1)	NE [NE; NE]	4/728 (0,5)	NE [NE; NE]	0,21 [0,02; 1,90] 0,1261
Postmenopausal	31/1284 (2,4)	NE [NE; NE]	20/1263 (1,6)	NE [NE; NE]	1,51 [0,86; 2,65] 0,1469
kontralateraler invasiver Brustkrebs					
Prämenopausal	6/777 (0,8)	NE [NE; NE]	7/728 (1,0)	NE [NE; NE]	0,74 [0,25; 2,19] 0,5795
Postmenopausal	4/1284 (0,3)	NE [NE; NE]	8/1263 (0,6)	NE [NE; NE]	0,49 [0,15; 1,63] 0,2356
Sekundäres Primärkarzinom (kein Brustkrebs)					
Prämenopausal	5/777 (0,6)	NE [NE; NE]	7/728 (1,0)	NE [NE; NE]	0,63 [0,20; 1,97] 0,4199

Population	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
Postmenopausal	24/1284 (1,9)	NE [NE; NE]	26/1263 (2,1)	NE [NE; NE]	0,90 [0,52; 1,57] 0,7132

Datenschnitt: 03.07.2023
ITT-Population
1: Aus Log-rank-Test; 2: In Monaten; 3: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; IDFS: Invasives krankheitsfreies Überleben (invasive disease-free survival); ITT: Intention to Treat; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte, kontrollierte Studie.

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Tabelle 003: Ergebnisse für IDFS-Rezidivrate aus RCT mit dem zu bewertenden Arzneimittel Kohorte 1 Population - ITT

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
IDFS (Rezidive, Gesamt)					
Prämenopausal	96/777 (12,4)	174/728 (23,9)	0,52 [0,41; 0,65] <,0001[2]	0,45 [0,34; 0,59] <,0001[3]	-11,5 [-15,4; -7,7] <,0001[3]
Postmenopausal	220/1284 (17,1)	302/1263 (23,9)	0,72 [0,61; 0,84] <,0001[2]	0,66 [0,54; 0,80] <,0001[3]	-6,8 [-9,9; -3,6] <,0001[3]
lokales Brustkrebsrezidiv					
Prämenopausal	7/777 (0,9)	16/728 (2,2)	0,41 [0,17; 0,99] 0,0476[2]	0,40 [0,17; 0,99] 0,0404[3]	-1,3 [-2,6; -0,0] 0,0404[3]
Postmenopausal	23/1284 (1,8)	24/1263 (1,9)	0,94 [0,53; 1,66] 0,8382[2]	0,94 [0,53; 1,68] 0,8381[3]	-0,1 [-1,2; 0,9] 0,8381[3]
regionäres invasives Brustkrebsrezidiv					
Prämenopausal	5/777 (0,6)	7/728 (1,0)	0,67 [0,21; 2,10] 0,4911[2]	0,67 [0,21; 2,11] 0,4881[3]	-0,3 [-1,2; 0,6] 0,4881[3]
Postmenopausal	12/1284 (0,9)	16/1263 (1,3)	0,74 [0,35; 1,55] 0,4232[2]	0,74 [0,35; 1,56] 0,4214[3]	-0,3 [-1,1; 0,5] 0,4214[3]
Fernrezidiv					
Prämenopausal	73/777 (9,4)	139/728 (19,1)	0,49 [0,38; 0,64] <,0001[2]	0,44 [0,32; 0,60] <,0001[3]	-9,7 [-13,2; -6,2] <,0001[3]
Postmenopausal	133/1284 (10,4)	214/1263 (16,9)	0,61 [0,50; 0,75] <,0001[2]	0,57 [0,45; 0,71] <,0001[3]	-6,6 [-9,2; -3,9] <,0001[3]
Tod jeglicher Ursache					
Prämenopausal	1/777 (0,1)	4/728 (0,5)	0,23 [0,03; 2,09] 0,1937[2]	0,23 [0,03; 2,09] 0,2039[4]	-0,4 [-1,0; 0,2] 0,2039[4]
Postmenopausal	31/1284 (2,4)	20/1263 (1,6)	1,52 [0,87; 2,66] 0,1376[2]	1,54 [0,87; 2,71] 0,1345[3]	0,8 [-0,3; 1,9] 0,1345[3]
kontralateraler invasiver Brustkrebs					
Prämenopausal	6/777 (0,8)	7/728 (1,0)	0,80 [0,27; 2,38] 0,6922[2]	0,80 [0,27; 2,40] 0,6916[3]	-0,2 [-1,1; 0,7] 0,6916[3]
Postmenopausal	4/1284 (0,3)	8/1263 (0,6)	0,49 [0,15; 1,63] 0,2455[2]	0,49 [0,15; 1,63] 0,2356[3]	-0,3 [-0,9; 0,2] 0,2356[3]
Sekundäres Primärkarzinom (kein Brustkrebs)					
Prämenopausal	5/777 (0,6)	7/728 (1,0)	0,67 [0,21; 2,10] 0,4911[2]	0,67 [0,21; 2,11] 0,4881[3]	-0,3 [-1,2; 0,6] 0,4881[3]

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Postmenopausal	24/1284 (1,9)	26/1263 (2,1)	0,91 [0,52; 1,57] 0,7305[2]	0,91 [0,52; 1,59] 0,7304[3]	-0,2 [-1,3; 0,9] 0,7304[3]

Datenschnitt: 03.07.2023
ITT-Population
1: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; IDFS: Invasives krankheitsfreies Überleben (invasive disease-free survival); ITT: Intention to Treat; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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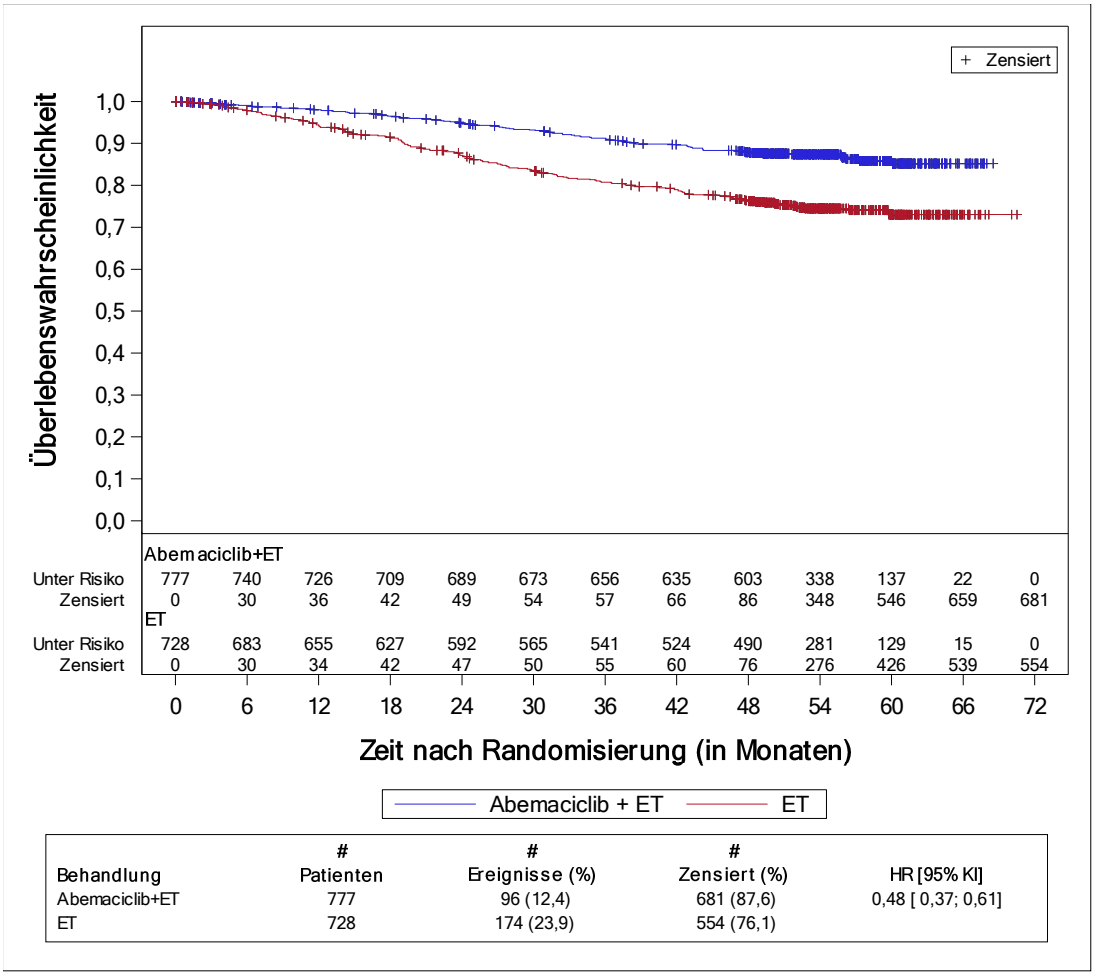
Anhang 4-G4.2.2: Kaplan-Meier-Kurven

