

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Blinatumomab (BLINCYTO®)

Amgen GmbH

Separater Anhang 4-G: Ergänzende Unterlagen

*Behandlung von neu diagnostizierten Erwachsenen mit
einer Philadelphia-Chromosom-negativen, CD19-
positiven B-Vorläufer akuten lymphatischen Leukämie
mit Status einer minimalen Resterkrankung im Rahmen
der Konsolidierungstherapie*

Stand: 26.05.2026

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Anhang 4-G1: Ergänzende Darstellung der Studien- und Patientencharakteristika

Anhang 4-G1.1: Patientendisposition

**Table 14-1.2. Subject Disposition for Step 3 Subjects
(Step 3 Analysis Set)**

Step 3 - Consolidation (Randomization/Registration)	SOC Chemotherapy + Blinatumomab			SOC Chemotherapy			Total
	MRD Positive (N = 40) n (%)	MRD Negative (N = 112) n (%)	Overall (N = 152) n (%)	MRD Positive (N = 22) n (%)	MRD Negative (N = 112) n (%)	Overall (N = 134) n (%)	Overall (N = 286) n (%)
Protocol treatment accounting							
Subjects who never started treatment	4 (10.0)	1 (0.9)	5 (3.3)	6 (27.3)	0 (0.0)	6 (4.5)	11 (3.8)
Reason treatment never started							
No treatment assigned per protocol	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Subject ineligible	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disease progression, relapse before protocol therapy	3 (7.5)	0 (0.0)	3 (2.0)	1 (4.5)	0 (0.0)	1 (0.7)	4 (1.4)
Adverse event/side effects/complications	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Death before beginning protocol therapy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Subject withdrawal/refusal before beginning protocol therapy	1 (2.5)	1 (0.9)	2 (1.3)	1 (4.5)	0 (0.0)	1 (0.7)	3 (1.0)

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

MRD positive prior to step 3: MRD value $\geq 0.01\%$. MRD negative prior to step 3: MRD value $< 0.01\%$.

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

ALL: Acute Lymphoblastic leukemia. SCT = Stem cell transplant.

First subject enrolled: 07JUN2014 Last subject enrolled: 18OCT2019

Step 3 subjects who complete treatment per protocol are subjects who complete all planned Step 3 treatment (i.e., all planned blinatumomab cycles, consolidation cycles or allogeneic transplant) and all maintenance cycles, when planned.

Subjects receiving allogeneic SCT: The subcategories within each category are mutually exclusive. Subjects are included within each subcategory.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary/tables/t-subj-dispo-stp3.sas

Output: t14-01-002-subj-dispo-stp3.rtf (Date Generated: 23AUG23:21:58:21) Source: adam.adsl

**Table 14-1.2. Subject Disposition for Step 3 Subjects
(Step 3 Analysis Set)**

Step 3 - Consolidation (Randomization/Registration)	SOC Chemotherapy + Blinatumomab			SOC Chemotherapy			Total
	MRD Positive (N = 40) n (%)	MRD Negative (N = 112) n (%)	Overall (N = 152) n (%)	MRD Positive (N = 22) n (%)	MRD Negative (N = 112) n (%)	Overall (N = 134) n (%)	Overall (N = 286) n (%)
Medical decision	0 (0.0)	0 (0.0)	0 (0.0)	3 (13.6)	0 (0.0)	3 (2.2)	3 (1.0)
PI discretion	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	1 (0.7)	1 (0.3)
Other	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Subjects who completed treatment per protocol	21 (52.5)	73 (65.2)	94 (61.8)	6 (27.3)	64 (57.1)	70 (52.2)	164 (57.3)
Subjects who discontinued treatment	15 (37.5)	38 (33.9)	53 (34.9)	10 (45.5)	48 (42.9)	58 (43.3)	111 (38.8)
Disease progression relapse during active treatment	2 (5.0)	7 (6.3)	9 (5.9)	7 (31.8)	14 (12.5)	21 (15.7)	30 (10.5)
Adverse event/side effects/complications	2 (5.0)	12 (10.7)	14 (9.2)	0 (0.0)	5 (4.5)	5 (3.7)	19 (6.6)
Death on study	0 (0.0)	6 (5.4)	6 (3.9)	1 (4.5)	3 (2.7)	4 (3.0)	10 (3.5)
Cause of Death							
Cardio-cerebrovascular event	0 (0.0)	2 (1.8)	2 (1.3)	1 (4.5)	0 (0.0)	1 (0.7)	3 (1.0)
Infection	0 (0.0)	4 (3.6)	4 (2.6)	0 (0.0)	2 (1.8)	2 (1.5)	6 (2.1)
Due to this disease	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.7)	1 (0.3)

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

MRD positive prior to step 3: MRD value $\geq 0.01\%$. MRD negative prior to step 3: MRD value $< 0.01\%$.

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

ALL: Acute Lymphoblastic leukemia. SCT = Stem cell transplant.

First subject enrolled: 07JUN2014 Last subject enrolled: 18OCT2019

Step 3 subjects who complete treatment per protocol are subjects who complete all planned Step 3 treatment (i.e., all planned blinatumomab cycles, consolidation cycles or allogeneic transplant) and all maintenance cycles, when planned.

Subjects receiving allogeneic SCT: The subcategories within each category are mutually exclusive. Subjects are included within each subcategory.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary/tables/t-subj-dispo-stp3.sas

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**Table 14-1.2. Subject Disposition for Step 3 Subjects
(Step 3 Analysis Set)**

Step 3 - Consolidation (Randomization/Registration)	SOC Chemotherapy + Blinatumomab			SOC Chemotherapy			Total
	MRD Positive (N = 40) n (%)	MRD Negative (N = 112) n (%)	Overall (N = 152) n (%)	MRD Positive (N = 22) n (%)	MRD Negative (N = 112) n (%)	Overall (N = 134) n (%)	Overall (N = 286) n (%)
Treatment related	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Subject withdrawal/refusal after beginning protocol therapy	3 (7.5)	5 (4.5)	8 (5.3)	0 (0.0)	9 (8.0)	9 (6.7)	17 (5.9)
Alternative therapy	3 (7.5)	2 (1.8)	5 (3.3)	1 (4.5)	3 (2.7)	4 (3.0)	9 (3.1)
Subject off-treatment for other complicating disease	0 (0.0)	3 (2.7)	3 (2.0)	0 (0.0)	2 (1.8)	2 (1.5)	5 (1.7)
Other	5 (12.5)	3 (2.7)	8 (5.3)	1 (4.5)	12 (10.7)	13 (9.7)	21 (7.3)
Subjects receiving off-protocol blinatumomab	0 (0.0)	0 (0.0)	0 (0.0)	12 (54.5)	22 (19.6)	34 (25.4)	34 (11.9)
Subjects receiving allogeneic SCT	20 (50.0)	28 (25.0)	48 (31.6)	11 (50.0)	33 (29.5)	44 (32.8)	92 (32.2)
On-protocol	15 (37.5)	22 (19.6)	37 (24.3)	6 (27.3)	22 (19.6)	28 (20.9)	65 (22.7)

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

MRD positive prior to step 3: MRD value $\geq 0.01\%$. MRD negative prior to step 3: MRD value $< 0.01\%$.

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

ALL: Acute Lymphoblastic leukemia. SCT = Stem cell transplant.

First subject enrolled: 07JUN2014 Last subject enrolled: 18OCT2019

Step 3 subjects who complete treatment per protocol are subjects who complete all planned Step 3 treatment (i.e., all planned blinatumomab cycles, consolidation cycles or allogeneic transplant) and all maintenance cycles, when planned.

Subjects receiving allogeneic SCT: The subcategories within each category are mutually exclusive. Subjects are included within each subcategory.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary/tables/t-subj-dispo-stp3.sas

Output: t14-01-002-subj-dispo-stp3.rtf (Date Generated: 23AUG23:21:58:21) Source: adam.adsl

**Table 14-1.2. Subject Disposition for Step 3 Subjects
(Step 3 Analysis Set)**

Step 3 - Consolidation (Randomization/Registration)	SOC Chemotherapy + Blinatumomab			SOC Chemotherapy			Total
	MRD Positive (N = 40) n (%)	MRD Negative (N = 112) n (%)	Overall (N = 152) n (%)	MRD Positive (N = 22) n (%)	MRD Negative (N = 112) n (%)	Overall (N = 134) n (%)	Overall (N = 286) n (%)
Off-protocol	6 (15.0)	6 (5.4)	12 (7.9)	5 (22.7)	12 (10.7)	17 (12.7)	29 (10.1)
Subjects receiving non-protocol therapy for ALL	2 (5.0)	2 (1.8)	4 (2.6)	0 (0.0)	6 (5.4)	6 (4.5)	10 (3.5)
Chemotherapy	1 (2.5)	1 (0.9)	2 (1.3)	0 (0.0)	3 (2.7)	3 (2.2)	5 (1.7)
Hormonal therapy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.7)	1 (0.3)
Immunotherapy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.7)	1 (0.3)
High dose chemotherapy/stem cell transplant (Autologous or Allogeneic)	1 (2.5)	0 (0.0)	1 (0.7)	0 (0.0)	3 (2.7)	3 (2.2)	4 (1.4)
Surgery	0 (0.0)	1 (0.9)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
Radiation therapy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Other therapy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Study completion accounting							
Subjects ongoing on study	27 (67.5)	88 (78.6)	115 (75.7)	7 (31.8)	64 (57.1)	71 (53.0)	186 (65.0)

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

MRD positive prior to step 3: MRD value $\geq 0.01\%$. MRD negative prior to step 3: MRD value $< 0.01\%$.

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

ALL: Acute Lymphoblastic leukemia. SCT = Stem cell transplant.

First subject enrolled: 07JUN2014 Last subject enrolled: 18OCT2019

Step 3 subjects who complete treatment per protocol are subjects who complete all planned Step 3 treatment (i.e., all planned blinatumomab cycles, consolidation cycles or allogeneic transplant) and all maintenance cycles, when planned.

Subjects receiving allogeneic SCT: The subcategories within each category are mutually exclusive. Subjects are included within each subcategory.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary/tables/t-subj-dispo-stp3.sas

Output: t14-01-002-subj-dispo-stp3.rtf (Date Generated: 23AUG23:21:58:21) Source: adam.adsl

**Table 14-1.2. Subject Disposition for Step 3 Subjects
(Step 3 Analysis Set)**

Step 3 - Consolidation (Randomization/Registration)	SOC Chemotherapy + Blinatumomab			SOC Chemotherapy			Total
	MRD Positive (N = 40) n (%)	MRD Negative (N = 112) n (%)	Overall (N = 152) n (%)	MRD Positive (N = 22) n (%)	MRD Negative (N = 112) n (%)	Overall (N = 134) n (%)	Overall (N = 286) n (%)
Subjects who completed study	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Subjects who discontinued study	13 (32.5)	24 (21.4)	37 (24.3)	15 (68.2)	48 (42.9)	63 (47.0)	100 (35.0)
Subjects refusal for follow-up or withdrawal of consent	2 (5.0)	4 (3.6)	6 (3.9)	1 (4.5)	6 (5.4)	7 (5.2)	13 (4.5)
Lost to follow-up	0 (0.0)	1 (0.9)	1 (0.7)	1 (4.5)	2 (1.8)	3 (2.2)	4 (1.4)
Death	11 (27.5)	19 (17.0)	30 (19.7)	13 (59.1)	40 (35.7)	53 (39.6)	83 (29.0)
Cause of Death							
Cardio-cerebrovascular event	0 (0.0)	3 (2.7)	3 (2.0)	1 (4.5)	1 (0.9)	2 (1.5)	5 (1.7)
Infection	0 (0.0)	4 (3.6)	4 (2.6)	1 (4.5)	10 (8.9)	11 (8.2)	15 (5.2)
Due to this disease	7 (17.5)	8 (7.1)	15 (9.9)	8 (36.4)	22 (19.6)	30 (22.4)	45 (15.7)
Treatment related	0 (0.0)	2 (1.8)	2 (1.3)	3 (13.6)	2 (1.8)	5 (3.7)	7 (2.4)
Other	1 (2.5)	1 (0.9)	2 (1.3)	0 (0.0)	3 (2.7)	3 (2.2)	5 (1.7)
Unknown	3 (7.5)	1 (0.9)	4 (2.6)	0 (0.0)	2 (1.8)	2 (1.5)	6 (2.1)

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

MRD positive prior to step 3: MRD value $\geq 0.01\%$. MRD negative prior to step 3: MRD value $< 0.01\%$.

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

ALL: Acute Lymphoblastic leukemia. SCT = Stem cell transplant.

First subject enrolled: 07JUN2014 Last subject enrolled: 18OCT2019

Step 3 subjects who complete treatment per protocol are subjects who complete all planned Step 3 treatment (i.e., all planned blinatumomab cycles, consolidation cycles or allogeneic transplant) and all maintenance cycles, when planned.

Subjects receiving allogeneic SCT: The subcategories within each category are mutually exclusive. Subjects are included within each subcategory.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary/tables/t-subj-dispo-stp3.sas

Output: t14-01-002-subj-dispo-stp3.rtf (Date Generated: 23AUG23:21:58:21) Source: adam.adsl

Anhang 4-G1.2: Behandlungs- und Beobachtungszeiten

Table 14-4.2.1. Summary of Duration of Observation for End Point (Step 3 Analysis Set)

	SOC Chemotherapy + Blinatumomab			SOC Chemotherapy			Total
	MRD Positive (N = 40)	MRD Negative (N = 112)	Overall (N = 152)	MRD Positive (N = 22)	MRD Negative (N = 112)	Overall (N = 134)	Overall (N = 286)
Overall survival (months)^a							
n	40	112	152	22	112	134	286
Mean	46.8	49.1	48.5	31.2	41.8	40.1	44.6
SD	28.3	20.6	22.8	28.1	22.0	23.3	23.4
Median	43.1	48.8	48.3	17.2	42.7	41.5	44.5
Min, Max	3, 91	0, 92	0, 92	4, 79	1, 91	1, 91	0, 92
Relapse-free survival (months)^b							
n	40	112	152	22	112	134	286
Mean	44.9	46.7	46.3	26.0	38.6	36.5	41.7
SD	30.1	23.3	25.1	30.4	24.3	25.7	25.8
Median	42.4	48.3	47.3	6.8	41.0	38.4	43.0
Min, Max	0, 91	0, 92	0, 92	1, 79	1, 91	1, 91	0, 92

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The Step 3 analysis set includes all Step 3 randomized or registered subjects, regardless of MRD status at Step 3.

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

MRD positive prior to step 3: MRD value $\geq 0.01\%$ (10^{-4} cut-off). MRD negative prior to step 3: MRD value $< 0.01\%$ (10^{-4} cut-off).

^a Months are calculated as days from step 3 randomization or registration to death or last observation on study in absence of death, divided by 30.5.

^b Months are calculated as days from step 3 randomization or registration to relapse/death or last contact date in absence of relapse/death, divided by 30.5.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-dur-obs-endpt-stp3.sas

Output: t14-04-002-001-dur-obs-endpt-stp3.rtf (Date Generated: 18APR24:04:25:31) Source: adam.adsl, adam.adtte

Table 14-6.2.16. Duration of Observation on Treatment-emergent Adverse Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy + Blinatumomab			SOC Chemotherapy			Total
	MRD Positive (N = 36)	MRD Negative (N = 111)	Overall (N = 147)	MRD Positive (N = 16)	MRD Negative (N = 112)	Overall (N = 128)	Overall (N = 275)
Treatment-emergent Adverse Event (months) ^a							
n	33	111	144	15	110	125	269
Mean	7.1	8.1	7.9	3.1	5.0	4.8	6.5
SD	2.8	3.9	3.7	1.7	1.9	1.9	3.4
Median	7.6	9.4	8.9	2.4	5.5	5.3	5.8
Min, Max	3, 11	1, 15	1, 15	1, 6	1, 9	1, 9	1, 15

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set. n = Number of subjects with observed data. SCT = Stem cell transplant.

MRD positive prior to step 3: MRD value $\geq 0.01\%$ (10^{-4} cut-off). MRD negative prior to step 3: MRD value $< 0.01\%$ (10^{-4} cut-off).

^a If any AE recorded during the step 3 treatment period (i.e., step 3 randomization/registration date (as start date)) including blinatumomab cycles, consolidation cycles, allogeneic SCT or late adverse events with onset within 30 days of end of step 3 treatment are considered as Step 3 treatment-emergent adverse event. Of multiple reported step 3 TEAE, will consider the last recorded observation of AE reporting period end date (as end date), by month (30.5) will be used for duration of observation on TEAE.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amq103/onc/20129152/analysis/primary_german_payer/tables/t-dur-obs-ae-s3saf.sas

Output: t14-06-002-016-dur-obs-ae-s3saf.rtf (Date Generated: 10MAY24:08:05:30) Source: adam.adsl, adampa.adae

**Table 14-6.17.1. Summary of Duration of Exposure
(All Enrolled Subjects)**

	N	Mean	SD	Median	Q1, Q3	Min, Max
STEP 1:						
SOC Chemotherapy						
Duration of dosing (days)	480	62.0	17.2	64.0	64, 70	1, 107
STEP 2:						
SOC Chemotherapy						
Duration of dosing (days)	331	12.3	3.6	11.0	10, 13	2, 41
STEP 3:						
SOC Chemotherapy + Blinatumomab						
Duration of dosing (days)	147	122.0	87.0	157.0	58, 173	2, 829
Blinatumomab						
Duration of dosing (days)	147	82.9	37.6	99.0	57, 116	2, 157
SOC Chemotherapy						
Duration of dosing (days)	120	42.2	25.9	57.0	10, 57	1, 108
STEP 4:						
SOC Chemotherapy + Blinatumomab						
Duration of dosing (days)	78	460.4	181.7	521.5	370, 550	5, 901
SOC Chemotherapy						
Duration of dosing (days)	71	515.8	243.3	637.0	329, 703	13, 798

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Any subject who received at least one dose of protocol specified therapy is considered as enrolled.
N = Number of subjects in the analysis set. SD = Standard deviation. Q1 = First quartile. Q3 = Third quartile.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-sum-dur-exposure-enrl.sas

Output: t14-06-017-001-sum-dur-exposure-enrl.rtf (Date generated: 23JUL2025:06:21) Source data: adampa.adsl, adam.adexsum

Anhang 4-G1.3: Erste Folgetherapien

Table 14-2.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Step 3 Safety Analysis Set)

Anti-cancer therapies	SOC Chemotherapy + Blinatumomab (N = 147) n (%)	SOC Chemotherapy (N = 128) n (%)
Number of subjects reporting use of first subsequent anti-cancer therapies during long term follow-up	78 (53.1)	71 (55.5)
6-Mercaptopurine	76 (51.7)	71 (55.5)
Methotrexate	77 (52.4)	70 (54.7)
Prednisone	76 (51.7)	69 (53.9)
Vincristine	76 (51.7)	68 (53.1)

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-sum-anti-cancer-therapy-step3.sas

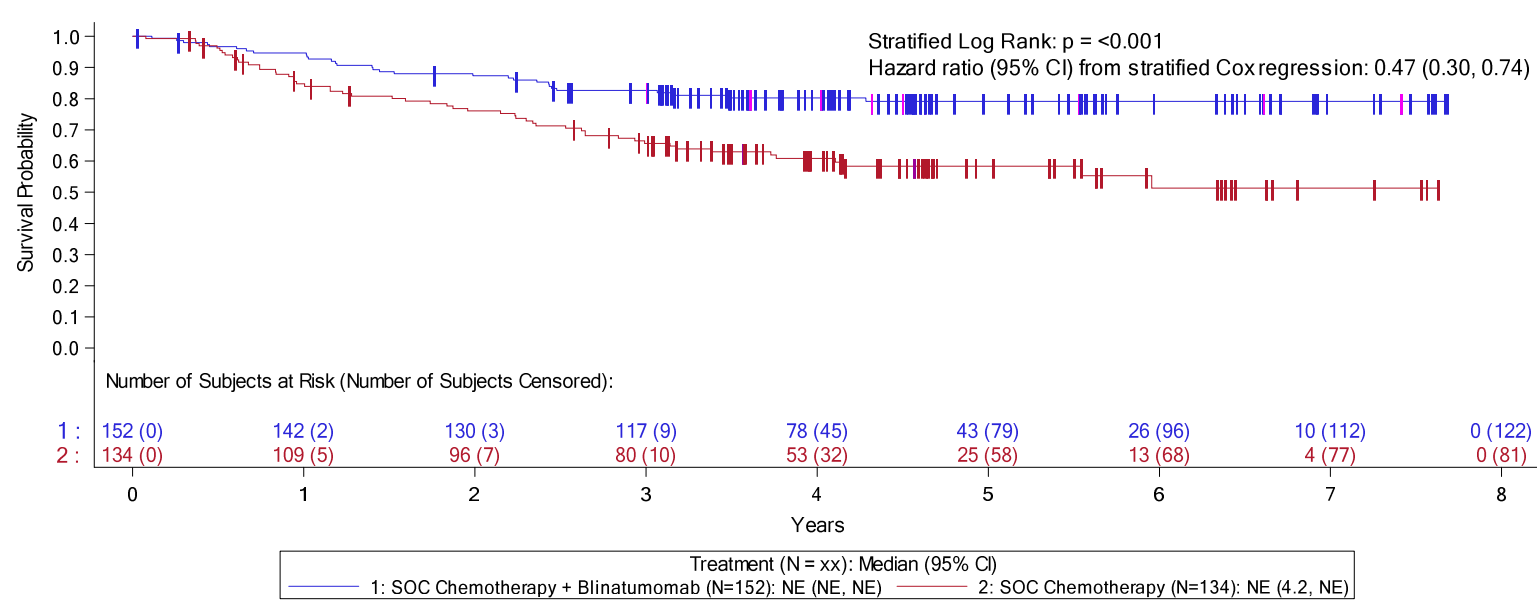
Output: t14-02-001-sum-anti-cancer-therapy-step3.rtf (Date generated: 30OCT2025:03:52) Source data: adampa.adsl, adampa.adex

Anhang 4-G2: Ergänzende Ergebnisdarstellung

Anhang 4-G2.1: Gesamtüberleben

Anhang 4-G2.1.1: Gesamtüberleben (MRD-positive und MRD-negative Patientinnen und Patienten)

Figure 14-4.1.1. Kaplan-Meier for Overall Survival Combining MRD Positive and MRD Negative at Step 3 (Step 3 Analysis Set)



Step 3 analysis set includes all Step 3 randomized or registered subjects.

MRD positive prior to step 3: MRD value $\geq 0.01\%$. MRD negative prior to step 3: MRD value $< 0.01\%$.

Censor indicated by vertical bar |. CI = Confidence interval.

Step 3 randomization or registration date is the reference date for descriptive OS analysis using MRD status of subjects at Step 3.

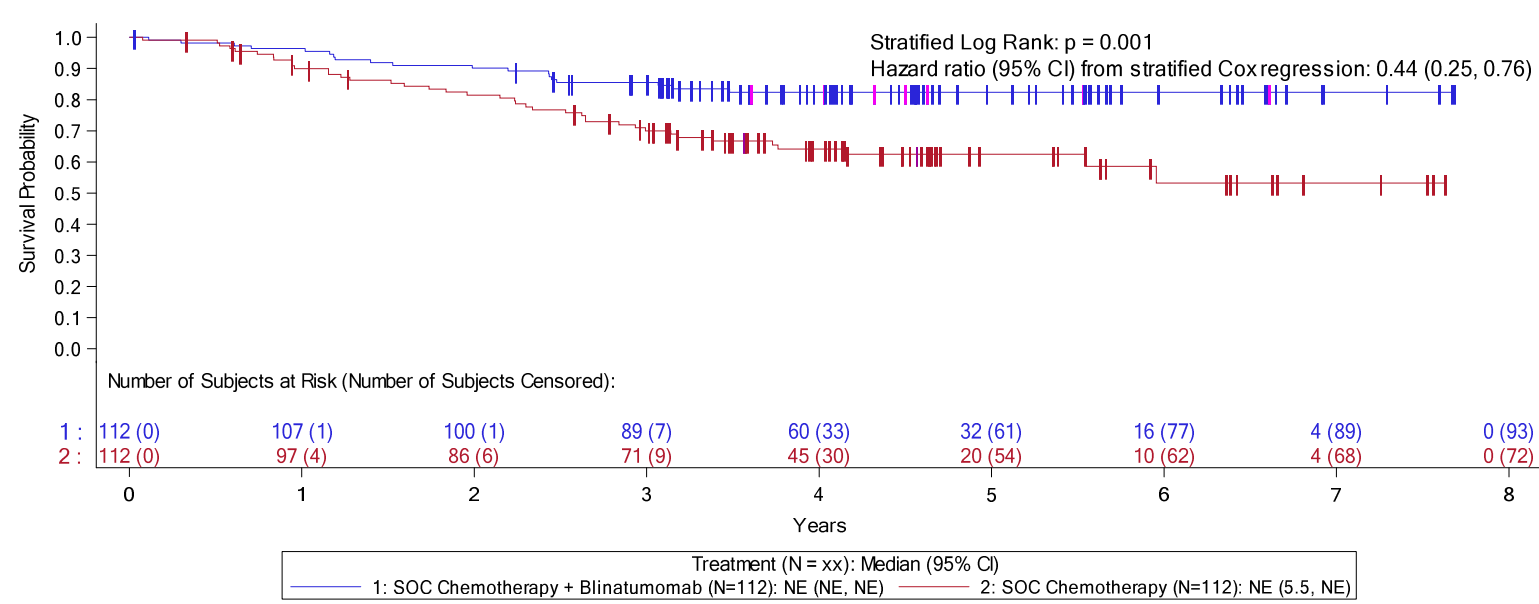
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/figures/f-km-os-comb-mrd-pos-neg-step3.sas

Output: f14-04-001-001-km-os-comb-mrd-pos-neg-step3.rtf (Date Generated: 30OCT25 06:46) Source Data: adampa.adsl, adampa.adtte

Anhang 4-G2.1.2: Gesamtüberleben (MRD-negative Patientinnen und Patienten)

**Figure 14-4.1.3. Kaplan-Meier for Overall Survival
(Full Analysis Set)**



Full analysis set includes all Step 3 randomized subjects who are assessed as MRD negative after induction and intensification chemotherapy.

Censor indicated by vertical bar |. CI = Confidence interval.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/figures/f-km-os-fas.sas

Output: f14-04-001-003-km-os-fas.rtf (Date Generated: 11NOV25 04:31) Source Data: adampa.adsl, adampa.adtte

Anhang 4-G2.1.3: Gesamtüberleben (zensiert bei alloHSZT – MRD-negative Patientinnen und Patienten, Sensitivitätsanalyse)

Product: Blinatumomab
Clinical Study Report: 20129152
Date: 18 October 2023

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Table 14-4.1.5. Overall Survival Censored at Allogeneic SCT for MRD Negative at Step 3 - Sensitivity Analysis 3 (Full Analysis Set)

	SOC Chemotherapy + Blinatumomab (N = 112)	SOC Chemotherapy (N = 112)	Treatment Difference
Subject status			
Number of subjects	112	112	
Events - n (%)	13 (11.6)	27 (24.1)	
Death due to any cause	13 (11.6)	27 (24.1)	
Censored - n (%)	99 (88.4)	85 (75.9)	
Completed study w/o event	0 (0.0)	0 (0.0)	
Continues on study	66 (58.9)	47 (42.0)	
Received allogeneic SCT	28 (25.0)	33 (29.5)	
Discontinued study	5 (4.5)	5 (4.5)	
Consent withdrawn	4 (3.6)	4 (3.6)	
Lost to follow-up	1 (0.9)	1 (0.9)	
Stratified log-rank test ^{a,b,c}			
n	112	112	
Normal score ^c			2.31
p-value			0.010
Time to event (KM) (years) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(6.0, NE)	
Q1, Q3	NE, NE	2.9, NE	
Min, Max	0.1, 3.5	0.1, 6.0	
Time to censoring (KM) (years) ^{d,e}			
Median	3.8	3.6	
95% CI (median)	(3.2, 4.2)	(3.1, 4.1)	
Q1, Q3	1.7, 5.0	0.6, 4.6	
Min, Max	0.0, 7.7	0.1, 7.5	

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Full analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy.

N = Number of subjects in the analysis set. n = Number of subjects with observed data. Q1 = First quartile. Q3 = Third quartile. KM = Kaplan-Meier. CI = Confidence interval. SCT = Stem cell transplant. Overall Survival (OS) is calculated from time of randomization until death due to any cause.

^a Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^b 1-sided stratified log-rank test p-value is provided.

^c A normal score < 0 indicates fewer than expected deaths for subjects in the SOC chemotherapy + blinatumomab arm relative to subjects in the SOC chemotherapy arm.

^d Years are calculated as days from randomization date to event/censor date, divided by 365.25.

^e Time to censoring measures follow-up time by reversing the status indicator for censored and events.

^f The hazard ratio estimates are obtained from a stratified Cox regression model. A hazard ratio < 1.0 indicates a lower average death rate and a longer survival for subjects in the SOC chemotherapy + blinatumomab arm relative to subjects in the SOC chemotherapy arm.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary/tables/t-os-cnsr-asct-sa3-fas.sas

Output: t14-04-001-005-os-cnsr-asct-sa3-fas.rtf (Date generated: 24AUG2023:02:26) Source data: adam.adsl, adam.adtte



Product: Blinatumomab
Clinical Study Report: 20129152
Date: 18 October 2023

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Table 14-4.1.5. Overall Survival Censored at Allogeneic SCT for MRD Negative at Step 3 - Sensitivity Analysis 3 (Full Analysis Set)

	SOC Chemotherapy + Blinatumomab (N = 112)	SOC Chemotherapy (N = 112)	Treatment Difference
KM estimate - %			
At 0.5 year (95% CI)	98.1 (92.7, 99.5)	99.1 (93.8, 99.9)	
At 1 year (95% CI)	95.8 (89.1, 98.4)	89.4 (80.6, 94.4)	
At 2 years (95% CI)	91.0 (82.8, 95.4)	84.3 (74.4, 90.6)	
At 3 years (95% CI)	87.3 (78.2, 92.8)	72.2 (60.8, 80.8)	
At 4 years (95% CI)	84.3 (74.3, 90.6)	66.8 (54.6, 76.4)	
At 5 years (95% CI)	84.3 (74.3, 90.6)	64.4 (51.7, 74.6)	
At 6 years (95% CI)	84.3 (74.3, 90.6)	53.7 (30.6, 72.1)	
At 7 years (95% CI)	84.3 (74.3, 90.6)	53.7 (30.6, 72.1)	
At 8 years (95% CI)	NE (NE, NE)	NE (NE, NE)	
At 9 years (95% CI)	NE (NE, NE)	NE (NE, NE)	
At 10 years (95% CI)	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio ^{a,f}			
Hazard ratio (95% CI)			0.46 (0.24, 0.90)
p-value			0.024

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Full analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy.

N = Number of subjects in the analysis set. n = Number of subjects with observed data. Q1 = First quartile. Q3 = Third quartile. KM = Kaplan-Meier. CI = Confidence interval. SCT = Stem cell transplant. Overall Survival (OS) is calculated from time of randomization until death due to any cause.

^a Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^b 1-sided stratified log-rank test p-value is provided.

^c A normal score < 0 indicates fewer than expected deaths for subjects in the SOC chemotherapy + blinatumomab arm relative to subjects in the SOC chemotherapy arm.

^d Years are calculated as days from randomization date to event/censor date, divided by 365.25.

^e Time to censoring measures follow-up time by reversing the status indicator for censored and events.

^f The hazard ratio estimates are obtained from a stratified Cox regression model. A hazard ratio < 1.0 indicates a lower average death rate and a longer survival for subjects in the SOC chemotherapy + blinatumomab arm relative to subjects in the SOC chemotherapy arm.

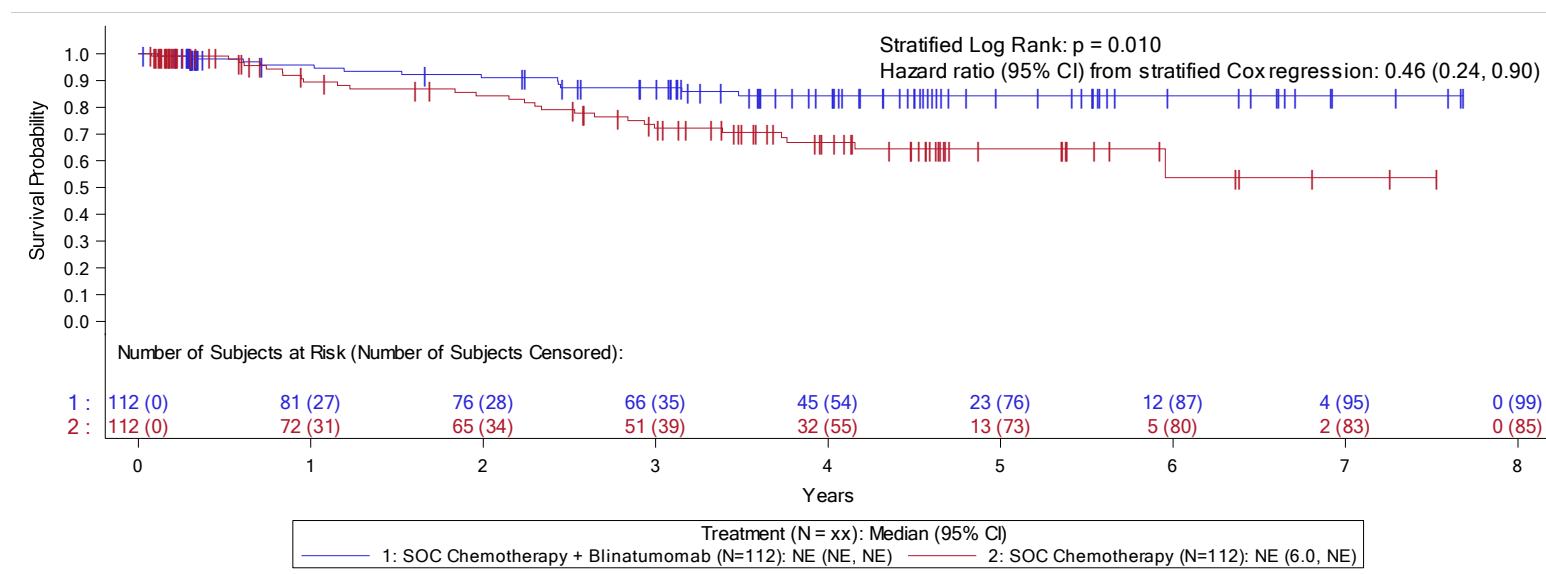
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary/tables/t-os-cnsr-asct-sa3-fas.sas

Output: t14-04-001-005-os-cnsr-asct-sa3-fas.rtf (Date generated: 24AUG2023:02:26) Source data: adam.adsl, adam.adtte



Figure 14-4.1.5. Kaplan-Meier for Overall Survival Censored at Allogeneic SCT for MRD Negative at Step 3 - Sensitivity Analysis 3 (Full Analysis Set)



Full analysis set includes all Step 3 randomized subjects who are assessed as MRD negative after induction and intensification chemotherapy.

Censor indicated by vertical bar |. CI = Confidence interval.

Date of allogeneic SCT is the reference date for the OS analysis of the secondary transplant objective (protocol objective 2.2.5).

Data cut-off date: 23JUN2023

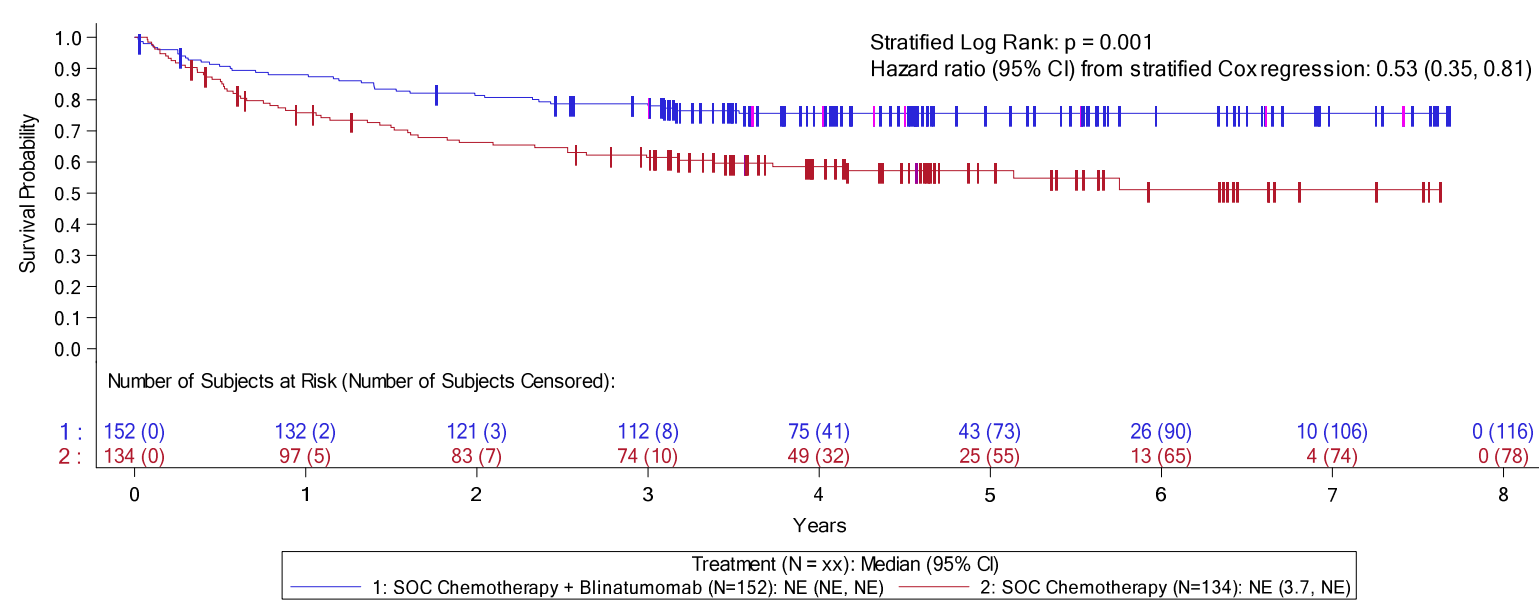
Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/figures/f-km-os-cnsr-asct-sa3-fas.sas

Output: f14-04-001-005-km-os-cnsr-asct-sa3-fas.rtf (Date Generated: 21JAN26 22:14) Source Data: adampa.adsl, adampa.adtte

Anhang 4-G2.2: Rezidivfreies Überleben

Anhang 4-G2.2.1: RFS (MRD-positive und MRD-negative Patientinnen und Patienten)

Figure 14-4.1.2. Kaplan-Meier for Relapse-free Survival Combining MRD Positive and MRD Negative at Step 3 (Step 3 Analysis Set)



Step 3 analysis set includes all Step 3 randomized or registered subjects.

MRD positive prior to step 3: MRD value $\geq 0.01\%$. MRD negative prior to step 3: MRD value $< 0.01\%$.

Censor indicated by vertical bar |. CI = Confidence interval.

Step 3 randomization or registration date is the reference date for descriptive RFS analysis using MRD status of subjects at Step 3.

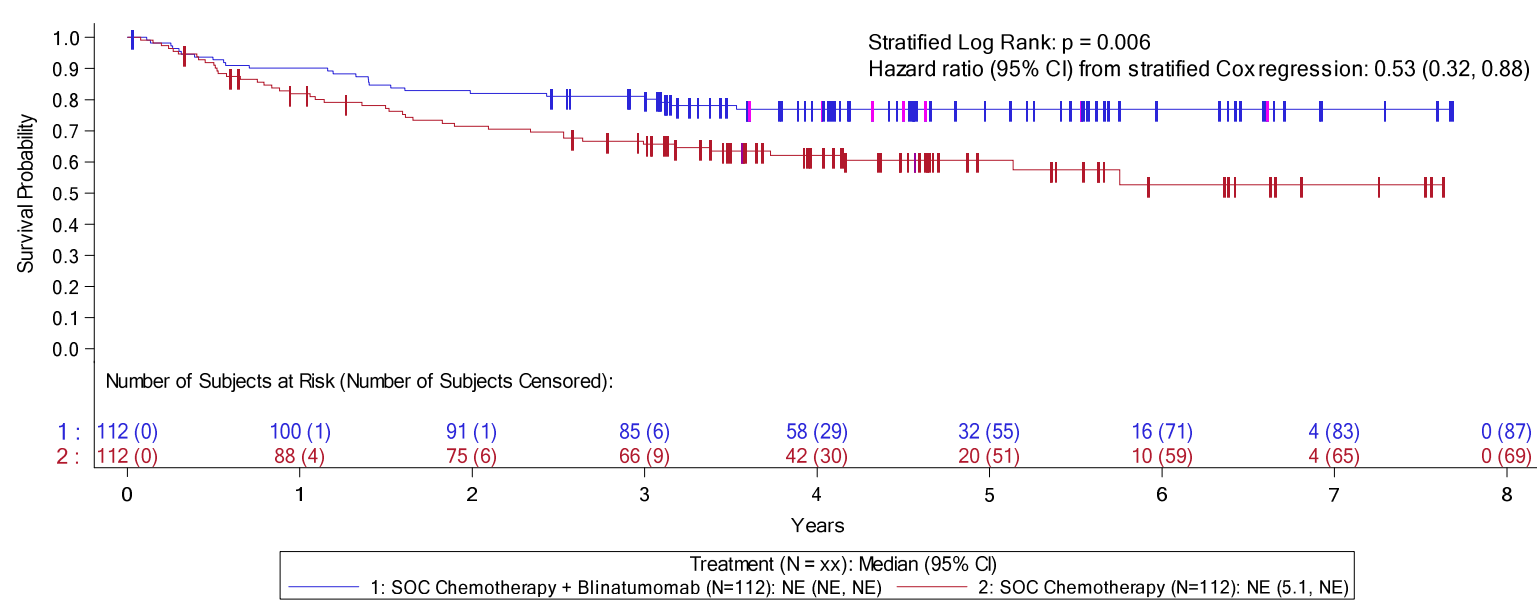
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/figures/f-km-rfs-comb-mrd-pos-neg-step3.sas

Output: f14-04-001-002-km-rfs-comb-mrd-pos-neg-step3.rtf (Date Generated: 30OCT25 06:59) Source Data: adampa.adsl, adampa.adtte

Anhang 4-G2.2.2: RFS (MRD-negative Patientinnen und Patienten)

**Figure 14-4.1.4. Kaplan-Meier for Relapse-free Survival
(Full Analysis Set)**



Full analysis set includes all Step 3 randomized subjects who are assessed as MRD negative after induction and intensification chemotherapy.

Censor indicated by vertical bar |. CI = Confidence interval.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/figures/f-km-rfs-fas.sas

Output: f14-04-001-004-km-rfs-fas.rtf (Date Generated: 11NOV25 04:31) Source Data: adampa.adsl, adampa.adtte

Anhang 4-G2.2.3: RFS (zensiert bei alloHSZT – MRD-negative Patientinnen und Patienten, Sensitivitätsanalyse)

Product: Blinatumomab
Clinical Study Report: 20129152
Date: 18 October 2023

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Table 14-4.2.5. Relapse-free Survival Censored at Allogeneic SCT for MRD Negative at Step 3 - Sensitivity Analysis 3 (Full Analysis Set)

	SOC Chemotherapy + Blinatumomab (N = 112)	SOC Chemotherapy (N = 112)	Treatment Difference
Subject status			
Number of subjects	112	112	
Events - n (%)	21 (18.8)	34 (30.4)	
Relapse	13 (11.6)	26 (23.2)	
Death due to any cause	8 (7.1)	8 (7.1)	
Censored - n (%)	91 (81.3)	78 (69.6)	
Relapsed before start of RFS assessment	0 (0.0)	0 (0.0)	
Completed study w/o event	0 (0.0)	0 (0.0)	
Continues on study	63 (56.3)	45 (40.2)	
Received allogeneic SCT	25 (22.3)	28 (25.0)	
Discontinued study	3 (2.7)	5 (4.5)	
Consent withdrawn	3 (2.7)	4 (3.6)	
Lost to follow-up	0 (0.0)	1 (0.9)	
Stratified log-rank test ^{a,b,c}			
n	112	112	
Normal score ^c			1.84
p-value			0.033
Time to event (KM) (years) ^d			
Median	NE	5.8	
95% CI (median)	(NE, NE)	(4.2, NE)	
Q1, Q3	NE, NE	1.8, NE	
Min, Max	0.1, 3.5	0.1, 5.8	
Time to censoring (KM) (years) ^{d,e}			
Median	4.0	3.6	
95% CI (median)	(3.3, 4.3)	(3.2, 4.1)	
Q1, Q3	2.5, 5.4	0.6, 4.6	
Min, Max	0.0, 7.7	0.1, 7.5	

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Full analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy.

N = Number of subjects in the analysis set. n = Number of subjects with observed data. Q1 = First quartile. Q3 = Third quartile. KM = Kaplan-Meier. CI = Confidence interval. SCT = Stem cell transplant. Relapse-free survival (RFS) is calculated from time of randomization until relapse or death due to any cause.

^a Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^b 1-sided stratified log-rank test p-value is provided.

^c A normal score < 0 indicates fewer than expected events for subjects in the SOC chemotherapy + blinatumomab arm relative to subjects in the SOC chemotherapy arm.

^d Years are calculated as days from randomization date to event/censor date, divided by 365.25.

^e Time to censoring measures follow-up time by reversing the status indicator for censored and events.

^f The hazard ratio estimates are obtained from a stratified Cox regression model. A hazard ratio < 1.0 indicates a lower average event rate and a longer relapse-free survival for subjects in the SOC chemotherapy + blinatumomab arm relative to subjects in the SOC chemotherapy arm.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary/tables/t-rfs-cnsr-asct-sa3-fas.sas

Output: t14-04-002-005-rfs-cnsr-asct-sa3-fas.rtf (Date generated: 24AUG2023:02:30) Source data: adam.adsl, adam.adtte



Product: Blinatumomab
Clinical Study Report: 20129152
Date: 18 October 2023

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Table 14-4.2.5. Relapse-free Survival Censored at Allogeneic SCT for MRD Negative at Step 3 - Sensitivity Analysis 3 (Full Analysis Set)

	SOC Chemotherapy + Blinatumomab (N = 112)	SOC Chemotherapy (N = 112)	Treatment Difference
KM estimate - %			
At 0.5 year (95% CI)	92.0 (84.5, 95.9)	91.4 (83.6, 95.6)	
At 1 year (95% CI)	90.8 (83.0, 95.1)	83.0 (73.4, 89.4)	
At 2 years (95% CI)	82.5 (73.0, 89.0)	73.1 (62.2, 81.3)	
At 3 years (95% CI)	81.4 (71.6, 88.0)	65.3 (54.0, 74.5)	
At 4 years (95% CI)	75.8 (65.1, 83.6)	61.9 (50.1, 71.7)	
At 5 years (95% CI)	75.8 (65.1, 83.6)	59.6 (47.4, 69.9)	
At 6 years (95% CI)	75.8 (65.1, 83.6)	47.2 (28.3, 63.9)	
At 7 years (95% CI)	75.8 (65.1, 83.6)	47.2 (28.3, 63.9)	
At 8 years (95% CI)	NE (NE, NE)	NE (NE, NE)	
At 9 years (95% CI)	NE (NE, NE)	NE (NE, NE)	
At 10 years (95% CI)	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio ^{a,f}			
Hazard ratio (95% CI)			0.60 (0.34, 1.04)
p-value			0.068

Page 2 of 2

Full analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy.

N = Number of subjects in the analysis set. n = Number of subjects with observed data. Q1 = First quartile. Q3 = Third quartile. KM = Kaplan-Meier. CI = Confidence interval. SCT = Stem cell transplant. Relapse-free survival (RFS) is calculated from time of randomization until relapse or death due to any cause.

^a Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^b 1-sided stratified log-rank test p-value is provided.

^c A normal score < 0 indicates fewer than expected events for subjects in the SOC chemotherapy + blinatumomab arm relative to subjects in the SOC chemotherapy arm.

^d Years are calculated as days from randomization date to event/censor date, divided by 365.25.

^e Time to censoring measures follow-up time by reversing the status indicator for censored and events.

^f The hazard ratio estimates are obtained from a stratified Cox regression model. A hazard ratio < 1.0 indicates a lower average event rate and a longer relapse-free survival for subjects in the SOC chemotherapy + blinatumomab arm relative to subjects in the SOC chemotherapy arm.

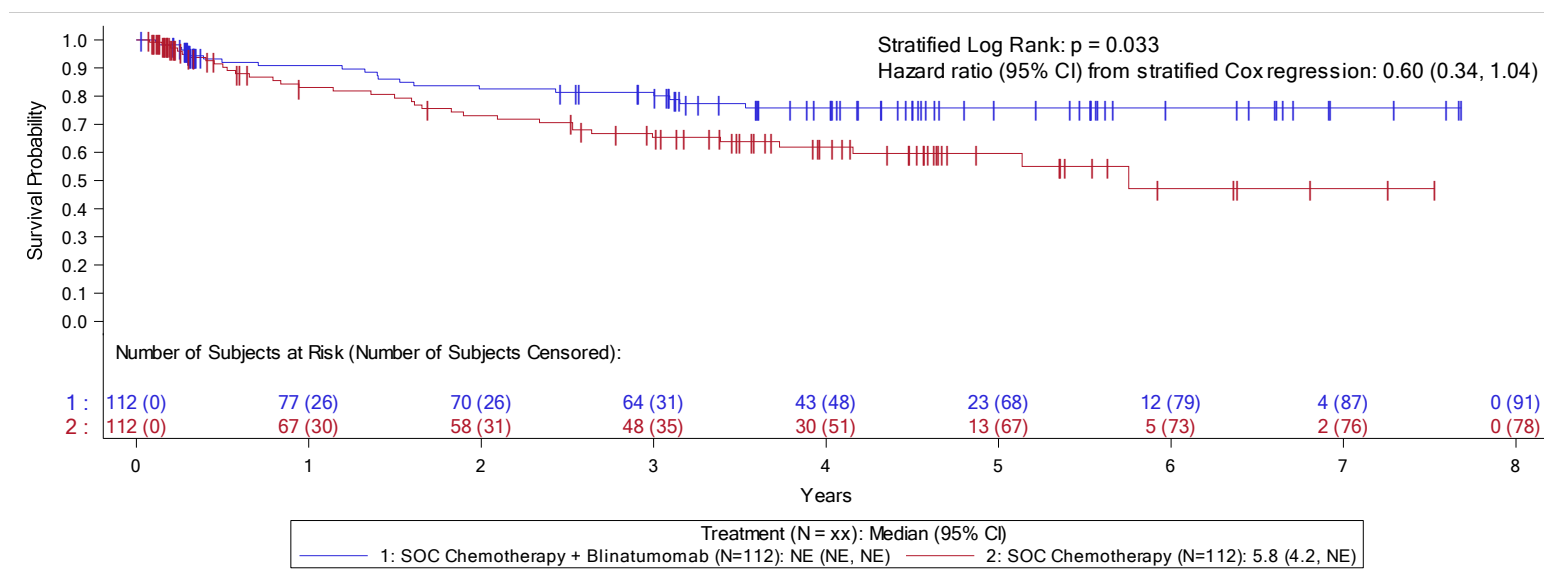
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary/tables/t-rfs-cnsr-asct-sa3-fas.sas

Output: t14-04-002-005-rfs-cnsr-asct-sa3-fas.rtf (Date generated: 24AUG2023:02:30) Source data: adam.adsl, adam.adtte



Figure 14-4.1.6. Kaplan-Meier for Relapse-free Survival Censored at Allogeneic SCT for MRD Negative at Step 3 - Sensitivity Analysis 3 (Full Analysis Set)



Full analysis set includes all Step 3 randomized subjects who are assessed as MRD negative after induction and intensification chemotherapy.

Censor indicated by vertical bar |. CI = Confidence interval.

Date of allogeneic SCT is the reference date for the RFS analysis of the secondary transplant objective (protocol objective 2.2.5).

