Dossier zur Nutzenbewertung gemäß § 35a SGB V

Blinatumomab (BLINCYTO®)

Amgen GmbH

Modul 4 F, Anhang 4-G

Zur Behandlung von Erwachsenen mit neu diagnostizierter und Säuglingen mit rezidivierter oder refraktärer B-Vorläufer ALL

Stand: 18.02.2025

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1.1.1 Unerwünschte Ereignisse (UE)

1.1.1.1 UE gesamt

Table 14-6.2.1. Summary Any Treatment-emergent Adverse Events (Safety Analysis Set- MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
Number of subjects reporting to any treatment-emergent adverse events - n (%)	111 (100.0)	110 (98.2)	1.79
(95% CI)	(96.73, 100.0)	(93.70, 99.78)	(-0.67, 4.24)
p-value[a, b]			0.17
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, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
[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-saf-mrdneg.sas
Output: t14-06-002-001-ae-sum-saf-mrdneg.rtf (Date generated: 09APR2024:22:42) Source data: adam.adsl, adampa.adae

Table 14-6.2.1. Summary Any Treatment-emergent Adverse Events (Safety Analysis Set- MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
Absolute risk reduction[d]			0.041
(95% CI)			(-0.153, 0.234)
p-value			0.68

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
[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-saf-mrdneg.sas
Output: t14-06-002-001-ae-sum-saf-mrdneg.rtf (Date generated: 09APR2024:22:42) Source data: adam.adsl, adampa.adae

Table 14-6.2.2. Summary Any Treatment-emergent Adverse Events (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
Number of subjects reporting to any treatment-emergent adverse events - n (%)	33 (91.7)	15 (93.8)	-2.08
(95% CI)	(77.53, 98.25)	(69.77, 99.84)	(-16.99, 12.82)
p-value[a, b]			0.79
Unstratified odds ratio[c]			0.733
(95% CI)			(0.070, 7.644)
p-value			0.80
Stratified odds ratio[b, c]			0.717
(95% CI)			(0.062, 8.341)
p-value			0.79
Unstratified risk ratio[c]			0.978
(95% CI)			(0.833, 1.148)
p-value			0.78
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.021
(95% CI)			(-0.170, 0.128)
p-value			0.78

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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-saf-mrdpos.sas Output: t14-06-002-002-ae-sum-saf-mrdpos.rtf (Date generated: 09APR2024:22:42) Source data: adam.adsl, adampa.adae

Table 14-6.2.3. Summary 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

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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: 09APR2024:22:43) Source data: adam.adsl, adampa.adae

1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.1 Unerwünschte Ereignisse (UE)

1.1.1.2 Schwere UE (CTCAE Grad ≥ 3)

Table 14-6.2.4. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events (Safety Analysis Set- MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting grade 3 and above treatment-emergent adverse events - n (%)	108 (97.3)	110 (98.2)	-0.92
(95% CI)	(92.30, 99.44)	(93.70, 99.78)	(-4.80, 2.97)
p-value[a, b]			0.61
Unstratified odds ratio[c]			0.655
(95% CI)			(0.107, 3.994)
p-value			0.65
Stratified odds ratio[b, c]			0.625
(95% CI)			(0.103, 3.795)
p-value			0.61
Unstratified risk ratio[c]			0.991
(95% CI)			(0.952, 1.031)

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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-gr3-saf-mrdneg.sas
Output: t14-06-002-004-ae-sum-gr3-saf-mrdneg.rtf (Date generated: 09APR2024:22:43)
Source data: adam.adsl, adampa.adae

Table 14-6.2.4. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events (Safety Analysis Set- MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.64
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.009
(95% CI)			(-0.048, 0.030)
p-value			0.64

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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-gr3-saf-mrdneg.sas
Output: t14-06-002-004-ae-sum-gr3-saf-mrdneg.rtf (Date generated: 09APR2024:22:43)
Source data: adam.adsl, adampa.adae

Table 14-6.2.5. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting grade 3 and above treatment-emergent adverse events - n (%)	31 (86.1)	15 (93.8)	-7.64
(95% CI)	(70.50, 95.33)	(69.77, 99.84)	(-24.02, 8.74)
p-value[a, b]			0.65
Unstratified odds ratio[c]			0.413
(95% CI)			(0.044, 3.859)
p-value			0.44
Stratified odds ratio[b, c]			0.569
(95% CI)			(0.050, 6.515)
p-value			0.65
Unstratified risk ratio[c]			0.919
(95% CI)			(0.765, 1.102)
p-value			0.36

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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-gr3-saf-mrdpos.sas
Output: t14-06-002-005-ae-sum-gr3-saf-mrdpos.rtf (Date generated: 09APR2024:22:43)
Source data: adam.adsl, adampa.adae

Table 14-6.2.5. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.076
(95% CI)			(-0.240, 0.087)
p-value			0.36

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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-gr3-saf-mrdpos.sas
Output: t14-06-002-005-ae-sum-gr3-saf-mrdpos.rtf (Date generated: 09APR2024:22:43)
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

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
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: 10APR2024:03:29) 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
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: 10APR2024:03:29) Source data: adam.adsl, adampa.adae

1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.1 Unerwünschte Ereignisse (UE)

1.1.1.3 Expedited UE

Table 14-6.2.7. Summary of Expedited Treatment-emergent Adverse Events (Safety Analysis Set- MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	67 (60.4)	31 (27.7)	32.68
(95% CI)	(50.63, 69.52)	(19.64, 36.93)	(20.37, 44.99)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			3.979
(95% CI)			(2.268, 6.980)
p-value			<0.001
Stratified odds ratio[b, c]			3.975
(95% CI)			(2.253, 7.015)
p-value			<0.001
Unstratified risk ratio[c]			2.181
(95% CI)			(1.560, 3.049)
p-value			<0.001

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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/tables/t-ae-sum-exp-saf-mrdneg.sas
Output: t14-06-002-007-ae-sum-exp-saf-mrdneg.rtf (Date generated: 09APR2024:22:44)
Source data: adam.adsl, adampa.adae

Table 14-6.2.7. Summary of Expedited Treatment-emergent Adverse Events (Safety Analysis Set- MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified risk ratio[b, c]			2.206
(95% CI)			(1.583, 3.073)
p-value			<0.001
Absolute risk reduction			0.327
(95% CI)			(0.204, 0.450)
p-value			<0.001

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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/tables/t-ae-sum-exp-saf-mrdneg.sas
Output: t14-06-002-007-ae-sum-exp-saf-mrdneg.rtf (Date generated: 09APR2024:22:44)
Source data: adam.adsl, adampa.adae

Table 14-6.2.8. Summary of Expedited Treatment-emergent Adverse Events (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting expedited treatment-emergent adverse events - n (%)	15 (41.7)	5 (31.3)	10.42
(95% CI)	(25.51, 59.24)	(11.02, 58.66)	(-17.43, 38.26)
p-value[a, b]			0.76
Unstratified odds ratio[c]			1.571
(95% CI)			(0.451, 5.472)
p-value			0.48
Stratified odds ratio[b, c]			1.287
(95% CI)			(0.261, 6.343)
p-value			0.76
Unstratified risk ratio[c]			1.333
(95% CI)			(0.585, 3.037)

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-exp-saf-mrdpos.sas
Output: t14-06-002-008-ae-sum-exp-saf-mrdpos.rtf (Date generated: 09APR2024:22:45)
Source data: adam.adsl, adampa.adae

Table 14-6.2.8. Summary of Expedited Treatment-emergent Adverse Events (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.49
Stratified risk ratio[b, c, d]			1.533
(95% CI)			(0.620, 3.789)
p-value			0.36
Absolute risk reduction			0.104
(95% CI)			(-0.174, 0.383)
p-value			0.46

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-exp-saf-mrdpos.sas
Output: t14-06-002-008-ae-sum-exp-saf-mrdpos.rtf (Date generated: 09APR2024:22:45)
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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/tables/t-ae-sum-exp-s3saf.sas
Output: t14-06-002-009-ae-sum-exp-s3saf.rtf (Date generated: 09APR2024:22:45) 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

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.
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 are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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/tables/t-ae-sum-exp-s3saf.sas
Output: t14-06-002-009-ae-sum-exp-s3saf.rtf (Date generated: 09APR2024:22:45) Source data: adam.adsl, adampa.adae

1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.1 Unerwünschte Ereignisse (UE)

1.1.1.4 Therapieabbruch aufgrund von UE

Table 14-6.2.13. Summary Treatment-emergent Adverse Events Leading to Treatment Discontinuation (Safety Analysis Set- MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	12 (10.8)	5 (4.5)	6.35
(95% CI)	(5.71, 18.12)	(1.47, 10.11)	(-0.58, 13.27)
p-value[a, b]			0.042
Unstratified odds ratio[c]			2.594
(95% CI)			(0.882, 7.627)
p-value			0.083
Stratified odds ratio[b, c]			3.055
(95% CI)			(1.000, 9.338)
p-value			0.050
Unstratified risk ratio[c]			2.422
(95% CI)			(0.882, 6.647)
p-value			0.086
Stratified risk ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.063

Page 1 of 2

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 treament 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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/tables/t-ae-sum-dct-saf-mrdneg.sas
Output: t14-06-002-013-ae-sum-dct-saf-mrdneg.rtf (Date generated: 14APR2024:10:03) Source data: adam.adsl, adampa.adae

Table 14-6.2.13. Summary Treatment-emergent Adverse Events Leading to Treatment Discontinuation (Safety Analysis Set- MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
(95% CI)			(-0.006, 0.133)
p-value			0.073

Page 2 of 2

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 treament 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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/tables/t-ae-sum-dct-saf-mrdneg.sas
Output: t14-06-002-013-ae-sum-dct-saf-mrdneg.rtf (Date generated: 14APR2024:10:03) Source data: adam.adsl, adampa.adae

Table 14-6.2.14. Summary Treatment-emergent Adverse Events Leading to Treatment Discontinuation (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
Number of subjects reporting treatment-emergent adverse events leading to treatment discontinuation - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
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

Page 1 of 2

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 treament 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program:
/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-dct-saf-mrdpos.sas
Output: t14-06-002-014-ae-sum-dct-saf-mrdpos.rtf (Date generated: 14APR2024:10:06) Source data: adam.adsl, adampa.adae

Table 14-6.2.14. Summary Treatment-emergent Adverse Events Leading to Treatment Discontinuation (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
Absolute risk reduction[d]			0.077
(95% CI)			(-0.423, 0.577)
p-value			0.76

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 treament 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program:
/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-dct-saf-mrdpos.sas
Output: t14-06-002-014-ae-sum-dct-saf-mrdpos.rtf (Date generated: 14APR2024:10:06) Source data: adam.adsl, adampa.adae

Table 14-6.2.15. Summary 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

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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 treament 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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/tables/t-ae-sum-dct-s3saf.sas Output: t14-06-002-015-ae-sum-dct-s3saf.rtf (Date generated: 14APR2024:10:03) Source data: adam.adsl, adampa.adae