Kaplan-Meier-Kurven - IDFS
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	96 (12,4)	681 (87,6)	0,48 [0,37; 0,61]
ET	728	174 (23,9)	554 (76,1)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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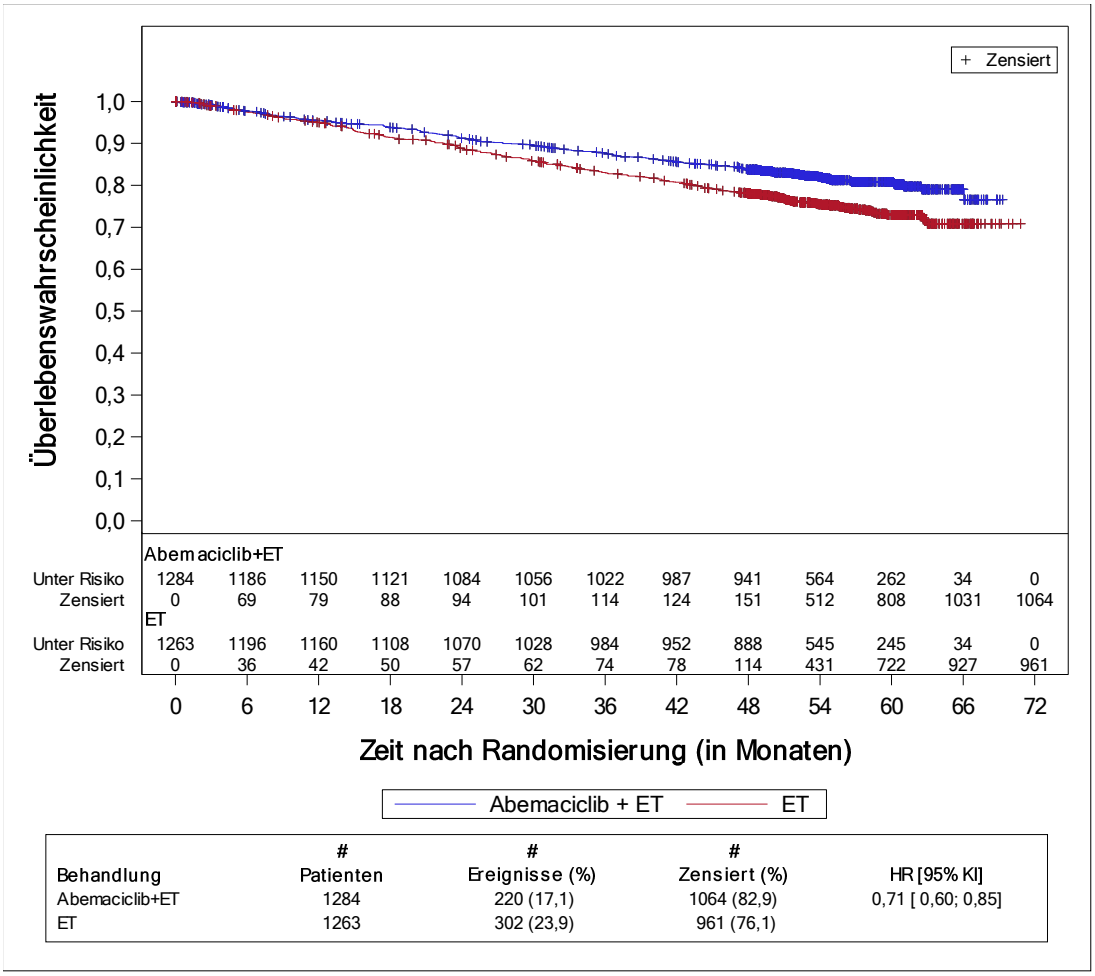
Kaplan-Meier-Kurven - IDFS
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	220 (17,1)	1064 (82,9)	0,71 [0,60; 0,85]
ET	1263	302 (23,9)	961 (76,1)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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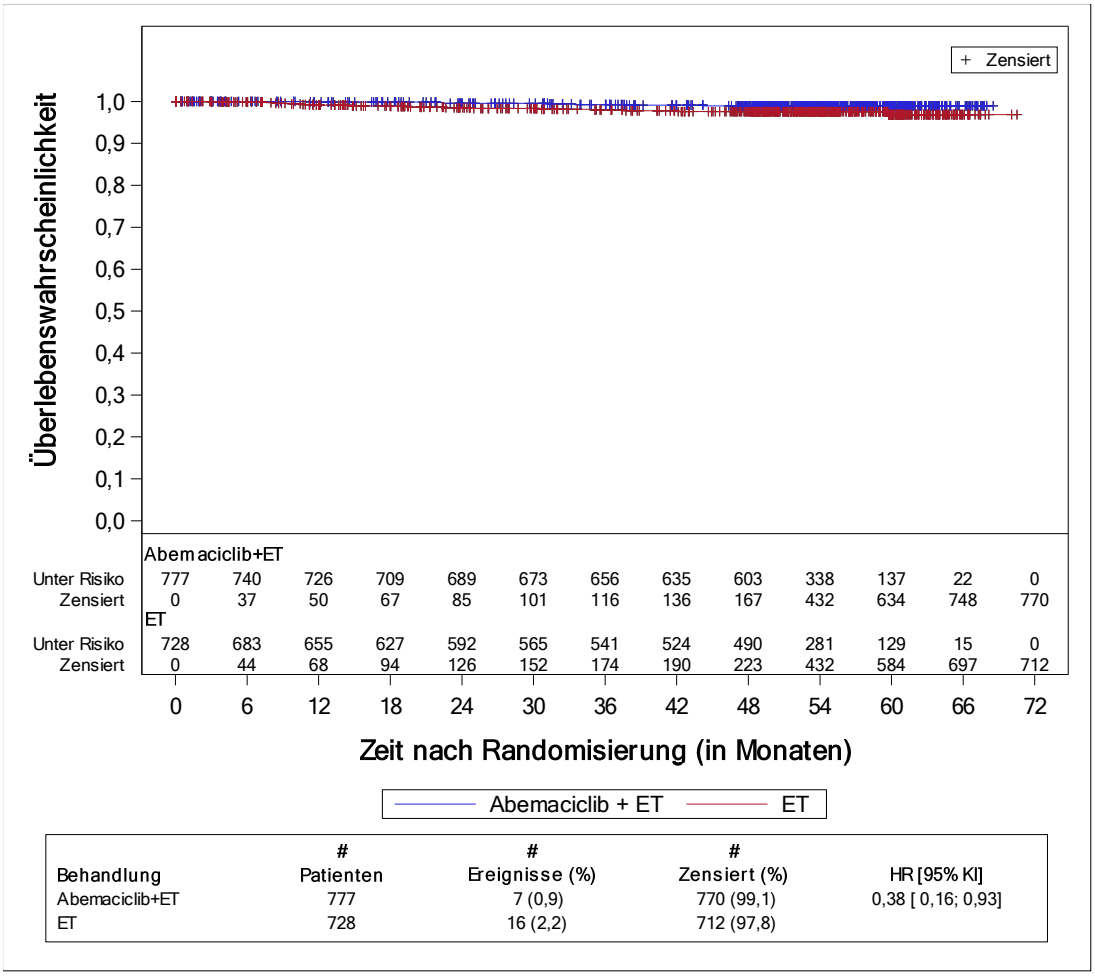
Kaplan-Meier-Kurven - lokales Brustkrebsrezidiv
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	7 (0,9)	770 (99,1)	0,38 [0,16; 0,93]
ET	728	16 (2,2)	712 (97,8)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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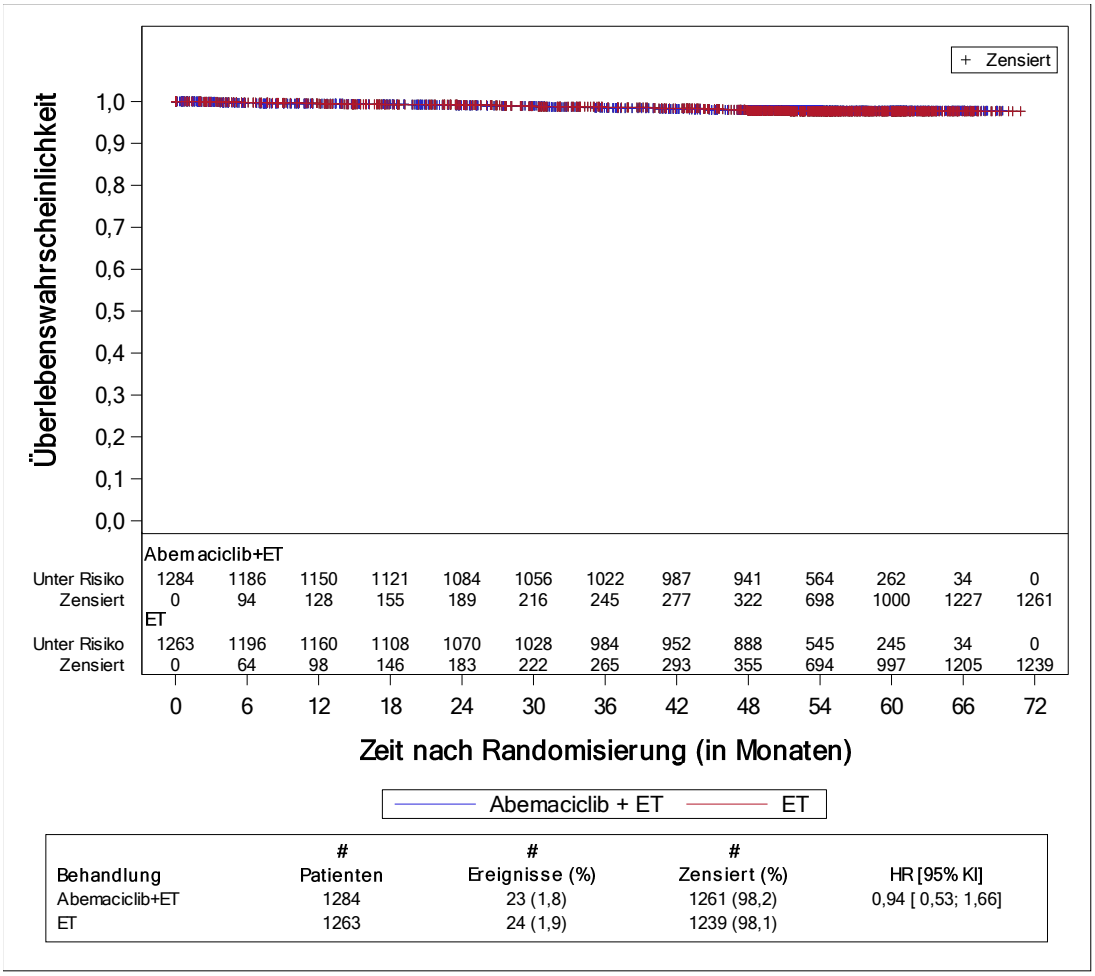
Kaplan-Meier-Kurven - lokales Brustkrebsrezidiv
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	23 (1,8)	1261 (98,2)	0,94 [0,53; 1,66]
ET	1263	24 (1,9)	1239 (98,1)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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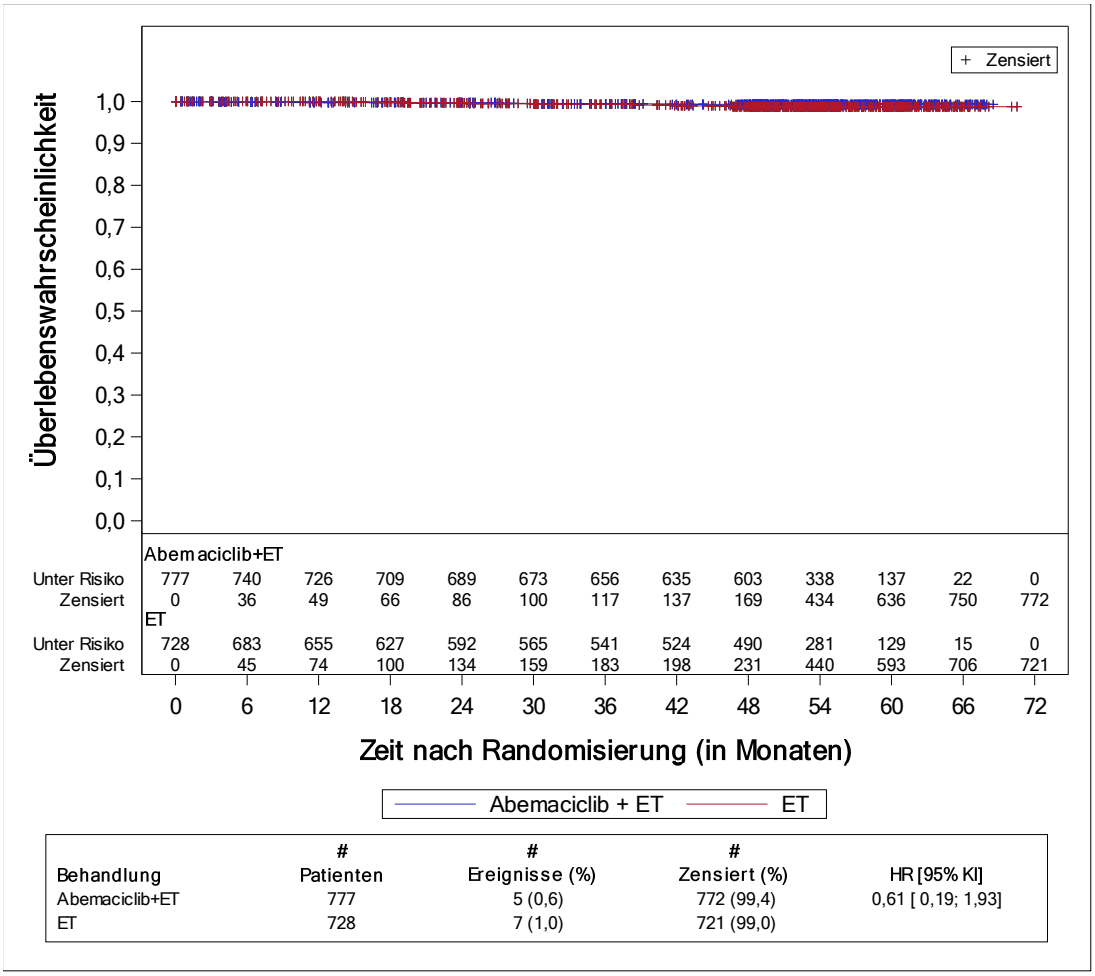
Kaplan-Meier-Kurven - regionäres invasives Brustkrebsrezidiv
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	5 (0,6)	772 (99,4)	0,61 [0,19; 1,93]
ET	728	7 (1,0)	721 (99,0)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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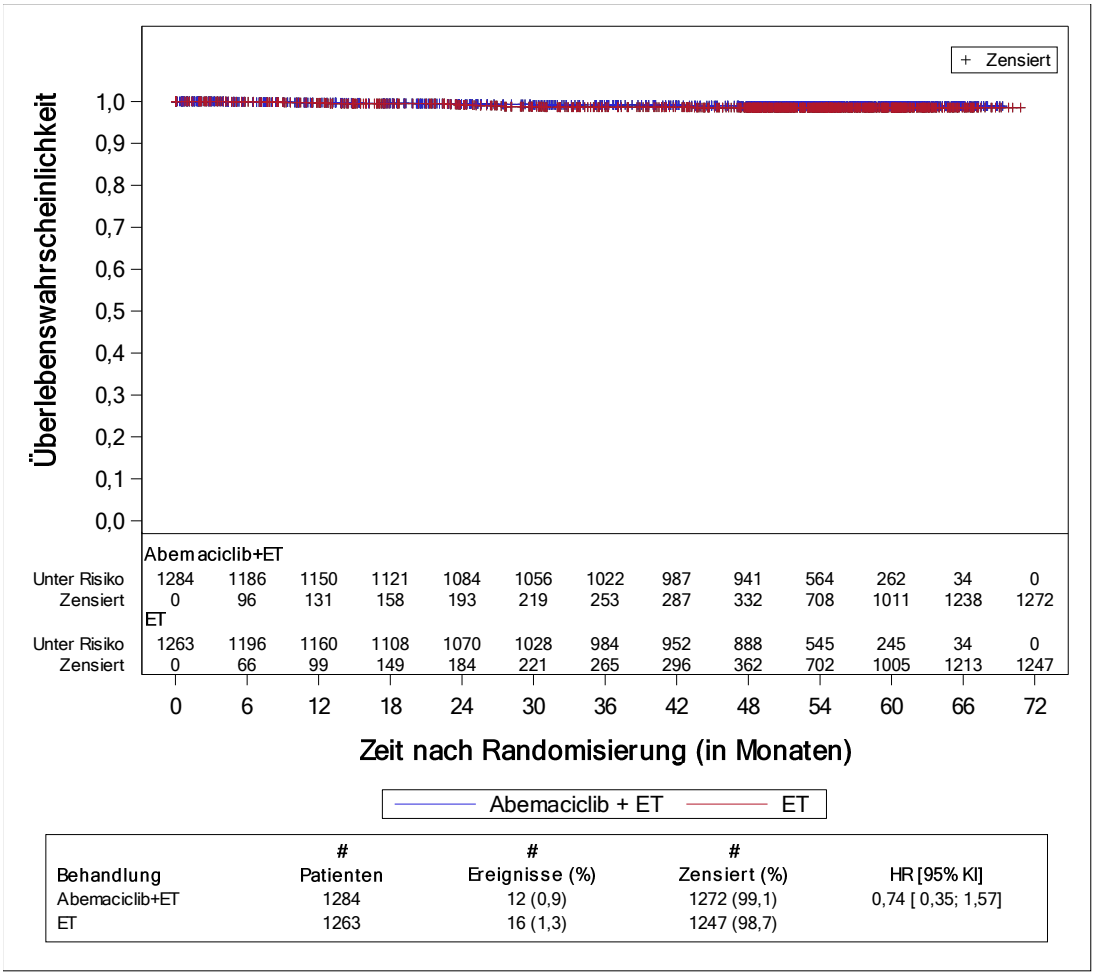
Kaplan-Meier-Kurven - regionäres invasives Brustkrebsrezidiv
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	12 (0,9)	1272 (99,1)	0,74 [0,35; 1,57]
ET	1263	16 (1,3)	1247 (98,7)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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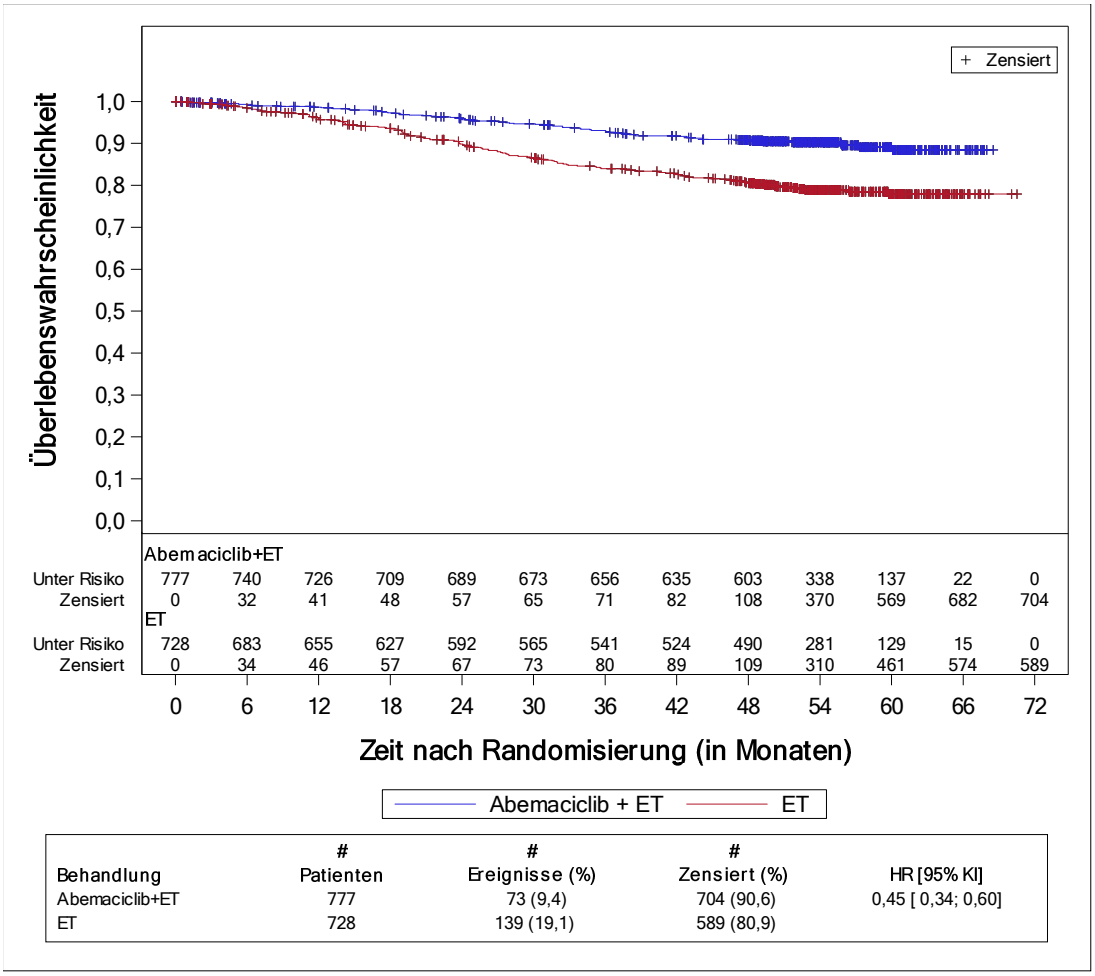
Kaplan-Meier-Kurven - Fernrezidiv
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	73 (9,4)	704 (90,6)	0,45 [0,34; 0,60]
ET	728	139 (19,1)	589 (80,9)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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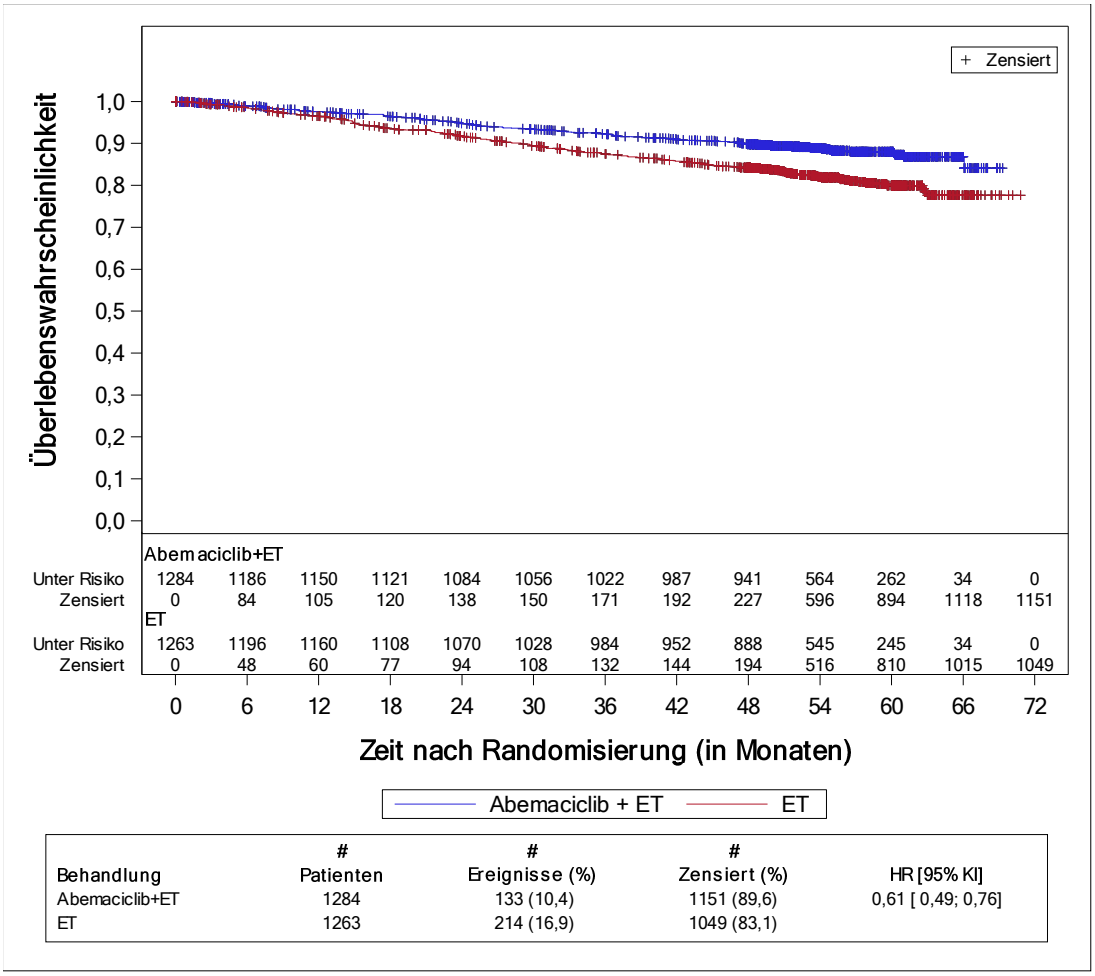
Kaplan-Meier-Kurven - Fernrezidiv
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	133 (10,4)	1151 (89,6)	0,61 [0,49; 0,76]
ET	1263	214 (16,9)	1049 (83,1)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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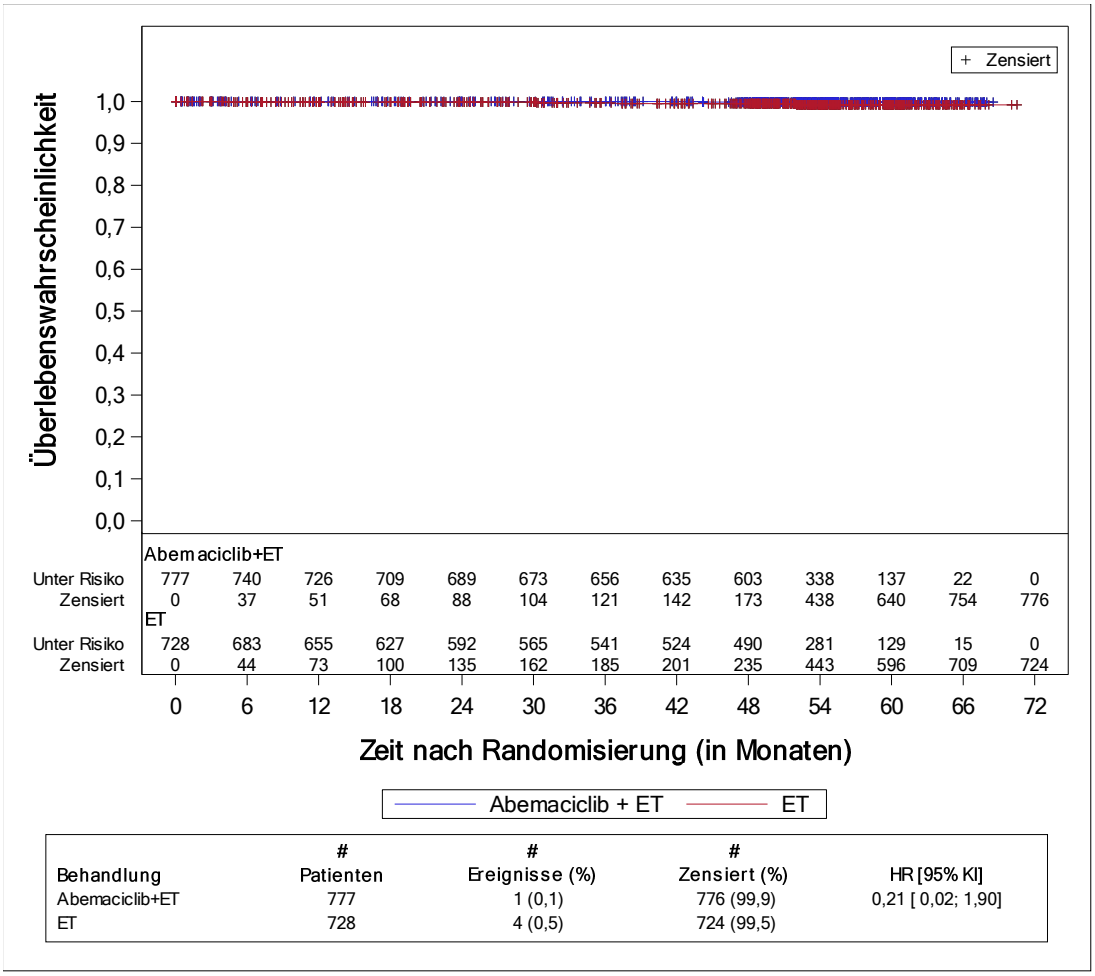
Kaplan-Meier-Kurven - Tod jeglicher Ursache
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	1 (0,1)	776 (99,9)	0,21 [0,02; 1,90]
ET	728	4 (0,5)	724 (99,5)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/f_gba3c1_km_eff.sas
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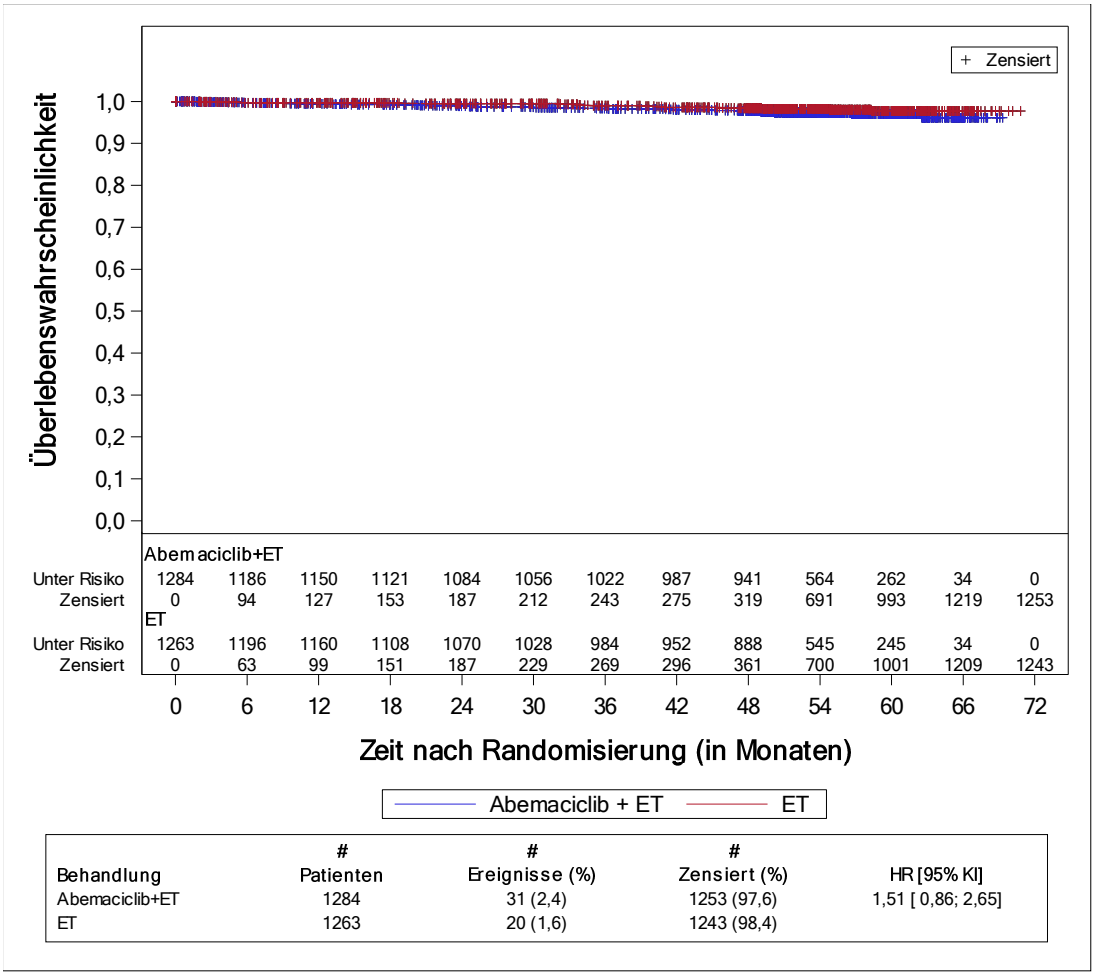
14OCT2025 / 07:36