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/figures/f-km-rfs-cnsr-asct-sa3-fas.sas

Output: f14-04-001-006-km-rfs-cnsr-asct-sa3-fas.rtf (Date Generated: 21JAN26 22:16) Source Data: adampa.adsl, adampa.adtte

Anhang 4-G2.3: Sicherheitsrelevante Endpunkte

Anhang 4-G2.3.1: Sicherheit: Gesamtraten

Table 14-6.2.3. Summary of Any Treatment-emergent Adverse Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting to any treatment-emergent adverse events - n (%)	144 (98.0)	125 (97.7)	0.30
(95% CI)	(94.15, 99.58)	(93.30, 99.51)	(-3.17, 3.78)
p-value ^{a, b}			0.76
Unstratified odds ratio ^c			1.152
(95% CI)			(0.228, 5.810)
p-value			0.86
Stratified odds ratio ^{b, c}			1.288
(95% CI)			(0.254, 6.537)
p-value			0.76
Unstratified risk ratio ^c			1.003
(95% CI)			(0.968, 1.039)
p-value			0.86
Stratified risk ratio ^{b, c, d}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.003
(95% CI)			(-0.032, 0.038)
p-value			0.86

Page 1 of 1

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The negative of the Hessian is not positive definite. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-s3saf.sas

Output: t14-06-002-003-ae-sum-s3saf.rtf (Date generated: 10MAY2024:08:06) Source data: adam.adsl, adampa.adae

**Table 14-6.2.6. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting grade 3 and above treatment-emergent adverse events - n (%)	139 (94.6)	125 (97.7)	-3.10
(95% CI)	(89.56, 97.62)	(93.30, 99.51)	(-7.61, 1.41)
p-value ^{a, b}			0.22
Unstratified odds ratio ^c			0.417
(95% CI)			(0.108, 1.607)
p-value			0.20
Stratified odds ratio ^{b, c}			0.438
(95% CI)			(0.113, 1.697)
p-value			0.23
Unstratified risk ratio ^c			0.968
(95% CI)			(0.924, 1.015)
p-value			0.18

Page 1 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-gr3-s3saf.sas

Output: t14-06-002-006-ae-sum-gr3-s3saf.rtf (Date generated: 10MAY2024:08:08) Source data: adam.adsl, adampa.adae

**Table 14-6.2.6. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c, d}			0.970
(95% CI)			(0.819, 1.149)
p-value			0.73
Absolute risk reduction			-0.031
(95% CI)			(-0.076, 0.014)
p-value			0.18

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-gr3-s3saf.sas

Output: t14-06-002-006-ae-sum-gr3-s3saf.rtf (Date generated: 10MAY2024:08:08) Source data: adam.adsl, adampa.adae

Table 14-6.2.9. Summary of Expedited Treatment-emergent Adverse Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	82 (55.8)	36 (28.1)	27.66
(95% CI)	(47.37, 63.96)	(20.54, 36.75)	(16.47, 38.84)
p-value ^{a, b}			<0.001
Unstratified odds ratio ^c			3.224
(95% CI)			(1.947, 5.339)
p-value			<0.001
Stratified odds ratio ^{b, c}			3.295
(95% CI)			(1.955, 5.554)
p-value			<0.001
Unstratified risk ratio ^c			1.983
(95% CI)			(1.452, 2.710)
p-value			<0.001

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-exp-s3saf.sas

Output: t14-06-002-009-ae-sum-exp-s3saf.rtf (Date generated: 10MAY2024:08:09) Source data: adam.adsl, adampa.adae

Table 14-6.2.9. Summary of Expedited Treatment-emergent Adverse Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c}			2.028
(95% CI)			(1.491, 2.758)
p-value			<0.001
Absolute risk reduction			0.277
(95% CI)			(0.165, 0.388)
p-value			<0.001

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-exp-s3saf.sas

Output: t14-06-002-009-ae-sum-exp-s3saf.rtf (Date generated: 10MAY2024:08:09) Source data: adam.adsl, adampa.adae

Table 14-6.2.15. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	14 (9.5)	5 (3.9)	5.62
(95% CI)	(5.31, 15.46)	(1.28, 8.88)	(-0.19, 11.43)
p-value ^{a, b}			0.044
Unstratified odds ratio ^c			2.589
(95% CI)			(0.906, 7.401)
p-value			0.076
Stratified odds ratio ^{b, c}			2.968
(95% CI)			(0.992, 8.879)
p-value			0.052
Unstratified risk ratio ^c			2.438
(95% CI)			(0.903, 6.583)
p-value			0.079
Stratified risk ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-dct-s3saf.sas

Output: t14-06-002-015-ae-sum-dct-s3saf.rtf (Date generated: 10MAY2024:08:11) Source data: adam.adsl, adampa.adae

Table 14-6.2.15. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(-0.002, 0.114)
p-value			0.058

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-dct-s3saf.sas

Output: t14-06-002-015-ae-sum-dct-s3saf.rtf (Date generated: 10MAY2024:08:11) Source data: adam.adsl, adampa.adae

Table 14-6.2.12. Summary of Fatal Treatment-emergent Adverse Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting fatal treatment-emergent adverse events - n (%)	3 (2.0)	2 (1.6)	0.48
(95% CI)	(0.42, 5.85)	(0.19, 5.53)	(-2.66, 3.62)
p-value ^{a, b}			0.70
Unstratified odds ratio ^c			1.312
(95% CI)			(0.216, 7.980)
p-value			0.77
Stratified odds ratio ^{b, c}			1.413
(95% CI)			(0.235, 8.510)
p-value			0.71
Unstratified risk ratio ^c			1.306
(95% CI)			(0.222, 7.694)
p-value			0.77
Stratified risk ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.005
(95% CI)			(-0.027, 0.036)
p-value			0.77

Page 1 of 1

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-fat-s3saf.sas

Output: t14-06-002-012-ae-sum-fat-s3saf.rtf (Date generated: 10MAY2024:08:10) Source data: adam.adsl, adampa.adae

Table 14-6.1.1. Summary of Any Treatment-emergent Adverse Events Excluding Disease-Related Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	144 (98.0)	125 (97.7)	0.3
(95% CI)	(94.15, 99.58)	(93.30, 99.51)	(-3.17, 3.78)
p-value ^{a, b}			0.7593
Unstratified odds ratio ^c			1.15
(95% CI)			(0.23, 5.81)
p-value			0.8639
Stratified odds ratio ^{b, c}			1.29
(95% CI)			(0.25, 6.54)
p-value			0.7599
Unstratified risk ratio ^c			1.00
(95% CI)			(0.97, 1.04)
p-value			0.8645
Stratified risk ratio ^{b, c}			1.00
(95% CI)			(0.96, 1.03)
p-value			0.8086
Absolute risk reduction			0.003
(95% CI)			(-0.03, 0.04)
p-value			0.8644

Page 1 of 1

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from logistic regression model with logit link and risk ratio obtained from generalized poisson model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-excl-dis-rel-s3saf.sas

Output: t14-06-001-001-ae-sum-excl-dis-rel-s3saf.rtf (Date generated: 29MAY2025:04:42) Source data: adampa.adsl, adam.adae

Table 14-6.1.2. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	82 (55.8)	36 (28.1)	27.7
(95% CI)	(47.37, 63.96)	(20.54, 36.75)	(16.47, 38.84)
p-value ^{a, b}			<0.0001
Unstratified odds ratio ^c			3.22
(95% CI)			(1.95, 5.34)
p-value			<0.0001
Stratified odds ratio ^{b, c}			3.30
(95% CI)			(1.96, 5.55)
p-value			<0.0001
Unstratified risk ratio ^c			1.98
(95% CI)			(1.45, 2.71)
p-value			<0.0001
Stratified risk ratio ^{b, c}			2.03
(95% CI)			(1.49, 2.76)
p-value			<0.0001

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-excl-dis-rel-s3saf.sas

Output: t14-06-001-002-ae-sum-exp-excl-dis-rel-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

**Table 14-6.1.2. Summary of Expedited Treatment-emergent Adverse Events
Excluding Disease-Related Events
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI)			0.28 (0.16, 0.39)
p-value			<0.0001

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-excl-dis-rel-s3saf.sas

Output: t14-06-001-002-ae-sum-exp-excl-dis-rel-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.1.3. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events Excluding Disease-Related Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	139 (94.6)	125 (97.7)	-3.1
(95% CI)	(89.56, 97.62)	(93.30, 99.51)	(-7.61, 1.41)
p-value ^{a, b}			0.2205
Unstratified odds ratio ^c			0.42
(95% CI)			(0.11, 1.61)
p-value			0.2037
Stratified odds ratio ^{b, c}			0.44
(95% CI)			(0.11, 1.70)
p-value			0.2321
Unstratified risk ratio ^c			0.97
(95% CI)			(0.92, 1.02)
p-value			0.1803
Stratified risk ratio ^{b, c, d}			0.97
(95% CI)			(0.82, 1.15)
p-value			0.7262

Page 1 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence Interval. SCT = Stem Cell Transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. $\geq$ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio is obtained from logistic regression model with logit link and risk ratio is obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-excl-dis-rel-s3saf.sas

Output: t14-06-001-003-ae-sum-sev-excl-dis-rel-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.1.3. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events Excluding Disease-Related Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI)			-0.03 (-0.08, 0.01)
p-value			0.1779

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence Interval. SCT = Stem Cell Transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. $\geq$ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio is obtained from logistic regression model with logit link and risk ratio is obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-excl-dis-rel-s3saf.sas

Output: t14-06-001-003-ae-sum-sev-excl-dis-rel-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.5.11. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	14 (9.5)	5 (3.9)	5.62
(95% CI)	(5.31, 15.46)	(1.28, 8.88)	(-0.19, 11.43)
p-value ^{a, b}			0.044
Unstratified odds ratio ^c			2.589
(95% CI)			(0.906, 7.401)
p-value			0.076
Stratified odds ratio ^{b, c}			2.968
(95% CI)			(0.992, 8.879)
p-value			0.052
Unstratified risk ratio ^c			2.438
(95% CI)			(0.903, 6.583)
p-value			0.079
Stratified risk ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE

Page 1 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant. Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression model with logit links and risk ratios are obtained from generalized binomial model with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-s3saf.sas

Output: t14-06-005-011-ae-sum-dct-excl-dis-rel-s3saf.rtf (Date generated: 04DEC2025:01:11) Source data: adampa.adsl, adampg.adae

Table 14-6.5.11. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI)			0.056 (-0.002, 0.114)
p-value			0.058

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression model with logit links and risk ratios are obtained from generalized binomial model with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-s3saf.sas

Output: t14-06-005-011-ae-sum-dct-excl-dis-rel-s3saf.rtf (Date generated: 04DEC2025:01:11) Source data: adampa.adsl, adampg.adae

Anhang 4-G2.3.2: Sicherheit: UE von besonderem Interesse

Table 14-6.5.3. Summary of Any Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting any cytokine release syndrome (EOI) - n (%)	23 (15.6)	0 (0.0)	15.65
(95% CI)	(10.18, 22.55)	(0.00, 2.84)	(9.77, 21.52)
p-value ^{a, b}			<0.001
Unstratified odds ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction ^d			0.173

Page 1 of 4

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The negative of the Hessian is not positive definite. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-s3saf.sas

Output: t14-06-005-003-ae-sum-eoi-s3saf.rtf (Date generated: 10MAY2024:08:12) Source data: adam.adsl, adampa.adae

Table 14-6.5.3. Summary of Any Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(-0.011, 0.358)
p-value			0.066
Number of subjects reporting any medication errors (EOI) - n (%)	1 (0.7)	0 (0.0)	0.68
(95% CI)	(0.02, 3.73)	(0.00, 2.84)	(-0.65, 2.01)
p-value ^{a, b}			0.48
Unstratified odds ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The negative of the Hessian is not positive definite. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-s3saf.sas

Output: t14-06-005-003-ae-sum-eoi-s3saf.rtf (Date generated: 10MAY2024:08:12) Source data: adam.adsl, adampa.adae

Table 14-6.5.3. Summary of Any Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction ^a (95% CI) p-value			NE (NE, NE) NE
Number of subjects reporting any neurological events (EOI) - n (%) (95% CI) p-value ^{a, b}	90 (61.2) (52.85, 69.14)	49 (38.3) (29.83, 47.28)	22.94 (11.41, 34.47) <0.001
Unstratified odds ratio ^c (95% CI) p-value			2.546 (1.564, 4.142) <0.001
Stratified odds ratio ^{b, c} (95% CI) p-value			2.601 (1.565, 4.321) <0.001
Unstratified risk ratio ^c (95% CI) p-value			1.599 (1.240, 2.064) <0.001
Stratified risk ratio ^{b, c}			1.646

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The negative of the Hessian is not positive definite. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-s3saf.sas

Output: t14-06-005-003-ae-sum-eoi-s3saf.rtf (Date generated: 10MAY2024:08:12) Source data: adam.adsl, adampa.adae

Table 14-6.5.3. Summary of Any Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(1.283, 2.114)
p-value			<0.001
Absolute risk reduction			0.229
(95% CI)			(0.114, 0.345)
p-value			<0.001

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The negative of the Hessian is not positive definite. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-s3saf.sas

Output: t14-06-005-003-ae-sum-eoi-s3saf.rtf (Date generated: 10MAY2024:08:12) Source data: adam.adsl, adampa.adae

Anhang 4-G2.3.3: Sicherheit: Schwere UE von besonderem Interesse

Table 14-6.5.6. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting grade 3 and above cytokine release syndrome (EOI) - n (%)	6 (4.1)	0 (0.0)	4.08
(95% CI)	(1.51, 8.67)	(0.00, 2.84)	(0.88, 7.28)
p-value ^{a, b}			0.018
Unstratified odds ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio ^{b, c}			NE

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The negative of the Hessian is not positive definite. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-gr3-s3saf.sas

Output: t14-06-005-006-ae-sum-eoi-gr3-s3saf.rtf (Date generated: 10MAY2024:08:14) Source data: adam.adsl, adampa.adae

Table 14-6.5.6. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			NE
(95% CI)			(NE, NE)
p-value			NE
Number of subjects reporting grade 3 and above medication errors (EOI) - n (%)	1 (0.7)	0 (0.0)	0.68
(95% CI)	(0.02, 3.73)	(0.00, 2.84)	(-0.65, 2.01)
p-value ^{a, b}			0.48
Unstratified odds ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			NE

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The negative of the Hessian is not positive definite. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-gr3-s3saf.sas

Output: t14-06-005-006-ae-sum-eoi-gr3-s3saf.rtf (Date generated: 10MAY2024:08:14) Source data: adam.adsl, adampa.adae

Table 14-6.5.6. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction ^d			NE
(95% CI)			(NE, NE)
p-value			NE
Number of subjects reporting grade 3 and above neurological events (EOI) - n (%)	42 (28.6)	14 (10.9)	17.63
(95% CI)	(21.43, 36.60)	(6.11, 17.67)	(8.55, 26.72)
p-value ^{a, b}			<0.001
Unstratified odds ratio ^c			3.257
(95% CI)			(1.683, 6.304)
p-value			<0.001

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The negative of the Hessian is not positive definite. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-gr3-s3saf.sas

Output: t14-06-005-006-ae-sum-eoi-gr3-s3saf.rtf (Date generated: 10MAY2024:08:14) Source data: adam.adsl, adampa.adae

Table 14-6.5.6. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			2.969
(95% CI)			(1.530, 5.761)
p-value			0.001
Unstratified risk ratio ^c			2.612
(95% CI)			(1.497, 4.557)
p-value			<0.001
Stratified risk ratio ^{b, c}			2.653
(95% CI)			(1.523, 4.619)
p-value			<0.001
Absolute risk reduction			0.176
(95% CI)			(0.085, 0.267)
p-value			<0.001

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The negative of the Hessian is not positive definite. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-gr3-s3saf.sas

Output: t14-06-005-006-ae-sum-eoi-gr3-s3saf.rtf (Date generated: 10MAY2024:08:14) Source data: adam.adsl, adampa.adae

Anhang 4-G2.3.4: Sicherheit: Expedited UE von besonderem Interesse

Table 14-6.5.9. Summary of Expedited Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting expedited cytokine release syndrome (EOI) - n (%)	5 (3.4)	0 (0.0)	3.40
(95% CI)	(1.11, 7.76)	(0.00, 2.84)	(0.47, 6.33)
p-value ^{a, b}			0.030
Unstratified odds ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio ^{b, c}			NE
(95% CI)			(NE, NE)

Page 1 of 4

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-exp-s3saf.sas

Output: t14-06-005-009-ae-sum-eoi-exp-s3saf.rtf (Date generated: 10MAY2024:08:15) Source data: adam.adsl, adampa.adae

Table 14-6.5.9. Summary of Expedited Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value			NE
Absolute risk reduction ^d (95% CI)			0.056 (-0.123, 0.236)
p-value			0.54
Number of subjects reporting expedited medication errors (EOI) - n (%)	0 (0.0)	0 (0.0)	NA
(95% CI)	(NA, NA)	(NA, NA)	(NA, NA)
p-value ^{a, b}			NA
Unstratified odds ratio ^c (95% CI)			NE (NE, NE)
p-value ^c			NE
Stratified odds ratio ^{b, c} (95% CI)			NE (NE, NE)
p-value			NE

Page 2 of 4

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-exp-s3saf.sas

Output: t14-06-005-009-ae-sum-eoi-exp-s3saf.rtf (Date generated: 10MAY2024:08:15) Source data: adam.adsl, adampa.adae

Table 14-6.5.9. Summary of Expedited Treatment-emergent Adverse Events of Interest (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified risk ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			NE
(95% CI)			(NE, NE)
p-value			NE
Number of subjects reporting expedited neurological events (EOI) - n (%)	27 (18.4)	2 (1.6)	16.80
(95% CI)	(12.47, 25.59)	(0.19, 5.53)	(10.19, 23.42)
p-value ^{a, b}			<0.001
Unstratified odds ratio ^c			14.175
(95% CI)			(3.299, 60.909)
p-value			<0.001

Page 3 of 4

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-exp-s3saf.sas

Output: t14-06-005-009-ae-sum-eoi-exp-s3saf.rtf (Date generated: 10MAY2024:08:15) Source data: adam.adsl, adampa.adae

**Table 14-6.5.9. Summary of Expedited Treatment-emergent Adverse Events of Interest
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			13.992
(95% CI)			(3.232, 60.568)
p-value			<0.001
Unstratified risk ratio ^c			11.755
(95% CI)			(2.851, 48.469)
p-value			<0.001
Stratified risk ratio ^{b, c}			12.083
(95% CI)			(2.946, 49.555)
p-value			<0.001
Absolute risk reduction			0.168
(95% CI)			(0.102, 0.234)
p-value			<0.001

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-exp-s3saf.sas

Output: t14-06-005-009-ae-sum-eoi-exp-s3saf.rtf (Date generated: 10MAY2024:08:15) Source data: adam.adsl, adampa.adae

Anhang 4-G2.3.5: Sicherheit: Häufige UE nach SOC, PT

Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting any blood and lymphatic system disorders (SOC) - n (%)	92 (62.6)	90 (70.3)	-7.73
(95% CI)	(54.23, 70.42)	(61.60, 78.06)	(-18.86, 3.40)
p-value ^{a, b}			0.27
Unstratified odds ratio ^c			0.706
(95% CI)			(0.426, 1.171)
p-value			0.18
Stratified odds ratio ^{b, c}			0.750
(95% CI)			(0.448, 1.255)
p-value			0.27
Unstratified risk ratio ^c			0.890
(95% CI)			(0.752, 1.053)
p-value			0.17
Stratified risk ratio ^{b, c}			0.936
(95% CI)			(0.794, 1.104)
p-value			0.43
Absolute risk reduction			-0.077

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

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Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-10pct-soc-pt-s3saf.sas

Output: t14-06-006-003-teae-10pct-soc-pt-s3saf.rtf (Date generated: 11MAY2024:00:02) Source data: adam.adsl, adampa.adae

Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(-0.189, 0.034)
p-value			0.20
Number of subjects reporting anaemia (PT) - n (%)	84 (57.1)	73 (57.0)	0.11
(95% CI)	(48.73, 65.26)	(47.99, 65.74)	(-11.62, 11.84)
p-value ^{a, b}			0.76
Unstratified odds ratio ^c			1.005
(95% CI)			(0.622, 1.621)
p-value			0.99
Stratified odds ratio ^{b, c}			1.079
(95% CI)			(0.661, 1.763)
p-value			0.76
Unstratified risk ratio ^c			1.002
(95% CI)			(0.816, 1.230)
p-value			0.99
Stratified risk ratio ^{b, c}			1.030
(95% CI)			(0.843, 1.257)
p-value			0.77

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.001 (-0.116, 0.118) >0.999
Number of subjects reporting febrile neutropenia (PT) - n (%) (95% CI) p-value ^{a, b}	32 (21.8) (15.39, 29.32)	37 (28.9) (21.24, 37.58)	-7.14 (-17.44, 3.17) 0.22
Unstratified odds ratio ^c (95% CI) p-value			0.684 (0.396, 1.183) 0.17
Stratified odds ratio ^{b, c} (95% CI) p-value			0.713 (0.416, 1.224) 0.22
Unstratified risk ratio ^c (95% CI) p-value			0.753 (0.500, 1.134) 0.17
Stratified risk ratio ^{b, c} (95% CI)			0.760 (0.502, 1.150)

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value			0.19
Absolute risk reduction (95% CI)			-0.071 (-0.174, 0.032)
p-value			0.21
Number of subjects reporting any gastrointestinal disorders (SOC) - n (%)	81 (55.1)	57 (44.5)	10.57
(95% CI)	(46.69, 63.31)	(35.75, 53.57)	(-1.21, 22.35)
p-value ^{a, b}			0.072
Unstratified odds ratio ^c (95% CI)			1.529 (0.949, 2.462)
p-value			0.081
Stratified odds ratio ^{b, c} (95% CI)			1.554 (0.961, 2.515)
p-value			0.072
Unstratified risk ratio ^c (95% CI)			1.237 (0.971, 1.577)
p-value			0.085

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c}			1.273
(95% CI)			(1.001, 1.618)
p-value			0.049
Absolute risk reduction			0.106
(95% CI)			(-0.012, 0.224)
p-value			0.091
Number of subjects reporting abdominal pain (PT) - n (%)	32 (21.8)	20 (15.6)	6.14
(95% CI)	(15.39, 29.32)	(9.81, 23.09)	(-3.03, 15.31)
p-value ^{a, b}			0.19
Unstratified odds ratio ^c			1.503
(95% CI)			(0.810, 2.786)
p-value			0.20
Stratified odds ratio ^{b, c}			1.512
(95% CI)			(0.810, 2.826)
p-value			0.19
Unstratified risk ratio ^c			1.393
(95% CI)			(0.840, 2.311)

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value			0.20
Stratified risk ratio ^{b, c}			1.435
(95% CI)			(0.866, 2.380)
p-value			0.16
Absolute risk reduction			0.061
(95% CI)			(-0.030, 0.153)
p-value			0.22
Number of subjects reporting diarrhoea (PT) - n (%)	49 (33.3)	30 (23.4)	9.90
(95% CI)	(25.78, 41.57)	(16.41, 31.74)	(-0.68, 20.48)
p-value ^{a, b}			0.074
Unstratified odds ratio ^c			1.633
(95% CI)			(0.958, 2.785)
p-value			0.072
Stratified odds ratio ^{b, c}			1.625
(95% CI)			(0.951, 2.776)
p-value			0.076
Unstratified risk ratio ^c			1.422

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.965, 2.096)
p-value			0.075
Stratified risk ratio ^{b, c}			1.533
(95% CI)			(1.045, 2.250)
p-value			0.029
Absolute risk reduction			0.099
(95% CI)			(-0.007, 0.205)
p-value			0.083
Number of subjects reporting nausea (PT) - n (%)	24 (16.3)	9 (7.0)	9.30
(95% CI)	(10.75, 23.31)	(3.27, 12.93)	(1.86, 16.73)
p-value ^{a, b}			0.020
Unstratified odds ratio ^c			2.580
(95% CI)			(1.152, 5.779)
p-value			0.021
Stratified odds ratio ^{b, c}			2.526
(95% CI)			(1.133, 5.635)
p-value			0.024

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified risk ratio ^c			2.322
(95% CI)			(1.121, 4.811)
p-value			0.023
Stratified risk ratio ^{b, c}			2.277
(95% CI)			(1.097, 4.723)
p-value			0.027
Absolute risk reduction			0.093
(95% CI)			(0.019, 0.167)
p-value			0.025
Number of subjects reporting vomiting (PT) - n (%)	45 (30.6)	30 (23.4)	7.17
(95% CI)	(23.28, 38.74)	(16.41, 31.74)	(-3.28, 17.63)
p-value ^{a, b}			0.21
Unstratified odds ratio ^c			1.441
(95% CI)			(0.841, 2.470)
p-value			0.18
Stratified odds ratio ^{b, c}			1.418
(95% CI)			(0.818, 2.460)

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value			0.21
Unstratified risk ratio ^c			1.306
(95% CI)			(0.879, 1.942)
p-value			0.19
Stratified risk ratio ^{b, c}			1.298
(95% CI)			(0.873, 1.930)
p-value			0.20
Absolute risk reduction			0.072
(95% CI)			(-0.033, 0.176)
p-value			0.22
Number of subjects reporting any general disorders and administration site conditions (SOC) - n (%)	44 (29.9)	19 (14.8)	15.09
(95% CI)	(22.66, 38.03)	(9.18, 22.21)	(5.46, 24.72)
p-value ^{a, b}			0.004
Unstratified odds ratio ^c			2.451
(95% CI)			(1.343, 4.473)
p-value			0.004

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			2.420
(95% CI)			(1.320, 4.434)
p-value			0.004
Unstratified risk ratio ^c			2.016
(95% CI)			(1.244, 3.269)
p-value			0.004
Stratified risk ratio ^{b, c}			1.988
(95% CI)			(1.224, 3.229)
p-value			0.005
Absolute risk reduction			0.151
(95% CI)			(0.055, 0.247)
p-value			0.004
Number of subjects reporting fatigue (PT) - n (%)	23 (15.6)	12 (9.4)	6.27
(95% CI)	(10.18, 22.55)	(4.94, 15.80)	(-1.47, 14.02)
p-value ^{a, b}			0.13
Unstratified odds ratio ^c			1.793
(95% CI)			(0.853, 3.767)

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value			0.12
Stratified odds ratio ^{b, c}			1.769
(95% CI)			(0.832, 3.762)
p-value			0.14
Unstratified risk ratio ^c			1.669
(95% CI)			(0.866, 3.218)
p-value			0.13
Stratified risk ratio ^{b, c}			1.631
(95% CI)			(0.844, 3.154)
p-value			0.15
Absolute risk reduction			0.063
(95% CI)			(-0.015, 0.140)
p-value			0.15
Number of subjects reporting pyrexia (PT) - n (%)	19 (12.9)	6 (4.7)	8.24
(95% CI)	(7.96, 19.45)	(1.74, 9.92)	(1.69, 14.78)
p-value ^{a, b}			0.022
Unstratified odds ratio ^c			3.018

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(1.166, 7.809)
p-value			0.023
Stratified odds ratio ^{b, c}			2.909
(95% CI)			(1.124, 7.527)
p-value			0.028
Unstratified risk ratio ^c			2.757
(95% CI)			(1.136, 6.693)
p-value			0.025
Stratified risk ratio ^{b, c}			2.681
(95% CI)			(1.114, 6.454)
p-value			0.028
Absolute risk reduction			0.082
(95% CI)			(0.017, 0.148)
p-value			0.020
Number of subjects reporting any immune system disorders (SOC) - n (%)	24 (16.3)	4 (3.1)	13.20
(95% CI)	(10.75, 23.31)	(0.86, 7.81)	(6.51, 19.89)
p-value ^{a, b}			<0.001

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified odds ratio ^c			6.049
(95% CI)			(2.039, 17.945)
p-value			0.001
Stratified odds ratio ^{b, c}			6.232
(95% CI)			(2.072, 18.742)
p-value			0.001
Unstratified risk ratio ^c			5.224
(95% CI)			(1.862, 14.658)
p-value			0.002
Stratified risk ratio ^{b, c, e}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.132
(95% CI)			(0.065, 0.199)
p-value			<0.001
Number of subjects reporting cytokine release syndrome (PT) - n (%)	23 (15.6)	0 (0.0)	15.65

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)	(10.18, 22.55)	(0.00, 2.84)	(9.77, 21.52)
p-value ^{a, b}			<0.001
Unstratified odds ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.156
(95% CI)			(0.098, 0.215)
p-value			<0.001

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting any infections and infestations (SOC) - n (%)	51 (34.7)	35 (27.3)	7.35
(95% CI)	(27.04, 42.98)	(19.84, 35.92)	(-3.55, 18.25)
p-value ^{a, b}			0.19
Unstratified odds ratio ^c			1.412
(95% CI)			(0.842, 2.365)
p-value			0.19
Stratified odds ratio ^{b, c}			1.413
(95% CI)			(0.844, 2.365)
p-value			0.19
Unstratified risk ratio ^c			1.269
(95% CI)			(0.886, 1.817)
p-value			0.19
Stratified risk ratio ^{b, c}			1.280
(95% CI)			(0.895, 1.831)
p-value			0.18
Absolute risk reduction			0.074

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(-0.036, 0.183)
p-value			0.20
Number of subjects reporting device related infection (PT) - n (%)	15 (10.2)	8 (6.3)	3.95
(95% CI)	(5.82, 16.27)	(2.74, 11.94)	(-2.49, 10.40)
p-value ^{a, b}			0.24
Unstratified odds ratio ^c			1.705
(95% CI)			(0.698, 4.163)
p-value			0.24
Stratified odds ratio ^{b, c}			1.698
(95% CI)			(0.701, 4.112)
p-value			0.24
Unstratified risk ratio ^c			1.633
(95% CI)			(0.716, 3.724)
p-value			0.24
Stratified risk ratio ^{b, c}			1.626
(95% CI)			(0.715, 3.701)
p-value			0.25

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.040 (-0.025, 0.104) 0.28
Number of subjects reporting sepsis (PT) - n (%) (95% CI) p-value ^{a, b}	15 (10.2) (5.82, 16.27)	13 (10.2) (5.52, 16.74)	0.05 (-7.12, 7.21) >0.999
Unstratified odds ratio ^c (95% CI) p-value			1.005 (0.459, 2.201) 0.99
Stratified odds ratio ^{b, c} (95% CI) p-value			1.002 (0.460, 2.181) >0.999
Unstratified risk ratio ^c (95% CI) p-value			1.005 (0.497, 2.031) 0.99
Stratified risk ratio ^{b, c} (95% CI)			1.035 (0.512, 2.094)

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value			0.92
Absolute risk reduction (95% CI)			0.000 (-0.071, 0.072)
p-value			>0.999
Number of subjects reporting any investigations (SOC) - n (%)	135 (91.8)	124 (96.9)	-5.04
(95% CI)	(86.17, 95.71)	(92.19, 99.14)	(-10.39, 0.32)
p-value ^{a, b}			0.14
Unstratified odds ratio ^c (95% CI)			0.363 (0.114, 1.155)
p-value			0.086
Stratified odds ratio ^{b, c} (95% CI)			0.415 (0.127, 1.360)
p-value			0.15
Unstratified risk ratio ^c (95% CI)			0.948 (0.895, 1.004)
p-value			0.068
Stratified risk ratio ^{b, c, d}			0.967

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.849, 1.100)
p-value			0.61
Absolute risk reduction			-0.050
(95% CI)			(-0.104, 0.003)
p-value			0.12
Number of subjects reporting alanine aminotransferase increased (PT) - n (%)	19 (12.9)	10 (7.8)	5.11
(95% CI)	(7.96, 19.45)	(3.81, 13.90)	(-2.03, 12.26)
p-value ^{a, b}			0.18
Unstratified odds ratio ^c			1.752
(95% CI)			(0.783, 3.920)
p-value			0.17
Stratified odds ratio ^{b, c}			1.781
(95% CI)			(0.766, 4.139)
p-value			0.18
Unstratified risk ratio ^c			1.654
(95% CI)			(0.799, 3.427)
p-value			0.18

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c} (95% CI) p-value			1.641 (0.808, 3.333) 0.17
Absolute risk reduction (95% CI) p-value			0.051 (-0.020, 0.123) 0.24
Number of subjects reporting aspartate aminotransferase increased (PT) - n (%) (95% CI) p-value ^{a, b}	15 (10.2) (5.82, 16.27)	5 (3.9) (1.28, 8.88)	6.30 (0.36, 12.23) 0.041
Unstratified odds ratio ^c (95% CI) p-value			2.795 (0.987, 7.920) 0.053
Stratified odds ratio ^{b, c} (95% CI) p-value			3.148 (0.998, 9.931) 0.050
Unstratified risk ratio ^c			2.612

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.976, 6.988)
p-value			0.056
Stratified risk ratio ^{b, c}			2.496
(95% CI)			(0.939, 6.633)
p-value			0.067
Absolute risk reduction			0.063
(95% CI)			(0.004, 0.122)
p-value			0.061
Number of subjects reporting lymphocyte count decreased (PT) - n (%)	44 (29.9)	37 (28.9)	1.03
(95% CI)	(22.66, 38.03)	(21.24, 37.58)	(-9.77, 11.82)
p-value ^{a, b}			0.82
Unstratified odds ratio ^c			1.051
(95% CI)			(0.624, 1.768)
p-value			0.85
Stratified odds ratio ^{b, c}			1.060
(95% CI)			(0.634, 1.775)
p-value			0.82

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified risk ratio ^c			1.035
(95% CI)			(0.717, 1.495)
p-value			0.85
Stratified risk ratio ^{b, c}			1.033
(95% CI)			(0.716, 1.490)
p-value			0.86
Absolute risk reduction			0.010
(95% CI)			(-0.098, 0.118)
p-value			0.89
Number of subjects reporting neutrophil count decreased (PT) - n (%)	129 (87.8)	119 (93.0)	-5.21
(95% CI)	(81.34, 92.58)	(87.07, 96.73)	(-12.12, 1.69)
p-value ^{a, b}			0.19
Unstratified odds ratio ^c			0.542
(95% CI)			(0.234, 1.253)
p-value			0.15
Stratified odds ratio ^{b, c}			0.567

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.241, 1.333)
p-value			0.19
Unstratified risk ratio ^c			0.944
(95% CI)			(0.874, 1.019)
p-value			0.14
Stratified risk ratio ^{b, c, d}			0.984
(95% CI)			(0.906, 1.069)
p-value			0.70
Absolute risk reduction			-0.052
(95% CI)			(-0.121, 0.017)
p-value			0.16
Number of subjects reporting platelet count decreased (PT) - n (%)	117 (79.6)	107 (83.6)	-4.00
(95% CI)	(72.17, 85.79)	(76.02, 89.55)	(-13.15, 5.14)
p-value ^{a, b}			0.57
Unstratified odds ratio ^c			0.765
(95% CI)			(0.413, 1.417)
p-value			0.40

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			0.833
(95% CI)			(0.445, 1.559)
p-value			0.57
Unstratified risk ratio ^c			0.952
(95% CI)			(0.851, 1.065)
p-value			0.39
Stratified risk ratio ^{b, c, d}			0.977
(95% CI)			(0.887, 1.075)
p-value			0.63
Absolute risk reduction			-0.040
(95% CI)			(-0.131, 0.051)
p-value			0.44
Number of subjects reporting white blood cell count decreased (PT) - n (%)	76 (51.7)	82 (64.1)	-12.36
(95% CI)	(43.32, 60.01)	(55.11, 72.35)	(-23.95, -0.77)
p-value ^{a, b}			0.050
Unstratified odds ratio ^c			0.600

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.370, 0.975)
p-value			0.039
Stratified odds ratio ^{b, c}			0.614
(95% CI)			(0.377, 1.001)
p-value			0.050
Unstratified risk ratio ^c			0.807
(95% CI)			(0.659, 0.989)
p-value			0.039
Stratified risk ratio ^{b, c}			0.782
(95% CI)			(0.641, 0.955)
p-value			0.016
Absolute risk reduction			-0.124
(95% CI)			(-0.240, -0.008)
p-value			0.050
Number of subjects reporting any metabolism and nutrition disorders (SOC) - n (%)	40 (27.2)	30 (23.4)	3.77
(95% CI)	(20.21, 35.16)	(16.41, 31.74)	(-6.50, 14.05)
p-value ^{a, b}			0.40

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified odds ratio ^c			1.221
(95% CI)			(0.707, 2.110)
p-value			0.47
Stratified odds ratio ^{b, c}			1.263
(95% CI)			(0.734, 2.174)
p-value			0.40
Unstratified risk ratio ^c			1.161
(95% CI)			(0.771, 1.749)
p-value			0.48
Stratified risk ratio ^{b, c}			1.188
(95% CI)			(0.788, 1.791)
p-value			0.41
Absolute risk reduction			0.038
(95% CI)			(-0.065, 0.141)
p-value			0.49
Number of subjects reporting hyperglycaemia (PT) - n (%)	20 (13.6)	12 (9.4)	4.23
(95% CI)	(8.51, 20.23)	(4.94, 15.80)	(-3.27, 11.73)

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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p-value ^{a, b}			0.23
Unstratified odds ratio ^c			1.522
(95% CI)			(0.713, 3.250)
p-value			0.28
Stratified odds ratio ^{b, c}			1.581
(95% CI)			(0.740, 3.377)
p-value			0.24
Unstratified risk ratio ^c			1.451
(95% CI)			(0.739, 2.851)
p-value			0.28
Stratified risk ratio ^{b, c}			1.468
(95% CI)			(0.748, 2.881)
p-value			0.26
Absolute risk reduction			0.042
(95% CI)			(-0.033, 0.117)
p-value			0.35

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting any musculoskeletal and connective tissue disorders (SOC) - n (%)	34 (23.1)	12 (9.4)	13.75
(95% CI)	(16.58, 30.79)	(4.94, 15.80)	(5.27, 22.24)
p-value ^{a, b}			0.002
Unstratified odds ratio ^c			2.908
(95% CI)			(1.434, 5.900)
p-value			0.003
Stratified odds ratio ^{b, c}			2.942
(95% CI)			(1.456, 5.948)
p-value			0.003
Unstratified risk ratio ^c			2.467
(95% CI)			(1.335, 4.559)
p-value			0.004
Stratified risk ratio ^{b, c}			2.517
(95% CI)			(1.363, 4.648)
p-value			0.003
Absolute risk reduction			0.138

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.053, 0.222)
p-value			0.003
Number of subjects reporting any nervous system disorders (SOC) - n (%)	85 (57.8)	48 (37.5)	20.32
(95% CI)	(49.41, 65.91)	(29.10, 46.49)	(8.74, 31.90)
p-value ^{a, b}			0.001
Unstratified odds ratio ^c			2.285
(95% CI)			(1.407, 3.711)
p-value			<0.001
Stratified odds ratio ^{b, c}			2.253
(95% CI)			(1.368, 3.709)
p-value			0.001
Unstratified risk ratio ^c			1.542
(95% CI)			(1.186, 2.005)
p-value			0.001
Stratified risk ratio ^{b, c}			1.554
(95% CI)			(1.196, 2.019)

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value			<0.001
Absolute risk reduction (95% CI)			0.203 (0.087, 0.319)
p-value			0.001
Number of subjects reporting headache (PT) - n (%)	61 (41.5)	42 (32.8)	8.68
(95% CI)	(33.44, 49.91)	(24.78, 41.67)	(-2.70, 20.07)
p-value ^{a, b}			0.15
Unstratified odds ratio ^c (95% CI)			1.452 (0.886, 2.380)
p-value			0.14
Stratified odds ratio ^{b, c} (95% CI)			1.448 (0.878, 2.389)
p-value			0.15
Unstratified risk ratio ^c (95% CI)			1.265 (0.924, 1.730)
p-value			0.14
Stratified risk ratio ^{b, c}			1.306

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-10pct-soc-pt-s3saf.sas

Output: t14-06-006-003-teae-10pct-soc-pt-s3saf.rtf (Date generated: 11MAY2024:00:02) Source data: adam.adsl, adampa.adae

Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.958, 1.781)
p-value			0.092
Absolute risk reduction			0.087
(95% CI)			(-0.027, 0.201)
p-value			0.17
Number of subjects reporting tremor (PT) - n (%)	30 (20.4)	5 (3.9)	16.50
(95% CI)	(14.21, 27.83)	(1.28, 8.88)	(9.17, 23.83)
p-value ^{a, b}			<0.001
Unstratified odds ratio ^c			6.308
(95% CI)			(2.367, 16.806)
p-value			<0.001
Stratified odds ratio ^{b, c}			5.963
(95% CI)			(2.238, 15.889)
p-value			<0.001
Unstratified risk ratio ^c			5.224
(95% CI)			(2.089, 13.066)
p-value			<0.001

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c}			5.202
(95% CI)			(2.081, 13.007)
p-value			<0.001
Absolute risk reduction			0.165
(95% CI)			(0.092, 0.238)
p-value			<0.001
Number of subjects reporting any psychiatric disorders (SOC) - n (%)	27 (18.4)	7 (5.5)	12.90
(95% CI)	(12.47, 25.59)	(2.23, 10.94)	(5.50, 20.29)
p-value ^{a, b}			0.002
Unstratified odds ratio ^c			3.888
(95% CI)			(1.631, 9.269)
p-value			0.002
Stratified odds ratio ^{b, c}			3.667
(95% CI)			(1.538, 8.747)
p-value			0.003
Unstratified risk ratio ^c			3.359

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(1.514, 7.451)
p-value			0.003
Stratified risk ratio ^{b, c, e}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.129
(95% CI)			(0.055, 0.203)
p-value			0.001
Number of subjects reporting any respiratory, thoracic and mediastinal disorders (SOC) - n (%)	24 (16.3)	13 (10.2)	6.17
(95% CI)	(10.75, 23.31)	(5.52, 16.74)	(-1.77, 14.11)
p-value ^{a, b}			0.12
Unstratified odds ratio ^c			1.726
(95% CI)			(0.839, 3.551)
p-value			0.14
Stratified odds ratio ^{b, c}			1.763
(95% CI)			(0.856, 3.629)
p-value			0.12

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified risk ratio ^c			1.608
(95% CI)			(0.854, 3.024)
p-value			0.14
Stratified risk ratio ^{b, c}			1.665
(95% CI)			(0.884, 3.137)
p-value			0.11
Absolute risk reduction			0.062
(95% CI)			(-0.018, 0.141)
p-value			0.16
Number of subjects reporting any vascular disorders (SOC) - n (%)	39 (26.5)	17 (13.3)	13.25
(95% CI)	(19.60, 34.44)	(7.93, 20.41)	(4.00, 22.50)
p-value ^{a, b}			0.005
Unstratified odds ratio ^c			2.358
(95% CI)			(1.258, 4.419)
p-value			0.007
Stratified odds ratio ^{b, c}			2.392
(95% CI)			(1.278, 4.476)

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value			0.006
Unstratified risk ratio ^c			1.998
(95% CI)			(1.190, 3.353)
p-value			0.009
Stratified risk ratio ^{b, c}			1.977
(95% CI)			(1.181, 3.309)
p-value			0.010
Absolute risk reduction			0.132
(95% CI)			(0.040, 0.225)
p-value			0.007
Number of subjects reporting embolism (PT) - n (%)	15 (10.2)	8 (6.3)	3.95
(95% CI)	(5.82, 16.27)	(2.74, 11.94)	(-2.49, 10.40)
p-value ^{a, b}			0.23
Unstratified odds ratio ^c			1.705
(95% CI)			(0.698, 4.163)
p-value			0.24
Stratified odds ratio ^{b, c}			1.714

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.704, 4.173)
p-value			0.24
Unstratified risk ratio ^c			1.633
(95% CI)			(0.716, 3.724)
p-value			0.24
Stratified risk ratio ^{b, c, e}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.040
(95% CI)			(-0.025, 0.104)
p-value			0.28
Number of subjects reporting hypertension (PT) - n (%)	16 (10.9)	6 (4.7)	6.20
(95% CI)	(6.35, 17.07)	(1.74, 9.92)	(-0.03, 12.42)
p-value ^{a, b}			0.042
Unstratified odds ratio ^c			2.483
(95% CI)			(0.941, 6.552)
p-value			0.066

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.3. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			2.676
(95% CI)			(1.004, 7.134)
p-value			0.049
Unstratified risk ratio ^c			2.322
(95% CI)			(0.937, 5.756)
p-value			0.069
Stratified risk ratio ^{b, c}			2.324
(95% CI)			(0.939, 5.752)
p-value			0.068
Absolute risk reduction			0.062
(95% CI)			(-0.000, 0.124)
p-value			0.075

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Anhang 4-G2.3.6: Sicherheit: Häufige schwere UE nach SOC, PT

Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting grade 3 and above any blood and lymphatic system disorders (SOC) - n (%)	58 (39.5)	73 (57.0)	-17.58
(95% CI)	(31.50, 47.84)	(47.99, 65.74)	(-29.24, -5.91)
p-value ^{a, b}			0.003
Unstratified odds ratio ^c			0.491
(95% CI)			(0.303, 0.795)
p-value			0.004
Stratified odds ratio ^{b, c}			0.482
(95% CI)			(0.295, 0.787)
p-value			0.004
Unstratified risk ratio ^c			0.692
(95% CI)			(0.539, 0.889)
p-value			0.004

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

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Output: t14-06-006-009-teae-soc-pt-gr3-ge5pct-s3saf.rtf (Date generated: 11MAY2024:00:01) Source data: adam.adsl, adampa.adae

Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c}			0.709
(95% CI)			(0.550, 0.915)
p-value			0.008
Absolute risk reduction			-0.176
(95% CI)			(-0.292, -0.059)
p-value			0.004
Number of subjects reporting grade 3 and above anaemia (PT) - n (%)	44 (29.9)	54 (42.2)	-12.26
(95% CI)	(22.66, 38.03)	(33.51, 51.23)	(-23.57, -0.94)
p-value ^{a, b}			0.032
Unstratified odds ratio ^c			0.585
(95% CI)			(0.356, 0.963)
p-value			0.035
Stratified odds ratio ^{b, c}			0.574

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.345, 0.956)
p-value			0.033
Unstratified risk ratio ^c			0.709
(95% CI)			(0.515, 0.977)
p-value			0.035
Stratified risk ratio ^{b, c}			0.737
(95% CI)			(0.536, 1.014)
p-value			0.061
Absolute risk reduction			-0.123
(95% CI)			(-0.236, -0.009)
p-value			0.043
Number of subjects reporting grade 3 and above febrile neutropenia (PT) - n (%)	32 (21.8)	37 (28.9)	-7.14
(95% CI)	(15.39, 29.32)	(21.24, 37.58)	(-17.44, 3.17)

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

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Data cut-off date: 23JUN2023

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value ^{a, b}			0.22
Unstratified odds ratio ^c			0.684
(95% CI)			(0.396, 1.183)
p-value			0.17
Stratified odds ratio ^{b, c}			0.713
(95% CI)			(0.416, 1.224)
p-value			0.22
Unstratified risk ratio ^c			0.753
(95% CI)			(0.500, 1.134)
p-value			0.17
Stratified risk ratio ^{b, c}			0.760
(95% CI)			(0.502, 1.150)
p-value			0.19
Absolute risk reduction			-0.071

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(-0.174, 0.032)
p-value			0.21
Number of subjects reporting grade 3 and above any gastrointestinal disorders (SOC) - n (%)	18 (12.2)	22 (17.2)	-4.94
(95% CI)	(7.42, 18.66)	(11.10, 24.86)	(-13.36, 3.47)
p-value ^{a, b}			0.28
Unstratified odds ratio ^c			0.672
(95% CI)			(0.343, 1.319)
p-value			0.25
Stratified odds ratio ^{b, c}			0.691
(95% CI)			(0.351, 1.361)
p-value			0.29
Unstratified risk ratio ^c			0.712

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.400, 1.267)
p-value			0.25
Stratified risk ratio ^{b, c}			0.735
(95% CI)			(0.414, 1.304)
p-value			0.29
Absolute risk reduction			-0.049
(95% CI)			(-0.134, 0.035)
p-value			0.30
Number of subjects reporting grade 3 and above diarrhoea (PT) - n (%)	7 (4.8)	7 (5.5)	-0.71
(95% CI)	(1.94, 9.57)	(2.23, 10.94)	(-5.94, 4.52)
p-value ^{a, b}			0.85
Unstratified odds ratio ^c			0.864
(95% CI)			(0.295, 2.534)

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value			0.79
Stratified odds ratio ^{b, c}			0.900
(95% CI)			(0.309, 2.626)
p-value			0.85
Unstratified risk ratio ^c			0.871
(95% CI)			(0.314, 2.416)
p-value			0.79
Stratified risk ratio ^{b, c, e}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.007
(95% CI)			(-0.059, 0.045)
p-value			0.79

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting grade 3 and above nausea (PT) - n (%)	8 (5.4)	2 (1.6)	3.88
(95% CI)	(2.38, 10.44)	(0.19, 5.53)	(-0.37, 8.13)
p-value ^{a, b}			0.083
Unstratified odds ratio ^c			3.626
(95% CI)			(0.756, 17.396)
p-value			0.11
Stratified odds ratio ^{b, c}			3.675
(95% CI)			(0.766, 17.632)
p-value			0.10
Unstratified risk ratio ^c			3.483
(95% CI)			(0.753, 16.105)
p-value			0.11
Stratified risk ratio ^{b, c}			3.482

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.755, 16.056)
p-value			0.11
Absolute risk reduction			0.039
(95% CI)			(-0.004, 0.081)
p-value			0.11
Number of subjects reporting grade 3 and above any general disorders and administration site conditions (SOC) - n (%)	15 (10.2)	7 (5.5)	4.74
(95% CI)	(5.82, 16.27)	(2.23, 10.94)	(-1.55, 11.02)
p-value ^{a, b}			0.14
Unstratified odds ratio ^c			1.964
(95% CI)			(0.775, 4.981)
p-value			0.15
Stratified odds ratio ^{b, c}			1.978

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.784, 4.991)
p-value			0.15
Unstratified risk ratio ^c			1.866
(95% CI)			(0.785, 4.433)
p-value			0.16
Stratified risk ratio ^{b, c}			1.893
(95% CI)			(0.794, 4.513)
p-value			0.15
Absolute risk reduction			0.047
(95% CI)			(-0.015, 0.110)
p-value			0.18
Number of subjects reporting grade 3 and above any infections and infestations (SOC) - n (%)	42 (28.6)	31 (24.2)	4.35

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)	(21.43, 36.60)	(17.09, 32.58)	(-6.06, 14.76)
p-value ^{a, b}			0.37
Unstratified odds ratio ^c			1.252
(95% CI)			(0.729, 2.148)
p-value			0.42
Stratified odds ratio ^{b, c}			1.281
(95% CI)			(0.746, 2.200)
p-value			0.37
Unstratified risk ratio ^c			1.180
(95% CI)			(0.792, 1.758)
p-value			0.42
Stratified risk ratio ^{b, c}			1.219
(95% CI)			(0.822, 1.809)
p-value			0.32

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI)			0.044 (-0.061, 0.148)
p-value			0.49
Number of subjects reporting grade 3 and above device related infection (PT) - n (%)	13 (8.8)	8 (6.3)	2.59
(95% CI)	(4.79, 14.65)	(2.74, 11.94)	(-3.62, 8.81)
p-value ^{a, b}			0.46
Unstratified odds ratio ^c			1.455
(95% CI)			(0.583, 3.631)
p-value			0.42
Stratified odds ratio ^{b, c}			1.403
(95% CI)			(0.565, 3.484)
p-value			0.47

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified risk ratio ^c			1.415
(95% CI)			(0.606, 3.305)
p-value			0.42
Stratified risk ratio ^{b, c}			1.386
(95% CI)			(0.597, 3.216)
p-value			0.45
Absolute risk reduction			0.026
(95% CI)			(-0.036, 0.088)
p-value			0.50
Number of subjects reporting grade 3 and above sepsis (PT) - n (%)	15 (10.2)	13 (10.2)	0.05
(95% CI)	(5.82, 16.27)	(5.52, 16.74)	(-7.12, 7.21)
p-value ^{a, b}			>0.999
Unstratified odds ratio ^c			1.005

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Output: t14-06-006-009-teae-soc-pt-gr3-ge5pct-s3saf.rtf (Date generated: 11MAY2024:00:01) Source data: adam.adsl, adampa.adae

Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.459, 2.201)
p-value			0.99
Stratified odds ratio ^{b, c}			1.002
(95% CI)			(0.460, 2.181)
p-value			>0.999
Unstratified risk ratio ^c			1.005
(95% CI)			(0.497, 2.031)
p-value			0.99
Stratified risk ratio ^{b, c}			1.035
(95% CI)			(0.512, 2.094)
p-value			0.92
Absolute risk reduction			0.000
(95% CI)			(-0.071, 0.072)
p-value			>0.999

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting grade 3 and above any investigations (SOC) - n (%)	132 (89.8)	123 (96.1)	-6.30
(95% CI)	(83.73, 94.18)	(91.12, 98.72)	(-12.23, -0.36)
p-value ^{a, b}			0.079
Unstratified odds ratio ^c			0.358
(95% CI)			(0.126, 1.014)
p-value			0.053
Stratified odds ratio ^{b, c}			0.396
(95% CI)			(0.137, 1.147)
p-value			0.088
Unstratified risk ratio ^c			0.934
(95% CI)			(0.876, 0.997)
p-value			0.040

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c, d}			0.944
(95% CI)			(0.867, 1.027)
p-value			0.18
Absolute risk reduction			-0.063
(95% CI)			(-0.122, -0.004)
p-value			0.061
Number of subjects reporting grade 3 and above alanine aminotransferase increased (PT) - n (%)	9 (6.1)	8 (6.3)	-0.13
(95% CI)	(2.84, 11.30)	(2.74, 11.94)	(-5.84, 5.58)
p-value ^{a, b}			0.91
Unstratified odds ratio ^c			0.978
(95% CI)			(0.366, 2.615)
p-value			0.97

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			0.944
(95% CI)			(0.357, 2.498)
p-value			0.91
Unstratified risk ratio ^c			0.980
(95% CI)			(0.389, 2.464)
p-value			0.97
Stratified risk ratio ^{b, c, e}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.001
(95% CI)			(-0.058, 0.056)
p-value			>0.999

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting grade 3 and above lymphocyte count decreased (PT) - n (%)	41 (27.9)	35 (27.3)	0.55
(95% CI)	(20.82, 35.88)	(19.84, 35.92)	(-10.04, 11.14)
p-value ^{a, b}			0.91
Unstratified odds ratio ^c			1.028
(95% CI)			(0.605, 1.746)
p-value			0.92
Stratified odds ratio ^{b, c}			1.032
(95% CI)			(0.612, 1.741)
p-value			0.91
Unstratified risk ratio ^c			1.020
(95% CI)			(0.695, 1.497)
p-value			0.92

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c}			1.018
(95% CI)			(0.694, 1.492)
p-value			0.93
Absolute risk reduction			0.005
(95% CI)			(-0.100, 0.111)
p-value			>0.999
Number of subjects reporting grade 3 and above neutrophil count decreased (PT) - n (%)	125 (85.0)	119 (93.0)	-7.93
(95% CI)	(78.22, 90.38)	(87.07, 96.73)	(-15.21, -0.66)
p-value ^{a, b}			0.048
Unstratified odds ratio ^c			0.430
(95% CI)			(0.190, 0.971)
p-value			0.042

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			0.442
(95% CI)			(0.194, 1.008)
p-value			0.052
Unstratified risk ratio ^c			0.915
(95% CI)			(0.842, 0.994)
p-value			0.035
Stratified risk ratio ^{b, c, d}			0.950
(95% CI)			(0.867, 1.042)
p-value			0.28
Absolute risk reduction			-0.079
(95% CI)			(-0.152, -0.007)
p-value			0.055

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting grade 3 and above platelet count decreased (PT) - n (%)	102 (69.4)	101 (78.9)	-9.52
(95% CI)	(61.26, 76.72)	(70.81, 85.62)	(-19.79, 0.75)
p-value ^{a, b}			0.084
Unstratified odds ratio ^c			0.606
(95% CI)			(0.349, 1.051)
p-value			0.075
Stratified odds ratio ^{b, c}			0.612
(95% CI)			(0.349, 1.071)
p-value			0.085
Unstratified risk ratio ^c			0.879
(95% CI)			(0.765, 1.011)
p-value			0.072

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c, d}			0.934
(95% CI)			(0.841, 1.038)
p-value			0.20
Absolute risk reduction			-0.095
(95% CI)			(-0.198, 0.008)
p-value			0.076
Number of subjects reporting grade 3 and above white blood cell count decreased (PT) - n (%)	74 (50.3)	81 (63.3)	-12.94
(95% CI)	(41.98, 58.68)	(54.31, 71.62)	(-24.56, -1.32)
p-value ^{a, b}			0.040
Unstratified odds ratio ^c			0.588
(95% CI)			(0.363, 0.954)
p-value			0.031

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			0.601
(95% CI)			(0.370, 0.978)
p-value			0.040
Unstratified risk ratio ^c			0.795
(95% CI)			(0.646, 0.979)
p-value			0.031
Stratified risk ratio ^{b, c, d}			0.783
(95% CI)			(0.638, 0.960)
p-value			0.019
Absolute risk reduction			-0.129
(95% CI)			(-0.246, -0.013)
p-value			0.038

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting grade 3 and above any metabolism and nutrition disorders (SOC) - n (%)	24 (16.3)	23 (18.0)	-1.64
(95% CI)	(10.75, 23.31)	(11.74, 25.73)	(-10.58, 7.30)
p-value ^{a, b}			0.85
Unstratified odds ratio ^c			0.891
(95% CI)			(0.475, 1.670)
p-value			0.72
Stratified odds ratio ^{b, c}			0.940
(95% CI)			(0.501, 1.763)
p-value			0.85
Unstratified risk ratio ^c			0.909
(95% CI)			(0.540, 1.529)
p-value			0.72

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-soc-pt-gr3-ge5pct-s3saf.sas

Output: t14-06-006-009-teae-soc-pt-gr3-ge5pct-s3saf.rtf (Date generated: 11MAY2024:00:01) Source data: adam.adsl, adampa.adae

Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c}			0.939
(95% CI)			(0.557, 1.583)
p-value			0.81
Absolute risk reduction			-0.016
(95% CI)			(-0.106, 0.073)
p-value			0.75
Number of subjects reporting grade 3 and above hyperglycaemia (PT) - n (%)	14 (9.5)	12 (9.4)	0.15
(95% CI)	(5.31, 15.46)	(4.94, 15.80)	(-6.78, 7.08)
p-value ^{a, b}			0.86
Unstratified odds ratio ^c			1.018
(95% CI)			(0.453, 2.288)
p-value			0.97
Stratified odds ratio ^{b, c}			1.079

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.474, 2.455)
p-value			0.86
Unstratified risk ratio ^c			1.016
(95% CI)			(0.488, 2.116)
p-value			0.97
Stratified risk ratio ^{b, c}			1.059
(95% CI)			(0.508, 2.205)
p-value			0.88
Absolute risk reduction			0.001
(95% CI)			(-0.068, 0.071)
p-value			>0.999
Number of subjects reporting grade 3 and above any musculoskeletal and connective tissue disorders (SOC) - n (%)	9 (6.1)	8 (6.3)	-0.13

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)	(2.84, 11.30)	(2.74, 11.94)	(-5.84, 5.58)
p-value ^{a, b}			0.97
Unstratified odds ratio ^c			0.978
(95% CI)			(0.366, 2.615)
p-value			0.97
Stratified odds ratio ^{b, c}			1.018
(95% CI)			(0.384, 2.698)
p-value			0.97
Unstratified risk ratio ^c			0.980
(95% CI)			(0.389, 2.464)
p-value			0.97
Stratified risk ratio ^{b, c}			1.029
(95% CI)			(0.409, 2.589)
p-value			0.95

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI) p-value			-0.001 (-0.058, 0.056) >0.999
Number of subjects reporting grade 3 and above any nervous system disorders (SOC) - n (%) (95% CI) p-value ^{a, b}	33 (22.4) (15.98, 30.06)	13 (10.2) (5.52, 16.74)	12.29 (3.76, 20.83) 0.021
Unstratified odds ratio ^c (95% CI) p-value			2.561 (1.282, 5.116) 0.008
Stratified odds ratio ^{b, c} (95% CI) p-value			2.228 (1.112, 4.464) 0.024

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified risk ratio ^c			2.210
(95% CI)			(1.217, 4.013)
p-value			0.009
Stratified risk ratio ^{b, c}			2.152
(95% CI)			(1.183, 3.915)
p-value			0.012
Absolute risk reduction			0.123
(95% CI)			(0.038, 0.208)
p-value			0.009
Number of subjects reporting grade 3 and above headache (PT) - n (%)	9 (6.1)	9 (7.0)	-0.91
(95% CI)	(2.84, 11.30)	(3.27, 12.93)	(-6.79, 4.98)
p-value ^{a, b}			0.61
Unstratified odds ratio ^c			0.862

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.332, 2.243)
p-value			0.76
Stratified odds ratio ^{b, c}			0.780
(95% CI)			(0.298, 2.037)
p-value			0.61
Unstratified risk ratio ^c			0.871
(95% CI)			(0.356, 2.127)
p-value			0.76
Stratified risk ratio ^{b, c}			0.856
(95% CI)			(0.352, 2.077)
p-value			0.73
Absolute risk reduction			-0.009
(95% CI)			(-0.068, 0.050)
p-value			0.81

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting grade 3 and above any psychiatric disorders (SOC) - n (%)	13 (8.8)	2 (1.6)	7.28
(95% CI)	(4.79, 14.65)	(0.19, 5.53)	(2.21, 12.35)
p-value ^{a, b}			0.007
Unstratified odds ratio ^c			6.112
(95% CI)			(1.352, 27.623)
p-value			0.019
Stratified odds ratio ^{b, c}			6.529
(95% CI)			(1.420, 30.023)
p-value			0.016
Unstratified risk ratio ^c			5.660
(95% CI)			(1.302, 24.609)
p-value			0.021

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c, e}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.073
(95% CI)			(0.022, 0.123)
p-value			0.008
Number of subjects reporting grade 3 and above any respiratory, thoracic and mediastinal disorders (SOC) - n (%)	10 (6.8)	8 (6.3)	0.55
(95% CI)	(3.31, 12.15)	(2.74, 11.94)	(-5.29, 6.40)
p-value ^{a, b}			0.75
Unstratified odds ratio ^c			1.095
(95% CI)			(0.419, 2.864)
p-value			0.85

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			1.173
(95% CI)			(0.446, 3.085)
p-value			0.75
Unstratified risk ratio ^c			1.088
(95% CI)			(0.443, 2.674)
p-value			0.85
Stratified risk ratio ^{b, c, e}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.006
(95% CI)			(-0.053, 0.064)
p-value			>0.999

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting grade 3 and above any vascular disorders (SOC) - n (%)	19 (12.9)	11 (8.6)	4.33
(95% CI)	(7.96, 19.45)	(4.37, 14.86)	(-2.95, 11.61)
p-value ^{a, b}			0.22
Unstratified odds ratio ^c			1.579
(95% CI)			(0.721, 3.456)
p-value			0.25
Stratified odds ratio ^{b, c}			1.635
(95% CI)			(0.744, 3.596)
p-value			0.22
Unstratified risk ratio ^c			1.504
(95% CI)			(0.744, 3.040)
p-value			0.26

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c}			1.516
(95% CI)			(0.749, 3.069)
p-value			0.25
Absolute risk reduction			0.043
(95% CI)			(-0.029, 0.116)
p-value			0.33
Number of subjects reporting grade 3 and above hypertension (PT) - n (%)	12 (8.2)	4 (3.1)	5.04
(95% CI)	(4.29, 13.83)	(0.86, 7.81)	(-0.32, 10.39)
p-value ^{a, b}			0.052
Unstratified odds ratio ^c			2.755
(95% CI)			(0.866, 8.768)
p-value			0.086
Stratified odds ratio ^{b, c}			3.044

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-soc-pt-gr3-ge5pct-s3saf.sas

Output: t14-06-006-009-teae-soc-pt-gr3-ge5pct-s3saf.rtf (Date generated: 11MAY2024:00:01) Source data: adam.adsl, adampa.adae

Table 14-6.6.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
(95% CI)			(0.946, 9.794)
p-value			0.062
Unstratified risk ratio ^c			2.612
(95% CI)			(0.864, 7.899)
p-value			0.089
Stratified risk ratio ^{b, c}			2.698
(95% CI)			(0.897, 8.114)
p-value			0.077
Absolute risk reduction			0.050
(95% CI)			(-0.003, 0.104)
p-value			0.12

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

^e The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-soc-pt-gr3-ge5pct-s3saf.sas

Output: t14-06-006-009-teae-soc-pt-gr3-ge5pct-s3saf.rtf (Date generated: 11MAY2024:00:01) Source data: adam.adsl, adampa.adae

Anhang 4-G2.3.7: Sicherheit: Häufige Expedited UE nach SOC, PT

Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting expedited any blood and lymphatic system disorders (SOC) - n (%)	20 (13.6)	15 (11.7)	1.89
(95% CI)	(8.51, 20.23)	(6.71, 18.59)	(-5.97, 9.75)
p-value ^{a, b}			0.50
Unstratified odds ratio ^c			1.186
(95% CI)			(0.580, 2.427)
p-value			0.64
Stratified odds ratio ^{b, c}			1.277
(95% CI)			(0.622, 2.624)
p-value			0.51
Unstratified risk ratio ^c			1.161
(95% CI)			(0.621, 2.171)
p-value			0.64
Stratified risk ratio ^{b, c}			1.217
(95% CI)			(0.654, 2.266)
p-value			0.54

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-sum-exp-soc-pt-ge5pct-s3saf.sas

Output: t14-06-006-015-teae-sum-exp-soc-pt-ge5pct-s3saf.rtf (Date generated: 10MAY2024:23:45)

Source data: adam.adsl, adampa.adae

Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq$ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.019 (-0.060, 0.097) 0.72
Number of subjects reporting expedited febrile neutropenia (PT) - n (%) (95% CI) p-value ^{a, b}	18 (12.2) (7.42, 18.66)	15 (11.7) (6.71, 18.59)	0.53 (-7.16, 8.22) 0.77
Unstratified odds ratio ^c (95% CI) p-value			1.051 (0.506, 2.182) 0.89
Stratified odds ratio ^{b, c} (95% CI) p-value			1.116 (0.537, 2.322) 0.77
Unstratified risk ratio ^c (95% CI) p-value			1.045 (0.549, 1.987) 0.89

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. $\geq$ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

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Output: t14-06-006-015-teae-sum-exp-soc-pt-ge5pct-s3saf.rtf (Date generated: 10MAY2024:23:45)

Source data: adam.adsl, adampa.adae

Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq$ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c}			1.091
(95% CI)			(0.578, 2.062)
p-value			0.79
Absolute risk reduction			0.005
(95% CI)			(-0.072, 0.082)
p-value			>0.999
Number of subjects reporting expedited any gastrointestinal disorders (SOC) - n (%)	10 (6.8)	3 (2.3)	4.46
(95% CI)	(3.31, 12.15)	(0.49, 6.70)	(-0.38, 9.30)
p-value ^{a, b}			0.076
Unstratified odds ratio ^c			3.041
(95% CI)			(0.818, 11.301)
p-value			0.097
Stratified odds ratio ^{b, c}			3.115
(95% CI)			(0.837, 11.593)
p-value			0.090

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. $\geq$ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

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Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq$ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified risk ratio ^c			2.902
(95% CI)			(0.817, 10.317)
p-value			0.100
Stratified risk ratio ^{b, c}			2.979
(95% CI)			(0.848, 10.462)
p-value			0.089
Absolute risk reduction			0.045
(95% CI)			(-0.004, 0.093)
p-value			0.095
Number of subjects reporting expedited any general disorders and administration site conditions (SOC) - n (%)	20 (13.6)	3 (2.3)	11.26
(95% CI)	(8.51, 20.23)	(0.49, 6.70)	(5.13, 17.39)
p-value ^{a, b}			0.001
Unstratified odds ratio ^c			6.562
(95% CI)			(1.902, 22.637)
p-value			0.003

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. $\geq$ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

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Source data: adam.adsl, adampa.adae

Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			6.296
(95% CI)			(1.826, 21.704)
p-value			0.004
Unstratified risk ratio ^c			5.805
(95% CI)			(1.766, 19.084)
p-value			0.004
Stratified risk ratio ^{b, c}			5.972
(95% CI)			(1.819, 19.603)
p-value			0.003
Absolute risk reduction			0.113
(95% CI)			(0.051, 0.174)
p-value			<0.001
Number of subjects reporting expedited pyrexia (PT) - n (%)	14 (9.5)	1 (0.8)	8.74
(95% CI)	(5.31, 15.46)	(0.02, 4.28)	(3.76, 13.73)
p-value ^{a, b}			0.002

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

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Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified odds ratio ^c			13.368
(95% CI)			(1.733, 103.148)
p-value			0.013
Stratified odds ratio ^{b, c}			12.312
(95% CI)			(1.598, 94.832)
p-value			0.016
Unstratified risk ratio ^c			12.190
(95% CI)			(1.625, 91.426)
p-value			0.015
Stratified risk ratio ^{b, c, d}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.087
(95% CI)			(0.038, 0.137)
p-value			0.001

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

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Source data: adam.adsl, adampa.adae

Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq$ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting expedited any infections and infestations (SOC) - n (%)	33 (22.4)	19 (14.8)	7.61
(95% CI)	(15.98, 30.06)	(9.18, 22.21)	(-1.53, 16.74)
p-value ^{a, b}			0.100
Unstratified odds ratio ^c			1.660
(95% CI)			(0.891, 3.094)
p-value			0.11
Stratified odds ratio ^{b, c}			1.681
(95% CI)			(0.902, 3.134)
p-value			0.10
Unstratified risk ratio ^c			1.512
(95% CI)			(0.906, 2.524)
p-value			0.11
Stratified risk ratio ^{b, c}			1.568
(95% CI)			(0.944, 2.603)
p-value			0.082