Table 14-6.2.15. Summary 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

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 treament 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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/tables/t-ae-sum-dct-s3saf.sas
Output: t14-06-002-015-ae-sum-dct-s3saf.rtf (Date generated: 14APR2024:10:03) Source data: adam.adsl, adampa.adae

1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.1 Unerwünschte Ereignisse (UE)

1.1.1.5 Tod aufgrund von UE

Table 14-6.2.10. Summary of Fatal Treatment-emergent Adverse Events (Safety Analysis Set- MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
Number of subjects reporting fatal treatment-emergent adverse events - n (%)	3 (2.7)	1 (0.9)	1.81
(95% CI)	(0.56, 7.70)	(0.02, 4.87)	(-1.67, 5.29)
p-value[a, b]			0.29
Unstratified odds ratio[c]			3.083
(95% CI)			(0.316, 30.095)
p-value			0.33
Stratified odds ratio[b, c]			3.215
(95% CI)			(0.334, 30.938)
p-value			0.31
Unstratified risk ratio[c]			3.027
(95% CI)			(0.320, 28.659)
p-value			0.33
Stratified risk ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.018
(95% CI)			(-0.017, 0.053)
p-value			0.31

Page 1 of 1

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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/tables/t-ae-sum-fat-saf-mrdneg.sas
Output: t14-06-002-010-ae-sum-fat-saf-mrdneg.rtf (Date generated: 10APR2024:03:30) Source data: adam.adsl, adampa.adae

Table 14-6.2.11. Summary of Fatal Treatment-emergent Adverse Events (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
Number of subjects reporting fatal treatment-emergent adverse events - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
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
Absolute risk reduction[d]			-0.084

Page 1 of 2

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-fat-saf-mrdpos.sas
Output: t14-06-002-011-ae-sum-fat-saf-mrdpos.rtf (Date generated: 10APR2024:03:31) Source data: adam.adsl, adampa.adae

Table 14-6.2.11. Summary of Fatal Treatment-emergent Adverse Events (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
(95% CI)			(-0.445, 0.278)
p-value			0.65

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-fat-saf-mrdpos.sas
Output: t14-06-002-011-ae-sum-fat-saf-mrdpos.rtf (Date generated: 10APR2024:03:31) 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

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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/tables/t-ae-sum-fat-s3saf.sas Output: t14-06-002-012-ae-sum-fat-s3saf.rtf (Date generated: 10APR2024:03:34) Source data: adam.adsl, adampa.adae

1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.1 Unerwünschte Ereignisse (UE)

1.1.1.6 UE nach schwerstem CTCAE Grad

Table 14-6.3.1. Summary of Treatment-emergent Adverse Events by Maximum CTCAE Grade (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy + Blinatumomab (N = 111) n (%)	SOC Chemotherapy (N = 112) n (%)
Number of subjects with Event - n (%)	111 (100.0)	110 (98.2)
Grade 1	1 (0.9)	0 (0.0)
Grade 2	2 (1.8)	0 (0.0)
Grade 3	8 (7.2)	4 (3.6)
Grade 4	97 (87.4)	105 (93.8)
Fatal	3 (2.7)	1 (0.9)

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. SCT = Stem cell transplant.
Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.
Treatment-emergent adverse event is any AE recorded during any treatment period.
Severity graded using CTCAE version 4.0.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-sum-teae-mctcae-neg-saf.sas
Output: t14-06-003-001-sum-teae-mctcae-neg-saf.rtf (Date Generated: 09APR24:22:48:37) Source: adam.adsl, adampa.adae

Table 14-6.3.2. Summary of Treatment-emergent Adverse Events by Maximum CTCAE Grade (Step 3 MRD positive Safety Analysis Set)

	SOC Chemotherapy + Blinatumomab (N = 36) n (%)	SOC Chemotherapy (N = 16) n (%)
Number of subjects with Event - n (%)	33 (91.7)	15 (93.8)
Grade 1	1 (2.8)	0 (0.0)
Grade 2	1 (2.8)	0 (0.0)
Grade 3	2 (5.6)	0 (0.0)
Grade 4	29 (80.6)	14 (87.5)
Fatal	0 (0.0)	1 (6.3)

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The Step 3 MRD positive analysis set includes all subjects from Step 3 analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. SCT = Stem cell transplant.
Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.
Treatment-emergent adverse event is any AE recorded during any treatment period.
Severity graded using CTCAE version 4.0.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-sum-teae-mctcae-pos-s3saf.sas
Output: t14-06-003-002-sum-teae-mctcae-pos-s3saf.rtf (Date Generated: 09APR24:22:49:09) Source: adam.adsl, adampa.adae

Table 14-6.3.3. Summary of Treatment-emergent Adverse Events by Maximum CTCAE Grade (Step 3 Safety Analysis Set)

	SOC Chemotherapy + Blinatumomab (N = 147) n (%)	SOC Chemotherapy (N = 128) n (%)
Number of subjects with Event - n (%)	144 (98.0)	125 (97.7)
Grade 1	2 (1.4)	0 (0.0)
Grade 2	3 (2.0)	0 (0.0)
Grade 3	10 (6.8)	4 (3.1)
Grade 4	126 (85.7)	119 (93.0)
Fatal	3 (2.0)	2 (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. n = Number of subjects with observed data. SCT = Stem cell transplant.
Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and AlloSCT.
Treatment-emergent adverse event is any AE recorded during any treatment period.
Severity graded using CTCAE version 4.0.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-sum-teae-mctcae-s3saf.sas Output: t14-06-003-003-sum-teae-mctcae-s3saf.rtf (Date Generated: 09APR24:22:51:56) Source: adam.adsl, adampa.adae

1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.2 UE von besonderem Interesse

1.1.2.1 UE von besonderem Interesse gesamt

Table 14-6.5.1. Summary of Any Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
Number of subjects reporting any cytokine release syndrome (EOI) - n (%)	19 (17.1)	0 (0.0)	17.12
(95% CI)	(10.63, 25.43)	(0.00, 3.24)	(10.11, 24.12)
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]			0.187

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program:
/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-saf-mrdneg.sas
Output: t14-06-005-001-ae-sum-eoi-saf-mrdneg.rtf (Date generated: 09APR2024:22:53) Source data: adam.adsl, adampa.adae

Table 14-6.5.1. Summary of Any Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
(95% CI)			(-0.013, 0.387)
p-value			0.066
Number of subjects reporting any medication errors (EOI) - n (%)	1 (0.9)	0 (0.0)	0.90
(95% CI)	(0.02, 4.92)	(0.00, 3.24)	(-0.86, 2.66)
p-value[a, b]			0.32
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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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-saf-mrdneg.sas
Output: t14-06-005-001-ae-sum-eoi-saf-mrdneg.rtf (Date generated: 09APR2024:22:53) Source data: adam.adsl, adampa.adae

Table 14-6.5.1. Summary of Any Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
Absolute risk reduction			NE
(95% CI)			(NE, NE)
p-value			NE
Number of subjects reporting any neurological events (EOI) - n (%)	72 (64.9)	43 (38.4)	26.47
(95% CI)	(55.23, 73.69)	(29.36, 48.06)	(13.82, 39.12)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			2.962
(95% CI)			(1.718, 5.108)
p-value			<0.001
Stratified odds ratio[b, c]			3.234
(95% CI)			(1.826, 5.728)
p-value			<0.001
Unstratified risk ratio[c]			1.690
(95% CI)			(1.288, 2.217)
p-value			<0.001
Stratified risk ratio[b, c]			1.705
(95% CI)			(1.303, 2.232)
p-value			<0.001

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-saf-mrdneg.sas
Output: t14-06-005-001-ae-sum-eoi-saf-mrdneg.rtf (Date generated: 09APR2024:22:53) Source data: adam.adsl, adampa.adae

Table 14-6.5.1. Summary of Any Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
Absolute risk reduction			0.265
(95% CI)			(0.138, 0.391)
p-value			<0.001

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program:
/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-saf-mrdneg.sas
Output: t14-06-005-001-ae-sum-eoi-saf-mrdneg.rtf (Date generated: 09APR2024:22:53) Source data: adam.adsl, adampa.adae

Table 14-6.5.2. Summary of Any Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
Number of subjects reporting any cytokine release syndrome (EOI) - n (%))	4 (11.1)	0 (0.0)	11.11
(95% CI)	(3.11, 26.06)	(0.00, 20.59)	(0.85, 21.38)
p-value[a, b]			0.32
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]			0.130

Page 1 of 4

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-saf-mrdpos.sas
Output: t14-06-005-002-ae-sum-eoi-saf-mrdpos.rtf (Date generated: 10APR2024:01:49) Source data: adam.adsl, adampa.adae

Table 14-6.5.2. Summary of Any Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
(95% CI)			(-0.374, 0.634)
p-value			0.61
Number of subjects reporting any 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]			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			NE

Page 2 of 4

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-saf-mrdpos.sas
Output: t14-06-005-002-ae-sum-eoi-saf-mrdpos.rtf (Date generated: 10APR2024:01:49) Source data: adam.adsl, adampa.adae

Table 14-6.5.2. Summary of Any Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Number of subjects reporting any neurological events (EOI) - n (%))	18 (50.0)	6 (37.5)	12.50
(95% CI)	(32.92, 67.08)	(15.20, 64.57)	(-16.30, 41.30)
p-value[a, b]			0.63
Unstratified odds ratio[c]			1.667
(95% CI)			(0.500, 5.559)
p-value			0.41
Stratified odds ratio[b, c]			0.709
(95% CI)			(0.172, 2.926)
p-value			0.63
Unstratified risk ratio[c]			1.333
(95% CI)			(0.654, 2.717)
p-value			0.43
Stratified risk ratio[b, c, d]			1.205
(95% CI)			(0.557, 2.608)
p-value			0.64
Absolute risk reduction			0.125

Page 3 of 4

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-saf-mrdpos.sas
Output: t14-06-005-002-ae-sum-eoi-saf-mrdpos.rtf (Date generated: 10APR2024:01:49) Source data: adam.adsl, adampa.adae

Table 14-6.5.2. Summary of Any Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
(95% CI)			(-0.163, 0.413)
p-value			0.39

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program:
/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-saf-mrdpos.sas
Output: t14-06-005-002-ae-sum-eoi-saf-mrdpos.rtf (Date generated: 10APR2024:01:49) 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
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

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
[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: 09APR2024:22:54) 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
[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: 09APR2024:22:54) 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[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Number of subjects reporting any neurological events (EOI) - n (%)	90 (61.2)	49 (38.3)	22.94
(95% CI)	(52.85, 69.14)	(29.83, 47.28)	(11.41, 34.47)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			2.546
(95% CI)			(1.564, 4.142)
p-value			<0.001
Stratified odds ratio[b, c]			2.601
(95% CI)			(1.565, 4.321)
p-value			<0.001
Unstratified risk ratio[c]			1.599
(95% CI)			(1.240, 2.064)
p-value			<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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
[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: 09APR2024:22:54) 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
[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: 09APR2024:22:54) Source data: adam.adsl, adampa.adae

1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.2 UE von besonderem Interesse