Kaplan-Meier-Kurven - Tod jeglicher Ursache
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	31 (2,4)	1253 (97,6)	1,51 [0,86; 2,65]
ET	1263	20 (1,6)	1243 (98,4)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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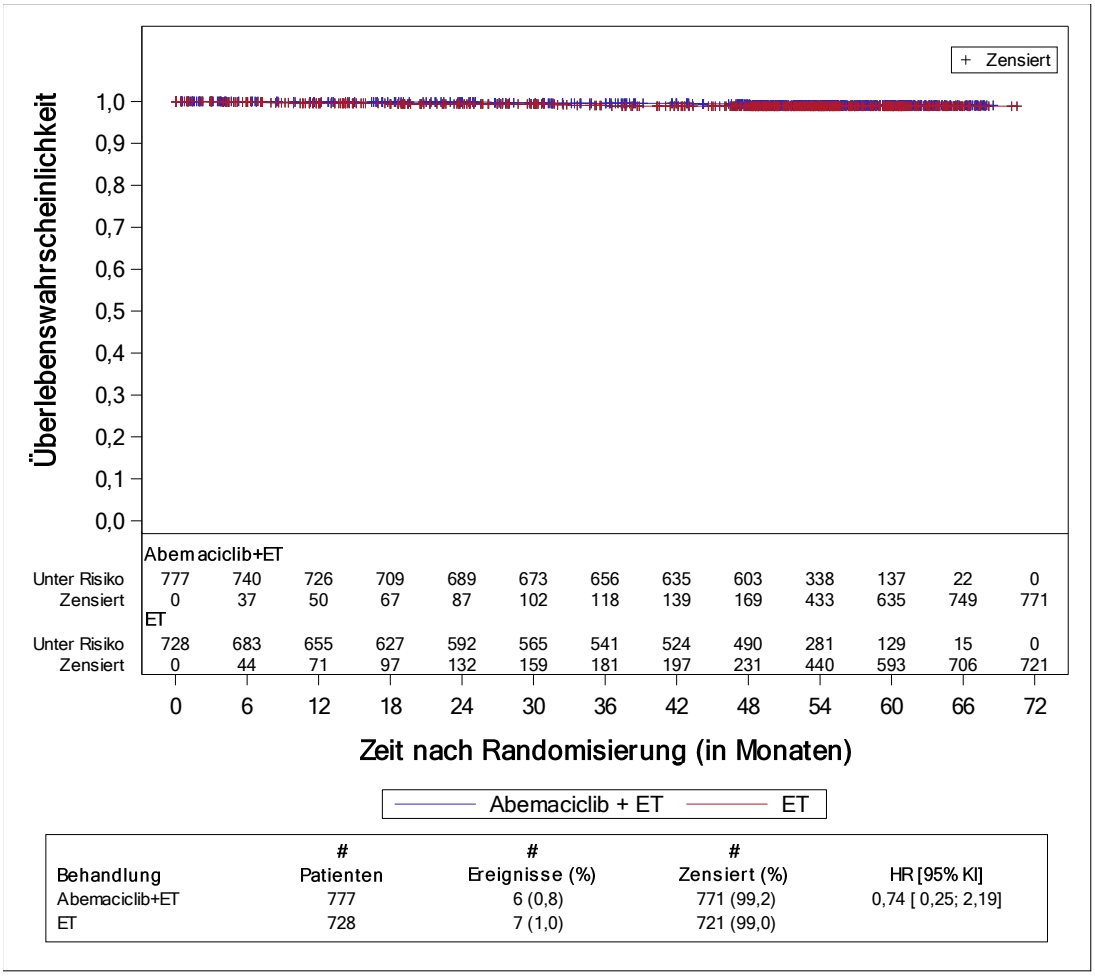
Kaplan-Meier-Kurven - kontralateraler invasiver Brustkrebs
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	6 (0,8)	771 (99,2)	0,74 [0,25; 2,19]
ET	728	7 (1,0)	721 (99,0)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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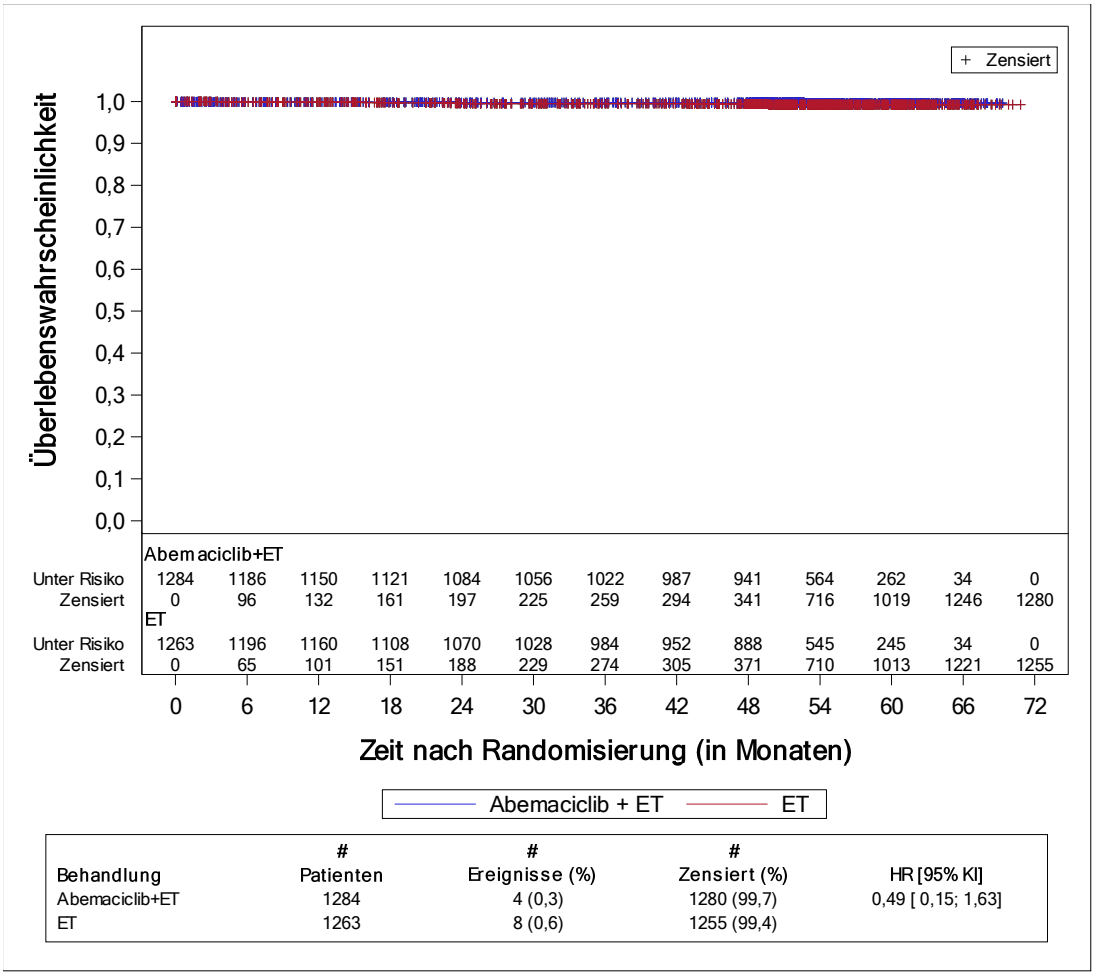
Kaplan-Meier-Kurven - kontralateraler invasiver Brustkrebs
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	4 (0,3)	1280 (99,7)	0,49 [0,15; 1,63]
ET	1263	8 (0,6)	1255 (99,4)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/f_gba3c1_km_eff.sas
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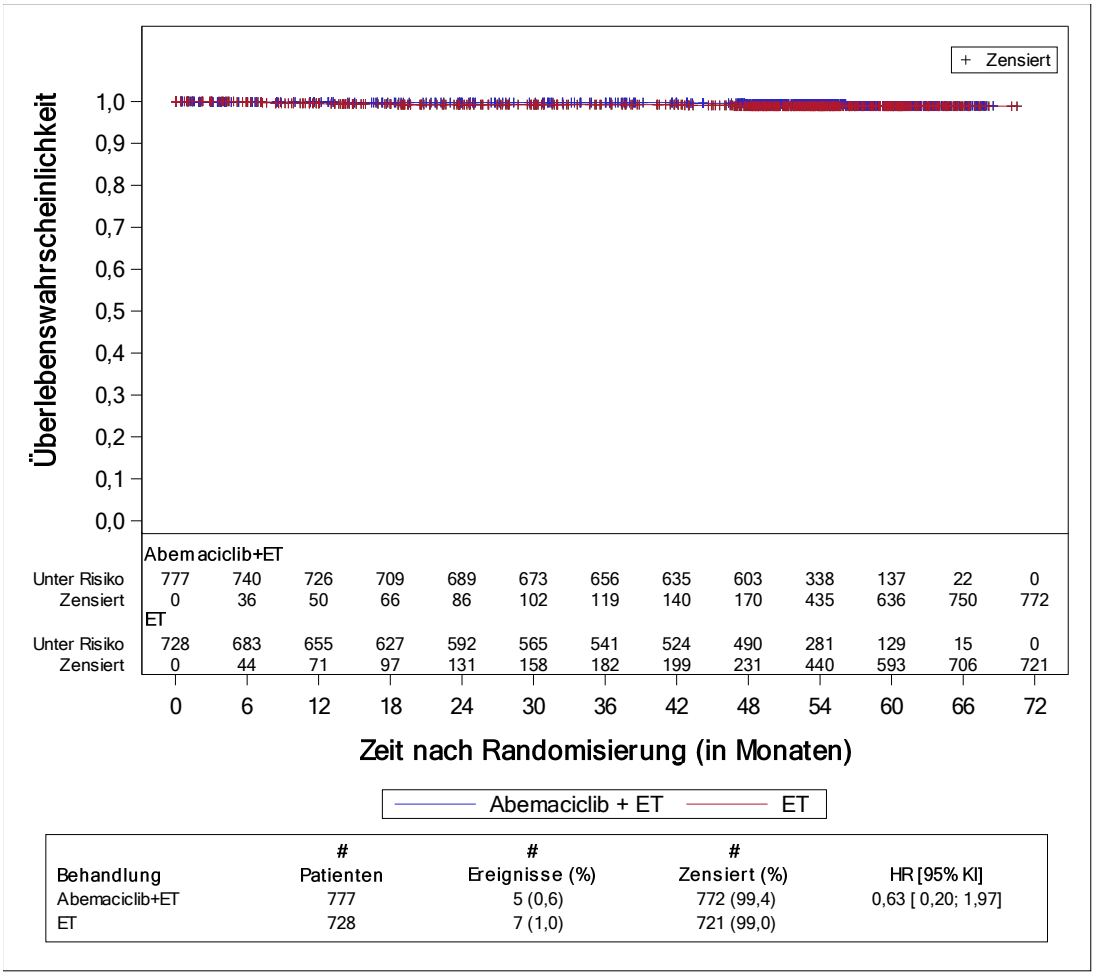
Kaplan-Meier-Kurven - Sekundäres Primärkarzinom (kein Brustkrebs)
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	5 (0,6)	772 (99,4)	0,63 [0,20; 1,97]
ET	728	7 (1,0)	721 (99,0)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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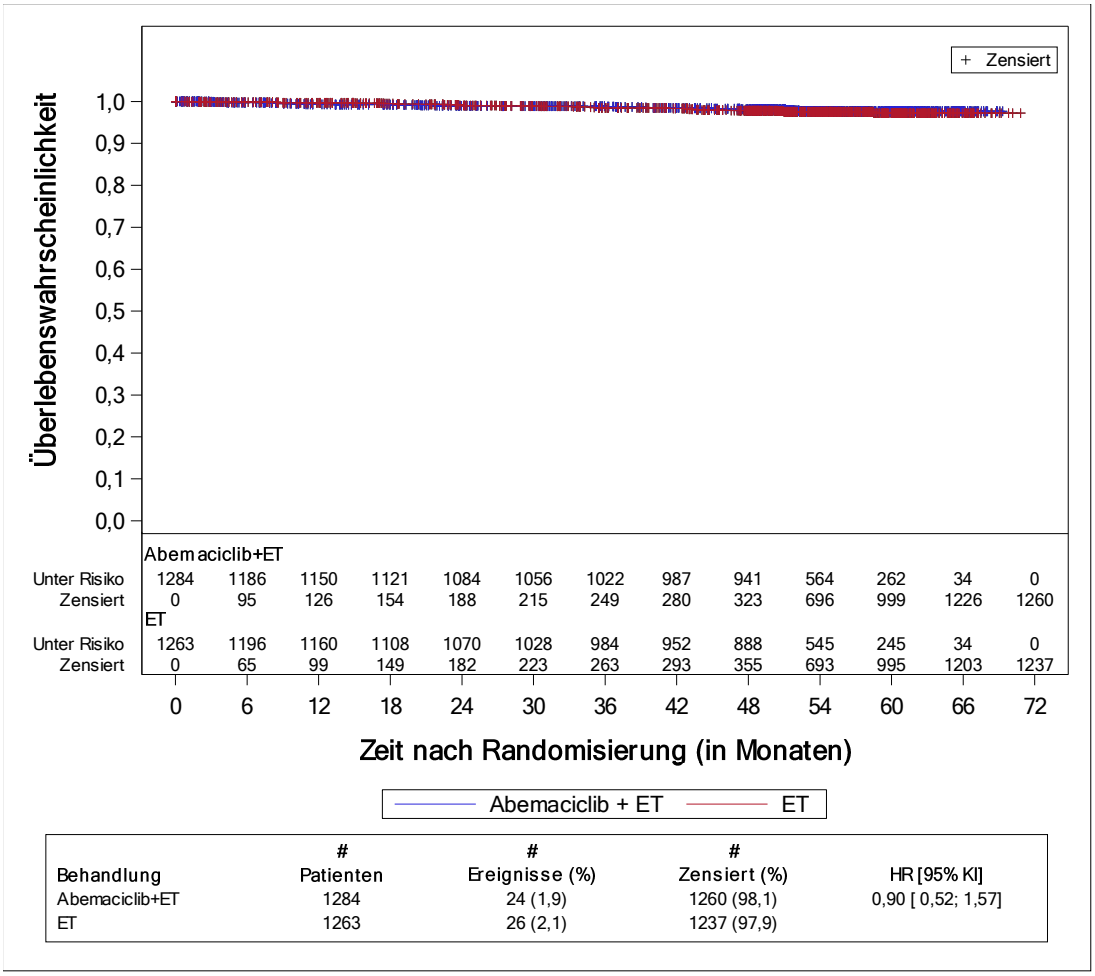
Kaplan-Meier-Kurven - Sekundäres Primärkarzinom (kein Brustkrebs)
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	24 (1,9)	1260 (98,1)	0,90 [0,52; 1,57]
ET	1263	26 (2,1)	1237 (97,9)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/f_gba3c1_km_eff.sas
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Anhang 4-G4.3: Fernmetastasenfreies Überleben

Anhang 4-G4.3.1: Ergänzende Ergebnissdarstellung

Tabelle 004: Ergebnisse für DRFS aus RCT mit dem zu bewertenden Arzneimittel Kohorte 1 Population - ITT

Population	Abemaciclib+ET[3]		ET[3]		Abemaciclib+ET vs. ET[3]
	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	Pat. mit Ereignis n/N (%)	Mediane Ereigniszeit[2] [95% KI]	HR [95% KI] p-Wert[1]
DRFS					
Prämenopausal	82/777 (10,6)	NE [NE; NE]	153/728 (21,0)	NE [NE; NE]	0,47 [0,36; 0,61] <,0001
Postmenopausal	183/1284 (14,3)	NE [NE; NE]	263/1263 (20,8)	NE [NE; NE]	0,68 [0,57; 0,83] <,0001

Datenschnitt: 03.07.2023
ITT-Population
1: Aus Log-rank-Test; 2: In Monaten; 3: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; DRFS: Fernmetastasenfreies Überleben (distant relapse-free survival); ITT: Intention to Treat; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte, kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_tte_eff.sas
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Tabelle 005: Ergebnisse für DRFS-Rezidivrate aus RCT mit dem zu bewertenden Arzneimittel

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
DRFS (Rezidive, Gesamt)					
Prämenopausal	82/777 (10,6)	153/728 (21,0)	0,50 [0,39; 0,64] <,0001[2]	0,44 [0,33; 0,59] <,0001[3]	-10,5 [-14,1; -6,8] <,0001[3]
Postmenopausal	183/1284 (14,3)	263/1263 (20,8)	0,68 [0,58; 0,81] <,0001[2]	0,63 [0,51; 0,78] <,0001[3]	-6,6 [-9,5; -3,6] <,0001[3]

Datenschnitt: 03.07.2023
ITT-Population
1: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test.
Abkürzungen: ARR: Absolute Risikoreduktion; DRFS: Fernmetastasenfreies Überleben (distant relapse-free survival); ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; ITT: Intention to Treat; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis ; N: Gesamtzahl der Patienten in der Analyse ; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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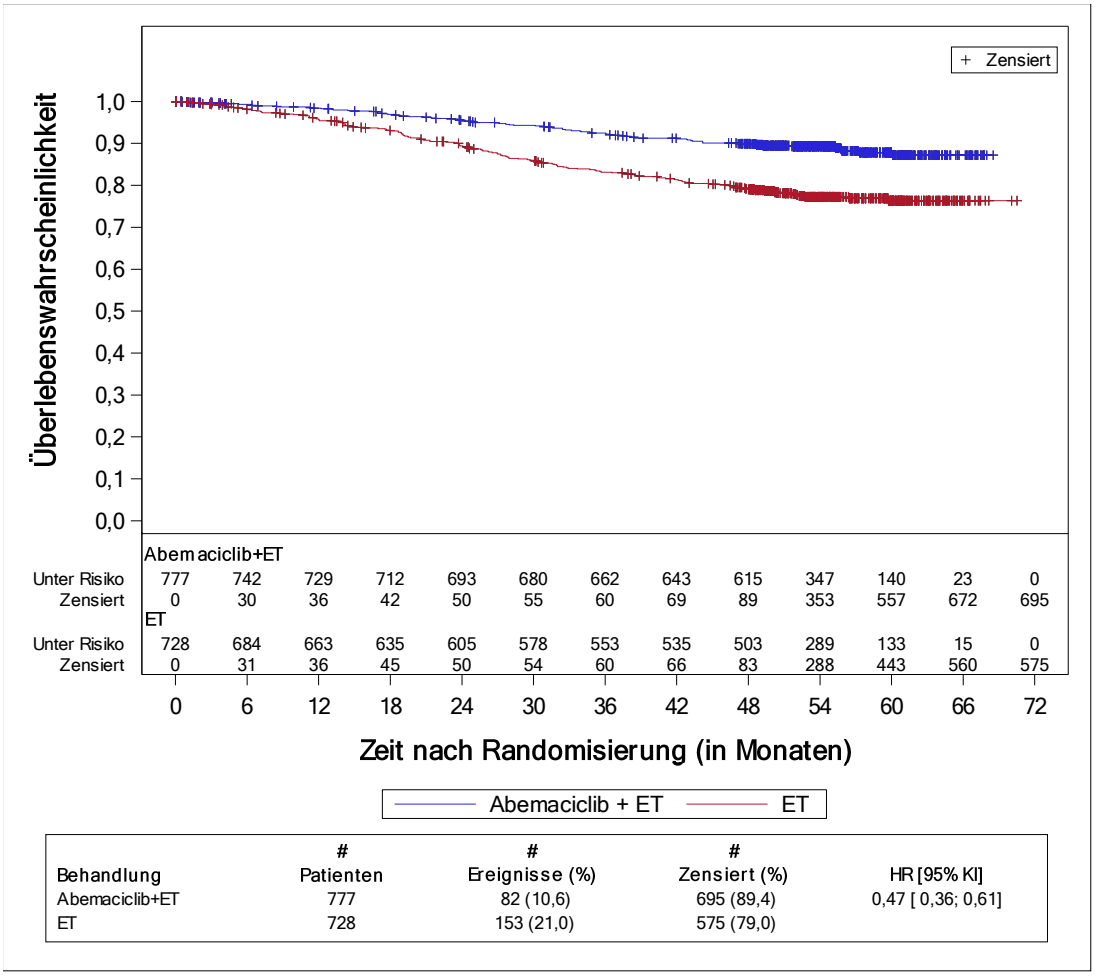
Anhang 4-G4.3.2: Kaplan-Meier-Kurven

Kaplan-Meier-Kurven - DRFS
Kohorte 1 Population - ITT - Prämenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	777	82 (10,6)	695 (89,4)	0,47 [0,36; 0,61]
ET	728	153 (21,0)	575 (79,0)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin.
Abkürzungen: ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

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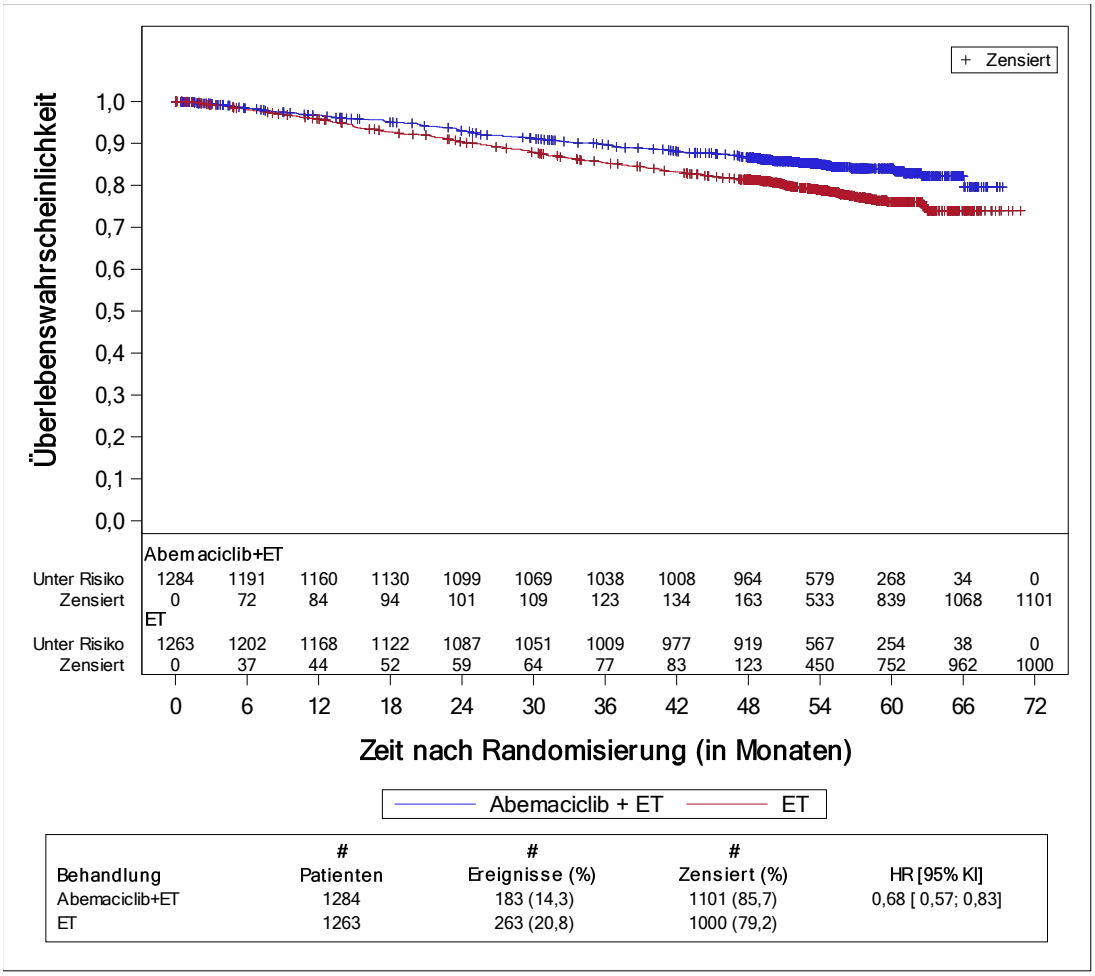
Kaplan-Meier-Kurven - DRFS
Kohorte 1 Population - ITT - Postmenopausal



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1284	183 (14,3)	1101 (85,7)	0,68 [0,57; 0,83]
ET	1263	263 (20,8)	1000 (79,2)	

Datenschnitt: 03.07.2023
ET gemäß ZVT des G-BA: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen.
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/f_gba3c1_km_eff.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpcf/misc10/data/analysis/shared/adamgba
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Anhang 4-G4.4: Unerwünschte Ereignisse

Anhang 4-G4.4.1: Unerwünschte Ereignisse (Gesamtraten)

Tabelle 049: Ergebnisse für unerwünschte Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Kohorte 1 Population - Safety

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Unerwünschtes Ereignis (jeglicher Schweregrad)					
Prämenopausal	761/776 (98,1)	640/729 (87,8)	1,12 [1,09; 1,15] <,0001[2]	7,06 [4,04; 12,31] <,0001[3]	10,3 [7,7; 12,8] <,0001[3]
Postmenopausal	1260/1283 (98,2)	1118/1264 (88,4)	1,11 [1,09; 1,13] <,0001[2]	7,15 [4,58; 11,19] <,0001[3]	9,8 [7,9; 11,7] <,0001[3]
Schwerwiegendes unerwünschtes Ereignis					
Prämenopausal	97/776 (12,5)	59/729 (8,1)	1,54 [1,14; 2,10] 0,0056[2]	1,62 [1,15; 2,28] 0,0051[3]	4,4 [1,4; 7,5] 0,0051[3]
Postmenopausal	206/1283 (16,1)	127/1264 (10,0)	1,60 [1,30; 1,97] <,0001[2]	1,71 [1,35; 2,17] <,0001[3]	6,0 [3,4; 8,6] <,0001[3]
Unerwünschtes Ereignis CTCAE Grad ≥ 3					
Prämenopausal	371/776 (47,8)	109/729 (15,0)	3,20 [2,65; 3,86] <,0001[2]	5,21 [4,07; 6,67] <,0001[3]	32,9 [28,5; 37,2] <,0001[3]
Postmenopausal	649/1283 (50,6)	221/1264 (17,5)	2,89 [2,54; 3,30] <,0001[2]	4,83 [4,03; 5,79] <,0001[3]	33,1 [29,7; 36,5] <,0001[3]
Behandlungsabbruch aufgrund unerwünschter Ereignisse					
Prämenopausal	94/776 (12,1)	6/729 (0,8)	14,72 [6,49; 33,39] <,0001[2]	16,61 [7,23; 38,16] <,0001[3]	11,3 [8,9; 13,7] <,0001[3]
Postmenopausal	282/1283 (22,0)	15/1264 (1,2)	18,52 [11,08; 30,95] <,0001[2]	23,46 [13,86; 39,69] <,0001[3]	20,8 [18,4; 23,1] <,0001[3]

Datenschnitt: 03.07.2023
Safety-Population
1: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_bp_ae.sas
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Anhang 4-G4.4.2: Unerwünschte Ereignisse von speziellem Interesse

Tabelle 050: Ergebnisse für unerwünschte Ereignisse: PT Neutropenie und erniedrigte Neutrophilenzahl aus RCT mit dem zu bewertenden Arzneimittel
Kohorte 1 Population - Safety