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. $\geq$ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

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Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.076 (-0.015, 0.167) 0.12
Number of subjects reporting expedited device related infection (PT) - n (%) (95% CI) p-value ^{a, b}	12 (8.2) (4.29, 13.83)	5 (3.9) (1.28, 8.88)	4.26 (-1.30, 9.81) 0.16
Unstratified odds ratio ^c (95% CI) p-value			2.187 (0.749, 6.384) 0.15
Stratified odds ratio ^{b, c} (95% CI) p-value			2.101 (0.723, 6.106) 0.17
Unstratified risk ratio ^c (95% CI) p-value			2.090 (0.757, 5.772) 0.16

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

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Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c}			2.037
(95% CI)			(0.741, 5.605)
p-value			0.17
Absolute risk reduction			0.043
(95% CI)			(-0.013, 0.098)
p-value			0.21
Number of subjects reporting expedited sepsis (PT) - n (%)	13 (8.8)	9 (7.0)	1.81
(95% CI)	(4.79, 14.65)	(3.27, 12.93)	(-4.57, 8.19)
p-value ^{a, b}			0.60
Unstratified odds ratio ^c			1.283
(95% CI)			(0.529, 3.108)
p-value			0.58
Stratified odds ratio ^{b, c}			1.268
(95% CI)			(0.527, 3.049)
p-value			0.60

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-sum-exp-soc-pt-ge5pct-s3saf.sas

Output: t14-06-006-015-teae-sum-exp-soc-pt-ge5pct-s3saf.rtf (Date generated: 10MAY2024:23:45)

Source data: adam.adsl, adampa.adae

Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq$ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified risk ratio ^c			1.258
(95% CI)			(0.556, 2.845)
p-value			0.58
Stratified risk ratio ^{b, c}			1.299
(95% CI)			(0.574, 2.938)
p-value			0.53
Absolute risk reduction			0.018
(95% CI)			(-0.046, 0.082)
p-value			0.66
Number of subjects reporting expedited any investigations (SOC)	23 (15.6)	6 (4.7)	10.96
- n (%)			
(95% CI)	(10.18, 22.55)	(1.74, 9.92)	(4.04, 17.88)
p-value ^{a, b}			0.003
Unstratified odds ratio ^c			3.770
(95% CI)			(1.484, 9.580)
p-value			0.005

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. $\geq$ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

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Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq$ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			3.848
(95% CI)			(1.501, 9.866)
p-value			0.005
Unstratified risk ratio ^c			3.338
(95% CI)			(1.403, 7.941)
p-value			0.006
Stratified risk ratio ^{b, c, d}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.110
(95% CI)			(0.040, 0.179)
p-value			0.003
Number of subjects reporting expedited alanine aminotransferase increased (PT) - n (%)	9 (6.1)	0 (0.0)	6.12
(95% CI)	(2.84, 11.30)	(0.00, 2.84)	(2.25, 10.00)
p-value ^{a, b}			0.005

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified odds ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio ^{b, c, d}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.061
(95% CI)			(0.022, 0.100)
p-value			0.004

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

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^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

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Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting expedited neutrophil count decreased (PT) - n (%)	12 (8.2)	2 (1.6)	6.60
(95% CI)	(4.29, 13.83)	(0.19, 5.53)	(1.68, 11.52)
p-value ^{a, b}			0.013
Unstratified odds ratio ^c			5.600
(95% CI)			(1.229, 25.515)
p-value			0.026
Stratified odds ratio ^{b, c}			5.767
(95% CI)			(1.246, 26.693)
p-value			0.025
Unstratified risk ratio ^c			5.224
(95% CI)			(1.192, 22.907)
p-value			0.028
Stratified risk ratio ^{b, c, d}			NE
(95% CI)			(NE, NE)
p-value			NE

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq$ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.066 (0.017, 0.115) 0.014
Number of subjects reporting expedited any metabolism and nutrition disorders (SOC) - n (%) (95% CI) p-value ^{a, b}	8 (5.4) (2.38, 10.44)	3 (2.3) (0.49, 6.70)	3.10 (-1.41, 7.61) 0.19
Unstratified odds ratio ^c (95% CI) p-value			2.398 (0.622, 9.238) 0.20
Stratified odds ratio ^{b, c} (95% CI) p-value			2.404 (0.619, 9.339) 0.21
Unstratified risk ratio ^c (95% CI) p-value			2.322 (0.629, 8.568) 0.21

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. $\geq$ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c, d}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.031
(95% CI)			(-0.014, 0.076)
p-value			0.23
Number of subjects reporting expedited any musculoskeletal and connective tissue disorders (SOC) - n (%)	8 (5.4)	1 (0.8)	4.66
(95% CI)	(2.38, 10.44)	(0.02, 4.28)	(0.69, 8.63)
p-value ^{a, b}			0.032
Unstratified odds ratio ^c			7.309
(95% CI)			(0.902, 59.245)
p-value			0.062
Stratified odds ratio ^{b, c}			7.258
(95% CI)			(0.891, 59.085)
p-value			0.064

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified risk ratio ^c			6.966
(95% CI)			(0.883, 54.946)
p-value			0.065
Stratified risk ratio ^{b, c}			7.000
(95% CI)			(0.896, 54.686)
p-value			0.064
Absolute risk reduction			0.047
(95% CI)			(0.007, 0.086)
p-value			0.040
Number of subjects reporting expedited any nervous system disorders (SOC) - n (%)	22 (15.0)	0 (0.0)	14.97
(95% CI)	(9.62, 21.78)	(0.00, 2.84)	(9.20, 20.73)
p-value ^{a, b}			<0.001
Unstratified odds ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.150
(95% CI)			(0.092, 0.207)
p-value			<0.001
Number of subjects reporting expedited aphasia (PT) - n (%)	8 (5.4)	0 (0.0)	5.44
(95% CI)	(2.38, 10.44)	(0.00, 2.84)	(1.78, 9.11)
p-value ^{a, b}			0.007

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Unstratified odds ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio ^{b, c, d}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.054
(95% CI)			(0.018, 0.091)
p-value			0.008

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Number of subjects reporting expedited any psychiatric disorders (SOC) - n (%)	9 (6.1)	1 (0.8)	5.34
(95% CI)	(2.84, 11.30)	(0.02, 4.28)	(1.18, 9.51)
p-value ^{a, b}			0.020
Unstratified odds ratio ^c			8.281
(95% CI)			(1.035, 66.268)
p-value			0.046
Stratified odds ratio ^{b, c}			8.045
(95% CI)			(1.006, 64.367)
p-value			0.049
Unstratified risk ratio ^c			7.837
(95% CI)			(1.006, 61.018)
p-value			0.049
Stratified risk ratio ^{b, c, d}			NE
(95% CI)			(NE, NE)
p-value			NE

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

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Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b Stratification factors: age (< 55 years vs. $\geq$ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-sum-exp-soc-pt-ge5pct-s3saf.sas

Output: t14-06-006-015-teae-sum-exp-soc-pt-ge5pct-s3saf.rtf (Date generated: 10MAY2024:23:45)

Source data: adam.adsl, adampa.adae

Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.053 (0.012, 0.095) 0.022
Number of subjects reporting expedited any respiratory, thoracic and mediastinal disorders (SOC) - n (%) (95% CI) p-value ^{a, b}	9 (6.1) (2.84, 11.30)	2 (1.6) (0.19, 5.53)	4.56 (0.13, 8.99) 0.051
Unstratified odds ratio ^c (95% CI) p-value			4.109 (0.871, 19.379) 0.074
Stratified odds ratio ^{b, c} (95% CI) p-value			4.207 (0.888, 19.939) 0.070
Unstratified risk ratio ^c (95% CI) p-value			3.918 (0.862, 17.804) 0.077

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-sum-exp-soc-pt-ge5pct-s3saf.sas

Output: t14-06-006-015-teae-sum-exp-soc-pt-ge5pct-s3saf.rtf (Date generated: 10MAY2024:23:45)

Source data: adam.adsl, adampa.adae

Table 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence $\geq 5\%$ (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Stratified risk ratio ^{b, c, d}			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.046
(95% CI)			(0.001, 0.090)
p-value			0.067

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Exact Binomial Confidence Interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratios are obtained from a logistic regression models with logit links and risk ratios are obtained from generalized binomial models with log links. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d The number of strata exceeds the number of events. This results in strata with uniform responses resulting in proc genmod failing to converge. Setting the result to NE.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-sum-exp-soc-pt-ge5pct-s3saf.sas

Output: t14-06-006-015-teae-sum-exp-soc-pt-ge5pct-s3saf.rtf (Date generated: 10MAY2024:23:45)

Source data: adam.adsl, adampa.adae

Anhang 4-G2.4: Sicherheitsrelevante Endpunkte für die Erhaltungstherapie

Anhang 4-G2.4.1: Sicherheit: Gesamtraten

**Table 14-6.15.1. Summary of Any Maintenance Treatment-emergent Adverse Events
(Safety Analysis Set - Subjects who Received Maintenance Treatment)**

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting any maintenance treatment-emergent adverse events - n (%)	64 (97.0)	62 (89.9)	7.1
(95% CI)	(89.48, 99.63)	(80.21, 95.82)	(-1.12, 15.35)
p-value ^{a, b}			0.1176
Unstratified odds ratio ^c			3.61
(95% CI)			(0.72, 18.06)
p-value			0.1179
Stratified odds ratio ^{b, c}			3.50
(95% CI)			(0.67, 18.32)
p-value			0.1375
Unstratified risk ratio ^c			1.08
(95% CI)			(0.99, 1.18)
p-value			0.0971
Stratified risk ratio ^{b, c}			0.93
(95% CI)			(0.67, 1.29)
p-value			0.6629
Absolute risk reduction			0.07
(95% CI)			(-0.01, 0.15)
p-value			0.0905

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The unstratified and stratified odds ratio obtained from logistic regression model with logit link and unstratified risk ratio obtained from generalized logit model with log link. Stratified risk ratio obtained from generalized poisson model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-saf-main.sas

Output: t14-06-015-001-ae-sum-saf-main.rtf (Date generated: 23JUL2025:06:26) Source data: adampa.adsl, adam.adae

**Table 14-6.15.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events
(Safety Analysis Set - Subjects who Received Maintenance Treatment)**

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting grade 3 and above maintenance treatment-emergent adverse events - n (%)	62 (93.9)	57 (82.6)	11.3
(95% CI)	(85.20, 98.32)	(71.59, 90.68)	(0.69, 21.97)
p-value ^{a, b}			0.0337
Unstratified odds ratio ^c			3.26
(95% CI)			(1.00, 10.70)
p-value			0.0509
Stratified odds ratio ^{b, c}			3.61
(95% CI)			(1.05, 12.45)
p-value			0.0419
Unstratified risk ratio ^c			1.14
(95% CI)			(1.00, 1.29)
p-value			0.0429
Stratified risk ratio ^{b, c}			0.89
(95% CI)			(0.64, 1.23)
p-value			0.4784
Absolute risk reduction			0.11
(95% CI)			(0.01, 0.22)
p-value			0.0368

Page 1 of 1

Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The unstratified and stratified odds ratio obtained from logistic regression model with logit link and unstratified risk ratio obtained from generalized logit model with log link. Stratified risk ratio obtained from generalized poisson model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-saf-main.sas

Output: t14-06-015-002-ae-sum-sev-saf-main.rtf (Date generated: 23JUL2025:06:26) Source data: adampa.adsl, adam.adae

**Table 14-6.15.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events
(Safety Analysis Set - Subjects who Received Maintenance Treatment)**

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting expedited maintenance treatment-emergent adverse events - n (%)	26 (39.4)	18 (26.1)	13.3
(95% CI)	(27.58, 52.19)	(16.25, 38.06)	(-2.39, 29.00)
p-value ^{a, b}			0.0342
Unstratified odds ratio ^c			1.84
(95% CI)			(0.89, 3.82)
p-value			0.1010
Stratified odds ratio ^{b, c}			2.26
(95% CI)			(1.05, 4.83)
p-value			0.0363
Unstratified risk ratio ^c			1.51
(95% CI)			(0.92, 2.48)
p-value			0.1043
Stratified risk ratio ^{b, c}			1.58
(95% CI)			(0.97, 2.54)
p-value			0.0634
Absolute risk reduction			0.13
(95% CI)			(-0.02, 0.29)
p-value			0.0965

Page 1 of 1

Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment. Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio is obtained from logistic regression model with logit link and risk ratio is obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-saf-main.sas

Output: t14-06-015-003-ae-sum-exp-saf-main.rtf (Date generated: 23JUL2025:06:26) Source data: adampa.adsl, adam.adae

Anhang 4-G2.4.2: Sicherheit: Häufige UE nach SOC, PT

Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting any blood and lymphatic system disorders (SOC) - n (%)	36 (54.5)	36 (52.2)	2.37
(95% CI)	(41.81, 66.86)	(39.80, 64.35)	(-14.46, 19.20)
p-value ^{a, b}			0.6953
Unstratified odds ratio ^c			1.10
(95% CI)			(0.56, 2.16)
p-value			0.7826
Stratified odds ratio ^{b, c}			1.15
(95% CI)			(0.57, 2.33)
p-value			0.6954
Unstratified risk ratio ^c			1.05
(95% CI)			(0.76, 1.43)
p-value			0.7824
Stratified risk ratio ^{b, c}			1.05
(95% CI)			(0.76, 1.44)
p-value			0.7671

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-10pct-by-soc-pt-saf-main.sas

Output: t14-06-016-001-ae-sum-10pct-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:40) Source data: adampa.adsl, adam.adae

Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.02 (-0.14, 0.19) 0.8634
Number of subjects reporting anaemia (PT) - n (%) (95% CI) p-value ^{a, b}	31 (47.0) (34.56, 59.66)	35 (50.7) (38.41, 62.98)	-3.75 (-20.61, 13.10) 0.6433
Unstratified odds ratio ^c (95% CI) p-value			0.86 (0.44, 1.69) 0.6629
Stratified odds ratio ^{b, c} (95% CI) p-value			0.85 (0.42, 1.70) 0.6435
Unstratified risk ratio ^c (95% CI) p-value			0.93 (0.66, 1.31) 0.6632

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-10pct-by-soc-pt-saf-main.sas

Output: t14-06-016-001-ae-sum-10pct-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:40) Source data: adampa.adsl, adam.adae

Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, c}			0.88
(95% CI)			(0.62, 1.24)
p-value			0.4581
Absolute risk reduction			-0.04
(95% CI)			(-0.21, 0.13)
p-value			0.7315
Number of subjects reporting febrile neutropenia (PT) - n (%)	9 (13.6)	3 (4.3)	9.29
(95% CI)	(6.43, 24.31)	(0.91, 12.18)	(-0.29, 18.86)
p-value ^{a, b}			0.0318
Unstratified odds ratio ^c			3.47
(95% CI)			(0.90, 13.45)
p-value			0.0715
Stratified odds ratio ^{b, c}			4.09
(95% CI)			(1.04, 16.07)
p-value			0.0434

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-10pct-by-soc-pt-saf-main.sas

Output: t14-06-016-001-ae-sum-10pct-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:40) Source data: adampa.adsl, adam.adae

Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c (95% CI) p-value			3.14 (0.89, 11.08) 0.0759
Stratified risk ratio ^{b, d} (95% CI) p-value			0.94 (0.74, 1.21) 0.6492
Absolute risk reduction (95% CI) p-value			0.09 (-0.00, 0.19) 0.0729
Number of subjects reporting any gastrointestinal disorders (SOC) - n (%) (95% CI) p-value ^{a, b}	35 (53.0) (40.34, 65.44)	26 (37.7) (26.29, 50.17)	15.35 (-1.26, 31.95) 0.0539
Unstratified odds ratio ^c (95% CI) p-value			1.87 (0.94, 3.71) 0.0745

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-10pct-by-soc-pt-saf-main.sas

Output: t14-06-016-001-ae-sum-10pct-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:40) Source data: adampa.adsl, adam.adae

Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			2.00
(95% CI)			(0.98, 4.08)
p-value			0.0557
Unstratified risk ratio ^c			1.41
(95% CI)			(0.96, 2.06)
p-value			0.0772
Stratified risk ratio ^{b, c}			1.40
(95% CI)			(0.95, 2.04)
p-value			0.0856
Absolute risk reduction			0.15
(95% CI)			(-0.01, 0.32)
p-value			0.0852
Number of subjects reporting abdominal pain (PT) - n (%)	15 (22.7)	12 (17.4)	5.34
(95% CI)	(13.31, 34.70)	(9.32, 28.41)	(-8.16, 18.83)
p-value ^{a, b}			0.2439

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-10pct-by-soc-pt-saf-main.sas

Output: t14-06-016-001-ae-sum-10pct-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:40) Source data: adampa.adsl, adam.adae

Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			1.40
(95% CI)			(0.60, 3.26)
p-value			0.4396
Stratified odds ratio ^{b, c}			1.70
(95% CI)			(0.69, 4.18)
p-value			0.2471
Unstratified risk ratio ^c			1.31
(95% CI)			(0.66, 2.58)
p-value			0.4405
Stratified risk ratio ^{b, d}			0.97
(95% CI)			(0.75, 1.25)
p-value			0.7882
Absolute risk reduction			0.05
(95% CI)			(-0.08, 0.19)
p-value			0.5205

Page 6 of 35

Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting diarrhoea (PT) - n (%)	16 (24.2)	13 (18.8)	5.40
(95% CI)	(14.54, 36.36)	(10.43, 30.06)	(-8.46, 19.26)
p-value ^{a, b}			0.6600
Unstratified odds ratio ^c			1.38
(95% CI)			(0.60, 3.15)
p-value			0.4459
Stratified odds ratio ^{b, c}			1.20
(95% CI)			(0.52, 2.77)
p-value			0.6603
Unstratified risk ratio ^c			1.29
(95% CI)			(0.67, 2.46)
p-value			0.4467
Stratified risk ratio ^{b, c}			1.20
(95% CI)			(0.63, 2.28)
p-value			0.5749

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.05 (-0.08, 0.19) 0.5310
Number of subjects reporting nausea (PT) - n (%) (95% CI) p-value ^{a, b}	13 (19.7) (10.93, 31.32)	3 (4.3) (0.91, 12.18)	15.35 (4.62, 26.08) 0.0150
Unstratified odds ratio ^c (95% CI) p-value			5.40 (1.46, 19.93) 0.0114
Stratified odds ratio ^{b, c} (95% CI) p-value			4.41 (1.22, 15.98) 0.0240
Unstratified risk ratio ^c (95% CI) p-value			4.53 (1.35, 15.18) 0.0143

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, c} (95% CI) p-value			4.25 (1.26, 14.36) 0.0199
Absolute risk reduction (95% CI) p-value			0.15 (0.05, 0.26) 0.0071
Number of subjects reporting vomiting (PT) - n (%) (95% CI) p-value ^{a, b}	11 (16.7) (8.62, 27.87)	10 (14.5) (7.17, 25.04)	2.17 (-10.07, 14.41) 0.9517
Unstratified odds ratio ^c (95% CI) p-value			1.18 (0.46, 3.00) 0.7277
Stratified odds ratio ^{b, c} (95% CI) p-value			1.03 (0.39, 2.74) 0.9517

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c			1.15
(95% CI)			(0.52, 2.53)
p-value			0.7278
Stratified risk ratio ^{b, c}			1.09
(95% CI)			(0.49, 2.38)
p-value			0.8368
Absolute risk reduction			0.02
(95% CI)			(-0.10, 0.14)
p-value			0.8141
Number of subjects reporting any general disorders and administration site conditions (SOC) - n (%)	20 (30.3)	12 (17.4)	12.91
(95% CI)	(19.59, 42.85)	(9.32, 28.41)	(-1.33, 27.16)
p-value ^{a, b}			0.0809
Unstratified odds ratio ^c			2.07
(95% CI)			(0.91, 4.66)
p-value			0.0809

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			2.07
(95% CI)			(0.91, 4.72)
p-value			0.0842
Unstratified risk ratio ^c			1.74
(95% CI)			(0.93, 3.28)
p-value			0.0846
Stratified risk ratio ^{b, c}			1.77
(95% CI)			(0.96, 3.28)
p-value			0.0680
Absolute risk reduction			0.13
(95% CI)			(-0.01, 0.27)
p-value			0.1051
Number of subjects reporting fatigue (PT) - n (%)	16 (24.2)	9 (13.0)	11.20
(95% CI)	(14.54, 36.36)	(6.14, 23.32)	(-1.84, 24.24)
p-value ^{a, b}			0.1158

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			2.13
(95% CI)			(0.87, 5.24)
p-value			0.0985
Stratified odds ratio ^{b, c}			2.06
(95% CI)			(0.83, 5.13)
p-value			0.1201
Unstratified risk ratio ^c			1.86
(95% CI)			(0.88, 3.91)
p-value			0.1024
Stratified risk ratio ^{b, c}			1.94
(95% CI)			(0.93, 4.05)
p-value			0.0766
Absolute risk reduction			0.11
(95% CI)			(-0.02, 0.24)
p-value			0.1215

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting any infections and infestations (SOC) - n (%)	30 (45.5)	16 (23.2)	22.27
(95% CI)	(33.14, 58.19)	(13.87, 34.91)	(6.66, 37.87)
p-value ^{a, b}			0.0041
Unstratified odds ratio ^c			2.76
(95% CI)			(1.32, 5.78)
p-value			0.0071
Stratified odds ratio ^{b, c}			2.98
(95% CI)			(1.39, 6.38)
p-value			0.0049
Unstratified risk ratio ^c			1.96
(95% CI)			(1.18, 3.25)
p-value			0.0089
Stratified risk ratio ^{b, c}			2.26
(95% CI)			(1.40, 3.65)
p-value			0.0009

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.22 (0.07, 0.38) 0.0070
Number of subjects reporting covid-19 (PT) - n (%) (95% CI) p-value ^{a, b}	8 (12.1) (5.38, 22.49)	4 (5.8) (1.60, 14.18)	6.32 (-3.29, 15.94) 0.1134
Unstratified odds ratio ^c (95% CI) p-value			2.24 (0.64, 7.83) 0.2062
Stratified odds ratio ^{b, c} (95% CI) p-value			2.74 (0.76, 9.93) 0.1239
Unstratified risk ratio ^c (95% CI) p-value			2.09 (0.66, 6.62) 0.2094

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, d}			0.95
(95% CI)			(0.75, 1.22)
p-value			0.7144
Absolute risk reduction			0.06
(95% CI)			(-0.03, 0.16)
p-value			0.2364
Number of subjects reporting pneumonia (PT) - n (%)	6 (9.1)	7 (10.1)	-1.05
(95% CI)	(3.41, 18.74)	(4.18, 19.79)	(-11.00, 8.89)
p-value ^{a, b}			0.8652
Unstratified odds ratio ^c			0.89
(95% CI)			(0.28, 2.79)
p-value			0.8357
Stratified odds ratio ^{b, c}			0.90
(95% CI)			(0.27, 2.98)
p-value			0.8652

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c (95% CI) p-value			0.90 (0.32, 2.53) 0.8357
Stratified risk ratio ^{b, d} (95% CI) p-value			1.01 (0.79, 1.29) 0.9421
Absolute risk reduction (95% CI) p-value			-0.01 (-0.11, 0.09) >0.9999
Number of subjects reporting any investigations (SOC) - n (%) (95% CI) p-value ^{a, b}	62 (93.9) (85.20, 98.32)	57 (82.6) (71.59, 90.68)	11.33 (0.69, 21.97) 0.0313
Unstratified odds ratio ^c (95% CI) p-value			3.26 (1.00, 10.70) 0.0509

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			3.57
(95% CI)			(1.06, 12.04)
p-value			0.0400
Unstratified risk ratio ^c			1.14
(95% CI)			(1.00, 1.29)
p-value			0.0429
Stratified risk ratio ^{b, d}			0.89
(95% CI)			(0.64, 1.23)
p-value			0.4836
Absolute risk reduction			0.11
(95% CI)			(0.01, 0.22)
p-value			0.0608
Number of subjects reporting alanine aminotransferase increased (PT) - n (%)	28 (42.4)	21 (30.4)	11.99
(95% CI)	(30.34, 55.21)	(19.92, 42.69)	(-4.14, 28.12)
p-value ^{a, b}			0.1482

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			1.68
(95% CI)			(0.83, 3.42)
p-value			0.1490
Stratified odds ratio ^{b, c}			1.69
(95% CI)			(0.83, 3.45)
p-value			0.1499
Unstratified risk ratio ^c			1.39
(95% CI)			(0.89, 2.20)
p-value			0.1517
Stratified risk ratio ^{b, c}			1.38
(95% CI)			(0.87, 2.21)
p-value			0.1744
Absolute risk reduction			0.12
(95% CI)			(-0.04, 0.28)
p-value			0.1572

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting aspartate aminotransferase increased (PT) - n (%)	15 (22.7)	12 (17.4)	5.34
(95% CI)	(13.31, 34.70)	(9.32, 28.41)	(-8.16, 18.83)
p-value ^{a, b}			0.6059
Unstratified odds ratio ^c			1.40
(95% CI)			(0.60, 3.26)
p-value			0.4396
Stratified odds ratio ^{b, c}			1.24
(95% CI)			(0.54, 2.84)
p-value			0.6063
Unstratified risk ratio ^c			1.31
(95% CI)			(0.66, 2.58)
p-value			0.4405
Stratified risk ratio ^{b, c}			1.28
(95% CI)			(0.64, 2.53)
p-value			0.4865

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.05 (-0.08, 0.19) 0.5205
Number of subjects reporting blood bilirubin increased (PT) - n (%) (95% CI) p-value ^{a, b}	10 (15.2) (7.51, 26.10)	12 (17.4) (9.32, 28.41)	-2.24 (-14.68, 10.20) 0.8520
Unstratified odds ratio ^c (95% CI) p-value			0.85 (0.34, 2.12) 0.7248
Stratified odds ratio ^{b, c} (95% CI) p-value			1.09 (0.42, 2.82) 0.8521
Unstratified risk ratio ^c (95% CI) p-value			0.87 (0.40, 1.88) 0.7251

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, c}			0.88
(95% CI)			(0.41, 1.88)
p-value			0.7440
Absolute risk reduction			-0.02
(95% CI)			(-0.15, 0.10)
p-value			0.8174
Number of subjects reporting lymphocyte count decreased (PT) - n (%)	16 (24.2)	18 (26.1)	-1.84
(95% CI)	(14.54, 36.36)	(16.25, 38.06)	(-16.48, 12.79)
p-value ^{a, b}			0.7419
Unstratified odds ratio ^c			0.91
(95% CI)			(0.42, 1.97)
p-value			0.8051
Stratified odds ratio ^{b, c}			0.88
(95% CI)			(0.40, 1.91)
p-value			0.7420

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c			0.93
(95% CI)			(0.52, 1.66)
p-value			0.8052
Stratified risk ratio ^{b, c}			0.91
(95% CI)			(0.51, 1.62)
p-value			0.7401
Absolute risk reduction			-0.02
(95% CI)			(-0.16, 0.13)
p-value			0.8448
Number of subjects reporting neutrophil count decreased (PT) - n (%)	51 (77.3)	47 (68.1)	9.16
(95% CI)	(65.30, 86.69)	(55.79, 78.83)	(-5.78, 24.09)
p-value ^{a, b}			0.1835
Unstratified odds ratio ^c			1.59
(95% CI)			(0.74, 3.43)
p-value			0.2349

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			1.75
(95% CI)			(0.76, 4.00)
p-value			0.1861
Unstratified risk ratio ^c			1.13
(95% CI)			(0.92, 1.40)
p-value			0.2342
Stratified risk ratio ^{b, d}			0.91
(95% CI)			(0.67, 1.23)
p-value			0.5230
Absolute risk reduction			0.09
(95% CI)			(-0.06, 0.24)
p-value			0.2527
Number of subjects reporting platelet count decreased (PT) - n (%)	33 (50.0)	35 (50.7)	-0.72
(95% CI)	(37.43, 62.57)	(38.41, 62.98)	(-17.60, 16.15)
p-value ^{a, b}			0.7110

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			0.97
(95% CI)			(0.49, 1.91)
p-value			0.9329
Stratified odds ratio ^{b, c}			0.88
(95% CI)			(0.43, 1.77)
p-value			0.7110
Unstratified risk ratio ^c			0.99
(95% CI)			(0.71, 1.38)
p-value			0.9329
Stratified risk ratio ^{b, c}			0.98
(95% CI)			(0.71, 1.33)
p-value			0.8775
Absolute risk reduction			-0.01
(95% CI)			(-0.18, 0.16)
p-value			>0.9999

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting white blood cell count decreased (PT) - n (%)	28 (42.4)	31 (44.9)	-2.50
(95% CI)	(30.34, 55.21)	(32.92, 57.38)	(-19.23, 14.23)
p-value ^{a, b}			0.8382
Unstratified odds ratio ^c			0.90
(95% CI)			(0.46, 1.78)
p-value			0.7695
Stratified odds ratio ^{b, c}			0.93
(95% CI)			(0.45, 1.91)
p-value			0.8383
Unstratified risk ratio ^c			0.94
(95% CI)			(0.64, 1.39)
p-value			0.7696
Stratified risk ratio ^{b, c}			1.00
(95% CI)			(0.71, 1.42)
p-value			0.9844

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			-0.03 (-0.19, 0.14) 0.8625
Number of subjects reporting any metabolism and nutrition disorders (SOC) - n (%)	18 (27.3)	12 (17.4)	9.88
(95% CI) p-value ^{a, b}	(17.03, 39.64)	(9.32, 28.41)	(-4.10, 23.86) 0.2322
Unstratified odds ratio ^c (95% CI) p-value			1.78 (0.78, 4.06) 0.1704
Stratified odds ratio ^{b, c} (95% CI) p-value			1.64 (0.73, 3.69) 0.2348
Unstratified risk ratio ^c (95% CI) p-value			1.57 (0.82, 3.00) 0.1734

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, c}			1.67
(95% CI)			(0.87, 3.18)
p-value			0.1203
Absolute risk reduction			0.10
(95% CI)			(-0.04, 0.24)
p-value			0.2147
Number of subjects reporting hyperglycaemia (PT) - n (%)	7 (10.6)	8 (11.6)	-0.99
(95% CI)	(4.37, 20.64)	(5.14, 21.57)	(-11.58, 9.61)
p-value ^{a, b}			0.7619
Unstratified odds ratio ^c			0.90
(95% CI)			(0.31, 2.65)
p-value			0.8551
Stratified odds ratio ^{b, c}			0.85
(95% CI)			(0.29, 2.48)
p-value			0.7621

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c			0.91
(95% CI)			(0.35, 2.38)
p-value			0.8552
Stratified risk ratio ^{b, d}			1.01
(95% CI)			(0.79, 1.29)
p-value			0.9619
Absolute risk reduction			-0.01
(95% CI)			(-0.12, 0.10)
p-value			>0.9999
Number of subjects reporting any musculoskeletal and connective tissue disorders (SOC) - n (%)	14 (21.2)	7 (10.1)	11.07
(95% CI)	(12.11, 33.02)	(4.18, 19.79)	(-1.10, 23.23)
p-value ^{a, b}			0.1291
Unstratified odds ratio ^c			2.38
(95% CI)			(0.90, 6.35)
p-value			0.0820

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-10pct-by-soc-pt-saf-main.sas

Output: t14-06-016-001-ae-sum-10pct-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:40) Source data: adampa.adsl, adam.adae

Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			2.22
(95% CI)			(0.78, 6.30)
p-value			0.1358
Unstratified risk ratio ^c			2.09
(95% CI)			(0.90, 4.85)
p-value			0.0861
Stratified risk ratio ^{b, d}			0.95
(95% CI)			(0.74, 1.22)
p-value			0.6724
Absolute risk reduction			0.11
(95% CI)			(-0.01, 0.23)
p-value			0.0974
Number of subjects reporting any nervous system disorders (SOC) - n (%)	29 (43.9)	26 (37.7)	6.26
(95% CI)	(31.74, 56.70)	(26.29, 50.17)	(-10.30, 22.81)
p-value ^{a, b}			0.3711

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			1.30
(95% CI)			(0.65, 2.58)
p-value			0.4598
Stratified odds ratio ^{b, c}			1.38
(95% CI)			(0.68, 2.82)
p-value			0.3718
Unstratified risk ratio ^c			1.17
(95% CI)			(0.78, 1.75)
p-value			0.4603
Stratified risk ratio ^{b, c}			1.21
(95% CI)			(0.80, 1.84)
p-value			0.3565
Absolute risk reduction			0.06
(95% CI)			(-0.10, 0.23)
p-value			0.4876

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting headache (PT) - n (%)	15 (22.7)	18 (26.1)	-3.36
(95% CI)	(13.31, 34.70)	(16.25, 38.06)	(-17.84, 11.12)
p-value ^{a, b}			0.7063
Unstratified odds ratio ^c			0.83
(95% CI)			(0.38, 1.83)
p-value			0.6500
Stratified odds ratio ^{b, c}			0.86
(95% CI)			(0.40, 1.87)
p-value			0.7064
Unstratified risk ratio ^c			0.87
(95% CI)			(0.48, 1.58)
p-value			0.6505
Stratified risk ratio ^{b, c}			0.89
(95% CI)			(0.48, 1.64)
p-value			0.7115

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			-0.03 (-0.18, 0.11) 0.6923
Number of subjects reporting peripheral sensory neuropathy (PT) - n (%) (95% CI) p-value ^{a, b}	12 (18.2) (9.76, 29.61)	6 (8.7) (3.26, 17.97)	9.49 (-1.95, 20.92) 0.0680
Unstratified odds ratio ^c (95% CI) p-value			2.33 (0.82, 6.64) 0.1121
Stratified odds ratio ^{b, c} (95% CI) p-value			2.74 (0.90, 8.37) 0.0761
Unstratified risk ratio ^c (95% CI) p-value			2.09 (0.83, 5.25) 0.1161

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, d} (95% CI) p-value			0.95 (0.74, 1.21) 0.6579
Absolute risk reduction (95% CI) p-value			0.09 (-0.02, 0.21) 0.1314
Number of subjects reporting any respiratory, thoracic and mediastinal disorders (SOC) - n (%) (95% CI) p-value ^{a, b}	17 (25.8) (15.78, 38.01)	13 (18.8) (10.43, 30.06)	6.92 (-7.10, 20.93) 0.3283
Unstratified odds ratio ^c (95% CI) p-value			1.49 (0.66, 3.39) 0.3355
Stratified odds ratio ^{b, c} (95% CI) p-value			1.51 (0.66, 3.49) 0.3301

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c (95% CI) p-value			1.37 (0.72, 2.59) 0.3370
Stratified risk ratio ^{b, c} (95% CI) p-value			1.38 (0.73, 2.61) 0.3174
Absolute risk reduction (95% CI) p-value			0.07 (-0.07, 0.21) 0.4089
Number of subjects reporting any vascular disorders (SOC) - n (%) (95% CI) p-value ^{a, b}	8 (12.1) (5.38, 22.49)	7 (10.1) (4.18, 19.79)	1.98 (-8.64, 12.59) 0.9437
Unstratified odds ratio ^c (95% CI) p-value			1.22 (0.42, 3.58) 0.7153

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-10pct-by-soc-pt-saf-main.sas

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Table 14-6.16.1. Summary of Maintenance Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			1.04
(95% CI)			(0.35, 3.05)
p-value			0.9437
Unstratified risk ratio ^c			1.19
(95% CI)			(0.46, 3.11)
p-value			0.7154
Stratified risk ratio ^{b, c}			1.14
(95% CI)			(0.43, 2.99)
p-value			0.7973
Absolute risk reduction			0.02
(95% CI)			(-0.09, 0.13)
p-value			0.7883

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Anhang 4-G2.4.3: Sicherheit: Häufige schwere UE nach SOC, PT

Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting any grade 3 and above blood and lymphatic system disorders (SOC) - n (%)	18 (27.3)	8 (11.6)	15.68
(95% CI)	(17.03, 39.64)	(5.14, 21.57)	(2.54, 28.81)
p-value ^{a, b}			0.0085
Unstratified odds ratio ^c			2.86
(95% CI)			(1.15, 7.14)
p-value			0.0244
Stratified odds ratio ^{b, c}			3.54
(95% CI)			(1.34, 9.38)
p-value			0.0109
Unstratified risk ratio ^c			2.35
(95% CI)			(1.10, 5.04)
p-value			0.0277
Stratified risk ratio ^{b, d}			0.91
(95% CI)			(0.70, 1.17)
p-value			0.4585

Page 1 of 35

Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-ge5-by-soc-pt-saf-main.sas

Output: t14-06-016-002-ae-sum-sev-ge5-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:35)

Source data: adampa.adsl, adam.adae

Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.16 (0.03, 0.29) 0.0284
Number of subjects reporting grade 3 and above anaemia (PT) - n (%) (95% CI) p-value ^{a, b}	11 (16.7) (8.62, 27.87)	7 (10.1) (4.18, 19.79)	6.52 (-4.95, 17.99) 0.2269
Unstratified odds ratio ^c (95% CI) p-value			1.77 (0.64, 4.89) 0.2694
Stratified odds ratio ^{b, c} (95% CI) p-value			1.86 (0.67, 5.14) 0.2318
Unstratified risk ratio ^c (95% CI) p-value			1.64 (0.68, 3.98) 0.2719

Page 2 of 35

Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adam.adae

Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, c}			1.68
(95% CI)			(0.70, 4.07)
p-value			0.2487
Absolute risk reduction			0.07
(95% CI)			(-0.05, 0.18)
p-value			0.3165
Number of subjects reporting grade 3 and above febrile neutropenia (PT) - n (%)	9 (13.6)	3 (4.3)	9.29
(95% CI)	(6.43, 24.31)	(0.91, 12.18)	(-0.29, 18.86)
p-value ^{a, b}			0.0318
Unstratified odds ratio ^c			3.47
(95% CI)			(0.90, 13.45)
p-value			0.0715
Stratified odds ratio ^{b, c}			4.09
(95% CI)			(1.04, 16.07)
p-value			0.0434

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-ge5-by-soc-pt-saf-main.sas

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Source data: adampa.adsl, adam.adae

Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c			3.14
(95% CI)			(0.89, 11.08)
p-value			0.0759
Stratified risk ratio ^{b, d}			0.94
(95% CI)			(0.74, 1.21)
p-value			0.6492
Absolute risk reduction			0.09
(95% CI)			(-0.00, 0.19)
p-value			0.0729
Number of subjects reporting any grade 3 and above gastrointestinal disorders (SOC) - n (%)	12 (18.2)	5 (7.2)	10.94
(95% CI)	(9.76, 29.61)	(2.39, 16.11)	(-0.20, 22.07)
p-value ^{a, b}			0.0178
Unstratified odds ratio ^c			2.84
(95% CI)			(0.94, 8.58)
p-value			0.0636

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-ge5-by-soc-pt-saf-main.sas

Output: t14-06-016-002-ae-sum-sev-ge5-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:35)

Source data: adampa.adsl, adam.adae

Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			4.19
(95% CI)			(1.20, 14.58)
p-value			0.0245
Unstratified risk ratio ^c			2.51
(95% CI)			(0.93, 6.73)
p-value			0.0678
Stratified risk ratio ^{b, c}			2.58
(95% CI)			(0.98, 6.80)
p-value			0.0552
Absolute risk reduction			0.11
(95% CI)			(-0.00, 0.22)
p-value			0.0706
Number of subjects reporting grade 3 and above abdominal pain (PT) - n (%)	4 (6.1)	1 (1.4)	4.61
(95% CI)	(1.68, 14.80)	(0.04, 7.81)	(-1.80, 11.02)
p-value ^{a, b}			0.0180

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			4.39
(95% CI)			(0.48, 40.32)
p-value			0.1914
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			4.18
(95% CI)			(0.48, 36.45)
p-value			0.1953
Stratified risk ratio ^{b, d}			0.97
(95% CI)			(0.76, 1.24)
p-value			0.8293
Absolute risk reduction			0.05
(95% CI)			(-0.02, 0.11)
p-value			0.2016

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting any grade 3 and above general disorders and administration site conditions (SOC) - n (%)	3 (4.5)	4 (5.8)	-1.25
(95% CI)	(0.95, 12.71)	(1.60, 14.18)	(-8.71, 6.21)
p-value ^{a, b}			0.7631
Unstratified odds ratio ^c			0.77
(95% CI)			(0.17, 3.60)
p-value			0.7436
Stratified odds ratio ^{b, c}			0.79
(95% CI)			(0.16, 3.79)
p-value			0.7635
Unstratified risk ratio ^c			0.78
(95% CI)			(0.18, 3.37)
p-value			0.7438
Stratified risk ratio ^{b, d}			1.00
(95% CI)			(0.79, 1.28)
p-value			0.9795

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			-0.01 (-0.09, 0.06) >0.9999
Number of subjects reporting any grade 3 and above infections and infestations (SOC) - n (%)	19 (28.8)	9 (13.0)	15.74
(95% CI) p-value ^{a, b}	(18.30, 41.25)	(6.14, 23.32)	(2.24, 29.25) 0.0065
Unstratified odds ratio ^c (95% CI) p-value			2.70 (1.12, 6.50) 0.0273
Stratified odds ratio ^{b, c} (95% CI) p-value			3.54 (1.38, 9.07) 0.0085
Unstratified risk ratio ^c (95% CI) p-value			2.21 (1.08, 4.52) 0.0306

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

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Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, c}			2.89
(95% CI)			(1.46, 5.72)
p-value			0.0023
Absolute risk reduction			0.16
(95% CI)			(0.02, 0.29)
p-value			0.0331
Number of subjects reporting grade 3 and above covid-19 (PT) - n (%)	5 (7.6)	3 (4.3)	3.23
(95% CI)	(2.51, 16.80)	(0.91, 12.18)	(-4.77, 11.22)
p-value ^{a, b}			0.2538
Unstratified odds ratio ^c			1.80
(95% CI)			(0.41, 7.87)
p-value			0.4328
Stratified odds ratio ^{b, c}			2.39
(95% CI)			(0.52, 11.00)
p-value			0.2638

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c (95% CI) p-value			1.74 (0.43, 7.00) 0.4340
Stratified risk ratio ^{b, d} (95% CI) p-value			0.97 (0.76, 1.24) 0.8308
Absolute risk reduction (95% CI) p-value			0.03 (-0.05, 0.11) 0.4865
Number of subjects reporting grade 3 and above pneumonia (PT) - n (%) (95% CI) p-value ^{a, b}	6 (9.1) (3.41, 18.74)	4 (5.8) (1.60, 14.18)	3.29 (-5.57, 12.15) 0.3751
Unstratified odds ratio ^c (95% CI) p-value			1.62 (0.44, 6.04) 0.4686

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			1.89
(95% CI)			(0.45, 7.92)
p-value			0.3820
Unstratified risk ratio ^c			1.57
(95% CI)			(0.46, 5.31)
p-value			0.4696
Stratified risk ratio ^{b, d}			0.99
(95% CI)			(0.77, 1.26)
p-value			0.9075
Absolute risk reduction			0.03
(95% CI)			(-0.06, 0.12)
p-value			0.5256
Number of subjects reporting grade 3 and above urinary tract infection (PT) - n (%)	4 (6.1)	0 (0.0)	6.06
(95% CI)	(1.68, 14.80)	(0.00, 5.21)	(0.30, 11.82)
p-value ^{a, b}			0.0411

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			10.00
(95% CI)			(0.53, 189.43)
p-value			0.1249
Stratified odds ratio ^{b, c}			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio ^c			9.40
(95% CI)			(0.52, 171.31)
p-value			0.1302
Stratified risk ratio ^{b, d}			0.97
(95% CI)			(0.76, 1.23)
p-value			0.7857
Absolute risk reduction			0.06
(95% CI)			(0.00, 0.12)
p-value			0.0545

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting any grade 3 and above investigations (SOC) - n (%)	58 (87.9)	52 (75.4)	12.52
(95% CI)	(77.51, 94.62)	(63.51, 84.95)	(-0.34, 25.38)
p-value ^{a, b}			0.0391
Unstratified odds ratio ^c			2.37
(95% CI)			(0.94, 5.95)
p-value			0.0660
Stratified odds ratio ^{b, c}			2.65
(95% CI)			(1.03, 6.83)
p-value			0.0435
Unstratified risk ratio ^c			1.17
(95% CI)			(0.99, 1.37)
p-value			0.0630
Stratified risk ratio ^{b, d}			0.88
(95% CI)			(0.64, 1.20)
p-value			0.4216

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.13 (-0.00, 0.25) 0.0771
Number of subjects reporting grade 3 and above alanine aminotransferase increased (PT) - n (%) (95% CI) p-value ^{a, b}	18 (27.3) (17.03, 39.64)	16 (23.2) (13.87, 34.91)	4.08 (-10.57, 18.73) 0.5476
Unstratified odds ratio ^c (95% CI) p-value			1.24 (0.57, 2.71) 0.5850
Stratified odds ratio ^{b, c} (95% CI) p-value			1.27 (0.58, 2.77) 0.5481
Unstratified risk ratio ^c (95% CI) p-value			1.18 (0.66, 2.11) 0.5853

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-ge5-by-soc-pt-saf-main.sas

Output: t14-06-016-002-ae-sum-sev-ge5-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:35)

Source data: adampa.adsl, adam.adae

Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, c}			1.14
(95% CI)			(0.63, 2.06)
p-value			0.6703
Absolute risk reduction			0.04
(95% CI)			(-0.11, 0.19)
p-value			0.6923
Number of subjects reporting grade 3 and above aspartate aminotransferase increased (PT) - n (%)	6 (9.1)	7 (10.1)	-1.05
(95% CI)	(3.41, 18.74)	(4.18, 19.79)	(-11.00, 8.89)
p-value ^{a, b}			0.6660
Unstratified odds ratio ^c			0.89
(95% CI)			(0.28, 2.79)
p-value			0.8357
Stratified odds ratio ^{b, c}			0.78
(95% CI)			(0.25, 2.43)
p-value			0.6666

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c (95% CI) p-value			0.90 (0.32, 2.53) 0.8357
Stratified risk ratio ^{b, d} (95% CI) p-value			1.01 (0.79, 1.29) 0.9287
Absolute risk reduction (95% CI) p-value			-0.01 (-0.11, 0.09) >0.9999
Number of subjects reporting grade 3 and above blood bilirubin increased (PT) - n (%) (95% CI) p-value ^{a, b}	3 (4.5) (0.95, 12.71)	9 (13.0) (6.14, 23.32)	-8.50 (-17.90, 0.90) 0.2771
Unstratified odds ratio ^c (95% CI) p-value			0.32 (0.08, 1.23) 0.0967

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			0.46
(95% CI)			(0.11, 1.91)
p-value			0.2860
Unstratified risk ratio ^c			0.35
(95% CI)			(0.10, 1.23)
p-value			0.1017
Stratified risk ratio ^{b, d}			1.04
(95% CI)			(0.81, 1.33)
p-value			0.7499
Absolute risk reduction			-0.08
(95% CI)			(-0.18, 0.01)
p-value			0.1290
Number of subjects reporting grade 3 and above lymphocyte count decreased (PT) - n (%)	11 (16.7)	16 (23.2)	-6.52
(95% CI)	(8.62, 27.87)	(13.87, 34.91)	(-19.94, 6.89)
p-value ^{a, b}			0.3129

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			0.66
(95% CI)			(0.28, 1.56)
p-value			0.3455
Stratified odds ratio ^{b, c}			0.64
(95% CI)			(0.27, 1.53)
p-value			0.3152
Unstratified risk ratio ^c			0.72
(95% CI)			(0.36, 1.43)
p-value			0.3479
Stratified risk ratio ^{b, c}			0.71
(95% CI)			(0.36, 1.41)
p-value			0.3263
Absolute risk reduction			-0.07
(95% CI)			(-0.20, 0.07)
p-value			0.3937

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting grade 3 and above neutrophil count decreased (PT) - n (%)	45 (68.2)	42 (60.9)	7.31
(95% CI)	(55.56, 79.11)	(48.37, 72.40)	(-8.78, 23.40)
p-value ^{a, b}			0.2281
Unstratified odds ratio ^c			1.38
(95% CI)			(0.68, 2.80)
p-value			0.3756
Stratified odds ratio ^{b, c}			1.60
(95% CI)			(0.74, 3.47)
p-value			0.2299
Unstratified risk ratio ^c			1.12
(95% CI)			(0.87, 1.44)
p-value			0.3755
Stratified risk ratio ^{b, c}			1.15
(95% CI)			(0.91, 1.45)
p-value			0.2483

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.07 (-0.09, 0.23) 0.4721
Number of subjects reporting grade 3 and above platelet count decreased (PT) - n (%) (95% CI) p-value ^{a, b}	21 (31.8) (20.89, 44.44)	15 (21.7) (12.71, 33.31)	10.08 (-4.79, 24.94) 0.2036
Unstratified odds ratio ^c (95% CI) p-value			1.68 (0.78, 3.63) 0.1877
Stratified odds ratio ^{b, c} (95% CI) p-value			1.66 (0.76, 3.65) 0.2057
Unstratified risk ratio ^c (95% CI) p-value			1.46 (0.83, 2.59) 0.1904

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, c}			1.49
(95% CI)			(0.85, 2.62)
p-value			0.1623
Absolute risk reduction			0.10
(95% CI)			(-0.05, 0.25)
p-value			0.2429
Number of subjects reporting grade 3 and above white blood cell count decreased (PT) - n (%)	25 (37.9)	27 (39.1)	-1.25
(95% CI)	(26.22, 50.66)	(27.60, 51.63)	(-17.67, 15.17)
p-value ^{a, b}			0.9439
Unstratified odds ratio ^c			0.95
(95% CI)			(0.47, 1.90)
p-value			0.8813
Stratified odds ratio ^{b, c}			0.97
(95% CI)			(0.48, 1.98)
p-value			0.9439

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c			0.97
(95% CI)			(0.63, 1.48)
p-value			0.8813
Stratified risk ratio ^{b, c}			1.01
(95% CI)			(0.67, 1.51)
p-value			0.9615
Absolute risk reduction			-0.01
(95% CI)			(-0.18, 0.15)
p-value			>0.9999
Number of subjects reporting any grade 3 and above metabolism and nutrition disorders (SOC) - n (%)	7 (10.6)	7 (10.1)	0.46
(95% CI)	(4.37, 20.64)	(4.18, 19.79)	(-9.83, 10.75)
p-value ^{a, b}			0.9791
Unstratified odds ratio ^c			1.05
(95% CI)			(0.35, 3.18)
p-value			0.9300

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			1.02
(95% CI)			(0.33, 3.10)
p-value			0.9791
Unstratified risk ratio ^c			1.05
(95% CI)			(0.39, 2.82)
p-value			0.9300
Stratified risk ratio ^{b, d}			1.00
(95% CI)			(0.78, 1.28)
p-value			0.9917
Absolute risk reduction			0.005
(95% CI)			(-0.10, 0.11)
p-value			>0.9999
Number of subjects reporting grade 3 and above hyperglycaemia (PT) - n (%)	3 (4.5)	5 (7.2)	-2.70
(95% CI)	(0.95, 12.71)	(2.39, 16.11)	(-10.62, 5.22)
p-value ^{a, b}			0.5075

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			0.61
(95% CI)			(0.14, 2.66)
p-value			0.5101
Stratified odds ratio ^{b, c}			0.61
(95% CI)			(0.14, 2.67)
p-value			0.5111
Unstratified risk ratio ^c			0.63
(95% CI)			(0.16, 2.52)
p-value			0.5111
Stratified risk ratio ^{b, d}			1.01
(95% CI)			(0.79, 1.29)
p-value			0.9181
Absolute risk reduction			-0.03
(95% CI)			(-0.11, 0.05)
p-value			0.7187

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-ge5-by-soc-pt-saf-main.sas

Output: t14-06-016-002-ae-sum-sev-ge5-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:35)

Source data: adampa.adsl, adam.adae

Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting any grade 3 and above musculoskeletal and connective tissue disorders (SOC) - n (%)	4 (6.1)	4 (5.8)	0.26
(95% CI)	(1.68, 14.80)	(1.60, 14.18)	(-7.71, 8.23)
p-value ^{a, b}			0.9081
Unstratified odds ratio ^c			1.05
(95% CI)			(0.25, 4.38)
p-value			0.9483
Stratified odds ratio ^{b, c}			0.92
(95% CI)			(0.21, 3.97)
p-value			0.9081
Unstratified risk ratio ^c			1.05
(95% CI)			(0.27, 4.01)
p-value			0.9483
Stratified risk ratio ^{b, d}			1.00
(95% CI)			(0.78, 1.28)
p-value			0.9904

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.003 (-0.08, 0.08) >0.9999
Number of subjects reporting any grade 3 and above neoplasms benign, malignant and unspecified (incl cysts and polyps) (SOC) - n (%) (95% CI) p-value ^{a, b}	2 (3.0) (0.37, 10.52)	5 (7.2) (2.39, 16.11)	-4.22 (-11.60, 3.17) 0.1698
Unstratified odds ratio ^c (95% CI) p-value			0.40 (0.07, 2.14) 0.2839
Stratified odds ratio ^{b, c} (95% CI) p-value			0.24 (0.03, 2.19) 0.2032
Unstratified risk ratio ^c (95% CI) p-value			0.42 (0.08, 2.08) 0.2870

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Source data: adampa.adsl, adam.adae

Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, d} (95% CI) p-value			1.02 (0.80, 1.30) 0.8802
Absolute risk reduction (95% CI) p-value			-0.04 (-0.12, 0.03) 0.4415
Number of subjects reporting any grade 3 and above nervous system disorders (SOC) - n (%) (95% CI) p-value ^{a, b}	5 (7.6) (2.51, 16.80)	9 (13.0) (6.14, 23.32)	-5.47 (-15.66, 4.73) 0.4317
Unstratified odds ratio ^c (95% CI) p-value			0.55 (0.17, 1.73) 0.3030
Stratified odds ratio ^{b, c} (95% CI) p-value			0.62 (0.19, 2.05) 0.4348

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.16.2. Summary of Severe (Grade ≥3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5 % (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c			0.58
(95% CI)			(0.21, 1.64)
p-value			0.3058
Stratified risk ratio ^{b, c}			0.60
(95% CI)			(0.21, 1.72)
p-value			0.3391
Absolute risk reduction			-0.05
(95% CI)			(-0.16, 0.05)
p-value			0.3998
Number of subjects reporting grade 3 and above headache (PT) - n (%)	1 (1.5)	5 (7.2)	-5.73
(95% CI)	(0.04, 8.16)	(2.39, 16.11)	(-12.52, 1.06)
p-value ^{a, b}			0.1185
Unstratified odds ratio ^c			0.20
(95% CI)			(0.02, 1.73)
p-value			0.1430

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			0.20
(95% CI)			(0.02, 1.82)
p-value			0.1520
Unstratified risk ratio ^c			0.21
(95% CI)			(0.03, 1.74)
p-value			0.1480
Stratified risk ratio ^{b, d}			1.03
(95% CI)			(0.81, 1.31)
p-value			0.8272
Absolute risk reduction			-0.06
(95% CI)			(-0.13, 0.01)
p-value			0.2089
Number of subjects reporting any grade 3 and above respiratory, thoracic and mediastinal disorders (SOC) - n (%)	6 (9.1)	7 (10.1)	-1.05
(95% CI)	(3.41, 18.74)	(4.18, 19.79)	(-11.00, 8.89)
p-value ^{a, b}			0.9782

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			0.89
(95% CI)			(0.28, 2.79)
p-value			0.8357
Stratified odds ratio ^{b, c}			0.98
(95% CI)			(0.30, 3.21)
p-value			0.9782
Unstratified risk ratio ^c			0.90
(95% CI)			(0.32, 2.53)
p-value			0.8357
Stratified risk ratio ^{b, c}			0.94
(95% CI)			(0.33, 2.67)
p-value			0.9123
Absolute risk reduction			-0.01
(95% CI)			(-0.11, 0.09)
p-value			>0.9999

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting grade 3 and above dyspnoea (PT) - n (%)	2 (3.0)	4 (5.8)	-2.77
(95% CI)	(0.37, 10.52)	(1.60, 14.18)	(-9.66, 4.13)
p-value ^{a, b}			0.4535
Unstratified odds ratio ^c			0.51
(95% CI)			(0.09, 2.87)
p-value			0.4432
Stratified odds ratio ^{b, c}			0.52
(95% CI)			(0.09, 2.95)
p-value			0.4604
Unstratified risk ratio ^c			0.52
(95% CI)			(0.10, 2.76)
p-value			0.4447
Stratified risk ratio ^{b, d}			1.01
(95% CI)			(0.79, 1.29)
p-value			0.9279

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			-0.03 (-0.10, 0.04) 0.6808
Number of subjects reporting grade 3 and above hypoxia (PT) - n (%) (95% CI) p-value ^{a, b}	2 (3.0) (0.37, 10.52)	4 (5.8) (1.60, 14.18)	-2.77 (-9.66, 4.13) 0.6764
Unstratified odds ratio ^c (95% CI) p-value			0.51 (0.09, 2.87) 0.4432
Stratified odds ratio ^{b, c} (95% CI) p-value			0.68 (0.11, 4.31) 0.6780
Unstratified risk ratio ^c (95% CI) p-value			0.52 (0.10, 2.76) 0.4447

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^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

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Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, d}			1.01
(95% CI)			(0.79, 1.29)
p-value			0.9208
Absolute risk reduction			-0.03
(95% CI)			(-0.10, 0.04)
p-value			0.6808
Number of subjects reporting any grade 3 and above vascular disorders (SOC) - n (%)	5 (7.6)	6 (8.7)	-1.12
(95% CI)	(2.51, 16.80)	(3.26, 17.97)	(-10.34, 8.10)
p-value ^{a, b}			0.6710
Unstratified odds ratio ^c			0.86
(95% CI)			(0.25, 2.97)
p-value			0.8122
Stratified odds ratio ^{b, c}			0.76
(95% CI)			(0.22, 2.65)
p-value			0.6717

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	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c			0.87
(95% CI)			(0.28, 2.72)
p-value			0.8123
Stratified risk ratio ^{b, c}			0.85
(95% CI)			(0.27, 2.66)
p-value			0.7823
Absolute risk reduction			-0.01
(95% CI)			(-0.10, 0.08)
p-value			>0.9999
Number of subjects reporting grade 3 and above hypertension (PT) - n (%)	2 (3.0)	4 (5.8)	-2.77
(95% CI)	(0.37, 10.52)	(1.60, 14.18)	(-9.66, 4.13)
p-value ^{a, b}			0.3982
Unstratified odds ratio ^c			0.51
(95% CI)			(0.09, 2.87)
p-value			0.4432

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-ge5-by-soc-pt-saf-main.sas

Output: t14-06-016-002-ae-sum-sev-ge5-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:35)

Source data: adampa.adsl, adam.adae

Table 14-6.16.2. Summary of Severe (Grade ≥ 3) Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			0.48
(95% CI)			(0.08, 2.74)
p-value			0.4072
Unstratified risk ratio ^c			0.52
(95% CI)			(0.10, 2.76)
p-value			0.4447
Stratified risk ratio ^{b, c}			0.53
(95% CI)			(0.10, 2.72)
p-value			0.4486
Absolute risk reduction			-0.03
(95% CI)			(-0.10, 0.04)
p-value			0.6808

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-ge5-by-soc-pt-saf-main.sas

Output: t14-06-016-002-ae-sum-sev-ge5-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:35)

Source data: adampa.adsl, adam.adae

Anhang 4-G2.4.4: Sicherheit: Häufige Expedited UE nach SOC, PT

Table 14-6.16.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting any expedited blood and lymphatic system disorders (SOC) - n (%)	5 (7.6)	3 (4.3)	3.23
(95% CI)	(2.51, 16.80)	(0.91, 12.18)	(-4.77, 11.22)
p-value ^{a, b}			0.3356
Unstratified odds ratio ^c			1.80
(95% CI)			(0.41, 7.87)
p-value			0.4328
Stratified odds ratio ^{b, c}			2.07
(95% CI)			(0.46, 9.33)
p-value			0.3433
Unstratified risk ratio ^c			1.74
(95% CI)			(0.43, 7.00)
p-value			0.4340
Stratified risk ratio ^{b, d}			0.98
(95% CI)			(0.77, 1.25)
p-value			0.8598

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-ge5-by-soc-pt-saf-main.sas

Output: t14-06-016-003-ae-sum-exp-ge5-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:30)

Source data: adampa.adsl, adam.adae

Table 14-6.16.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.03 (-0.05, 0.11) 0.4865
Number of subjects reporting expedited febrile neutropenia (PT) - n (%) (95% CI) p-value ^{a, b}	5 (7.6) (2.51, 16.80)	2 (2.9) (0.35, 10.08)	4.68 (-2.83, 12.19) 0.1788
Unstratified odds ratio ^c (95% CI) p-value			2.75 (0.51, 14.68) 0.2375
Stratified odds ratio ^{b, c} (95% CI) p-value			3.03 (0.56, 16.33) 0.1976
Unstratified risk ratio ^c (95% CI) p-value			2.61 (0.53, 13.01) 0.2406

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment. Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-ge5-by-soc-pt-saf-main.sas

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Source data: adampa.adsl, adam.adae

Table 14-6.16.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, d}			0.97
(95% CI)			(0.76, 1.24)
p-value			0.8146
Absolute risk reduction			0.05
(95% CI)			(-0.03, 0.12)
p-value			0.2673
Number of subjects reporting any expedited gastrointestinal disorders (SOC) - n (%)	5 (7.6)	4 (5.8)	1.78
(95% CI)	(2.51, 16.80)	(1.60, 14.18)	(-6.66, 10.21)
p-value ^{a, b}			0.3786
Unstratified odds ratio ^c			1.33
(95% CI)			(0.34, 5.19)
p-value			0.6796
Stratified odds ratio ^{b, c}			1.96
(95% CI)			(0.43, 8.95)
p-value			0.3853

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment. Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.16.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c			1.31
(95% CI)			(0.37, 4.66)
p-value			0.6798
Stratified risk ratio ^{b, d}			0.99
(95% CI)			(0.77, 1.26)
p-value			0.9318
Absolute risk reduction			0.02
(95% CI)			(-0.07, 0.10)
p-value			0.7408
Number of subjects reporting any expedited infections and infestations (SOC) - n (%)	11 (16.7)	4 (5.8)	10.87
(95% CI)	(8.62, 27.87)	(1.60, 14.18)	(0.32, 21.42)
p-value ^{a, b}			0.0430
Unstratified odds ratio ^c			3.25
(95% CI)			(0.98, 10.78)
p-value			0.0541

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adam.adae

Table 14-6.16.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified odds ratio ^{b, c}			3.29
(95% CI)			(0.99, 10.93)
p-value			0.0523
Unstratified risk ratio ^c			2.87
(95% CI)			(0.96, 8.58)
p-value			0.0584
Stratified risk ratio ^{b, c}			3.00
(95% CI)			(1.02, 8.81)
p-value			0.0451
Absolute risk reduction			0.11
(95% CI)			(0.00, 0.21)
p-value			0.0565
Number of subjects reporting expedited pneumonia (PT) - n (%)	4 (6.1)	2 (2.9)	3.16
(95% CI)	(1.68, 14.80)	(0.35, 10.08)	(-3.82, 10.15)
p-value ^{a, b}			0.5050

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment. Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.16.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified odds ratio ^c			2.16
(95% CI)			(0.38, 12.22)
p-value			0.3832
Stratified odds ratio ^{b, c}			1.78
(95% CI)			(0.32, 10.00)
p-value			0.5104
Unstratified risk ratio ^c			2.09
(95% CI)			(0.40, 11.04)
p-value			0.3848
Stratified risk ratio ^{b, d}			0.99
(95% CI)			(0.77, 1.26)
p-value			0.9170
Absolute risk reduction			0.03
(95% CI)			(-0.04, 0.10)
p-value			0.4340

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.16.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Number of subjects reporting any expedited investigations (SOC) - n (%)	4 (6.1)	8 (11.6)	-5.53
(95% CI)	(1.68, 14.80)	(5.14, 21.57)	(-15.03, 3.96)
p-value ^{a, b}			0.4763
Unstratified odds ratio ^c			0.49
(95% CI)			(0.14, 1.72)
p-value			0.2665
Stratified odds ratio ^{b, c}			0.63
(95% CI)			(0.18, 2.26)
p-value			0.4794
Unstratified risk ratio ^c			0.52
(95% CI)			(0.17, 1.65)
p-value			0.2697
Stratified risk ratio ^{b, d}			1.02
(95% CI)			(0.80, 1.31)
p-value			0.8502

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment. Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adam.adae

Table 14-6.16.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Absolute risk reduction (95% CI) p-value			-0.06 (-0.15, 0.04) 0.3667
Number of subjects reporting expedited blood bilirubin increased (PT) - n (%) (95% CI) p-value ^{a, b}	1 (1.5) (0.04, 8.16)	4 (5.8) (1.60, 14.18)	-4.28 (-10.53, 1.97) 0.4177
Unstratified odds ratio ^c (95% CI) p-value			0.25 (0.03, 2.30) 0.2206
Stratified odds ratio ^{b, c} (95% CI) p-value			0.40 (0.04, 3.90) 0.4332
Unstratified risk ratio ^c (95% CI) p-value			0.26 (0.03, 2.28) 0.2245

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment. Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.16.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Stratified risk ratio ^{b, d} (95% CI) p-value			1.02 (0.80, 1.30) 0.8755
Absolute risk reduction (95% CI) p-value			-0.04 (-0.11, 0.02) 0.3662
Number of subjects reporting any expedited respiratory, thoracic and mediastinal disorders (SOC) - n (%) (95% CI) p-value ^{a, b}	4 (6.1) (1.68, 14.80)	3 (4.3) (0.91, 12.18)	1.71 (-5.79, 9.22) 0.7102
Unstratified odds ratio ^c (95% CI) p-value			1.42 (0.31, 6.60) 0.6551
Stratified odds ratio ^{b, c} (95% CI) p-value			1.34 (0.28, 6.37) 0.7110

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

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Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment. Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-ge5-by-soc-pt-saf-main.sas

Output: t14-06-016-003-ae-sum-exp-ge5-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:30)

Source data: adampa.adsl, adam.adae

Table 14-6.16.3. Summary of Expedited Maintenance Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence $\geq 5\%$ (Safety Analysis Set - Subjects who Received Maintenance Treatment)

	SOC Chemotherapy+ Blinatumomab (N = 66)	SOC Chemotherapy (N = 69)	Treatment Difference
Unstratified risk ratio ^c			1.39
(95% CI)			(0.32, 5.99)
p-value			0.6553
Stratified risk ratio ^{b, d}			0.99
(95% CI)			(0.78, 1.27)
p-value			0.9558
Absolute risk reduction			0.02
(95% CI)			(-0.06, 0.09)
p-value			0.7142

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Safety analysis set includes all subjects in the full analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Maintenance treatment-emergent adverse event is any AE recorded during the Step 4 maintenance treatment period or late adverse events with onset within 30 days of end of maintenance treatment.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b Stratification factors: age (< 55 years vs. ≥ 55 years), CD20 status (positive vs. negative vs. not collected), rituximab use (yes vs. no vs. not collected), intent to receive allogeneic SCT (yes vs. no).