1.1.2.2 Schwere UE (CTCAE Grad ≥ 3) von besonderem Interesse gesamt

Table 14-6.5.4. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
Number of subjects reporting grade 3 and above cytokine release syndrome (EOI) - n (%)	4 (3.6)	0 (0.0)	3.60
(95% CI)	(0.99, 8.97)	(0.00, 3.24)	(0.14, 7.07)
p-value[a, b]			0.033
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

Page 1 of 4

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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-saf-mrdneg.sas
Output: t14-06-005-004-ae-sum-eoi-gr3-saf-mrdneg.rtf (Date generated: 09APR2024:22:54) Source data: adam.adsl, adampa.adae

Table 14-6.5.4. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
(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 medication errors (EOI) - n (%)	1 (0.9)	0 (0.0)	0.90
(95% CI)	(0.02, 4.92)	(0.00, 3.24)	(-0.86, 2.66)
p-value[a, b]			0.32
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

Page 2 of 4

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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-saf-mrdneg.sas
Output: t14-06-005-004-ae-sum-eoi-gr3-saf-mrdneg.rtf (Date generated: 09APR2024:22:54) Source data: adam.adsl, adampa.adae

Table 14-6.5.4. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	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 grade 3 and above neurological events (EOI) - n (%)	34 (30.6)	12 (10.7)	19.92
(95% CI)	(22.23, 40.09)	(5.66, 17.97)	(9.60, 30.23)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			3.680
(95% CI)			(1.787, 7.575)

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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-saf-mrdneg.sas
Output: t14-06-005-004-ae-sum-eoi-gr3-saf-mrdneg.rtf (Date generated: 09APR2024:22:54) Source data: adam.adsl, adampa.adae

Table 14-6.5.4. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
p-value			<0.001
Stratified odds ratio[b, c]			3.548
(95% CI)			(1.729, 7.282)
p-value			<0.001
Unstratified risk ratio[c]			2.859
(95% CI)			(1.564, 5.227)
p-value			<0.001
Stratified risk ratio[b, c]			2.919
(95% CI)			(1.599, 5.329)
p-value			<0.001
Absolute risk reduction			0.199
(95% CI)			(0.096, 0.302)
p-value			<0.001

Page 4 of 4

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 negative of the Hessian is not positive definite. The convergence is questionable.
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Table 14-6.5.5. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
Number of subjects reporting grade 3 and above cytokine release syndrome (EOI) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			0.32
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 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

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Table 14-6.5.5. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
p-value			NE
Absolute risk reduction[d]			0.077
(95% CI)			(-0.423, 0.577)
p-value			0.76
Number of subjects reporting grade 3 and above 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]			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

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

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Output: t14-06-005-005-ae-sum-eoi-gr3-saf-mrdpos.rtf (Date generated: 09APR2024:22:55) Source data: adam.adsl, adampa.adae

Table 14-6.5.5. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	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			NE
(95% CI)			(NE, NE)
p-value			NE
Number of subjects reporting grade 3 and above neurological events (EOI) - n (%)	8 (22.2)	2 (12.5)	9.72
(95% CI)	(10.12, 39.15)	(1.55, 38.35)	(-11.42, 30.87)
p-value[a, b]			0.30
Unstratified odds ratio[c]			2.000
(95% CI)			(0.374, 10.699)
p-value			0.42
Stratified odds ratio[b, c]			0.310

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-gr3-saf-mrdpos.sas
Output: t14-06-005-005-ae-sum-eoi-gr3-saf-mrdpos.rtf (Date generated: 09APR2024:22:55) Source data: adam.adsl, adampa.adae

Table 14-6.5.5. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
(95% CI)			(0.032, 2.958)
p-value			0.31
Unstratified risk ratio[c]			1.778
(95% CI)			(0.424, 7.453)
p-value			0.43
Stratified risk ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.097
(95% CI)			(-0.114, 0.309)
p-value			0.37

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-gr3-saf-mrdpos.sas
Output: t14-06-005-005-ae-sum-eoi-gr3-saf-mrdpos.rtf (Date generated: 09APR2024:22:55) 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
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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: 10APR2024:06:26) 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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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: 10APR2024:06:26) 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

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
[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 are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 negative of the Hessian is not positive definite. The convergence is questionable.
Data cut-off date: 23JUN2023

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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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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: 10APR2024:06:26) Source data: adam.adsl, adampa.adae

1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.2 UE von besonderem Interesse

1.1.2.3 Expedited UE von besonderem Interesse gesamt

Table 14-6.5.7. Summary of Expedited Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
Number of subjects reporting expedited cytokine release syndrome (EOI) - n (%))	4 (3.6)	0 (0.0)	3.60
(95% CI)	(0.99, 8.97)	(0.00, 3.24)	(0.14, 7.07)
p-value[a, b]			0.035
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

Page 1 of 4

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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-exp-saf-mrdneg.sas
Output: t14-06-005-007-ae-sum-eoi-exp-saf-mrdneg.rtf (Date generated: 10APR2024:06:19) Source data: adam.adsl, adampa.adae

Table 14-6.5.7. Summary of Expedited Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction[d]			NE
(95% CI)			(NE, NE)
p-value			NE
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]			NE
(95% CI)			(NE, NE)
p-value'			NE
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 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-exp-saf-mrdneg.sas
Output: t14-06-005-007-ae-sum-eoi-exp-saf-mrdneg.rtf (Date generated: 10APR2024:06:19) Source data: adam.adsl, adampa.adae

Table 14-6.5.7. Summary of Expedited Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	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 (%))	23 (20.7)	2 (1.8)	18.94
(95% CI)	(13.61, 29.45)	(0.22, 6.30)	(11.01, 26.86)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			14.375
(95% CI)			(3.299, 62.636)

Page 3 of 4

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 negative of the Hessian is not positive definite. The convergence is questionable.
Data cut-off date: 23JUN2023

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Table 14-6.5.7. Summary of Expedited Treatment-emergent Adverse Events of Interest (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N=111)	SOC Chemotherapy (N=112)	Treatment Difference
p-value			<0.001
Stratified odds ratio[b, c]			14.838
(95% CI)			(3.384, 65.069)
p-value			<0.001
Unstratified risk ratio[c]			11.604
(95% CI)			(2.802, 48.047)
p-value			<0.001
Stratified risk ratio[b, c]			12.095
(95% CI)			(2.934, 49.859)
p-value			<0.001
Absolute risk reduction			0.189
(95% CI)			(0.110, 0.269)
p-value			<0.001

Page 4 of 4

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 negative of the Hessian is not positive definite. The convergence is questionable.
Data cut-off date: 23JUN2023

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Output: t14-06-005-007-ae-sum-eoi-exp-saf-mrdneg.rtf (Date generated: 10APR2024:06:19) Source data: adam.adsl, adampa.adae

Table 14-6.5.8. Summary of Expedited Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
Number of subjects reporting expedited cytokine release syndrome (EOI) - n (%)	1 (2.8)	0 (0.0)	2.78
(95% CI)	(0.07, 14.53)	(0.00, 20.59)	(-2.59, 8.15)
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

Page 1 of 4

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-exp-saf-mrdpos.sas
Output: t14-06-005-008-ae-sum-eoi-exp-saf-mrdpos.rtf (Date generated: 10APR2024:06:19) Source data: adam.adsl, adampa.adae

Table 14-6.5.8. Summary of Expedited Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction[d]			0.050
(95% CI)			(-0.449, 0.549)
p-value			0.84
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]			NE
(95% CI)			(NE, NE)
p-value'			NE
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

Program: /userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-ae-sum-eoi-exp-saf-mrdpos.sas
Output: t14-06-005-008-ae-sum-eoi-exp-saf-mrdpos.rtf (Date generated: 10APR2024:06:19) Source data: adam.adsl, adampa.adae

Table 14-6.5.8. Summary of Expedited Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	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 (%)	4 (11.1)	0 (0.0)	11.11
(95% CI)	(3.11, 26.06)	(0.00, 20.59)	(0.85, 21.38)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)

Page 3 of 4

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

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Output: t14-06-005-008-ae-sum-eoi-exp-saf-mrdpos.rtf (Date generated: 10APR2024:06:19) Source data: adam.adsl, adampa.adae

Table 14-6.5.8. Summary of Expedited Treatment-emergent Adverse Events of Interest (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N=36)	SOC Chemotherapy (N=16)	Treatment Difference
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]			16.841
(95% CI)			(0.167, NE)
p-value			0.23
Absolute risk reduction[d]			0.130
(95% CI)			(-0.374, 0.634)
p-value			0.61

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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[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 are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
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Output: t14-06-005-008-ae-sum-eoi-exp-saf-mrdpos.rtf (Date generated: 10APR2024:06:19) 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
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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
Data cut-off date: 23JUN2023

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Output: t14-06-005-009-ae-sum-eoi-exp-s3saf.rtf (Date generated: 10APR2024:06:19) 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]			0.056
(95% CI)			(-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]			NE
(95% CI)			(NE, NE)
p-value'			NE
Stratified odds 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.
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] 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 are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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.
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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 ratio are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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 14-6.5.9. 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

Page 4 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.
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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 are obtained from a logistic regression model with logit link and risk ratio are obtained from generalized binomial model with 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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1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.3 UE nach SOC/PT

1.1.3.1 UE gesamt nach SOC/PT bei ≥ 10 % der Patientinnen und Patienten

Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting any blood and lymphatic system disorders (SOC) - n (%)	70 (63.1)	76 (67.9)	-4.79
(95% CI)	(53.38, 72.03)	(58.37, 76.37)	(-17.26, 7.67)
p-value[a, b]			0.51
Unstratified odds ratio[c]			0.809
(95% CI)			(0.465, 1.406)
p-value			0.45
Stratified odds ratio[b, c]			0.827
(95% CI)			(0.473, 1.447)
p-value			0.51
Unstratified risk ratio[c]			0.929
(95% CI)			(0.768, 1.125)
p-value			0.45
Stratified risk ratio[b, c]			0.981
(95% CI)			(0.815, 1.182)
p-value			0.84

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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-saf-mrdneg.sas
Output: t14-06-006-001-teae-10pct-soc-pt-saf-mrdneg.rtf (Date generated: 11MAY2024:00:02) Source data: adam.adsl, adampa.adae

Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Absolute risk reduction			-0.048
(95% CI)			(-0.173, 0.077)
p-value			0.48
Number of subjects reporting anaemia (PT) - n (%)	65 (58.6)	60 (53.6)	4.99
(95% CI)	(48.82, 67.83)	(43.90, 63.05)	(-8.02, 18.00)
p-value[a, b]			0.41
Unstratified odds ratio[c]			1.225
(95% CI)			(0.721, 2.080)
p-value			0.45
Stratified odds ratio[b, c]			1.258
(95% CI)			(0.729, 2.172)
p-value			0.41
Unstratified risk ratio[c]			1.093
(95% CI)			(0.866, 1.380)
p-value			0.45
Stratified risk ratio[b, c]			1.122