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Unerwünschtes Ereignis: PT Neutropenie und erniedrigte Neutrophilenzahl (jeglicher Schweregrad)					
Prämenopausal	362/776 (46,6)	63/729 (8,6)	5,40 [4,21; 6,92] <,0001[2]	9,24 [6,89; 12,41] <,0001[3]	38,0 [33,9; 42,1] <,0001[3]
Postmenopausal	559/1283 (43,6)	51/1264 (4,0)	10,80 [8,19; 14,23] <,0001[2]	18,36 [13,59; 24,82] <,0001[3]	39,5 [36,6; 42,5] <,0001[3]
Unerwünschtes Ereignis CTCAE Grad ≥ 3: PT Neutropenie und erniedrigte Neutrophilenzahl					
Prämenopausal	146/776 (18,8)	11/729 (1,5)	12,47 [6,81; 22,82] <,0001[2]	15,13 [8,12; 28,18] <,0001[3]	17,3 [14,4; 20,2] <,0001[3]
Postmenopausal	259/1283 (20,2)	8/1264 (0,6)	31,90 [15,85; 64,18] <,0001[2]	39,71 [19,55; 80,64] <,0001[3]	19,6 [17,3; 21,8] <,0001[3]
Schwerwiegendes unerwünschtes Ereignis: PT Neutropenie und erniedrigte Neutrophilenzahl					
Prämenopausal	0/776 (0,0)	0/729 (0,0)	NB	NB	NB
Postmenopausal	2/1283 (0,2)	0/1264 (0,0)	4,93 [0,24;102,50] 0,3032[2]	4,93 [0,24;102,87] 0,4998[4]	0,2 [-0,1; 0,4] 0,4998[4]

Datenschnitt: 03.07.2023
Safety-Population
1: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NB: Nicht berechnet; OR: Odds Ratio; PT: Preferred Term; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_bp_ae.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/output/shared/tfl/german_dossier/gba3c1/t050_bp_ae_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr5/data/analysis/shared/adam,
/lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/data/analysis/shared/adamgba
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Tabelle 051: Ergebnisse für unerwünschte Ereignisse: Infektionen (SOC) aus RCT mit dem zu bewertenden Arzneimittel
Kohorte 1 Population - Safety

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Unerwünschtes Ereignis: SOC Infektionen (jeglicher Schweregrad)					
Prämenopausal	425/776 (54,8)	304/729 (41,7)	1,31 [1,18; 1,46] <,0001[2]	1,69 [1,38; 2,08] <,0001[3]	13,1 [8,1; 18,1] <,0001[3]
Postmenopausal	608/1283 (47,4)	464/1264 (36,7)	1,29 [1,18; 1,42] <,0001[2]	1,55 [1,33; 1,82] <,0001[3]	10,7 [6,9; 14,5] <,0001[3]
Unerwünschtes Ereignis CTCAE Grad ≥ 3: SOC Infektionen					
Prämenopausal	37/776 (4,8)	17/729 (2,3)	2,04 [1,16; 3,60] 0,0131[2]	2,10 [1,17; 3,76] 0,0111[3]	2,4 [0,6; 4,3] 0,0111[3]
Postmenopausal	72/1283 (5,6)	37/1264 (2,9)	1,92 [1,30; 2,83] 0,0010[2]	1,97 [1,32; 2,95] 0,0008[3]	2,7 [1,1; 4,2] 0,0008[3]
Schwerwiegendes unerwünschtes Ereignis: SOC Infektionen					
Prämenopausal	34/776 (4,4)	19/729 (2,6)	1,68 [0,97; 2,92] 0,0652[2]	1,71 [0,97; 3,03] 0,0619[3]	1,8 [-0,1; 3,6] 0,0619[3]
Postmenopausal	71/1283 (5,5)	35/1264 (2,8)	2,00 [1,34; 2,97] 0,0006[2]	2,06 [1,36; 3,11] 0,0005[3]	2,8 [1,2; 4,3] 0,0005[3]

Datenschnitt: 03.07.2023
Safety-Population
1: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_bp_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr5/data/analysis/shared/adam,
/lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/data/analysis/shared/adamgba
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Tabelle 052: Ergebnisse für unerwünschte Ereignisse: Diarrhoe (PT) aus RCT mit dem zu bewertenden Arzneimittel
Kohorte 1 Population - Safety

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Unerwünschtes Ereignis: PT Diarrhoe (jeglicher Schweregrad)					
Prämenopausal	642/776 (82,7)	43/729 (5,9)	14,03 [10,48; 18,78] <,0001[2]	76,43 [53,33;109,55] <,0001[3]	76,8 [73,7; 80,0] <,0001[3]
Postmenopausal	1060/1283 (82,6)	111/1264 (8,8)	9,41 [7,86; 11,26] <,0001[2]	49,38 [38,74; 62,92] <,0001[3]	73,8 [71,2; 76,4] <,0001[3]
Unerwünschtes Ereignis CTCAE Grad ≥ 3: PT Diarrhoe					
Prämenopausal	46/776 (5,9)	3/729 (0,4)	14,40 [4,50; 46,11] <,0001[2]	15,25 [4,72; 49,25] <,0001[3]	5,5 [3,8; 7,2] <,0001[3]
Postmenopausal	125/1283 (9,7)	2/1264 (0,2)	61,57 [15,26;248,40] <,0001[2]	68,11 [16,81;276,00] <,0001[3]	9,6 [7,9; 11,2] <,0001[3]
Schwerwiegendes unerwünschtes Ereignis: PT Diarrhoe					
Prämenopausal	1/776 (0,1)	0/729 (0,0)	2,82 [0,12; 69,08] 0,5255[2]	2,82 [0,11; 69,38] 1,0000[4]	0,1 [-0,1; 0,4] 1,0000[4]
Postmenopausal	11/1283 (0,9)	0/1264 (0,0)	22,66 [1,34;384,12] 0,0307[2]	22,86 [1,35;388,26] 0,0010[3]	0,9 [0,4; 1,4] 0,0010[3]

Datenschnitt: 03.07.2023
Safety-Population
1: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; PT: Preferred Term; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_bp_ae.sas
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Tabelle 053: Ergebnisse für unerwünschte Ereignisse: Hepatische Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Kohorte 1 Population - Safety

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Unerwünschtes Ereignis: Hepatische Ereignisse (jeglicher Schweregrad)					
Prämenopausal	147/776 (18,9)	86/729 (11,8)	1,61 [1,26; 2,05] 0,0002[2]	1,75 [1,31; 2,33] 0,0001[3]	7,1 [3,5; 10,8] 0,0001[3]
Postmenopausal	233/1283 (18,2)	158/1264 (12,5)	1,45 [1,21; 1,75] <,0001[2]	1,55 [1,25; 1,93] <,0001[3]	5,7 [2,9; 8,4] <,0001[3]
Unerwünschtes Ereignis CTCAE Grad ≥ 3: Hepatische Ereignisse					
Prämenopausal	31/776 (4,0)	4/729 (0,5)	7,28 [2,58; 20,52] 0,0002[2]	7,54 [2,65; 21,47] <,0001[3]	3,4 [2,0; 4,9] <,0001[3]
Postmenopausal	60/1283 (4,7)	14/1264 (1,1)	4,22 [2,37; 7,51] <,0001[2]	4,38 [2,44; 7,88] <,0001[3]	3,6 [2,3; 4,9] <,0001[3]
Schwerwiegendes unerwünschtes Ereignis: Hepatische Ereignisse					
Prämenopausal	4/776 (0,5)	0/729 (0,0)	8,46 [0,46;156,78] 0,1519[2]	8,50 [0,46;158,13] 0,1252[4]	0,5 [0,0; 1,0] 0,1252[4]
Postmenopausal	4/1283 (0,3)	1/1264 (0,1)	3,94 [0,44; 35,21] 0,2197[2]	3,95 [0,44; 35,39] 0,3746[4]	0,2 [-0,1; 0,6] 0,3746[4]

Datenschnitt: 03.07.2023
Safety-Population
1: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

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Tabelle 054: Ergebnisse für unerwünschte Ereignisse: Venöse Thromboembolie aus RCT mit dem zu bewertenden Arzneimittel
Kohorte 1 Population - Safety

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Unerwünschtes Ereignis: Venöse Thromboembolie (jeglicher Schweregrad)					
Prämenopausal	14/776 (1,8)	4/729 (0,5)	3,29 [1,09; 9,94] 0,0350[2]	3,33 [1,09; 10,16] 0,0252[3]	1,3 [0,2; 2,3] 0,0252[3]
Postmenopausal	44/1283 (3,4)	9/1264 (0,7)	4,82 [2,36; 9,82] <,0001[2]	4,95 [2,41; 10,19] <,0001[3]	2,7 [1,6; 3,8] <,0001[3]
Unerwünschtes Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie					
Prämenopausal	6/776 (0,8)	1/729 (0,1)	5,64 [0,68; 46,71] 0,1090[2]	5,67 [0,68; 47,23] 0,1254[4]	0,6 [-0,0; 1,3] 0,1254[4]
Postmenopausal	14/1283 (1,1)	4/1264 (0,3)	3,45 [1,14; 10,45] 0,0286[2]	3,48 [1,14; 10,59] 0,0196[3]	0,8 [0,1; 1,4] 0,0196[3]
Schwerwiegendes unerwünschtes Ereignis: Venöse Thromboembolie					
Prämenopausal	5/776 (0,6)	1/729 (0,1)	4,70 [0,55; 40,11] 0,1574[2]	4,72 [0,55; 40,51] 0,2192[4]	0,5 [-0,1; 1,1] 0,2192[4]
Postmenopausal	16/1283 (1,2)	5/1264 (0,4)	3,15 [1,16; 8,58] 0,0246[2]	3,18 [1,16; 8,71] 0,0175[3]	0,9 [0,2; 1,6] 0,0175[3]

Datenschnitt: 03.07.2023
Safety-Population
1: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_bp_ae.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/output/shared/tfl/german_dossier/gba3c1/t054_bp_ae_saf3c1.rtf
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Tabelle 055: Ergebnisse für unerwünschte Ereignisse: ILD/Pneumonitis aus RCT mit dem zu bewertenden Arzneimittel
Kohorte 1 Population - Safety

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Unerwünschtes Ereignis: ILD/Pneumonitis (jeglicher Schweregrad)					
Prämenopausal	34/776 (4,4)	14/729 (1,9)	2,28 [1,23; 4,22] 0,0085[2]	2,34 [1,25; 4,40] 0,0066[3]	2,5 [0,7; 4,2] 0,0066[3]
Postmenopausal	31/1283 (2,4)	16/1264 (1,3)	1,91 [1,05; 3,47] 0,0342[2]	1,93 [1,05; 3,55] 0,0310[3]	1,2 [0,1; 2,2] 0,0310[3]
Unerwünschtes Ereignis CTCAE Grad ≥ 3: ILD/Pneumonitis					
Prämenopausal	2/776 (0,3)	0/729 (0,0)	4,70 [0,23; 97,68] 0,3177[2]	4,71 [0,23; 98,26] 0,5002[4]	0,3 [-0,1; 0,6] 0,5002[4]
Postmenopausal	6/1283 (0,5)	1/1264 (0,1)	5,91 [0,71; 49,03] 0,0997[2]	5,93 [0,71; 49,36] 0,1246[4]	0,4 [-0,0; 0,8] 0,1246[4]
Schwerwiegendes unerwünschtes Ereignis: ILD/Pneumonitis					
Prämenopausal	3/776 (0,4)	0/729 (0,0)	6,58 [0,34;127,10] 0,2126[2]	6,60 [0,34;128,03] 0,2502[4]	0,4 [-0,1; 0,8] 0,2502[4]
Postmenopausal	7/1283 (0,5)	1/1264 (0,1)	6,90 [0,85; 55,97] 0,0707[2]	6,93 [0,85; 56,40] 0,0699[4]	0,5 [0,0; 0,9] 0,0699[4]

Datenschnitt: 03.07.2023
Safety-Population
1: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; ILD: Interstitial Lung Disease; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_bp_ae.sas
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Tabelle 056: Ergebnisse für unerwünschte Ereignisse: Erkrankungen der Nieren und Harnwege (SOC) aus RCT mit dem zu bewertenden Arzneimittel
Kohorte 1 Population - Safety

Population	Abemaciclib+ET[1] Pat. mit Ereignis n/N (%)	ET[1] Pat. mit Ereignis n/N (%)	Abemaciclib+ET vs. ET[1] RR [95% KI] p-Wert	OR [95% KI] p-Wert	ARR [95% KI] p-Wert
Unerwünschtes Ereignis: Erkrankungen der Nieren und Harnwege (SOC) (jeglicher Schweregrad)					
Prämenopausal	55/776 (7,1)	33/729 (4,5)	1,57 [1,03; 2,38] 0,0362[2]	1,61 [1,03; 2,51] 0,0343[3]	2,6 [0,2; 4,9] 0,0343[3]
Postmenopausal	102/1283 (8,0)	69/1264 (5,5)	1,46 [1,08; 1,96] 0,0126[2]	1,50 [1,09; 2,05] 0,0120[3]	2,5 [0,6; 4,4] 0,0120[3]
Unerwünschtes Ereignis CTCAE Grad ≥ 3: Erkrankungen der Nieren und Harnwege (SOC)					
Prämenopausal	3/776 (0,4)	1/729 (0,1)	2,82 [0,29; 27,03] 0,3691[2]	2,83 [0,29; 27,22] 0,6252[4]	0,2 [-0,3; 0,8] 0,6252[4]
Postmenopausal	13/1283 (1,0)	4/1264 (0,3)	3,20 [1,05; 9,79] 0,0413[2]	3,22 [1,05; 9,92] 0,0308[3]	0,7 [0,1; 1,3] 0,0308[3]
Schwerwiegendes unerwünschtes Ereignis: Erkrankungen der Nieren und Harnwege (SOC)					
Prämenopausal	4/776 (0,5)	0/729 (0,0)	8,46 [0,46;156,78] 0,1519[2]	8,50 [0,46;158,13] 0,1252[4]	0,5 [0,0; 1,0] 0,1252[4]
Postmenopausal	9/1283 (0,7)	4/1264 (0,3)	2,22 [0,68; 7,18] 0,1843[2]	2,23 [0,68; 7,24] 0,1728[3]	0,4 [-0,2; 0,9] 0,1728[3]

Datenschnitt: 03.07.2023
Safety-Population
1: gemäß ZVT des G-BA: Prämenopausal: Tamoxifen, Anastrozol oder Letrozol in Kombination mit GnRH, Exemestan in Kombination mit Triptorelin; Postmenopausal: Anastrozol, Letrozol; Anastrozol oder Exemestan in Sequenz nach Tamoxifen; 2: p-Wert basierend auf Z-Test; 3: p-Wert basierend auf Chi^2-Test; 4: p-Wert basierend auf exaktem Fisher Test.
Abkürzungen: ARR: Absolute Risikoreduktion; CTCAE: Common Terminology Criteria for Adverse Events; ET: Endokrine Therapie; GnRH: Gonadotropin-Releasing Hormon; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: Randomisierte, kontrollierte Studie; RR: Relatives Risiko; SOC: System Organ Class.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_bp_ae.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/output/shared/tfl/german_dossier/gba3c1/t056_bp_ae_saf3c1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpcf/csr5/data/analysis/shared/adam, /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/data/analysis/shared/adamgba
29SEP2025 / 08:28