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^d Stratified risk ratio obtained from generalized poisson model with log link.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-ge5-by-soc-pt-saf-main.sas

Output: t14-06-016-003-ae-sum-exp-ge5-by-soc-pt-saf-main.rtf (Date generated: 27JUL2025:22:30)

Source data: adampa.adsl, adam.adae

Anhang 4-G3: Subgruppenanalysen

Anhang 4-G3.1: Subgruppenanalysen zum Gesamtüberleben

**Table 14-4.1. Overall Survival - Subgroup Analysis
(Step 3 Analysis Set)**

	SOC Chemotherapy + Blinatumomab (N = 152)		SOC Chemotherapy (N = 134)		Hazard Ratio (95% CI)	p-value ^a	Interaction p-value ^b
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group 1							0.0720
<55 years	11/92 (12.0)	NE (NE, NE)	27/76 (35.5)	NE (4.16, NE)	0.28 (0.14, 0.56)	0.0001	
≥55 years	19/60 (31.7)	NE (NE, NE)	26/58 (44.8)	5.95 (2.99, NE)	0.65 (0.36, 1.18)	0.1516	
Age group 2							0.0907
≥18 - <35 years	1/18 (5.6)	NE (NE, NE)	3/19 (15.8)	NE (NE, NE)	0.28 (0.03, 2.69)	0.2383	
≥35 - <55 years	10/74 (13.5)	NE (NE, NE)	24/57 (42.1)	NE (2.84, NE)	0.27 (0.13, 0.57)	0.0002	
≥55 - <65 years	13/48 (27.1)	NE (NE, NE)	17/38 (44.7)	NE (1.96, NE)	0.51 (0.25, 1.04)	0.0601	
≥65 years	6/12 (50.0)	3.48 (0.44, NE)	9/20 (45.0)	5.95 (2.64, NE)	1.34 (0.47, 3.81)	0.5867	

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Overall Survival (OS) is calculated from time of Step 3 randomization until death due to any cause.

^a 2-sided p-values were calculated using the unstratified log-rank test.

^b p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariates and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-os-subgrp-step3.sas

Output: t14-04-001-os-subgrp-step3.rtf (Date generated: 29MAY2025:04:41) Source data: adampa.adsl, adampa.adtte

**Table 14-4.1. Overall Survival - Subgroup Analysis
(Step 3 Analysis Set)**

	SOC Chemotherapy + Blinatumomab (N = 152)		SOC Chemotherapy (N = 134)		Hazard Ratio (95% CI)	p-value ^a	Interaction p-value ^b
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Sex							0.5635
Male	13/69 (18.8)	NE (NE, NE)	28/70 (40.0)	5.95 (3.14, NE)	0.37 (0.19, 0.72)	0.0022	
Female	17/83 (20.5)	NE (NE, NE)	25/64 (39.1)	NE (3.76, NE)	0.49 (0.27, 0.91)	0.0213	
Region							0.9824
USA	30/140 (21.4)	NE (NE, NE)	50/120 (41.7)	5.95 (3.76, NE)	0.44 (0.28, 0.70)	0.0003	
Rest of the world	0/12 (0.0)	NE (NE, NE)	3/14 (21.4)	NE (2.30, NE)	0.00 (0.00, NE)	0.0863	
Race							0.4889
Caucasian	25/117 (21.4)	NE (NE, NE)	43/110 (39.1)	NE (4.11, NE)	0.46 (0.28, 0.76)	0.0018	
Others	4/19 (21.1)	NE (NE, NE)	2/8 (25.0)	NE (0.51, NE)	0.89 (0.16, 4.88)	0.8968	

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Overall Survival (OS) is calculated from time of Step 3 randomization until death due to any cause.

^a 2-sided p-values were calculated using the unstratified log-rank test.^b p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariates and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-os-subgrp-step3.sas

Output: t14-04-001-os-subgrp-step3.rtf (Date generated: 29MAY2025:04:41) Source data: adampa.adsl, adampa.adtte

**Table 14-4.1. Overall Survival - Subgroup Analysis
(Step 3 Analysis Set)**

	SOC Chemotherapy + Blinatumomab (N = 152)		SOC Chemotherapy (N = 134)		Hazard Ratio (95% CI)	p-value ^a	Interaction p-value ^b
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Ethnicity							0.1486
Hispanic or Latino	2/21 (9.5)	NE (NE, NE)	7/15 (46.7)	NE (0.61, NE)	0.16 (0.03, 0.79)	0.0100	
Not Hispanic or Latino	27/125 (21.6)	NE (NE, NE)	41/111 (36.9)	NE (4.16, NE)	0.52 (0.32, 0.84)	0.0068	
CD20 status							0.9931
Positive	16/76 (21.1)	NE (NE, NE)	32/72 (44.4)	NE (3.17, NE)	0.43 (0.24, 0.79)	0.0047	
Negative	13/75 (17.3)	NE (NE, NE)	20/60 (33.3)	NE (5.55, NE)	0.44 (0.22, 0.89)	0.0180	
Rituximab use							0.7349
Yes	9/45 (20.0)	NE (4.28, NE)	16/40 (40.0)	NE (3.14, NE)	0.48 (0.21, 1.09)	0.0722	
No	21/107 (19.6)	NE (NE, NE)	37/94 (39.4)	NE (4.11, NE)	0.41 (0.24, 0.71)	0.0009	

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Overall Survival (OS) is calculated from time of Step 3 randomization until death due to any cause.

^a 2-sided p-values were calculated using the unstratified log-rank test.^b p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariates and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-os-subgrp-step3.sas

Output: t14-04-001-os-subgrp-step3.rtf (Date generated: 29MAY2025:04:41) Source data: adampa.adsl, adampa.adtte

**Table 14-4.1. Overall Survival - Subgroup Analysis
(Step 3 Analysis Set)**

	SOC Chemotherapy + Blinatumomab (N = 152)		SOC Chemotherapy (N = 134)		Hazard Ratio (95% CI)	p-value ^a	Interaction p-value ^b
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Allogeneic SCT							0.8806
Yes	10/48 (20.8)	NE (NE, NE)	17/44 (38.6)	NE (2.64, NE)	0.45 (0.21, 0.98)	0.0399	
No	20/104 (19.2)	NE (NE, NE)	36/90 (40.0)	5.95 (3.76, NE)	0.42 (0.24, 0.73)	0.0015	
MRD status							0.5741
Positive	11/40 (27.5)	NE (NE, NE)	13/22 (59.1)	1.87 (0.62, NE)	0.35 (0.15, 0.78)	0.0072	
Negative	19/112 (17.0)	NE (NE, NE)	40/112 (35.7)	NE (5.55, NE)	0.41 (0.24, 0.71)	0.0011	
All subjects	30/152 (19.7)	NE (NE, NE)	53/134 (39.6)	NE (4.16, NE)	0.43 (0.28, 0.68)	0.0002	

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Overall Survival (OS) is calculated from time of Step 3 randomization until death due to any cause.

^a 2-sided p-values were calculated using the unstratified log-rank test.

^b p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariates and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-os-subgrp-step3.sas

Output: t14-04-001-os-subgrp-step3.rtf (Date generated: 29MAY2025:04:41) Source data: adampa.adsl, adampa.adtte

Anhang 4-G3.2: Subgruppenanalysen zum rezidivfreien Überleben

**Table 14-4.2. Relapse-free Survival - Subgroup Analysis
(Step 3 Analysis Set)**

	SOC Chemotherapy + Blinatumomab (N = 152)		SOC Chemotherapy (N = 134)		Hazard Ratio (95% CI)	p-value ^a	Interaction p-value ^b
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group 1							0.1838
<55 years	15/92 (16.3)	NE (NE, NE)	28/76 (36.8)	NE (4.16, NE)	0.37 (0.20, 0.70)	0.0013	
≥55 years	21/60 (35.0)	NE (NE, NE)	28/58 (48.3)	5.75 (1.61, NE)	0.66 (0.38, 1.17)	0.1545	
Age group 2							0.2795
≥18 - <35 years	1/18 (5.6)	NE (NE, NE)	4/19 (21.1)	NE (2.64, NE)	0.22 (0.02, 1.93)	0.1316	
≥35 - <55 years	14/74 (18.9)	NE (NE, NE)	24/57 (42.1)	NE (2.53, NE)	0.39 (0.20, 0.75)	0.0036	
≥55 - <65 years	15/48 (31.3)	NE (NE, NE)	19/38 (50.0)	2.99 (1.06, NE)	0.55 (0.28, 1.08)	0.0789	
≥65 years	6/12 (50.0)	NE (0.30, NE)	9/20 (45.0)	5.75 (1.09, NE)	1.10 (0.39, 3.13)	0.8542	

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Relapse-free survival (RFS) is calculated from time of Step 3 randomization until relapse or death due to any cause.

^a 2-sided p-values were calculated using the unstratified log-rank test.^b p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariates and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-rfs-subgrp-step3.sas

Output: t14-04-002-rfs-subgrp-step3.rtf (Date generated: 29MAY2025:04:42) Source data: adampa.adsl, adampa.adtte

**Table 14-4.2. Relapse-free Survival - Subgroup Analysis
(Step 3 Analysis Set)**

	SOC Chemotherapy + Blinatumomab (N = 152)		SOC Chemotherapy (N = 134)		Hazard Ratio (95% CI)	p-value ^a	Interaction p-value ^b
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Sex							0.5892
Male	19/69 (27.5)	NE (NE, NE)	29/70 (41.4)	5.75 (2.53, NE)	0.55 (0.31, 0.98)	0.0395	
Female	17/83 (20.5)	NE (NE, NE)	27/64 (42.2)	NE (2.99, NE)	0.45 (0.24, 0.82)	0.0079	
Region							0.5457
USA	35/140 (25.0)	NE (NE, NE)	52/120 (43.3)	5.75 (3.17, NE)	0.50 (0.33, 0.77)	0.0013	
Rest of the world	1/12 (8.3)	NE (NE, NE)	4/14 (28.6)	NE (1.50, NE)	0.25 (0.03, 2.26)	0.1830	
Race							0.4831
Caucasian	29/117 (24.8)	NE (NE, NE)	46/110 (41.8)	NE (2.53, NE)	0.49 (0.31, 0.79)	0.0025	
Others	4/19 (21.1)	NE (NE, NE)	2/8 (25.0)	NE (0.51, NE)	0.91 (0.17, 4.98)	0.9158	

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Step 3 analysis set includes all Step 3 randomized or registered subjects.

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Relapse-free survival (RFS) is calculated from time of Step 3 randomization until relapse or death due to any cause.

^a 2-sided p-values were calculated using the unstratified log-rank test.

^b p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariates and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-rfs-subgrp-step3.sas

Output: t14-04-002-rfs-subgrp-step3.rtf (Date generated: 29MAY2025:04:42) Source data: adampa.adsl, adampa.adtte

**Table 14-4.2. Relapse-free Survival - Subgroup Analysis
(Step 3 Analysis Set)**

	SOC Chemotherapy + Blinatumomab (N = 152)		SOC Chemotherapy (N = 134)		Hazard Ratio (95% CI)	p-value ^a	Interaction p-value ^b
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Ethnicity							0.7424
Hispanic or Latino	5/21 (23.8)	NE (3.00, NE)	7/15 (46.7)	NE (0.30, NE)	0.45 (0.14, 1.44)	0.1681	
Not Hispanic or Latino	30/125 (24.0)	NE (NE, NE)	44/111 (39.6)	NE (3.73, NE)	0.53 (0.33, 0.85)	0.0067	
CD20 status							0.9578
Positive	20/76 (26.3)	NE (NE, NE)	35/72 (48.6)	4.16 (2.34, NE)	0.49 (0.28, 0.85)	0.0098	
Negative	15/75 (20.0)	NE (NE, NE)	20/60 (33.3)	NE (5.14, NE)	0.52 (0.26, 1.01)	0.0487	
Rituximab use							0.4442
Yes	12/45 (26.7)	NE (NE, NE)	17/40 (42.5)	NE (2.53, NE)	0.63 (0.30, 1.31)	0.2106	
No	24/107 (22.4)	NE (NE, NE)	39/94 (41.5)	NE (3.73, NE)	0.45 (0.27, 0.74)	0.0014	

Page 3 of 4

Step 3 analysis set includes all Step 3 randomized or registered subjects.

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Relapse-free survival (RFS) is calculated from time of Step 3 randomization until relapse or death due to any cause.

^a 2-sided p-values were calculated using the unstratified log-rank test.^b p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariates and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-rfs-subgrp-step3.sas

Output: t14-04-002-rfs-subgrp-step3.rtf (Date generated: 29MAY2025:04:42) Source data: adampa.adsl, adampa.adtte

**Table 14-4.2. Relapse-free Survival - Subgroup Analysis
(Step 3 Analysis Set)**

	SOC Chemotherapy + Blinatumomab (N = 152)		SOC Chemotherapy (N = 134)		Hazard Ratio (95% CI)	p-value ^a	Interaction p-value ^b
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Allogeneic SCT							0.8964
Yes	11/48 (22.9)	NE (NE, NE)	18/44 (40.9)	NE (1.52, NE)	0.46 (0.22, 0.97)	0.0372	
No	25/104 (24.0)	NE (NE, NE)	38/90 (42.2)	5.75 (2.99, NE)	0.51 (0.31, 0.84)	0.0071	
MRD status							0.2409
Positive	11/40 (27.5)	NE (NE, NE)	13/22 (59.1)	0.60 (0.18, NE)	0.34 (0.15, 0.78)	0.0071	
Negative	25/112 (22.3)	NE (NE, NE)	43/112 (38.4)	NE (5.14, NE)	0.51 (0.31, 0.84)	0.0072	
All subjects	36/152 (23.7)	NE (NE, NE)	56/134 (41.8)	NE (3.73, NE)	0.49 (0.32, 0.75)	0.0008	

Page 4 of 4

Step 3 analysis set includes all Step 3 randomized or registered subjects.

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Relapse-free survival (RFS) is calculated from time of Step 3 randomization until relapse or death due to any cause.

^a 2-sided p-values were calculated using the unstratified log-rank test.

^b p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariates and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-rfs-subgrp-step3.sas

Output: t14-04-002-rfs-subgrp-step3.rtf (Date generated: 29MAY2025:04:42) Source data: adampa.adsl, adampa.adtte

Anhang 4-G3.3: Subgruppenanalysen zu Sicherheitsrelevanten Endpunkten

Anhang 4-G3.3.1: Subgruppenanalysen zu Gesamtraten UE

Table 14-6.2.1. Summary of Any Treatment-emergent Adverse Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 1: Age group: <55 years	91	72		0.3559
Number of subjects reporting any treatment-emergent adverse events - n (%)	89 (97.8)	69 (95.8)	2.0	
Unstratified odds ratio ^a (95% CI) p-value			1.93 (0.31, 11.90) 0.4764	
Unstratified risk ratio ^a (95% CI) p-value			1.02 (0.96, 1.08) 0.4857	
Absolute risk reduction (95% CI) p-value			0.02 (-0.04, 0.07) 0.4838	

Page 1 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence Interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-001-ae-sum-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.1. Summary of Any Treatment-emergent Adverse Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 years	56	56		
Number of subjects reporting any treatment-emergent adverse events - n (%)	55 (98.2)	56 (100.0)	-1.8	
Unstratified odds ratio ^a (95% CI) p-value			0.33 (0.01, 8.21) 0.4971	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.94, 1.03) 0.4766	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.07, 0.03) 0.4746	

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence Interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-001-ae-sum-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.2. Summary of Any Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 2: Age group: ≥18 - <35 years	18	18		0.5256
Number of subjects reporting any treatment-emergent adverse events - n (%)	17 (94.4)	18 (100.0)	-5.6	
Unstratified odds ratio ^a (95% CI) p-value			0.32 (0.01, 8.27) 0.4887	
Unstratified risk ratio ^a (95% CI) p-value			0.95 (0.81, 1.10) 0.4707	
Absolute risk reduction (95% CI) p-value			-0.05 (-0.19, 0.09) 0.4644	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-002-ae-sum-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.2. Summary of Any Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥35 - <55 years	73	54		
Number of subjects reporting any treatment-emergent adverse events - n (%)	72 (98.6)	51 (94.4)	4.2	
Unstratified odds ratio ^a (95% CI) p-value			4.24 (0.43, 41.88) 0.2170	
Unstratified risk ratio ^a (95% CI) p-value			1.04 (0.97, 1.12) 0.2254	
Absolute risk reduction (95% CI) p-value			0.04 (-0.02, 0.11) 0.2184	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-002-ae-sum-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.2. Summary of Any Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 - <65 years	44	36		
Number of subjects reporting any treatment-emergent adverse events - n (%)	43 (97.7)	36 (100.0)	-2.3	
Unstratified odds ratio ^a (95% CI) p-value			0.40 (0.02, 10.05) 0.5755	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.92, 1.05) 0.5472	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.08, 0.04) 0.5458	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-002-ae-sum-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.2. Summary of Any Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥65 years	12	20		
Number of subjects reporting any treatment-emergent adverse events - n (%)	12 (100.0)	20 (100.0)	0.0	
Unstratified odds ratio ^a (95% CI) p-value			0.61 (0.01, 32.71) 0.8076	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.87, 1.12) 0.8163	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.14, 0.11) 0.8157	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-002-ae-sum-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.3. Summary of Any Treatment-emergent Adverse Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex:				0.4866
Sex: Male	68	65		
Number of subjects reporting any treatment-emergent adverse events - n (%)	66 (97.1)	62 (95.4)	1.7	
Unstratified odds ratio ^a (95% CI) p-value			1.60 (0.26, 9.88) 0.6148	
Unstratified risk ratio ^a (95% CI) p-value			1.02 (0.95, 1.09) 0.6140	
Absolute risk reduction (95% CI) p-value			0.02 (-0.05, 0.08) 0.6132	

Page 1 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem Cell Transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-003-ae-sum-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.3. Summary of Any Treatment-emergent Adverse Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex: Female	79	63		
Number of subjects reporting any treatment-emergent adverse events - n (%)	78 (98.7)	63 (100.0)	-1.3	
Unstratified odds ratio ^a (95% CI) p-value			0.41 (0.02, 10.29) 0.5892	
Unstratified risk ratio ^a (95% CI) p-value			0.99 (0.95, 1.03) 0.5601	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.05, 0.03) 0.5594	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem Cell Transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-003-ae-sum-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.4. Summary of Any Treatment-emergent Adverse Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region:				0.4955
Region: USA	135	115		
Number of subjects reporting any treatment-emergent adverse events - n (%)	132 (97.8)	113 (98.3)	-0.5	
Unstratified odds ratio ^a (95% CI) p-value			0.78 (0.13, 4.74) 0.7862	
Unstratified risk ratio ^a (95% CI) p-value			1.00 (0.96, 1.03) 0.7837	
Absolute risk reduction (95% CI) p-value			-0.005 (-0.04, 0.03) 0.7836	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-004-ae-sum-by-region-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.4. Summary of Any Treatment-emergent Adverse Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region: Rest of the world	12	13		
Number of subjects reporting any treatment-emergent adverse events - n (%)	12 (100.0)	12 (92.3)	7.7	
Unstratified odds ratio ^a (95% CI) p-value			3.00 (0.11, 80.94) 0.5135	
Unstratified risk ratio ^a (95% CI) p-value			1.08 (0.87, 1.33) 0.4923	
Absolute risk reduction (95% CI) p-value			0.07 (-0.12, 0.26) 0.4851	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-004-ae-sum-by-region-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.5. Summary of Any Treatment-emergent Adverse Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race:				0.7357
Race: Caucasian	114	104		
Number of subjects reporting any treatment-emergent adverse events - n (%)	111 (97.4)	101 (97.1)	0.3	
Unstratified odds ratio ^a (95% CI) p-value			1.10 (0.22, 5.57) 0.9092	
Unstratified risk ratio ^a (95% CI) p-value			1.00 (0.96, 1.05) 0.9094	
Absolute risk reduction (95% CI) p-value			0.003 (-0.04, 0.05) 0.9094	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-005-ae-sum-by-race-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.5. Summary of Any Treatment-emergent Adverse Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race: Others	19	8		
Number of subjects reporting any treatment-emergent adverse events - n (%)	19 (100.0)	8 (100.0)	0.0	
Unstratified odds ratio ^a (95% CI) p-value			2.29 (0.04, 125.49) 0.6842	
Unstratified risk ratio ^a (95% CI) p-value			1.03 (0.87, 1.23) 0.7188	
Absolute risk reduction (95% CI) p-value			0.03 (-0.13, 0.20) 0.7159	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-005-ae-sum-by-race-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.6. Summary of Any Treatment-emergent Adverse Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity:				0.8494
Ethnicity: Hispanic or Latino	19	11		
Number of subjects reporting any treatment-emergent adverse events - n (%)	19 (100.0)	11 (100.0)	0.0	
Unstratified odds ratio ^a (95% CI) p-value			1.70 (0.03, 91.39) 0.7952	
Unstratified risk ratio ^a (95% CI) p-value			1.02 (0.89, 1.17) 0.8055	
Absolute risk reduction (95% CI) p-value			0.02 (-0.12, 0.15) 0.8048	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-006-ae-sum-by-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.6. Summary of Any Treatment-emergent Adverse Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity: Not Hispanic or Latino	122	109		
Number of subjects reporting any treatment-emergent adverse events - n (%)	119 (97.5)	106 (97.2)	0.3	
Unstratified odds ratio ^a (95% CI) p-value			1.12 (0.22, 5.68) 0.8888	
Unstratified risk ratio ^a (95% CI) p-value			1.00 (0.96, 1.05) 0.8891	
Absolute risk reduction (95% CI) p-value			0.003 (-0.04, 0.04) 0.8891	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-006-ae-sum-by-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

**Table 14-6.2.7. Summary of Any Treatment-emergent Adverse Events by CD20 Status
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status:				0.4870
CD20 status: Positive	74	70		
Number of subjects reporting any treatment-emergent adverse events - n (%)	73 (98.6)	68 (97.1)	1.5	
Unstratified odds ratio ^a (95% CI) p-value			2.15 (0.19, 24.22) 0.5365	
Unstratified risk ratio ^a (95% CI) p-value			1.02 (0.97, 1.07) 0.5318	
Absolute risk reduction (95% CI) p-value			0.02 (-0.03, 0.06) 0.5306	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-007-ae-sum-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

**Table 14-6.2.7. Summary of Any Treatment-emergent Adverse Events by CD20 Status
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status: Negative	72	56		
Number of subjects reporting any treatment-emergent adverse events - n (%)	70 (97.2)	55 (98.2)	-1.0	
Unstratified odds ratio ^a (95% CI) p-value			0.64 (0.06, 7.20) 0.7150	
Unstratified risk ratio ^a (95% CI) p-value			0.99 (0.94, 1.04) 0.7055	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.06, 0.04) 0.7053	

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-007-ae-sum-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.8. Summary of Any Treatment-emergent Adverse Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use:				0.1889
Rituximab use: Yes	43	40		
Number of subjects reporting any treatment-emergent adverse events - n (%)	43 (100.0)	38 (95.0)	5.0	
Unstratified odds ratio ^a (95% CI) p-value			5.65 (0.26, 121.35) 0.2685	
Unstratified risk ratio ^a (95% CI) p-value			1.05 (0.97, 1.15) 0.2307	
Absolute risk reduction (95% CI) p-value			0.05 (-0.03, 0.13) 0.2222	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-008-ae-sum-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.8. Summary of Any Treatment-emergent Adverse Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use: No	104	88		
Number of subjects reporting any treatment-emergent adverse events - n (%)	101 (97.1)	87 (98.9)	-1.7	
Unstratified odds ratio ^a (95% CI) p-value			0.39 (0.04, 3.79) 0.4147	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.94, 1.02) 0.3818	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.06, 0.02) 0.3803	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-008-ae-sum-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.9. Summary of Any Treatment-emergent Adverse Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT:				0.9818
Allogeneic SCT: Yes	47	40		
Number of subjects reporting any treatment-emergent adverse events - n (%)	45 (95.7)	38 (95.0)	0.7	
Unstratified odds ratio ^a (95% CI) p-value			1.18 (0.16, 8.81) 0.8689	
Unstratified risk ratio ^a (95% CI) p-value			1.01 (0.92, 1.11) 0.8696	
Absolute risk reduction (95% CI) p-value			0.01 (-0.08, 0.10) 0.8695	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-009-ae-sum-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

Table 14-6.2.9. Summary of Any Treatment-emergent Adverse Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT: No	100	88		
Number of subjects reporting any treatment-emergent adverse events - n (%)	99 (99.0)	87 (98.9)	0.1	
Unstratified odds ratio ^a (95% CI) p-value			1.14 (0.07, 18.47) 0.9276	
Unstratified risk ratio ^a (95% CI) p-value			1.00 (0.97, 1.03) 0.9278	
Absolute risk reduction (95% CI) p-value			0.001 (-0.03, 0.03) 0.9278	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-009-ae-sum-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:43) Source data: adampa.adsl, adam.adae

**Table 14-6.2.10. Summary of Any Treatment-emergent Adverse Events by MRD Status
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status:				0.3625
MRD status: Positive	36	16		
Number of subjects reporting any treatment-emergent adverse events - n (%)	33 (91.7)	15 (93.8)	-2.1	
Unstratified odds ratio ^a (95% CI) p-value			0.73 (0.07, 7.64) 0.7955	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.83, 1.15) 0.7835	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.17, 0.13) 0.7841	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-010-ae-sum-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:44) Source data: adampa.adsl, adam.adae

**Table 14-6.2.10. Summary of Any Treatment-emergent Adverse Events by MRD Status
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status: Negative	111	112		
Number of subjects reporting any treatment-emergent adverse events - n (%)	111 (100.0)	110 (98.2)	1.8	
Unstratified odds ratio ^a (95% CI) p-value			5.05 (0.24, 106.29) 0.2980	
Unstratified risk ratio ^a (95% CI) p-value			1.02 (0.99, 1.05) 0.2482	
Absolute risk reduction (95% CI) p-value			0.02 (-0.01, 0.05) 0.2454	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-002-010-ae-sum-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:44) Source data: adampa.adsl, adam.adae

Table 14-6.3.1. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 1:				0.2923
Age group: <55 years	91	72		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	86 (94.5)	69 (95.8)	-1.3	
Unstratified odds ratio ^a (95% CI) p-value			0.75 (0.17, 3.24) 0.6977	
Unstratified risk ratio ^a (95% CI) p-value			0.99 (0.92, 1.06) 0.6923	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.08, 0.05) 0.6922	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-001-ae-sum-sev-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.1. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥ 55 years	56	56		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	53 (94.6)	56 (100.0)	-5.4	
Unstratified odds ratio ^a (95% CI) p-value			0.14 (0.01, 2.68) 0.1893	
Unstratified risk ratio ^a (95% CI) p-value			0.95 (0.88, 1.02) 0.1307	
Absolute risk reduction (95% CI) p-value			-0.05 (-0.12, 0.01) 0.1229	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-001-ae-sum-sev-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.2. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 2:				0.2790
Age group: ≥ 18 - <35 years	18	18		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	15 (83.3)	18 (100.0)	-16.7	
Unstratified odds ratio ^a			0.12	
(95% CI)			(0.01, 2.50)	
p-value			0.1710	
Unstratified risk ratio ^a			0.84	
(95% CI)			(0.67, 1.05)	
p-value			0.1251	
Absolute risk reduction			-0.16	
(95% CI)			(-0.35, 0.03)	
p-value			0.1008	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-002-ae-sum-sev-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.2. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥ 35 - <55 years	73	54		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	71 (97.3)	51 (94.4)	2.8	
Unstratified odds ratio ^a (95% CI) p-value			2.09 (0.34, 12.95) 0.4291	
Unstratified risk ratio ^a (95% CI) p-value			1.03 (0.96, 1.11) 0.4443	
Absolute risk reduction (95% CI) p-value			0.03 (-0.04, 0.10) 0.4412	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-002-ae-sum-sev-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.2. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥ 55 - <65 years	44	36		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	42 (95.5)	36 (100.0)	-4.5	
Unstratified odds ratio ^a (95% CI) p-value			0.23 (0.01, 5.01) 0.3519	
Unstratified risk ratio ^a (95% CI) p-value			0.96 (0.88, 1.04) 0.2876	
Absolute risk reduction (95% CI) p-value			-0.04 (-0.12, 0.03) 0.2819	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-002-ae-sum-sev-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.2. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥ 65 years	12	20		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	11 (91.7)	20 (100.0)	-8.3	
Unstratified odds ratio ^a (95% CI) p-value			0.19 (0.01, 4.97) 0.3165	
Unstratified risk ratio ^a (95% CI) p-value			0.91 (0.74, 1.12) 0.3519	
Absolute risk reduction (95% CI) p-value			-0.09 (-0.28, 0.09) 0.3333	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-002-ae-sum-sev-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.3. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex:				0.4301
Sex: Male	68	65		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	63 (92.6)	62 (95.4)	-2.7	
Unstratified odds ratio ^a			0.61	
(95% CI)			(0.14, 2.66)	
p-value			0.5105	
Unstratified risk ratio ^a			0.97	
(95% CI)			(0.89, 1.06)	
p-value			0.5054	
Absolute risk reduction			-0.03	
(95% CI)			(-0.11, 0.05)	
p-value			0.5041	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-003-ae-sum-sev-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.3. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex: Female	79	63		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	76 (96.2)	63 (100.0)	-3.8	
Unstratified odds ratio ^a (95% CI) p-value			0.17 (0.01, 3.39) 0.2474	
Unstratified risk ratio ^a (95% CI) p-value			0.96 (0.92, 1.01) 0.1617	
Absolute risk reduction (95% CI) p-value			-0.04 (-0.09, 0.01) 0.1568	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-ae-sum-sev-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.4. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region:				0.2288
Region: USA	135	115		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	127 (94.1)	113 (98.3)	-4.2	
Unstratified odds ratio ^a (95% CI) p-value			0.28 (0.06, 1.35) 0.1130	
Unstratified risk ratio ^a (95% CI) p-value			0.96 (0.91, 1.01) 0.0805	
Absolute risk reduction (95% CI) p-value			-0.04 (-0.09, 0.00) 0.0773	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-004-ae-sum-sev-by-region-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.4. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region: Rest of the world	12	13		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	12 (100.0)	12 (92.3)	7.7	
Unstratified odds ratio ^a (95% CI) p-value			3.00 (0.11, 80.94) 0.5135	
Unstratified risk ratio ^a (95% CI) p-value			1.08 (0.87, 1.33) 0.4923	
Absolute risk reduction (95% CI) p-value			0.07 (-0.12, 0.26) 0.4851	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-004-ae-sum-sev-by-region-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.5. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race:				0.5204
Race: Caucasian	114	104		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	108 (94.7)	101 (97.1)	-2.4	
Unstratified odds ratio ^a (95% CI) p-value			0.53 (0.13, 2.19) 0.3848	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.92, 1.03) 0.3724	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.08, 0.03) 0.3709	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-005-ae-sum-sev-by-race-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

**Table 14-6.3.5. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Race
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race: Others	19	8		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	19 (100.0)	8 (100.0)	0.0	
Unstratified odds ratio ^a (95% CI) p-value			2.29 (0.04, 125.49) 0.6842	
Unstratified risk ratio ^a (95% CI) p-value			1.03 (0.87, 1.23) 0.7188	
Absolute risk reduction (95% CI) p-value			0.03 (-0.13, 0.20) 0.7159	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-005-ae-sum-sev-by-race-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.3.6. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity:				0.6219
Ethnicity: Hispanic or Latino	19	11		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	19 (100.0)	11 (100.0)	0.0	
Unstratified odds ratio ^a (95% CI) p-value			1.70 (0.03, 91.39) 0.7952	
Unstratified risk ratio ^a (95% CI) p-value			1.02 (0.89, 1.17) 0.8055	
Absolute risk reduction (95% CI) p-value			0.02 (-0.12, 0.15) 0.8048	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-006-ae-sum-sev-by-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.3.6. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity: Not Hispanic or Latino	122	109		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	116 (95.1)	106 (97.2)	-2.2	
Unstratified odds ratio ^a (95% CI) p-value			0.55 (0.13, 2.24) 0.4022	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.93, 1.03) 0.3890	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.07, 0.03) 0.3878	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-006-ae-sum-sev-by-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.3.7. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status:				0.4684
CD20 status: Positive	74	70		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	71 (95.9)	68 (97.1)	-1.2	
Unstratified odds ratio ^a (95% CI) p-value			0.70 (0.11, 4.30) 0.6964	
Unstratified risk ratio ^a (95% CI) p-value			0.99 (0.93, 1.05) 0.6937	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.07, 0.05) 0.6935	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-007-ae-sum-sev-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.3.7. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status: Negative	72	56		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	67 (93.1)	55 (98.2)	-5.2	
Unstratified odds ratio ^a (95% CI) p-value			0.24 (0.03, 2.15) 0.2035	
Unstratified risk ratio ^a (95% CI) p-value			0.95 (0.88, 1.02) 0.1436	
Absolute risk reduction (95% CI) p-value			-0.05 (-0.12, 0.02) 0.1382	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-007-ae-sum-sev-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.3.8. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use:				0.1104
Rituximab use: Yes	43	40		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	42 (97.7)	38 (95.0)	2.7	
Unstratified odds ratio ^a (95% CI) p-value			2.21 (0.19, 25.37) 0.5241	
Unstratified risk ratio ^a (95% CI) p-value			1.03 (0.94, 1.12) 0.5208	
Absolute risk reduction (95% CI) p-value			0.03 (-0.05, 0.11) 0.5185	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-008-ae-sum-sev-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.3.8. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use: No	104	88		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	97 (93.3)	87 (98.9)	-5.6	
Unstratified odds ratio ^a (95% CI) p-value			0.16 (0.02, 1.32) 0.0887	
Unstratified risk ratio ^a (95% CI) p-value			0.94 (0.89, 1.00) 0.0425	
Absolute risk reduction (95% CI) p-value			-0.06 (-0.11, -0.00) 0.0386	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-008-ae-sum-sev-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.3.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT:				0.6177
Allogeneic SCT: Yes	47	40		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	43 (91.5)	38 (95.0)	-3.5	
Unstratified odds ratio ^a (95% CI) p-value			0.57 (0.10, 3.26) 0.5242	
Unstratified risk ratio ^a (95% CI) p-value			0.96 (0.86, 1.08) 0.5118	
Absolute risk reduction (95% CI) p-value			-0.04 (-0.14, 0.07) 0.5104	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-009-ae-sum-sev-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.3.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT: No	100	88		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	96 (96.0)	87 (98.9)	-2.9	
Unstratified odds ratio ^a (95% CI) p-value			0.28 (0.03, 2.52) 0.2535	
Unstratified risk ratio ^a (95% CI) p-value			0.97 (0.93, 1.02) 0.2090	
Absolute risk reduction (95% CI) p-value			-0.03 (-0.07, 0.02) 0.2055	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-009-ae-sum-sev-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.3.10. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status:				0.7538
MRD status: Positive	36	16		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	31 (86.1)	15 (93.8)	-7.6	
Unstratified odds ratio ^a (95% CI) p-value			0.41 (0.04, 3.86) 0.4382	
Unstratified risk ratio ^a (95% CI) p-value			0.92 (0.77, 1.10) 0.3607	
Absolute risk reduction (95% CI) p-value			-0.08 (-0.24, 0.09) 0.3607	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an un-stratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-010-ae-sum-sev-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.3.10. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status: Negative	111	112		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events - n (%)	108 (97.3)	110 (98.2)	-0.9	
Unstratified odds ratio ^a (95% CI) p-value			0.65 (0.11, 3.99) 0.6461	
Unstratified risk ratio ^a (95% CI) p-value			0.99 (0.95, 1.03) 0.6442	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.05, 0.03) 0.6439	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an un-stratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-003-010-ae-sum-sev-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.4.1. Summary of Expedited Treatment-emergent Adverse Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 1:				0.9599
Age group: <55 years	91	72		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	52 (57.1)	21 (29.2)	28.0	
Unstratified odds ratio ^a			3.24	
(95% CI)			(1.68, 6.24)	
p-value			0.0004	
Unstratified risk ratio ^a			1.96	
(95% CI)			(1.31, 2.93)	
p-value			0.0010	
Absolute risk reduction			0.28	
(95% CI)			(0.13, 0.43)	
p-value			0.0002	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-001-ae-sum-exp-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:45) Source data: adampa.adsl, adam.adae

Table 14-6.4.1. Summary of Expedited Treatment-emergent Adverse Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 years	56	56		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	30 (53.6)	15 (26.8)	26.8	
Unstratified odds ratio ^a (95% CI) p-value			3.15 (1.43, 6.96) 0.0044	
Unstratified risk ratio ^a (95% CI) p-value			2.00 (1.22, 3.29) 0.0063	
Absolute risk reduction (95% CI) p-value			0.27 (0.09, 0.44) 0.0027	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-001-ae-sum-exp-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:45) Source data: adampa.adsl, adam.adae

Table 14-6.4.2. Summary of Expedited Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 2: Age group: ≥18 - <35 years	18	18		0.9514
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	9 (50.0)	5 (27.8)	22.2	
Unstratified odds ratio ^a (95% CI) p-value			2.60 (0.65, 10.38) 0.1762	
Unstratified risk ratio ^a (95% CI) p-value			1.80 (0.75, 4.32) 0.1887	
Absolute risk reduction (95% CI) p-value			0.22 (-0.09, 0.53) 0.1602	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-002-ae-sum-exp-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.2. Summary of Expedited Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥35 - <55 years	73	54		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	43 (58.9)	16 (29.6)	29.3	
Unstratified odds ratio ^a (95% CI) p-value			3.40 (1.61, 7.19) 0.0013	
Unstratified risk ratio ^a (95% CI) p-value			1.99 (1.26, 3.13) 0.0030	
Absolute risk reduction (95% CI) p-value			0.29 (0.13, 0.46) 0.0005	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-002-ae-sum-exp-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.2. Summary of Expedited Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 - <65 years	44	36		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	24 (54.5)	9 (25.0)	29.5	
Unstratified odds ratio ^a (95% CI) p-value			3.60 (1.38, 9.40) 0.0089	
Unstratified risk ratio ^a (95% CI) p-value			2.18 (1.17, 4.08) 0.0147	
Absolute risk reduction (95% CI) p-value			0.30 (0.09, 0.50) 0.0045	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-002-ae-sum-exp-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.2. Summary of Expedited Treatment-emergent Adverse Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥65 years	12	20		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	6 (50.0)	6 (30.0)	20.0	
Unstratified odds ratio ^a (95% CI) p-value			2.33 (0.53, 10.27) 0.2624	
Unstratified risk ratio ^a (95% CI) p-value			1.67 (0.69, 4.00) 0.2534	
Absolute risk reduction (95% CI) p-value			0.20 (-0.15, 0.55) 0.2585	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-002-ae-sum-exp-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.3. Summary of Expedited Treatment-emergent Adverse Events by Sex
(Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex:				0.6280
Sex: Male	68	65		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	37 (54.4)	16 (24.6)	29.8	
Unstratified odds ratio ^a			3.66	
(95% CI)			(1.75, 7.65)	
p-value			0.0006	
Unstratified risk ratio ^a			2.21	
(95% CI)			(1.37, 3.56)	
p-value			0.0011	
Absolute risk reduction			0.30	
(95% CI)			(0.14, 0.46)	
p-value			0.0002	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-003-ae-sum-exp-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.3. Summary of Expedited Treatment-emergent Adverse Events by Sex
(Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex: Female	79	63		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	45 (57.0)	20 (31.7)	25.2	
Unstratified odds ratio ^a (95% CI) p-value			2.85 (1.42, 5.69) 0.0031	
Unstratified risk ratio ^a (95% CI) p-value			1.79 (1.19, 2.70) 0.0052	
Absolute risk reduction (95% CI) p-value			0.25 (0.09, 0.41) 0.0018	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-003-ae-sum-exp-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.4. Summary of Expedited Treatment-emergent Adverse Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region:				0.3435
Region: USA	135	115		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	75 (55.6)	34 (29.6)	26.0	
Unstratified odds ratio ^a (95% CI) p-value			2.98 (1.76, 5.03) <0.0001	
Unstratified risk ratio ^a (95% CI) p-value			1.88 (1.36, 2.59) 0.0001	
Absolute risk reduction (95% CI) p-value			0.26 (0.14, 0.38) <0.0001	

Page 1 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-004-ae-sum-exp-by-region-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.4. Summary of Expedited Treatment-emergent Adverse Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region: Rest of the world	12	13		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	7 (58.3)	2 (15.4)	42.9	
Unstratified odds ratio ^a (95% CI) p-value			7.70 (1.16, 51.16) 0.0347	
Unstratified risk ratio ^a (95% CI) p-value			3.79 (0.97, 14.80) 0.0550	
Absolute risk reduction (95% CI) p-value			0.43 (0.09, 0.77) 0.0136	

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-004-ae-sum-exp-by-region-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

**Table 14-6.4.5. Summary of Expedited Treatment-emergent Adverse Events by Race
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race:				0.1143
Race: Caucasian	114	104		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	61 (53.5)	30 (28.8)	24.7	
Unstratified odds ratio ^a (95% CI) p-value			2.84 (1.62, 4.98) 0.0003	
Unstratified risk ratio ^a (95% CI) p-value			1.85 (1.31, 2.62) 0.0005	
Absolute risk reduction (95% CI) p-value			0.25 (0.12, 0.37) 0.0001	

Page 1 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-005-ae-sum-exp-by-race-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

**Table 14-6.4.5. Summary of Expedited Treatment-emergent Adverse Events by Race
(Step 3 Safety Analysis Set)**

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race: Others	19	8		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	14 (73.7)	1 (12.5)	61.2	
Unstratified odds ratio ^a (95% CI) p-value			19.60 (1.91, 201.62) 0.0123	
Unstratified risk ratio ^a (95% CI) p-value			5.89 (0.92, 37.60) 0.0606	
Absolute risk reduction (95% CI) p-value			0.61 (0.31, 0.91) <0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-005-ae-sum-exp-by-race-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.6. Summary of Expedited Treatment-emergent Adverse Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity:				0.3792
Ethnicity: Hispanic or Latino	19	11		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	10 (52.6)	4 (36.4)	16.3	
Unstratified odds ratio ^a			1.94	
(95% CI)			(0.42, 8.92)	
p-value			0.3922	
Unstratified risk ratio ^a			1.45	
(95% CI)			(0.59, 3.53)	
p-value			0.4158	
Absolute risk reduction			0.16	
(95% CI)			(-0.20, 0.52)	
p-value			0.3787	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-006-ae-sum-exp-by-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.6. Summary of Expedited Treatment-emergent Adverse Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity: Not Hispanic or Latino	122	109		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	71 (58.2)	28 (25.7)	32.5	
Unstratified odds ratio ^a (95% CI) p-value			4.03 (2.30, 7.05) <0.0001	
Unstratified risk ratio ^a (95% CI) p-value			2.27 (1.59, 3.22) <0.0001	
Absolute risk reduction (95% CI) p-value			0.33 (0.21, 0.45) <0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

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Output: t14-06-004-006-ae-sum-exp-by-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.7. Summary of Expedited Treatment-emergent Adverse Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status:				0.2351
CD20 status: Positive	74	70		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	48 (64.9)	21 (30.0)	34.9	
Unstratified odds ratio ^a			4.31	
(95% CI)			(2.14, 8.67)	
p-value			<0.0001	
Unstratified risk ratio ^a			2.16	
(95% CI)			(1.46, 3.21)	
p-value			0.0001	
Absolute risk reduction			0.35	
(95% CI)			(0.20, 0.50)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-007-ae-sum-exp-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.7. Summary of Expedited Treatment-emergent Adverse Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status: Negative	72	56		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	33 (45.8)	15 (26.8)	19.0	
Unstratified odds ratio ^a (95% CI) p-value			2.31 (1.09, 4.90) 0.0288	
Unstratified risk ratio ^a (95% CI) p-value			1.71 (1.04, 2.82) 0.0354	
Absolute risk reduction (95% CI) p-value			0.19 (0.03, 0.35) 0.0223	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-007-ae-sum-exp-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.8. Summary of Expedited Treatment-emergent Adverse Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use:				0.7080
Rituximab use: Yes	43	40		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	29 (67.4)	14 (35.0)	32.4	
Unstratified odds ratio ^a			3.85	
(95% CI)			(1.55, 9.56)	
p-value			0.0037	
Unstratified risk ratio ^a			1.93	
(95% CI)			(1.20, 3.08)	
p-value			0.0063	
Absolute risk reduction			0.32	
(95% CI)			(0.12, 0.53)	
p-value			0.0018	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-004-008-ae-sum-exp-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.8. Summary of Expedited Treatment-emergent Adverse Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use: No	104	88		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	53 (51.0)	22 (25.0)	26.0	
Unstratified odds ratio ^a (95% CI) p-value			3.12 (1.68, 5.78) 0.0003	
Unstratified risk ratio ^a (95% CI) p-value			2.04 (1.36, 3.07) 0.0006	
Absolute risk reduction (95% CI) p-value			0.26 (0.13, 0.39) 0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.4.9. Summary of Expedited Treatment-emergent Adverse Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT:				0.3843
Allogeneic SCT: Yes	47	40		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	19 (40.4)	9 (22.5)	17.9	
Unstratified odds ratio ^a			2.34	
(95% CI)			(0.91, 6.00)	
p-value			0.0778	
Unstratified risk ratio ^a			1.80	
(95% CI)			(0.92, 3.52)	
p-value			0.0873	
Absolute risk reduction			0.18	
(95% CI)			(-0.01, 0.37)	
p-value			0.0657	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence Interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.4.9. Summary of Expedited Treatment-emergent Adverse Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT: No	100	88		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	63 (63.0)	27 (30.7)	32.3	
Unstratified odds ratio ^a (95% CI) p-value			3.85 (2.09, 7.07) <0.0001	
Unstratified risk ratio ^a (95% CI) p-value			2.05 (1.45, 2.91) <0.0001	
Absolute risk reduction (95% CI) p-value			0.32 (0.19, 0.46) <0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence Interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Output: t14-06-004-009-ae-sum-exp-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.10. Summary of Expedited Treatment-emergent Adverse Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status:				0.1833
MRD status: Positive	36	16		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	15 (41.7)	5 (31.3)	10.4	
Unstratified odds ratio ^a			1.57	
(95% CI)			(0.45, 5.47)	
p-value			0.4777	
Unstratified risk ratio ^a			1.33	
(95% CI)			(0.59, 3.04)	
p-value			0.4934	
Absolute risk reduction			0.10	
(95% CI)			(-0.17, 0.38)	
p-value			0.4634	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

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Output: t14-06-004-010-ae-sum-exp-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.4.10. Summary of Expedited Treatment-emergent Adverse Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status: Negative	111	112		
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	67 (60.4)	31 (27.7)	32.7	
Unstratified odds ratio ^a (95% CI) p-value			3.98 (2.27, 6.98) <0.0001	
Unstratified risk ratio ^a (95% CI) p-value			2.18 (1.56, 3.05) <0.0001	
Absolute risk reduction (95% CI) p-value			0.33 (0.20, 0.45) <0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.5.1. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 1:				0.3501
Age group: <55 years	91	72		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	6 (6.6)	3 (4.2)	2.4	
Unstratified odds ratio ^a (95% CI) p-value			1.62 (0.39, 6.73) 0.5041	
Unstratified risk ratio ^a (95% CI) p-value			1.58 (0.41, 6.11) 0.5055	
Absolute risk reduction (95% CI) p-value			0.02 (-0.04, 0.09) 0.4892	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

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Output: t14-06-005-001-ae-sum-by-trt-disc-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.1. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 years	56	56		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	8 (14.3)	2 (3.6)	10.7	
Unstratified odds ratio ^a (95% CI) p-value			4.50 (0.91, 22.23) 0.0650	
Unstratified risk ratio ^a (95% CI) p-value			4.00 (0.89, 18.01) 0.0709	
Absolute risk reduction (95% CI) p-value			0.11 (0.00, 0.21) 0.0429	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-001-ae-sum-by-trt-disc-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.2. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 2:				0.8117
Age group: ≥18 - <35 years	18	18		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	2 (11.1)	1 (5.6)	-	
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-002-ae-sum-by-trt-disc-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.2. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥35 - <55 years	73	54		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	4 (5.5)	2 (3.7)	-	
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-002-ae-sum-by-trt-disc-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.2. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 - <65 years	44	36		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	6 (13.6)	1 (2.8)	-	
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-002-ae-sum-by-trt-disc-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.2. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥65 years	12	20		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	2 (16.7)	1 (5.0)	-	
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-002-ae-sum-by-trt-disc-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.3. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex:				0.2925
Sex: Male	68	65		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	9 (13.2)	5 (7.7)	5.5	
Unstratified odds ratio ^a (95% CI) p-value			1.83 (0.58, 5.79) 0.3031	
Unstratified risk ratio ^a (95% CI) p-value			1.72 (0.61, 4.86) 0.3060	
Absolute risk reduction (95% CI) p-value			0.06 (-0.05, 0.16) 0.2932	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-003-ae-sum-by-trt-disc-sex-s3saf.rtf (Date generated: 29MAY2025:04:45) Source data: adampa.adsl, adam.adae

Table 14-6.5.3. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex: Female	79	63		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	5 (6.3)	0 (0.0)	6.3	
Unstratified odds ratio ^a (95% CI) p-value			9.37 (0.51, 172.63) 0.1323	
Unstratified risk ratio ^a (95% CI) p-value			8.80 (0.50, 156.19) 0.1384	
Absolute risk reduction (95% CI) p-value			0.06 (0.00, 0.12) 0.0447	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-003-ae-sum-by-trt-disc-sex-s3saf.rtf (Date generated: 29MAY2025:04:45) Source data: adampa.adsl, adam.adae

Table 14-6.5.4. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region:				0.7922
Region: USA	135	115		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	13 (9.6)	5 (4.3)	5.3	
Unstratified odds ratio ^a (95% CI) p-value			2.34 (0.81, 6.79) 0.1163	
Unstratified risk ratio ^a (95% CI) p-value			2.21 (0.81, 6.03) 0.1195	
Absolute risk reduction (95% CI) p-value			0.05 (-0.01, 0.11) 0.0959	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-004-ae-sum-by-trt-disc-region-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.4. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region: Rest of the world	12	13		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	1 (8.3)	0 (0.0)	8.3	
Unstratified odds ratio ^a (95% CI) p-value			3.52 (0.13, 95.05) 0.4541	
Unstratified risk ratio ^a (95% CI) p-value			3.23 (0.14, 72.46) 0.4599	
Absolute risk reduction (95% CI) p-value			0.08 (-0.12, 0.28) 0.4327	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-004-ae-sum-by-trt-disc-region-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.5. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race:				0.9547
Race: Caucasian	114	104		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	12 (10.5)	5 (4.8)	5.7	
Unstratified odds ratio ^a (95% CI) p-value			2.33 (0.79, 6.85) 0.1246	
Unstratified risk ratio ^a (95% CI) p-value			2.19 (0.80, 6.00) 0.1279	
Absolute risk reduction (95% CI) p-value			0.06 (-0.01, 0.13) 0.1080	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-005-ae-sum-by-trt-disc-race-s3saf.rtf (Date generated: 29MAY2025:04:45) Source data: adampa.adsl, adam.adae

Table 14-6.5.5. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race: Others	19	8		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	2 (10.5)	0 (0.0)	10.5	
Unstratified odds ratio ^a (95% CI) p-value			2.43 (0.10, 56.38) 0.5803	
Unstratified risk ratio ^a (95% CI) p-value			2.25 (0.12, 42.25) 0.5878	
Absolute risk reduction (95% CI) p-value			0.07 (-0.14, 0.28) 0.5136	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-005-ae-sum-by-trt-disc-race-s3saf.rtf (Date generated: 29MAY2025:04:45) Source data: adampa.adsl, adam.adae

Table 14-6.5.6. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity:				0.2743
Ethnicity: Hispanic or Latino	19	11		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	1 (5.3)	1 (9.1)	-3.8	
Unstratified odds ratio ^a (95% CI) p-value			0.56 (0.03, 9.87) 0.6889	
Unstratified risk ratio ^a (95% CI) p-value			0.58 (0.04, 8.36) 0.6883	
Absolute risk reduction (95% CI) p-value			-0.04 (-0.24, 0.16) 0.7038	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-006-ae-sum-by-trt-disc-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.6. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity: Not Hispanic or Latino	122	109		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	13 (10.7)	4 (3.7)	7.0	
Unstratified odds ratio ^a (95% CI) p-value			3.13 (0.99, 9.91) 0.0522	
Unstratified risk ratio ^a (95% CI) p-value			2.90 (0.98, 8.64) 0.0554	
Absolute risk reduction (95% CI) p-value			0.07 (0.00, 0.14) 0.0356	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-006-ae-sum-by-trt-disc-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.7. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status:				0.4016
CD20 status: Positive	74	70		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	10 (13.5)	5 (7.1)	6.4	
Unstratified odds ratio ^a (95% CI) p-value			2.03 (0.66, 6.27) 0.2181	
Unstratified risk ratio ^a (95% CI) p-value			1.89 (0.68, 5.26) 0.2217	
Absolute risk reduction (95% CI) p-value			0.06 (-0.03, 0.16) 0.2050	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an un-stratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-007-ae-sum-by-trt-disc-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.7. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status: Negative	72	56		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	4 (5.6)	0 (0.0)	5.6	
Unstratified odds ratio ^a (95% CI) p-value			7.42 (0.39, 140.78) 0.1819	
Unstratified risk ratio ^a (95% CI) p-value			7.03 (0.39, 127.86) 0.1877	
Absolute risk reduction (95% CI) p-value			0.05 (-0.01, 0.11) 0.0854	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an un-stratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-007-ae-sum-by-trt-disc-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.8. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use:				0.4547
Rituximab use: Yes	43	40		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	8 (18.6)	4 (10.0)	8.6	
Unstratified odds ratio ^a (95% CI) p-value			2.06 (0.57, 7.45) 0.2721	
Unstratified risk ratio ^a (95% CI) p-value			1.86 (0.61, 5.70) 0.2774	
Absolute risk reduction (95% CI) p-value			0.09 (-0.06, 0.23) 0.2574	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-008-ae-sum-by-trt-disc-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.8. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use: No	104	88		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	6 (5.8)	1 (1.1)	4.6	
Unstratified odds ratio ^a (95% CI) p-value			5.33 (0.63, 45.12) 0.1249	
Unstratified risk ratio ^a (95% CI) p-value			5.08 (0.62, 41.37) 0.1290	
Absolute risk reduction (95% CI) p-value			0.05 (-0.00, 0.10) 0.0693	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-008-ae-sum-by-trt-disc-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.9. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT:				0.0983
Allogeneic SCT: Yes	47	40		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	1 (2.1)	2 (5.0)	-2.9	
Unstratified odds ratio ^a (95% CI) p-value			0.41 (0.04, 4.73) 0.4773	
Unstratified risk ratio ^a (95% CI) p-value			0.43 (0.04, 4.52) 0.4785	
Absolute risk reduction (95% CI) p-value			-0.03 (-0.11, 0.05) 0.4769	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-009-ae-sum-by-trt-disc-asct-s3saf.rtf (Date generated: 29MAY2025:04:45) Source data: adampa.adsl, adam.adae