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.899, 1.400)
p-value			0.31
Absolute risk reduction			0.050
(95% CI)			(-0.080, 0.180)
p-value			0.50
Number of subjects reporting febrile neutropenia (PT) - n (%)	23 (20.7)	32 (28.6)	-7.85
(95% CI)	(13.61, 29.45)	(20.43, 37.88)	(-19.11, 3.41)
p-value[a, b]			0.20
Unstratified odds ratio[c]			0.653
(95% CI)			(0.353, 1.209)
p-value			0.18
Stratified odds ratio[b, c]			0.676
(95% CI)			(0.372, 1.231)
p-value			0.20
Unstratified risk ratio[c]			0.725
(95% CI)			(0.455, 1.157)
p-value			0.18

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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[a] Cochran-Mantel-Haenszel test adjusting for the stratification factors.
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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified risk ratio[b, c]			0.722
(95% CI)			(0.452, 1.153)
p-value			0.17
Absolute risk reduction			-0.079
(95% CI)			(-0.191, 0.034)
p-value			0.21
Number of subjects reporting any gastrointestinal disorders (SOC) - n (%)	64 (57.7)	48 (42.9)	14.80
(95% CI)	(47.92, 66.98)	(33.55, 52.55)	(1.82, 27.78)
p-value[a, b]			0.022
Unstratified odds ratio[c]			1.816
(95% CI)			(1.068, 3.087)
p-value			0.028
Stratified odds ratio[b, c]			1.868
(95% CI)			(1.092, 3.193)
p-value			0.022

Page 4 of 39

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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[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 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified risk ratio[c]			1.345
(95% CI)			(1.030, 1.757)
p-value			0.029
Stratified risk ratio[b, c]			1.401
(95% CI)			(1.081, 1.814)
p-value			0.011
Absolute risk reduction			0.148
(95% CI)			(0.018, 0.278)
p-value			0.032
Number of subjects reporting abdominal pain (PT) - n (%)	24 (21.6)	18 (16.1)	5.55
(95% CI)	(14.37, 30.44)	(9.81, 24.21)	(-4.69, 15.79)
p-value[a, b]			0.29
Unstratified odds ratio[c]			1.441
(95% CI)			(0.732, 2.835)
p-value			0.29
Stratified odds ratio[b, c]			1.438

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.732, 2.826)
p-value			0.29
Unstratified risk ratio[c]			1.345
(95% CI)			(0.775, 2.336)
p-value			0.29
Stratified risk ratio[b, c]			1.379
(95% CI)			(0.799, 2.380)
p-value			0.25
Absolute risk reduction			0.056
(95% CI)			(-0.047, 0.158)
p-value			0.31
Number of subjects reporting diarrhoea (PT) - n (%)	37 (33.3)	24 (21.4)	11.90
(95% CI)	(24.67, 42.91)	(14.24, 30.19)	(0.30, 23.51)
p-value[a, b]			0.043
Unstratified odds ratio[c]			1.833
(95% CI)			(1.007, 3.339)
p-value			0.048

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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified odds ratio[b, c]			1.846
(95% CI)			(1.014, 3.360)
p-value			0.045
Unstratified risk ratio[c]			1.556
(95% CI)			(1.000, 2.419)
p-value			0.050
Stratified risk ratio[b, c]			1.658
(95% CI)			(1.072, 2.566)
p-value			0.023
Absolute risk reduction			0.119
(95% CI)			(0.003, 0.235)
p-value			0.052
Number of subjects reporting nausea (PT) - n (%)	18 (16.2)	8 (7.1)	9.07
(95% CI)	(9.90, 24.41)	(3.13, 13.59)	(0.72, 17.43)
p-value[a, b]			0.036
Unstratified odds ratio[c]			2.516

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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(1.045, 6.057)
p-value			0.040
Stratified odds ratio[b, c]			2.488
(95% CI)			(1.039, 5.959)
p-value			0.041
Unstratified risk ratio[c]			2.270
(95% CI)			(1.030, 5.004)
p-value			0.042
Stratified risk ratio[b, c]			2.327
(95% CI)			(1.058, 5.117)
p-value			0.036
Absolute risk reduction			0.091
(95% CI)			(0.007, 0.174)
p-value			0.039
Number of subjects reporting vomiting (PT) - n (%)	37 (33.3)	27 (24.1)	9.23
(95% CI)	(24.67, 42.91)	(16.53, 33.10)	(-2.59, 21.04)
p-value[a, b]			0.12

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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified odds ratio[c]			1.574
(95% CI)			(0.876, 2.828)
p-value			0.13
Stratified odds ratio[b, c]			1.617
(95% CI)			(0.885, 2.953)
p-value			0.12
Unstratified risk ratio[c]			1.383
(95% CI)			(0.908, 2.106)
p-value			0.13
Stratified risk ratio[b, c]			1.390
(95% CI)			(0.917, 2.107)
p-value			0.12
Absolute risk reduction			0.092
(95% CI)			(-0.026, 0.210)
p-value			0.14

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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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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting any general disorders and administration site conditions (SOC) - n (%)	37 (33.3)	16 (14.3)	19.05
(95% CI)	(24.67, 42.91)	(8.39, 22.16)	(8.14, 29.95)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			3.000
(95% CI)			(1.550, 5.805)
p-value			0.001
Stratified odds ratio[b, c]			3.038
(95% CI)			(1.568, 5.887)
p-value			<0.001
Unstratified risk ratio[c]			2.333
(95% CI)			(1.381, 3.942)
p-value			0.002
Stratified risk ratio[b, c]			2.338
(95% CI)			(1.383, 3.953)
p-value			0.002

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Absolute risk reduction			0.190
(95% CI)			(0.081, 0.300)
p-value			<0.001
Number of subjects reporting fatigue (PT) - n (%)	20 (18.0)	11 (9.8)	8.20
(95% CI)	(11.37, 26.45)	(5.01, 16.89)	(-0.83, 17.22)
p-value[a, b]			0.076
Unstratified odds ratio[c]			2.018
(95% CI)			(0.917, 4.439)
p-value			0.081
Stratified odds ratio[b, c]			2.033
(95% CI)			(0.919, 4.498)
p-value			0.080
Unstratified risk ratio[c]			1.835
(95% CI)			(0.923, 3.648)
p-value			0.084
Stratified risk ratio[b, c]			1.824

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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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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.916, 3.631)
p-value			0.087
Absolute risk reduction			0.082
(95% CI)			(-0.008, 0.172)
p-value			0.085
Number of subjects reporting pyrexia (PT) - n (%)	17 (15.3)	6 (5.4)	9.96
(95% CI)	(9.18, 23.39)	(1.99, 11.30)	(2.07, 17.85)
p-value[a, b]			0.014
Unstratified odds ratio[c]			3.195
(95% CI)			(1.210, 8.438)
p-value			0.019
Stratified odds ratio[b, c]			3.178
(95% CI)			(1.213, 8.329)
p-value			0.019
Unstratified risk ratio[c]			2.859
(95% CI)			(1.171, 6.982)
p-value			0.021

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified risk ratio[b, c]			2.865
(95% CI)			(1.183, 6.937)
p-value			0.020
Absolute risk reduction			0.100
(95% CI)			(0.021, 0.178)
p-value			0.016
Number of subjects reporting any immune system disorders (SOC) - n (%)	20 (18.0)	4 (3.6)	14.45
(95% CI)	(11.37, 26.45)	(0.98, 8.89)	(6.51, 22.38)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			5.934
(95% CI)			(1.957, 17.991)
p-value			0.002
Stratified odds ratio[b, c]			6.155
(95% CI)			(2.024, 18.722)
p-value			0.001

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified risk ratio[c]			5.045
(95% CI)			(1.782, 14.287)
p-value			0.002
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.144
(95% CI)			(0.065, 0.224)
p-value			<0.001
Number of subjects reporting cytokine release syndrome (PT) - n (%)	19 (17.1)	0 (0.0)	17.12
(95% CI)	(10.63, 25.43)	(0.00, 3.24)	(10.11, 24.12)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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[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 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	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			0.171
(95% CI)			(0.101, 0.241)
p-value			<0.001
Number of subjects reporting any infections and infestations (SOC) - n (%)	43 (38.7)	30 (26.8)	11.95
(95% CI)	(29.64, 48.45)	(18.86, 35.98)	(-0.27, 24.18)
p-value[a, b]			0.055

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified odds ratio[c]			1.728
(95% CI)			(0.981, 3.045)
p-value			0.058
Stratified odds ratio[b, c]			1.727
(95% CI)			(0.984, 3.030)
p-value			0.057
Unstratified risk ratio[c]			1.446
(95% CI)			(0.984, 2.126)
p-value			0.061
Stratified risk ratio[b, c]			1.495
(95% CI)			(1.022, 2.187)
p-value			0.038
Absolute risk reduction			0.120
(95% CI)			(-0.003, 0.242)
p-value			0.064
Number of subjects reporting device related infection (PT) - n (%)	14 (12.6)	6 (5.4)	7.26

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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)	(7.07, 20.26)	(1.99, 11.30)	(-0.20, 14.71)
p-value[a, b]			0.064
Unstratified odds ratio[c]			2.550
(95% CI)			(0.943, 6.898)
p-value			0.065
Stratified odds ratio[b, c]			2.463
(95% CI)			(0.921, 6.583)
p-value			0.072
Unstratified risk ratio[c]			2.354
(95% CI)			(0.939, 5.906)
p-value			0.068
Stratified risk ratio[b, c]			2.346
(95% CI)			(0.941, 5.847)
p-value			0.067
Absolute risk reduction			0.073
(95% CI)			(-0.002, 0.147)
p-value			0.065

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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting sepsis (PT) - n (%)	15 (13.5)	11 (9.8)	3.69
(95% CI)	(7.77, 21.31)	(5.01, 16.89)	(-4.72, 12.11)
p-value[a, b]			0.41
Unstratified odds ratio[c]			1.435
(95% CI)			(0.628, 3.279)
p-value			0.39
Stratified odds ratio[b, c]			1.405
(95% CI)			(0.622, 3.175)
p-value			0.41
Unstratified risk ratio[c]			1.376
(95% CI)			(0.661, 2.862)
p-value			0.39
Stratified risk ratio[b, c]			1.413
(95% CI)			(0.681, 2.930)
p-value			0.35
Absolute risk reduction			0.037

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(-0.047, 0.121)
p-value			0.41
Number of subjects reporting any investigations (SOC) - n (%)	105 (94.6)	109 (97.3)	-2.73
(95% CI)	(88.61, 97.99)	(92.37, 99.44)	(-7.89, 2.43)
p-value[a, b]			0.34
Unstratified odds ratio[c]			0.482
(95% CI)			(0.117, 1.976)
p-value			0.31
Stratified odds ratio[b, c]			0.515
(95% CI)			(0.127, 2.085)
p-value			0.35
Unstratified risk ratio[c]			0.972
(95% CI)			(0.921, 1.026)
p-value			0.30
Stratified risk ratio[b, c, d]			0.973
(95% CI)			(0.839, 1.128)