Anhang 4-G4.4.3: Häufige unerwünschte Ereignisse nach SOC und PT

Table 057.1: Results from binary analysis for adverse events according PT - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Abdominal distension				
24/776 (3,1)	7/729 (1,0)	3,22 [1,40; 7,43] 0,0061[2]	3,29 [1,41; 7,69] 0,0036[3]	2,1 [0,7; 3,5] 0,0036[3]
Abdominal pain				
207/776 (26,7)	35/729 (4,8)	5,56 [3,94; 7,83] <,0001[2]	7,21 [4,96; 10,50] <,0001[3]	21,9 [18,4; 25,4] <,0001[3]
Abdominal pain upper				
97/776 (12,5)	25/729 (3,4)	3,65 [2,38; 5,59] <,0001[2]	4,02 [2,56; 6,32] <,0001[3]	9,1 [6,4; 11,7] <,0001[3]
Alanine aminotransferase increased				
85/776 (11,0)	38/729 (5,2)	2,10 [1,45; 3,04] <,0001[2]	2,24 [1,50; 3,33] <,0001[3]	5,7 [3,0; 8,5] <,0001[3]
Alopecia				
72/776 (9,3)	13/729 (1,8)	5,20 [2,91; 9,31] <,0001[2]	5,63 [3,09; 10,26] <,0001[3]	7,5 [5,2; 9,8] <,0001[3]
Anaemia				
159/776 (20,5)	30/729 (4,1)	4,98 [3,42; 7,26] <,0001[2]	6,00 [4,01; 9,00] <,0001[3]	16,4 [13,2; 19,6] <,0001[3]
Anxiety				
31/776 (4,0)	37/729 (5,1)	0,79 [0,49; 1,25] 0,3144[2]	0,78 [0,48; 1,27] 0,3131[3]	-1,1 [-3,2; 1,0] 0,3131[3]
Arthralgia				
165/776 (21,3)	219/729 (30,0)	0,71 [0,59; 0,84] 0,0001[2]	0,63 [0,50; 0,79] <,0001[3]	-8,8 [-13,2; -4,4] <,0001[3]
Aspartate aminotransferase increased				
90/776 (11,6)	32/729 (4,4)	2,64 [1,79; 3,90] <,0001[2]	2,86 [1,88; 4,34] <,0001[3]	7,2 [4,5; 9,9] <,0001[3]
Asthenia				
76/776 (9,8)	33/729 (4,5)	2,16 [1,46; 3,21] 0,0001[2]	2,29 [1,50; 3,49] <,0001[3]	5,3 [2,7; 7,8] <,0001[3]
Axillary pain				
11/776 (1,4)	8/729 (1,1)	1,29 [0,52; 3,19] 0,5794[2]	1,30 [0,52; 3,24] 0,5783[3]	0,3 [-0,8; 1,4] 0,5783[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Back pain				
83/776 (10,7)	91/729 (12,5)	0,86 [0,65; 1,13] 0,2791[2]	0,84 [0,61; 1,15] 0,2786[3]	-1,8 [-5,0; 1,5] 0,2786[3]
Blood alkaline phosphatase increased				
25/776 (3,2)	13/729 (1,8)	1,81 [0,93; 3,50] 0,0802[2]	1,83 [0,93; 3,61] 0,0755[3]	1,4 [-0,1; 3,0] 0,0755[3]
Blood cholesterol increased				
20/776 (2,6)	17/729 (2,3)	1,11 [0,58; 2,09] 0,7588[2]	1,11 [0,58; 2,13] 0,7587[3]	0,2 [-1,3; 1,8] 0,7587[3]
Blood creatinine increased				
71/776 (9,1)	3/729 (0,4)	22,23 [7,03; 70,27] <,0001[2]	24,37 [7,64; 77,73] <,0001[3]	8,7 [6,7; 10,8] <,0001[3]
Bone pain				
12/776 (1,5)	19/729 (2,6)	0,59 [0,29; 1,21] 0,1528[2]	0,59 [0,28; 1,22] 0,1480[3]	-1,1 [-2,5; 0,4] 0,1480[3]
Breast pain				
34/776 (4,4)	33/729 (4,5)	0,97 [0,61; 1,55] 0,8914[2]	0,97 [0,59; 1,58] 0,8914[3]	-0,1 [-2,2; 1,9] 0,8914[3]
Breast reconstruction				
11/776 (1,4)	10/729 (1,4)	1,03 [0,44; 2,42] 0,9397[2]	1,03 [0,44; 2,45] 0,9397[3]	0,0 [-1,1; 1,2] 0,9397[3]
COVID-19				
11/776 (1,4)	5/729 (0,7)	2,07 [0,72; 5,92] 0,1763[2]	2,08 [0,72; 6,02] 0,1666[3]	0,7 [-0,3; 1,8] 0,1666[3]
Cellulitis				
21/776 (2,7)	6/729 (0,8)	3,29 [1,33; 8,10] 0,0097[2]	3,35 [1,35; 8,35] 0,0059[3]	1,9 [0,6; 3,2] 0,0059[3]
Chest discomfort				
10/776 (1,3)	5/729 (0,7)	1,88 [0,65; 5,47] 0,2474[2]	1,89 [0,64; 5,56] 0,2394[3]	0,6 [-0,4; 1,6] 0,2394[3]
Chest pain				
14/776 (1,8)	8/729 (1,1)	1,64 [0,69; 3,90] 0,2587[2]	1,66 [0,69; 3,97] 0,2536[3]	0,7 [-0,5; 1,9] 0,2536[3]
Chills				
18/776 (2,3)	2/729 (0,3)	8,45 [1,97; 36,31] 0,0041[2]	8,63 [2,00; 37,33] 0,0005[3]	2,0 [0,9; 3,2] 0,0005[3]
Conjunctivitis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
15/776 (1,9)	5/729 (0,7)	2,82 [1,03; 7,72] 0,0437[2]	2,85 [1,03; 7,89] 0,0347[3]	1,2 [0,1; 2,4] 0,0347[3]
Constipation				
99/776 (12,8)	47/729 (6,4)	1,98 [1,42; 2,76] <,0001[2]	2,12 [1,48; 3,05] <,0001[3]	6,3 [3,4; 9,3] <,0001[3]
Contusion				
11/776 (1,4)	11/729 (1,5)	0,94 [0,41; 2,15] 0,8827[2]	0,94 [0,40; 2,18] 0,8826[3]	-0,1 [-1,3; 1,1] 0,8826[3]
Cough				
90/776 (11,6)	42/729 (5,8)	2,01 [1,42; 2,86] <,0001[2]	2,15 [1,47; 3,14] <,0001[3]	5,8 [3,0; 8,7] <,0001[3]
Cystitis				
22/776 (2,8)	11/729 (1,5)	1,88 [0,92; 3,85] 0,0846[2]	1,90 [0,92; 3,96] 0,0791[3]	1,3 [-0,1; 2,8] 0,0791[3]
Decreased appetite				
69/776 (8,9)	10/729 (1,4)	6,48 [3,37; 12,48] <,0001[2]	7,02 [3,59; 13,73] <,0001[3]	7,5 [5,3; 9,7] <,0001[3]
Depression				
34/776 (4,4)	24/729 (3,3)	1,33 [0,80; 2,22] 0,2745[2]	1,35 [0,79; 2,29] 0,2726[3]	1,1 [-0,8; 3,0] 0,2726[3]
Diarrhoea				
642/776 (82,7)	43/729 (5,9)	14,03 [10,48; 18,78] <,0001[2]	76,43 [53,33; 109,55] <,0001[3]	76,8 [73,7; 80,0] <,0001[3]
Dizziness				
73/776 (9,4)	49/729 (6,7)	1,40 [0,99; 1,98] 0,0580[2]	1,44 [0,99; 2,10] 0,0564[3]	2,7 [-0,1; 5,4] 0,0564[3]
Dry eye				
26/776 (3,4)	12/729 (1,6)	2,04 [1,03; 4,00] 0,0395[2]	2,07 [1,04; 4,14] 0,0352[3]	1,7 [0,1; 3,3] 0,0352[3]
Dry mouth				
19/776 (2,4)	4/729 (0,5)	4,46 [1,53; 13,05] 0,0063[2]	4,55 [1,54; 13,44] 0,0027[3]	1,9 [0,7; 3,1] 0,0027[3]
Dry skin				
40/776 (5,2)	17/729 (2,3)	2,21 [1,26; 3,86] 0,0054[2]	2,28 [1,28; 4,05] 0,0041[3]	2,8 [0,9; 4,7] 0,0041[3]
Dysgeusia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
20/776 (2,6)	1/729 (0,1)	18,79 [2,53; 139,64] 0,0042[2]	19,26 [2,58; 143,87] <,0001[3]	2,4 [1,3; 3,6] <,0001[3]
Dyspepsia				
69/776 (8,9)	17/729 (2,3)	3,81 [2,26; 6,42] <,0001[2]	4,09 [2,38; 7,02] <,0001[3]	6,6 [4,3; 8,8] <,0001[3]
Dyspnoea				
42/776 (5,4)	17/729 (2,3)	2,32 [1,33; 4,04] 0,0029[2]	2,40 [1,35; 4,25] 0,0021[3]	3,1 [1,1; 5,0] 0,0021[3]
Dysuria				
11/776 (1,4)	11/729 (1,5)	0,94 [0,41; 2,15] 0,8827[2]	0,94 [0,40; 2,18] 0,8826[3]	-0,1 [-1,3; 1,1] 0,8826[3]
Eczema				
6/776 (0,8)	14/729 (1,9)	0,40 [0,16; 1,04] 0,0608[2]	0,40 [0,15; 1,04] 0,0521[3]	-1,1 [-2,3; 0,0] 0,0521[3]
Epistaxis				
10/776 (1,3)	1/729 (0,1)	9,39 [1,21; 73,20] 0,0325[2]	9,50 [1,21; 74,43] 0,0088[3]	1,2 [0,3; 2,0] 0,0088[3]
Erythema				
16/776 (2,1)	3/729 (0,4)	5,01 [1,47; 17,12] 0,0102[2]	5,09 [1,48; 17,56] 0,0042[3]	1,7 [0,5; 2,8] 0,0042[3]
Fall				
10/776 (1,3)	4/729 (0,5)	2,35 [0,74; 7,46] 0,1474[2]	2,37 [0,74; 7,58] 0,1351[3]	0,7 [-0,2; 1,7] 0,1351[3]
Fatigue				
202/776 (26,0)	86/729 (11,8)	2,21 [1,75; 2,78] <,0001[2]	2,63 [2,00; 3,47] <,0001[3]	14,2 [10,4; 18,1] <,0001[3]
Flatulence				
13/776 (1,7)	2/729 (0,3)	6,11 [1,38; 26,97] 0,0170[2]	6,19 [1,39; 27,54] 0,0063[3]	1,4 [0,4; 2,4] 0,0063[3]
Gamma-glutamyltransferase increased				
28/776 (3,6)	8/729 (1,1)	3,29 [1,51; 7,17] 0,0028[2]	3,37 [1,53; 7,45] 0,0014[3]	2,5 [1,0; 4,0] 0,0014[3]
Gastritis				
22/776 (2,8)	7/729 (1,0)	2,95 [1,27; 6,87] 0,0120[2]	3,01 [1,28; 7,09] 0,0082[3]	1,9 [0,5; 3,2] 0,0082[3]
Gastroenteritis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
17/776 (2,2)	8/729 (1,1)	2,00 [0,87; 4,60] 0,1043[2]	2,02 [0,87; 4,71] 0,0972[3]	1,1 [-0,2; 2,4] 0,0972[3]
Gastrooesophageal reflux disease				
18/776 (2,3)	11/729 (1,5)	1,54 [0,73; 3,23] 0,2568[2]	1,55 [0,73; 3,30] 0,2529[3]	0,8 [-0,6; 2,2] 0,2529[3]
Haemorrhoids				
28/776 (3,6)	11/729 (1,5)	2,39 [1,20; 4,77] 0,0133[2]	2,44 [1,21; 4,94] 0,0104[3]	2,1 [0,5; 3,7] 0,0104[3]
Headache				
156/776 (20,1)	128/729 (17,6)	1,14 [0,93; 1,41] 0,2081[2]	1,18 [0,91; 1,53] 0,2073[3]	2,5 [-1,4; 6,5] 0,2073[3]
Hepatic steatosis				
15/776 (1,9)	12/729 (1,6)	1,17 [0,55; 2,49] 0,6755[2]	1,18 [0,55; 2,53] 0,6752[3]	0,3 [-1,1; 1,6] 0,6752[3]
Herpes zoster				
9/776 (1,2)	10/729 (1,4)	0,85 [0,35; 2,07] 0,7132[2]	0,84 [0,34; 2,09] 0,7128[3]	-0,2 [-1,3; 0,9] 0,7128[3]
Hot flush				
132/776 (17,0)	174/729 (23,9)	0,71 [0,58; 0,87] 0,0010[2]	0,65 [0,51; 0,84] 0,0010[3]	-6,9 [-10,9; -2,8] 0,0010[3]
Hypercalcaemia				
11/776 (1,4)	5/729 (0,7)	2,07 [0,72; 5,92] 0,1763[2]	2,08 [0,72; 6,02] 0,1666[3]	0,7 [-0,3; 1,8] 0,1666[3]
Hyperglycaemia				
11/776 (1,4)	14/729 (1,9)	0,74 [0,34; 1,62] 0,4473[2]	0,73 [0,33; 1,63] 0,4455[3]	-0,5 [-1,8; 0,8] 0,4455[3]
Hypertension				
44/776 (5,7)	36/729 (4,9)	1,15 [0,75; 1,76] 0,5275[2]	1,16 [0,74; 1,82] 0,5271[3]	0,7 [-1,5; 3,0] 0,5271[3]
Hypertriglyceridaemia				
28/776 (3,6)	12/729 (1,6)	2,19 [1,12; 4,28] 0,0214[2]	2,24 [1,13; 4,43] 0,0180[3]	2,0 [0,4; 3,6] 0,0180[3]
Hyperuricaemia				
10/776 (1,3)	1/729 (0,1)	9,39 [1,21; 73,20] 0,0325[2]	9,50 [1,21; 74,43] 0,0088[3]	1,2 [0,3; 2,0] 0,0088[3]
Hypokalaemia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
25/776 (3,2)	6/729 (0,8)	3,91 [1,62; 9,49] 0,0025[2]	4,01 [1,64; 9,84] 0,0011[3]	2,4 [1,0; 3,8] 0,0011[3]
Hypothyroidism				
10/776 (1,3)	16/729 (2,2)	0,59 [0,27; 1,29] 0,1829[2]	0,58 [0,26; 1,29] 0,1776[3]	-0,9 [-2,2; 0,4] 0,1776[3]
Influenza				
43/776 (5,5)	35/729 (4,8)	1,15 [0,75; 1,78] 0,5179[2]	1,16 [0,74; 1,84] 0,5174[3]	0,7 [-1,5; 3,0] 0,5174[3]
Influenza like illness				
60/776 (7,7)	39/729 (5,3)	1,45 [0,98; 2,14] 0,0644[2]	1,48 [0,98; 2,25] 0,0625[3]	2,4 [-0,1; 4,9] 0,0625[3]
Insomnia				
80/776 (10,3)	71/729 (9,7)	1,06 [0,78; 1,43] 0,7131[2]	1,07 [0,76; 1,49] 0,7130[3]	0,6 [-2,5; 3,6] 0,7130[3]
Irritability				
4/776 (0,5)	10/729 (1,4)	0,38 [0,12; 1,19] 0,0968[2]	0,37 [0,12; 1,19] 0,0838[3]	-0,9 [-1,8; 0,1] 0,0838[3]
Lacrimation increased				
34/776 (4,4)	2/729 (0,3)	15,97 [3,85; 66,24] 0,0001[2]	16,66 [3,99; 69,58] <,0001[3]	4,1 [2,6; 5,6] <,0001[3]
Leukopenia				
84/776 (10,8)	15/729 (2,1)	5,26 [3,07; 9,03] <,0001[2]	5,78 [3,30; 10,11] <,0001[3]	8,8 [6,4; 11,2] <,0001[3]
Libido decreased				
10/776 (1,3)	11/729 (1,5)	0,85 [0,36; 2,00] 0,7161[2]	0,85 [0,36; 2,02] 0,7158[3]	-0,2 [-1,4; 1,0] 0,7158[3]
Lymphocyte count decreased				
76/776 (9,8)	25/729 (3,4)	2,86 [1,84; 4,44] <,0001[2]	3,06 [1,92; 4,86] <,0001[3]	6,4 [3,9; 8,8] <,0001[3]
Lymphoedema				
105/776 (13,5)	67/729 (9,2)	1,47 [1,10; 1,97] 0,0088[2]	1,55 [1,12; 2,14] 0,0082[3]	4,3 [1,1; 7,5] 0,0082[3]
Lymphopenia				
33/776 (4,3)	13/729 (1,8)	2,38 [1,27; 4,49] 0,0072[2]	2,45 [1,28; 4,69] 0,0054[3]	2,5 [0,8; 4,2] 0,0054[3]
Malaise				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
30/776 (3,9)	11/729 (1,5)	2,56 [1,29; 5,07] 0,0070[2]	2,62 [1,31; 5,28] 0,0050[3]	2,4 [0,7; 4,0] 0,0050[3]
Mastitis				
10/776 (1,3)	10/729 (1,4)	0,94 [0,39; 2,24] 0,8882[2]	0,94 [0,39; 2,27] 0,8881[3]	-0,1 [-1,2; 1,1] 0,8881[3]
Memory impairment				
10/776 (1,3)	8/729 (1,1)	1,17 [0,47; 2,96] 0,7333[2]	1,18 [0,46; 3,00] 0,7330[3]	0,2 [-0,9; 1,3] 0,7330[3]
Mouth ulceration				
13/776 (1,7)	1/729 (0,1)	12,21 [1,60; 93,12] 0,0158[2]	12,40 [1,62; 95,06] 0,0019[3]	1,5 [0,6; 2,5] 0,0019[3]
Mucosal inflammation				
18/776 (2,3)	6/729 (0,8)	2,82 [1,12; 7,06] 0,0270[2]	2,86 [1,13; 7,25] 0,0205[3]	1,5 [0,3; 2,7] 0,0205[3]
Muscle spasms				
46/776 (5,9)	33/729 (4,5)	1,31 [0,85; 2,02] 0,2250[2]	1,33 [0,84; 2,10] 0,2232[3]	1,4 [-0,8; 3,6] 0,2232[3]
Musculoskeletal chest pain				
19/776 (2,4)	15/729 (2,1)	1,19 [0,61; 2,32] 0,6106[2]	1,19 [0,60; 2,37] 0,6101[3]	0,4 [-1,1; 1,9] 0,6101[3]
Musculoskeletal pain				
11/776 (1,4)	18/729 (2,5)	0,57 [0,27; 1,21] 0,1433[2]	0,57 [0,27; 1,21] 0,1380[3]	-1,1 [-2,5; 0,3] 0,1380[3]
Myalgia				
50/776 (6,4)	45/729 (6,2)	1,04 [0,71; 1,54] 0,8293[2]	1,05 [0,69; 1,59] 0,8293[3]	0,3 [-2,2; 2,7] 0,8293[3]
Nail disorder				
20/776 (2,6)	2/729 (0,3)	9,39 [2,20; 40,05] 0,0025[2]	9,62 [2,24; 41,29] 0,0002[3]	2,3 [1,1; 3,5] 0,0002[3]
Nasopharyngitis				
97/776 (12,5)	67/729 (9,2)	1,36 [1,01; 1,83] 0,0407[2]	1,41 [1,02; 1,96] 0,0395[3]	3,3 [0,2; 6,4] 0,0395[3]
Nausea				
210/776 (27,1)	55/729 (7,5)	3,59 [2,71; 4,74] <,0001[2]	4,55 [3,31; 6,24] <,0001[3]	19,5 [15,9; 23,2] <,0001[3]
Neck pain				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
20/776 (2,6)	11/729 (1,5)	1,71 [0,82; 3,54] 0,1499[2]	1,73 [0,82; 3,63] 0,1447[3]	1,1 [-0,4; 2,5] 0,1447[3]
Neuropathy peripheral				
14/776 (1,8)	10/729 (1,4)	1,32 [0,59; 2,94] 0,5048[2]	1,32 [0,58; 2,99] 0,5034[3]	0,4 [-0,8; 1,7] 0,5034[3]
Neutropenia				
155/776 (20,0)	25/729 (3,4)	5,82 [3,86; 8,78] <,0001[2]	7,03 [4,54; 10,87] <,0001[3]	16,5 [13,4; 19,7] <,0001[3]
Neutrophil count decreased				
216/776 (27,8)	41/729 (5,6)	4,95 [3,60; 6,80] <,0001[2]	6,47 [4,55; 9,20] <,0001[3]	22,2 [18,6; 25,8] <,0001[3]
Night sweats				
11/776 (1,4)	8/729 (1,1)	1,29 [0,52; 3,19] 0,5794[2]	1,30 [0,52; 3,24] 0,5783[3]	0,3 [-0,8; 1,4] 0,5783[3]
Oedema				
13/776 (1,7)	3/729 (0,4)	4,07 [1,16; 14,23] 0,0279[2]	4,12 [1,17; 14,53] 0,0169[3]	1,3 [0,2; 2,3] 0,0169[3]
Oedema peripheral				
55/776 (7,1)	34/729 (4,7)	1,52 [1,00; 2,30] 0,0484[2]	1,56 [1,00; 2,42] 0,0464[3]	2,4 [0,1; 4,8] 0,0464[3]
Onychoclasis				
18/776 (2,3)	4/729 (0,5)	4,23 [1,44; 12,43] 0,0088[2]	4,30 [1,45; 12,78] 0,0042[3]	1,8 [0,6; 3,0] 0,0042[3]
Oropharyngeal pain				
40/776 (5,2)	23/729 (3,2)	1,63 [0,99; 2,70] 0,0557[2]	1,67 [0,99; 2,81] 0,0529[3]	2,0 [-0,0; 4,0] 0,0529[3]
Osteopenia				
12/776 (1,5)	4/729 (0,5)	2,82 [0,91; 8,70] 0,0716[2]	2,85 [0,91; 8,87] 0,0593[3]	1,0 [-0,0; 2,0] 0,0593[3]
Osteoporosis				
16/776 (2,1)	21/729 (2,9)	0,72 [0,38; 1,36] 0,3077[2]	0,71 [0,37; 1,37] 0,3053[3]	-0,8 [-2,4; 0,8] 0,3053[3]
Pain				
21/776 (2,7)	14/729 (1,9)	1,41 [0,72; 2,75] 0,3147[2]	1,42 [0,72; 2,82] 0,3121[3]	0,8 [-0,7; 2,3] 0,3121[3]
Pain in extremity				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
75/776 (9,7)	75/729 (10,3)	0,94 [0,69; 1,27] 0,6868[2]	0,93 [0,67; 1,31] 0,6867[3]	-0,6 [-3,7; 2,4] 0,6867[3]
Palpitations				
10/776 (1,3)	1/729 (0,1)	9,39 [1,21; 73,20] 0,0325[2]	9,50 [1,21; 74,43] 0,0088[3]	1,2 [0,3; 2,0] 0,0088[3]
Paraesthesia				
10/776 (1,3)	11/729 (1,5)	0,85 [0,36; 2,00] 0,7161[2]	0,85 [0,36; 2,02] 0,7158[3]	-0,2 [-1,4; 1,0] 0,7158[3]
Peripheral sensory neuropathy				
14/776 (1,8)	15/729 (2,1)	0,88 [0,43; 1,80] 0,7209[2]	0,87 [0,42; 1,82] 0,7207[3]	-0,3 [-1,6; 1,1] 0,7207[3]
Peripheral swelling				
11/776 (1,4)	11/729 (1,5)	0,94 [0,41; 2,15] 0,8827[2]	0,94 [0,40; 2,18] 0,8826[3]	-0,1 [-1,3; 1,1] 0,8826[3]
Pharyngitis				
9/776 (1,2)	12/729 (1,6)	0,70 [0,30; 1,66] 0,4240[2]	0,70 [0,29; 1,67] 0,4215[3]	-0,5 [-1,7; 0,7] 0,4215[3]
Platelet count decreased				
59/776 (7,6)	12/729 (1,6)	4,62 [2,50; 8,52] <,0001[2]	4,92 [2,62; 9,22] <,0001[3]	6,0 [3,9; 8,0] <,0001[3]
Pneumonia				
21/776 (2,7)	9/729 (1,2)	2,19 [1,01; 4,75] 0,0470[2]	2,23 [1,01; 4,89] 0,0412[3]	1,5 [0,1; 2,9] 0,0412[3]
Pneumonitis				
16/776 (2,1)	3/729 (0,4)	5,01 [1,47; 17,12] 0,0102[2]	5,09 [1,48; 17,56] 0,0042[3]	1,7 [0,5; 2,8] 0,0042[3]
Procedural pain				
27/776 (3,5)	17/729 (2,3)	1,49 [0,82; 2,71] 0,1900[2]	1,51 [0,82; 2,79] 0,1867[3]	1,1 [-0,5; 2,8] 0,1867[3]
Productive cough				
14/776 (1,8)	4/729 (0,5)	3,29 [1,09; 9,94] 0,0350[2]	3,33 [1,09; 10,16] 0,0252[3]	1,3 [0,2; 2,3] 0,0252[3]
Pruritus				
70/776 (9,0)	32/729 (4,4)	2,06 [1,37; 3,08] 0,0005[2]	2,16 [1,40; 3,32] 0,0004[3]	4,6 [2,1; 7,1] 0,0004[3]
Pyrexia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
86/776 (11,1)	36/729 (4,9)	2,24 [1,54; 3,27] <,0001[2]	2,40 [1,60; 3,59] <,0001[3]	6,1 [3,4; 8,9] <,0001[3]
Radiation pneumonitis				
12/776 (1,5)	8/729 (1,1)	1,41 [0,58; 3,43] 0,4495[2]	1,42 [0,58; 3,48] 0,4471[3]	0,4 [-0,7; 1,6] 0,4471[3]
Rash				
63/776 (8,1)	24/729 (3,3)	2,47 [1,56; 3,90] 0,0001[2]	2,60 [1,60; 4,20] <,0001[3]	4,8 [2,5; 7,1] <,0001[3]
Rash maculo-papular				
11/776 (1,4)	4/729 (0,5)	2,58 [0,83; 8,08] 0,1027[2]	2,61 [0,83; 8,22] 0,0899[3]	0,9 [-0,1; 1,9] 0,0899[3]
Rectal haemorrhage				
14/776 (1,8)	2/729 (0,3)	6,58 [1,50; 28,83] 0,0125[2]	6,68 [1,51; 29,49] 0,0038[3]	1,5 [0,5; 2,5] 0,0038[3]
Rhinitis allergic				
16/776 (2,1)	13/729 (1,8)	1,16 [0,56; 2,39] 0,6947[2]	1,16 [0,55; 2,43] 0,6944[3]	0,3 [-1,1; 1,7] 0,6944[3]
Rhinorrhoea				
10/776 (1,3)	6/729 (0,8)	1,57 [0,57; 4,29] 0,3829[2]	1,57 [0,57; 4,35] 0,3788[3]	0,5 [-0,6; 1,5] 0,3788[3]
Seasonal allergy				
10/776 (1,3)	6/729 (0,8)	1,57 [0,57; 4,29] 0,3829[2]	1,57 [0,57; 4,35] 0,3788[3]	0,5 [-0,6; 1,5] 0,3788[3]
Sinusitis				
29/776 (3,7)	9/729 (1,2)	3,03 [1,44; 6,35] 0,0034[2]	3,11 [1,46; 6,61] 0,0020[3]	2,5 [0,9; 4,1] 0,0020[3]
Skin infection				
13/776 (1,7)	6/729 (0,8)	2,04 [0,78; 5,33] 0,1476[2]	2,05 [0,78; 5,43] 0,1389[3]	0,9 [-0,3; 2,0] 0,1389[3]
Stomatitis				
58/776 (7,5)	13/729 (1,8)	4,19 [2,32; 7,58] <,0001[2]	4,45 [2,42; 8,19] <,0001[3]	5,7 [3,6; 7,8] <,0001[3]
Thrombocytopenia				
28/776 (3,6)	9/729 (1,2)	2,92 [1,39; 6,15] 0,0047[2]	2,99 [1,40; 6,39] 0,0030[3]	2,4 [0,8; 3,9] 0,0030[3]
Toothache				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
25/776 (3,2)	13/729 (1,8)	1,81 [0,93; 3,50] 0,0802[2]	1,83 [0,93; 3,61] 0,0755[3]	1,4 [-0,1; 3,0] 0,0755[3]
Upper respiratory tract infection				
90/776 (11,6)	71/729 (9,7)	1,19 [0,89; 1,60] 0,2447[2]	1,22 [0,88; 1,69] 0,2437[3]	1,9 [-1,3; 5,0] 0,2437[3]
Urinary tract infection				
68/776 (8,8)	33/729 (4,5)	1,94 [1,29; 2,90] 0,0013[2]	2,03 [1,32; 3,11] 0,0010[3]	4,2 [1,7; 6,7] 0,0010[3]
Urticaria				
12/776 (1,5)	5/729 (0,7)	2,25 [0,80; 6,37] 0,1249[2]	2,27 [0,80; 6,49] 0,1144[3]	0,9 [-0,2; 1,9] 0,1144[3]
Vaginal discharge				
11/776 (1,4)	26/729 (3,6)	0,40 [0,20; 0,80] 0,0095[2]	0,39 [0,19; 0,79] 0,0071[3]	-2,1 [-3,7; -0,6] 0,0071[3]
Vaginal haemorrhage				
14/776 (1,8)	9/729 (1,2)	1,46 [0,64; 3,36] 0,3711[2]	1,47 [0,63; 3,42] 0,3680[3]	0,6 [-0,7; 1,8] 0,3680[3]
Vaginal infection				
14/776 (1,8)	10/729 (1,4)	1,32 [0,59; 2,94] 0,5048[2]	1,32 [0,58; 2,99] 0,5034[3]	0,4 [-0,8; 1,7] 0,5034[3]
Vertigo				
23/776 (3,0)	13/729 (1,8)	1,66 [0,85; 3,26] 0,1387[2]	1,68 [0,85; 3,35] 0,1341[3]	1,2 [-0,4; 2,7] 0,1341[3]
Viral infection				
11/776 (1,4)	5/729 (0,7)	2,07 [0,72; 5,92] 0,1763[2]	2,08 [0,72; 6,02] 0,1666[3]	0,7 [-0,3; 1,8] 0,1666[3]
Vision blurred				
12/776 (1,5)	8/729 (1,1)	1,41 [0,58; 3,43] 0,4495[2]	1,42 [0,58; 3,48] 0,4471[3]	0,4 [-0,7; 1,6] 0,4471[3]
Vitamin D deficiency				
10/776 (1,3)	13/729 (1,8)	0,72 [0,32; 1,64] 0,4365[2]	0,72 [0,31; 1,65] 0,4344[3]	-0,5 [-1,7; 0,8] 0,4344[3]
Vomiting				
124/776 (16,0)	23/729 (3,2)	5,06 [3,28; 7,81] <,0001[2]	5,84 [3,69; 9,22] <,0001[3]	12,8 [10,0; 15,7] <,0001[3]
Vulvovaginal dryness				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
40/776 (5,2)	42/729 (5,8)	0,89 [0,59; 1,36] 0,6045[2]	0,89 [0,57; 1,39] 0,6043[3]	-0,6 [-2,9; 1,7] 0,6043[3]
Weight decreased				
20/776 (2,6)	11/729 (1,5)	1,71 [0,82; 3,54] 0,1499[2]	1,73 [0,82; 3,63] 0,1447[3]	1,1 [-0,4; 2,5] 0,1447[3]
Weight increased				
19/776 (2,4)	14/729 (1,9)	1,27 [0,64; 2,52] 0,4857[2]	1,28 [0,64; 2,58] 0,4845[3]	0,5 [-0,9; 2,0] 0,4845[3]
White blood cell count decreased				
215/776 (27,7)	55/729 (7,5)	3,67 [2,78; 4,85] <,0001[2]	4,70 [3,42; 6,45] <,0001[3]	20,2 [16,5; 23,8] <,0001[3]