Table 14-6.5.9. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT: No	100	88		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	13 (13.0)	3 (3.4)	9.6	
Unstratified odds ratio ^a (95% CI) p-value			4.23 (1.16, 15.39) 0.0284	
Unstratified risk ratio ^a (95% CI) p-value			3.81 (1.12, 12.95) 0.0318	
Absolute risk reduction (95% CI) p-value			0.10 (0.02, 0.17) 0.0134	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-009-ae-sum-by-trt-disc-asct-s3saf.rtf (Date generated: 29MAY2025:04:45) Source data: adampa.adsl, adam.adae

Table 14-6.5.10. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status:				0.9868
MRD status: Positive	36	16		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	2 (5.6)	0 (0.0)	5.6	
Unstratified odds ratio ^a (95% CI) p-value			2.39 (0.11, 52.68) 0.5806	
Unstratified risk ratio ^a (95% CI) p-value			2.30 (0.12, 45.30) 0.5846	
Absolute risk reduction (95% CI) p-value			0.04 (-0.08, 0.15) 0.5118	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-010-ae-sum-by-trt-disc-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.5.10. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status: Negative	111	112		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	12 (10.8)	5 (4.5)	6.3	
Unstratified odds ratio ^a (95% CI) p-value			2.59 (0.88, 7.63) 0.0832	
Unstratified risk ratio ^a (95% CI) p-value			2.42 (0.88, 6.65) 0.0860	
Absolute risk reduction (95% CI) p-value			0.06 (-0.01, 0.13) 0.0726	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-trt-disc-by-subgrp-s3saf.sas

Output: t14-06-005-010-ae-sum-by-trt-disc-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:45)

Source data: adampa.adsl, adam.adae

Table 14-6.12.1. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 1:				0.3559
Age group: <55 years	91	72		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	89 (97.8)	69 (95.8)	2.0	
Unstratified odds ratio ^a (95% CI) p-value			1.93 (0.31, 11.90) 0.4764	
Unstratified risk ratio ^a (95% CI) p-value			1.02 (0.96, 1.08) 0.4857	
Absolute risk reduction (95% CI) p-value			0.02 (-0.04, 0.07) 0.4838	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-001-ae-sum-excl-dis-rel-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.1. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 years	56	56		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	55 (98.2)	56 (100.0)	-1.8	
Unstratified odds ratio ^a			0.33	
(95% CI)			(0.01, 8.21)	
p-value			0.4971	
Unstratified risk ratio ^a			0.98	
(95% CI)			(0.94, 1.03)	
p-value			0.4766	
Absolute risk reduction			-0.02	
(95% CI)			(-0.07, 0.03)	
p-value			0.4746	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-001-ae-sum-excl-dis-rel-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.2. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 2: Age group: ≥18 - <35 years	18	18		0.5256
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	17 (94.4)	18 (100.0)	-5.6	
Unstratified odds ratio ^a (95% CI) p-value			0.32 (0.01, 8.27) 0.4887	
Unstratified risk ratio ^a (95% CI) p-value			0.95 (0.81, 1.10) 0.4707	
Absolute risk reduction (95% CI) p-value			-0.05 (-0.19, 0.09) 0.4644	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-002-ae-sum-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.2. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥35 - <55 years	73	54		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	72 (98.6)	51 (94.4)	4.2	
Unstratified odds ratio ^a (95% CI) p-value			4.24 (0.43, 41.88) 0.2170	
Unstratified risk ratio ^a (95% CI) p-value			1.04 (0.97, 1.12) 0.2254	
Absolute risk reduction (95% CI) p-value			0.04 (-0.02, 0.11) 0.2184	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-002-ae-sum-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.2. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 - <65 years	44	36		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	43 (97.7)	36 (100.0)	-2.3	
Unstratified odds ratio ^a (95% CI) p-value			0.40 (0.02, 10.05) 0.5755	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.92, 1.05) 0.5472	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.08, 0.04) 0.5458	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-002-ae-sum-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.2. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥65 years	12	20		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	12 (100.0)	20 (100.0)	0.0	
Unstratified odds ratio ^a (95% CI) p-value			0.61 (0.01, 32.71) 0.8076	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.87, 1.12) 0.8163	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.14, 0.11) 0.8157	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-002-ae-sum-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.3. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex:				0.4866
Sex: Male	68	65		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	66 (97.1)	62 (95.4)	1.7	
Unstratified odds ratio ^a (95% CI) p-value			1.60 (0.26, 9.88) 0.6148	
Unstratified risk ratio ^a (95% CI) p-value			1.02 (0.95, 1.09) 0.6140	
Absolute risk reduction (95% CI) p-value			0.02 (-0.05, 0.08) 0.6132	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence Interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-003-ae-sum-excl-dis-rel-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.3. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex: Female	79	63		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	78 (98.7)	63 (100.0)	-1.3	
Unstratified odds ratio ^a (95% CI) p-value			0.41 (0.02, 10.29) 0.5892	
Unstratified risk ratio ^a (95% CI) p-value			0.99 (0.95, 1.03) 0.5601	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.05, 0.03) 0.5594	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence Interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-003-ae-sum-excl-dis-rel-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.4. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region:				0.4955
Region: USA	135	115		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	132 (97.8)	113 (98.3)	-0.5	
Unstratified odds ratio ^a (95% CI) p-value			0.78 (0.13, 4.74) 0.7862	
Unstratified risk ratio ^a (95% CI) p-value			1.00 (0.96, 1.03) 0.7837	
Absolute risk reduction (95% CI) p-value			-0.005 (-0.04, 0.03) 0.7836	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-004-ae-sum-excl-dis-rel-by-region-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.4. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region: Rest of the world	12	13		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	12 (100.0)	12 (92.3)	7.7	
Unstratified odds ratio ^a (95% CI) p-value			3.00 (0.11, 80.94) 0.5135	
Unstratified risk ratio ^a (95% CI) p-value			1.08 (0.87, 1.33) 0.4923	
Absolute risk reduction (95% CI) p-value			0.07 (-0.12, 0.26) 0.4851	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-004-ae-sum-excl-dis-rel-by-region-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.5. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race:				0.7357
Race: Caucasian	114	104		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	111 (97.4)	101 (97.1)	0.3	
Unstratified odds ratio ^a (95% CI) p-value			1.10 (0.22, 5.57) 0.9092	
Unstratified risk ratio ^a (95% CI) p-value			1.00 (0.96, 1.05) 0.9094	
Absolute risk reduction (95% CI) p-value			0.003 (-0.04, 0.05) 0.9094	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-005-ae-sum-excl-dis-rel-by-race-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.5. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race: Others	19	8		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	19 (100.0)	8 (100.0)	0.0	
Unstratified odds ratio ^a			2.29	
(95% CI)			(0.04, 125.49)	
p-value			0.6842	
Unstratified risk ratio ^a			1.03	
(95% CI)			(0.87, 1.23)	
p-value			0.7188	
Absolute risk reduction			0.03	
(95% CI)			(-0.13, 0.20)	
p-value			0.7159	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-005-ae-sum-excl-dis-rel-by-race-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.6. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity:				0.8494
Ethnicity: Hispanic or Latino	19	11		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	19 (100.0)	11 (100.0)	0.0	
Unstratified odds ratio ^a (95% CI) p-value			1.70 (0.03, 91.39) 0.7952	
Unstratified risk ratio ^a (95% CI) p-value			1.02 (0.89, 1.17) 0.8055	
Absolute risk reduction (95% CI) p-value			0.02 (-0.12, 0.15) 0.8048	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-006-ae-sum-excl-dis-rel-by-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.6. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity: Not Hispanic or Latino	122	109		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	119 (97.5)	106 (97.2)	0.3	
Unstratified odds ratio ^a (95% CI) p-value			1.12 (0.22, 5.68) 0.8888	
Unstratified risk ratio ^a (95% CI) p-value			1.00 (0.96, 1.05) 0.8891	
Absolute risk reduction (95% CI) p-value			0.003 (-0.04, 0.04) 0.8891	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-006-ae-sum-excl-dis-rel-by-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.7. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status:				0.4870
CD20 status: Positive	74	70		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	73 (98.6)	68 (97.1)	1.5	
Unstratified odds ratio ^a (95% CI) p-value			2.15 (0.19, 24.22) 0.5365	
Unstratified risk ratio ^a (95% CI) p-value			1.02 (0.97, 1.07) 0.5318	
Absolute risk reduction (95% CI) p-value			0.02 (-0.03, 0.06) 0.5306	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-007-ae-sum-excl-dis-rel-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.7. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status: Negative	72	56		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	70 (97.2)	55 (98.2)	-1.0	
Unstratified odds ratio ^a (95% CI) p-value			0.64 (0.06, 7.20) 0.7150	
Unstratified risk ratio ^a (95% CI) p-value			0.99 (0.94, 1.04) 0.7055	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.06, 0.04) 0.7053	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-007-ae-sum-excl-dis-rel-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.8. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use:				0.1889
Rituximab use: Yes	43	40		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	43 (100.0)	38 (95.0)	5.0	
Unstratified odds ratio ^a (95% CI) p-value			5.65 (0.26, 121.35) 0.2685	
Unstratified risk ratio ^a (95% CI) p-value			1.05 (0.97, 1.15) 0.2307	
Absolute risk reduction (95% CI) p-value			0.05 (-0.03, 0.13) 0.2222	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-008-ae-sum-excl-dis-rel-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.8. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use: No	104	88		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	101 (97.1)	87 (98.9)	-1.7	
Unstratified odds ratio ^a (95% CI) p-value			0.39 (0.04, 3.79) 0.4147	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.94, 1.02) 0.3818	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.06, 0.02) 0.3803	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-008-ae-sum-excl-dis-rel-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.9. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT:				0.9818
Allogeneic SCT: Yes	47	40		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	45 (95.7)	38 (95.0)	0.7	
Unstratified odds ratio ^a (95% CI) p-value			1.18 (0.16, 8.81) 0.8689	
Unstratified risk ratio ^a (95% CI) p-value			1.01 (0.92, 1.11) 0.8696	
Absolute risk reduction (95% CI) p-value			0.01 (-0.08, 0.10) 0.8695	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-009-ae-sum-excl-dis-rel-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.9. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT: No	100	88		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	99 (99.0)	87 (98.9)	0.1	
Unstratified odds ratio ^a (95% CI) p-value			1.14 (0.07, 18.47) 0.9276	
Unstratified risk ratio ^a (95% CI) p-value			1.00 (0.97, 1.03) 0.9278	
Absolute risk reduction (95% CI) p-value			0.001 (-0.03, 0.03) 0.9278	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-009-ae-sum-excl-dis-rel-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.10. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status:				0.3625
MRD status: Positive	36	16		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	33 (91.7)	15 (93.8)	-2.1	
Unstratified odds ratio ^a (95% CI) p-value			0.73 (0.07, 7.64) 0.7955	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.83, 1.15) 0.7835	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.17, 0.13) 0.7841	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-010-ae-sum-excl-dis-rel-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.12.10. Summary of Treatment-emergent Adverse Events Excluding Disease-Related Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status: Negative	111	112		
Number of subjects reporting any treatment-emergent adverse events excluding disease-related events - n (%)	111 (100.0)	110 (98.2)	1.8	
Unstratified odds ratio ^a			5.05	
(95% CI)			(0.24, 106.29)	
p-value			0.2980	
Unstratified risk ratio ^a			1.02	
(95% CI)			(0.99, 1.05)	
p-value			0.2482	
Absolute risk reduction			0.02	
(95% CI)			(-0.01, 0.05)	
p-value			0.2454	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-all-by-subgrp-s3saf.sas

Output: t14-06-012-010-ae-sum-excl-dis-rel-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:44)

Source data: adampa.adsl, adam.adae

Table 14-6.14.1. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 1: Age group: <55 years	91	72		0.2923
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease- related events - n (%)	86 (94.5)	69 (95.8)	-1.3	
Unstratified odds ratio ^a (95% CI) p-value			0.75 (0.17, 3.24) 0.6977	
Unstratified risk ratio ^a (95% CI) p-value			0.99 (0.92, 1.06) 0.6923	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.08, 0.05) 0.6922	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-001-ae-sum-sev-excl-dis-rel-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.1. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 years	56	56		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	53 (94.6)	56 (100.0)	-5.4	
Unstratified odds ratio ^a			0.14	
(95% CI)			(0.01, 2.68)	
p-value			0.1893	
Unstratified risk ratio ^a			0.95	
(95% CI)			(0.88, 1.02)	
p-value			0.1307	
Absolute risk reduction			-0.05	
(95% CI)			(-0.12, 0.01)	
p-value			0.1229	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-001-ae-sum-sev-excl-dis-rel-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.2. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 2: Age group: ≥18 - <35 years	18	18		0.2790
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease- related events - n (%)	15 (83.3)	18 (100.0)	-16.7	
Unstratified odds ratio ^a			0.12	
(95% CI)			(0.01, 2.50)	
p-value			0.1710	
Unstratified risk ratio ^a			0.84	
(95% CI)			(0.67, 1.05)	
p-value			0.1251	
Absolute risk reduction			-0.16	
(95% CI)			(-0.35, 0.03)	
p-value			0.1008	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-002-ae-sum-sev-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.2. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥35 - <55 years	73	54		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	71 (97.3)	51 (94.4)	2.8	
Unstratified odds ratio ^a (95% CI) p-value			2.09 (0.34, 12.95) 0.4291	
Unstratified risk ratio ^a (95% CI) p-value			1.03 (0.96, 1.11) 0.4443	
Absolute risk reduction (95% CI) p-value			0.03 (-0.04, 0.10) 0.4412	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-002-ae-sum-sev-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.2. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 - <65 years	44	36		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	42 (95.5)	36 (100.0)	-4.5	
Unstratified odds ratio ^a (95% CI) p-value			0.23 (0.01, 5.01) 0.3519	
Unstratified risk ratio ^a (95% CI) p-value			0.96 (0.88, 1.04) 0.2876	
Absolute risk reduction (95% CI) p-value			-0.04 (-0.12, 0.03) 0.2819	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-002-ae-sum-sev-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.2. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥65 years	12	20		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	11 (91.7)	20 (100.0)	-8.3	
Unstratified odds ratio ^a (95% CI) p-value			0.19 (0.01, 4.97) 0.3165	
Unstratified risk ratio ^a (95% CI) p-value			0.91 (0.74, 1.12) 0.3519	
Absolute risk reduction (95% CI) p-value			-0.09 (-0.28, 0.09) 0.3333	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-002-ae-sum-sev-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.3. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex:				0.4301
Sex: Male	68	65		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease- related events - n (%)	63 (92.6)	62 (95.4)	-2.7	
Unstratified odds ratio ^a			0.61	
(95% CI)			(0.14, 2.66)	
p-value			0.5105	
Unstratified risk ratio ^a			0.97	
(95% CI)			(0.89, 1.06)	
p-value			0.5054	
Absolute risk reduction			-0.03	
(95% CI)			(-0.11, 0.05)	
p-value			0.5041	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-003-ae-sum-sev-excl-dis-rel-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:48)

Source data: adampa.adsl, adam.adae

Table 14-6.14.3. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex: Female	79	63		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	76 (96.2)	63 (100.0)	-3.8	
Unstratified odds ratio ^a (95% CI) p-value			0.17 (0.01, 3.39) 0.2474	
Unstratified risk ratio ^a (95% CI) p-value			0.96 (0.92, 1.01) 0.1617	
Absolute risk reduction (95% CI) p-value			-0.04 (-0.09, 0.01) 0.1568	

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-003-ae-sum-sev-excl-dis-rel-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:48)

Source data: adampa.adsl, adam.adae

Table 14-6.14.4. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region:				0.2288
Region: USA	135	115		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	127 (94.1)	113 (98.3)	-4.2	
Unstratified odds ratio ^a			0.28	
(95% CI)			(0.06, 1.35)	
p-value			0.1130	
Unstratified risk ratio ^a			0.96	
(95% CI)			(0.91, 1.01)	
p-value			0.0805	
Absolute risk reduction			-0.04	
(95% CI)			(-0.09, 0.00)	
p-value			0.0773	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-004-ae-sum-sev-excl-dis-rel-by-region-s3saf.rtf (Date generated:

29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.4. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region: Rest of the world	12	13		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	12 (100.0)	12 (92.3)	7.7	
Unstratified odds ratio ^a (95% CI) p-value			3.00 (0.11, 80.94) 0.5135	
Unstratified risk ratio ^a (95% CI) p-value			1.08 (0.87, 1.33) 0.4923	
Absolute risk reduction (95% CI) p-value			0.07 (-0.12, 0.26) 0.4851	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-004-ae-sum-sev-excl-dis-rel-by-region-s3saf.rtf (Date generated:

29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.5. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race:				0.5204
Race: Caucasian	114	104		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease- related events - n (%)	108 (94.7)	101 (97.1)	-2.4	
Unstratified odds ratio ^a			0.53	
(95% CI)			(0.13, 2.19)	
p-value			0.3848	
Unstratified risk ratio ^a			0.98	
(95% CI)			(0.92, 1.03)	
p-value			0.3724	
Absolute risk reduction			-0.02	
(95% CI)			(-0.08, 0.03)	
p-value			0.3709	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-005-ae-sum-sev-excl-dis-rel-by-race-s3saf.rtf (Date generated: 29MAY2025:04:48)

Source data: adampa.adsl, adam.adae

Table 14-6.14.5. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race: Others	19	8		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	19 (100.0)	8 (100.0)	0.0	
Unstratified odds ratio ^a			2.29	
(95% CI)			(0.04, 125.49)	
p-value			0.6842	
Unstratified risk ratio ^a			1.03	
(95% CI)			(0.87, 1.23)	
p-value			0.7188	
Absolute risk reduction			0.03	
(95% CI)			(-0.13, 0.20)	
p-value			0.7159	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-005-ae-sum-sev-excl-dis-rel-by-race-s3saf.rtf (Date generated: 29MAY2025:04:48)

Source data: adampa.adsl, adam.adae

Table 14-6.14.6. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity:				0.6219
Ethnicity: Hispanic or Latino	19	11		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease- related events - n (%)	19 (100.0)	11 (100.0)	0.0	
Unstratified odds ratio ^a			1.70	
(95% CI)			(0.03, 91.39)	
p-value			0.7952	
Unstratified risk ratio ^a			1.02	
(95% CI)			(0.89, 1.17)	
p-value			0.8055	
Absolute risk reduction			0.02	
(95% CI)			(-0.12, 0.15)	
p-value			0.8048	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-006-ae-sum-sev-excl-dis-rel-by-ethnic-s3saf.rtf (Date generated:

29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.6. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity: Not Hispanic or Latino	122	109		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	116 (95.1)	106 (97.2)	-2.2	
Unstratified odds ratio ^a (95% CI) p-value			0.55 (0.13, 2.24) 0.4022	
Unstratified risk ratio ^a (95% CI) p-value			0.98 (0.93, 1.03) 0.3890	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.07, 0.03) 0.3878	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-006-ae-sum-sev-excl-dis-rel-by-ethnic-s3saf.rtf (Date generated:

29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status:				0.4684
CD20 status: Positive	74	70		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease- related events - n (%)	71 (95.9)	68 (97.1)	-1.2	
Unstratified odds ratio ^a (95% CI) p-value			0.70 (0.11, 4.30) 0.6964	
Unstratified risk ratio ^a (95% CI) p-value			0.99 (0.93, 1.05) 0.6937	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.07, 0.05) 0.6935	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-007-ae-sum-sev-excl-dis-rel-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status: Negative	72	56		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	67 (93.1)	55 (98.2)	-5.2	
Unstratified odds ratio ^a (95% CI) p-value			0.24 (0.03, 2.15) 0.2035	
Unstratified risk ratio ^a (95% CI) p-value			0.95 (0.88, 1.02) 0.1436	
Absolute risk reduction (95% CI) p-value			-0.05 (-0.12, 0.02) 0.1382	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-007-ae-sum-sev-excl-dis-rel-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.8. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use:				0.1104
Rituximab use: Yes	43	40		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease- related events - n (%)	42 (97.7)	38 (95.0)	2.7	
Unstratified odds ratio ^a (95% CI) p-value			2.21 (0.19, 25.37) 0.5241	
Unstratified risk ratio ^a (95% CI) p-value			1.03 (0.94, 1.12) 0.5208	
Absolute risk reduction (95% CI) p-value			0.03 (-0.05, 0.11) 0.5185	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-008-ae-sum-sev-excl-dis-rel-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use: No	104	88		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	97 (93.3)	87 (98.9)	-5.6	
Unstratified odds ratio ^a (95% CI) p-value			0.16 (0.02, 1.32) 0.0887	
Unstratified risk ratio ^a (95% CI) p-value			0.94 (0.89, 1.00) 0.0425	
Absolute risk reduction (95% CI) p-value			-0.06 (-0.11, -0.00) 0.0386	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-008-ae-sum-sev-excl-dis-rel-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:48) Source data: adampa.adsl, adam.adae

Table 14-6.14.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT:				0.6177
Allogeneic SCT: Yes	47	40		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease- related events - n (%)	43 (91.5)	38 (95.0)	-3.5	
Unstratified odds ratio ^a (95% CI) p-value			0.57 (0.10, 3.26) 0.5242	
Unstratified risk ratio ^a (95% CI) p-value			0.96 (0.86, 1.08) 0.5118	
Absolute risk reduction (95% CI) p-value			-0.04 (-0.14, 0.07) 0.5104	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-009-ae-sum-sev-excl-dis-rel-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:49)

Source data: adampa.adsl, adam.adae

Table 14-6.14.9. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events Excluding Disease-Related Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT: No	100	88		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	96 (96.0)	87 (98.9)	-2.9	
Unstratified odds ratio ^a (95% CI) p-value			0.28 (0.03, 2.52) 0.2535	
Unstratified risk ratio ^a (95% CI) p-value			0.97 (0.93, 1.02) 0.2090	
Absolute risk reduction (95% CI) p-value			-0.03 (-0.07, 0.02) 0.2055	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-009-ae-sum-sev-excl-dis-rel-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:49)

Source data: adampa.adsl, adam.adae

Table 14-6.14.10. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events Excluding Disease-Related Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status:				0.7538
MRD status: Positive	36	16		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	31 (86.1)	15 (93.8)	-7.6	
Unstratified odds ratio ^a			0.41	
(95% CI)			(0.04, 3.86)	
p-value			0.4382	
Unstratified risk ratio ^a			0.92	
(95% CI)			(0.77, 1.10)	
p-value			0.3607	
Absolute risk reduction			-0.08	
(95% CI)			(-0.24, 0.09)	
p-value			0.3607	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-010-ae-sum-sev-excl-dis-rel-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:49) Source data: adampa.adsl, adam.adae

Table 14-6.14.10. Summary of Severe (Grade ≥ 3) Treatment-emergent Adverse Events Excluding Disease-Related Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status: Negative	111	112		
Number of subjects reporting severe (grade 3 and above) treatment-emergent adverse events excluding disease-related events - n (%)	108 (97.3)	110 (98.2)	-0.9	
Unstratified odds ratio ^a (95% CI) p-value			0.65 (0.11, 3.99) 0.6461	
Unstratified risk ratio ^a (95% CI) p-value			0.99 (0.95, 1.03) 0.6442	
Absolute risk reduction (95% CI) p-value			-0.01 (-0.05, 0.03) 0.6439	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-sev-all-by-subgrp-s3saf.sas

Output: t14-06-014-010-ae-sum-sev-excl-dis-rel-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:49) Source data: adampa.adsl, adam.adae

Table 14-6.13.1. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 1:				0.9599
Age group: <55 years	91	72		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	52 (57.1)	21 (29.2)	28.0	
Unstratified odds ratio ^a			3.24	
(95% CI)			(1.68, 6.24)	
p-value			0.0004	
Unstratified risk ratio ^a			1.96	
(95% CI)			(1.31, 2.93)	
p-value			0.0010	
Absolute risk reduction			0.28	
(95% CI)			(0.13, 0.43)	
p-value			0.0002	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-001-ae-sum-exp-excl-dis-rel-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.13.1. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 years	56	56		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	30 (53.6)	15 (26.8)	26.8	
Unstratified odds ratio ^a (95% CI) p-value			3.15 (1.43, 6.96) 0.0044	
Unstratified risk ratio ^a (95% CI) p-value			2.00 (1.22, 3.29) 0.0063	
Absolute risk reduction (95% CI) p-value			0.27 (0.09, 0.44) 0.0027	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-001-ae-sum-exp-excl-dis-rel-by-agegrp1-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.13.2. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group 2: Age group: ≥18 - <35 years	18	18		0.9514
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	9 (50.0)	5 (27.8)	22.2	
Unstratified odds ratio ^a (95% CI) p-value			2.60 (0.65, 10.38) 0.1762	
Unstratified risk ratio ^a (95% CI) p-value			1.80 (0.75, 4.32) 0.1887	
Absolute risk reduction (95% CI) p-value			0.22 (-0.09, 0.53) 0.1602	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-002-ae-sum-exp-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.13.2. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥35 - <55 years	73	54		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	43 (58.9)	16 (29.6)	29.3	
Unstratified odds ratio ^a (95% CI) p-value			3.40 (1.61, 7.19) 0.0013	
Unstratified risk ratio ^a (95% CI) p-value			1.99 (1.26, 3.13) 0.0030	
Absolute risk reduction (95% CI) p-value			0.29 (0.13, 0.46) 0.0005	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-002-ae-sum-exp-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.13.2. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥55 - <65 years	44	36		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	24 (54.5)	9 (25.0)	29.5	
Unstratified odds ratio ^a (95% CI) p-value			3.60 (1.38, 9.40) 0.0089	
Unstratified risk ratio ^a (95% CI) p-value			2.18 (1.17, 4.08) 0.0147	
Absolute risk reduction (95% CI) p-value			0.30 (0.09, 0.50) 0.0045	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-002-ae-sum-exp-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.13.2. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Age group: ≥65 years	12	20		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	6 (50.0)	6 (30.0)	20.0	
Unstratified odds ratio ^a			2.33	
(95% CI)			(0.53, 10.27)	
p-value			0.2624	
Unstratified risk ratio ^a			1.67	
(95% CI)			(0.69, 4.00)	
p-value			0.2534	
Absolute risk reduction			0.20	
(95% CI)			(-0.15, 0.55)	
p-value			0.2585	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-002-ae-sum-exp-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.13.3. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex:				0.6280
Sex: Male	68	65		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	37 (54.4)	16 (24.6)	29.8	
Unstratified odds ratio ^a			3.66	
(95% CI)			(1.75, 7.65)	
p-value			0.0006	
Unstratified risk ratio ^a			2.21	
(95% CI)			(1.37, 3.56)	
p-value			0.0011	
Absolute risk reduction			0.30	
(95% CI)			(0.14, 0.46)	
p-value			0.0002	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-ae-sum-exp-excl-dis-rel-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:46)

Source data: adampa.adsl, adam.adae

Table 14-6.13.3. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Sex: Female	79	63		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	45 (57.0)	20 (31.7)	25.2	
Unstratified odds ratio ^a			2.85	
(95% CI)			(1.42, 5.69)	
p-value			0.0031	
Unstratified risk ratio ^a			1.79	
(95% CI)			(1.19, 2.70)	
p-value			0.0052	
Absolute risk reduction			0.25	
(95% CI)			(0.09, 0.41)	
p-value			0.0018	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-003-ae-sum-exp-excl-dis-rel-by-sex-s3saf.rtf (Date generated: 29MAY2025:04:46)

Source data: adampa.adsl, adam.adae

Table 14-6.13.4. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region:				0.3435
Region: USA	135	115		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	75 (55.6)	34 (29.6)	26.0	
Unstratified odds ratio ^a			2.98	
(95% CI)			(1.76, 5.03)	
p-value			<0.0001	
Unstratified risk ratio ^a			1.88	
(95% CI)			(1.36, 2.59)	
p-value			0.0001	
Absolute risk reduction			0.26	
(95% CI)			(0.14, 0.38)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-004-ae-sum-exp-excl-dis-rel-by-region-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.13.4. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Region: Rest of the world	12	13		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	7 (58.3)	2 (15.4)	42.9	
Unstratified odds ratio ^a (95% CI) p-value			7.70 (1.16, 51.16) 0.0347	
Unstratified risk ratio ^a (95% CI) p-value			3.79 (0.97, 14.80) 0.0550	
Absolute risk reduction (95% CI) p-value			0.43 (0.09, 0.77) 0.0136	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-004-ae-sum-exp-excl-dis-rel-by-region-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.13.5. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race:				0.1143
Race: Caucasian	114	104		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	61 (53.5)	30 (28.8)	24.7	
Unstratified odds ratio ^a			2.84	
(95% CI)			(1.62, 4.98)	
p-value			0.0003	
Unstratified risk ratio ^a			1.85	
(95% CI)			(1.31, 2.62)	
p-value			0.0005	
Absolute risk reduction			0.25	
(95% CI)			(0.12, 0.37)	
p-value			0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-005-ae-sum-exp-excl-dis-rel-by-race-s3saf.rtf (Date generated: 29MAY2025:04:46)

Source data: adampa.adsl, adam.adae

Table 14-6.13.5. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Race: Others	19	8		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	14 (73.7)	1 (12.5)	61.2	
Unstratified odds ratio ^a (95% CI) p-value			19.60 (1.91, 201.62) 0.0123	
Unstratified risk ratio ^a (95% CI) p-value			5.89 (0.92, 37.60) 0.0606	
Absolute risk reduction (95% CI) p-value			0.61 (0.31, 0.91) <0.0001	

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-005-ae-sum-exp-excl-dis-rel-by-race-s3saf.rtf (Date generated: 29MAY2025:04:46)

Source data: adampa.adsl, adam.adae

Table 14-6.13.6. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity:				0.3792
Ethnicity: Hispanic or Latino	19	11		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	10 (52.6)	4 (36.4)	16.3	
Unstratified odds ratio ^a			1.94	
(95% CI)			(0.42, 8.92)	
p-value			0.3922	
Unstratified risk ratio ^a			1.45	
(95% CI)			(0.59, 3.53)	
p-value			0.4158	
Absolute risk reduction			0.16	
(95% CI)			(-0.20, 0.52)	
p-value			0.3787	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-006-ae-sum-exp-excl-dis-rel-by-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.13.6. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Ethnicity: Not Hispanic or Latino	122	109		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	71 (58.2)	28 (25.7)	32.5	
Unstratified odds ratio ^a (95% CI) p-value			4.03 (2.30, 7.05) <0.0001	
Unstratified risk ratio ^a (95% CI) p-value			2.27 (1.59, 3.22) <0.0001	
Absolute risk reduction (95% CI) p-value			0.33 (0.21, 0.45) <0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-006-ae-sum-exp-excl-dis-rel-by-ethnic-s3saf.rtf (Date generated: 29MAY2025:04:46) Source data: adampa.adsl, adam.adae

Table 14-6.13.7. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status:				0.2351
CD20 status: Positive	74	70		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	48 (64.9)	21 (30.0)	34.9	
Unstratified odds ratio ^a			4.31	
(95% CI)			(2.14, 8.67)	
p-value			<0.0001	
Unstratified risk ratio ^a			2.16	
(95% CI)			(1.46, 3.21)	
p-value			0.0001	
Absolute risk reduction			0.35	
(95% CI)			(0.20, 0.50)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-ae-sum-exp-excl-dis-rel-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.13.7. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
CD20 status: Negative	72	56		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	33 (45.8)	15 (26.8)	19.0	
Unstratified odds ratio ^a (95% CI) p-value			2.31 (1.09, 4.90) 0.0288	
Unstratified risk ratio ^a (95% CI) p-value			1.71 (1.04, 2.82) 0.0354	
Absolute risk reduction (95% CI) p-value			0.19 (0.03, 0.35) 0.0223	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-007-ae-sum-exp-excl-dis-rel-by-cd20stat-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.13.8. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use:				0.7080
Rituximab use: Yes	43	40		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	29 (67.4)	14 (35.0)	32.4	
Unstratified odds ratio ^a			3.85	
(95% CI)			(1.55, 9.56)	
p-value			0.0037	
Unstratified risk ratio ^a			1.93	
(95% CI)			(1.20, 3.08)	
p-value			0.0063	
Absolute risk reduction			0.32	
(95% CI)			(0.12, 0.53)	
p-value			0.0018	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-008-ae-sum-exp-excl-dis-rel-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.13.8. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Rituximab use: No	104	88		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	53 (51.0)	22 (25.0)	26.0	
Unstratified odds ratio ^a (95% CI) p-value			3.12 (1.68, 5.78) 0.0003	
Unstratified risk ratio ^a (95% CI) p-value			2.04 (1.36, 3.07) 0.0006	
Absolute risk reduction (95% CI) p-value			0.26 (0.13, 0.39) 0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-008-ae-sum-exp-excl-dis-rel-by-rituxmb-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.13.9. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT:				0.3843
Allogeneic SCT: Yes	47	40		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	19 (40.4)	9 (22.5)	17.9	
Unstratified odds ratio ^a			2.34	
(95% CI)			(0.91, 6.00)	
p-value			0.0778	
Unstratified risk ratio ^a			1.80	
(95% CI)			(0.92, 3.52)	
p-value			0.0873	
Absolute risk reduction			0.18	
(95% CI)			(-0.01, 0.37)	
p-value			0.0657	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-ae-sum-exp-excl-dis-rel-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:47)

Source data: adampa.adsl, adam.adae

Table 14-6.13.9. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
Allogeneic SCT: No	100	88		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	63 (63.0)	27 (30.7)	32.3	
Unstratified odds ratio ^a (95% CI) p-value			3.85 (2.09, 7.07) <0.0001	
Unstratified risk ratio ^a (95% CI) p-value			2.05 (1.45, 2.91) <0.0001	
Absolute risk reduction (95% CI) p-value			0.32 (0.19, 0.46) <0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-009-ae-sum-exp-excl-dis-rel-by-asct-s3saf.rtf (Date generated: 29MAY2025:04:47)

Source data: adampa.adsl, adam.adae

Table 14-6.13.10. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status:				0.1833
MRD status: Positive	36	16		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	15 (41.7)	5 (31.3)	10.4	
Unstratified odds ratio ^a			1.57	
(95% CI)			(0.45, 5.47)	
p-value			0.4777	
Unstratified risk ratio ^a			1.33	
(95% CI)			(0.59, 3.04)	
p-value			0.4934	
Absolute risk reduction			0.10	
(95% CI)			(-0.17, 0.38)	
p-value			0.4634	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-010-ae-sum-exp-excl-dis-rel-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.13.10. Summary of Expedited Treatment-emergent Adverse Events Excluding Disease-Related Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p- value ^b
MRD status: Negative	111	112		
Number of subjects reporting expedited treatment-emergent adverse events excluding disease-related events - n (%)	67 (60.4)	31 (27.7)	32.7	
Unstratified odds ratio ^a			3.98	
(95% CI)			(2.27, 6.98)	
p-value			<0.0001	
Unstratified risk ratio ^a			2.18	
(95% CI)			(1.56, 3.05)	
p-value			<0.0001	
Absolute risk reduction			0.33	
(95% CI)			(0.20, 0.45)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202504/tables/t-ae-sum-exp-all-by-subgrp-s3saf.sas

Output: t14-06-013-010-ae-sum-exp-excl-dis-rel-by-mrd-stat-s3saf.rtf (Date generated: 29MAY2025:04:47) Source data: adampa.adsl, adam.adae

Table 14-6.5.12. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 1:				0.3501
Age group: <55 years	91	72		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	6 (6.6)	3 (4.2)	2.4	
Unstratified odds ratio ^a (95% CI) p-value			1.62 (0.39, 6.73) 0.5041	
Unstratified risk ratio ^a (95% CI) p-value			1.58 (0.41, 6.11) 0.5055	
Absolute risk reduction (95% CI) p-value			0.02 (-0.04, 0.09) 0.4892	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-012-ae-sum-dct-excl-dis-rel-by-agegrp1-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adamgp.adae

Table 14-6.5.12. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Age Group 1 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years	56	56		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	8 (14.3)	2 (3.6)	10.7	
Unstratified odds ratio ^a			4.50	
(95% CI)			(0.91, 22.23)	
p-value			0.0650	
Unstratified risk ratio ^a			4.00	
(95% CI)			(0.89, 18.01)	
p-value			0.0709	
Absolute risk reduction			0.11	
(95% CI)			(0.00, 0.21)	
p-value			0.0429	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-012-ae-sum-dct-excl-dis-rel-by-agegrp1-s3saf.rtf (Date generated:

04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Table 14-6.5.13. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2: Age group: ≥18 - <35 years	18	18		0.8117
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	2 (11.1)	1 (5.6)	-	
Unstratified odds ratio ^a (95% CI) p-value			- - -	
Unstratified risk ratio ^a (95% CI) p-value			- - -	
Absolute risk reduction (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-013-ae-sum-dct-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adamgp.adae

Table 14-6.5.13. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years	73	54		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	4 (5.5)	2 (3.7)	-	
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-013-ae-sum-dct-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated:

04DEC2025:01:52) Source data: adampa.adsl, adamgp.adae

Table 14-6.5.13. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years	44	36		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	6 (13.6)	1 (2.8)	-	
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-013-ae-sum-dct-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated:

04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Table 14-6.5.13. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Age Group 2 (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years	12	20		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	2 (16.7)	1 (5.0)	-	
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-013-ae-sum-dct-excl-dis-rel-by-agegrp2-s3saf.rtf (Date generated:

04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Table 14-6.5.14. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:				0.2925
Sex: Male	68	65		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	9 (13.2)	5 (7.7)	5.5	
Unstratified odds ratio ^a (95% CI) p-value			1.83 (0.58, 5.79) 0.3031	
Unstratified risk ratio ^a (95% CI) p-value			1.72 (0.61, 4.86) 0.3060	
Absolute risk reduction (95% CI) p-value			0.06 (-0.05, 0.16) 0.2932	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-014-ae-sum-dct-excl-dis-rel-by-sex-s3saf.rtf (Date generated: 04DEC2025:01:52)

Source data: adampa.adsl, adamg.adae

Table 14-6.5.14. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Sex (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female	79	63		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	5 (6.3)	0 (0.0)	6.3	
Unstratified odds ratio ^a			9.37	
(95% CI)			(0.51, 172.63)	
p-value			0.1323	
Unstratified risk ratio ^a			8.80	
(95% CI)			(0.50, 156.19)	
p-value			0.1384	
Absolute risk reduction			0.06	
(95% CI)			(0.00, 0.12)	
p-value			0.0447	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-ex-cl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-014-ae-sum-dct-excl-dis-rel-by-sex-s3saf.rtf (Date generated: 04DEC2025:01:52)

Source data: adampa.adsl, adamapg.adae

Table 14-6.5.15. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:				0.7922
Region: USA	135	115		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	13 (9.6)	5 (4.3)	5.3	
Unstratified odds ratio ^a (95% CI) p-value			2.34 (0.81, 6.79) 0.1163	
Unstratified risk ratio ^a (95% CI) p-value			2.21 (0.81, 6.03) 0.1195	
Absolute risk reduction (95% CI) p-value			0.05 (-0.01, 0.11) 0.0959	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-015-ae-sum-dct-excl-dis-rel-by-region-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Table 14-6.5.15. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Region (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world	12	13		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	1 (8.3)	0 (0.0)	8.3	
Unstratified odds ratio ^a			3.52	
(95% CI)			(0.13, 95.05)	
p-value			0.4541	
Unstratified risk ratio ^a			3.23	
(95% CI)			(0.14, 72.46)	
p-value			0.4599	
Absolute risk reduction			0.08	
(95% CI)			(-0.12, 0.28)	
p-value			0.4327	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-015-ae-sum-dct-excl-dis-rel-by-region-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Table 14-6.5.16. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:				0.9547
Race: Caucasian	114	104		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	12 (10.5)	5 (4.8)	5.7	
Unstratified odds ratio ^a (95% CI) p-value			2.33 (0.79, 6.85) 0.1246	
Unstratified risk ratio ^a (95% CI) p-value			2.19 (0.80, 6.00) 0.1279	
Absolute risk reduction (95% CI) p-value			0.06 (-0.01, 0.13) 0.1080	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-016-ae-sum-dct-excl-dis-rel-by-race-s3saf.rtf (Date generated: 04DEC2025:01:52)

Source data: adampa.adsl, adampg.adae

Table 14-6.5.16. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Race (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others	19	8		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	2 (10.5)	0 (0.0)	10.5	
Unstratified odds ratio ^a			2.43	
(95% CI)			(0.10, 56.38)	
p-value			0.5803	
Unstratified risk ratio ^a			2.25	
(95% CI)			(0.12, 42.25)	
p-value			0.5878	
Absolute risk reduction			0.07	
(95% CI)			(-0.14, 0.28)	
p-value			0.5136	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-016-ae-sum-dct-excl-dis-rel-by-race-s3saf.rtf (Date generated: 04DEC2025:01:52)

Source data: adampa.adsl, adamprg.adae

Table 14-6.5.17. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:				0.2743
Ethnicity: Hispanic or Latino	19	11		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	1 (5.3)	1 (9.1)	-3.8	
Unstratified odds ratio ^a (95% CI) p-value			0.56 (0.03, 9.87) 0.6889	
Unstratified risk ratio ^a (95% CI) p-value			0.58 (0.04, 8.36) 0.6883	
Absolute risk reduction (95% CI) p-value			-0.04 (-0.24, 0.16) 0.7038	

Page 1 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-017-ae-sum-dct-excl-dis-rel-by-ethnic-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adamgp.adae

Table 14-6.5.17. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Ethnicity (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino	122	109		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	13 (10.7)	4 (3.7)	7.0	
Unstratified odds ratio ^a			3.13	
(95% CI)			(0.99, 9.91)	
p-value			0.0522	
Unstratified risk ratio ^a			2.90	
(95% CI)			(0.98, 8.64)	
p-value			0.0554	
Absolute risk reduction			0.07	
(95% CI)			(0.00, 0.14)	
p-value			0.0356	

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-017-ae-sum-dct-excl-dis-rel-by-ethnic-s3saf.rtf (Date generated:

04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Table 14-6.5.18. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:				0.4016
CD20 status: Positive	74	70		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	10 (13.5)	5 (7.1)	6.4	
Unstratified odds ratio ^a (95% CI) p-value			2.03 (0.66, 6.27) 0.2181	
Unstratified risk ratio ^a (95% CI) p-value			1.89 (0.68, 5.26) 0.2217	
Absolute risk reduction (95% CI) p-value			0.06 (-0.03, 0.16) 0.2050	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an un-stratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-018-ae-sum-dct-excl-dis-rel-by-cd20stat-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Table 14-6.5.18. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by CD20 Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative	72	56		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	4 (5.6)	0 (0.0)	5.6	
Unstratified odds ratio ^a			7.42	
(95% CI)			(0.39, 140.78)	
p-value			0.1819	
Unstratified risk ratio ^a			7.03	
(95% CI)			(0.39, 127.86)	
p-value			0.1877	
Absolute risk reduction			0.05	
(95% CI)			(-0.01, 0.11)	
p-value			0.0854	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an un-stratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-018-ae-sum-dct-excl-dis-rel-by-cd20stat-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adamgp.adae

Table 14-6.5.19. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:				0.4547
Rituximab use: Yes	43	40		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	8 (18.6)	4 (10.0)	8.6	
Unstratified odds ratio ^a			2.06	
(95% CI)			(0.57, 7.45)	
p-value			0.2721	
Unstratified risk ratio ^a			1.86	
(95% CI)			(0.61, 5.70)	
p-value			0.2774	
Absolute risk reduction			0.09	
(95% CI)			(-0.06, 0.23)	
p-value			0.2574	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-019-ae-sum-dct-excl-dis-rel-by-rituxmb-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Table 14-6.5.19. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Rituximab Use (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No	104	88		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	6 (5.8)	1 (1.1)	4.6	
Unstratified odds ratio ^a (95% CI) p-value			5.33 (0.63, 45.12) 0.1249	
Unstratified risk ratio ^a (95% CI) p-value			5.08 (0.62, 41.37) 0.1290	
Absolute risk reduction (95% CI) p-value			0.05 (-0.00, 0.10) 0.0693	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-019-ae-sum-dct-excl-dis-rel-by-rituxmb-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Table 14-6.5.20. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Allogeneic SCT (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:				0.0983
Allogeneic SCT: Yes	47	40		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	1 (2.1)	2 (5.0)	-2.9	
Unstratified odds ratio ^a			0.41	
(95% CI)			(0.04, 4.73)	
p-value			0.4773	
Unstratified risk ratio ^a			0.43	
(95% CI)			(0.04, 4.52)	
p-value			0.4785	
Absolute risk reduction			-0.03	
(95% CI)			(-0.11, 0.05)	
p-value			0.4769	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-020-ae-sum-dct-excl-dis-rel-by-asct-s3saf.rtf (Date generated: 04DEC2025:01:52)

Source data: adampa.adsl, adampg.adae

Table 14-6.5.20. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by Allogeneic SCT
(Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No	100	88		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	13 (13.0)	3 (3.4)	9.6	
Unstratified odds ratio ^a (95% CI) p-value			4.23 (1.16, 15.39) 0.0284	
Unstratified risk ratio ^a (95% CI) p-value			3.81 (1.12, 12.95) 0.0318	
Absolute risk reduction (95% CI) p-value			0.10 (0.02, 0.17) 0.0134	

Page 2 of 2

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-020-ae-sum-dct-excl-dis-rel-by-asct-s3saf.rtf (Date generated: 04DEC2025:01:52)

Source data: adampa.adsl, adampg.adae

Table 14-6.5.21. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:				0.9868
MRD status: Positive	36	16		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	2 (5.6)	0 (0.0)	5.6	
Unstratified odds ratio ^a			2.39	
(95% CI)			(0.11, 52.68)	
p-value			0.5806	
Unstratified risk ratio ^a			2.30	
(95% CI)			(0.12, 45.30)	
p-value			0.5846	
Absolute risk reduction			0.04	
(95% CI)			(-0.08, 0.15)	
p-value			0.5118	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program:

/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-dct-excl-dis-rel-by-subgrp-s3saf.sas

Output: t14-06-005-021-ae-sum-dct-excl-dis-rel-by-mrd-stat-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Table 14-6.5.21. Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation Excluding Disease-Progression Events by MRD Status (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative	111	112		
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation excluding disease-progression events - n (%)	12 (10.8)	5 (4.5)	6.3	
Unstratified odds ratio ^a			2.59	
(95% CI)			(0.88, 7.63)	
p-value			0.0832	
Unstratified risk ratio ^a			2.42	
(95% CI)			(0.88, 6.65)	
p-value			0.0860	
Absolute risk reduction			0.06	
(95% CI)			(-0.01, 0.13)	
p-value			0.0726	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE leading to treatment discontinuation (which are captured in Off-treatment form) have reasons as adverse event/side effects/complications are recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program:

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Output: t14-06-005-021-ae-sum-dct-excl-dis-rel-by-mrd-stat-s3saf.rtf (Date generated: 04DEC2025:01:52) Source data: adampa.adsl, adampg.adae

Anhang 4-G3.3.2: Subgruppenanalysen zu UE von besonderem Interesse

Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting any cytokine release syndrome (EOI) - n (%)	23 (15.6)	0 (0.0)	15.6	
Age group 1:	23	0		0.7595
Age group: <55 years (n/N1 (%))	10/91 (11.0)	0/72 (0.0)		
Unstratified odds ratio ^a			18.68	
(95% CI)			(1.08, 324.41)	
p-value			0.0444	
Unstratified risk ratio ^a			16.66	
(95% CI)			(0.99, 279.65)	
p-value			0.0506	
Absolute risk reduction			0.11	
(95% CI)			(0.04, 0.17)	
p-value			0.0019	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-aesi-by-subgrp-s3saf.sas

Output: t14-06-009-001-ae-sum-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:10) Source data: adampa.adsl, adampa.adae

Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years (n/N1 (%))	13/56 (23.2)	0/56 (0.0)		
Unstratified odds ratio ^a			35.05	
(95% CI)			(2.03, 605.64)	
p-value			0.0144	
Unstratified risk ratio ^a			27.00	
(95% CI)			(1.64, 443.43)	
p-value			0.0210	
Absolute risk reduction			0.23	
(95% CI)			(0.12, 0.34)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-aesi-by-subgrp-s3saf.sas

Output: t14-06-009-001-ae-sum-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:10) Source data: adampa.adsl, adampa.adae

Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	23	0		-
Age group: ≥18 - <35 years (n/N1 (%))	1/18 (5.6)	0/18 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-aesi-by-subgrp-s3saf.sas

Output: t14-06-009-001-ae-sum-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:10) Source data: adampa.adsl, adampa.adae

Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	9/73 (12.3)	0/54 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-aesi-by-subgrp-s3saf.sas

Output: t14-06-009-001-ae-sum-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:10) Source data: adampa.adsl, adampa.adae

Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	9/44 (20.5)	0/36 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-aesi-by-subgrp-s3saf.sas

Output: t14-06-009-001-ae-sum-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:10) Source data: adampa.adsl, adampa.adae

Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	4/12 (33.3)	0/20 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	23	0		-
Sex: Male (n/N1 (%))	6/68 (8.8)	0/65 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	17/79 (21.5)	0/63 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	23	0		-
Region: USA (n/N1 (%))	21/135 (15.6)	0/115 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	2/12 (16.7)	0/13 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	21	0		-
Race: Caucasian (n/N1 (%))	15/114 (13.2)	0/104 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	6/19 (31.6)	0/8 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	22	0		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	22/122 (18.0)	0/109 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	22	0		-
CD20 status: Positive (n/N1 (%))	13/74 (17.6)	0/70 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	9/72 (12.5)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	23	0		0.9300
Rituximab use: Yes (n/N1 (%))	11/43 (25.6)	0/40 (0.0)		
Unstratified odds ratio ^a			28.66	
(95% CI)			(1.63, 504.73)	
p-value			0.0219	
Unstratified risk ratio ^a			21.43	
(95% CI)			(1.30, 352.18)	
p-value			0.0319	
Absolute risk reduction			0.25	
(95% CI)			(0.12, 0.38)	
p-value			0.0003	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	12/104 (11.5)	0/88 (0.0)		
Unstratified odds ratio ^a			23.91	
(95% CI)			(1.40, 409.84)	
p-value			0.0285	
Unstratified risk ratio ^a			21.19	
(95% CI)			(1.27, 352.87)	
p-value			0.0333	
Absolute risk reduction			0.11	
(95% CI)			(0.05, 0.18)	
p-value			0.0005	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-aesi-by-subgrp-s3saf.sas

Output: t14-06-009-001-ae-sum-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:10) Source data: adampa.adsl, adampa.adae

Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	23	0		-
Allogeneic SCT: Yes (n/N1 (%))	5/47 (10.6)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	18/100 (18.0)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	23	0		-
MRD status: Positive (n/N1 (%))	4/36 (11.1)	0/16 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	19/111 (17.1)	0/112 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting any medication errors (EOI) - n (%)	1 (0.7)	0 (0.0)	0.7	
Age group 1:	1	0		-
Age group: <55 years (n/N1 (%))	0/91 (0.0)	0/72 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years (n/N1 (%))	1/56 (1.8)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	1	0		-
Age group: ≥18 - <35 years (n/N1 (%))	0/18 (0.0)	0/18 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	0/73 (0.0)	0/54 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	0/44 (0.0)	0/36 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	1/12 (8.3)	0/20 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	1	0		-
Sex: Male (n/N1 (%))	1/68 (1.5)	0/65 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	0/79 (0.0)	0/63 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	1	0		-
Region: USA (n/N1 (%))	1/135 (0.7)	0/115 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-aesi-by-subgrp-s3saf.sas

Output: t14-06-009-001-ae-sum-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:10) Source data: adampa.adsl, adampa.adae

Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	0/12 (0.0)	0/13 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	1	0		-
Race: Caucasian (n/N1 (%))	1/114 (0.9)	0/104 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	0/19 (0.0)	0/8 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	1	0		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	1/122 (0.8)	0/109 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	1	0		-
CD20 status: Positive (n/N1 (%))	0/74 (0.0)	0/70 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	1/72 (1.4)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	1	0		-
Rituximab use: Yes (n/N1 (%))	0/43 (0.0)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	1/104 (1.0)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	1	0		-
Allogeneic SCT: Yes (n/N1 (%))	0/47 (0.0)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	1/100 (1.0)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	1	0		-
MRD status: Positive (n/N1 (%))	0/36 (0.0)	0/16 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	1/111 (0.9)	0/112 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting any neurological events (EOI) - n (%)	90 (61.2)	49 (38.3)	22.9	
Age group 1:	90	49		0.1859
Age group: <55 years (n/N1 (%))	64/91 (70.3)	30/72 (41.7)		
Unstratified odds ratio ^a			3.32	
(95% CI)			(1.73, 6.35)	
p-value			0.0003	
Unstratified risk ratio ^a			1.69	
(95% CI)			(1.25, 2.29)	
p-value			0.0007	
Absolute risk reduction			0.29	
(95% CI)			(0.14, 0.43)	
p-value			0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years (n/N1 (%))	26/56 (46.4)	19/56 (33.9)		
Unstratified odds ratio ^a			1.69	
(95% CI)			(0.79, 3.62)	
p-value			0.1787	
Unstratified risk ratio ^a			1.37	
(95% CI)			(0.86, 2.17)	
p-value			0.1826	
Absolute risk reduction			0.13	
(95% CI)			(-0.06, 0.31)	
p-value			0.1737	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	90	49		0.4207
Age group: ≥18 - <35 years (n/N1 (%))	14/18 (77.8)	9/18 (50.0)		
Unstratified odds ratio ^a			3.50	
(95% CI)			(0.83, 14.85)	
p-value			0.0893	
Unstratified risk ratio ^a			1.56	
(95% CI)			(0.92, 2.63)	
p-value			0.0983	
Absolute risk reduction			0.28	
(95% CI)			(-0.02, 0.58)	
p-value			0.0699	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	50/73 (68.5)	21/54 (38.9)		
Unstratified odds ratio ^a			3.42	
(95% CI)			(1.63, 7.14)	
p-value			0.0011	
Unstratified risk ratio ^a			1.76	
(95% CI)			(1.22, 2.55)	
p-value			0.0026	
Absolute risk reduction			0.30	
(95% CI)			(0.13, 0.46)	
p-value			0.0006	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	19/44 (43.2)	13/36 (36.1)		
Unstratified odds ratio ^a			1.34	
(95% CI)			(0.54, 3.32)	
p-value			0.5212	
Unstratified risk ratio ^a			1.20	
(95% CI)			(0.69, 2.07)	
p-value			0.5248	
Absolute risk reduction			0.07	
(95% CI)			(-0.14, 0.29)	
p-value			0.5184	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	7/12 (58.3)	6/20 (30.0)		
Unstratified odds ratio ^a			3.27	
(95% CI)			(0.73, 14.55)	
p-value			0.1205	
Unstratified risk ratio ^a			1.94	
(95% CI)			(0.85, 4.43)	
p-value			0.1131	
Absolute risk reduction			0.28	
(95% CI)			(-0.06, 0.63)	
p-value			0.1062	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	90	49		0.3649
Sex: Male (n/N1 (%))	39/68 (57.4)	26/65 (40.0)		
Unstratified odds ratio ^a			2.02	
(95% CI)			(1.01, 4.03)	
p-value			0.0465	
Unstratified risk ratio ^a			1.43	
(95% CI)			(1.00, 2.06)	
p-value			0.0507	
Absolute risk reduction			0.17	
(95% CI)			(0.01, 0.34)	
p-value			0.0421	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	51/79 (64.6)	23/63 (36.5)		
Unstratified odds ratio ^a			3.17	
(95% CI)			(1.59, 6.31)	
p-value			0.0010	
Unstratified risk ratio ^a			1.77	
(95% CI)			(1.23, 2.55)	
p-value			0.0022	
Absolute risk reduction			0.28	
(95% CI)			(0.12, 0.44)	
p-value			0.0005	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	90	49		0.0931
Region: USA (n/N1 (%))	79/135 (58.5)	44/115 (38.3)		
Unstratified odds ratio ^a			2.28	
(95% CI)			(1.37, 3.79)	
p-value			0.0015	
Unstratified risk ratio ^a			1.53	
(95% CI)			(1.17, 2.01)	
p-value			0.0022	
Absolute risk reduction			0.20	
(95% CI)			(0.08, 0.32)	
p-value			0.0011	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	11/12 (91.7)	5/13 (38.5)		
Unstratified odds ratio ^a			17.60	
(95% CI)			(1.71, 181.29)	
p-value			0.0159	
Unstratified risk ratio ^a			2.38	
(95% CI)			(1.17, 4.84)	
p-value			0.0163	
Absolute risk reduction			0.53	
(95% CI)			(0.22, 0.84)	
p-value			0.0007	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	80	44		0.5470
Race: Caucasian (n/N1 (%))	65/114 (57.0)	40/104 (38.5)		
Unstratified odds ratio ^a			2.12	
(95% CI)			(1.23, 3.65)	
p-value			0.0065	
Unstratified risk ratio ^a			1.48	
(95% CI)			(1.11, 1.98)	
p-value			0.0079	
Absolute risk reduction			0.19	
(95% CI)			(0.06, 0.32)	
p-value			0.0053	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	15/19 (78.9)	4/8 (50.0)		
Unstratified odds ratio ^a			3.75	
(95% CI)			(0.64, 22.04)	
p-value			0.1436	
Unstratified risk ratio ^a			1.58	
(95% CI)			(0.76, 3.28)	
p-value			0.2206	
Absolute risk reduction			0.29	
(95% CI)			(-0.10, 0.68)	
p-value			0.1478	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	87	48		0.4791
Ethnicity: Hispanic or Latino (n/N1 (%))	12/19 (63.2)	6/11 (54.5)		
Unstratified odds ratio ^a			1.43	
(95% CI)			(0.32, 6.46)	
p-value			0.6432	
Unstratified risk ratio ^a			1.16	
(95% CI)			(0.61, 2.19)	
p-value			0.6532	
Absolute risk reduction			0.09	
(95% CI)			(-0.28, 0.45)	
p-value			0.6442	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	75/122 (61.5)	42/109 (38.5)		
Unstratified odds ratio ^a			2.55	
(95% CI)			(1.50, 4.33)	
p-value			0.0006	
Unstratified risk ratio ^a			1.60	
(95% CI)			(1.21, 2.10)	
p-value			0.0009	
Absolute risk reduction			0.23	
(95% CI)			(0.10, 0.36)	
p-value			0.0003	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	90	48		0.0233
CD20 status: Positive (n/N1 (%))	50/74 (67.6)	22/70 (31.4)		
Unstratified odds ratio ^a			4.55	
(95% CI)			(2.25, 9.16)	
p-value			<0.0001	
Unstratified risk ratio ^a			2.15	
(95% CI)			(1.47, 3.14)	
p-value			<0.0001	
Absolute risk reduction			0.36	
(95% CI)			(0.21, 0.51)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	40/72 (55.6)	26/56 (46.4)		
Unstratified odds ratio ^a			1.44	
(95% CI)			(0.72, 2.91)	
p-value			0.3061	
Unstratified risk ratio ^a			1.20	
(95% CI)			(0.84, 1.70)	
p-value			0.3136	
Absolute risk reduction			0.09	
(95% CI)			(-0.08, 0.27)	
p-value			0.3036	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	90	49		0.1050
Rituximab use: Yes (n/N1 (%))	29/43 (67.4)	12/40 (30.0)		
Unstratified odds ratio ^a			4.83	
(95% CI)			(1.91, 12.25)	
p-value			0.0009	
Unstratified risk ratio ^a			2.25	
(95% CI)			(1.34, 3.77)	
p-value			0.0021	
Absolute risk reduction			0.37	
(95% CI)			(0.17, 0.57)	
p-value			0.0002	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	61/104 (58.7)	37/88 (42.0)		
Unstratified odds ratio ^a			1.96	
(95% CI)			(1.10, 3.48)	
p-value			0.0224	
Unstratified risk ratio ^a			1.40	
(95% CI)			(1.04, 1.87)	
p-value			0.0263	
Absolute risk reduction			0.17	
(95% CI)			(0.03, 0.31)	
p-value			0.0200	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	90	49		0.4727
Allogeneic SCT: Yes (n/N1 (%))	23/47 (48.9)	13/40 (32.5)		
Unstratified odds ratio ^a			1.99	
(95% CI)			(0.83, 4.77)	
p-value			0.1230	
Unstratified risk ratio ^a			1.51	
(95% CI)			(0.88, 2.57)	
p-value			0.1328	
Absolute risk reduction			0.16	
(95% CI)			(-0.04, 0.37)	
p-value			0.1138	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	67/100 (67.0)	36/88 (40.9)		
Unstratified odds ratio ^a			2.93	
(95% CI)			(1.62, 5.32)	
p-value			0.0004	
Unstratified risk ratio ^a			1.64	
(95% CI)			(1.23, 2.18)	
p-value			0.0007	
Absolute risk reduction			0.26	
(95% CI)			(0.12, 0.40)	
p-value			0.0002	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	90	49		0.3939
MRD status: Positive (n/N1 (%))	18/36 (50.0)	6/16 (37.5)		
Unstratified odds ratio ^a			1.67	
(95% CI)			(0.50, 5.56)	
p-value			0.4059	
Unstratified risk ratio ^a			1.33	
(95% CI)			(0.65, 2.72)	
p-value			0.4284	
Absolute risk reduction			0.13	
(95% CI)			(-0.16, 0.41)	
p-value			0.3950	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.9.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (AE of any grade) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	72/111 (64.9)	43/112 (38.4)		
Unstratified odds ratio ^a			2.96	
(95% CI)			(1.72, 5.11)	
p-value			<0.0001	
Unstratified risk ratio ^a			1.69	
(95% CI)			(1.29, 2.22)	
p-value			0.0002	
Absolute risk reduction			0.26	
(95% CI)			(0.14, 0.39)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Anhang 4-G3.3.3: Subgruppenanalysen zu schweren UE von besonderem Interesse