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.72
Absolute risk reduction			-0.027
(95% CI)			(-0.079, 0.024)
p-value			0.33
Number of subjects reporting alanine aminotransferase increased (PT) - n (%)	18 (16.2)	10 (8.9)	7.29
(95% CI)	(9.90, 24.41)	(4.36, 15.81)	(-1.37, 15.94)
p-value[a, b]			0.091
Unstratified odds ratio[c]			1.974
(95% CI)			(0.867, 4.494)
p-value			0.11
Stratified odds ratio[b, c]			2.071
(95% CI)			(0.880, 4.878)
p-value			0.096
Unstratified risk ratio[c]			1.816
(95% CI)			(0.878, 3.758)
p-value			0.11

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified risk ratio[b, c]			1.885
(95% CI)			(0.928, 3.828)
p-value			0.079
Absolute risk reduction			0.073
(95% CI)			(-0.014, 0.159)
p-value			0.11
Number of subjects reporting aspartate aminotransferase increased (PT) - n (%)	13 (11.7)	5 (4.5)	7.25
(95% CI)	(6.39, 19.19)	(1.47, 10.11)	(0.15, 14.35)
p-value[a, b]			0.037
Unstratified odds ratio[c]			2.839
(95% CI)			(0.976, 8.252)
p-value			0.055
Stratified odds ratio[b, c]			3.285
(95% CI)			(1.021, 10.567)
p-value			0.046

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified risk ratio[c]			2.623
(95% CI)			(0.968, 7.113)
p-value			0.058
Stratified risk ratio[b, c]			2.600
(95% CI)			(0.966, 7.000)
p-value			0.059
Absolute risk reduction			0.072
(95% CI)			(0.001, 0.143)
p-value			0.053
Number of subjects reporting lymphocyte count decreased (PT) - n (%)	41 (36.9)	33 (29.5)	7.47
(95% CI)	(27.97, 46.62)	(21.23, 38.82)	(-4.85, 19.80)
p-value[a, b]			0.25
Unstratified odds ratio[c]			1.402
(95% CI)			(0.801, 2.455)
p-value			0.24

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified odds ratio[b, c]			1.378
(95% CI)			(0.797, 2.383)
p-value			0.25
Unstratified risk ratio[c]			1.254
(95% CI)			(0.861, 1.825)
p-value			0.24
Stratified risk ratio[b, c]			1.261
(95% CI)			(0.866, 1.837)
p-value			0.23
Absolute risk reduction			0.075
(95% CI)			(-0.049, 0.198)
p-value			0.26
Number of subjects reporting neutrophil count decreased (PT) - n (%)	100 (90.1)	106 (94.6)	-4.55
(95% CI)	(82.96, 94.95)	(88.70, 98.01)	(-11.50, 2.40)
p-value[a, b]			0.25

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified odds ratio[c]			0.515
(95% CI)			(0.183, 1.444)
p-value			0.21
Stratified odds ratio[b, c]			0.548
(95% CI)			(0.196, 1.535)
p-value			0.25
Unstratified risk ratio[c]			0.952
(95% CI)			(0.882, 1.027)
p-value			0.20
Stratified risk ratio[b, c, d]			0.984
(95% CI)			(0.892, 1.087)
p-value			0.76
Absolute risk reduction			-0.046
(95% CI)			(-0.115, 0.024)
p-value			0.22
Number of subjects reporting platelet count decreased (PT) - n (%)	91 (82.0)	92 (82.1)	-0.16

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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.
Data cut-off date: 23JUN2023

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/userdata/stat/amg103/onc/20129152/analysis/primary_german_payer/tables/t-teae-10pct-soc-pt-saf-mrdneg.sas
Output: t14-06-006-001-teae-10pct-soc-pt-saf-mrdneg.rtf (Date generated: 11MAY2024:00:02) Source data: adam.adsl, adampa.adae

Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)	(73.55, 88.63)	(73.78, 88.74)	(-10.23, 9.91)
p-value[a, b]			0.93
Unstratified odds ratio[c]			0.989
(95% CI)			(0.499, 1.961)
p-value			0.98
Stratified odds ratio[b, c]			1.030
(95% CI)			(0.515, 2.062)
p-value			0.93
Unstratified risk ratio[c]			0.998
(95% CI)			(0.883, 1.128)
p-value			0.98
Stratified risk ratio[b, c, d]			0.996
(95% CI)			(0.887, 1.119)
p-value			0.95
Absolute risk reduction			-0.002
(95% CI)			(-0.102, 0.099)
p-value			>0.999

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting white blood cell count decreased (PT) - n (%)	62 (55.9)	75 (67.0)	-11.11
(95% CI)	(46.12, 65.27)	(57.44, 75.56)	(-23.81, 1.59)
p-value[a, b]			0.10
Unstratified odds ratio[c]			0.624
(95% CI)			(0.362, 1.075)
p-value			0.089
Stratified odds ratio[b, c]			0.638
(95% CI)			(0.372, 1.092)
p-value			0.10
Unstratified risk ratio[c]			0.834
(95% CI)			(0.676, 1.029)
p-value			0.091
Stratified risk ratio[b, c, d]			0.851
(95% CI)			(0.698, 1.038)
p-value			0.11

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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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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Absolute risk reduction			-0.111
(95% CI)			(-0.238, 0.016)
p-value			0.100
Number of subjects reporting any metabolism and nutrition disorders (SOC) - n (%)	35 (31.5)	26 (23.2)	8.32
(95% CI)	(23.04, 41.04)	(15.76, 32.14)	(-3.34, 19.97)
p-value[a, b]			0.15
Unstratified odds ratio[c]			1.523
(95% CI)			(0.841, 2.759)
p-value			0.16
Stratified odds ratio[b, c]			1.537
(95% CI)			(0.854, 2.767)
p-value			0.15
Unstratified risk ratio[c]			1.358
(95% CI)			(0.880, 2.097)
p-value			0.17

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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified risk ratio[b, c]			1.399
(95% CI)			(0.908, 2.156)
p-value			0.13
Absolute risk reduction			0.083
(95% CI)			(-0.033, 0.200)
p-value			0.18
Number of subjects reporting hyperglycaemia (PT) - n (%)	17 (15.3)	9 (8.0)	7.28
(95% CI)	(9.18, 23.39)	(3.74, 14.71)	(-1.10, 15.66)
p-value[a, b]			0.10
Unstratified odds ratio[c]			2.070
(95% CI)			(0.880, 4.867)
p-value			0.095
Stratified odds ratio[b, c]			1.985
(95% CI)			(0.856, 4.606)
p-value			0.11
Unstratified risk ratio[c]			1.906

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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.888, 4.092)
p-value			0.098
Stratified risk ratio[b, c]			1.906
(95% CI)			(0.892, 4.073)
p-value			0.096
Absolute risk reduction			0.073
(95% CI)			(-0.011, 0.157)
p-value			0.099
Number of subjects reporting any musculoskeletal and connective tissue disorders (SOC) - n (%)	27 (24.3)	11 (9.8)	14.50
(95% CI)	(16.68, 33.38)	(5.01, 16.89)	(4.80, 24.20)
p-value[a, b]			0.004
Unstratified odds ratio[c]			2.951
(95% CI)			(1.382, 6.301)
p-value			0.005
Stratified odds ratio[b, c]			2.862
(95% CI)			(1.359, 6.026)

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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.006
Unstratified risk ratio[c]			2.477
(95% CI)			(1.293, 4.744)
p-value			0.006
Stratified risk ratio[b, c]			2.476
(95% CI)			(1.291, 4.747)
p-value			0.006
Absolute risk reduction			0.145
(95% CI)			(0.048, 0.242)
p-value			0.004
Number of subjects reporting any nervous system disorders (SOC) - n (%)	68 (61.3)	42 (37.5)	23.76
(95% CI)	(51.55, 70.36)	(28.53, 47.15)	(11.01, 36.51)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			2.636
(95% CI)			(1.535, 4.525)
p-value			<0.001

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified odds ratio[b, c]			2.823
(95% CI)			(1.609, 4.951)
p-value			<0.001
Unstratified risk ratio[c]			1.634
(95% CI)			(1.233, 2.164)
p-value			<0.001
Stratified risk ratio[b, c]			1.642
(95% CI)			(1.242, 2.172)
p-value			<0.001
Absolute risk reduction			0.238
(95% CI)			(0.110, 0.365)
p-value			<0.001
Number of subjects reporting headache (PT) - n (%)	46 (41.4)	36 (32.1)	9.30
(95% CI)	(32.17, 51.18)	(23.63, 41.63)	(-3.30, 21.90)
p-value[a, b]			0.13
Unstratified odds ratio[c]			1.494

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.864, 2.583)
p-value			0.15
Stratified odds ratio[b, c]			1.536
(95% CI)			(0.884, 2.670)
p-value			0.13
Unstratified risk ratio[c]			1.289
(95% CI)			(0.910, 1.826)
p-value			0.15
Stratified risk ratio[b, c]			1.326
(95% CI)			(0.940, 1.870)
p-value			0.11
Absolute risk reduction			0.093
(95% CI)			(-0.033, 0.219)
p-value			0.17
Number of subjects reporting tremor (PT) - n (%)	26 (23.4)	5 (4.5)	18.96
(95% CI)	(15.91, 32.41)	(1.47, 10.11)	(10.20, 27.72)
p-value[a, b]			<0.001

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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified odds ratio[c]			6.546
(95% CI)			(2.412, 17.768)
p-value			<0.001
Stratified odds ratio[b, c]			6.637
(95% CI)			(2.454, 17.953)
p-value			<0.001
Unstratified risk ratio[c]			5.247
(95% CI)			(2.090, 13.171)
p-value			<0.001
Stratified risk ratio[b, c]			5.247
(95% CI)			(2.093, 13.153)
p-value			<0.001
Absolute risk reduction			0.190
(95% CI)			(0.102, 0.277)
p-value			<0.001

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting any psychiatric disorders (SOC) - n (%)	20 (18.0)	7 (6.3)	11.77
(95% CI)	(11.37, 26.45)	(2.55, 12.45)	(3.33, 20.21)
p-value[a, b]			0.007
Unstratified odds ratio[c]			3.296
(95% CI)			(1.333, 8.151)
p-value			0.010
Stratified odds ratio[b, c]			3.278
(95% CI)			(1.331, 8.074)
p-value			0.010
Unstratified risk ratio[c]			2.883
(95% CI)			(1.270, 6.544)
p-value			0.011
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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-saf-mrdneg.sas
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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Absolute risk reduction			0.118
(95% CI)			(0.033, 0.202)
p-value			0.008
Number of subjects reporting any respiratory, thoracic and mediastinal disorders (SOC) - n (%)	19 (17.1)	9 (8.0)	9.08
(95% CI)	(10.63, 25.43)	(3.74, 14.71)	(0.45, 17.71)
p-value[a, b]			0.047
Unstratified odds ratio[c]			2.364
(95% CI)			(1.019, 5.483)
p-value			0.045
Stratified odds ratio[b, c]			2.318
(95% CI)			(0.994, 5.409)
p-value			0.052
Unstratified risk ratio[c]			2.130
(95% CI)			(1.008, 4.502)
p-value			0.048