Data cut-off: 03.07.2023
Safety Population - Premenopausal
1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; GnRH: Gonadotropine releasing hormone; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_bp_aesocpt.sas
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Table 057.2: Results from binary analysis for adverse events according PT - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Abdominal discomfort				
19/1283 (1,5)	7/1264 (0,6)	2,67 [1,13; 6,34] 0,0255[2]	2,70 [1,13; 6,44] 0,0199[3]	0,9 [0,1; 1,7] 0,0199[3]
Abdominal distension				
34/1283 (2,7)	12/1264 (0,9)	2,79 [1,45; 5,37] 0,0021[2]	2,84 [1,46; 5,51] 0,0013[3]	1,7 [0,7; 2,7] 0,0013[3]
Abdominal pain				
312/1283 (24,3)	64/1264 (5,1)	4,80 [3,71; 6,21] <,0001[2]	6,02 [4,54; 7,99] <,0001[3]	19,3 [16,6; 21,9] <,0001[3]
Abdominal pain upper				
124/1283 (9,7)	45/1264 (3,6)	2,71 [1,95; 3,78] <,0001[2]	2,90 [2,04; 4,11] <,0001[3]	6,1 [4,2; 8,0] <,0001[3]
Alanine aminotransferase increased				
156/1283 (12,2)	68/1264 (5,4)	2,26 [1,72; 2,97] <,0001[2]	2,43 [1,81; 3,27] <,0001[3]	6,8 [4,6; 9,0] <,0001[3]
Alopecia				
152/1283 (11,8)	36/1264 (2,8)	4,16 [2,92; 5,93] <,0001[2]	4,58 [3,16; 6,65] <,0001[3]	9,0 [7,0; 11,0] <,0001[3]
Anaemia				
333/1283 (26,0)	48/1264 (3,8)	6,83 [5,10; 9,16] <,0001[2]	8,88 [6,49; 12,16] <,0001[3]	22,2 [19,5; 24,8] <,0001[3]
Anxiety				
37/1283 (2,9)	55/1264 (4,4)	0,66 [0,44; 1,00] 0,0489[2]	0,65 [0,43; 1,00] 0,0472[3]	-1,5 [-2,9; -0,0] 0,0472[3]
Arthralgia				
341/1283 (26,6)	489/1264 (38,7)	0,69 [0,61; 0,77] <,0001[2]	0,57 [0,49; 0,68] <,0001[3]	-12,1 [-15,7; -8,5] <,0001[3]
Arthritis				
11/1283 (0,9)	18/1264 (1,4)	0,60 [0,29; 1,27] 0,1825[2]	0,60 [0,28; 1,27] 0,1777[3]	-0,6 [-1,4; 0,3] 0,1777[3]
Aspartate aminotransferase increased				
147/1283 (11,5)	65/1264 (5,1)	2,23 [1,68; 2,95] <,0001[2]	2,39 [1,76; 3,23] <,0001[3]	6,3 [4,2; 8,4] <,0001[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Asthenia				
147/1283 (11,5)	69/1264 (5,5)	2,10 [1,59; 2,76] <,0001[2]	2,24 [1,66; 3,02] <,0001[3]	6,0 [3,9; 8,1] <,0001[3]
Axillary pain				
24/1283 (1,9)	19/1264 (1,5)	1,24 [0,69; 2,26] 0,4726[2]	1,25 [0,68; 2,29] 0,4717[3]	0,4 [-0,6; 1,4] 0,4717[3]
Back pain				
115/1283 (9,0)	148/1264 (11,7)	0,77 [0,61; 0,96] 0,0233[2]	0,74 [0,57; 0,96] 0,0228[3]	-2,7 [-5,1; -0,4] 0,0228[3]
Blood alkaline phosphatase increased				
61/1283 (4,8)	39/1264 (3,1)	1,54 [1,04; 2,29] 0,0316[2]	1,57 [1,04; 2,36] 0,0301[3]	1,7 [0,2; 3,2] 0,0301[3]
Blood bilirubin increased				
17/1283 (1,3)	8/1264 (0,6)	2,09 [0,91; 4,83] 0,0835[2]	2,11 [0,91; 4,90] 0,0765[3]	0,7 [-0,1; 1,5] 0,0765[3]
Blood cholesterol increased				
16/1283 (1,2)	22/1264 (1,7)	0,72 [0,38; 1,36] 0,3067[2]	0,71 [0,37; 1,36] 0,3044[3]	-0,5 [-1,4; 0,4] 0,3044[3]
Blood creatinine increased				
150/1283 (11,7)	15/1264 (1,2)	9,85 [5,83; 16,66] <,0001[2]	11,02 [6,44; 18,86] <,0001[3]	10,5 [8,6; 12,4] <,0001[3]
Bone pain				
33/1283 (2,6)	49/1264 (3,9)	0,66 [0,43; 1,02] 0,0642[2]	0,65 [0,42; 1,02] 0,0622[3]	-1,3 [-2,7; 0,1] 0,0622[3]
Breast pain				
44/1283 (3,4)	58/1264 (4,6)	0,75 [0,51; 1,10] 0,1373[2]	0,74 [0,50; 1,10] 0,1358[3]	-1,2 [-2,7; 0,4] 0,1358[3]
Bronchitis				
24/1283 (1,9)	29/1264 (2,3)	0,82 [0,48; 1,39] 0,4547[2]	0,81 [0,47; 1,40] 0,4539[3]	-0,4 [-1,5; 0,7] 0,4539[3]
COVID-19				
37/1283 (2,9)	8/1264 (0,6)	4,56 [2,13; 9,75] <,0001[2]	4,66 [2,16; 10,05] <,0001[3]	2,3 [1,2; 3,3] <,0001[3]
Cataract				
27/1283 (2,1)	10/1264 (0,8)	2,66 [1,29; 5,47] 0,0079[2]	2,70 [1,30; 5,59] 0,0056[3]	1,3 [0,4; 2,2] 0,0056[3]
Cellulitis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
27/1283 (2,1)	20/1264 (1,6)	1,33 [0,75; 2,36] 0,3293[2]	1,34 [0,75; 2,40] 0,3276[3]	0,5 [-0,5; 1,6] 0,3276[3]
Chest pain				
27/1283 (2,1)	25/1264 (2,0)	1,06 [0,62; 1,82] 0,8213[2]	1,07 [0,61; 1,85] 0,8213[3]	0,1 [-1,0; 1,2] 0,8213[3]
Chills				
19/1283 (1,5)	11/1264 (0,9)	1,70 [0,81; 3,56] 0,1583[2]	1,71 [0,81; 3,61] 0,1532[3]	0,6 [-0,2; 1,4] 0,1532[3]
Conjunctivitis				
22/1283 (1,7)	13/1264 (1,0)	1,67 [0,84; 3,29] 0,1414[2]	1,68 [0,84; 3,35] 0,1369[3]	0,7 [-0,2; 1,6] 0,1369[3]
Constipation				
154/1283 (12,0)	72/1264 (5,7)	2,11 [1,61; 2,76] <,0001[2]	2,26 [1,69; 3,02] <,0001[3]	6,3 [4,1; 8,5] <,0001[3]
Contusion				
21/1283 (1,6)	17/1264 (1,3)	1,22 [0,65; 2,30] 0,5442[2]	1,22 [0,64; 2,32] 0,5435[3]	0,3 [-0,6; 1,2] 0,5435[3]
Cough				
185/1283 (14,4)	111/1264 (8,8)	1,64 [1,31; 2,05] <,0001[2]	1,75 [1,36; 2,25] <,0001[3]	5,6 [3,2; 8,1] <,0001[3]
Cystitis				
37/1283 (2,9)	32/1264 (2,5)	1,14 [0,71; 1,82] 0,5844[2]	1,14 [0,71; 1,85] 0,5841[3]	0,4 [-0,9; 1,6] 0,5841[3]
Decreased appetite				
164/1283 (12,8)	43/1264 (3,4)	3,76 [2,71; 5,21] <,0001[2]	4,16 [2,95; 5,88] <,0001[3]	9,4 [7,3; 11,5] <,0001[3]
Deep vein thrombosis				
21/1283 (1,6)	3/1264 (0,2)	6,90 [2,06; 23,06] 0,0017[2]	6,99 [2,08; 23,51] 0,0003[3]	1,4 [0,7; 2,1] 0,0003[3]
Dehydration				
26/1283 (2,0)	3/1264 (0,2)	8,54 [2,59; 28,14] 0,0004[2]	8,69 [2,62; 28,80] <,0001[3]	1,8 [1,0; 2,6] <,0001[3]
Depression				
50/1283 (3,9)	48/1264 (3,8)	1,03 [0,70; 1,51] 0,8960[2]	1,03 [0,69; 1,54] 0,8960[3]	0,1 [-1,4; 1,6] 0,8960[3]
Dermatitis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
19/1283 (1,5)	7/1264 (0,6)	2,67 [1,13; 6,34] 0,0255[2]	2,70 [1,13; 6,44] 0,0199[3]	0,9 [0,1; 1,7] 0,0199[3]
Diarrhoea				
1060/1283 (82,6)	111/1264 (8,8)	9,41 [7,86; 11,26] <,0001[2]	49,38 [38,74; 62,92] <,0001[3]	73,8 [71,2; 76,4] <,0001[3]
Dizziness				
138/1283 (10,8)	85/1264 (6,7)	1,60 [1,23; 2,07] 0,0004[2]	1,67 [1,26; 2,22] 0,0003[3]	4,0 [1,8; 6,2] 0,0003[3]
Dry eye				
38/1283 (3,0)	11/1264 (0,9)	3,40 [1,75; 6,63] 0,0003[2]	3,48 [1,77; 6,83] 0,0001[3]	2,1 [1,0; 3,2] 0,0001[3]
Dry mouth				
45/1283 (3,5)	17/1264 (1,3)	2,61 [1,50; 4,53] 0,0007[2]	2,67 [1,52; 4,68] 0,0004[3]	2,2 [1,0; 3,4] 0,0004[3]
Dry skin				
51/1283 (4,0)	25/1264 (2,0)	2,01 [1,25; 3,22] 0,0038[2]	2,05 [1,26; 3,33] 0,0031[3]	2,0 [0,7; 3,3] 0,0031[3]
Dysgeusia				
60/1283 (4,7)	6/1264 (0,5)	9,85 [4,27; 22,72] <,0001[2]	10,29 [4,43; 23,90] <,0001[3]	4,2 [3,0; 5,4] <,0001[3]
Dyspepsia				
96/1283 (7,5)	32/1264 (2,5)	2,96 [2,00; 4,38] <,0001[2]	3,11 [2,07; 4,68] <,0001[3]	5,0 [3,3; 6,6] <,0001[3]
Dyspnoea				
95/1283 (7,4)	50/1264 (4,0)	1,87 [1,34; 2,61] 0,0002[2]	1,94 [1,37; 2,76] 0,0002[3]	3,4 [1,7; 5,2] 0,0002[3]
Dysuria				
26/1283 (2,0)	13/1264 (1,0)	1,97 [1,02; 3,82] 0,0444[2]	1,99 [1,02; 3,89] 0,0403[3]	1,0 [0,0; 1,9] 0,0403[3]
Eczema				
13/1283 (1,0)	16/1264 (1,3)	0,80 [0,39; 1,66] 0,5489[2]	0,80 [0,38; 1,67] 0,5480[3]	-0,3 [-1,1; 0,6] 0,5480[3]
Epistaxis				
23/1283 (1,8)	3/1264 (0,2)	7,55 [2,27; 25,09] 0,0010[2]	7,67 [2,30; 25,62] <,0001[3]	1,6 [0,8; 2,3] <,0001[3]
Erythema				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
17/1283 (1,3)	16/1264 (1,3)	1,05 [0,53; 2,06] 0,8949[2]	1,05 [0,53; 2,08] 0,8949[3]	0,1 [-0,8; 0,9] 0,8949[3]
Fall				
45/1283 (3,5)	27/1264 (2,1)	1,64 [1,03; 2,63] 0,0390[2]	1,67 [1,03; 2,70] 0,0368[3]	1,4 [0,1; 2,7] 0,0368[3]
Fatigue				
397/1283 (30,9)	150/1264 (11,9)	2,61 [2,20; 3,09] <,0001[2]	3,33 [2,70; 4,10] <,0001[3]	19,1 [16,0; 22,2] <,0001[3]
Flatulence				
42/1283 (3,3)	9/1264 (0,7)	4,60 [2,25; 9,41] <,0001[2]	4,72 [2,29; 9,74] <,0001[3]	2,6 [1,5; 3,6] <,0001[3]
Gamma-glutamyltransferase increased				
42/1283 (3,3)	17/1264 (1,3)	2,43 [1,39; 4,25] 0,0018[2]	2,48 [1,41; 4,38] 0,0012[3]	1,9 [0,8; 3,1] 0,0012[3]
Gastritis				
30/1283 (2,3)	21/1264 (1,7)	1,41 [0,81; 2,44] 0,2251[2]	1,42 [0,81; 2,49] 0,2227[3]	0,7 [-0,4; 1,8] 0,2227[3]
Gastroenteritis				
18/1283 (1,4)	13/1264 (1,0)	1,36 [0,67; 2,77] 0,3908[2]	1,37 [0,67; 2,81] 0,3888[3]	0,4 [-0,5; 1,2] 0,3888[3]
Gastrointestinal pain				
17/1283 (1,3)	1/1264 (0,1)	16,75 [2,23; 125,66] 0,0061[2]	16,96 [2,25; 127,63] 0,0002[3]	1,2 [0,6; 1,9] 0,0002[3]
Gastrooesophageal reflux disease				
41/1283 (3,2)	25/1264 (2,0)	1,62 [0,99; 2,64] 0,0556[2]	1,64 [0,99; 2,71] 0,0531[3]	1,2 [-0,0; 2,4] 0,0531[3]
Haemorrhoids				
28/1283 (2,2)	13/1264 (1,0)	2,12 [1,10; 4,08] 0,0240[2]	2,15 [1,11; 4,16] 0,0207[3]	1,2 [0,2; 2,1] 0,0207[3]
Headache				
224/1283 (17,5)	149/1264 (11,8)	1,48 [1,22; 1,79] <,0001[2]	1,58 [1,27; 1,98] <,0001[3]	5,7 [2,9; 8,4] <,0001[3]
Hepatic steatosis				
23/1283 (1,8)	22/1264 (1,7)	1,03 [0,58; 1,84] 0,9204[2]	1,03 [0,57; 1,86] 0,9204[3]	0,1 [-1,0; 1,1] 0,9204[3]
Herpes zoster				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
23/1283 (1,8)	23/1264 (1,8)	0,99 [0,56; 1,75] 0,9593[2]	0,98 [0,55; 1,76] 0,9593[3]	-0,0 [-1,1; 1,0] 0,9593[3]
Hot flush				
147/1283 (11,5)	216/1264 (17,1)	0,67 [0,55; 0,81] <,0001[2]	0,63 [0,50; 0,79] <,0001[3]	-5,6 [-8,3; -2,9] <,0001[3]
Hypercalcaemia				
27/1283 (2,1)	18/1264 (1,4)	1,48 [0,82; 2,67] 0,1955[2]	1,49 [0,82; 2,72] 0,1925[3]	0,7 [-0,3; 1,7] 0,1925[3]
Hypercholesterolaemia				
15/1283 (1,2)	24/1264 (1,9)	0,62 [0,32; 1,17] 0,1378[2]	0,61 [0,32; 1,17] 0,1338[3]	-0,7 [-1,7; 0,2] 0,1338[3]
Hyperglycaemia				
20/1283 (1,6)	30/1264 (2,4)	0,66 [0,38; 1,15] 0,1415[2]	0,65 [0,37; 1,15] 0,1384[3]	-0,8 [-1,9; 0,3] 0,1384[3]
Hyperhidrosis				
17/1283 (1,3)	21/1264 (1,7)	0,80 [0,42; 1,50] 0,4848[2]	0,79 [0,42; 1,51] 0,4838[3]	-0,3 [-1,3; 0,6] 0,4838[3]
Hyperkalaemia				
14/1283 (1,1)	9/1264 (0,7)	1,53 [0,67; 3,53] 0,3156[2]	1,54 [0,66; 3,57] 0,3118[3]	0,4 [-0,4; 1,1] 0,3118[3]
Hypersensitivity				
13/1283 (1,0)	11/1264 (0,9)	1,16 [0,52; 2,59] 0,7091[2]	1,17 [0,52; 2,61] 0,7088[3]	0,1 [-0,6; 0,9] 0,7088[3]
Hypertension				
56/1283 (4,4)	72/1264 (5,7)	0,77 [0,55; 1,08] 0,1254[2]	0,76 [0,53; 1,08] 0,1241[3]	-1,3 [-3,0; 0,4] 0,1241[3]
Hypertriglyceridaemia				
25/1283 (1,9)	28/1264 (2,2)	0,88 [0,52; 1,50] 0,6376[2]	0,88 [0,51; 1,51] 0,6374[3]	-0,3 [-1,4; 0,8] 0,6374[3]
Hyperuricaemia				
20/1283 (1,6)	10/1264 (0,8)	1,97 [0,93; 4,19] 0,0783[2]	1,99 [0,93; 4,26] 0,0726[3]	0,8 [-0,1; 1,6] 0,0726[3]
Hypoalbuminaemia				
14/1283 (1,1)	8/1264 (0,6)	1,72 [0,73; 4,10] 0,2172[2]	1,73 [0,72; 4,14] 0,2114[3]	0,5 [-0,3; 1,2] 0,2114[3]
Hypokalaemia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
57/1283 (4,4)	15/1264 (1,2)	3,74 [2,13; 6,58] <,0001[2]	3,87 [2,18; 6,87] <,0001[3]	3,3 [2,0; 4,5] <,0001[3]
Hyponatraemia				
19/1283 (1,5)	9/1264 (0,7)	2,08 [0,94; 4,58] 0,0690[2]	2,10 [0,94; 4,65] 0,0628[3]	0,8 [-0,0; 1,6] 0,0628[3]
Hypotension				
24/1283 (1,9)	7/1264 (0,6)	3,38 [1,46; 7,81] 0,0044[2]	3,42 [1,47; 7,97] 0,0024[3]	1,3 [0,5; 2,2] 0,0024[3]
Hypothyroidism				
15/1283 (1,2)	19/1264 (1,5)	0,78 [0,40; 1,52] 0,4639[2]	0,78 [0,39; 1,53] 0,4627[3]	-0,3 [-1,2; 0,6] 0,4627[3]
Influenza				
47/1283 (3,7)	43/1264 (3,4)	1,08 [0,72; 1,62] 0,7210[2]	1,08 [0,71; 1,65] 0,7209[3]	0,3 [-1,2; 1,7] 0,7209[3]
Influenza like illness				
56/1283 (4,4)	43/1264 (3,4)	1,28 [0,87; 1,89] 0,2101[2]	1,30 [0,86; 1,94] 0,2087[3]	1,0 [-0,5; 2,5] 0,2087[3]
Insomnia				
96/1283 (7,5)	92/1264 (7,3)	1,03 [0,78; 1,35] 0,8439[2]	1,03 [0,77; 1,39] 0,8439[3]	0,2 [-1,8; 2,2] 0,8439[3]
Joint stiffness				
14/1283 (1,1)	30/1264 (2,4)	0,46 [0,24; 0,86] 0,0156[2]	0,45 [0,24; 0,86] 0,0130[3]	-1,3 [-2,3; -0,3] 0,0130[3]
Lacrimation increased				
72/1283 (5,6)	5/1264 (0,4)	14,19 [5,75; 35,00] <,0001[2]	14,97 [6,03; 37,19] <,0001[3]	5,2 [3,9; 6,5] <,0001[3]
Leukopenia				
188/1283 (14,7)	25/1264 (2,0)	7,41 [4,92; 11,16] <,0001[2]	8,51 [5,56; 13,02] <,0001[3]	12,7 [10,6; 14,8] <,0001[3]
Lymphocyte count decreased				
112/1283 (8,7)	28/1264 (2,2)	3,94 [2,62; 5,92] <,0001[2]	4,22 [2,77; 6,44] <,0001[3]	6,5 [4,8; 8,3] <,0001[3]
Lymphoedema				
155/1283 (12,1)	105/1264 (8,3)	1,45 [1,15; 1,84] 0,0018[2]	1,52 [1,17; 1,97] 0,0017[3]	3,8 [1,4; 6,1] 0,0017[3]
Lymphopenia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
69/1283 (5,4)	10/1264 (0,8)	6,80 [3,52; 13,13] <,0001[2]	7,13 [3,65; 13,90] <,0001[3]	4,6 [3,3; 5,9] <,0001[3]
Malaise				
33/1283 (2,6)	12/1264 (0,9)	2,71 [1,41; 5,22] 0,0029[2]	2,75 [1,42; 5,36] 0,0019[3]	1,6 [0,6; 2,6] 0,0019[3]
Mastitis				
10/1283 (0,8)	18/1264 (1,4)	0,55 [0,25; 1,18] 0,1246[2]	0,54 [0,25; 1,18] 0,1188[3]	-0,6 [-1,5; 0,2] 0,1188[3]
Memory impairment				
17/1283 (1,3)	10/1264 (0,8)	1,67 [0,77; 3,64] 0,1934[2]	1,68 [0,77; 3,69] 0,1884[3]	0,5 [-0,3; 1,3] 0,1884[3]
Mucosal inflammation				
37/1283 (2,9)	9/1264 (0,7)	4,05 [1,96; 8,36] 0,0002[2]	4,14 [1,99; 8,62] <,0001[3]	2,2 [1,1; 3,2] <,0001[3]
Muscle spasms				
73/1283 (5,7)	49/1264 (3,9)	1,47 [1,03; 2,09] 0,0334[2]	1,50 [1,03; 2,17] 0,0322[3]	1,8 [0,2; 3,5] 0,0322[3]
Muscular weakness				
18/1283 (1,4)	8/1264 (0,6)	2,22 [0,97; 5,08] 0,0599[2]	2,23 [0,97; 5,16] 0,0532[3]	0,8 [-0,0; 1,5] 0,0532[3]
Musculoskeletal chest pain				
38/1283 (3,0)	30/1264 (2,4)	1,25 [0,78; 2,00] 0,3581[2]	1,26 [0,77; 2,04] 0,3570[3]	0,6 [-0,7; 1,8] 0,3570[3]
Musculoskeletal pain				
17/1283 (1,3)	27/1264 (2,1)	0,62 [0,34; 1,13] 0,1199[2]	0,62 [0,33; 1,13] 0,1163[3]	-0,8 [-1,8; 0,2] 0,1163[3]
Musculoskeletal stiffness				
16/1283 (1,2)	18/1264 (1,4)	0,88 [0,45; 1,71] 0,6974[2]	0,87 [0,44; 1,72] 0,6972[3]	-0,2 [-1,1; 0,7] 0,6972[3]
Myalgia				
74/1283 (5,8)	83/1264 (6,6)	0,88 [0,65; 1,19] 0,4024[2]	0,87 [0,63; 1,20] 0,4020[3]	-0,8 [-2,7; 1,1] 0,4020[3]
Nail disorder				
24/1283 (1,9)	2/1264 (0,2)	11,82 [2,80; 49,92] 0,0008[2]	12,03 [2,84; 51,00] <,0001[3]	1,7 [0,9; 2,5] <,0001[3]
Nasal congestion				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
17/1283 (1,3)	13/1264 (1,0)	1,29 [0,63; 2,64] 0,4892[2]	1,29 [0,63; 2,67] 0,4880[3]	0,3 [-0,5; 1,1] 0,4880[3]
Nasopharyngitis				
106/1283 (8,3)	90/1264 (7,1)	1,16 [0,89; 1,52] 0,2803[2]	1,17 [0,88; 1,57] 0,2798[3]	1,1 [-0,9; 3,2] 0,2798[3]
Nausea				
385/1283 (30,0)	97/1264 (7,7)	3,91 [3,17; 4,82] <,0001[2]	5,16 [4,06; 6,55] <,0001[3]	22,3 [19,4; 25,2] <,0001[3]
Neck pain				
28/1283 (2,2)	32/1264 (2,5)	0,86 [0,52; 1,42] 0,5616[2]	0,86 [0,51; 1,44] 0,5612[3]	-0,3 [-1,5; 0,8] 0,5612[3]
Neuropathy peripheral				
39/1283 (3,0)	36/1264 (2,8)	1,07 [0,68; 1,67] 0,7749[2]	1,07 [0,68; 1,69] 0,7748[3]	0,2 [-1,1; 1,5] 0,7748[3]
Neutropenia				
297/1283 (23,1)	29/1264 (2,3)	10,09 [6,95; 14,66] <,0001[2]	12,83 [8,68; 18,95] <,0001[3]	20,9 [18,4; 23,3] <,0001[3]
Neutrophil count decreased				
282/1283 (22,0)	22/1264 (1,7)	12,63 [8,24; 19,35] <,0001[2]	15,90 [10,22; 24,74] <,0001[3]	20,2 [17,9; 22,6] <,0001[3]
Night sweats				
10/1283 (0,8)	14/1264 (1,1)	0,70 [0,31; 1,58] 0,3939[2]	0,70 [0,31; 1,58] 0,3914[3]	-0,3 [-1,1; 0,4] 0,3914[3]
Oedema				
16/1283 (1,2)	8/1264 (0,6)	1,97 [0,85; 4,59] 0,1157[2]	1,98 [0,85; 4,65] 0,1087[3]	0,6 [-0,1; 1,4] 0,1087[3]
Oedema peripheral				
93/1283 (7,2)	49/1264 (3,9)	1,87 [1,33; 2,62] 0,0003[2]	1,94 [1,36; 2,76] 0,0002[3]	3,4 [1,6; 5,1] 0,0002[3]
Onychoclasis				
21/1283 (1,6)	3/1264 (0,2)	6,90 [2,06; 23,06] 0,0017[2]	6,99 [2,08; 23,51] 0,0003[3]	1,4 [0,7; 2,1] 0,0003[3]
Oral herpes				
16/1283 (1,2)	5/1264 (0,4)	3,15 [1,16; 8,58] 0,0246[2]	3,18 [1,16; 8,71] 0,0175[3]	0,9 [0,2; 1,6] 0,0175[3]
Oropharyngeal pain				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
49/1283 (3,8)	32/1264 (2,5)	1,51 [0,97; 2,34] 0,0662[2]	1,53 [0,97; 2,40] 0,0641[3]	1,3 [-0,1; 2,6] 0,0641[3]
Osteoarthritis				
15/1283 (1,2)	26/1264 (2,1)	0,57 [0,30; 1,07] 0,0792[2]	0,56 [0,30; 1,07] 0,0751[3]	-0,9 [-1,9; 0,1] 0,0751[3]
Osteopenia				
23/1283 (1,8)	25/1264 (2,0)	0,91 [0,52; 1,59] 0,7312[2]	0,90 [0,51; 1,60] 0,7311[3]	-0,2 [-1,2; 0,9] 0,7311[3]
Osteoporosis				
30/1283 (2,3)	47/1264 (3,7)	0,63 [0,40; 0,99] 0,0440[2]	0,62 [0,39; 0,99] 0,0420[3]	-1,4 [-2,7; -0,0] 0,0420[3]
Pain				
29/1283 (2,3)	30/1264 (2,4)	0,95 [0,58; 1,58] 0,8496[2]	0,95 [0,57; 1,59] 0,8495[3]	-0,1 [-1,3; 1,1] 0,8495[3]
Pain in extremity				
128/1283 (10,0)	141/1264 (11,2)	0,89 [0,71; 1,12] 0,3336[2]	0,88 [0,69; 1,14] 0,3333[3]	-1,2 [-3,6; 1,2] 0,3333[3]
Palpitations				
27/1283 (2,1)	12/1264 (0,9)	2,22 [1,13; 4,36] 0,0209[2]	2,24 [1,13; 4,45] 0,0176[3]	1,2 [0,2; 2,1] 0,0176[3]
Paraesthesia				
32/1283 (2,5)	30/1264 (2,4)	1,05 [0,64; 1,72] 0,8433[2]	1,05 [0,64; 1,74] 0,8433[3]	0,1 [-1,1; 1,3] 0,8433[3]
Paronychia				
15/1283 (1,2)	4/1264 (0,3)	3,69 [1,23; 11,10] 0,0199[2]	3,73 [1,23; 11,26] 0,0124[3]	0,9 [0,2; 1,5] 0,0124[3]
Peripheral sensory neuropathy				
16/1283 (1,2)	13/1264 (1,0)	1,21 [0,59; 2,51] 0,6037[2]	1,22 [0,58; 2,54] 0,6031[3]	0,2 [-0,6; 1,0] 0,6031[3]
Peripheral swelling				
30/1283 (2,3)	25/1264 (2,0)	1,18 [0,70; 2,00] 0,5320[2]	1,19 [0,69; 2,03] 0,5315[3]	0,4 [-0,8; 1,5] 0,5315[3]
Platelet count decreased				
116/1283 (9,0)	9/1264 (0,7)	12,70 [6,47; 24,91] <,0001[2]	13,86 [7,00; 27,44] <,0001[3]	8,3 [6,7; 10,0] <,0001[3]
Pneumonia				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
31/1283 (2,4)	19/1264 (1,5)	1,61 [0,91; 2,83] 0,1001[2]	1,62 [0,91; 2,89] 0,0968[3]	0,9 [-0,2; 2,0] 0,0968[3]
Pneumonitis				
18/1283 (1,4)	3/1264 (0,2)	5,91 [1,75; 20,02] 0,0043[2]	5,98 [1,76; 20,36] 0,0011[3]	1,2 [0,5; 1,9] 0,0011[3]
Procedural pain				
36/1283 (2,8)	26/1264 (2,1)	1,36 [0,83; 2,25] 0,2221[2]	1,37 [0,83; 2,29] 0,2201[3]	0,7 [-0,4; 1,9] 0,2201[3]
Productive cough				
21/1283 (1,6)	13/1264 (1,0)	1,59 [0,80; 3,16] 0,1852[2]	1,60 [0,80; 3,21] 0,1811[3]	0,6 [-0,3; 1,5] 0,1811[3]
Pruritus				
109/1283 (8,5)	59/1264 (4,7)	1,82 [1,34; 2,47] 0,0001[2]	1,90 [1,37; 2,63] <,0001[3]	3,8 [1,9; 5,7] <,0001[3]
Pyrexia				
99/1283 (7,7)	45/1264 (3,6)	2,17 [1,54; 3,06] <,0001[2]	2,27 [1,58; 3,25] <,0001[3]	4,2 [2,4; 5,9] <,0001[3]
Rash				
113/1283 (8,8)	37/1264 (2,9)	3,01 [2,09; 4,33] <,0001[2]	3,20 [2,19; 4,68] <,0001[3]	5,9 [4,1; 7,7] <,0001[3]
Rash maculo-papular				
22/1283 (1,7)	3/1264 (0,2)	7,22 [2,17; 24,08] 0,0013[2]	7,33 [2,19; 24,56] 0,0002[3]	1,5 [0,7; 2,2] 0,0002[3]
Respiratory tract infection				
15/1283 (1,2)	9/1264 (0,7)	1,64 [0,72; 3,74] 0,2375[2]	1,65 [0,72; 3,78] 0,2325[3]	0,5 [-0,3; 1,2] 0,2325[3]
Rhinitis allergic				
23/1283 (1,8)	24/1264 (1,9)	0,94 [0,54; 1,66] 0,8424[2]	0,94 [0,53; 1,68] 0,8424[3]	-0,1 [-1,2; 0,9] 0,8424[3]
Sciatica				
13/1283 (1,0)	15/1264 (1,2)	0,85 [0,41; 1,79] 0,6750[2]	0,85 [0,40; 1,80] 0,6747[3]	-0,2 [-1,0; 0,6] 0,6747[3]
Seroma				
16/1283 (1,2)	5/1264 (0,4)	3,15 [1,16; 8,58] 0,0246[2]	3,18 [1,16; 8,71] 0,0175[3]	0,9 [0,2; 1,6] 0,0175[3]
Sinusitis				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
30/1283 (2,3)	32/1264 (2,5)	0,92 [0,56; 1,51] 0,7516[2]	0,92 [0,56; 1,53] 0,7515[3]	-0,2 [-1,4; 1,0] 0,7515[3]
Stomatitis				
68/1283 (5,3)	12/1264 (0,9)	5,58 [3,04; 10,26] <,0001[2]	5,84 [3,15; 10,84] <,0001[3]	4,4 [3,0; 5,7] <,0001[3]
Syncope				
14/1283 (1,1)	8/1264 (0,6)	1,72 [0,73; 4,10] 0,2172[2]	1,73 [0,72; 4,14] 0,2114[3]	0,5 [-0,3; 1,2] 0,2114[3]
Taste disorder				
21/1283 (1,6)	2/1264 (0,2)	10,34 [2,43; 44,03] 0,0016[2]	10,50 [2,46; 44,87] <,0001[3]	1,5 [0,8; 2,2] <,0001[3]
Tendonitis				
10/1283 (0,8)	18/1264 (1,4)	0,55 [0,25; 1,18] 0,1246[2]	0,54 [0,25; 1,18] 0,1188[3]	-0,6 [-1,5; 0,2] 0,1188[3]
Thrombocytopenia				
86/1283 (6,7)	9/1264 (0,7)	9,41 [4,76; 18,62] <,0001[2]	10,02 [5,02; 20,00] <,0001[3]	6,0 [4,5; 7,4] <,0001[3]
Tooth extraction				
8/1283 (0,6)	13/1264 (1,0)	0,61 [0,25; 1,46] 0,2636[2]	0,60 [0,25; 1,46] 0,2585[3]	-0,4 [-1,1; 0,3] 0,2585[3]
Toothache				
18/1283 (1,4)	19/1264 (1,5)	0,93 [0,49; 1,77] 0,8327[2]	0,93 [0,49; 1,78] 0,8326[3]	-0,1 [-1,0; 0,8] 0,8326[3]
Tremor				
15/1283 (1,2)	6/1264 (0,5)	2,46 [0,96; 6,33] 0,0612[2]	2,48 [0,96; 6,41] 0,0526[3]	0,7 [-0,0; 1,4] 0,0526[3]
Trigger finger				
13/1283 (1,0)	14/1264 (1,1)	0,91 [0,43; 1,94] 0,8162[2]	0,91 [0,43; 1,95] 0,8162[3]	-0,1 [-0,9; 0,7] 0,8162[3]
Upper respiratory tract infection				
107/1283 (8,3)	88/1264 (7,0)	1,20 [0,91; 1,57] 0,1918[2]	1,22 [0,91; 1,63] 0,1910[3]	1,4 [-0,7; 3,4] 0,1910[3]
Urinary tract infection				
118/1283 (9,2)	68/1264 (5,4)	1,71 [1,28; 2,28] 0,0003[2]	1,78 [1,31; 2,43] 0,0002[3]	3,8 [1,8; 5,8] 0,0002[3]
Urticaria				