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting severe (grade 3 and above) cytokine release syndrome (EOI) - n (%)	6 (4.1)	0 (0.0)	4.1	
Age group 1:	6	0		-
Age group: <55 years (n/N1 (%))	3/91 (3.3)	0/72 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years (n/N1 (%))	3/56 (5.4)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	6	0		-
Age group: ≥18 - <35 years (n/N1 (%))	0/18 (0.0)	0/18 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	3/73 (4.1)	0/54 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-grd3-aesi-by-subgrp-s3saf.sas

Output: t14-06-010-001-ae-sum-grd3-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:09)

Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	3/44 (6.8)	0/36 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	0/12 (0.0)	0/20 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	6	0		-
Sex: Male (n/N1 (%))	1/68 (1.5)	0/65 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	5/79 (6.3)	0/63 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	6	0		-
Region: USA (n/N1 (%))	6/135 (4.4)	0/115 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	0/12 (0.0)	0/13 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	6	0		-
Race: Caucasian (n/N1 (%))	4/114 (3.5)	0/104 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	2/19 (10.5)	0/8 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	6	0		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	6/122 (4.9)	0/109 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	6	0		-
CD20 status: Positive (n/N1 (%))	1/74 (1.4)	0/70 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	5/72 (6.9)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	6	0		-
Rituximab use: Yes (n/N1 (%))	2/43 (4.7)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-grd3-aei-by-subgrp-s3saf.sas

Output: t14-06-010-001-ae-sum-grd3-aei-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:09)

Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	4/104 (3.8)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Data cut-off date: 23JUN2023

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	6	0		-
Allogeneic SCT: Yes (n/N1 (%))	2/47 (4.3)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	4/100 (4.0)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	6	0		-
MRD status: Positive (n/N1 (%))	2/36 (5.6)	0/16 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	4/111 (3.6)	0/112 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting severe (grade 3 and above) medication errors (EOI) - n (%)	1 (0.7)	0 (0.0)	0.7	
Age group 1:	1	0		-
Age group: <55 years (n/N1 (%))	0/91 (0.0)	0/72 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years (n/N1 (%))	1/56 (1.8)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	1	0		-
Age group: ≥18 - <35 years (n/N1 (%))	0/18 (0.0)	0/18 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	0/73 (0.0)	0/54 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	0/44 (0.0)	0/36 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	1/12 (8.3)	0/20 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	1	0		-
Sex: Male (n/N1 (%))	1/68 (1.5)	0/65 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	0/79 (0.0)	0/63 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	1	0		-
Region: USA (n/N1 (%))	1/135 (0.7)	0/115 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-grd3-aei-by-subgrp-s3saf.sas

Output: t14-06-010-001-ae-sum-grd3-aei-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:09)

Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	0/12 (0.0)	0/13 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	1	0		-
Race: Caucasian (n/N1 (%))	1/114 (0.9)	0/104 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	0/19 (0.0)	0/8 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	1	0		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	1/122 (0.8)	0/109 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	1	0		-
CD20 status: Positive (n/N1 (%))	0/74 (0.0)	0/70 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	1/72 (1.4)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	1	0		-
Rituximab use: Yes (n/N1 (%))	0/43 (0.0)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	1/104 (1.0)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	1	0		-
Allogeneic SCT: Yes (n/N1 (%))	0/47 (0.0)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	1/100 (1.0)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	1	0		-
MRD status: Positive (n/N1 (%))	0/36 (0.0)	0/16 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	1/111 (0.9)	0/112 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-grd3-aesi-by-subgrp-s3saf.sas

Output: t14-06-010-001-ae-sum-grd3-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:09)

Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting severe (grade 3 and above) neurological events (EOI) - n (%)	42 (28.6)	14 (10.9)	17.6	
Age group 1:	42	14		0.9320
Age group: <55 years (n/N1 (%))	29/91 (31.9)	9/72 (12.5)		
Unstratified odds ratio ^a			3.27	
(95% CI)			(1.43, 7.48)	
p-value			0.0049	
Unstratified risk ratio ^a			2.55	
(95% CI)			(1.29, 5.04)	
p-value			0.0071	
Absolute risk reduction			0.19	
(95% CI)			(0.07, 0.32)	
p-value			0.0019	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years (n/N1 (%))	13/56 (23.2)	5/56 (8.9)		
Unstratified odds ratio ^a			3.08	
(95% CI)			(1.02, 9.34)	
p-value			0.0464	
Unstratified risk ratio ^a			2.60	
(95% CI)			(0.99, 6.81)	
p-value			0.0517	
Absolute risk reduction			0.14	
(95% CI)			(0.01, 0.28)	
p-value			0.0359	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	42	14		-
Age group: ≥18 - <35 years (n/N1 (%))	8/18 (44.4)	1/18 (5.6)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	21/73 (28.8)	8/54 (14.8)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	9/44 (20.5)	4/36 (11.1)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	4/12 (33.3)	1/20 (5.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	42	14		0.3592
Sex: Male (n/N1 (%))	19/68 (27.9)	5/65 (7.7)		
Unstratified odds ratio ^a			4.65	
(95% CI)			(1.62, 13.36)	
p-value			0.0043	
Unstratified risk ratio ^a			3.63	
(95% CI)			(1.44, 9.16)	
p-value			0.0063	
Absolute risk reduction			0.20	
(95% CI)			(0.08, 0.33)	
p-value			0.0015	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	23/79 (29.1)	9/63 (14.3)		
Unstratified odds ratio ^a			2.46	
(95% CI)			(1.05, 5.80)	
p-value			0.0390	
Unstratified risk ratio ^a			2.04	
(95% CI)			(1.02, 4.09)	
p-value			0.0449	
Absolute risk reduction			0.15	
(95% CI)			(0.02, 0.28)	
p-value			0.0280	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	42	14		-
Region: USA (n/N1 (%))	35/135 (25.9)	14/115 (12.2)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	7/12 (58.3)	0/13 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	39	12		-
Race: Caucasian (n/N1 (%))	30/114 (26.3)	12/104 (11.5)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	9/19 (47.4)	0/8 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	41	14		-
Ethnicity: Hispanic or Latino (n/N1 (%))	3/19 (15.8)	3/11 (27.3)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

Severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-grd3-aesi-by-subgrp-s3saf.sas

Output: t14-06-010-001-ae-sum-grd3-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:01:09)

Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	38/122 (31.1)	11/109 (10.1)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	42	14		0.1147
CD20 status: Positive (n/N1 (%))	25/74 (33.8)	6/70 (8.6)		
Unstratified odds ratio ^a			5.44	
(95% CI)			(2.07, 14.29)	
p-value			0.0006	
Unstratified risk ratio ^a			3.94	
(95% CI)			(1.72, 9.03)	
p-value			0.0012	
Absolute risk reduction			0.25	
(95% CI)			(0.13, 0.38)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	17/72 (23.6)	8/56 (14.3)		
Unstratified odds ratio ^a			1.85	
(95% CI)			(0.74, 4.68)	
p-value			0.1907	
Unstratified risk ratio ^a			1.65	
(95% CI)			(0.77, 3.55)	
p-value			0.1976	
Absolute risk reduction			0.09	
(95% CI)			(-0.04, 0.23)	
p-value			0.1734	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Source data: adampa.adsl, adampa.adae

Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	42	14		0.0570
Rituximab use: Yes (n/N1 (%))	16/43 (37.2)	2/40 (5.0)		
Unstratified odds ratio ^a			11.26	
(95% CI)			(2.39, 53.07)	
p-value			0.0022	
Unstratified risk ratio ^a			7.44	
(95% CI)			(1.83, 30.34)	
p-value			0.0051	
Absolute risk reduction			0.32	
(95% CI)			(0.16, 0.48)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	26/104 (25.0)	12/88 (13.6)		
Unstratified odds ratio ^a			2.11	
(95% CI)			(0.99, 4.48)	
p-value			0.0519	
Unstratified risk ratio ^a			1.83	
(95% CI)			(0.98, 3.42)	
p-value			0.0563	
Absolute risk reduction			0.11	
(95% CI)			(0.00, 0.22)	
p-value			0.0426	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	42	14		0.4365
Allogeneic SCT: Yes (n/N1 (%))	9/47 (19.1)	4/40 (10.0)		
Unstratified odds ratio ^a			2.13	
(95% CI)			(0.60, 7.54)	
p-value			0.2402	
Unstratified risk ratio ^a			1.91	
(95% CI)			(0.64, 5.75)	
p-value			0.2469	
Absolute risk reduction			0.09	
(95% CI)			(-0.05, 0.24)	
p-value			0.2192	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	33/100 (33.0)	10/88 (11.4)		
Unstratified odds ratio ^a			3.84	
(95% CI)			(1.76, 8.37)	
p-value			0.0007	
Unstratified risk ratio ^a			2.90	
(95% CI)			(1.52, 5.55)	
p-value			0.0012	
Absolute risk reduction			0.22	
(95% CI)			(0.10, 0.33)	
p-value			0.0002	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	42	14		0.5129
MRD status: Positive (n/N1 (%))	8/36 (22.2)	2/16 (12.5)		
Unstratified odds ratio ^a			2.00	
(95% CI)			(0.37, 10.70)	
p-value			0.4179	
Unstratified risk ratio ^a			1.78	
(95% CI)			(0.42, 7.45)	
p-value			0.4314	
Absolute risk reduction			0.10	
(95% CI)			(-0.11, 0.31)	
p-value			0.3675	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Table 14-6.10.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Severe (Grade ≥3)) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	34/111 (30.6)	12/112 (10.7)		
Unstratified odds ratio ^a			3.68	
(95% CI)			(1.79, 7.58)	
p-value			0.0004	
Unstratified risk ratio ^a			2.86	
(95% CI)			(1.56, 5.23)	
p-value			0.0006	
Absolute risk reduction			0.20	
(95% CI)			(0.10, 0.30)	
p-value			0.0002	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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Anhang 4-G3.3.4: Subgruppenanalysen zu Expedited UE von besonderem Interesse

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting expedited cytokine release syndrome (EOI) - n (%)	5 (3.4)	0 (0.0)	3.4	
Age group 1:	5	0		-
Age group: <55 years (n/N1 (%))	2/91 (2.2)	0/72 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years (n/N1 (%))	3/56 (5.4)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	5	0		-
Age group: ≥18 - <35 years (n/N1 (%))	0/18 (0.0)	0/18 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	2/73 (2.7)	0/54 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-aei-by-subgrp-s3saf.sas

Output: t14-06-011-ae-sum-exp-aei-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:02:03)

Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	2/44 (4.5)	0/36 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	1/12 (8.3)	0/20 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	5	0		-
Sex: Male (n/N1 (%))	2/68 (2.9)	0/65 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	3/79 (3.8)	0/63 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	5	0		-
Region: USA (n/N1 (%))	5/135 (3.7)	0/115 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	0/12 (0.0)	0/13 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	5	0		-
Race: Caucasian (n/N1 (%))	4/114 (3.5)	0/104 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	1/19 (5.3)	0/8 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	5	0		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	5/122 (4.1)	0/109 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	5	0		-
CD20 status: Positive (n/N1 (%))	3/74 (4.1)	0/70 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	2/72 (2.8)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-ae-si-by-subgrp-s3saf.sas

Output: t14-06-011-001-ae-sum-exp-ae-si-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:02:03)

Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	5	0		-
Rituximab use: Yes (n/N1 (%))	3/43 (7.0)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	2/104 (1.9)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	5	0		-
Allogeneic SCT: Yes (n/N1 (%))	0/47 (0.0)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	5/100 (5.0)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	5	0		-
MRD status: Positive (n/N1 (%))	1/36 (2.8)	0/16 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	4/111 (3.6)	0/112 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting expedited medication errors (EOI) - n (%)	0 (0.0)	0 (0.0)	NA	
Age group 1:	0	0		-
Age group: <55 years (n/N1 (%))	0/91 (0.0)	0/72 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years (n/N1 (%))	0/56 (0.0)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	0	0		-
Age group: ≥18 - <35 years (n/N1 (%))	0/18 (0.0)	0/18 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	0/73 (0.0)	0/54 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	0/44 (0.0)	0/36 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	0/12 (0.0)	0/20 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-ae-si-by-subgrp-s3saf.sas

Output: t14-06-011-001-ae-sum-exp-ae-si-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:02:03)

Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	0	0		-
Sex: Male (n/N1 (%))	0/68 (0.0)	0/65 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-aesi-by-subgrp-s3saf.sas

Output: t14-06-011-001-ae-sum-exp-aesi-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:02:03)

Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	0/79 (0.0)	0/63 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-ae-si-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	0	0		-
Region: USA (n/N1 (%))	0/135 (0.0)	0/115 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	0/12 (0.0)	0/13 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	0	0		-
Race: Caucasian (n/N1 (%))	0/114 (0.0)	0/104 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	0/19 (0.0)	0/8 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	0	0		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	0/122 (0.0)	0/109 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	0	0		-
CD20 status: Positive (n/N1 (%))	0/74 (0.0)	0/70 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	0/72 (0.0)	0/56 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	0	0		-
Rituximab use: Yes (n/N1 (%))	0/43 (0.0)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	0/104 (0.0)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	0	0		-
Allogeneic SCT: Yes (n/N1 (%))	0/47 (0.0)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-aei-by-subgrp-s3saf.sas

Output: t14-06-011-001-ae-sum-exp-aei-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:02:03)

Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	0/100 (0.0)	0/88 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	0	0		-
MRD status: Positive (n/N1 (%))	0/36 (0.0)	0/16 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	0/111 (0.0)	0/112 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting expedited neurological events (EOI) - n (%)	27 (18.4)	2 (1.6)	16.8	
Age group 1:	27	2		0.9362
Age group: <55 years (n/N1 (%))	16/91 (17.6)	1/72 (1.4)		
Unstratified odds ratio ^a			15.15	
(95% CI)			(1.96, 117.21)	
p-value			0.0092	
Unstratified risk ratio ^a			12.66	
(95% CI)			(1.72, 93.21)	
p-value			0.0127	
Absolute risk reduction			0.16	
(95% CI)			(0.08, 0.24)	
p-value			0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years (n/N1 (%))	11/56 (19.6)	1/56 (1.8)		
Unstratified odds ratio ^a			13.44	
(95% CI)			(1.67, 108.12)	
p-value			0.0146	
Unstratified risk ratio ^a			11.00	
(95% CI)			(1.47, 82.37)	
p-value			0.0196	
Absolute risk reduction			0.18	
(95% CI)			(0.07, 0.29)	
p-value			0.0014	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	27	2		-
Age group: ≥18 - <35 years (n/N1 (%))	6/18 (33.3)	1/18 (5.6)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	10/73 (13.7)	0/54 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	7/44 (15.9)	1/36 (2.8)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	4/12 (33.3)	0/20 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	27	2		0.3251
Sex: Male (n/N1 (%))	12/68 (17.6)	0/65 (0.0)		
Unstratified odds ratio ^a			28.97	
(95% CI)			(1.68, 500.16)	
p-value			0.0205	
Unstratified risk ratio ^a			23.91	
(95% CI)			(1.44, 395.80)	
p-value			0.0266	
Absolute risk reduction			0.17	
(95% CI)			(0.08, 0.27)	
p-value			0.0003	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	15/79 (19.0)	2/63 (3.2)		
Unstratified odds ratio ^a			7.15	
(95% CI)			(1.57, 32.57)	
p-value			0.0110	
Unstratified risk ratio ^a			5.98	
(95% CI)			(1.42, 25.19)	
p-value			0.0148	
Absolute risk reduction			0.16	
(95% CI)			(0.06, 0.25)	
p-value			0.0014	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	27	2		-
Region: USA (n/N1 (%))	22/135 (16.3)	2/115 (1.7)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-aei-by-subgrp-s3saf.sas

Output: t14-06-011-001-ae-sum-exp-aei-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:02:03)

Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	5/12 (41.7)	0/13 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	25	2		-
Race: Caucasian (n/N1 (%))	18/114 (15.8)	2/104 (1.9)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	7/19 (36.8)	0/8 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	26	2		-
Ethnicity: Hispanic or Latino (n/N1 (%))	2/19 (10.5)	0/11 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	24/122 (19.7)	2/109 (1.8)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	27	2		-
CD20 status: Positive (n/N1 (%))	20/74 (27.0)	1/70 (1.4)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	7/72 (9.7)	1/56 (1.8)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	27	2		0.2048
Rituximab use: Yes (n/N1 (%))	14/43 (32.6)	0/40 (0.0)		
Unstratified odds ratio ^a			39.79	
(95% CI)			(2.28, 693.56)	
p-value			0.0115	
Unstratified risk ratio ^a			27.02	
(95% CI)			(1.66, 438.60)	
p-value			0.0204	
Absolute risk reduction			0.32	
(95% CI)			(0.17, 0.46)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	13/104 (12.5)	2/88 (2.3)		
Unstratified odds ratio ^a			6.14	
(95% CI)			(1.35, 28.02)	
p-value			0.0191	
Unstratified risk ratio ^a			5.50	
(95% CI)			(1.28, 23.72)	
p-value			0.0222	
Absolute risk reduction			0.10	
(95% CI)			(0.03, 0.17)	
p-value			0.0046	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	27	2		-
Allogeneic SCT: Yes (n/N1 (%))	6/47 (12.8)	0/40 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	21/100 (21.0)	2/88 (2.3)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

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Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	27	2		-
MRD status: Positive (n/N1 (%))	4/36 (11.1)	0/16 (0.0)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-aei-by-subgrp-s3saf.sas

Output: t14-06-011-001-ae-sum-exp-aei-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:02:03)

Source data: adampa.adsl, adampa.adae

Table 14-6.11.1. Subgroup Analysis of Prior Defined Treatment-emergent Adverse Events of Special Interest (Expedited) (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	23/111 (20.7)	2/112 (1.8)		
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NA = Not Applicable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-ae-si-by-subgrp-s3saf.sas

Output: t14-06-011-001-ae-sum-exp-ae-si-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:02:03)

Source data: adampa.adsl, adampa.adae

Anhang 4-G3.3.5: Subgruppenanalysen häufiger UE nach SOC und PT

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting blood and lymphatic system disorders (SOC) - n (%)	92 (62.6)	90 (70.3)	-7.7	
(95% CI)	(54.23, 70.42)	(61.60, 78.06)	(-18.86, 3.40)	
p-value ^a			0.2731	
Number of subjects reporting anaemia (PT) - n (%)	84 (57.1)	73 (57.0)	0.1	
(95% CI)	(48.73, 65.26)	(47.99, 65.74)	(-11.62, 11.84)	
p-value ^a			0.7607	
Number of subjects reporting febrile neutropenia (PT) - n (%)	32 (21.8)	37 (28.9)	-7.1	
(95% CI)	(15.39, 29.32)	(21.24, 37.58)	(-17.44, 3.17)	
p-value ^a			0.2188	
Number of subjects reporting cardiac disorders (SOC) - n (%)	13 (8.8)	6 (4.7)	4.2	
(95% CI)	(4.79, 14.65)	(1.74, 9.92)	(-1.72, 10.03)	
p-value ^a			0.1837	
Number of subjects reporting gastrointestinal disorders (SOC) - n (%)	81 (55.1)	57 (44.5)	10.6	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)	(46.69, 63.31)	(35.75, 53.57)	(-1.21, 22.35)	
p-value ^a			0.0718	
Number of subjects reporting abdominal pain (PT) - n (%)	32 (21.8)	20 (15.6)	6.1	
(95% CI)	(15.39, 29.32)	(9.81, 23.09)	(-3.03, 15.31)	
p-value ^a			0.1927	
Number of subjects reporting constipation (PT) - n (%)	11 (7.5)	1 (0.8)	6.7	
(95% CI)	(3.79, 12.99)	(0.02, 4.28)	(2.18, 11.22)	
p-value ^a			0.0068	
Age group 1:	11	1		-
Age group: <55 years (n/N1 (%))	8/91 (8.8)	0/72 (0.0)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: >=55 years (n/N1 (%))	3/56 (5.4)	1/56 (1.8)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group 2:	11	1		-
Age group: >=18 - <35 years (n/N1 (%))	2/18 (11.1)	0/18 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	6/73 (8.2)	0/54 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: >=55 - <65 years (n/N1 (%))	1/44 (2.3)	1/36 (2.8)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥65 years (n/N1 (%))	2/12 (16.7)	0/20 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Sex:	11	1		-
Sex: Male (n/N1 (%))	5/68 (7.4)	0/65 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Sex: Female (n/N1 (%))	6/79 (7.6)	1/63 (1.6)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region:	11	1		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: USA (n/N1 (%))	8/135 (5.9)	1/115 (0.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	3/12 (25.0)	0/13 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	9	1		-
Race: Caucasian (n/N1 (%))	9/114 (7.9)	1/104 (1.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	0/19 (0.0)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	10	1		-
Ethnicity: Hispanic or Latino (n/N1 (%))	1/19 (5.3)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	9/122 (7.4)	1/109 (0.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	11	1		-
CD20 status: Positive (n/N1 (%))	5/74 (6.8)	1/70 (1.4)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	6/72 (8.3)	0/56 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	11	1		-
Rituximab use: Yes (n/N1 (%))	2/43 (4.7)	1/40 (2.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	9/104 (8.7)	0/88 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	11	1		-
Allogeneic SCT: Yes (n/N1 (%))	3/47 (6.4)	0/40 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	8/100 (8.0)	1/88 (1.1)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	11	1		-
MRD status: Positive (n/N1 (%))	2/36 (5.6)	0/16 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
MRD status: Negative (n/N1 (%))	9/111 (8.1)	1/112 (0.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Number of subjects reporting diarrhoea (PT) - n (%)	49 (33.3)	30 (23.4)	9.9	
(95% CI)	(25.78, 41.57)	(16.41, 31.74)	(-0.68, 20.48)	
p-value ^a			0.0744	
Number of subjects reporting nausea (PT) - n (%)	24 (16.3)	9 (7.0)	9.3	
(95% CI)	(10.75, 23.31)	(3.27, 12.93)	(1.86, 16.73)	
p-value ^a			0.0200	
Age group 1:	24	9		0.3867
Age group: <55 years (n/N1 (%))	16/91 (17.6)	7/72 (9.7)		
Unstratified odds ratio ^c			1.98	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.77, 5.11)	
p-value			0.1577	
Unstratified risk ratio ^c			1.81	
(95% CI)			(0.79, 4.16)	
p-value			0.1631	
Absolute risk reduction			0.08	
(95% CI)			(-0.03, 0.18)	
p-value			0.1382	
Age group: >=55 years (n/N1 (%))	8/56 (14.3)	2/56 (3.6)		
Unstratified odds ratio ^c			4.50	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.91, 22.23)	
p-value			0.0650	
Unstratified risk ratio ^c			4.00	
(95% CI)			(0.89, 18.01)	
p-value			0.0709	
Absolute risk reduction			0.11	
(95% CI)			(0.00, 0.21)	
p-value			0.0429	
Age group 2:	24	9		-
Age group: >=18 - <35 years (n/N1 (%))	5/18 (27.8)	5/18 (27.8)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	11/73 (15.1)	2/54 (3.7)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: >=55 - <65 years (n/N1 (%))	6/44 (13.6)	2/36 (5.6)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥65 years (n/N1 (%))	2/12 (16.7)	0/20 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Sex:	24	9		0.7840
Sex: Male (n/N1 (%))	11/68 (16.2)	5/65 (7.7)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			2.32	
(95% CI)			(0.76, 7.08)	
p-value			0.1408	
Unstratified risk ratio ^c			2.10	
(95% CI)			(0.77, 5.72)	
p-value			0.1455	
Absolute risk reduction			0.08	
(95% CI)			(-0.02, 0.19)	
p-value			0.1267	
Sex: Female (n/N1 (%))	13/79 (16.5)	4/63 (6.3)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			2.91	
(95% CI)			(0.90, 9.40)	
p-value			0.0751	
Unstratified risk ratio ^c			2.59	
(95% CI)			(0.89, 7.56)	
p-value			0.0813	
Absolute risk reduction			0.10	
(95% CI)			(-0.00, 0.20)	
p-value			0.0511	
Region:	24	9		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: USA (n/N1 (%))	19/135 (14.1)	5/115 (4.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	5/12 (41.7)	4/13 (30.8)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	21	9		-
Race: Caucasian (n/N1 (%))	19/114 (16.7)	8/104 (7.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	2/19 (10.5)	1/8 (12.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	22	9		-
Ethnicity: Hispanic or Latino (n/N1 (%))	3/19 (15.8)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	19/122 (15.6)	9/109 (8.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	24	9		0.0704
CD20 status: Positive (n/N1 (%))	15/74 (20.3)	3/70 (4.3)		
Unstratified odds ratio ^c (95% CI)			5.68 (1.57, 20.59)	
p-value			0.0082	
Unstratified risk ratio ^c (95% CI)			4.73 (1.43, 15.64)	
p-value			0.0109	
Absolute risk reduction (95% CI)			0.16 (0.06, 0.26)	
p-value			0.0024	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	9/72 (12.5)	6/56 (10.7)		
Unstratified odds ratio ^c (95% CI) p-value			1.19 (0.40, 3.57) 0.7556	
Unstratified risk ratio ^c (95% CI) p-value			1.17 (0.44, 3.08) 0.7560	
Absolute risk reduction (95% CI) p-value			0.02 (-0.09, 0.13) 0.7533	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	24	9		0.8854
Rituximab use: Yes (n/N1 (%))	8/43 (18.6)	3/40 (7.5)		
Unstratified odds ratio ^c			2.82	
(95% CI)			(0.69, 11.49)	
p-value			0.1483	
Unstratified risk ratio ^c			2.48	
(95% CI)			(0.71, 8.70)	
p-value			0.1560	
Absolute risk reduction			0.11	
(95% CI)			(-0.03, 0.25)	
p-value			0.1256	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	16/104 (15.4)	6/88 (6.8)		
Unstratified odds ratio ^c			2.48	
(95% CI)			(0.93, 6.66)	
p-value			0.0702	
Unstratified risk ratio ^c			2.26	
(95% CI)			(0.92, 5.52)	
p-value			0.0745	
Absolute risk reduction			0.09	
(95% CI)			(-0.00, 0.17)	
p-value			0.0538	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	24	9		0.5246
Allogeneic SCT: Yes (n/N1 (%))	8/47 (17.0)	4/40 (10.0)		
Unstratified odds ratio ^c (95% CI)			1.85 (0.51, 6.66)	
p-value			0.3489	
Unstratified risk ratio ^c (95% CI)			1.70 (0.55, 5.24)	
p-value			0.3536	
Absolute risk reduction (95% CI)			0.07 (-0.07, 0.21)	
p-value			0.3328	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	16/100 (16.0)	5/88 (5.7)		
Unstratified odds ratio ^c			3.16	
(95% CI)			(1.11, 9.03)	
p-value			0.0315	
Unstratified risk ratio ^c			2.82	
(95% CI)			(1.08, 7.37)	
p-value			0.0350	
Absolute risk reduction			0.10	
(95% CI)			(0.02, 0.19)	
p-value			0.0196	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	24	9		-
MRD status: Positive (n/N1 (%))	6/36 (16.7)	1/16 (6.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
MRD status: Negative (n/N1 (%))	18/111 (16.2)	8/112 (7.1)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Number of subjects reporting vomiting (PT) - n (%)	45 (30.6)	30 (23.4)	7.2	
(95% CI)	(23.28, 38.74)	(16.41, 31.74)	(-3.28, 17.63)	
p-value ^a			0.2126	
Number of subjects reporting general disorders and administration site conditions (SOC) - n (%)	44 (29.9)	19 (14.8)	15.1	
(95% CI)	(22.66, 38.03)	(9.18, 22.21)	(5.46, 24.72)	
p-value ^a			0.0036	
Age group 1:	44	19		0.7156
Age group: <55 years (n/N1 (%))	28/91 (30.8)	12/72 (16.7)		
Unstratified odds ratio ^c			2.22	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(1.04, 4.77)	
p-value			0.0403	
Unstratified risk ratio ^c			1.85	
(95% CI)			(1.01, 3.37)	
p-value			0.0457	
Absolute risk reduction			0.14	
(95% CI)			(0.01, 0.27)	
p-value			0.0309	
Age group: ≥55 years (n/N1 (%))	16/56 (28.6)	7/56 (12.5)		
Unstratified odds ratio ^c			2.80	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(1.05, 7.47)	
p-value			0.0398	
Unstratified risk ratio ^c			2.29	
(95% CI)			(1.02, 5.12)	
p-value			0.0447	
Absolute risk reduction			0.16	
(95% CI)			(0.01, 0.31)	
p-value			0.0317	
Age group 2:	44	19		-
Age group: >=18 - <35 years (n/N1 (%))	7/18 (38.9)	6/18 (33.3)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	21/73 (28.8)	6/54 (11.1)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥55 - <65 years (n/N1 (%))	13/44 (29.5)	5/36 (13.9)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥65 years (n/N1 (%))	3/12 (25.0)	2/20 (10.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Sex:	44	19		0.2830
Sex: Male (n/N1 (%))	16/68 (23.5)	10/65 (15.4)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			1.69	
(95% CI)			(0.70, 4.06)	
p-value			0.2394	
Unstratified risk ratio ^c			1.53	
(95% CI)			(0.75, 3.12)	
p-value			0.2430	
Absolute risk reduction			0.08	
(95% CI)			(-0.05, 0.22)	
p-value			0.2323	
Sex: Female (n/N1 (%))	28/79 (35.4)	9/63 (14.3)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			3.29	
(95% CI)			(1.42, 7.65)	
p-value			0.0056	
Unstratified risk ratio ^c			2.48	
(95% CI)			(1.26, 4.87)	
p-value			0.0082	
Absolute risk reduction			0.21	
(95% CI)			(0.08, 0.35)	
p-value			0.0024	
Region:	44	19		0.5185

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: USA (n/N1 (%))	38/135 (28.1)	14/115 (12.2)		
Unstratified odds ratio ^c			2.83	
(95% CI)			(1.44, 5.54)	
p-value			0.0025	
Unstratified risk ratio ^c			2.31	
(95% CI)			(1.32, 4.05)	
p-value			0.0034	
Absolute risk reduction			0.16	
(95% CI)			(0.06, 0.26)	
p-value			0.0012	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	6/12 (50.0)	5/13 (38.5)		
Unstratified odds ratio ^c (95% CI) p-value			1.60 (0.33, 7.85) 0.5624	
Unstratified risk ratio ^c (95% CI) p-value			1.30 (0.53, 3.17) 0.5636	
Absolute risk reduction (95% CI) p-value			0.12 (-0.27, 0.50) 0.5592	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	39	17		0.3369
Race: Caucasian (n/N1 (%))	30/114 (26.3)	16/104 (15.4)		
Unstratified odds ratio ^c			1.96	
(95% CI)			(1.00, 3.86)	
p-value			0.0504	
Unstratified risk ratio ^c			1.71	
(95% CI)			(0.99, 2.95)	
p-value			0.0537	
Absolute risk reduction			0.11	
(95% CI)			(0.00, 0.22)	
p-value			0.0443	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	9/19 (47.4)	1/8 (12.5)		
Unstratified odds ratio ^c			6.30	
(95% CI)			(0.64, 61.63)	
p-value			0.1137	
Unstratified risk ratio ^c			3.79	
(95% CI)			(0.57, 25.18)	
p-value			0.1679	
Absolute risk reduction			0.35	
(95% CI)			(0.03, 0.67)	
p-value			0.0332	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	42	18		-
Ethnicity: Hispanic or Latino (n/N1 (%))	4/19 (21.1)	2/11 (18.2)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	38/122 (31.1)	16/109 (14.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	43	19		0.0020
CD20 status: Positive (n/N1 (%))	28/74 (37.8)	6/70 (8.6)		
Unstratified odds ratio ^c (95% CI)			6.49 (2.49, 16.95)	
p-value			0.0001	
Unstratified risk ratio ^c (95% CI)			4.41 (1.95, 10.01)	
p-value			0.0004	
Absolute risk reduction (95% CI)			0.29 (0.16, 0.42)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	15/72 (20.8)	13/56 (23.2)		
Unstratified odds ratio ^c (95% CI) p-value			0.87 (0.38, 2.02) 0.7466	
Unstratified risk ratio ^c (95% CI) p-value			0.90 (0.47, 1.73) 0.7463	
Absolute risk reduction (95% CI) p-value			-0.02 (-0.17, 0.12) 0.7476	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	44	19		0.1830
Rituximab use: Yes (n/N1 (%))	17/43 (39.5)	5/40 (12.5)		
Unstratified odds ratio ^c			4.58	
(95% CI)			(1.50, 14.01)	
p-value			0.0077	
Unstratified risk ratio ^c			3.16	
(95% CI)			(1.29, 7.77)	
p-value			0.0121	
Absolute risk reduction			0.27	
(95% CI)			(0.09, 0.45)	
p-value			0.0030	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	27/104 (26.0)	14/88 (15.9)		
Unstratified odds ratio ^c			1.85	
(95% CI)			(0.90, 3.81)	
p-value			0.0930	
Unstratified risk ratio ^c			1.63	
(95% CI)			(0.91, 2.91)	
p-value			0.0978	
Absolute risk reduction			0.10	
(95% CI)			(-0.01, 0.21)	
p-value			0.0833	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	44	19		0.0964
Allogeneic SCT: Yes (n/N1 (%))	9/47 (19.1)	7/40 (17.5)		
Unstratified odds ratio ^c (95% CI)			1.12 (0.37, 3.33)	
p-value			0.8432	
Unstratified risk ratio ^c (95% CI)			1.09 (0.45, 2.67)	
p-value			0.8434	
Absolute risk reduction (95% CI)			0.02 (-0.15, 0.18)	
p-value			0.8427	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	35/100 (35.0)	12/88 (13.6)		
Unstratified odds ratio ^c (95% CI)			3.41 (1.64, 7.11)	
p-value			0.0011	
Unstratified risk ratio ^c (95% CI)			2.57 (1.42, 4.63)	
p-value			0.0017	
Absolute risk reduction (95% CI)			0.21 (0.10, 0.33)	
p-value			0.0004	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	44	19		0.2082
MRD status: Positive (n/N1 (%))	7/36 (19.4)	3/16 (18.8)		
Unstratified odds ratio ^c			1.05	
(95% CI)			(0.23, 4.70)	
p-value			0.9535	
Unstratified risk ratio ^c			1.04	
(95% CI)			(0.31, 3.50)	
p-value			0.9533	
Absolute risk reduction			0.01	
(95% CI)			(-0.22, 0.24)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.9530	
MRD status: Negative (n/N1 (%))	37/111 (33.3)	16/112 (14.3)		
Unstratified odds ratio ^c (95% CI)			3.00 (1.55, 5.81)	
p-value			0.0011	
Unstratified risk ratio ^c (95% CI)			2.33 (1.38, 3.94)	
p-value			0.0015	
Absolute risk reduction (95% CI)			0.19 (0.08, 0.30)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0006	
Number of subjects reporting fatigue (PT) - n (%)	23 (15.6)	12 (9.4)	6.3	
(95% CI)	(10.18, 22.55)	(4.94, 15.80)	(-1.47, 14.02)	
p-value ^a			0.1349	
Number of subjects reporting pyrexia (PT) - n (%)	19 (12.9)	6 (4.7)	8.2	
(95% CI)	(7.96, 19.45)	(1.74, 9.92)	(1.69, 14.78)	
p-value ^a			0.0223	
Age group 1:	19	6		-
Age group: <55 years (n/N1 (%))	12/91 (13.2)	5/72 (6.9)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: >=55 years (n/N1 (%))	7/56 (12.5)	1/56 (1.8)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group 2:	19	6		-
Age group: >=18 - <35 years (n/N1 (%))	1/18 (5.6)	3/18 (16.7)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	11/73 (15.1)	2/54 (3.7)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥55 - <65 years (n/N1 (%))	7/44 (15.9)	0/36 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥65 years (n/N1 (%))	0/12 (0.0)	1/20 (5.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Sex:	19	6		0.2644
Sex: Male (n/N1 (%))	7/68 (10.3)	4/65 (6.2)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			1.75	
(95% CI)			(0.49, 6.29)	
p-value			0.3910	
Unstratified risk ratio ^c			1.67	
(95% CI)			(0.51, 5.45)	
p-value			0.3930	
Absolute risk reduction			0.04	
(95% CI)			(-0.05, 0.13)	
p-value			0.3824	
Sex: Female (n/N1 (%))	12/79 (15.2)	2/63 (3.2)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			5.46	
(95% CI)			(1.18, 25.39)	
p-value			0.0303	
Unstratified risk ratio ^c			4.78	
(95% CI)			(1.11, 20.60)	
p-value			0.0356	
Absolute risk reduction			0.12	
(95% CI)			(0.03, 0.21)	
p-value			0.0090	
Region:	19	6		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: USA (n/N1 (%))	18/135 (13.3)	4/115 (3.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	1/12 (8.3)	2/13 (15.4)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	17	5		-
Race: Caucasian (n/N1 (%))	13/114 (11.4)	5/104 (4.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	4/19 (21.1)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	19	5		-
Ethnicity: Hispanic or Latino (n/N1 (%))	2/19 (10.5)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	17/122 (13.9)	5/109 (4.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	19	6		0.4019
CD20 status: Positive (n/N1 (%))	12/74 (16.2)	3/70 (4.3)		
Unstratified odds ratio ^c (95% CI)			4.32 (1.16, 16.04)	
p-value			0.0287	
Unstratified risk ratio ^c (95% CI)			3.78 (1.11, 12.84)	
p-value			0.0328	
Absolute risk reduction (95% CI)			0.12 (0.02, 0.22)	
p-value			0.0153	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	7/72 (9.7)	3/56 (5.4)		
Unstratified odds ratio ^c (95% CI) p-value			1.90 (0.47, 7.72) 0.3680	
Unstratified risk ratio ^c (95% CI) p-value			1.81 (0.49, 6.70) 0.3713	
Absolute risk reduction (95% CI) p-value			0.04 (-0.05, 0.13) 0.3436	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	19	6		0.6606
Rituximab use: Yes (n/N1 (%))	7/43 (16.3)	3/40 (7.5)		
Unstratified odds ratio ^c			2.40	
(95% CI)			(0.57, 10.00)	
p-value			0.2300	
Unstratified risk ratio ^c			2.17	
(95% CI)			(0.60, 7.82)	
p-value			0.2361	
Absolute risk reduction			0.09	
(95% CI)			(-0.05, 0.23)	
p-value			0.2100	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	12/104 (11.5)	3/88 (3.4)		
Unstratified odds ratio ^c			3.69	
(95% CI)			(1.01, 13.54)	
p-value			0.0486	
Unstratified risk ratio ^c			3.38	
(95% CI)			(0.99, 11.61)	
p-value			0.0526	
Absolute risk reduction			0.08	
(95% CI)			(0.01, 0.15)	
p-value			0.0272	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	19	6		-
Allogeneic SCT: Yes (n/N1 (%))	1/47 (2.1)	0/40 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	18/100 (18.0)	6/88 (6.8)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	19	6		-
MRD status: Positive (n/N1 (%))	2/36 (5.6)	0/16 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
MRD status: Negative (n/N1 (%))	17/111 (15.3)	6/112 (5.4)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Number of subjects reporting immune system disorders (SOC) - n (%)	24 (16.3)	4 (3.1)	13.2	
(95% CI)	(10.75, 23.31)	(0.86, 7.81)	(6.51, 19.89)	
p-value ^a			0.0003	
Age group 1:	24	4		0.0757
Age group: <55 years (n/N1 (%))	11/91 (12.1)	4/72 (5.6)		
Unstratified odds ratio ^c			2.34	
(95% CI)			(0.71, 7.68)	
p-value			0.1617	
Unstratified risk ratio ^c			2.18	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.72, 6.55)	
p-value			0.1667	
Absolute risk reduction			0.07	
(95% CI)			(-0.02, 0.15)	
p-value			0.1336	
Age group: >=55 years (n/N1 (%))	13/56 (23.2)	0/56 (0.0)		
Unstratified odds ratio ^c			35.05	
(95% CI)			(2.03, 605.64)	
p-value			0.0144	
Unstratified risk ratio ^c			27.00	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(1.64, 443.43)	
p-value			0.0210	
Absolute risk reduction			0.23	
(95% CI)			(0.12, 0.34)	
p-value			<0.0001	
Age group 2:	24	4		-
Age group: ≥18 - <35 years (n/N1 (%))	1/18 (5.6)	3/18 (16.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	10/73 (13.7)	1/54 (1.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥55 - <65 years (n/N1 (%))	9/44 (20.5)	0/36 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥65 years (n/N1 (%))	4/12 (33.3)	0/20 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Sex:	24	4		-
Sex: Male (n/N1 (%))	7/68 (10.3)	1/65 (1.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Sex: Female (n/N1 (%))	17/79 (21.5)	3/63 (4.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region:	24	4		-
Region: USA (n/N1 (%))	22/135 (16.3)	2/115 (1.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	2/12 (16.7)	2/13 (15.4)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race:	22	4		-
Race: Caucasian (n/N1 (%))	16/114 (14.0)	4/104 (3.8)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	6/19 (31.6)	0/8 (0.0)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity:	23	4		-
Ethnicity: Hispanic or Latino (n/N1 (%))	1/19 (5.3)	0/11 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	22/122 (18.0)	4/109 (3.7)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status:	23	4		0.5186
CD20 status: Positive (n/N1 (%))	14/74 (18.9)	2/70 (2.9)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c (95% CI) p-value			7.93 (1.73, 36.33) 0.0076	
Unstratified risk ratio ^c (95% CI) p-value			6.62 (1.56, 28.09) 0.0104	
Absolute risk reduction (95% CI) p-value			0.16 (0.06, 0.26) 0.0012	
CD20 status: Negative (n/N1 (%))	9/72 (12.5)	2/56 (3.6)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			3.86	
(95% CI)			(0.80, 18.63)	
p-value			0.0929	
Unstratified risk ratio ^c			3.50	
(95% CI)			(0.79, 15.56)	
p-value			0.0998	
Absolute risk reduction			0.09	
(95% CI)			(-0.00, 0.18)	
p-value			0.0533	
Rituximab use:	24	4		0.1364

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: Yes (n/N1 (%))	11/43 (25.6)	0/40 (0.0)		
Unstratified odds ratio ^c			28.66	
(95% CI)			(1.63, 504.73)	
p-value			0.0219	
Unstratified risk ratio ^c			21.43	
(95% CI)			(1.30, 352.18)	
p-value			0.0319	
Absolute risk reduction			0.25	
(95% CI)			(0.12, 0.38)	
p-value			0.0003	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	13/104 (12.5)	4/88 (4.5)		
Unstratified odds ratio ^c			3.00	
(95% CI)			(0.94, 9.56)	
p-value			0.0633	
Unstratified risk ratio ^c			2.75	
(95% CI)			(0.93, 8.13)	
p-value			0.0674	
Absolute risk reduction			0.08	
(95% CI)			(0.00, 0.16)	
p-value			0.0430	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	24	4		-
Allogeneic SCT: Yes (n/N1 (%))	6/47 (12.8)	3/40 (7.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	18/100 (18.0)	1/88 (1.1)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	24	4		-
MRD status: Positive (n/N1 (%))	4/36 (11.1)	0/16 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	20/111 (18.0)	4/112 (3.6)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting cytokine release syndrome (PT) - n (%)	23 (15.6)	0 (0.0)	15.6	
(95% CI)	(10.18, 22.55)	(0.00, 2.84)	(9.77, 21.52)	
p-value ^a			<0.0001	
Age group 1:	23	0		0.7595
Age group: <55 years (n/N1 (%))	10/91 (11.0)	0/72 (0.0)		
Unstratified odds ratio ^c			18.68	
(95% CI)			(1.08, 324.41)	
p-value			0.0444	
Unstratified risk ratio ^c			16.66	
(95% CI)			(0.99, 279.65)	
p-value			0.0506	
Absolute risk reduction			0.11	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.04, 0.17)	
p-value			0.0019	
Age group: >=55 years (n/N1 (%))	13/56 (23.2)	0/56 (0.0)		
Unstratified odds ratio ^c			35.05	
(95% CI)			(2.03, 605.64)	
p-value			0.0144	
Unstratified risk ratio ^c			27.00	
(95% CI)			(1.64, 443.43)	
p-value			0.0210	
Absolute risk reduction			0.23	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference (0.12, 0.34)	Interaction p-value ^b
(95% CI)				
p-value			<0.0001	
Age group 2:	23	0		-
Age group: ≥18 - <35 years (n/N1 (%))	1/18 (5.6)	0/18 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: ≥35 - <55 years (n/N1 (%))	9/73 (12.3)	0/54 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: ≥55 - <65 years (n/N1 (%))	9/44 (20.5)	0/36 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: ≥65 years (n/N1 (%))	4/12 (33.3)	0/20 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Sex:	23	0		-
Sex: Male (n/N1 (%))	6/68 (8.8)	0/65 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Sex: Female (n/N1 (%))	17/79 (21.5)	0/63 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Region:	23	0		-
Region: USA (n/N1 (%))	21/135 (15.6)	0/115 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI)			- -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	2/12 (16.7)	0/13 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Race:	21	0		-
Race: Caucasian (n/N1 (%))	15/114 (13.2)	0/104 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	6/19 (31.6)	0/8 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity:	22	0		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	22/122 (18.0)	0/109 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status:	22	0		-
CD20 status: Positive (n/N1 (%))	13/74 (17.6)	0/70 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status: Negative (n/N1 (%))	9/72 (12.5)	0/56 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Rituximab use:	23	0		0.9300
Rituximab use: Yes (n/N1 (%))	11/43 (25.6)	0/40 (0.0)		
Unstratified odds ratio ^c			28.66	
(95% CI)			(1.63, 504.73)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0219	
Unstratified risk ratio ^c (95% CI)			21.43 (1.30, 352.18)	
p-value			0.0319	
Absolute risk reduction (95% CI)			0.25 (0.12, 0.38)	
p-value			0.0003	
Rituximab use: No (n/N1 (%))	12/104 (11.5)	0/88 (0.0)		
Unstratified odds ratio ^c (95% CI)			23.91 (1.40, 409.84)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0285	
Unstratified risk ratio ^c			21.19	
(95% CI)			(1.27, 352.87)	
p-value			0.0333	
Absolute risk reduction			0.11	
(95% CI)			(0.05, 0.18)	
p-value			0.0005	
Allogeneic SCT:	23	0		-
Allogeneic SCT: Yes (n/N1 (%))	5/47 (10.6)	0/40 (0.0)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	18/100 (18.0)	0/88 (0.0)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	23	0		-
MRD status: Positive (n/N1 (%))	4/36 (11.1)	0/16 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status: Negative (n/N1 (%))	19/111 (17.1)	0/112 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Number of subjects reporting infections and infestations (SOC) - n (%)	51 (34.7)	35 (27.3)	7.4	
(95% CI)	(27.04, 42.98)	(19.84, 35.92)	(-3.55, 18.25)	
p-value ^a			0.1879	
Number of subjects reporting device related infection (PT) - n (%)	15 (10.2)	8 (6.3)	4.0	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI) p-value ^a	(5.82, 16.27)	(2.74, 11.94)	(-2.49, 10.40) 0.2365	
Number of subjects reporting sepsis (PT) - n (%)	15 (10.2)	13 (10.2)	0.0	
(95% CI) p-value ^a	(5.82, 16.27)	(5.52, 16.74)	(-7.12, 7.21) 0.9960	
Number of subjects reporting injury, poisoning and procedural complications (SOC) - n (%)	9 (6.1)	10 (7.8)	-1.7	
(95% CI) p-value ^a	(2.84, 11.30)	(3.81, 13.90)	(-7.74, 4.36) 0.5605	
Number of subjects reporting investigations (SOC) - n (%)	135 (91.8)	124 (96.9)	-5.0	
(95% CI) p-value ^a	(86.17, 95.71)	(92.19, 99.14)	(-10.39, 0.32) 0.1366	
Number of subjects reporting alanine aminotransferase increased (PT) - n (%)	19 (12.9)	10 (7.8)	5.1	
(95% CI) p-value ^a	(7.96, 19.45)	(3.81, 13.90)	(-2.03, 12.26) 0.1754	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting aspartate aminotransferase increased (PT) - n (%)	15 (10.2)	5 (3.9)	6.3	
(95% CI)	(5.82, 16.27)	(1.28, 8.88)	(0.36, 12.23)	
p-value ^a			0.0410	
Age group 1:	15	5		-
Age group: <55 years (n/N1 (%))	11/91 (12.1)	4/72 (5.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: >=55 years (n/N1 (%))	4/56 (7.1)	1/56 (1.8)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group 2: Age group: >=18 - <35 years (n/N1 (%))	15 4/18 (22.2)	5 1/18 (5.6)		-
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI)			- -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	7/73 (9.6)	3/54 (5.6)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥55 - <65 years (n/N1 (%))	2/44 (4.5)	0/36 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥65 years (n/N1 (%))	2/12 (16.7)	1/20 (5.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Sex:	15	5		-
Sex: Male (n/N1 (%))	5/68 (7.4)	2/65 (3.1)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Sex: Female (n/N1 (%))	10/79 (12.7)	3/63 (4.8)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region:	15	5		-
Region: USA (n/N1 (%))	13/135 (9.6)	5/115 (4.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	2/12 (16.7)	0/13 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race:	12	5		-
Race: Caucasian (n/N1 (%))	10/114 (8.8)	5/104 (4.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	2/19 (10.5)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity:	14	5		-
Ethnicity: Hispanic or Latino (n/N1 (%))	3/19 (15.8)	1/11 (9.1)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	11/122 (9.0)	4/109 (3.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status:	15	5		-
CD20 status: Positive (n/N1 (%))	9/74 (12.2)	2/70 (2.9)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status: Negative (n/N1 (%))	6/72 (8.3)	3/56 (5.4)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Rituximab use:	15	5		-
Rituximab use: Yes (n/N1 (%))	4/43 (9.3)	4/40 (10.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Rituximab use: No (n/N1 (%))	11/104 (10.6)	1/88 (1.1)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT:	15	5		-
Allogeneic SCT: Yes (n/N1 (%))	2/47 (4.3)	0/40 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	13/100 (13.0)	5/88 (5.7)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	15	5		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Positive (n/N1 (%))	2/36 (5.6)	0/16 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	13/111 (11.7)	5/112 (4.5)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	
Absolute risk reduction (95% CI) p-value			- - -	
Number of subjects reporting lymphocyte count decreased (PT) - n (%) (95% CI) p-value ^a	44 (29.9) (22.66, 38.03)	37 (28.9) (21.24, 37.58)	1.0 (-9.77, 11.82) 0.8233	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting neutrophil count decreased (PT) - n (%)	129 (87.8)	119 (93.0)	-5.2	
(95% CI)	(81.34, 92.58)	(87.07, 96.73)	(-12.12, 1.69)	
p-value ^a			0.1893	
Number of subjects reporting platelet count decreased (PT) - n (%)	117 (79.6)	107 (83.6)	-4.0	
(95% CI)	(72.17, 85.79)	(76.02, 89.55)	(-13.15, 5.14)	
p-value ^a			0.5677	
Number of subjects reporting white blood cell count decreased (PT) - n (%)	76 (51.7)	82 (64.1)	-12.4	
(95% CI)	(43.32, 60.01)	(55.11, 72.35)	(-23.95, -0.77)	
p-value ^a			0.0497	
Age group 1:	76	82		0.3770
Age group: <55 years (n/N1 (%))	49/91 (53.8)	51/72 (70.8)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			0.48	
(95% CI)			(0.25, 0.92)	
p-value			0.0281	
Unstratified risk ratio ^c			0.76	
(95% CI)			(0.60, 0.97)	
p-value			0.0258	
Absolute risk reduction			-0.17	
(95% CI)			(-0.32, -0.02)	
p-value			0.0232	
Age group: ≥55 years (n/N1 (%))	27/56 (48.2)	31/56 (55.4)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			0.75	
(95% CI)			(0.36, 1.58)	
p-value			0.4498	
Unstratified risk ratio ^c			0.87	
(95% CI)			(0.61, 1.25)	
p-value			0.4509	
Absolute risk reduction			-0.07	
(95% CI)			(-0.26, 0.11)	
p-value			0.4482	
Age group 2:	76	82		0.5200

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥18 - <35 years (n/N1 (%))	12/18 (66.7)	12/18 (66.7)		
Unstratified odds ratio ^c (95% CI) p-value			1.00 (0.25, 4.00) >0.9999	
Unstratified risk ratio ^c (95% CI) p-value			1.00 (0.63, 1.59) >0.9999	
Absolute risk reduction (95% CI) p-value			0.00 (-0.31, 0.31) >0.9999	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	37/73 (50.7)	39/54 (72.2)		
Unstratified odds ratio ^c (95% CI) p-value			0.40 (0.19, 0.84) 0.0155	
Unstratified risk ratio ^c (95% CI) p-value			0.70 (0.53, 0.93) 0.0133	
Absolute risk reduction (95% CI) p-value			-0.22 (-0.38, -0.05) 0.0108	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 - <65 years (n/N1 (%))	22/44 (50.0)	23/36 (63.9)		
Unstratified odds ratio ^c (95% CI) p-value			0.57 (0.23, 1.39) 0.2146	
Unstratified risk ratio ^c (95% CI) p-value			0.78 (0.53, 1.15) 0.2111	
Absolute risk reduction (95% CI) p-value			-0.14 (-0.35, 0.08) 0.2065	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	5/12 (41.7)	8/20 (40.0)		
Unstratified odds ratio ^c (95% CI) p-value			1.07 (0.25, 4.59) 0.9258	
Unstratified risk ratio ^c (95% CI) p-value			1.04 (0.44, 2.46) 0.9257	
Absolute risk reduction (95% CI) p-value			0.02 (-0.34, 0.37) 0.9261	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	76	82		0.3958
Sex: Male (n/N1 (%))	33/68 (48.5)	43/65 (66.2)		
Unstratified odds ratio ^c			0.48	
(95% CI)			(0.24, 0.97)	
p-value			0.0413	
Unstratified risk ratio ^c			0.73	
(95% CI)			(0.54, 0.99)	
p-value			0.0431	
Absolute risk reduction			-0.18	
(95% CI)			(-0.34, -0.01)	
p-value			0.0367	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	43/79 (54.4)	39/63 (61.9)		
Unstratified odds ratio ^c			0.74	
(95% CI)			(0.37, 1.44)	
p-value			0.3709	
Unstratified risk ratio ^c			0.88	
(95% CI)			(0.66, 1.16)	
p-value			0.3672	
Absolute risk reduction			-0.07	
(95% CI)			(-0.24, 0.09)	
p-value			0.3676	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	76	82		0.6620
Region: USA (n/N1 (%))	67/135 (49.6)	72/115 (62.6)		
Unstratified odds ratio ^c			0.59	
(95% CI)			(0.35, 0.98)	
p-value			0.0402	
Unstratified risk ratio ^c			0.79	
(95% CI)			(0.64, 0.99)	
p-value			0.0393	
Absolute risk reduction			-0.13	
(95% CI)			(-0.25, -0.01)	
p-value			0.0374	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	9/12 (75.0)	10/13 (76.9)		
Unstratified odds ratio ^c (95% CI)			0.90 (0.14, 5.65)	
p-value			0.9105	
Unstratified risk ratio ^c (95% CI)			0.98 (0.63, 1.52)	
p-value			0.9106	
Absolute risk reduction (95% CI)			-0.02 (-0.35, 0.32)	
p-value			0.9105	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	68	72		0.4265
Race: Caucasian (n/N1 (%))	58/114 (50.9)	68/104 (65.4)		
Unstratified odds ratio ^c			0.55	
(95% CI)			(0.32, 0.95)	
p-value			0.0310	
Unstratified risk ratio ^c			0.78	
(95% CI)			(0.62, 0.98)	
p-value			0.0312	
Absolute risk reduction			-0.15	
(95% CI)			(-0.27, -0.02)	
p-value			0.0282	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	10/19 (52.6)	4/8 (50.0)		
Unstratified odds ratio ^c			1.11	
(95% CI)			(0.21, 5.80)	
p-value			0.9005	
Unstratified risk ratio ^c			1.05	
(95% CI)			(0.47, 2.38)	
p-value			0.9017	
Absolute risk reduction			0.03	
(95% CI)			(-0.39, 0.44)	
p-value			0.9006	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	72	78		0.8980
Ethnicity: Hispanic or Latino (n/N1 (%))	9/19 (47.4)	7/11 (63.6)		
Unstratified odds ratio ^c			0.51	
(95% CI)			(0.11, 2.36)	
p-value			0.3922	
Unstratified risk ratio ^c			0.74	
(95% CI)			(0.39, 1.43)	
p-value			0.3743	
Absolute risk reduction			-0.16	
(95% CI)			(-0.52, 0.20)	
p-value			0.3787	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	63/122 (51.6)	71/109 (65.1)		
Unstratified odds ratio ^c (95% CI) p-value			0.57 (0.34, 0.97) 0.0387	
Unstratified risk ratio ^c (95% CI) p-value			0.79 (0.64, 0.99) 0.0385	
Absolute risk reduction (95% CI) p-value			-0.13 (-0.26, -0.01) 0.0357	