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Table 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified risk ratio[b, c]			2.201
(95% CI)			(1.045, 4.633)
p-value			0.038
Absolute risk reduction			0.091
(95% CI)			(0.005, 0.177)
p-value			0.045
Number of subjects reporting any vascular disorders (SOC) - n (%)	34 (30.6)	16 (14.3)	16.34
(95% CI)	(22.23, 40.09)	(8.39, 22.16)	(5.60, 27.09)
p-value[a, b]			0.003
Unstratified odds ratio[c]			2.649
(95% CI)			(1.362, 5.155)
p-value			0.004
Stratified odds ratio[b, c]			2.609
(95% CI)			(1.354, 5.027)
p-value			0.004
Unstratified risk ratio[c]			2.144

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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 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(1.258, 3.654)
p-value			0.005
Stratified risk ratio[b, c]			2.126
(95% CI)			(1.248, 3.620)
p-value			0.006
Absolute risk reduction			0.163
(95% CI)			(0.056, 0.271)
p-value			0.004
Number of subjects reporting embolism (PT) - n (%)	13 (11.7)	8 (7.1)	4.57
(95% CI)	(6.39, 19.19)	(3.13, 13.59)	(-3.08, 12.22)
p-value[a, b]			0.23
Unstratified odds ratio[c]			1.724
(95% CI)			(0.685, 4.340)
p-value			0.25
Stratified odds ratio[b, c]			1.731
(95% CI)			(0.698, 4.290)
p-value			0.24

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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 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified risk ratio[c]			1.640
(95% CI)			(0.707, 3.801)
p-value			0.25
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.046
(95% CI)			(-0.031, 0.122)
p-value			0.26
Number of subjects reporting hypertension (PT) - n (%)	14 (12.6)	5 (4.5)	8.15
(95% CI)	(7.07, 20.26)	(1.47, 10.11)	(0.88, 15.41)
p-value[a, b]			0.029
Unstratified odds ratio[c]			3.088
(95% CI)			(1.073, 8.891)
p-value			0.037
Stratified odds ratio[b, c]			3.116

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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 14-6.6.1. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(1.077, 9.013)
p-value			0.036
Unstratified risk ratio[c]			2.825
(95% CI)			(1.053, 7.579)
p-value			0.039
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.081
(95% CI)			(0.009, 0.154)
p-value			0.033

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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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[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 14-6.6.2. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting any blood and lymphatic system disorders (SOC) - n (%)	22 (61.1)	14 (87.5)	-26.39
(95% CI)	(43.46, 76.86)	(61.65, 98.45)	(-49.11, -3.67)
p-value[a, b]			0.065
Unstratified odds ratio[c]			0.225
(95% CI)			(0.044, 1.141)
p-value			0.072
Stratified odds ratio[b, c]			0.213
(95% CI)			(0.038, 1.206)
p-value			0.080
Unstratified risk ratio[c]			0.698
(95% CI)			(0.507, 0.962)
p-value			0.028
Stratified risk ratio[b, c, d]			0.822
(95% CI)			(0.511, 1.322)

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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[f] 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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Data cut-off date: 23JUN2023

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Table 14-6.6.2. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.42
Absolute risk reduction			-0.264
(95% CI)			(-0.491, -0.037)
p-value			0.10
Number of subjects reporting anaemia (PT) - n (%)	19 (52.8)	13 (81.3)	-28.47
(95% CI)	(35.49, 69.59)	(54.35, 95.95)	(-53.61, -3.34)
p-value[a, b]			0.038
Unstratified odds ratio[c]			0.258
(95% CI)			(0.063, 1.062)
p-value			0.061
Stratified odds ratio[b, c]			0.218
(95% CI)			(0.048, 0.986)
p-value			0.048
Unstratified risk ratio[c]			0.650
(95% CI)			(0.440, 0.958)
p-value			0.029

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, d]			0.860
(95% CI)			(0.601, 1.230)
p-value			0.41
Absolute risk reduction			-0.285
(95% CI)			(-0.536, -0.033)
p-value			0.068
Number of subjects reporting febrile neutropenia (PT) - n (%)	9 (25.0)	5 (31.3)	-6.25
(95% CI)	(12.12, 42.20)	(11.02, 58.66)	(-33.01, 20.51)
p-value[a, b]			0.93
Unstratified odds ratio[c]			0.733
(95% CI)			(0.200, 2.687)
p-value			0.64
Stratified odds ratio[b, c]			1.066
(95% CI)			(0.240, 4.732)
p-value			0.93

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified risk ratio[c]			0.800
(95% CI)			(0.318, 2.010)
p-value			0.63
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.330, 0.205)
p-value			0.74
Number of subjects reporting any cardiac disorders (SOC) - n (%)	4 (11.1)	2 (12.5)	-1.39
(95% CI)	(3.11, 26.06)	(1.55, 38.35)	(-20.57, 17.79)
p-value[a, b]			0.83
Unstratified odds ratio[c]			0.875
(95% CI)			(0.143, 5.346)
p-value			0.89

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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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Data cut-off date: 23JUN2023

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Output: t14-06-006-002-teae-10pct-soc-pt-saf-mrdpos.rtf (Date generated: 11MAY2024:00:02) Source data: adam.adsl, adampa.adae

Table 14-6.6.2. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified odds ratio[b, c]			1.231
(95% CI)			(0.183, 8.267)
p-value			0.83
Unstratified risk ratio[c]			0.889
(95% CI)			(0.181, 4.367)
p-value			0.88
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.014
(95% CI)			(-0.206, 0.178)
p-value			>0.999
Number of subjects reporting any gastrointestinal disorders (SOC) - n (%)	17 (47.2)	9 (56.3)	-9.03
(95% CI)	(30.41, 64.51)	(29.88, 80.25)	(-38.30, 20.24)
p-value[a, b]			0.34

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			0.696
(95% CI)			(0.213, 2.276)
p-value			0.55
Stratified odds ratio[b, c]			0.491
(95% CI)			(0.111, 2.166)
p-value			0.35
Unstratified risk ratio[c]			0.840
(95% CI)			(0.483, 1.460)
p-value			0.54
Stratified risk ratio[b, c, d]			0.803
(95% CI)			(0.391, 1.650)
p-value			0.55
Absolute risk reduction			-0.090
(95% CI)			(-0.383, 0.202)
p-value			0.76

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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 14-6.6.2. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting abdominal pain (PT) - n (%)	8 (22.2)	2 (12.5)	9.72
(95% CI)	(10.12, 39.15)	(1.55, 38.35)	(-11.42, 30.87)
p-value[a, b]			0.72
Unstratified odds ratio[c]			2.000
(95% CI)			(0.374, 10.699)
p-value			0.42
Stratified odds ratio[b, c]			0.674
(95% CI)			(0.080, 5.648)
p-value			0.72
Unstratified risk ratio[c]			1.778
(95% CI)			(0.424, 7.453)
p-value			0.43
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE

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Table 14-6.6.2. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Absolute risk reduction			0.097
(95% CI)			(-0.114, 0.309)
p-value			0.70
Number of subjects reporting diarrhoea (PT) - n (%)	12 (33.3)	6 (37.5)	-4.17
(95% CI)	(18.56, 50.97)	(15.20, 64.57)	(-32.45, 24.11)
p-value[a, b]			0.93
Unstratified odds ratio[c]			0.833
(95% CI)			(0.244, 2.841)
p-value			0.77
Stratified odds ratio[b, c]			0.937
(95% CI)			(0.210, 4.184)
p-value			0.93
Unstratified risk ratio[c]			0.889
(95% CI)			(0.406, 1.946)
p-value			0.77

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, d]			1.058
(95% CI)			(0.521, 2.149)
p-value			0.88
Absolute risk reduction			-0.042
(95% CI)			(-0.324, 0.241)
p-value			0.76
Number of subjects reporting nausea (PT) - n (%)	6 (16.7)	1 (6.3)	10.42
(95% CI)	(6.37, 32.81)	(0.16, 30.23)	(-6.58, 27.41)
p-value[a, b]			0.82
Unstratified odds ratio[c]			2.999
(95% CI)			(0.330, 27.225)
p-value			0.33
Stratified odds ratio[b, c]			1.375
(95% CI)			(0.088, 21.580)
p-value			0.82

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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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified risk ratio[c]			2.667
(95% CI)			(0.349, 20.374)
p-value			0.34
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.104
(95% CI)			(-0.066, 0.274)
p-value			0.42
Number of subjects reporting stomatitis (PT) - n (%)	2 (5.6)	3 (18.8)	-13.19
(95% CI)	(0.68, 18.66)	(4.05, 45.65)	(-33.73, 7.34)
p-value[a, b]			0.46
Unstratified odds ratio[c]			0.255
(95% CI)			(0.038, 1.704)
p-value			0.16

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified odds ratio[b, c]			0.322
(95% CI)			(0.016, 6.513)
p-value			0.46
Unstratified risk ratio[c]			0.296
(95% CI)			(0.055, 1.605)
p-value			0.16
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.132
(95% CI)			(-0.337, 0.073)
p-value			0.16
Number of subjects reporting vomiting (PT) - n (%)	8 (22.2)	3 (18.8)	3.47
(95% CI)	(10.12, 39.15)	(4.05, 45.65)	(-19.98, 26.93)
p-value[a, b]			0.19

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			1.238
(95% CI)			(0.282, 5.444)
p-value			0.78
Stratified odds ratio[b, c]			0.239
(95% CI)			(0.024, 2.376)
p-value			0.22
Unstratified risk ratio[c]			1.185
(95% CI)			(0.361, 3.892)
p-value			0.78
Stratified risk ratio[b, c, d]			0.638
(95% CI)			(0.134, 3.040)
p-value			0.57
Absolute risk reduction			0.035
(95% CI)			(-0.200, 0.269)
p-value			>0.999

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting any general disorders and administration site conditions (SOC) - n (%)	7 (19.4)	3 (18.8)	0.69
(95% CI)	(8.19, 36.02)	(4.05, 45.65)	(-22.39, 23.78)
p-value[a, b]			0.59
Unstratified odds ratio[c]			1.046
(95% CI)			(0.233, 4.697)
p-value			0.95
Stratified odds ratio[b, c]			0.571
(95% CI)			(0.073, 4.484)
p-value			0.59
Unstratified risk ratio[c]			1.037
(95% CI)			(0.307, 3.504)
p-value			0.95
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Absolute risk reduction			0.007
(95% CI)			(-0.224, 0.238)
p-value			>0.999
Number of subjects reporting any immune system disorders (SOC) - n (%)	4 (11.1)	0 (0.0)	11.11
(95% CI)	(3.11, 26.06)	(0.00, 20.59)	(0.85, 21.38)
p-value[a, b]			0.32
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

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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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Data cut-off date: 23JUN2023

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.111
(95% CI)			(0.008, 0.214)
p-value			0.30
Number of subjects reporting cytokine release syndrome (PT) - n (%)	4 (11.1)	0 (0.0)	11.11
(95% CI)	(3.11, 26.06)	(0.00, 20.59)	(0.85, 21.38)
p-value[a, b]			0.32
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c]			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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(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.111
(95% CI)			(0.008, 0.214)
p-value			0.30
Number of subjects reporting any infections and infestations (SOC) - n (%)	8 (22.2)	5 (31.3)	-9.03
(95% CI)	(10.12, 39.15)	(11.02, 58.66)	(-35.49, 17.43)
p-value[a, b]			0.28
Unstratified odds ratio[c]			0.629