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
13/1283 (1,0)	10/1264 (0,8)	1,28 [0,56; 2,91] 0,5546[2]	1,28 [0,56; 2,94] 0,5535[3]	0,2 [-0,5; 1,0] 0,5535[3]
Vertigo				
40/1283 (3,1)	27/1264 (2,1)	1,46 [0,90; 2,36] 0,1241[2]	1,47 [0,90; 2,42] 0,1217[3]	1,0 [-0,3; 2,2] 0,1217[3]
Viral infection				
15/1283 (1,2)	2/1264 (0,2)	7,39 [1,69; 32,24] 0,0078[2]	7,46 [1,70; 32,71] 0,0017[3]	1,0 [0,4; 1,6] 0,0017[3]
Vision blurred				
29/1283 (2,3)	10/1264 (0,8)	2,86 [1,40; 5,84] 0,0040[2]	2,90 [1,41; 5,98] 0,0025[3]	1,5 [0,5; 2,4] 0,0025[3]
Vitamin B12 deficiency				
16/1283 (1,2)	4/1264 (0,3)	3,94 [1,32; 11,75] 0,0139[2]	3,98 [1,33; 11,93] 0,0078[3]	0,9 [0,2; 1,6] 0,0078[3]
Vitamin D deficiency				
16/1283 (1,2)	15/1264 (1,2)	1,05 [0,52; 2,12] 0,8895[2]	1,05 [0,52; 2,14] 0,8895[3]	0,1 [-0,8; 0,9] 0,8895[3]
Vomiting				
222/1283 (17,3)	53/1264 (4,2)	4,13 [3,09; 5,51] <,0001[2]	4,78 [3,50; 6,52] <,0001[3]	13,1 [10,8; 15,5] <,0001[3]
Vulvovaginal dryness				
27/1283 (2,1)	40/1264 (3,2)	0,67 [0,41; 1,08] 0,0971[2]	0,66 [0,40; 1,08] 0,0946[3]	-1,1 [-2,3; 0,2] 0,0946[3]
Weight decreased				
59/1283 (4,6)	15/1264 (1,2)	3,88 [2,21; 6,79] <,0001[2]	4,01 [2,26; 7,11] <,0001[3]	3,4 [2,1; 4,7] <,0001[3]
Weight increased				
19/1283 (1,5)	33/1264 (2,6)	0,57 [0,32; 0,99] 0,0468[2]	0,56 [0,32; 0,99] 0,0438[3]	-1,1 [-2,2; -0,0] 0,0438[3]
White blood cell count decreased				
287/1283 (22,4)	51/1264 (4,0)	5,54 [4,16; 7,39] <,0001[2]	6,85 [5,03; 9,34] <,0001[3]	18,3 [15,8; 20,9] <,0001[3]

Data cut-off: 03.07.2023
Safety Population - Postmenopausal
1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

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Table 058.1: Results from binary analysis for adverse events according SOC - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Blood and lymphatic system disorders				
286/776 (36,9)	80/729 (11,0)	3,36 [2,68; 4,21] <,0001[2]	4,74 [3,60; 6,23] <,0001[3]	25,9 [21,8; 30,0] <,0001[3]
Cardiac disorders				
30/776 (3,9)	20/729 (2,7)	1,41 [0,81; 2,46] 0,2272[2]	1,43 [0,80; 2,53] 0,2246[3]	1,1 [-0,7; 2,9] 0,2246[3]
Ear and labyrinth disorders				
40/776 (5,2)	36/729 (4,9)	1,04 [0,67; 1,62] 0,8481[2]	1,05 [0,66; 1,66] 0,8481[3]	0,2 [-2,0; 2,4] 0,8481[3]
Endocrine disorders				
14/776 (1,8)	27/729 (3,7)	0,49 [0,26; 0,92] 0,0270[2]	0,48 [0,25; 0,92] 0,0237[3]	-1,9 [-3,6; -0,2] 0,0237[3]
Eye disorders				
103/776 (13,3)	48/729 (6,6)	2,02 [1,45; 2,80] <,0001[2]	2,17 [1,52; 3,11] <,0001[3]	6,7 [3,7; 9,7] <,0001[3]
Gastrointestinal disorders				
698/776 (89,9)	225/729 (30,9)	2,91 [2,61; 3,26] <,0001[2]	20,05 [15,12; 26,57] <,0001[3]	59,1 [55,1; 63,0] <,0001[3]
General disorders and administration site conditions				
422/776 (54,4)	232/729 (31,8)	1,71 [1,51; 1,93] <,0001[2]	2,55 [2,07; 3,15] <,0001[3]	22,6 [17,7; 27,4] <,0001[3]
Hepatobiliary disorders				
42/776 (5,4)	25/729 (3,4)	1,58 [0,97; 2,56] 0,0650[2]	1,61 [0,97; 2,67] 0,0623[3]	2,0 [-0,1; 4,1] 0,0623[3]
Immune system disorders				
15/776 (1,9)	13/729 (1,8)	1,08 [0,52; 2,26] 0,8300[2]	1,09 [0,51; 2,30] 0,8299[3]	0,1 [-1,2; 1,5] 0,8299[3]
Infections and infestations				
425/776 (54,8)	304/729 (41,7)	1,31 [1,18; 1,46] <,0001[2]	1,69 [1,38; 2,08] <,0001[3]	13,1 [8,1; 18,1] <,0001[3]
Injury, poisoning and procedural complications				
123/776 (15,9)	98/729 (13,4)	1,18 [0,92; 1,51] 0,1882[2]	1,21 [0,91; 1,62] 0,1873[3]	2,4 [-1,2; 6,0] 0,1873[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Investigations				
405/776 (52,2)	159/729 (21,8)	2,39 [2,05; 2,79] <,0001[2]	3,91 [3,12; 4,90] <,0001[3]	30,4 [25,8; 35,0] <,0001[3]
Metabolism and nutrition disorders				
174/776 (22,4)	85/729 (11,7)	1,92 [1,51; 2,44] <,0001[2]	2,19 [1,65; 2,90] <,0001[3]	10,8 [7,0; 14,5] <,0001[3]
Musculoskeletal and connective tissue disorders				
364/776 (46,9)	390/729 (53,5)	0,88 [0,79; 0,97] 0,0107[2]	0,77 [0,63; 0,94] 0,0106[3]	-6,6 [-11,6; -1,5] 0,0106[3]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
21/776 (2,7)	24/729 (3,3)	0,82 [0,46; 1,46] 0,5054[2]	0,82 [0,45; 1,48] 0,5047[3]	-0,6 [-2,3; 1,1] 0,5047[3]
Nervous system disorders				
282/776 (36,3)	216/729 (29,6)	1,23 [1,06; 1,42] 0,0060[2]	1,36 [1,09; 1,68] 0,0057[3]	6,7 [2,0; 11,4] 0,0057[3]
Psychiatric disorders				
163/776 (21,0)	152/729 (20,9)	1,01 [0,83; 1,23] 0,9412[2]	1,01 [0,79; 1,29] 0,9412[3]	0,2 [-4,0; 4,3] 0,9412[3]
Renal and urinary disorders				
55/776 (7,1)	33/729 (4,5)	1,57 [1,03; 2,38] 0,0362[2]	1,61 [1,03; 2,51] 0,0343[3]	2,6 [0,2; 4,9] 0,0343[3]
Reproductive system and breast disorders				
144/776 (18,6)	153/729 (21,0)	0,88 [0,72; 1,08] 0,2366[2]	0,86 [0,67; 1,11] 0,2363[3]	-2,4 [-6,5; 1,6] 0,2363[3]
Respiratory, thoracic and mediastinal disorders				
217/776 (28,0)	112/729 (15,4)	1,82 [1,48; 2,23] <,0001[2]	2,14 [1,66; 2,76] <,0001[3]	12,6 [8,5; 16,7] <,0001[3]
Skin and subcutaneous tissue disorders				
305/776 (39,3)	145/729 (19,9)	1,98 [1,67; 2,34] <,0001[2]	2,61 [2,07; 3,29] <,0001[3]	19,4 [14,9; 23,9] <,0001[3]
Surgical and medical procedures				
45/776 (5,8)	41/729 (5,6)	1,03 [0,68; 1,56] 0,8839[2]	1,03 [0,67; 1,60] 0,8839[3]	0,2 [-2,2; 2,5] 0,8839[3]
Vascular disorders				
265/776 (34,1)	261/729 (35,8)	0,95 [0,83; 1,09] 0,5014[2]	0,93 [0,75; 1,15] 0,5015[3]	-1,7 [-6,5; 3,2] 0,5015[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 03.07.2023 Safety Population - Premenopausal 1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; GnRH: Gonadotropine releasing hormone; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.				