Page 178 of 394

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	76	81		0.3408
CD20 status: Positive (n/N1 (%))	38/74 (51.4)	48/70 (68.6)		
Unstratified odds ratio ^c (95% CI)			0.48 (0.25, 0.96)	
p-value			0.0364	
Unstratified risk ratio ^c (95% CI)			0.75 (0.57, 0.98)	
p-value			0.0376	
Absolute risk reduction (95% CI)			-0.17 (-0.33, -0.01)	
p-value			0.0321	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	38/72 (52.8)	33/56 (58.9)		
Unstratified odds ratio ^c (95% CI)			0.78 (0.38, 1.58)	
p-value			0.4876	
Unstratified risk ratio ^c (95% CI)			0.90 (0.66, 1.22)	
p-value			0.4846	
Absolute risk reduction (95% CI)			-0.06 (-0.23, 0.11)	
p-value			0.4857	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	76	82		0.7872
Rituximab use: Yes (n/N1 (%))	25/43 (58.1)	27/40 (67.5)		
Unstratified odds ratio ^c			0.67	
(95% CI)			(0.27, 1.64)	
p-value			0.3794	
Unstratified risk ratio ^c			0.86	
(95% CI)			(0.62, 1.20)	
p-value			0.3789	
Absolute risk reduction			-0.09	
(95% CI)			(-0.30, 0.11)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.3752	
Rituximab use: No (n/N1 (%))	51/104 (49.0)	55/88 (62.5)		
Unstratified odds ratio ^c (95% CI)			0.58 (0.32, 1.03)	
p-value			0.0625	
Unstratified risk ratio ^c (95% CI)			0.78 (0.61, 1.01)	
p-value			0.0614	
Absolute risk reduction (95% CI)			-0.13 (-0.27, 0.00)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0586	
Allogeneic SCT:	76	82		0.8234
Allogeneic SCT: Yes (n/N1 (%))	27/47 (57.4)	27/40 (67.5)		
Unstratified odds ratio ^c (95% CI)			0.65 (0.27, 1.57)	
p-value			0.3366	
Unstratified risk ratio ^c (95% CI)			0.85 (0.61, 1.18)	
p-value			0.3334	
Absolute risk reduction			-0.10	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(-0.30, 0.10)	
p-value			0.3308	
Allogeneic SCT: No (n/N1 (%))	49/100 (49.0)	55/88 (62.5)		
Unstratified odds ratio ^c			0.58	
(95% CI)			(0.32, 1.03)	
p-value			0.0641	
Unstratified risk ratio ^c			0.78	
(95% CI)			(0.61, 1.01)	
p-value			0.0637	
Absolute risk reduction			-0.14	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(-0.28, 0.01)	
p-value			0.0603	
MRD status:	76	82		0.6860
MRD status: Positive (n/N1 (%))	14/36 (38.9)	7/16 (43.8)		
Unstratified odds ratio ^c			0.82	
(95% CI)			(0.25, 2.70)	
p-value			0.7418	
Unstratified risk ratio ^c			0.89	
(95% CI)			(0.45, 1.77)	
p-value			0.7380	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.05 (-0.34, 0.24) 0.7430	
MRD status: Negative (n/N1 (%))	62/111 (55.9)	75/112 (67.0)		
Unstratified odds ratio ^c (95% CI) p-value			0.62 (0.36, 1.07) 0.0892	
Unstratified risk ratio ^c (95% CI) p-value			0.83 (0.68, 1.03) 0.0911	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.11 (-0.24, 0.02) 0.0864	
Number of subjects reporting metabolism and nutrition disorders (SOC) - n (%) (95% CI) p-value ^a	40 (27.2) (20.21, 35.16)	30 (23.4) (16.41, 31.74)	3.8 (-6.50, 14.05) 0.3983	
Number of subjects reporting decreased appetite (PT) - n (%) (95% CI) p-value ^a	12 (8.2) (4.29, 13.83)	4 (3.1) (0.86, 7.81)	5.0 (-0.32, 10.39) 0.0515	
Number of subjects reporting hyperglycaemia (PT) - n (%) (95% CI) p-value ^a	20 (13.6) (8.51, 20.23)	12 (9.4) (4.94, 15.80)	4.2 (-3.27, 11.73) 0.2339	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting musculoskeletal and connective tissue disorders (SOC) - n (%)	34 (23.1)	12 (9.4)	13.8	
(95% CI)	(16.58, 30.79)	(4.94, 15.80)	(5.27, 22.24)	
p-value ^a			0.0019	
Age group 1:	34	12		0.0252
Age group: <55 years (n/N1 (%))	23/91 (25.3)	3/72 (4.2)		
Unstratified odds ratio ^c			7.78	
(95% CI)			(2.23, 27.12)	
p-value			0.0013	
Unstratified risk ratio ^c			6.07	
(95% CI)			(1.90, 19.40)	
p-value			0.0024	
Absolute risk reduction			0.21	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.11, 0.31)	
p-value			<0.0001	
Age group: ≥55 years (n/N1 (%))	11/56 (19.6)	9/56 (16.1)		
Unstratified odds ratio ^c			1.28	
(95% CI)			(0.48, 3.37)	
p-value			0.6222	
Unstratified risk ratio ^c			1.22	
(95% CI)			(0.55, 2.72)	
p-value			0.6227	
Absolute risk reduction			0.04	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(-0.11, 0.18)	
p-value			0.6213	
Age group 2:	34	12		-
Age group: ≥18 - <35 years (n/N1 (%))	7/18 (38.9)	3/18 (16.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: ≥35 - <55 years (n/N1 (%))	16/73 (21.9)	0/54 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: ≥55 - <65 years (n/N1 (%))	7/44 (15.9)	5/36 (13.9)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: ≥65 years (n/N1 (%))	4/12 (33.3)	4/20 (20.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Sex:	34	12		0.0097
Sex: Male (n/N1 (%))	10/68 (14.7)	9/65 (13.8)		
Unstratified odds ratio ^c (95% CI) p-value			1.07 (0.41, 2.84) 0.8874	
Unstratified risk ratio ^c (95% CI) p-value			1.06 (0.46, 2.45) 0.8874	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			0.01 (-0.11, 0.13) 0.8873	
Sex: Female (n/N1 (%))	24/79 (30.4)	3/63 (4.8)		
Unstratified odds ratio ^c (95% CI) p-value			8.73 (2.49, 30.61) 0.0007	
Unstratified risk ratio ^c (95% CI) p-value			6.38 (2.01, 20.22) 0.0016	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			0.26 (0.14, 0.37) <0.0001	
Region:	34	12		-
Region: USA (n/N1 (%))	29/135 (21.5)	11/115 (9.6)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI)			- -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	5/12 (41.7)	1/13 (7.7)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Race:	31	12		-
Race: Caucasian (n/N1 (%))	25/114 (21.9)	12/104 (11.5)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	6/19 (31.6)	0/8 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity:	32	12		-
Ethnicity: Hispanic or Latino (n/N1 (%))	5/19 (26.3)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	27/122 (22.1)	12/109 (11.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status:	34	12		0.8254
CD20 status: Positive (n/N1 (%))	17/74 (23.0)	7/70 (10.0)		
Unstratified odds ratio ^c			2.68	
(95% CI)			(1.04, 6.94)	
p-value			0.0417	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			2.30	
(95% CI)			(1.01, 5.20)	
p-value			0.0461	
Absolute risk reduction			0.13	
(95% CI)			(0.01, 0.25)	
p-value			0.0324	
CD20 status: Negative (n/N1 (%))	17/72 (23.6)	5/56 (8.9)		
Unstratified odds ratio ^c			3.15	
(95% CI)			(1.08, 9.17)	
p-value			0.0350	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c (95% CI) p-value			2.64 (1.04, 6.73) 0.0413	
Absolute risk reduction (95% CI) p-value			0.15 (0.02, 0.27) 0.0196	
Rituximab use: Rituximab use: Yes (n/N1 (%))	34 10/43 (23.3)	12 6/40 (15.0)		0.2446
Unstratified odds ratio ^c (95% CI)			1.72 (0.56, 5.26)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.3439	
Unstratified risk ratio ^c			1.55	
(95% CI)			(0.62, 3.87)	
p-value			0.3481	
Absolute risk reduction			0.08	
(95% CI)			(-0.09, 0.25)	
p-value			0.3352	
Rituximab use: No (n/N1 (%))	24/104 (23.1)	6/88 (6.8)		
Unstratified odds ratio ^c			4.10	
(95% CI)			(1.59, 10.56)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0035	
Unstratified risk ratio ^c			3.38	
(95% CI)			(1.45, 7.91)	
p-value			0.0049	
Absolute risk reduction			0.16	
(95% CI)			(0.07, 0.26)	
p-value			0.0010	
Allogeneic SCT:	34	12		-
Allogeneic SCT: Yes (n/N1 (%))	4/47 (8.5)	5/40 (12.5)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	30/100 (30.0)	7/88 (8.0)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	34	12		-
MRD status: Positive (n/N1 (%))	7/36 (19.4)	1/16 (6.3)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status: Negative (n/N1 (%))	27/111 (24.3)	11/112 (9.8)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Number of subjects reporting back pain (PT) - n (%)	14 (9.5)	4 (3.1)	6.4	
(95% CI)	(5.31, 15.46)	(0.86, 7.81)	(0.78, 12.02)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value ^a			0.0280	
Age group 1:	14	4		-
Age group: <55 years (n/N1 (%))	10/91 (11.0)	1/72 (1.4)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 years (n/N1 (%))	4/56 (7.1)	3/56 (5.4)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	14	4		-
Age group: ≥18 - <35 years (n/N1 (%))	4/18 (22.2)	1/18 (5.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	6/73 (8.2)	0/54 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	1/44 (2.3)	2/36 (5.6)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	3/12 (25.0)	1/20 (5.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	14	4		-
Sex: Male (n/N1 (%))	3/68 (4.4)	4/65 (6.2)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	11/79 (13.9)	0/63 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	14	4		-
Region: USA (n/N1 (%))	9/135 (6.7)	3/115 (2.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Region: Rest of the world (n/N1 (%))	5/12 (41.7)	1/13 (7.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Race:	13	4		-
Race: Caucasian (n/N1 (%))	12/114 (10.5)	4/104 (3.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	1/19 (5.3)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Ethnicity:	13	4		-
Ethnicity: Hispanic or Latino (n/N1 (%))	3/19 (15.8)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	10/122 (8.2)	4/109 (3.7)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
CD20 status:	14	4		-
CD20 status: Positive (n/N1 (%))	6/74 (8.1)	3/70 (4.3)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
CD20 status: Negative (n/N1 (%))	8/72 (11.1)	1/56 (1.8)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Rituximab use:	14	4		-
Rituximab use: Yes (n/N1 (%))	4/43 (9.3)	1/40 (2.5)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI)			- -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Rituximab use: No (n/N1 (%))	10/104 (9.6)	3/88 (3.4)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Allogeneic SCT:	14	4		-
Allogeneic SCT: Yes (n/N1 (%))	3/47 (6.4)	2/40 (5.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	11/100 (11.0)	2/88 (2.3)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	14	4		-
MRD status: Positive (n/N1 (%))	3/36 (8.3)	1/16 (6.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status: Negative (n/N1 (%))	11/111 (9.9)	3/112 (2.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Number of subjects reporting pain in extremity (PT) - n (%)	12 (8.2)	0 (0.0)	8.2	
(95% CI)	(4.29, 13.83)	(0.00, 2.84)	(3.74, 12.59)	
p-value ^a			0.0008	
Age group 1:	12	0		-
Age group: <55 years (n/N1 (%))	7/91 (7.7)	0/72 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥55 years (n/N1 (%))	5/56 (8.9)	0/56 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group 2:	12	0		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥ 18 - < 35 years (n/N1 (%))	5/18 (27.8)	0/18 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	2/73 (2.7)	0/54 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	4/44 (9.1)	0/36 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=65 years (n/N1 (%))	1/12 (8.3)	0/20 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	12	0		-
Sex: Male (n/N1 (%))	1/68 (1.5)	0/65 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	11/79 (13.9)	0/63 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	12	0		-
Region: USA (n/N1 (%))	10/135 (7.4)	0/115 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	2/12 (16.7)	0/13 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	11	0		-
Race: Caucasian (n/N1 (%))	8/114 (7.0)	0/104 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	3/19 (15.8)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	12	0		-
Ethnicity: Hispanic or Latino (n/N1 (%))	2/19 (10.5)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	10/122 (8.2)	0/109 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	12	0		-
CD20 status: Positive (n/N1 (%))	6/74 (8.1)	0/70 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	6/72 (8.3)	0/56 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	-
p-value			-	-
Unstratified risk ratio ^c (95% CI)			-	-
p-value			-	-
Absolute risk reduction (95% CI)			-	-
p-value			-	-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	12	0		-
Rituximab use: Yes (n/N1 (%))	4/43 (9.3)	0/40 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Rituximab use: No (n/N1 (%))	8/104 (7.7)	0/88 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Allogeneic SCT:	12	0		-
Allogeneic SCT: Yes (n/N1 (%))	0/47 (0.0)	0/40 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	12/100 (12.0)	0/88 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
MRD status:	12	0		-
MRD status: Positive (n/N1 (%))	2/36 (5.6)	0/16 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
MRD status: Negative (n/N1 (%))	10/111 (9.0)	0/112 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Number of subjects reporting nervous system disorders (SOC) - n (%) (95% CI) p-value ^a	85 (57.8) (49.41, 65.91)	48 (37.5) (29.10, 46.49)	20.3 (8.74, 31.90) 0.0013	
Age group 1: Age group: <55 years (n/N1 (%))	85 60/91 (65.9)	48 30/72 (41.7)		0.3622
Unstratified odds ratio ^c (95% CI) p-value			2.71 (1.43, 5.13) 0.0022	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			1.58	
(95% CI)			(1.16, 2.16)	
p-value			0.0038	
Absolute risk reduction			0.24	
(95% CI)			(0.09, 0.39)	
p-value			0.0015	
Age group: >=55 years (n/N1 (%))	25/56 (44.6)	18/56 (32.1)		
Unstratified odds ratio ^c			1.70	
(95% CI)			(0.79, 3.68)	
p-value			0.1753	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			1.39	
(95% CI)			(0.86, 2.24)	
p-value			0.1793	
Absolute risk reduction			0.13	
(95% CI)			(-0.05, 0.30)	
p-value			0.1703	
Age group 2:	85	48		0.5348
Age group: >=18 - <35 years	14/18 (77.8)	8/18 (44.4)		
(n/N1 (%))				
Unstratified odds ratio ^c			4.37	
(95% CI)			(1.03, 18.63)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0459	
Unstratified risk ratio ^c			1.75	
(95% CI)			(0.99, 3.10)	
p-value			0.0554	
Absolute risk reduction			0.33	
(95% CI)			(0.03, 0.63)	
p-value			0.0290	
Age group: ≥35 - <55 years (n/N1 (%))	46/73 (63.0)	22/54 (40.7)		
Unstratified odds ratio ^c			2.48	
(95% CI)			(1.20, 5.10)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0137	
Unstratified risk ratio ^c			1.55	
(95% CI)			(1.07, 2.23)	
p-value			0.0197	
Absolute risk reduction			0.22	
(95% CI)			(0.05, 0.39)	
p-value			0.0110	
Age group: ≥55 - <65 years (n/N1 (%))	18/44 (40.9)	12/36 (33.3)		
Unstratified odds ratio ^c			1.38	
(95% CI)			(0.55, 3.46)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.4868	
Unstratified risk ratio ^c			1.23	
(95% CI)			(0.69, 2.20)	
p-value			0.4909	
Absolute risk reduction			0.08	
(95% CI)			(-0.14, 0.29)	
p-value			0.4831	
Age group: ≥65 years (n/N1 (%))	7/12 (58.3)	6/20 (30.0)		
Unstratified odds ratio ^c			3.27	
(95% CI)			(0.73, 14.55)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.1205	
Unstratified risk ratio ^c			1.94	
(95% CI)			(0.85, 4.43)	
p-value			0.1131	
Absolute risk reduction			0.28	
(95% CI)			(-0.06, 0.63)	
p-value			0.1062	
Sex:	85	48		0.2350
Sex: Male (n/N1 (%))	36/68 (52.9)	26/65 (40.0)		
Unstratified odds ratio ^c			1.69	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.85, 3.36)	
p-value			0.1359	
Unstratified risk ratio ^c			1.32	
(95% CI)			(0.91, 1.92)	
p-value			0.1404	
Absolute risk reduction			0.13	
(95% CI)			(-0.04, 0.30)	
p-value			0.1313	
Sex: Female (n/N1 (%))	49/79 (62.0)	22/63 (34.9)		
Unstratified odds ratio ^c			3.04	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(1.53, 6.06)	
p-value			0.0015	
Unstratified risk ratio ^c			1.78	
(95% CI)			(1.22, 2.59)	
p-value			0.0029	
Absolute risk reduction			0.27	
(95% CI)			(0.11, 0.43)	
p-value			0.0008	
Region:	85	48		0.1783
Region: USA (n/N1 (%))	75/135 (55.6)	43/115 (37.4)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			2.09	
(95% CI)			(1.26, 3.48)	
p-value			0.0044	
Unstratified risk ratio ^c			1.49	
(95% CI)			(1.12, 1.97)	
p-value			0.0057	
Absolute risk reduction			0.18	
(95% CI)			(0.06, 0.30)	
p-value			0.0035	
Region: Rest of the world (n/N1 (%))	10/12 (83.3)	5/13 (38.5)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			8.00	
(95% CI)			(1.21, 52.69)	
p-value			0.0306	
Unstratified risk ratio ^c			2.17	
(95% CI)			(1.04, 4.51)	
p-value			0.0386	
Absolute risk reduction			0.45	
(95% CI)			(0.11, 0.79)	
p-value			0.0093	
Race:	75	43		0.8531
Race: Caucasian (n/N1 (%))	61/114 (53.5)	38/104 (36.5)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			2.00	
(95% CI)			(1.16, 3.44)	
p-value			0.0124	
Unstratified risk ratio ^c			1.46	
(95% CI)			(1.08, 1.99)	
p-value			0.0144	
Absolute risk reduction			0.17	
(95% CI)			(0.04, 0.30)	
p-value			0.0106	
Race: Others (n/N1 (%))	14/19 (73.7)	5/8 (62.5)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			1.68	
(95% CI)			(0.29, 9.75)	
p-value			0.5630	
Unstratified risk ratio ^c			1.18	
(95% CI)			(0.65, 2.15)	
p-value			0.5909	
Absolute risk reduction			0.11	
(95% CI)			(-0.28, 0.50)	
p-value			0.5736	
Ethnicity:	82	47		0.5841

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Hispanic or Latino (n/N1 (%))	12/19 (63.2)	6/11 (54.5)		
Unstratified odds ratio ^c (95% CI) p-value			1.43 (0.32, 6.46) 0.6432	
Unstratified risk ratio ^c (95% CI) p-value			1.16 (0.61, 2.19) 0.6532	
Absolute risk reduction (95% CI) p-value			0.09 (-0.28, 0.45) 0.6442	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	70/122 (57.4)	41/109 (37.6)		
Unstratified odds ratio ^c (95% CI) p-value			2.23 (1.32, 3.79) 0.0029	
Unstratified risk ratio ^c (95% CI) p-value			1.53 (1.15, 2.03) 0.0038	
Absolute risk reduction (95% CI) p-value			0.20 (0.07, 0.32) 0.0022	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	85	47		0.0228
CD20 status: Positive (n/N1 (%))	47/74 (63.5)	21/70 (30.0)		
Unstratified odds ratio ^c (95% CI)			4.06 (2.02, 8.15)	
p-value			<0.0001	
Unstratified risk ratio ^c (95% CI)			2.12 (1.42, 3.15)	
p-value			0.0002	
Absolute risk reduction (95% CI)			0.34 (0.18, 0.49)	
p-value			<0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	38/72 (52.8)	26/56 (46.4)		
Unstratified odds ratio ^c (95% CI) p-value			1.29 (0.64, 2.60) 0.4763	
Unstratified risk ratio ^c (95% CI) p-value			1.14 (0.80, 1.62) 0.4807	
Absolute risk reduction (95% CI) p-value			0.06 (-0.11, 0.24) 0.4751	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	85	48		0.1626
Rituximab use: Yes (n/N1 (%))	27/43 (62.8)	12/40 (30.0)		
Unstratified odds ratio ^c			3.94	
(95% CI)			(1.57, 9.84)	
p-value			0.0034	
Unstratified risk ratio ^c			2.09	
(95% CI)			(1.24, 3.54)	
p-value			0.0060	
Absolute risk reduction			0.33	
(95% CI)			(0.13, 0.53)	
p-value			0.0015	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	58/104 (55.8)	36/88 (40.9)		
Unstratified odds ratio ^c			1.82	
(95% CI)			(1.03, 3.24)	
p-value			0.0409	
Unstratified risk ratio ^c			1.36	
(95% CI)			(1.01, 1.85)	
p-value			0.0457	
Absolute risk reduction			0.15	
(95% CI)			(0.01, 0.29)	
p-value			0.0378	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	85	48		0.5225
Allogeneic SCT: Yes (n/N1 (%))	22/47 (46.8)	13/40 (32.5)		
Unstratified odds ratio ^c (95% CI)			1.83 (0.76, 4.39)	
p-value			0.1769	
Unstratified risk ratio ^c (95% CI)			1.44 (0.84, 2.47)	
p-value			0.1860	
Absolute risk reduction (95% CI)			0.14 (-0.06, 0.35)	
p-value			0.1682	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	63/100 (63.0)	35/88 (39.8)		
Unstratified odds ratio ^c (95% CI) p-value			2.58 (1.43, 4.65) 0.0016	
Unstratified risk ratio ^c (95% CI) p-value			1.58 (1.18, 2.13) 0.0025	
Absolute risk reduction (95% CI) p-value			0.23 (0.09, 0.37) 0.0011	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	85	48		0.3981
MRD status: Positive (n/N1 (%))	17/36 (47.2)	6/16 (37.5)		
Unstratified odds ratio ^c (95% CI)			1.49 (0.45, 4.98)	
p-value			0.5158	
Unstratified risk ratio ^c (95% CI)			1.26 (0.61, 2.59)	
p-value			0.5307	
Absolute risk reduction (95% CI)			0.10 (-0.19, 0.39)	
p-value			0.5080	

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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	68/111 (61.3)	42/112 (37.5)		
Unstratified odds ratio ^c (95% CI) p-value			2.64 (1.54, 4.53) 0.0004	
Unstratified risk ratio ^c (95% CI) p-value			1.63 (1.23, 2.16) 0.0006	
Absolute risk reduction (95% CI) p-value			0.24 (0.11, 0.37) 0.0003	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting headache (PT) - n (%) (95% CI) p-value ^a	61 (41.5) (33.44, 49.91)	42 (32.8) (24.78, 41.67)	8.7 (-2.70, 20.07) 0.1460	
Number of subjects reporting peripheral sensory neuropathy (PT) - n (%) (95% CI) p-value ^a	11 (7.5) (3.79, 12.99)	5 (3.9) (1.28, 8.88)	3.6 (-1.84, 8.99) 0.1889	
Number of subjects reporting tremor (PT) - n (%) (95% CI) p-value ^a	30 (20.4) (14.21, 27.83)	5 (3.9) (1.28, 8.88)	16.5 (9.17, 23.83) <0.0001	
Age group 1: Age group: <55 years (n/N1 (%))	30 20/91 (22.0)	5 2/72 (2.8)		0.3581

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			9.86	
(95% CI)			(2.22, 43.76)	
p-value			0.0026	
Unstratified risk ratio ^c			7.91	
(95% CI)			(1.91, 32.74)	
p-value			0.0043	
Absolute risk reduction			0.19	
(95% CI)			(0.10, 0.29)	
p-value			<0.0001	
Age group: ≥55 years (n/N1 (%))	10/56 (17.9)	3/56 (5.4)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			3.84	
(95% CI)			(1.00, 14.80)	
p-value			0.0506	
Unstratified risk ratio ^c			3.33	
(95% CI)			(0.97, 11.47)	
p-value			0.0562	
Absolute risk reduction			0.13	
(95% CI)			(0.01, 0.24)	
p-value			0.0353	
Age group 2:	30	5		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥ 18 - < 35 years (n/N1 (%))	6/18 (33.3)	1/18 (5.6)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	
Absolute risk reduction (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	14/73 (19.2)	1/54 (1.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 - <65 years (n/N1 (%))	7/44 (15.9)	2/36 (5.6)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=65 years (n/N1 (%))	3/12 (25.0)	1/20 (5.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	30	5		0.6406
Sex: Male (n/N1 (%))	14/68 (20.6)	2/65 (3.1)		
Unstratified odds ratio ^c			8.17	
(95% CI)			(1.78, 37.54)	
p-value			0.0070	
Unstratified risk ratio ^c			6.69	
(95% CI)			(1.58, 28.30)	
p-value			0.0098	
Absolute risk reduction			0.18	
(95% CI)			(0.07, 0.28)	
p-value			0.0011	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	16/79 (20.3)	3/63 (4.8)		
Unstratified odds ratio ^c			5.08	
(95% CI)			(1.41, 18.32)	
p-value			0.0130	
Unstratified risk ratio ^c			4.25	
(95% CI)			(1.30, 13.95)	
p-value			0.0169	
Absolute risk reduction			0.15	
(95% CI)			(0.05, 0.26)	
p-value			0.0032	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	30	5		-
Region: USA (n/N1 (%))	26/135 (19.3)	4/115 (3.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	4/12 (33.3)	1/13 (7.7)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	28	3		-
Race: Caucasian (n/N1 (%))	20/114 (17.5)	2/104 (1.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	8/19 (42.1)	1/8 (12.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	30	5		-
Ethnicity: Hispanic or Latino (n/N1 (%))	3/19 (15.8)	2/11 (18.2)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	27/122 (22.1)	3/109 (2.8)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	30	5		0.9116
CD20 status: Positive (n/N1 (%))	17/74 (23.0)	3/70 (4.3)		
Unstratified odds ratio ^c			6.66	
(95% CI)			(1.86, 23.89)	
p-value			0.0036	
Unstratified risk ratio ^c			5.36	
(95% CI)			(1.64, 17.50)	
p-value			0.0054	
Absolute risk reduction			0.19	
(95% CI)			(0.08, 0.29)	
p-value			0.0006	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	13/72 (18.1)	2/56 (3.6)		
Unstratified odds ratio ^c			5.95	
(95% CI)			(1.28, 27.58)	
p-value			0.0227	
Unstratified risk ratio ^c			5.06	
(95% CI)			(1.19, 21.49)	
p-value			0.0282	
Absolute risk reduction			0.14	
(95% CI)			(0.04, 0.25)	
p-value			0.0051	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	30	5		0.1724
Rituximab use: Yes (n/N1 (%))	11/43 (25.6)	0/40 (0.0)		
Unstratified odds ratio ^c			28.66	
(95% CI)			(1.63, 504.73)	
p-value			0.0219	
Unstratified risk ratio ^c			21.43	
(95% CI)			(1.30, 352.18)	
p-value			0.0319	
Absolute risk reduction			0.25	
(95% CI)			(0.12, 0.38)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0003	
Rituximab use: No (n/N1 (%))	19/104 (18.3)	5/88 (5.7)		
Unstratified odds ratio ^c (95% CI)			3.71 (1.32, 10.40)	
p-value			0.0126	
Unstratified risk ratio ^c (95% CI)			3.22 (1.25, 8.26)	
p-value			0.0152	
Absolute risk reduction (95% CI)			0.13 (0.04, 0.21)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0054	
Allogeneic SCT:	30	5		-
Allogeneic SCT: Yes (n/N1 (%))	6/47 (12.8)	3/40 (7.5)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	24/100 (24.0)	2/88 (2.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
MRD status:	30	5		-
MRD status: Positive (n/N1 (%))	4/36 (11.1)	0/16 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
MRD status: Negative (n/N1 (%))	26/111 (23.4)	5/112 (4.5)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Number of subjects reporting psychiatric disorders (SOC) - n (%) (95% CI) p-value ^a	27 (18.4) (12.47, 25.59)	7 (5.5) (2.23, 10.94)	12.9 (5.50, 20.29) 0.0020	
Age group 1: Age group: <55 years (n/N1 (%))	27 20/91 (22.0)	7 5/72 (6.9)		-
Unstratified odds ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: >=55 years (n/N1 (%))	7/56 (12.5)	2/56 (3.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group 2:	27	7		-
Age group: >=18 - <35 years (n/N1 (%))	7/18 (38.9)	3/18 (16.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	13/73 (17.8)	2/54 (3.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥55 - <65 years (n/N1 (%))	5/44 (11.4)	2/36 (5.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥65 years (n/N1 (%))	2/12 (16.7)	0/20 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Sex:	27	7		0.2081
Sex: Male (n/N1 (%))	11/68 (16.2)	5/65 (7.7)		
Unstratified odds ratio ^c			2.32	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.76, 7.08)	
p-value			0.1408	
Unstratified risk ratio ^c			2.10	
(95% CI)			(0.77, 5.72)	
p-value			0.1455	
Absolute risk reduction			0.08	
(95% CI)			(-0.02, 0.19)	
p-value			0.1267	
Sex: Female (n/N1 (%))	16/79 (20.3)	2/63 (3.2)		
Unstratified odds ratio ^c			7.75	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(1.71, 35.12)	
p-value			0.0079	
Unstratified risk ratio ^c			6.38	
(95% CI)			(1.52, 26.72)	
p-value			0.0112	
Absolute risk reduction			0.17	
(95% CI)			(0.07, 0.27)	
p-value			0.0007	
Region:	27	7		-
Region: USA (n/N1 (%))	22/135 (16.3)	5/115 (4.3)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	5/12 (41.7)	2/13 (15.4)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race:	24	7		-
Race: Caucasian (n/N1 (%))	20/114 (17.5)	7/104 (6.7)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	4/19 (21.1)	0/8 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity:	26	7		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Hispanic or Latino (n/N1 (%))	3/19 (15.8)	0/11 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	23/122 (18.9)	7/109 (6.4)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	27	7		0.1318
CD20 status: Positive (n/N1 (%))	15/74 (20.3)	2/70 (2.9)		
Unstratified odds ratio ^c			8.64	
(95% CI)			(1.90, 39.36)	
p-value			0.0053	
Unstratified risk ratio ^c			7.09	
(95% CI)			(1.68, 29.91)	
p-value			0.0076	
Absolute risk reduction			0.17	
(95% CI)			(0.07, 0.27)	
p-value			0.0006	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	12/72 (16.7)	5/56 (8.9)		
Unstratified odds ratio ^c (95% CI) p-value			2.04 (0.67, 6.18) 0.2073	
Unstratified risk ratio ^c (95% CI) p-value			1.87 (0.70, 4.99) 0.2134	
Absolute risk reduction (95% CI) p-value			0.08 (-0.04, 0.19) 0.1833	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	27	7		0.4245
Rituximab use: Yes (n/N1 (%))	11/43 (25.6)	2/40 (5.0)		
Unstratified odds ratio ^c			6.53	
(95% CI)			(1.35, 31.66)	
p-value			0.0198	
Unstratified risk ratio ^c			5.12	
(95% CI)			(1.21, 21.68)	
p-value			0.0267	
Absolute risk reduction			0.21	
(95% CI)			(0.06, 0.35)	
p-value			0.0060	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	16/104 (15.4)	5/88 (5.7)		
Unstratified odds ratio ^c			3.02	
(95% CI)			(1.06, 8.61)	
p-value			0.0388	
Unstratified risk ratio ^c			2.71	
(95% CI)			(1.03, 7.09)	
p-value			0.0427	
Absolute risk reduction			0.10	
(95% CI)			(0.01, 0.18)	
p-value			0.0245	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	27	7		-
Allogeneic SCT: Yes (n/N1 (%))	6/47 (12.8)	3/40 (7.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	21/100 (21.0)	4/88 (4.5)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	27	7		-
MRD status: Positive (n/N1 (%))	7/36 (19.4)	0/16 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	20/111 (18.0)	7/112 (6.3)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting insomnia (PT) - n (%)	11 (7.5)	2 (1.6)	5.9	
(95% CI)	(3.79, 12.99)	(0.19, 5.53)	(1.16, 10.69)	
p-value ^a			0.0221	
Age group 1:	11	2		-
Age group: <55 years (n/N1 (%))	9/91 (9.9)	1/72 (1.4)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: >=55 years (n/N1 (%))	2/56 (3.6)	1/56 (1.8)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group 2: Age group: ≥18 - <35 years (n/N1 (%))	11 3/18 (16.7)	2 1/18 (5.6)		-
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI)			- -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	6/73 (8.2)	0/54 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥55 - <65 years (n/N1 (%))	2/44 (4.5)	1/36 (2.8)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥65 years (n/N1 (%))	0/12 (0.0)	0/20 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Sex:	11	2		-
Sex: Male (n/N1 (%))	6/68 (8.8)	2/65 (3.1)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Sex: Female (n/N1 (%))	5/79 (6.3)	0/63 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region:	11	2		-
Region: USA (n/N1 (%))	9/135 (6.7)	1/115 (0.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	2/12 (16.7)	1/13 (7.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race:	10	2		-
Race: Caucasian (n/N1 (%))	9/114 (7.9)	2/104 (1.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	1/19 (5.3)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity:	11	2		-
Ethnicity: Hispanic or Latino (n/N1 (%))	1/19 (5.3)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	10/122 (8.2)	2/109 (1.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status:	11	2		-
CD20 status: Positive (n/N1 (%))	6/74 (8.1)	1/70 (1.4)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status: Negative (n/N1 (%))	5/72 (6.9)	1/56 (1.8)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Rituximab use:	11	2		-
Rituximab use: Yes (n/N1 (%))	3/43 (7.0)	0/40 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Rituximab use: No (n/N1 (%))	8/104 (7.7)	2/88 (2.3)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT:	11	2		-
Allogeneic SCT: Yes (n/N1 (%))	1/47 (2.1)	1/40 (2.5)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	10/100 (10.0)	1/88 (1.1)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	11	2		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Positive (n/N1 (%))	2/36 (5.6)	0/16 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	9/111 (8.1)	2/112 (1.8)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	
Absolute risk reduction (95% CI) p-value			- - -	
Number of subjects reporting renal and urinary disorders (SOC) - n (%) (95% CI) p-value ^a	13 (8.8) (4.79, 14.65)	8 (6.3) (2.74, 11.94)	2.6 (-3.62, 8.81) 0.3747	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting respiratory, thoracic and mediastinal disorders (SOC) - n (%)	24 (16.3)	13 (10.2)	6.2	
(95% CI)	(10.75, 23.31)	(5.52, 16.74)	(-1.77, 14.11)	
p-value ^a			0.1203	
Number of subjects reporting skin and subcutaneous tissue disorders (SOC) - n (%)	14 (9.5)	9 (7.0)	2.5	
(95% CI)	(5.31, 15.46)	(3.27, 12.93)	(-4.00, 8.98)	
p-value ^a			0.3552	
Number of subjects reporting vascular disorders (SOC) - n (%)	39 (26.5)	17 (13.3)	13.2	
(95% CI)	(19.60, 34.44)	(7.93, 20.41)	(4.00, 22.50)	
p-value ^a			0.0055	
Age group 1:	39	17		0.6647
Age group: <55 years (n/N1 (%))	25/91 (27.5)	9/72 (12.5)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			2.65	
(95% CI)			(1.15, 6.12)	
p-value			0.0223	
Unstratified risk ratio ^c			2.20	
(95% CI)			(1.10, 4.41)	
p-value			0.0267	
Absolute risk reduction			0.15	
(95% CI)			(0.03, 0.27)	
p-value			0.0139	
Age group: ≥55 years (n/N1 (%))	14/56 (25.0)	8/56 (14.3)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			2.00	
(95% CI)			(0.76, 5.24)	
p-value			0.1580	
Unstratified risk ratio ^c			1.75	
(95% CI)			(0.80, 3.84)	
p-value			0.1627	
Absolute risk reduction			0.11	
(95% CI)			(-0.04, 0.25)	
p-value			0.1498	
Age group 2:	39	17		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥ 18 - < 35 years (n/N1 (%))	9/18 (50.0)	4/18 (22.2)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	16/73 (21.9)	5/54 (9.3)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 - <65 years (n/N1 (%))	10/44 (22.7)	5/36 (13.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	4/12 (33.3)	3/20 (15.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	39	17		0.0239
Sex: Male (n/N1 (%))	14/68 (20.6)	12/65 (18.5)		
Unstratified odds ratio ^c			1.15	
(95% CI)			(0.48, 2.70)	
p-value			0.7573	
Unstratified risk ratio ^c			1.12	
(95% CI)			(0.56, 2.23)	
p-value			0.7575	
Absolute risk reduction			0.02	
(95% CI)			(-0.11, 0.16)	
p-value			0.7569	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	25/79 (31.6)	5/63 (7.9)		
Unstratified odds ratio ^c			5.37	
(95% CI)			(1.92, 15.03)	
p-value			0.0014	
Unstratified risk ratio ^c			3.99	
(95% CI)			(1.62, 9.82)	
p-value			0.0026	
Absolute risk reduction			0.24	
(95% CI)			(0.11, 0.36)	
p-value			0.0001	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	39	17		-
Region: USA (n/N1 (%))	34/135 (25.2)	13/115 (11.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	5/12 (41.7)	4/13 (30.8)		
Unstratified odds ratio ^c (95% CI)			-	-
p-value			-	-
Unstratified risk ratio ^c (95% CI)			-	-
p-value			-	-
Absolute risk reduction (95% CI)			-	-
p-value			-	-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	35	15		-
Race: Caucasian (n/N1 (%))	31/114 (27.2)	14/104 (13.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	4/19 (21.1)	1/8 (12.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	37	16		-
Ethnicity: Hispanic or Latino (n/N1 (%))	4/19 (21.1)	1/11 (9.1)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	33/122 (27.0)	15/109 (13.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	39	17		0.0327
CD20 status: Positive (n/N1 (%))	23/74 (31.1)	6/70 (8.6)		
Unstratified odds ratio ^c (95% CI)			4.81 (1.82, 12.70)	
p-value			0.0015	
Unstratified risk ratio ^c (95% CI)			3.63 (1.57, 8.37)	
p-value			0.0026	
Absolute risk reduction (95% CI)			0.23 (0.10, 0.35)	
p-value			0.0004	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	16/72 (22.2)	11/56 (19.6)		
Unstratified odds ratio ^c (95% CI) p-value			1.17 (0.49, 2.77) 0.7228	
Unstratified risk ratio ^c (95% CI) p-value			1.13 (0.57, 2.24) 0.7235	
Absolute risk reduction (95% CI) p-value			0.03 (-0.12, 0.17) 0.7211	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	39	17		0.7764
Rituximab use: Yes (n/N1 (%))	12/43 (27.9)	5/40 (12.5)		
Unstratified odds ratio ^c			2.71	
(95% CI)			(0.86, 8.56)	
p-value			0.0893	
Unstratified risk ratio ^c			2.23	
(95% CI)			(0.86, 5.77)	
p-value			0.0976	
Absolute risk reduction			0.15	
(95% CI)			(-0.01, 0.32)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0735	
Rituximab use: No (n/N1 (%))	27/104 (26.0)	12/88 (13.6)		
Unstratified odds ratio ^c (95% CI)			2.22 (1.05, 4.70)	
p-value			0.0371	
Unstratified risk ratio ^c (95% CI)			1.90 (1.03, 3.53)	
p-value			0.0411	
Absolute risk reduction (95% CI)			0.12 (0.01, 0.23)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0290	
Allogeneic SCT:	39	17		0.0764
Allogeneic SCT: Yes (n/N1 (%))	5/47 (10.6)	5/40 (12.5)		
Unstratified odds ratio ^c (95% CI)			0.83 (0.22, 3.11)	
p-value			0.7863	
Unstratified risk ratio ^c (95% CI)			0.85 (0.27, 2.73)	
p-value			0.7863	
Absolute risk reduction			-0.02	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(-0.15, 0.12)	
p-value			0.7872	
Allogeneic SCT: No (n/N1 (%))	34/100 (34.0)	12/88 (13.6)		
Unstratified odds ratio ^c			3.26	
(95% CI)			(1.56, 6.81)	
p-value			0.0016	
Unstratified risk ratio ^c			2.49	
(95% CI)			(1.38, 4.51)	
p-value			0.0025	
Absolute risk reduction			0.20	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference (0.09, 0.32)	Interaction p-value ^b
(95% CI)				
p-value			0.0007	
MRD status:	39	17		-
MRD status: Positive (n/N1 (%))	5/36 (13.9)	1/16 (6.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
MRD status: Negative (n/N1 (%))	34/111 (30.6)	16/112 (14.3)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Number of subjects reporting embolism (PT) - n (%) (95% CI) p-value ^a	15 (10.2) (5.82, 16.27)	8 (6.3) (2.74, 11.94)	4.0 (-2.49, 10.40) 0.2309	
Number of subjects reporting hypertension (PT) - n (%) (95% CI) p-value ^a	16 (10.9) (6.35, 17.07)	6 (4.7) (1.74, 9.92)	6.2 (-0.03, 12.42) 0.0422	
Age group 1: Age group: <55 years (n/N1 (%))	16 9/91 (9.9)	6 3/72 (4.2)		0.9999

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			2.52	
(95% CI)			(0.66, 9.69)	
p-value			0.1773	
Unstratified risk ratio ^c			2.37	
(95% CI)			(0.67, 8.45)	
p-value			0.1820	
Absolute risk reduction			0.06	
(95% CI)			(-0.02, 0.13)	
p-value			0.1439	
Age group: >=55 years (n/N1 (%))	7/56 (12.5)	3/56 (5.4)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			2.52	
(95% CI)			(0.62, 10.31)	
p-value			0.1972	
Unstratified risk ratio ^c			2.33	
(95% CI)			(0.64, 8.57)	
p-value			0.2017	
Absolute risk reduction			0.07	
(95% CI)			(-0.03, 0.18)	
p-value			0.1816	
Age group 2:	16	6		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥18 - <35 years (n/N1 (%))	4/18 (22.2)	2/18 (11.1)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=35 - <55 years (n/N1 (%))	5/73 (6.8)	1/54 (1.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 - <65 years (n/N1 (%))	4/44 (9.1)	3/36 (8.3)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=65 years (n/N1 (%))	3/12 (25.0)	0/20 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	16	6		0.1541
Sex: Male (n/N1 (%))	7/68 (10.3)	5/65 (7.7)		
Unstratified odds ratio ^c			1.38	
(95% CI)			(0.41, 4.58)	
p-value			0.6018	
Unstratified risk ratio ^c			1.34	
(95% CI)			(0.45, 4.00)	
p-value			0.6024	
Absolute risk reduction			0.03	
(95% CI)			(-0.07, 0.12)	
p-value			0.5992	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	9/79 (11.4)	1/63 (1.6)		
Unstratified odds ratio ^c			7.97	
(95% CI)			(0.98, 64.69)	
p-value			0.0520	
Unstratified risk ratio ^c			7.18	
(95% CI)			(0.93, 55.16)	
p-value			0.0582	
Absolute risk reduction			0.10	
(95% CI)			(0.02, 0.17)	
p-value			0.0121	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	16	6		-
Region: USA (n/N1 (%))	14/135 (10.4)	4/115 (3.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	2/12 (16.7)	2/13 (15.4)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	15	6		-
Race: Caucasian (n/N1 (%))	14/114 (12.3)	5/104 (4.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	1/19 (5.3)	1/8 (12.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	16	6		-
Ethnicity: Hispanic or Latino (n/N1 (%))	3/19 (15.8)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	13/122 (10.7)	6/109 (5.5)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	16	6		0.1484
CD20 status: Positive (n/N1 (%))	10/74 (13.5)	2/70 (2.9)		
Unstratified odds ratio ^c			5.31	
(95% CI)			(1.12, 25.18)	
p-value			0.0354	
Unstratified risk ratio ^c			4.73	
(95% CI)			(1.07, 20.83)	
p-value			0.0400	
Absolute risk reduction			0.11	
(95% CI)			(0.02, 0.19)	
p-value			0.0165	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	6/72 (8.3)	4/56 (7.1)		
Unstratified odds ratio ^c (95% CI)			1.18 (0.32, 4.41)	
p-value			0.8036	
Unstratified risk ratio ^c (95% CI)			1.17 (0.35, 3.94)	
p-value			0.8038	
Absolute risk reduction (95% CI)			0.01 (-0.08, 0.10)	
p-value			0.8016	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	16	6		-
Rituximab use: Yes (n/N1 (%))	4/43 (9.3)	0/40 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Rituximab use: No (n/N1 (%))	12/104 (11.5)	6/88 (6.8)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Allogeneic SCT:	16	6		-
Allogeneic SCT: Yes (n/N1 (%))	2/47 (4.3)	2/40 (5.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	14/100 (14.0)	4/88 (4.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
MRD status:	16	6		-
MRD status: Positive (n/N1 (%))	2/36 (5.6)	1/16 (6.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
MRD status: Negative (n/N1 (%))	14/111 (12.6)	5/112 (4.5)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-006-001-ae-sum-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 25NOV2025:03:21)

Source data: adampa.adsl, adampa.adae

Table 14-6.6.1. Subgroup Analysis of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Number of subjects reporting hypotension (PT) - n (%) (95% CI) p-value ^a	12 (8.2) (4.29, 13.83)	5 (3.9) (1.28, 8.88)	4.3 (-1.30, 9.81) 0.1603	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-by-soc-pt-by-subgrp-s3saf.sas

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Source data: adampa.adsl, adampa.adae

Anhang 4-G3.3.6: Subgruppenanalysen häufiger schwerer UE nach SOC und PT

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting grade 3 and above blood and lymphatic system disorders (SOC) - n (%)	58 (39.5)	73 (57.0)	-17.6	
(95% CI)	(31.50, 47.84)	(47.99, 65.74)	(-29.24, -5.91)	
p-value ^a			0.0033	
Age group 1:	58	73		0.4429
Age group: <55 years (n/N1 (%))	39/91 (42.9)	41/72 (56.9)		
Unstratified odds ratio ^c			0.57	
(95% CI)			(0.30, 1.06)	
p-value			0.0750	
Unstratified risk ratio ^c			0.75	
(95% CI)			(0.55, 1.03)	
p-value			0.0731	
Absolute risk reduction			-0.14	
(95% CI)			(-0.29, 0.01)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0712	
Age group: ≥ 55 years (n/N1 (%))	19/56 (33.9)	32/56 (57.1)		
Unstratified odds ratio ^c (95% CI)			0.39 (0.18, 0.83)	
p-value			0.0146	
Unstratified risk ratio ^c (95% CI)			0.59 (0.39, 0.91)	
p-value			0.0175	
Absolute risk reduction (95% CI)			-0.23 (-0.41, -0.05)	
p-value			0.0112	
Age group 2:	58	73		0.3936
Age group: ≥ 18 - < 35 years (n/N1 (%))	10/18 (55.6)	9/18 (50.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated:

24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			1.25	
(95% CI)			(0.34, 4.64)	
p-value			0.7386	
Unstratified risk ratio ^c			1.11	
(95% CI)			(0.60, 2.07)	
p-value			0.7390	
Absolute risk reduction			0.06	
(95% CI)			(-0.27, 0.38)	
p-value			0.7381	
Age group: ≥ 35 - < 55 years (n/N1 (%))	29/73 (39.7)	32/54 (59.3)		
Unstratified odds ratio ^c			0.45	
(95% CI)			(0.22, 0.93)	
p-value			0.0305	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c (95% CI) p-value			0.67 (0.47, 0.96) 0.0289	
Absolute risk reduction (95% CI) p-value			-0.20 (-0.37, -0.02) 0.0265	
Age group: ≥ 55 - < 65 years (n/N1 (%))	16/44 (36.4)	20/36 (55.6)		
Unstratified odds ratio ^c (95% CI) p-value			0.46 (0.19, 1.12) 0.0882	
Unstratified risk ratio ^c (95% CI) p-value			0.65 (0.40, 1.07) 0.0887	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.19 (-0.41, 0.02) 0.0813	
Age group: ≥ 65 years (n/N1 (%))	3/12 (25.0)	12/20 (60.0)		
Unstratified odds ratio ^c (95% CI) p-value			0.22 (0.05, 1.08) 0.0627	
Unstratified risk ratio ^c (95% CI) p-value			0.42 (0.15, 1.18) 0.1000	
Absolute risk reduction (95% CI) p-value			-0.35 (-0.68, -0.02) 0.0352	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	58	73		0.7512
Sex: Male (n/N1 (%))	27/68 (39.7)	36/65 (55.4)		
Unstratified odds ratio ^c (95% CI)			0.53 (0.27, 1.06)	
p-value			0.0715	
Unstratified risk ratio ^c (95% CI)			0.72 (0.50, 1.03)	
p-value			0.0741	
Absolute risk reduction (95% CI)			-0.16 (-0.32, 0.01)	
p-value			0.0669	
Sex: Female (n/N1 (%))	31/79 (39.2)	37/63 (58.7)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			0.45	
(95% CI)			(0.23, 0.89)	
p-value			0.0218	
Unstratified risk ratio ^c			0.67	
(95% CI)			(0.47, 0.94)	
p-value			0.0215	
Absolute risk reduction			-0.19	
(95% CI)			(-0.36, -0.03)	
p-value			0.0187	
Region:	58	73		0.5716
Region: USA (n/N1 (%))	54/135 (40.0)	65/115 (56.5)		
Unstratified odds ratio ^c			0.51	
(95% CI)			(0.31, 0.85)	
p-value			0.0095	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c (95% CI) p-value			0.71 (0.54, 0.92) 0.0096	
Absolute risk reduction (95% CI) p-value			-0.17 (-0.29, -0.04) 0.0083	
Region: Rest of the world (n/N1 (%))	4/12 (33.3)	8/13 (61.5)		
Unstratified odds ratio ^c (95% CI) p-value			0.31 (0.06, 1.61) 0.1645	
Unstratified risk ratio ^c (95% CI) p-value			0.54 (0.22, 1.34) 0.1858	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.28 (-0.66, 0.09) 0.1411	
Race:	49	64		0.2288
Race: Caucasian (n/N1 (%))	39/114 (34.2)	60/104 (57.7)		
Unstratified odds ratio ^c (95% CI) p-value			0.38 (0.22, 0.66) 0.0006	
Unstratified risk ratio ^c (95% CI) p-value			0.59 (0.44, 0.80) 0.0007	
Absolute risk reduction (95% CI)			-0.23 (-0.36, -0.11)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0004	
Race: Others (n/N1 (%))	10/19 (52.6)	4/8 (50.0)		
Unstratified odds ratio ^c (95% CI)			1.11 (0.21, 5.80)	
p-value			0.9005	
Unstratified risk ratio ^c (95% CI)			1.05 (0.47, 2.38)	
p-value			0.9017	
Absolute risk reduction (95% CI)			0.03 (-0.39, 0.44)	
p-value			0.9006	
Ethnicity:	57	67		0.2779
Ethnicity: Hispanic or Latino (n/N1 (%))	11/19 (57.9)	6/11 (54.5)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			1.15	
(95% CI)			(0.26, 5.11)	
p-value			0.8584	
Unstratified risk ratio ^c			1.06	
(95% CI)			(0.55, 2.06)	
p-value			0.8599	
Absolute risk reduction			0.03	
(95% CI)			(-0.34, 0.40)	
p-value			0.8587	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	46/122 (37.7)	61/109 (56.0)		
Unstratified odds ratio ^c			0.48	
(95% CI)			(0.28, 0.81)	
p-value			0.0057	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c (95% CI) p-value			0.67 (0.51, 0.89) 0.0061	
Absolute risk reduction (95% CI) p-value			-0.18 (-0.31, -0.06) 0.0048	
CD20 status:	58	72		0.3501
CD20 status: Positive (n/N1 (%))	30/74 (40.5)	37/70 (52.9)		
Unstratified odds ratio ^c (95% CI) p-value			0.61 (0.31, 1.18) 0.1396	
Unstratified risk ratio ^c (95% CI)			0.77 (0.54, 1.09)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.1415	
Absolute risk reduction (95% CI)			-0.12 (-0.28, 0.04)	
p-value			0.1358	
CD20 status: Negative (n/N1 (%))	28/72 (38.9)	35/56 (62.5)		
Unstratified odds ratio ^c (95% CI)			0.38 (0.19, 0.78)	
p-value			0.0087	
Unstratified risk ratio ^c (95% CI)			0.62 (0.44, 0.89)	
p-value			0.0085	
Absolute risk reduction (95% CI)			-0.24 (-0.41, -0.07)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0064	
Rituximab use:	58	73		0.6099
Rituximab use: Yes (n/N1 (%))	17/43 (39.5)	21/40 (52.5)		
Unstratified odds ratio ^c			0.59	
(95% CI)			(0.25, 1.41)	
p-value			0.2375	
Unstratified risk ratio ^c			0.75	
(95% CI)			(0.47, 1.21)	
p-value			0.2397	
Absolute risk reduction			-0.13	
(95% CI)			(-0.34, 0.08)	
p-value			0.2325	
Rituximab use: No (n/N1 (%))	41/104 (39.4)	52/88 (59.1)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c (95% CI) p-value			0.45 (0.25, 0.80) 0.0070	
Unstratified risk ratio ^c (95% CI) p-value			0.67 (0.50, 0.90) 0.0072	
Absolute risk reduction (95% CI) p-value			-0.20 (-0.34, -0.06) 0.0056	
Allogeneic SCT:	58	73		0.5066
Allogeneic SCT: Yes (n/N1 (%))	15/47 (31.9)	22/40 (55.0)		
Unstratified odds ratio ^c (95% CI)			0.38 (0.16, 0.92)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0317	
Unstratified risk ratio ^c			0.58	
(95% CI)			(0.35, 0.96)	
p-value			0.0339	
Absolute risk reduction			-0.23	
(95% CI)			(-0.43, -0.03)	
p-value			0.0264	
Allogeneic SCT: No (n/N1 (%))	43/100 (43.0)	51/88 (58.0)		
Unstratified odds ratio ^c			0.55	
(95% CI)			(0.31, 0.98)	
p-value			0.0415	
Unstratified risk ratio ^c			0.74	
(95% CI)			(0.56, 0.99)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0418	
Absolute risk reduction (95% CI)			-0.15 (-0.29, -0.01)	
p-value			0.0385	
MRD status:	58	73		0.9942
MRD status: Positive (n/N1 (%))	14/36 (38.9)	9/16 (56.3)		
Unstratified odds ratio ^c (95% CI)			0.49 (0.15, 1.63)	
p-value			0.2481	
Unstratified risk ratio ^c (95% CI)			0.69 (0.38, 1.25)	
p-value			0.2243	
Absolute risk reduction			-0.17	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(-0.46, 0.12)	
p-value			0.2416	
MRD status: Negative (n/N1 (%))	44/111 (39.6)	64/112 (57.1)		
Unstratified odds ratio ^c			0.49	
(95% CI)			(0.29, 0.84)	
p-value			0.0093	
Unstratified risk ratio ^c			0.69	
(95% CI)			(0.52, 0.92)	
p-value			0.0105	
Absolute risk reduction			-0.18	
(95% CI)			(-0.30, -0.05)	
p-value			0.0079	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting grade 3 and above anaemia (PT) - n (%)	44 (29.9)	54 (42.2)	-12.3	
(95% CI)	(22.66, 38.03)	(33.51, 51.23)	(-23.57, -0.94)	
p-value ^a			0.0321	
Age group 1:	44	54		0.2789
Age group: <55 years (n/N1 (%))	30/91 (33.0)	29/72 (40.3)		
Unstratified odds ratio ^c			0.73	
(95% CI)			(0.38, 1.39)	
p-value			0.3354	
Unstratified risk ratio ^c			0.82	
(95% CI)			(0.55, 1.23)	
p-value			0.3338	
Absolute risk reduction			-0.07	
(95% CI)			(-0.22, 0.08)	
p-value			0.3358	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥ 55 years (n/N1 (%))	14/56 (25.0)	25/56 (44.6)		
Unstratified odds ratio ^c (95% CI) p-value			0.41 (0.19, 0.92) 0.0309	
Unstratified risk ratio ^c (95% CI) p-value			0.56 (0.33, 0.96) 0.0351	
Absolute risk reduction (95% CI) p-value			-0.20 (-0.37, -0.02) 0.0258	
Age group 2: Age group: ≥ 18 - <35 years (n/N1 (%))	44 10/18 (55.6)	54 3/18 (16.7)		0.0144

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			6.25	
(95% CI)			(1.33, 29.43)	
p-value			0.0204	
Unstratified risk ratio ^c			3.33	
(95% CI)			(1.10, 10.14)	
p-value			0.0339	
Absolute risk reduction			0.39	
(95% CI)			(0.10, 0.68)	
p-value			0.0079	
Age group: ≥ 35 - < 55 years (n/N1 (%))	20/73 (27.4)	26/54 (48.1)		
Unstratified odds ratio ^c			0.41	
(95% CI)			(0.19, 0.85)	
p-value			0.0173	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			0.57	
(95% CI)			(0.36, 0.91)	
p-value			0.0174	
Absolute risk reduction			-0.21	
(95% CI)			(-0.38, -0.04)	
p-value			0.0155	
Age group: ≥ 55 - < 65 years (n/N1 (%))	11/44 (25.0)	16/36 (44.4)		
Unstratified odds ratio ^c			0.42	
(95% CI)			(0.16, 1.07)	
p-value			0.0702	
Unstratified risk ratio ^c			0.56	
(95% CI)			(0.30, 1.05)	
p-value			0.0729	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.19 (-0.40, 0.01) 0.0652	
Age group: ≥ 65 years (n/N1 (%))	3/12 (25.0)	9/20 (45.0)		
Unstratified odds ratio ^c (95% CI) p-value			0.41 (0.08, 1.97) 0.2641	
Unstratified risk ratio ^c (95% CI) p-value			0.56 (0.19, 1.66) 0.2920	
Absolute risk reduction (95% CI) p-value			-0.20 (-0.53, 0.13) 0.2320	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	44	54		0.4589
Sex: Male (n/N1 (%))	20/68 (29.4)	30/65 (46.2)		
Unstratified odds ratio ^c			0.49	
(95% CI)			(0.24, 0.99)	
p-value			0.0477	
Unstratified risk ratio ^c			0.64	
(95% CI)			(0.41, 1.00)	
p-value			0.0508	
Absolute risk reduction			-0.17	
(95% CI)			(-0.33, -0.00)	
p-value			0.0435	
Sex: Female (n/N1 (%))	24/79 (30.4)	24/63 (38.1)		
Unstratified odds ratio ^c			0.71	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.35, 1.43)	
p-value			0.3350	
Unstratified risk ratio ^c			0.80	
(95% CI)			(0.50, 1.26)	
p-value			0.3337	
Absolute risk reduction			-0.08	
(95% CI)			(-0.23, 0.08)	
p-value			0.3356	
Region:	44	54		-
Region: USA (n/N1 (%))	41/135 (30.4)	51/115 (44.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	3/12 (25.0)	3/13 (23.1)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Race:	38	47		-
Race: Caucasian (n/N1 (%))	31/114 (27.2)	45/104 (43.3)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	
Absolute risk reduction (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	7/19 (36.8)	2/8 (25.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	
Absolute risk reduction (95% CI) p-value			- - -	
Ethnicity:	43	48		0.9167
Ethnicity: Hispanic or Latino (n/N1 (%))	7/19 (36.8)	5/11 (45.5)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			0.70	
(95% CI)			(0.15, 3.17)	
p-value			0.6432	
Unstratified risk ratio ^c			0.81	
(95% CI)			(0.34, 1.94)	
p-value			0.6380	
Absolute risk reduction			-0.09	
(95% CI)			(-0.45, 0.28)	
p-value			0.6442	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	36/122 (29.5)	43/109 (39.4)		
Unstratified odds ratio ^c			0.64	
(95% CI)			(0.37, 1.11)	
p-value			0.1128	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			0.75	
(95% CI)			(0.52, 1.07)	
p-value			0.1135	
Absolute risk reduction			-0.10	
(95% CI)			(-0.22, 0.02)	
p-value			0.1112	
CD20 status:	44	53		0.5848
CD20 status: Positive (n/N1 (%))	24/74 (32.4)	29/70 (41.4)		
Unstratified odds ratio ^c			0.68	
(95% CI)			(0.34, 1.34)	
p-value			0.2641	
Unstratified risk ratio ^c			0.78	
(95% CI)			(0.51, 1.20)	
p-value			0.2656	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.09 (-0.25, 0.07) 0.2618	
CD20 status: Negative (n/N1 (%))	20/72 (27.8)	24/56 (42.9)		
Unstratified odds ratio ^c (95% CI) p-value			0.51 (0.24, 1.07) 0.0765	
Unstratified risk ratio ^c (95% CI) p-value			0.65 (0.40, 1.05) 0.0765	
Absolute risk reduction (95% CI) p-value			-0.15 (-0.32, 0.02) 0.0747	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	44	54		0.2689
Rituximab use: Yes (n/N1 (%))	15/43 (34.9)	15/40 (37.5)		
Unstratified odds ratio ^c			0.89	
(95% CI)			(0.36, 2.19)	
p-value			0.8042	
Unstratified risk ratio ^c			0.93	
(95% CI)			(0.53, 1.65)	
p-value			0.8042	
Absolute risk reduction			-0.03	
(95% CI)			(-0.23, 0.18)	
p-value			0.8042	
Rituximab use: No (n/N1 (%))	29/104 (27.9)	39/88 (44.3)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			0.49	
(95% CI)			(0.27, 0.89)	
p-value			0.0185	
Unstratified risk ratio ^c			0.63	
(95% CI)			(0.43, 0.93)	
p-value			0.0192	
Absolute risk reduction			-0.16	
(95% CI)			(-0.30, -0.03)	
p-value			0.0170	
Allogeneic SCT:	44	54		0.7386
Allogeneic SCT: Yes (n/N1 (%))	12/47 (25.5)	16/40 (40.0)		
Unstratified odds ratio ^c			0.51	
(95% CI)			(0.21, 1.28)	
p-value			0.1526	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c (95% CI) p-value			0.64 (0.34, 1.18) 0.1548	
Absolute risk reduction (95% CI) p-value			-0.14 (-0.34, 0.05) 0.1489	
Allogeneic SCT: No (n/N1 (%))	32/100 (32.0)	38/88 (43.2)		
Unstratified odds ratio ^c (95% CI) p-value			0.62 (0.34, 1.12) 0.1146	
Unstratified risk ratio ^c (95% CI) p-value			0.74 (0.51, 1.08) 0.1152	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.11 (-0.25, 0.03) 0.1125	
MRD status:	44	54		0.3220
MRD status: Positive (n/N1 (%))	9/36 (25.0)	8/16 (50.0)		
Unstratified odds ratio ^c (95% CI) p-value			0.33 (0.10, 1.15) 0.0817	
Unstratified risk ratio ^c (95% CI) p-value			0.50 (0.24, 1.06) 0.0695	
Absolute risk reduction (95% CI)			-0.25 (-0.53, 0.03)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0833	
MRD status: Negative (n/N1 (%))	35/111 (31.5)	46/112 (41.1)		
Unstratified odds ratio ^c (95% CI)			0.66 (0.38, 1.14)	
p-value			0.1395	
Unstratified risk ratio ^c (95% CI)			0.77 (0.54, 1.09)	
p-value			0.1418	
Absolute risk reduction (95% CI)			-0.10 (-0.22, 0.03)	
p-value			0.1365	
Number of subjects reporting grade 3 and above febrile neutropenia (PT) - n (%)	32 (21.8)	37 (28.9)	-7.1	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)	(15.39, 29.32)	(21.24, 37.58)	(-17.44, 3.17)	
p-value ^a			0.2188	
Number of subjects reporting grade 3 and above gastrointestinal disorders (SOC) - n (%)	18 (12.2)	22 (17.2)	-4.9	
(95% CI)	(7.42, 18.66)	(11.10, 24.86)	(-13.36, 3.47)	
p-value ^a			0.2836	
Number of subjects reporting grade 3 and above diarrhoea (PT) - n (%)	7 (4.8)	7 (5.5)	-0.7	
(95% CI)	(1.94, 9.57)	(2.23, 10.94)	(-5.94, 4.52)	
p-value ^a			0.8475	
Number of subjects reporting grade 3 and above nausea (PT) - n (%)	8 (5.4)	2 (1.6)	3.9	
(95% CI)	(2.38, 10.44)	(0.19, 5.53)	(-0.37, 8.13)	
p-value ^a			0.0828	
Number of subjects reporting grade 3 and above general disorders and administration site conditions (SOC) - n (%)	15 (10.2)	7 (5.5)	4.7	