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.168, 2.346)
p-value			0.49
Stratified odds ratio[b, c]			0.382
(95% CI)			(0.064, 2.291)
p-value			0.29
Unstratified risk ratio[c]			0.711
(95% CI)			(0.275, 1.838)
p-value			0.48
Stratified risk ratio[b, c]			0.619
(95% CI)			(0.178, 2.156)
p-value			0.45
Absolute risk reduction			-0.090
(95% CI)			(-0.355, 0.174)
p-value			0.51
Number of subjects reporting device related infection (PT) - n (%)	1 (2.8)	2 (12.5)	-9.72
(95% CI)	(0.07, 14.53)	(1.55, 38.35)	(-26.79, 7.35)

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value[a, b]			0.013
Unstratified odds ratio[c]			0.200
(95% CI)			(0.017, 2.386)
p-value			0.20
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			0.222
(95% CI)			(0.022, 2.277)
p-value			0.21
Stratified risk ratio[b, c, d]			0.043
(95% CI)			(0.000, 13.489)
p-value			0.28
Absolute risk reduction			-0.097
(95% CI)			(-0.268, 0.073)
p-value			0.22

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting sepsis (PT) - n (%)	0 (0.0)	2 (12.5)	-12.50
(95% CI)	(0.00, 9.74)	(1.55, 38.35)	(-28.70, 3.70)
p-value[a, b]			0.013
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

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Absolute risk reduction			-0.125
(95% CI)			(-0.287, 0.037)
p-value			0.090
Number of subjects reporting any investigations (SOC) - n (%)	30 (83.3)	15 (93.8)	-10.42
(95% CI)	(67.19, 93.63)	(69.77, 99.84)	(-27.41, 6.58)
p-value[a, b]			0.50
Unstratified odds ratio[c]			0.333
(95% CI)			(0.037, 3.026)
p-value			0.33
Stratified odds ratio[b, c]			0.438
(95% CI)			(0.037, 5.225)
p-value			0.51
Unstratified risk ratio[c]			0.889
(95% CI)			(0.733, 1.078)
p-value			0.23

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.104
(95% CI)			(-0.274, 0.066)
p-value			0.42
Number of subjects reporting lymphocyte count decreased (PT) - n (%)	3 (8.3)	4 (25.0)	-16.67
(95% CI)	(1.75, 22.47)	(7.27, 52.38)	(-39.72, 6.39)
p-value[a, b]			0.093
Unstratified odds ratio[c]			0.273
(95% CI)			(0.053, 1.401)
p-value			0.12
Stratified odds ratio[b, c]			0.144
(95% CI)			(0.012, 1.657)
p-value			0.12

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified risk ratio[c]			0.333
(95% CI)			(0.084, 1.320)
p-value			0.12
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.167
(95% CI)			(-0.397, 0.064)
p-value			0.18
Number of subjects reporting neutrophil count decreased (PT) - n (%)	29 (80.6)	13 (81.3)	-0.69
(95% CI)	(63.98, 91.81)	(54.35, 95.95)	(-23.78, 22.39)
p-value[a, b]			0.91
Unstratified odds ratio[c]			0.956
(95% CI)			(0.213, 4.296)
p-value			0.95

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified odds ratio[b, c]			0.881
(95% CI)			(0.109, 7.131)
p-value			0.91
Unstratified risk ratio[c]			0.991
(95% CI)			(0.746, 1.318)
p-value			0.95
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.007
(95% CI)			(-0.238, 0.224)
p-value			>0.999
Number of subjects reporting platelet count decreased (PT) - n (%)	26 (72.2)	15 (93.8)	-21.53
(95% CI)	(54.81, 85.80)	(69.77, 99.84)	(-40.36, -2.69)
p-value[a, b]			0.19

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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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Table 14-6.6.2. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			0.173
(95% CI)			(0.020, 1.490)
p-value			0.11
Stratified odds ratio[b, c]			0.244
(95% CI)			(0.026, 2.313)
p-value			0.22
Unstratified risk ratio[c]			0.770
(95% CI)			(0.607, 0.978)
p-value			0.032
Stratified risk ratio[b, c, d]			0.912
(95% CI)			(0.543, 1.531)
p-value			0.73
Absolute risk reduction			-0.215
(95% CI)			(-0.404, -0.027)
p-value			0.14

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting white blood cell count decreased (PT) - n (%)	14 (38.9)	7 (43.8)	-4.86
(95% CI)	(23.14, 56.54)	(19.75, 70.12)	(-33.92, 24.20)
p-value[a, b]			0.30
Unstratified odds ratio[c]			0.818
(95% CI)			(0.248, 2.699)
p-value			0.74
Stratified odds ratio[b, c]			0.392
(95% CI)			(0.064, 2.383)
p-value			0.31
Unstratified risk ratio[c]			0.889
(95% CI)			(0.446, 1.773)
p-value			0.74
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, 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.
Treatment-emergent adverse event is any AE recorded during any treatment period.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Absolute risk reduction			-0.049
(95% CI)			(-0.339, 0.242)
p-value			0.77
Number of subjects reporting any metabolism and nutrition disorders (SOC) - n (%)	5 (13.9)	4 (25.0)	-11.11
(95% CI)	(4.67, 29.50)	(7.27, 52.38)	(-35.15, 12.93)
p-value[a, b]			0.27
Unstratified odds ratio[c]			0.484
(95% CI)			(0.111, 2.113)
p-value			0.33
Stratified odds ratio[b, c]			0.319
(95% CI)			(0.040, 2.520)
p-value			0.28
Unstratified risk ratio[c]			0.556

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.171, 1.800)
p-value			0.33
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.111
(95% CI)			(-0.351, 0.129)
p-value			0.43
Number of subjects reporting decreased appetite (PT) - n (%)	3 (8.3)	2 (12.5)	-4.17
(95% CI)	(1.75, 22.47)	(1.55, 38.35)	(-22.72, 14.38)
p-value[a, b]			0.46
Unstratified odds ratio[c]			0.636
(95% CI)			(0.096, 4.235)
p-value			0.64
Stratified odds ratio[b, c]			0.322
(95% CI)			(0.016, 6.513)

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Table 14-6.6.2. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.46
Unstratified risk ratio[c]			0.667
(95% CI)			(0.123, 3.611)
p-value			0.64
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.042
(95% CI)			(-0.227, 0.144)
p-value			0.64
Number of subjects reporting hyperglycaemia (PT) - n (%)	3 (8.3)	3 (18.8)	-10.42
(95% CI)	(1.75, 22.47)	(4.05, 45.65)	(-31.57, 10.73)
p-value[a, b]			0.40
Unstratified odds ratio[c]			0.394
(95% CI)			(0.070, 2.209)
p-value			0.29

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified odds ratio[b, c]			0.345
(95% CI)			(0.027, 4.393)
p-value			0.41
Unstratified risk ratio[c]			0.444
(95% CI)			(0.100, 1.968)
p-value			0.29
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.104
(95% CI)			(-0.316, 0.107)
p-value			0.36
Number of subjects reporting any musculoskeletal and connective tissue disorders (SOC) - n (%)	7 (19.4)	1 (6.3)	13.19
(95% CI)	(8.19, 36.02)	(0.16, 30.23)	(-4.35, 30.74)
p-value[a, b]			0.14

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			3.621
(95% CI)			(0.407, 32.224)
p-value			0.25
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			3.111
(95% CI)			(0.417, 23.239)
p-value			0.27
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.132
(95% CI)			(-0.044, 0.307)
p-value			0.41

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting any nervous system disorders (SOC) - n (%)	17 (47.2)	6 (37.5)	9.72
(95% CI)	(30.41, 64.51)	(15.20, 64.57)	(-19.06, 38.51)
p-value[a, b]			0.63
Unstratified odds ratio[c]			1.491
(95% CI)			(0.447, 4.977)
p-value			0.52
Stratified odds ratio[b, c]			0.709
(95% CI)			(0.172, 2.926)
p-value			0.63
Unstratified risk ratio[c]			1.259
(95% CI)			(0.613, 2.589)
p-value			0.53
Stratified risk ratio[b, c]			1.194
(95% CI)			(0.535, 2.665)

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.66
Absolute risk reduction			0.097
(95% CI)			(-0.191, 0.385)
p-value			0.56
Number of subjects reporting headache (PT) - n (%)	15 (41.7)	6 (37.5)	4.17
(95% CI)	(25.51, 59.24)	(15.20, 64.57)	(-24.51, 32.84)
p-value[a, b]			0.63
Unstratified odds ratio[c]			1.190
(95% CI)			(0.355, 3.991)
p-value			0.78
Stratified odds ratio[b, c]			0.709
(95% CI)			(0.172, 2.926)
p-value			0.63
Unstratified risk ratio[c]			1.111
(95% CI)			(0.529, 2.332)
p-value			0.78

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Output: t14-06-006-002-teae-10pct-soc-pt-saf-mrdpos.rtf (Date generated: 11MAY2024:00:02) Source data: adam.adsl, adampa.adae

Table 14-6.6.2. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c]			1.089
(95% CI)			(0.482, 2.463)
p-value			0.84
Absolute risk reduction			0.042
(95% CI)			(-0.245, 0.328)
p-value			>0.999
Number of subjects reporting tremor (PT) - n (%)	4 (11.1)	0 (0.0)	11.11
(95% CI)	(3.11, 26.06)	(0.00, 20.59)	(0.85, 21.38)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, g]			NE
(95% CI)			(NE, NE)
p-value			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.111
(95% CI)			(0.008, 0.214)
p-value			0.30
Number of subjects reporting any psychiatric disorders (SOC) - n (%)	7 (19.4)	0 (0.0)	19.44
(95% CI)	(8.19, 36.02)	(0.00, 20.59)	(6.52, 32.37)
p-value[a, b]			0.41
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	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, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.194
(95% CI)			(0.065, 0.324)
p-value			0.085
Number of subjects reporting confusional state (PT) - n (%)	4 (11.1)	0 (0.0)	11.11
(95% CI)	(3.11, 26.06)	(0.00, 20.59)	(0.85, 21.38)
p-value[a, b]			<0.001

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, g]			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, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.111
(95% CI)			(0.008, 0.214)
p-value			0.30

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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Table 14-6.6.2. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting any renal and urinary disorders (SOC) - n (%)	2 (5.6)	2 (12.5)	-6.94
(95% CI)	(0.68, 18.66)	(1.55, 38.35)	(-24.79, 10.90)
p-value[a, b]			0.64
Unstratified odds ratio[c]			0.412
(95% CI)			(0.053, 3.219)
p-value			0.40
Stratified odds ratio[b, c]			0.553
(95% CI)			(0.046, 6.681)
p-value			0.64
Unstratified risk ratio[c]			0.444
(95% CI)			(0.069, 2.882)
p-value			0.40
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.2. Summary of Treatment-emergent Adverse Events (at least 10% in one arm) by MedDRA System Organ Class and Preferred Term (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Absolute risk reduction			-0.069
(95% CI)			(-0.248, 0.109)
p-value			0.58
Number of subjects reporting any respiratory, thoracic and mediastinal disorders (SOC) - n (%)	5 (13.9)	4 (25.0)	-11.11
(95% CI)	(4.67, 29.50)	(7.27, 52.38)	(-35.15, 12.93)
p-value[a, b]			0.23
Unstratified odds ratio[c]			0.484
(95% CI)			(0.111, 2.113)
p-value			0.33
Stratified odds ratio[b, c]			0.256
(95% CI)			(0.024, 2.729)
p-value			0.26
Unstratified risk ratio[c]			0.556