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Table 058.2: Results from binary analysis for adverse events according SOC - events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Blood and lymphatic system disorders				
591/1283 (46,1)	114/1264 (9,0)	5,11 [4,25; 6,14] <,0001[2]	8,62 [6,90; 10,75] <,0001[3]	37,0 [33,9; 40,2] <,0001[3]
Cardiac disorders				
90/1283 (7,0)	60/1264 (4,7)	1,48 [1,08; 2,03] 0,0158[2]	1,51 [1,08; 2,12] 0,0151[3]	2,3 [0,4; 4,1] 0,0151[3]
Ear and labyrinth disorders				
52/1283 (4,1)	56/1264 (4,4)	0,91 [0,63; 1,32] 0,6366[2]	0,91 [0,62; 1,34] 0,6365[3]	-0,4 [-1,9; 1,2] 0,6365[3]
Endocrine disorders				
24/1283 (1,9)	31/1264 (2,5)	0,76 [0,45; 1,29] 0,3140[2]	0,76 [0,44; 1,30] 0,3124[3]	-0,6 [-1,7; 0,5] 0,3124[3]
Eye disorders				
197/1283 (15,4)	66/1264 (5,2)	2,94 [2,25; 3,84] <,0001[2]	3,29 [2,46; 4,40] <,0001[3]	10,1 [7,8; 12,5] <,0001[3]
Gastrointestinal disorders				
1142/1283 (89,0)	412/1264 (32,6)	2,73 [2,52; 2,96] <,0001[2]	16,75 [13,57; 20,68] <,0001[3]	56,4 [53,3; 59,5] <,0001[3]
General disorders and administration site conditions				
716/1283 (55,8)	412/1264 (32,6)	1,71 [1,56; 1,88] <,0001[2]	2,61 [2,22; 3,07] <,0001[3]	23,2 [19,5; 27,0] <,0001[3]
Hepatobiliary disorders				
62/1283 (4,8)	55/1264 (4,4)	1,11 [0,78; 1,58] 0,5622[2]	1,12 [0,77; 1,62] 0,5619[3]	0,5 [-1,1; 2,1] 0,5619[3]
Immune system disorders				
30/1283 (2,3)	30/1264 (2,4)	0,99 [0,60; 1,62] 0,9534[2]	0,98 [0,59; 1,64] 0,9534[3]	-0,0 [-1,2; 1,1] 0,9534[3]
Infections and infestations				
608/1283 (47,4)	464/1264 (36,7)	1,29 [1,18; 1,42] <,0001[2]	1,55 [1,33; 1,82] <,0001[3]	10,7 [6,9; 14,5] <,0001[3]
Injury, poisoning and procedural complications				
221/1283 (17,2)	187/1264 (14,8)	1,16 [0,97; 1,39] 0,0950[2]	1,20 [0,97; 1,48] 0,0944[3]	2,4 [-0,4; 5,3] 0,0944[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Investigations				
623/1283 (48,6)	281/1264 (22,2)	2,18 [1,94; 2,46] <,0001[2]	3,30 [2,78; 3,92] <,0001[3]	26,3 [22,8; 29,9] <,0001[3]
Metabolism and nutrition disorders				
363/1283 (28,3)	211/1264 (16,7)	1,69 [1,46; 1,97] <,0001[2]	1,97 [1,63; 2,38] <,0001[3]	11,6 [8,4; 14,8] <,0001[3]
Musculoskeletal and connective tissue disorders				
631/1283 (49,2)	745/1264 (58,9)	0,83 [0,78; 0,90] <,0001[2]	0,67 [0,58; 0,79] <,0001[3]	-9,8 [-13,6; -5,9] <,0001[3]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
39/1283 (3,0)	38/1264 (3,0)	1,01 [0,65; 1,57] 0,9607[2]	1,01 [0,64; 1,59] 0,9607[3]	0,0 [-1,3; 1,4] 0,9607[3]
Nervous system disorders				
500/1283 (39,0)	347/1264 (27,5)	1,42 [1,27; 1,59] <,0001[2]	1,69 [1,43; 1,99] <,0001[3]	11,5 [7,9; 15,1] <,0001[3]
Psychiatric disorders				
204/1283 (15,9)	214/1264 (16,9)	0,94 [0,79; 1,12] 0,4829[2]	0,93 [0,75; 1,14] 0,4828[3]	-1,0 [-3,9; 1,8] 0,4828[3]
Renal and urinary disorders				
102/1283 (8,0)	69/1264 (5,5)	1,46 [1,08; 1,96] 0,0126[2]	1,50 [1,09; 2,05] 0,0120[3]	2,5 [0,6; 4,4] 0,0120[3]
Reproductive system and breast disorders				
125/1283 (9,7)	168/1264 (13,3)	0,73 [0,59; 0,91] 0,0053[2]	0,70 [0,55; 0,90] 0,0050[3]	-3,5 [-6,0; -1,1] 0,0050[3]
Respiratory, thoracic and mediastinal disorders				
376/1283 (29,3)	247/1264 (19,5)	1,50 [1,30; 1,73] <,0001[2]	1,71 [1,42; 2,05] <,0001[3]	9,8 [6,5; 13,1] <,0001[3]
Skin and subcutaneous tissue disorders				
508/1283 (39,6)	282/1264 (22,3)	1,77 [1,57; 2,01] <,0001[2]	2,28 [1,92; 2,71] <,0001[3]	17,3 [13,8; 20,8] <,0001[3]
Surgical and medical procedures				
67/1283 (5,2)	71/1264 (5,6)	0,93 [0,67; 1,29] 0,6598[2]	0,93 [0,66; 1,30] 0,6598[3]	-0,4 [-2,2; 1,4] 0,6598[3]
Vascular disorders				
393/1283 (30,6)	375/1264 (29,7)	1,03 [0,92; 1,16] 0,5963[2]	1,05 [0,88; 1,24] 0,5962[3]	1,0 [-2,6; 4,5] 0,5962[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Data cut-off: 03.07.2023 Safety Population - Postmenopausal 1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test. Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.				

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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/data/analysis/shared/adamgba
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Anhang 4-G4.4.4: Häufige schwerwiegende unerwünschte Ereignisse nach SOC und PT

Table 059.1: Results from binary analysis for serious adverse events according PT - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
No events in category				
-	-	-	-	-

Data cut-off: 03.07.2023
Safety Population - Premenopausal
1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_bp_aesocpt.sas
Output Location:
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/lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/data/analysis/shared/adamgba
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Table 059.2: Results from binary analysis for serious adverse events according PT - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Pneumonia				
15/1283 (1,2)	7/1264 (0,6)	2,11 [0,86; 5,16] 0,1013[2]	2,12 [0,86; 5,23] 0,0934[3]	0,6 [-0,1; 1,3] 0,0934[3]

Data cut-off: 03.07.2023
Safety Population - Postmenopausal
1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpcf/misc10/programs/primary/tfl/german_dossier/t_gba3c1_bp_aesocpt.sas
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Table 060.1: Results from binary analysis for serious adverse events according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Hepatobiliary disorders				
10/776 (1,3)	1/729 (0,1)	9,39 [1,21; 73,20] 0,0325[2]	9,50 [1,21; 74,43] 0,0088[3]	1,2 [0,3; 2,0] 0,0088[3]
Infections and infestations				
34/776 (4,4)	19/729 (2,6)	1,68 [0,97; 2,92] 0,0652[2]	1,71 [0,97; 3,03] 0,0619[3]	1,8 [-0,1; 3,6] 0,0619[3]
Reproductive system and breast disorders				
6/776 (0,8)	10/729 (1,4)	0,56 [0,21; 1,54] 0,2645[2]	0,56 [0,20; 1,55] 0,2578[3]	-0,6 [-1,6; 0,4] 0,2578[3]

Data cut-off: 03.07.2023
Safety Population - Premenopausal
1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 060.2: Results from binary analysis for serious adverse events according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Cardiac disorders				
17/1283 (1,3)	8/1264 (0,6)	2,09 [0,91; 4,83] 0,0835[2]	2,11 [0,91; 4,90] 0,0765[3]	0,7 [-0,1; 1,5] 0,0765[3]
Gastrointestinal disorders				
31/1283 (2,4)	14/1264 (1,1)	2,18 [1,17; 4,08] 0,0146[2]	2,21 [1,17; 4,18] 0,0122[3]	1,3 [0,3; 2,3] 0,0122[3]
Infections and infestations				
71/1283 (5,5)	35/1264 (2,8)	2,00 [1,34; 2,97] 0,0006[2]	2,06 [1,36; 3,11] 0,0005[3]	2,8 [1,2; 4,3] 0,0005[3]
Injury, poisoning and procedural complications				
18/1283 (1,4)	15/1264 (1,2)	1,18 [0,60; 2,34] 0,6298[2]	1,18 [0,59; 2,36] 0,6294[3]	0,2 [-0,7; 1,1] 0,6294[3]
Metabolism and nutrition disorders				
13/1283 (1,0)	4/1264 (0,3)	3,20 [1,05; 9,79] 0,0413[2]	3,22 [1,05; 9,92] 0,0308[3]	0,7 [0,1; 1,3] 0,0308[3]
Nervous system disorders				
13/1283 (1,0)	13/1264 (1,0)	0,99 [0,46; 2,12] 0,9695[2]	0,99 [0,45; 2,13] 0,9695[3]	-0,0 [-0,8; 0,8] 0,9695[3]
Respiratory, thoracic and mediastinal disorders				
16/1283 (1,2)	8/1264 (0,6)	1,97 [0,85; 4,59] 0,1157[2]	1,98 [0,85; 4,65] 0,1087[3]	0,6 [-0,1; 1,4] 0,1087[3]
Vascular disorders				
16/1283 (1,2)	6/1264 (0,5)	2,63 [1,03; 6,69] 0,0429[2]	2,65 [1,03; 6,79] 0,0352[3]	0,8 [0,1; 1,5] 0,0352[3]

Data cut-off: 03.07.2023
Safety Population - Postmenopausal
1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.

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Anhang 4-G4.4.5: Häufige schwere unerwünschte Ereignisse (CTCAE Grade >=3) nach SOC und PT

Table 061.1: Results from binary analysis for adverse events with CTCAE Grade ≥ 3 according PT - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Alanine aminotransferase increased				
21/776 (2,7)	3/729 (0,4)	6,58 [1,97; 21,95] 0,0022[2]	6,73 [2,00; 22,66] 0,0004[3]	2,3 [1,1; 3,5] 0,0004[3]
Aspartate aminotransferase increased				
16/776 (2,1)	2/729 (0,3)	7,52 [1,73; 32,57] 0,0070[2]	7,65 [1,75; 33,40] 0,0014[3]	1,8 [0,7; 2,9] 0,0014[3]
Diarrhoea				
46/776 (5,9)	3/729 (0,4)	14,40 [4,50; 46,11] <,0001[2]	15,25 [4,72; 49,25] <,0001[3]	5,5 [3,8; 7,2] <,0001[3]
Fatigue				
10/776 (1,3)	0/729 (0,0)	19,73 [1,16; 336,08] 0,0393[2]	19,99 [1,17; 341,69] 0,0020[4]	1,3 [0,5; 2,1] 0,0020[4]
Gamma-glutamyltransferase increased				
11/776 (1,4)	0/729 (0,0)	21,61 [1,28; 366,03] 0,0333[2]	21,92 [1,29; 372,62] 0,0013[3]	1,4 [0,6; 2,2] 0,0013[3]
Hypertension				
10/776 (1,3)	10/729 (1,4)	0,94 [0,39; 2,24] 0,8882[2]	0,94 [0,39; 2,27] 0,8881[3]	-0,1 [-1,2; 1,1] 0,8881[3]
Leukopenia				
22/776 (2,8)	0/729 (0,0)	42,28 [2,57; 695,67] 0,0088[2]	43,51 [2,63; 718,56] <,0001[3]	2,8 [1,7; 4,0] <,0001[3]
Lymphocyte count decreased				
34/776 (4,4)	2/729 (0,3)	15,97 [3,85; 66,24] 0,0001[2]	16,66 [3,99; 69,58] <,0001[3]	4,1 [2,6; 5,6] <,0001[3]
Lymphopenia				
12/776 (1,5)	3/729 (0,4)	3,76 [1,06; 13,26] 0,0396[2]	3,80 [1,07; 13,52] 0,0268[3]	1,1 [0,2; 2,1] 0,0268[3]
Neutropenia				
60/776 (7,7)	5/729 (0,7)	11,27 [4,55; 27,91] <,0001[2]	12,13 [4,84; 30,39] <,0001[3]	7,0 [5,1; 9,0] <,0001[3]
Neutrophil count decreased				
87/776 (11,2)	6/729 (0,8)	13,62 [5,99; 30,96] <,0001[2]	15,22 [6,61; 35,03] <,0001[3]	10,4 [8,1; 12,7] <,0001[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
White blood cell count decreased				
68/776 (8,8)	6/729 (0,8)	10,65 [4,65; 24,38] <,0001[2]	11,57 [4,99; 26,84] <,0001[3]	7,9 [5,8; 10,0] <,0001[3]

Data cut-off: 03.07.2023
Safety Population - Premenopausal
1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test; 4: from Fisher's exact test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; GnRH: Gonadotropine releasing hormone; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

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Table 061.2: Results from binary analysis for adverse events with CTCAE Grade ≥ 3 according PT - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Alanine aminotransferase increased				
35/1283 (2,7)	7/1264 (0,6)	4,93 [2,20; 11,05] 0,0001[2]	5,04 [2,23; 11,38] <,0001[3]	2,2 [1,2; 3,2] <,0001[3]
Anaemia				
39/1283 (3,0)	6/1264 (0,5)	6,40 [2,72; 15,07] <,0001[2]	6,57 [2,77; 15,58] <,0001[3]	2,6 [1,6; 3,6] <,0001[3]
Aspartate aminotransferase increased				
22/1283 (1,7)	4/1264 (0,3)	5,42 [1,87; 15,68] 0,0018[2]	5,50 [1,89; 15,99] 0,0004[3]	1,4 [0,6; 2,2] 0,0004[3]
Diarrhoea				
125/1283 (9,7)	2/1264 (0,2)	61,57 [15,26; 248,40] <,0001[2]	68,11 [16,81; 276,00] <,0001[3]	9,6 [7,9; 11,2] <,0001[3]
Fatigue				
34/1283 (2,7)	2/1264 (0,2)	16,75 [4,03; 69,56] 0,0001[2]	17,18 [4,12; 71,65] <,0001[3]	2,5 [1,6; 3,4] <,0001[3]
Gamma-glutamyltransferase increased				
20/1283 (1,6)	5/1264 (0,4)	3,94 [1,48; 10,47] 0,0059[2]	3,99 [1,49; 10,66] 0,0029[3]	1,2 [0,4; 1,9] 0,0029[3]
Hypertension				
17/1283 (1,3)	21/1264 (1,7)	0,80 [0,42; 1,50] 0,4848[2]	0,79 [0,42; 1,51] 0,4838[3]	-0,3 [-1,3; 0,6] 0,4838[3]
Hypokalaemia				
18/1283 (1,4)	4/1264 (0,3)	4,43 [1,50; 13,06] 0,0069[2]	4,48 [1,51; 13,28] 0,0030[3]	1,1 [0,4; 1,8] 0,0030[3]
Leukopenia				
48/1283 (3,7)	2/1264 (0,2)	23,64 [5,76; 97,07] <,0001[2]	24,52 [5,95; 101,12] <,0001[3]	3,6 [2,5; 4,6] <,0001[3]
Lymphocyte count decreased				
42/1283 (3,3)	5/1264 (0,4)	8,28 [3,28; 20,85] <,0001[2]	8,52 [3,36; 21,61] <,0001[3]	2,9 [1,8; 3,9] <,0001[3]
Lymphopenia				
22/1283 (1,7)	2/1264 (0,2)	10,84 [2,55; 45,99] 0,0012[2]	11,01 [2,58; 46,91] <,0001[3]	1,6 [0,8; 2,3] <,0001[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Neutropenia				
140/1283 (10,9)	4/1264 (0,3)	34,48 [12,80; 92,88] <,0001[2]	38,58 [14,23; 104,58] <,0001[3]	10,6 [8,9; 12,3] <,0001[3]
Neutrophil count decreased				
129/1283 (10,1)	4/1264 (0,3)	31,77 [11,78; 85,68] <,0001[2]	35,21 [12,98; 95,55] <,0001[3]	9,7 [8,1; 11,4] <,0001[3]
Platelet count decreased				
13/1283 (1,0)	0/1264 (0,0)	26,60 [1,58; 446,99] 0,0227[2]	26,87 [1,60; 452,53] 0,0003[3]	1,0 [0,5; 1,6] 0,0003[3]
White blood cell count decreased				
99/1283 (7,7)	3/1264 (0,2)	32,51 [10,34; 102,26] <,0001[2]	35,15 [11,11; 111,15] <,0001[3]	7,5 [6,0; 9,0] <,0001[3]

Data cut-off: 03.07.2023
Safety Population - Postmenopausal
1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; PT: preferred term; RCT: Randomized, controlled study; RR: relative risk.

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Table 062.1: Results from binary analysis for adverse events with CTCAE Grade ≥ 3 according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Premenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Blood and lymphatic system disorders				
91/776 (11,7)	14/729 (1,9)	6,11 [3,51; 10,62] <,0001[2]	6,78 [3,83; 12,03] <,0001[3]	9,8 [7,3; 12,3] <,0001[3]
Gastrointestinal disorders				
62/776 (8,0)	7/729 (1,0)	8,32 [3,83; 18,06] <,0001[2]	8,96 [4,07; 19,70] <,0001[3]	7,0 [5,0; 9,1] <,0001[3]
General disorders and administration site conditions				
16/776 (2,1)	5/729 (0,7)	3,01 [1,11; 8,16] 0,0308[2]	3,05 [1,11; 8,36] 0,0229[3]	1,4 [0,2; 2,5] 0,0229[3]
Hepatobiliary disorders				
11/776 (1,4)	2/729 (0,3)	5,17 [1,15; 23,23] 0,0323[2]	5,23 [1,15; 23,66] 0,0166[3]	1,1 [0,2; 2,1] 0,0166[3]
Infections and infestations				
37/776 (4,8)	17/729 (2,3)	2,04 [1,16; 3,60] 0,0131[2]	2,10 [1,17; 3,76] 0,0111[3]	2,4 [0,6; 4,3] 0,0111[3]
Investigations				
162/776 (20,9)	14/729 (1,9)	10,87 [6,36; 18,59] <,0001[2]	13,47 [7,72; 23,51] <,0001[3]	19,0 [15,9; 22,0] <,0001[3]
Metabolism and nutrition disorders				
16/776 (2,1)	6/729 (0,8)	2,51 [0,99; 6,37] 0,0537[2]	2,54 [0,99; 6,52] 0,0454[3]	1,2 [0,0; 2,4] 0,0454[3]
Musculoskeletal and connective tissue disorders				
6/776 (0,8)	10/729 (1,4)	0,56 [0,21; 1,54] 0,2645[2]	0,56 [0,20; 1,55] 0,2578[3]	-0,6 [-1,6; 0,4] 0,2578[3]
Nervous system disorders				
11/776 (1,4)	6/729 (0,8)	1,72 [0,64; 4,63] 0,2816[2]	1,73 [0,64; 4,71] 0,2754[3]	0,6 [-0,5; 1,7] 0,2754[3]
Reproductive system and breast disorders				
5/776 (0,6)	13/729 (1,8)	0,36 [0,13; 1,01] 0,0519[2]	0,36 [0,13; 1,01] 0,0422[3]	-1,1 [-2,3; -0,0] 0,0422[3]
Respiratory, thoracic and mediastinal disorders				
10/776 (1,3)	1/729 (0,1)	9,39 [1,21; 73,20] 0,0325[2]	9,50 [1,21; 74,43] 0,0088[3]	1,2 [0,3; 2,0] 0,0088[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Surgical and medical procedures				
9/776 (1,2)	10/729 (1,4)	0,85 [0,35; 2,07] 0,7132[2]	0,84 [0,34; 2,09] 0,7128[3]	-0,2 [-1,3; 0,9] 0,7128[3]
Vascular disorders				
14/776 (1,8)	15/729 (2,1)	0,88 [0,43; 1,80] 0,7209[2]	0,87 [0,42; 1,82] 0,7207[3]	-0,3 [-1,6; 1,1] 0,7207[3]

Data cut-off: 03.07.2023
Safety Population - Premenopausal
1: According to appropriate comparator by G-BA: Tamoxifen, Anastrozol or Letrozol together with GnRH, Exemestan together with Triptorelin; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; GnRH: Gonadotropine releasing hormone; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.

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Table 062.2: Results from binary analysis for adverse events with CTCAE Grade ≥ 3 according SOC - events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm – from RCT with medical drug to be assessed - Cohort 1 Population - Safety - Postmenopausal

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Blood and lymphatic system disorders				
210/1283 (16,4)	15/1264 (1,2)	13,79 [8,22; 23,15] <,0001[2]	16,30 [9,59; 27,69] <,0001[3]	15,2 [13,1; 17,3] <,0001[3]
Cardiac disorders				
14/1283 (1,1)	11/1264 (0,9)	1,25 [0,57; 2,75] 0,5726[2]	1,26 [0,57; 2,78] 0,5717[3]	0,2 [-0,5; 1,0] 0,5717[3]
Eye disorders				
15/1283 (1,2)	6/1264 (0,5)	2,46 [0,96; 6,33] 0,0612[2]	2,48 [0,96; 6,41] 0,0526[3]	0,7 [-0,0; 1,4] 0,0526[3]
Gastrointestinal disorders				
148/1283 (11,5)	18/1264 (1,4)	8,10 [5,00; 13,13] <,0001[2]	9,03 [5,50; 14,82] <,0001[3]	10,1 [8,2; 12,0] <,0001[3]
General disorders and administration site conditions				
53/1283 (4,1)	7/1264 (0,6)	7,46 [3,40; 16,34] <,0001[2]	7,74 [3,50; 17,09] <,0001[3]	3,6 [2,4; 4,7] <,0001[3]
Infections and infestations				
72/1283 (5,6)	37/1264 (2,9)	1,92 [1,30; 2,83] 0,0010[2]	1,97 [1,32; 2,95] 0,0008[3]	2,7 [1,1; 4,2] 0,0008[3]
Injury, poisoning and procedural complications				
17/1283 (1,3)	17/1264 (1,3)	0,99 [0,51; 1,92] 0,9651[2]	0,98 [0,50; 1,94] 0,9651[3]	-0,0 [-0,9; 0,9] 0,9651[3]
Investigations				
246/1283 (19,2)	30/1264 (2,4)	8,08 [5,57; 11,71] <,0001[2]	9,76 [6,62; 14,38] <,0001[3]	16,8 [14,5; 19,1] <,0001[3]
Metabolism and nutrition disorders				
65/1283 (5,1)	25/1264 (2,0)	2,56 [1,63; 4,04] <,0001[2]	2,64 [1,66; 4,22] <,0001[3]	3,1 [1,7; 4,5] <,0001[3]
Musculoskeletal and connective tissue disorders				
15/1283 (1,2)	25/1264 (2,0)	0,59 [0,31; 1,12] 0,1049[2]	0,59 [0,31; 1,12] 0,1007[3]	-0,8 [-1,8; 0,2] 0,1007[3]
Nervous system disorders				
26/1283 (2,0)	17/1264 (1,3)	1,51 [0,82; 2,76] 0,1851[2]	1,52 [0,82; 2,81] 0,1819[3]	0,7 [-0,3; 1,7] 0,1819[3]

Abemaciclib+ET[1]	ET[1]	Abemaciclib+ET vs. ET[1]		
Pat. with event n/N (%)	Pat. with event n/N (%)	RR [95% CI] p-value	OR [95% CI] p-value	ARR [95% CI] p-value
Renal and urinary disorders				
13/1283 (1,0)	4/1264 (0,3)	3,20 [1,05; 9,79] 0,0413[2]	3,22 [1,05; 9,92] 0,0308[3]	0,7 [0,1; 1,3] 0,0308[3]
Respiratory, thoracic and mediastinal disorders				
23/1283 (1,8)	9/1264 (0,7)	2,52 [1,17; 5,42] 0,0183[2]	2,55 [1,17; 5,52] 0,0144[3]	1,1 [0,2; 1,9] 0,0144[3]
Surgical and medical procedures				
14/1283 (1,1)	9/1264 (0,7)	1,53 [0,67; 3,53] 0,3156[2]	1,54 [0,66; 3,57] 0,3118[3]	0,4 [-0,4; 1,1] 0,3118[3]
Vascular disorders				
29/1283 (2,3)	31/1264 (2,5)	0,92 [0,56; 1,52] 0,7492[2]	0,92 [0,55; 1,54] 0,7491[3]	-0,2 [-1,4; 1,0] 0,7491[3]

Data cut-off: 03.07.2023
Safety Population - Postmenopausal
1: According to appropriate comparator by G-BA: Anastrozol, Letrozol; Anastrozol or Exemestan in sequence after Tamoxifen; 2: from Z-test; 3: from Chi^2-test.
Abbreviations: ARR: absolute risk reduction; CI: confidence interval; CTCAE: common terminology criteria for adverse events; ET: endocrine therapy; n: number of patients with event; N: total number of patients in analysis; OR: odds ratio; RCT: Randomized, controlled study; RR: relative risk; SOC: system organ class.

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