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SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)	(5.82, 16.27)	(2.23, 10.94)	(-1.55, 11.02)	
p-value ^a			0.1423	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting grade 3 and above infections and infestations (SOC) - n (%)	42 (28.6)	31 (24.2)	4.4	
(95% CI)	(21.43, 36.60)	(17.09, 32.58)	(-6.06, 14.76)	
p-value ^a			0.3695	
Number of subjects reporting grade 3 and above device related infection (PT) - n (%)	13 (8.8)	8 (6.3)	2.6	
(95% CI)	(4.79, 14.65)	(2.74, 11.94)	(-3.62, 8.81)	
p-value ^a			0.4643	
Number of subjects reporting grade 3 and above sepsis (PT) - n (%)	15 (10.2)	13 (10.2)	0.0	
(95% CI)	(5.82, 16.27)	(5.52, 16.74)	(-7.12, 7.21)	
p-value ^a			0.9960	
Number of subjects reporting grade 3 and above investigations (SOC) - n (%)	132 (89.8)	123 (96.1)	-6.3	
(95% CI)	(83.73, 94.18)	(91.12, 98.72)	(-12.23, -0.36)	
p-value ^a			0.0795	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated:

24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting grade 3 and above alanine aminotransferase increased (PT) - n (%)	9 (6.1)	8 (6.3)	-0.1	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)	(2.84, 11.30)	(2.74, 11.94)	(-5.84, 5.58)	
p-value ^a			0.9074	
Number of subjects reporting grade 3 and above lymphocyte count decreased (PT) - n (%)	41 (27.9)	35 (27.3)	0.5	
(95% CI)	(20.82, 35.88)	(19.84, 35.92)	(-10.04, 11.14)	
p-value ^a			0.9055	
Number of subjects reporting grade 3 and above neutrophil count decreased (PT) - n (%)	125 (85.0)	119 (93.0)	-7.9	
(95% CI)	(78.22, 90.38)	(87.07, 96.73)	(-15.21, -0.66)	
p-value ^a			0.0478	
Age group 1:	125	119		0.5149
Age group: <55 years (n/N1 (%))	80/91 (87.9)	67/72 (93.1)		
Unstratified odds ratio ^c			0.54	
(95% CI)			(0.18, 1.64)	
p-value			0.2787	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			0.94	
(95% CI)			(0.86, 1.04)	
p-value			0.2599	
Absolute risk reduction			-0.05	
(95% CI)			(-0.14, 0.04)	
p-value			0.2577	
Age group: ≥ 55 years (n/N1 (%))	45/56 (80.4)	52/56 (92.9)		
Unstratified odds ratio ^c			0.31	
(95% CI)			(0.09, 1.06)	
p-value			0.0615	
Unstratified risk ratio ^c			0.87	
(95% CI)			(0.75, 1.00)	
p-value			0.0563	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.13 (-0.25, -0.00) 0.0482	
Age group 2: Age group: ≥ 18 - < 35 years (n/N1 (%))	125 14/18 (77.8)	119 17/18 (94.4)		0.6321
Unstratified odds ratio ^c (95% CI) p-value			0.21 (0.02, 2.06) 0.1785	
Unstratified risk ratio ^c (95% CI) p-value			0.82 (0.63, 1.08) 0.1605	
Absolute risk reduction (95% CI) p-value			-0.17 (-0.39, 0.05) 0.1363	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥ 35 - < 55 years (n/N1 (%))	66/73 (90.4)	50/54 (92.6)		
Unstratified odds ratio ^c (95% CI)			0.75 (0.21, 2.72)	
p-value			0.6665	
Unstratified risk ratio ^c (95% CI)			0.98 (0.88, 1.09)	
p-value			0.6598	
Absolute risk reduction (95% CI)			-0.02 (-0.12, 0.08)	
p-value			0.6599	
Age group: ≥ 55 - < 65 years (n/N1 (%))	37/44 (84.1)	34/36 (94.4)		
Unstratified odds ratio ^c			0.31	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.06, 1.60)	
p-value			0.1624	
Unstratified risk ratio ^c			0.89	
(95% CI)			(0.77, 1.04)	
p-value			0.1317	
Absolute risk reduction			-0.10	
(95% CI)			(-0.23, 0.03)	
p-value			0.1226	
Age group: ≥ 65 years (n/N1 (%))	8/12 (66.7)	18/20 (90.0)		
Unstratified odds ratio ^c			0.22	
(95% CI)			(0.03, 1.47)	
p-value			0.1190	
Unstratified risk ratio ^c			0.74	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.48, 1.13)	
p-value			0.1673	
Absolute risk reduction			-0.23	
(95% CI)			(-0.53, 0.06)	
p-value			0.1241	
Sex:	125	119		0.4635
Sex: Male (n/N1 (%))	55/68 (80.9)	58/65 (89.2)		
Unstratified odds ratio ^c			0.51	
(95% CI)			(0.19, 1.37)	
p-value			0.1833	
Unstratified risk ratio ^c			0.91	
(95% CI)			(0.79, 1.05)	
p-value			0.1786	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.08 (-0.20, 0.04) 0.1729	
Sex: Female (n/N1 (%))	70/79 (88.6)	61/63 (96.8)		
Unstratified odds ratio ^c (95% CI) p-value			0.26 (0.05, 1.23) 0.0881	
Unstratified risk ratio ^c (95% CI) p-value			0.92 (0.84, 1.00) 0.0557	
Absolute risk reduction (95% CI) p-value			-0.08 (-0.16, 0.00) 0.0505	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	125	119		0.5963
Region: USA (n/N1 (%))	114/135 (84.4)	107/115 (93.0)		
Unstratified odds ratio ^c			0.41	
(95% CI)			(0.17, 0.96)	
p-value			0.0390	
Unstratified risk ratio ^c			0.91	
(95% CI)			(0.83, 0.99)	
p-value			0.0307	
Absolute risk reduction			-0.09	
(95% CI)			(-0.16, -0.01)	
p-value			0.0282	
Region: Rest of the world (n/N1 (%))	11/12 (91.7)	12/13 (92.3)		
Unstratified odds ratio ^c			0.92	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.05, 16.49)	
p-value			0.9529	
Unstratified risk ratio ^c			0.99	
(95% CI)			(0.79, 1.25)	
p-value			0.9530	
Absolute risk reduction			-0.01	
(95% CI)			(-0.22, 0.21)	
p-value			0.9530	
Race:	113	104		0.9476
Race: Caucasian (n/N1 (%))	96/114 (84.2)	96/104 (92.3)		
Unstratified odds ratio ^c			0.44	
(95% CI)			(0.18, 1.07)	
p-value			0.0708	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			0.91	
(95% CI)			(0.83, 1.01)	
p-value			0.0634	
Absolute risk reduction			-0.08	
(95% CI)			(-0.17, 0.00)	
p-value			0.0597	
Race: Others (n/N1 (%))	17/19 (89.5)	8/8 (100.0)		
Unstratified odds ratio ^c			0.41	
(95% CI)			(0.02, 9.56)	
p-value			0.5803	
Unstratified risk ratio ^c			0.93	
(95% CI)			(0.74, 1.17)	
p-value			0.5138	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.07 (-0.28, 0.14) 0.5136	
Ethnicity: Ethnicity: Hispanic or Latino (n/N1 (%))	121 19/19 (100.0)	112 11/11 (100.0)		0.5012
Unstratified odds ratio ^c (95% CI) p-value			1.70 (0.03, 91.39) 0.7952	
Unstratified risk ratio ^c (95% CI) p-value			1.02 (0.89, 1.17) 0.8055	
Absolute risk reduction (95% CI) p-value			0.02 (-0.12, 0.15) 0.8048	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	102/122 (83.6)	101/109 (92.7)		
Unstratified odds ratio ^c (95% CI) p-value			0.40 (0.17, 0.96) 0.0400	
Unstratified risk ratio ^c (95% CI) p-value			0.90 (0.82, 0.99) 0.0333	
Absolute risk reduction (95% CI) p-value			-0.09 (-0.17, -0.01) 0.0303	
CD20 status:	124	117		0.5915
CD20 status: Positive (n/N1 (%))	63/74 (85.1)	66/70 (94.3)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			0.35	
(95% CI)			(0.11, 1.15)	
p-value			0.0827	
Unstratified risk ratio ^c			0.90	
(95% CI)			(0.81, 1.01)	
p-value			0.0722	
Absolute risk reduction			-0.09	
(95% CI)			(-0.19, 0.01)	
p-value			0.0661	
CD20 status: Negative (n/N1 (%))	61/72 (84.7)	51/56 (91.1)		
Unstratified odds ratio ^c			0.54	
(95% CI)			(0.18, 1.67)	
p-value			0.2865	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			0.93	
(95% CI)			(0.82, 1.06)	
p-value			0.2679	
Absolute risk reduction			-0.06	
(95% CI)			(-0.18, 0.05)	
p-value			0.2654	
Rituximab use:	125	119		0.5859
Rituximab use: Yes (n/N1 (%))	38/43 (88.4)	37/40 (92.5)		
Unstratified odds ratio ^c			0.62	
(95% CI)			(0.14, 2.77)	
p-value			0.5273	
Unstratified risk ratio ^c			0.96	
(95% CI)			(0.83, 1.10)	
p-value			0.5221	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.04 (-0.17, 0.08) 0.5204	
Rituximab use: No (n/N1 (%))	87/104 (83.7)	82/88 (93.2)		
Unstratified odds ratio ^c (95% CI) p-value			0.37 (0.14, 1.00) 0.0491	
Unstratified risk ratio ^c (95% CI) p-value			0.90 (0.81, 0.99) 0.0383	
Absolute risk reduction (95% CI) p-value			-0.10 (-0.18, -0.01) 0.0348	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	125	119		0.9319
Allogeneic SCT: Yes (n/N1 (%))	37/47 (78.7)	36/40 (90.0)		
Unstratified odds ratio ^c			0.41	
(95% CI)			(0.12, 1.43)	
p-value			0.1624	
Unstratified risk ratio ^c			0.87	
(95% CI)			(0.73, 1.05)	
p-value			0.1472	
Absolute risk reduction			-0.11	
(95% CI)			(-0.26, 0.04)	
p-value			0.1392	
Allogeneic SCT: No (n/N1 (%))	88/100 (88.0)	83/88 (94.3)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			0.44	
(95% CI)			(0.15, 1.31)	
p-value			0.1402	
Unstratified risk ratio ^c			0.93	
(95% CI)			(0.85, 1.02)	
p-value			0.1255	
Absolute risk reduction			-0.06	
(95% CI)			(-0.14, 0.02)	
p-value			0.1215	
MRD status:	125	119		0.4276
MRD status: Positive (n/N1 (%))	28/36 (77.8)	13/16 (81.3)		
Unstratified odds ratio ^c			0.81	
(95% CI)			(0.18, 3.55)	
p-value			0.7775	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c (95% CI) p-value			0.96 (0.71, 1.28) 0.7702	
Absolute risk reduction (95% CI) p-value			-0.03 (-0.27, 0.20) 0.7717	
MRD status: Negative (n/N1 (%))	97/111 (87.4)	106/112 (94.6)		
Unstratified odds ratio ^c (95% CI) p-value			0.39 (0.14, 1.06) 0.0653	
Unstratified risk ratio ^c (95% CI) p-value			0.92 (0.85, 1.00) 0.0605	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.07 (-0.15, 0.00) 0.0564	
Number of subjects reporting grade 3 and above platelet count decreased (PT) - n (%) (95% CI) p-value ^a	102 (69.4) (61.26, 76.72)	101 (78.9) (70.81, 85.62)	-9.5 (-19.79, 0.75) 0.0839	
Number of subjects reporting grade 3 and above white blood cell count decreased (PT) - n (%) (95% CI) p-value ^a	74 (50.3) (41.98, 58.68)	81 (63.3) (54.31, 71.62)	-12.9 (-24.56, -1.32) 0.0396	
Age group 1: Age group: <55 years (n/N1 (%))	74 47/91 (51.6)	81 50/72 (69.4)		0.3521
Unstratified odds ratio ^c			0.47	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.25, 0.90)	
p-value			0.0225	
Unstratified risk ratio ^c			0.74	
(95% CI)			(0.58, 0.96)	
p-value			0.0208	
Absolute risk reduction			-0.18	
(95% CI)			(-0.33, -0.03)	
p-value			0.0183	
Age group: ≥ 55 years (n/N1 (%))	27/56 (48.2)	31/56 (55.4)		
Unstratified odds ratio ^c			0.75	
(95% CI)			(0.36, 1.58)	
p-value			0.4498	
Unstratified risk ratio ^c			0.87	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.61, 1.25)	
p-value			0.4509	
Absolute risk reduction			-0.07	
(95% CI)			(-0.26, 0.11)	
p-value			0.4482	
Age group 2:	74	81		0.4605
Age group: ≥ 18 - < 35 years	11/18 (61.1)	11/18 (61.1)		
(n/N1 (%))				
Unstratified odds ratio ^c			1.00	
(95% CI)			(0.26, 3.82)	
p-value			> 0.9999	
Unstratified risk ratio ^c			1.00	
(95% CI)			(0.59, 1.68)	
p-value			> 0.9999	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			0.00 (-0.32, 0.32) >0.9999	
Age group: ≥ 35 - <55 years (n/N1 (%))	36/73 (49.3)	39/54 (72.2)		
Unstratified odds ratio ^c (95% CI) p-value			0.37 (0.18, 0.79) 0.0104	
Unstratified risk ratio ^c (95% CI) p-value			0.68 (0.51, 0.91) 0.0088	
Absolute risk reduction (95% CI) p-value			-0.23 (-0.39, -0.06) 0.0067	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥ 55 - < 65 years (n/N1 (%))	22/44 (50.0)	23/36 (63.9)		
Unstratified odds ratio ^c (95% CI)			0.57 (0.23, 1.39)	
p-value			0.2146	
Unstratified risk ratio ^c (95% CI)			0.78 (0.53, 1.15)	
p-value			0.2111	
Absolute risk reduction (95% CI)			-0.14 (-0.35, 0.08)	
p-value			0.2065	
Age group: ≥ 65 years (n/N1 (%))	5/12 (41.7)	8/20 (40.0)		
Unstratified odds ratio ^c (95% CI)			1.07 (0.25, 4.59)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.9258	
Unstratified risk ratio ^c			1.04	
(95% CI)			(0.44, 2.46)	
p-value			0.9257	
Absolute risk reduction			0.02	
(95% CI)			(-0.34, 0.37)	
p-value			0.9261	
Sex:	74	81		0.4651
Sex: Male (n/N1 (%))	32/68 (47.1)	42/65 (64.6)		
Unstratified odds ratio ^c			0.49	
(95% CI)			(0.24, 0.98)	
p-value			0.0428	
Unstratified risk ratio ^c			0.73	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.53, 0.99)	
p-value			0.0448	
Absolute risk reduction (95% CI)			-0.18 (-0.34, -0.01)	
p-value			0.0383	
Sex: Female (n/N1 (%))	42/79 (53.2)	39/63 (61.9)		
Unstratified odds ratio ^c (95% CI)			0.70 (0.36, 1.37)	
p-value			0.2966	
Unstratified risk ratio ^c (95% CI)			0.86 (0.65, 1.14)	
p-value			0.2926	
Absolute risk reduction			-0.09	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

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SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(-0.25, 0.08)	
p-value			0.2925	
Region:	74	81		0.6453
Region: USA (n/N1 (%))	65/135 (48.1)	71/115 (61.7)		
Unstratified odds ratio ^c			0.58	
(95% CI)			(0.35, 0.95)	
p-value			0.0321	
Unstratified risk ratio ^c			0.78	
(95% CI)			(0.62, 0.98)	
p-value			0.0315	
Absolute risk reduction			-0.14	
(95% CI)			(-0.26, -0.01)	
p-value			0.0296	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	9/12 (75.0)	10/13 (76.9)		
Unstratified odds ratio ^c (95% CI)			0.90 (0.14, 5.65)	
p-value			0.9105	
Unstratified risk ratio ^c (95% CI)			0.98 (0.63, 1.52)	
p-value			0.9106	
Absolute risk reduction (95% CI)			-0.02 (-0.35, 0.32)	
p-value			0.9105	
Race:	67	71		0.4310
Race: Caucasian (n/N1 (%))	57/114 (50.0)	67/104 (64.4)		
Unstratified odds ratio ^c			0.55	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.32, 0.95)	
p-value			0.0324	
Unstratified risk ratio ^c			0.78	
(95% CI)			(0.62, 0.98)	
p-value			0.0327	
Absolute risk reduction			-0.14	
(95% CI)			(-0.27, -0.01)	
p-value			0.0296	
Race: Others (n/N1 (%))	10/19 (52.6)	4/8 (50.0)		
Unstratified odds ratio ^c			1.11	
(95% CI)			(0.21, 5.80)	
p-value			0.9005	
Unstratified risk ratio ^c			1.05	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.47, 2.38)	
p-value			0.9017	
Absolute risk reduction			0.03	
(95% CI)			(-0.39, 0.44)	
p-value			0.9006	
Ethnicity:	70	77		0.6930
Ethnicity: Hispanic or Latino (n/N1 (%))	8/19 (42.1)	7/11 (63.6)		
Unstratified odds ratio ^c			0.42	
(95% CI)			(0.09, 1.92)	
p-value			0.2604	
Unstratified risk ratio ^c			0.66	
(95% CI)			(0.33, 1.32)	
p-value			0.2414	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.22 (-0.58, 0.15) 0.2420	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	62/122 (50.8)	70/109 (64.2)		
Unstratified odds ratio ^c (95% CI) p-value			0.58 (0.34, 0.98) 0.0406	
Unstratified risk ratio ^c (95% CI) p-value			0.79 (0.63, 0.99) 0.0404	
Absolute risk reduction (95% CI) p-value			-0.13 (-0.26, -0.01) 0.0377	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	74	80		0.4115
CD20 status: Positive (n/N1 (%))	37/74 (50.0)	47/70 (67.1)		
Unstratified odds ratio ^c (95% CI)			0.49 (0.25, 0.96)	
p-value			0.0382	
Unstratified risk ratio ^c (95% CI)			0.74 (0.56, 0.99)	
p-value			0.0395	
Absolute risk reduction (95% CI)			-0.17 (-0.33, -0.01)	
p-value			0.0339	
CD20 status: Negative (n/N1 (%))	37/72 (51.4)	33/56 (58.9)		
Unstratified odds ratio ^c			0.74	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.36, 1.49)	
p-value			0.3958	
Unstratified risk ratio ^c			0.87	
(95% CI)			(0.64, 1.19)	
p-value			0.3920	
Absolute risk reduction			-0.08	
(95% CI)			(-0.25, 0.10)	
p-value			0.3930	
Rituximab use:	74	81		0.9378
Rituximab use: Yes (n/N1 (%))	24/43 (55.8)	27/40 (67.5)		
Unstratified odds ratio ^c			0.61	
(95% CI)			(0.25, 1.49)	
p-value			0.2759	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			0.83	
(95% CI)			(0.59, 1.16)	
p-value			0.2760	
Absolute risk reduction			-0.12	
(95% CI)			(-0.32, 0.09)	
p-value			0.2699	
Rituximab use: No (n/N1 (%))	50/104 (48.1)	54/88 (61.4)		
Unstratified odds ratio ^c			0.58	
(95% CI)			(0.33, 1.04)	
p-value			0.0665	
Unstratified risk ratio ^c			0.78	
(95% CI)			(0.60, 1.02)	
p-value			0.0654	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			-0.13 (-0.27, 0.01) 0.0627	
Allogeneic SCT: Allogeneic SCT: Yes (n/N1 (%))	74 27/47 (57.4)	81 26/40 (65.0)		0.5592
Unstratified odds ratio ^c (95% CI) p-value			0.73 (0.30, 1.73) 0.4723	
Unstratified risk ratio ^c (95% CI) p-value			0.88 (0.63, 1.24) 0.4699	
Absolute risk reduction (95% CI) p-value			-0.08 (-0.28, 0.13) 0.4692	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	47/100 (47.0)	55/88 (62.5)		
Unstratified odds ratio ^c (95% CI)			0.53 (0.30, 0.95)	
p-value			0.0341	
Unstratified risk ratio ^c (95% CI)			0.75 (0.58, 0.98)	
p-value			0.0341	
Absolute risk reduction (95% CI)			-0.16 (-0.30, -0.01)	
p-value			0.0309	
MRD status:	74	81		0.6501
MRD status: Positive (n/N1 (%))	14/36 (38.9)	7/16 (43.8)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			0.82	
(95% CI)			(0.25, 2.70)	
p-value			0.7418	
Unstratified risk ratio ^c			0.89	
(95% CI)			(0.45, 1.77)	
p-value			0.7380	
Absolute risk reduction			-0.05	
(95% CI)			(-0.34, 0.24)	
p-value			0.7430	
MRD status: Negative (n/N1 (%))	60/111 (54.1)	74/112 (66.1)		
Unstratified odds ratio ^c			0.60	
(95% CI)			(0.35, 1.04)	
p-value			0.0677	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c (95% CI) p-value			0.82 (0.66, 1.02) 0.0696	
Absolute risk reduction (95% CI) p-value			-0.12 (-0.25, 0.01) 0.0649	
Number of subjects reporting grade 3 and above metabolism and nutrition disorders (SOC) - n (%) (95% CI) p-value ^a	24 (16.3) (10.75, 23.31)	23 (18.0) (11.74, 25.73)	-1.6 (-10.58, 7.30) 0.8462	
Number of subjects reporting grade 3 and above hyperglycaemia (PT) - n (%) (95% CI) p-value ^a	14 (9.5) (5.31, 15.46)	12 (9.4) (4.94, 15.80)	0.1 (-6.78, 7.08) 0.8557	
Number of subjects reporting grade 3 and above musculoskeletal and connective tissue disorders (SOC) - n (%)	9 (6.1)	8 (6.3)	-0.1	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

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SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)	(2.84, 11.30)	(2.74, 11.94)	(-5.84, 5.58)	
p-value ^a			0.9711	
Number of subjects reporting grade 3 and above nervous system disorders (SOC) - n (%)	33 (22.4)	13 (10.2)	12.3	
(95% CI)	(15.98, 30.06)	(5.52, 16.74)	(3.76, 20.83)	
p-value ^a			0.0215	
Age group 1:	33	13		0.6399
Age group: <55 years (n/N1 (%))	22/91 (24.2)	9/72 (12.5)		
Unstratified odds ratio ^c			2.23	
(95% CI)			(0.96, 5.21)	
p-value			0.0633	
Unstratified risk ratio ^c			1.93	
(95% CI)			(0.95, 3.94)	
p-value			0.0691	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			0.12 (0.00, 0.23) 0.0495	
Age group: ≥ 55 years (n/N1 (%))	11/56 (19.6)	4/56 (7.1)		
Unstratified odds ratio ^c (95% CI) p-value			3.18 (0.95, 10.68) 0.0615	
Unstratified risk ratio ^c (95% CI) p-value			2.75 (0.93, 8.12) 0.0671	
Absolute risk reduction (95% CI) p-value			0.13 (0.00, 0.25) 0.0482	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	33	13		-
Age group: ≥ 18 - < 35 years (n/N1 (%))	6/18 (33.3)	0/18 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥ 35 - < 55 years (n/N1 (%))	16/73 (21.9)	9/54 (16.7)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥ 55 - < 65 years (n/N1 (%))	7/44 (15.9)	2/36 (5.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥ 65 years (n/N1 (%))	4/12 (33.3)	2/20 (10.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Sex:	33	13		0.6204
Sex: Male (n/N1 (%))	14/68 (20.6)	5/65 (7.7)		
Unstratified odds ratio ^c			3.11	
(95% CI)			(1.05, 9.21)	
p-value			0.0404	
Unstratified risk ratio ^c			2.68	
(95% CI)			(1.02, 7.01)	
p-value			0.0451	
Absolute risk reduction			0.13	
(95% CI)			(0.01, 0.24)	
p-value			0.0292	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	19/79 (24.1)	8/63 (12.7)		
Unstratified odds ratio ^c			2.18	
(95% CI)			(0.88, 5.37)	
p-value			0.0915	
Unstratified risk ratio ^c			1.89	
(95% CI)			(0.89, 4.04)	
p-value			0.0981	
Absolute risk reduction			0.11	
(95% CI)			(-0.01, 0.24)	
p-value			0.0752	
Region:	33	13		-
Region: USA (n/N1 (%))	27/135 (20.0)	13/115 (11.3)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	6/12 (50.0)	0/13 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race:	32	11		-
Race: Caucasian (n/N1 (%))	26/114 (22.8)	10/104 (9.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Race: Others (n/N1 (%))	6/19 (31.6)	1/8 (12.5)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	
Absolute risk reduction (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	32	13		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	3/11 (27.3)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	32/122 (26.2)	10/109 (9.2)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated:

24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status:	33	13		0.1768
CD20 status: Positive (n/N1 (%))	18/74 (24.3)	5/70 (7.1)		
Unstratified odds ratio ^c			4.18	
(95% CI)			(1.46, 11.98)	
p-value			0.0078	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c (95% CI) p-value			3.41 (1.34, 8.68) 0.0102	
Absolute risk reduction (95% CI) p-value			0.17 (0.06, 0.29) 0.0034	
CD20 status: Negative (n/N1 (%))	15/72 (20.8)	8/56 (14.3)		
Unstratified odds ratio ^c (95% CI) p-value			1.58 (0.62, 4.04) 0.3411	
Unstratified risk ratio ^c (95% CI) p-value			1.46 (0.67, 3.19) 0.3454	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			0.07 (-0.07, 0.20) 0.3278	
Rituximab use: Rituximab use: Yes (n/N1 (%))	33 10/43 (23.3)	13 3/40 (7.5)		0.5195
Unstratified odds ratio ^c (95% CI) p-value			3.74 (0.95, 14.75) 0.0598	
Unstratified risk ratio ^c (95% CI) p-value			3.10 (0.92, 10.46) 0.0682	
Absolute risk reduction (95% CI) p-value			0.16 (0.01, 0.31) 0.0400	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	23/104 (22.1)	10/88 (11.4)		
Unstratified odds ratio ^c (95% CI) p-value			2.21 (0.99, 4.95) 0.0528	
Unstratified risk ratio ^c (95% CI) p-value			1.95 (0.98, 3.86) 0.0571	
Absolute risk reduction (95% CI) p-value			0.11 (0.00, 0.21) 0.0422	
Allogeneic SCT: Allogeneic SCT: Yes (n/N1 (%))	33 7/47 (14.9)	13 3/40 (7.5)		0.7740

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			2.16	
(95% CI)			(0.52, 8.97)	
p-value			0.2898	
Unstratified risk ratio ^c			1.99	
(95% CI)			(0.55, 7.18)	
p-value			0.2954	
Absolute risk reduction			0.07	
(95% CI)			(-0.06, 0.20)	
p-value			0.2667	
Allogeneic SCT: No (n/N1 (%))	26/100 (26.0)	10/88 (11.4)		
Unstratified odds ratio ^c			2.74	
(95% CI)			(1.24, 6.07)	
p-value			0.0130	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			2.29	
(95% CI)			(1.17, 4.47)	
p-value			0.0156	
Absolute risk reduction			0.15	
(95% CI)			(0.04, 0.25)	
p-value			0.0082	
MRD status:	33	13		-
MRD status: Positive (n/N1 (%))	6/36 (16.7)	2/16 (12.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
MRD status: Negative (n/N1 (%))	27/111 (24.3)	11/112 (9.8)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	
Absolute risk reduction (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting grade 3 and above headache (PT) - n (%)	9 (6.1)	9 (7.0)	-0.9	
(95% CI)	(2.84, 11.30)	(3.27, 12.93)	(-6.79, 4.98)	
p-value ^a			0.6106	
Number of subjects reporting grade 3 and above psychiatric disorders (SOC) - n (%)	13 (8.8)	2 (1.6)	7.3	
(95% CI)	(4.79, 14.65)	(0.19, 5.53)	(2.21, 12.35)	
p-value ^a			0.0066	
Age group 1:	13	2		-
Age group: <55 years (n/N1 (%))	9/91 (9.9)	2/72 (2.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥ 55 years (n/N1 (%))	4/56 (7.1)	0/56 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Age group 2:	13	2		-
Age group: ≥ 18 - < 35 years (n/N1 (%))	3/18 (16.7)	1/18 (5.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥ 35 - < 55 years (n/N1 (%))	6/73 (8.2)	1/54 (1.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥ 55 - < 65 years (n/N1 (%))	3/44 (6.8)	0/36 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥ 65 years (n/N1 (%))	1/12 (8.3)	0/20 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Sex:	13	2		-
Sex: Male (n/N1 (%))	5/68 (7.4)	1/65 (1.5)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Sex: Female (n/N1 (%))	8/79 (10.1)	1/63 (1.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region:	13	2		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: USA (n/N1 (%))	11/135 (8.1)	2/115 (1.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	2/12 (16.7)	0/13 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race:	11	2		-
Race: Caucasian (n/N1 (%))	7/114 (6.1)	2/104 (1.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	4/19 (21.1)	0/8 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Ethnicity:	13	2		-
Ethnicity: Hispanic or Latino (n/N1 (%))	3/19 (15.8)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-007-001-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	10/122 (8.2)	2/109 (1.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status:	13	2		-
CD20 status: Positive (n/N1 (%))	9/74 (12.2)	0/70 (0.0)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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24NOV2025:00:27) Source data: adampa.adsl, adampa.adae

Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status: Negative (n/N1 (%))	4/72 (5.6)	2/56 (3.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Rituximab use:	13	2		-
Rituximab use: Yes (n/N1 (%))	8/43 (18.6)	0/40 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Rituximab use: No (n/N1 (%))	5/104 (4.8)	2/88 (2.3)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	
Absolute risk reduction (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	13	2		-
Allogeneic SCT: Yes (n/N1 (%))	2/47 (4.3)	1/40 (2.5)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	11/100 (11.0)	1/88 (1.1)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-sev-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	13	2		-
MRD status: Positive (n/N1 (%))	3/36 (8.3)	0/16 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status: Negative (n/N1 (%))	10/111 (9.0)	2/112 (1.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Table 14-6.7.1. Subgroup Analysis of Severe (Grade ≥ 3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Number of subjects reporting grade 3 and above respiratory, thoracic and mediastinal disorders (SOC) - n (%) (95% CI) p-value ^a	10 (6.8) (3.31, 12.15)	8 (6.3) (2.74, 11.94)	0.6 (-5.29, 6.40) 0.7465	
Number of subjects reporting grade 3 and above vascular disorders (SOC) - n (%) (95% CI) p-value ^a	19 (12.9) (7.96, 19.45)	11 (8.6) (4.37, 14.86)	4.3 (-2.95, 11.61) 0.2180	
Number of subjects reporting grade 3 and above hypertension (PT) - n (%) (95% CI) p-value ^a	12 (8.2) (4.29, 13.83)	4 (3.1) (0.86, 7.81)	5.0 (-0.32, 10.39) 0.0515	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1 and severity graded using CTCAE version 4.0.

Data cut-off date: 23JUN2023

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Anhang 4-G3.3.7: Subgruppenanalysen häufiger Expedited UE nach SOC und PT

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting expedited blood and lymphatic system disorders (SOC) - n (%)	20 (13.6)	15 (11.7)	1.9	
(95% CI)	(8.51, 20.23)	(6.71, 18.59)	(-5.97, 9.75)	
p-value ^a			0.5044	
Number of subjects reporting expedited febrile neutropenia (PT) - n (%)	18 (12.2)	15 (11.7)	0.5	
(95% CI)	(7.42, 18.66)	(6.71, 18.59)	(-7.16, 8.22)	
p-value ^a			0.7685	
Number of subjects reporting expedited gastrointestinal disorders (SOC) - n (%)	10 (6.8)	3 (2.3)	4.5	
(95% CI)	(3.31, 12.15)	(0.49, 6.70)	(-0.38, 9.30)	
p-value ^a			0.0756	
Number of subjects reporting expedited general disorders and administration site conditions (SOC) - n (%)	20 (13.6)	3 (2.3)	11.3	
(95% CI)	(8.51, 20.23)	(0.49, 6.70)	(5.13, 17.39)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value ^a			0.0010	
Age group 1:	20	3		-
Age group: <55 years (n/N1 (%))	13/91 (14.3)	1/72 (1.4)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated:

24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 years (n/N1 (%))	7/56 (12.5)	2/56 (3.6)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	20	3		-
Age group: ≥18 - <35 years (n/N1 (%))	2/18 (11.1)	0/18 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	11/73 (15.1)	1/54 (1.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 - <65 years (n/N1 (%))	7/44 (15.9)	1/36 (2.8)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	0/12 (0.0)	1/20 (5.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	20	3		0.4911
Sex: Male (n/N1 (%))	10/68 (14.7)	1/65 (1.5)		
Unstratified odds ratio ^c			11.03	
(95% CI)			(1.37, 88.78)	
p-value			0.0241	
Unstratified risk ratio ^c			9.56	
(95% CI)			(1.26, 72.59)	
p-value			0.0291	
Absolute risk reduction			0.13	
(95% CI)			(0.04, 0.22)	
p-value			0.0039	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	10/79 (12.7)	2/63 (3.2)		
Unstratified odds ratio ^c			4.42	
(95% CI)			(0.93, 20.97)	
p-value			0.0613	
Unstratified risk ratio ^c			3.99	
(95% CI)			(0.91, 17.54)	
p-value			0.0673	
Absolute risk reduction			0.09	
(95% CI)			(0.01, 0.18)	
p-value			0.0290	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	20	3		-
Region: USA (n/N1 (%))	18/135 (13.3)	3/115 (2.6)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Region: Rest of the world (n/N1 (%))	2/12 (16.7)	0/13 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Race:	19	2		-
Race: Caucasian (n/N1 (%))	15/114 (13.2)	2/104 (1.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	4/19 (21.1)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Ethnicity:	20	3		-
Ethnicity: Hispanic or Latino (n/N1 (%))	1/19 (5.3)	1/11 (9.1)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	19/122 (15.6)	2/109 (1.8)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
CD20 status: CD20 status: Positive (n/N1 (%))	20 16/74 (21.6)	3 0/70 (0.0)		-
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
CD20 status: Negative (n/N1 (%))	4/72 (5.6)	3/56 (5.4)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Rituximab use:	20	3		0.1617
Rituximab use: Yes (n/N1 (%))	10/43 (23.3)	0/40 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			25.39 (1.43, 449.35) 0.0274	
Unstratified risk ratio ^c (95% CI)			19.57 (1.18, 323.39)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0377	
Absolute risk reduction (95% CI)			0.23 (0.10, 0.36)	
p-value			0.0007	
Rituximab use: No (n/N1 (%))	10/104 (9.6)	3/88 (3.4)		
Unstratified odds ratio ^c (95% CI)			3.01 (0.80, 11.32)	
p-value			0.1022	
Unstratified risk ratio ^c (95% CI)			2.82 (0.80, 9.93)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.1064	
Absolute risk reduction (95% CI)			0.06 (-0.01, 0.13)	
p-value			0.0744	
Allogeneic SCT:	20	3		-
Allogeneic SCT: Yes (n/N1 (%))	2/47 (4.3)	1/40 (2.5)		
Unstratified odds ratio ^c (95% CI)			- -	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	18/100 (18.0)	2/88 (2.3)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	20	3		-
MRD status: Positive (n/N1 (%))	2/36 (5.6)	1/16 (6.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status: Negative (n/N1 (%))	18/111 (16.2)	2/112 (1.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Number of subjects reporting expedited pyrexia (PT) - n (%)	14 (9.5)	1 (0.8)	8.7	
(95% CI)	(5.31, 15.46)	(0.02, 4.28)	(3.76, 13.73)	
p-value ^a			0.0023	
Age group 1:	14	1		-
Age group: <55 years (n/N1 (%))	9/91 (9.9)	0/72 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥55 years (n/N1 (%))	5/56 (8.9)	1/56 (1.8)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group 2:	14	1		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated:

24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥18 - <35 years (n/N1 (%))	0/18 (0.0)	0/18 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	9/73 (12.3)	0/54 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 - <65 years (n/N1 (%))	5/44 (11.4)	0/36 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	0/12 (0.0)	1/20 (5.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	14	1		-
Sex: Male (n/N1 (%))	7/68 (10.3)	1/65 (1.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	7/79 (8.9)	0/63 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	14	1		-
Region: USA (n/N1 (%))	13/135 (9.6)	1/115 (0.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	1/12 (8.3)	0/13 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	14	1		-
Race: Caucasian (n/N1 (%))	11/114 (9.6)	1/104 (1.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	3/19 (15.8)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	14	1		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	14/122 (11.5)	1/109 (0.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	14	1		-
CD20 status: Positive (n/N1 (%))	10/74 (13.5)	0/70 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	4/72 (5.6)	1/56 (1.8)		
Unstratified odds ratio ^c (95% CI)			-	-
p-value			-	-
Unstratified risk ratio ^c (95% CI)			-	-
p-value			-	-
Absolute risk reduction (95% CI)			-	-
p-value			-	-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	14	1		-
Rituximab use: Yes (n/N1 (%))	5/43 (11.6)	0/40 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Rituximab use: No (n/N1 (%))	9/104 (8.7)	1/88 (1.1)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Allogeneic SCT:	14	1		-
Allogeneic SCT: Yes (n/N1 (%))	1/47 (2.1)	0/40 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	13/100 (13.0)	1/88 (1.1)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
MRD status:	14	1		-
MRD status: Positive (n/N1 (%))	1/36 (2.8)	0/16 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
MRD status: Negative (n/N1 (%))	13/111 (11.7)	1/112 (0.9)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Number of subjects reporting expedited infections and infestations (SOC) - n (%) (95% CI) p-value ^a	33 (22.4) (15.98, 30.06)	19 (14.8) (9.18, 22.21)	7.6 (-1.53, 16.74) 0.0998	
Number of subjects reporting expedited device related infection (PT) - n (%) (95% CI) p-value ^a	12 (8.2) (4.29, 13.83)	5 (3.9) (1.28, 8.88)	4.3 (-1.30, 9.81) 0.1639	
Number of subjects reporting expedited sepsis (PT) - n (%) (95% CI) p-value ^a	13 (8.8) (4.79, 14.65)	9 (7.0) (3.27, 12.93)	1.8 (-4.57, 8.19) 0.5958	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting expedited investigations (SOC) - n (%) (95% CI) p-value ^a	23 (15.6) (10.18, 22.55)	6 (4.7) (1.74, 9.92)	11.0 (4.04, 17.88) 0.0030	
Age group 1: Age group: <55 years (n/N1 (%))	23 15/91 (16.5)	6 2/72 (2.8)		0.2484
Unstratified odds ratio ^c (95% CI) p-value			6.91 (1.52, 31.29) 0.0122	
Unstratified risk ratio ^c (95% CI) p-value			5.93 (1.40, 25.11) 0.0156	
Absolute risk reduction			0.14	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(0.05, 0.22)	
p-value			0.0016	
Age group: ≥55 years (n/N1 (%))	8/56 (14.3)	4/56 (7.1)		
Unstratified odds ratio ^c			2.17	
(95% CI)			(0.61, 7.66)	
p-value			0.2301	
Unstratified risk ratio ^c			2.00	
(95% CI)			(0.64, 6.26)	
p-value			0.2341	
Absolute risk reduction			0.07	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference (-0.04, 0.19)	Interaction p-value ^b
(95% CI)				
p-value			0.2186	
Age group 2:	23	6		-
Age group: >=18 - <35 years (n/N1 (%))	6/18 (33.3)	1/18 (5.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: ≥35 - <55 years (n/N1 (%))	9/73 (12.3)	1/54 (1.9)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: ≥55 - <65 years (n/N1 (%))	6/44 (13.6)	4/36 (11.1)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: ≥65 years (n/N1 (%))	2/12 (16.7)	0/20 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Sex:	23	6		-
Sex: Male (n/N1 (%))	7/68 (10.3)	2/65 (3.1)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Sex: Female (n/N1 (%))	16/79 (20.3)	4/63 (6.3)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Region:	23	6		-
Region: USA (n/N1 (%))	20/135 (14.8)	6/115 (5.2)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI)			- -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	3/12 (25.0)	0/13 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Race:	21	4		-
Race: Caucasian (n/N1 (%))	18/114 (15.8)	3/104 (2.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	3/19 (15.8)	1/8 (12.5)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity:	22	6		-
Ethnicity: Hispanic or Latino (n/N1 (%))	4/19 (21.1)	3/11 (27.3)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	18/122 (14.8)	3/109 (2.8)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status:	23	6		0.8285
CD20 status: Positive (n/N1 (%))	15/74 (20.3)	4/70 (5.7)		
Unstratified odds ratio ^c			4.19	
(95% CI)			(1.32, 13.34)	
p-value			0.0152	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			3.55	
(95% CI)			(1.24, 10.17)	
p-value			0.0185	
Absolute risk reduction			0.15	
(95% CI)			(0.04, 0.25)	
p-value			0.0074	
CD20 status: Negative (n/N1 (%))	8/72 (11.1)	2/56 (3.6)		
Unstratified odds ratio ^c			3.37	
(95% CI)			(0.69, 16.56)	
p-value			0.1341	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			3.11	
(95% CI)			(0.69, 14.08)	
p-value			0.1406	
Absolute risk reduction			0.08	
(95% CI)			(-0.01, 0.16)	
p-value			0.0907	
Rituximab use:	23	6		0.7126
Rituximab use: Yes (n/N1 (%))	12/43 (27.9)	3/40 (7.5)		
Unstratified odds ratio ^c			4.77	
(95% CI)			(1.23, 18.46)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0235	
Unstratified risk ratio ^c			3.72	
(95% CI)			(1.13, 12.23)	
p-value			0.0304	
Absolute risk reduction			0.20	
(95% CI)			(0.05, 0.36)	
p-value			0.0108	
Rituximab use: No (n/N1 (%))	11/104 (10.6)	3/88 (3.4)		
Unstratified odds ratio ^c			3.35	
(95% CI)			(0.90, 12.42)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			0.0704	
Unstratified risk ratio ^c			3.10	
(95% CI)			(0.89, 10.77)	
p-value			0.0746	
Absolute risk reduction			0.07	
(95% CI)			(0.00, 0.14)	
p-value			0.0454	
Allogeneic SCT:	23	6		-
Allogeneic SCT: Yes (n/N1 (%))	5/47 (10.6)	1/40 (2.5)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	18/100 (18.0)	5/88 (5.7)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	23	6		-
MRD status: Positive (n/N1 (%))	5/36 (13.9)	0/16 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status: Negative (n/N1 (%))	18/111 (16.2)	6/112 (5.4)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Number of subjects reporting expedited alanine aminotransferase increased (PT) - n (%)	9 (6.1)	0 (0.0)	6.1	
(95% CI)	(2.84, 11.30)	(0.00, 2.84)	(2.25, 10.00)	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value ^a			0.0054	
Age group 1:	9	0		-
Age group: <55 years (n/N1 (%))	9/91 (9.9)	0/72 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 years (n/N1 (%))	0/56 (0.0)	0/56 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	9	0		-
Age group: ≥18 - <35 years (n/N1 (%))	3/18 (16.7)	0/18 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated:

24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	6/73 (8.2)	0/54 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	
Absolute risk reduction (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 - <65 years (n/N1 (%))	0/44 (0.0)	0/36 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	0/12 (0.0)	0/20 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	9	0		-
Sex: Male (n/N1 (%))	4/68 (5.9)	0/65 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	5/79 (6.3)	0/63 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	9	0		-
Region: USA (n/N1 (%))	6/135 (4.4)	0/115 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Region: Rest of the world (n/N1 (%))	3/12 (25.0)	0/13 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Race:	9	0		-
Race: Caucasian (n/N1 (%))	7/114 (6.1)	0/104 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	2/19 (10.5)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Ethnicity:	9	0		-
Ethnicity: Hispanic or Latino (n/N1 (%))	1/19 (5.3)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	8/122 (6.6)	0/109 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status:	9	0		-
CD20 status: Positive (n/N1 (%))	6/74 (8.1)	0/70 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
CD20 status: Negative (n/N1 (%))	3/72 (4.2)	0/56 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Rituximab use:	9	0		-
Rituximab use: Yes (n/N1 (%))	3/43 (7.0)	0/40 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI)			- -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Rituximab use: No (n/N1 (%))	6/104 (5.8)	0/88 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Allogeneic SCT:	9	0		-
Allogeneic SCT: Yes (n/N1 (%))	1/47 (2.1)	0/40 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	8/100 (8.0)	0/88 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	9	0		-
MRD status: Positive (n/N1 (%))	0/36 (0.0)	0/16 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status: Negative (n/N1 (%))	9/111 (8.1)	0/112 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Number of subjects reporting expedited neutrophil count decreased (PT) - n (%)	12 (8.2)	2 (1.6)	6.6	
(95% CI)	(4.29, 13.83)	(0.19, 5.53)	(1.68, 11.52)	
p-value ^a			0.0128	
Age group 1:	12	2		-
Age group: <55 years (n/N1 (%))	6/91 (6.6)	1/72 (1.4)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: >=55 years (n/N1 (%))	6/56 (10.7)	1/56 (1.8)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group 2:	12	2		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥18 - <35 years (n/N1 (%))	3/18 (16.7)	0/18 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	3/73 (4.1)	1/54 (1.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 - <65 years (n/N1 (%))	4/44 (9.1)	1/36 (2.8)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥65 years (n/N1 (%))	2/12 (16.7)	0/20 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	12	2		-
Sex: Male (n/N1 (%))	3/68 (4.4)	2/65 (3.1)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	9/79 (11.4)	0/63 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	12	2		-
Region: USA (n/N1 (%))	12/135 (8.9)	2/115 (1.7)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	0/12 (0.0)	0/13 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	10	2		-
Race: Caucasian (n/N1 (%))	10/114 (8.8)	2/104 (1.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	0/19 (0.0)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

Page 105 of 207

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	11	2		-
Ethnicity: Hispanic or Latino (n/N1 (%))	2/19 (10.5)	1/11 (9.1)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	9/122 (7.4)	1/109 (0.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	12	2		-
CD20 status: Positive (n/N1 (%))	8/74 (10.8)	2/70 (2.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	4/72 (5.6)	0/56 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	12	2		-
Rituximab use: Yes (n/N1 (%))	8/43 (18.6)	2/40 (5.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Rituximab use: No (n/N1 (%))	4/104 (3.8)	0/88 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Allogeneic SCT:	12	2		-
Allogeneic SCT: Yes (n/N1 (%))	2/47 (4.3)	1/40 (2.5)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	10/100 (10.0)	1/88 (1.1)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
MRD status:	12	2		-
MRD status: Positive (n/N1 (%))	3/36 (8.3)	0/16 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
MRD status: Negative (n/N1 (%))	9/111 (8.1)	2/112 (1.8)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Number of subjects reporting expedited metabolism and nutrition disorders (SOC) - n (%) (95% CI) p-value ^a	8 (5.4) (2.38, 10.44)	3 (2.3) (0.49, 6.70)	3.1 (-1.41, 7.61) 0.1929	
Number of subjects reporting expedited musculoskeletal and connective tissue disorders (SOC) - n (%) (95% CI) p-value ^a	8 (5.4) (2.38, 10.44)	1 (0.8) (0.02, 4.28)	4.7 (0.69, 8.63) 0.0317	
Age group 1: Age group: <55 years (n/N1 (%))	8 6/91 (6.6)	1 0/72 (0.0)		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: >=55 years (n/N1 (%))	2/56 (3.6)	1/56 (1.8)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group 2:	8	1		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥18 - <35 years (n/N1 (%))	1/18 (5.6)	0/18 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

Page 119 of 207

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥35 - <55 years (n/N1 (%))	5/73 (6.8)	0/54 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=55 - <65 years (n/N1 (%))	1/44 (2.3)	1/36 (2.8)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: >=65 years (n/N1 (%))	1/12 (8.3)	0/20 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex:	8	1		-
Sex: Male (n/N1 (%))	3/68 (4.4)	1/65 (1.5)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Sex: Female (n/N1 (%))	5/79 (6.3)	0/63 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region:	8	1		-
Region: USA (n/N1 (%))	7/135 (5.2)	1/115 (0.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Region: Rest of the world (n/N1 (%))	1/12 (8.3)	0/13 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race:	8	1		-
Race: Caucasian (n/N1 (%))	6/114 (5.3)	1/104 (1.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Race: Others (n/N1 (%))	2/19 (10.5)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity:	8	1		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	8/122 (6.6)	1/109 (0.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	8	1		-
CD20 status: Positive (n/N1 (%))	6/74 (8.1)	1/70 (1.4)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	2/72 (2.8)	0/56 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	-
p-value			-	-
Unstratified risk ratio ^c (95% CI)			-	-
p-value			-	-
Absolute risk reduction (95% CI)			-	-
p-value			-	-

Page 132 of 207

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	8	1		-
Rituximab use: Yes (n/N1 (%))	3/43 (7.0)	1/40 (2.5)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Rituximab use: No (n/N1 (%))	5/104 (4.8)	0/88 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Allogeneic SCT:	8	1		-
Allogeneic SCT: Yes (n/N1 (%))	0/47 (0.0)	0/40 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	8/100 (8.0)	1/88 (1.1)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
MRD status:	8	1		-
MRD status: Positive (n/N1 (%))	2/36 (5.6)	0/16 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
MRD status: Negative (n/N1 (%))	6/111 (5.4)	1/112 (0.9)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Number of subjects reporting expedited nervous system disorders (SOC) - n (%) (95% CI) p-value ^a	22 (15.0) (9.62, 21.78)	0 (0.0) (0.00, 2.84)	15.0 (9.20, 20.73) <0.0001	
Age group 1: Age group: <55 years (n/N1 (%))	22 13/91 (14.3)	0 0/72 (0.0)		-
Unstratified odds ratio ^c (95% CI) p-value			- - -	

Page 139 of 207

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: >=55 years (n/N1 (%))	9/56 (16.1)	0/56 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group 2:	22	0		-
Age group: ≥18 - <35 years	5/18 (27.8)	0/18 (0.0)		
(n/N1 (%))				
Unstratified odds ratio ^c			-	
(95% CI)			-	

Page 141 of 207

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	8/73 (11.0)	0/54 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

Page 142 of 207

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: ≥55 - <65 years (n/N1 (%))	5/44 (11.4)	0/36 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

Page 143 of 207

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Age group: >=65 years (n/N1 (%))	4/12 (33.3)	0/20 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

Page 144 of 207

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Sex:	22	0		0.9203
Sex: Male (n/N1 (%))	11/68 (16.2)	0/65 (0.0)		
Unstratified odds ratio ^c			26.19	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(1.51, 454.31)	
p-value			0.0249	
Unstratified risk ratio ^c			22.00	
(95% CI)			(1.32, 365.87)	
p-value			0.0312	
Absolute risk reduction			0.16	
(95% CI)			(0.07, 0.25)	
p-value			0.0006	
Sex: Female (n/N1 (%))	11/79 (13.9)	0/63 (0.0)		
Unstratified odds ratio ^c			21.32	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			(1.23, 369.22)	
p-value			0.0355	
Unstratified risk ratio ^c			18.40	
(95% CI)			(1.11, 306.32)	
p-value			0.0424	
Absolute risk reduction			0.14	
(95% CI)			(0.06, 0.22)	
p-value			0.0008	
Region:	22	0		-
Region: USA (n/N1 (%))	17/135 (12.6)	0/115 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	5/12 (41.7)	0/13 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race:	21	0		-
Race: Caucasian (n/N1 (%))	17/114 (14.9)	0/104 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	4/19 (21.1)	0/8 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity:	21	0		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Ethnicity: Not Hispanic or Latino (n/N1 (%))	21/122 (17.2)	0/109 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status:	22	0		-
CD20 status: Positive (n/N1 (%))	16/74 (21.6)	0/70 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
CD20 status: Negative (n/N1 (%))	6/72 (8.3)	0/56 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use:	22	0		0.9765
Rituximab use: Yes (n/N1 (%))	10/43 (23.3)	0/40 (0.0)		
Unstratified odds ratio ^c			25.39	
(95% CI)			(1.43, 449.35)	
p-value			0.0274	
Unstratified risk ratio ^c			19.57	
(95% CI)			(1.18, 323.39)	
p-value			0.0377	
Absolute risk reduction			0.23	
(95% CI)			(0.10, 0.36)	
p-value			0.0007	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Rituximab use: No (n/N1 (%))	12/104 (11.5)	0/88 (0.0)		
Unstratified odds ratio ^c			23.91	
(95% CI)			(1.40, 409.84)	
p-value			0.0285	
Unstratified risk ratio ^c			21.19	
(95% CI)			(1.27, 352.87)	
p-value			0.0333	
Absolute risk reduction			0.11	
(95% CI)			(0.05, 0.18)	
p-value			0.0005	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT:	22	0		-
Allogeneic SCT: Yes (n/N1 (%))	5/47 (10.6)	0/40 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Allogeneic SCT: No (n/N1 (%))	17/100 (17.0)	0/88 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status:	22	0		-
MRD status: Positive (n/N1 (%))	3/36 (8.3)	0/16 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	19/111 (17.1)	0/112 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting expedited aphasia (PT) - n (%)	8 (5.4)	0 (0.0)	5.4	
(95% CI)	(2.38, 10.44)	(0.00, 2.84)	(1.78, 9.11)	
p-value ^a			0.0065	
Age group 1:	8	0		-
Age group: <55 years (n/N1 (%))	2/91 (2.2)	0/72 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group: >=55 years (n/N1 (%))	6/56 (10.7)	0/56 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Age group 2: Age group: ≥18 - <35 years (n/N1 (%))	8 2/18 (11.1)	0 0/18 (0.0)		-
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI)			- -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	0/73 (0.0)	0/54 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥55 - <65 years (n/N1 (%))	5/44 (11.4)	0/36 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Age group: ≥65 years (n/N1 (%))	1/12 (8.3)	0/20 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

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Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Sex:	8	0		-
Sex: Male (n/N1 (%))	6/68 (8.8)	0/65 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated:

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Sex: Female (n/N1 (%))	2/79 (2.5)	0/63 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region:	8	0		-
Region: USA (n/N1 (%))	6/135 (4.4)	0/115 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Region: Rest of the world (n/N1 (%))	2/12 (16.7)	0/13 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race:	7	0		-
Race: Caucasian (n/N1 (%))	7/114 (6.1)	0/104 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Race: Others (n/N1 (%))	0/19 (0.0)	0/8 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity:	7	0		-
Ethnicity: Hispanic or Latino (n/N1 (%))	0/19 (0.0)	0/11 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	7/122 (5.7)	0/109 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status:	8	0		-
CD20 status: Positive (n/N1 (%))	7/74 (9.5)	0/70 (0.0)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
CD20 status: Negative (n/N1 (%))	1/72 (1.4)	0/56 (0.0)		
Unstratified odds ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Rituximab use:	8	0		-
Rituximab use: Yes (n/N1 (%))	4/43 (9.3)	0/40 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Rituximab use: No (n/N1 (%))	4/104 (3.8)	0/88 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated:

24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT:	8	0		-
Allogeneic SCT: Yes (n/N1 (%))	3/47 (6.4)	0/40 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	5/100 (5.0)	0/88 (0.0)		

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	8	0		-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Positive (n/N1 (%))	0/36 (0.0)	0/16 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
MRD status: Negative (n/N1 (%))	8/111 (7.2)	0/112 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Number of subjects reporting expedited psychiatric disorders (SOC) - n (%)	9 (6.1)	1 (0.8)	5.3	
(95% CI)	(2.84, 11.30)	(0.02, 4.28)	(1.18, 9.51)	
p-value ^a			0.0204	
Age group 1:	9	1		-
Age group: <55 years (n/N1 (%))	6/91 (6.6)	1/72 (1.4)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group: ≥55 years (n/N1 (%))	3/56 (5.4)	0/56 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	-
p-value			-	-
Unstratified risk ratio ^c (95% CI)			-	-
p-value			-	-
Absolute risk reduction (95% CI)			-	-
p-value			-	-

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Age group 2:	9	1		-
Age group: >=18 - <35 years (n/N1 (%))	2/18 (11.1)	1/18 (5.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Age group: ≥35 - <55 years (n/N1 (%))	4/73 (5.5)	0/54 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Age group: >=55 - <65 years (n/N1 (%))	2/44 (4.5)	0/36 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Age group: ≥65 years (n/N1 (%))	1/12 (8.3)	0/20 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Sex:	9	1		-
Sex: Male (n/N1 (%))	4/68 (5.9)	0/65 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated:

24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Sex: Female (n/N1 (%))	5/79 (6.3)	1/63 (1.6)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Region:	9	1		-
Region: USA (n/N1 (%))	9/135 (6.7)	1/115 (0.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Region: Rest of the world (n/N1 (%))	0/12 (0.0)	0/13 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Race:	8	1		-
Race: Caucasian (n/N1 (%))	5/114 (4.4)	1/104 (1.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Race: Others (n/N1 (%))	3/19 (15.8)	0/8 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI) p-value			- - -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Absolute risk reduction (95% CI) p-value			- - -	
Ethnicity:	9	1		-
Ethnicity: Hispanic or Latino (n/N1 (%))	2/19 (10.5)	0/11 (0.0)		
Unstratified odds ratio ^c (95% CI) p-value			- - -	
Unstratified risk ratio ^c (95% CI)			- -	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP

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^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Ethnicity: Not Hispanic or Latino (n/N1 (%))	7/122 (5.7)	1/109 (0.9)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c (95% CI)			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
CD20 status:	9	1		-
CD20 status: Positive (n/N1 (%))	6/74 (8.1)	0/70 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
CD20 status: Negative (n/N1 (%))	3/72 (4.2)	1/56 (1.8)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	
Unstratified risk ratio ^c			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
(95% CI)			-	
p-value			-	
Absolute risk reduction (95% CI)			-	
p-value			-	
Rituximab use:	9	1		-
Rituximab use: Yes (n/N1 (%))	5/43 (11.6)	0/40 (0.0)		
Unstratified odds ratio ^c (95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Rituximab use: No (n/N1 (%))	4/104 (3.8)	1/88 (1.1)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT:	9	1		-
Allogeneic SCT: Yes (n/N1 (%))	2/47 (4.3)	0/40 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

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AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Adverse events coded using MedDRA version 25.1.

Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer_202510/tables/t-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.sas

Output: t14-06-008-001-ae-sum-exp-by-soc-pt-by-subgrp-s3saf.rtf (Date generated: 24NOV2025:00:26) Source data: adampa.adsl, adampa.adae

Table 14-6.8.1. Subgroup Analysis of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Allogeneic SCT: No (n/N1 (%))	7/100 (7.0)	1/88 (1.1)		
Unstratified odds ratio ^c			-	
(95% CI)			-	
p-value			-	

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 1 dose of protocol-specified therapies.

N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable. SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status:	9	1		-
MRD status: Positive (n/N1 (%))	1/36 (2.8)	0/16 (0.0)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. N1 = Number of subjects within each subgroup. CI = Confidence interval. NE = Not estimable.

SCT = Stem cell transplant.

Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.

Treatment-emergent adverse event is any AE recorded during any treatment period.

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AERS is called an expedited adverse event.

^a Cochran-Mantel-Haenszel test adjusting for the stratification factors.

^b p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.

^c The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for SOC Chemotherapy+Blinatumomab relative to SOC Chemotherapy.

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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference	Interaction p-value ^b
p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
MRD status: Negative (n/N1 (%))	8/111 (7.2)	1/112 (0.9)		
Unstratified odds ratio ^c			-	
(95% CI)			-	

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p-value			-	
Unstratified risk ratio ^c			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	
Number of subjects reporting expedited respiratory, thoracic and mediastinal disorders (SOC) - n (%)	9 (6.1)	2 (1.6)	4.6	
(95% CI)	(2.84, 11.30)	(0.19, 5.53)	(0.13, 8.99)	
p-value ^a			0.0509	

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