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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.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.171, 1.800)
p-value			0.33
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.111
(95% CI)			(-0.351, 0.129)
p-value			0.43
Number of subjects reporting dyspnoea (PT) - n (%)	0 (0.0)	2 (12.5)	-12.50
(95% CI)	(0.00, 9.74)	(1.55, 38.35)	(-28.70, 3.70)
p-value[a, b]			0.033
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
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			-0.125
(95% CI)			(-0.287, 0.037)
p-value			0.090
Number of subjects reporting any skin and subcutaneous tissue disorders (SOC) - n (%)	4 (11.1)	2 (12.5)	-1.39
(95% CI)	(3.11, 26.06)	(1.55, 38.35)	(-20.57, 17.79)
p-value[a, b]			0.71
Unstratified odds ratio[c]			0.875
(95% CI)			(0.143, 5.346)
p-value			0.89

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified odds ratio[b, c]			1.654
(95% CI)			(0.112, 24.511)
p-value			0.71
Unstratified risk ratio[c]			0.889
(95% CI)			(0.181, 4.367)
p-value			0.88
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.014
(95% CI)			(-0.206, 0.178)
p-value			>0.999
Number of subjects reporting any vascular disorders (SOC) - n (%)	5 (13.9)	1 (6.3)	7.64
(95% CI)	(4.67, 29.50)	(0.16, 30.23)	(-8.74, 24.02)
p-value[a, b]			<0.001

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			2.419
(95% CI)			(0.259, 22.583)
p-value			0.44
Stratified odds ratio[b, c, g]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			2.222
(95% CI)			(0.282, 17.517)
p-value			0.45
Stratified risk ratio[b, c, d]			0.299
(95% CI)			(0.068, 1.307)
p-value			0.11
Absolute risk reduction			0.076
(95% CI)			(-0.087, 0.240)
p-value			0.65

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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.
[g] The number of events in one group is zero 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-saf-mrdpos.sas
Output: t14-06-006-002-teae-10pct-soc-pt-saf-mrdpos.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
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

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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)			(-0.189, 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

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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
Absolute risk reduction			0.001
(95% CI)			(-0.116, 0.118)
p-value			>0.999
Number of subjects reporting 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)
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)

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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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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
p-value			0.19
Absolute risk reduction			-0.071
(95% CI)			(-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]			1.529
(95% CI)			(0.949, 2.462)
p-value			0.081
Stratified odds ratio[b, c]			1.554
(95% CI)			(0.961, 2.515)
p-value			0.072
Unstratified risk ratio[c]			1.237
(95% CI)			(0.971, 1.577)
p-value			0.085

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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
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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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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			0.20
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.
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.
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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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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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
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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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.
[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
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.
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 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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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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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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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
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.
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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)	(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.
[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
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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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and 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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	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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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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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction			0.040
(95% CI)			(-0.025, 0.104)
p-value			0.28
Number of subjects reporting 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
(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)

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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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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
p-value			0.92
Absolute risk reduction			0.000
(95% CI)			(-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]			0.363
(95% CI)			(0.114, 1.155)
p-value			0.086
Stratified odds ratio[b, c]			0.415
(95% CI)			(0.127, 1.360)
p-value			0.15
Unstratified risk ratio[c]			0.948
(95% CI)			(0.895, 1.004)
p-value			0.068
Stratified risk ratio[b, c, d]			0.967

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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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[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
Stratified risk ratio[b, c]			1.641
(95% CI)			(0.808, 3.333)
p-value			0.17
Absolute risk reduction			0.051
(95% CI)			(-0.020, 0.123)
p-value			0.24
Number of subjects reporting aspartate aminotransferase increased (PT) - n (%)	15 (10.2)	5 (3.9)	6.30
(95% CI)	(5.82, 16.27)	(1.28, 8.88)	(0.36, 12.23)
p-value[a, b]			0.041
Unstratified odds ratio[c]			2.795
(95% CI)			(0.987, 7.920)
p-value			0.053
Stratified odds ratio[b, c]			3.148
(95% CI)			(0.998, 9.931)
p-value			0.050
Unstratified risk ratio[c]			2.612

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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.
[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
(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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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
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.
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)			(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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Treatment-emergent adverse event is any AE recorded during any treatment period.
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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.
Treatment-emergent adverse event is any AE recorded during any treatment period.
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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-emergent adverse event is any AE recorded during any treatment period.
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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.
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[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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Treatment period includes 3 distinct periods: blinatumomab (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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	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			0.203
(95% CI)			(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]			1.452
(95% CI)			(0.886, 2.380)
p-value			0.14
Stratified odds ratio[b, c]			1.448
(95% CI)			(0.878, 2.389)
p-value			0.15
Unstratified risk ratio[c]			1.265
(95% CI)			(0.924, 1.730)
p-value			0.14
Stratified risk ratio[b, c]			1.306

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

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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	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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	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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Treatment period includes 3 distinct periods: blinatumomab (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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1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.3 UE nach SOC/PT

1.1.3.2 Schwere UE (CTCAE Grad ≥ 3) nach SOC/PT bei ≥ 5 % der Patientinnen und Patienten

Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting grade 3 and above any blood and lymphatic system disorders (SOC) - n (%)	44 (39.6)	64 (57.1)	-17.50
(95% CI)	(30.48, 49.37)	(47.45, 66.45)	(-30.42, -4.59)
p-value[a, b]			0.009
Unstratified odds ratio[c]			0.493
(95% CI)			(0.289, 0.840)
p-value			0.009
Stratified odds ratio[b, c]			0.489
(95% CI)			(0.285, 0.837)
p-value			0.009
Unstratified risk ratio[c]			0.694
(95% CI)			(0.524, 0.918)
p-value			0.010
Stratified risk ratio[b, c]			0.722

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.544, 0.959)
p-value			0.024
Absolute risk reduction			-0.175
(95% CI)			(-0.304, -0.046)
p-value			0.011
Number of subjects reporting grade 3 and above anaemia (PT) - n (%)	35 (31.5)	46 (41.1)	-9.54
(95% CI)	(23.04, 41.04)	(31.86, 50.76)	(-22.10, 3.02)
p-value[a, b]			0.13
Unstratified odds ratio[c]			0.661
(95% CI)			(0.381, 1.145)
p-value			0.14
Stratified odds ratio[b, c]			0.645
(95% CI)			(0.367, 1.135)
p-value			0.13

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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Source data: adam.adsl, adampa.adae

Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified risk ratio[c]			0.768
(95% CI)			(0.540, 1.092)
p-value			0.14
Stratified risk ratio[b, c]			0.814
(95% CI)			(0.575, 1.152)
p-value			0.24
Absolute risk reduction			-0.095
(95% CI)			(-0.221, 0.030)
p-value			0.16
Number of subjects reporting grade 3 and above febrile neutropenia (PT) - n (%)	23 (20.7)	32 (28.6)	-7.85
(95% CI)	(13.61, 29.45)	(20.43, 37.88)	(-19.11, 3.41)
p-value[a, b]			0.20
Unstratified odds ratio[c]			0.653
(95% CI)			(0.353, 1.209)

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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-saf-mrdneg.sas
Output: t14-06-006-007-teae-soc-pt-gr3-ge5pct-saf-mrdneg.rtf (Date generated: 11MAY2024:00:01)
Source data: adam.adsl, adampa.adae

Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.18
Stratified odds ratio[b, c]			0.676
(95% CI)			(0.372, 1.231)
p-value			0.20
Unstratified risk ratio[c]			0.725
(95% CI)			(0.455, 1.157)
p-value			0.18
Stratified risk ratio[b, c]			0.722
(95% CI)			(0.452, 1.153)
p-value			0.17
Absolute risk reduction			-0.079
(95% CI)			(-0.191, 0.034)
p-value			0.21

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting grade 3 and above any gastrointestinal disorders (SOC) - n (%)	13 (11.7)	18 (16.1)	-4.36
(95% CI)	(6.39, 19.19)	(9.81, 24.21)	(-13.42, 4.70)
p-value[a, b]			0.30
Unstratified odds ratio[c]			0.693
(95% CI)			(0.322, 1.492)
p-value			0.35
Stratified odds ratio[b, c]			0.668
(95% CI)			(0.310, 1.440)
p-value			0.30
Unstratified risk ratio[c]			0.729
(95% CI)			(0.375, 1.415)
p-value			0.35
Stratified risk ratio[b, c]			0.727

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.376, 1.406)
p-value			0.34
Absolute risk reduction			-0.044
(95% CI)			(-0.134, 0.047)
p-value			0.44
Number of subjects reporting grade 3 and above diarrhoea (PT) - n (%)	4 (3.6)	6 (5.4)	-1.75
(95% CI)	(0.99, 8.97)	(1.99, 11.30)	(-7.18, 3.67)
p-value[a, b]			0.54
Unstratified odds ratio[c]			0.661
(95% CI)			(0.181, 2.407)
p-value			0.53
Stratified odds ratio[b, c]			0.675
(95% CI)			(0.190, 2.407)
p-value			0.54

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified risk ratio[c]			0.673
(95% CI)			(0.195, 2.319)
p-value			0.53
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.018
(95% CI)			(-0.072, 0.037)
p-value			0.75
Number of subjects reporting grade 3 and above nausea (PT) - n (%)	6 (5.4)	1 (0.9)	4.51
(95% CI)	(2.01, 11.39)	(0.02, 4.87)	(-0.04, 9.07)
p-value[a, b]			0.056
Unstratified odds ratio[c]			6.343
(95% CI)			(0.751, 53.573)
p-value			0.090

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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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified odds ratio[b, c]			6.283
(95% CI)			(0.741, 53.290)
p-value			0.092
Unstratified risk ratio[c]			6.054
(95% CI)			(0.741, 49.471)
p-value			0.093
Stratified risk ratio[b, c]			5.878
(95% CI)			(0.726, 47.610)
p-value			0.097
Absolute risk reduction			0.045
(95% CI)			(-0.000, 0.091)
p-value			0.065
Number of subjects reporting grade 3 and above any general disorders and administration site conditions (SOC) - n (%)	12 (10.8)	5 (4.5)	6.35

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)	(5.71, 18.12)	(1.47, 10.11)	(-0.58, 13.27)
p-value[a, b]			0.069
Unstratified odds ratio[c]			2.594
(95% CI)			(0.882, 7.627)
p-value			0.083
Stratified odds ratio[b, c]			2.613
(95% CI)			(0.897, 7.610)
p-value			0.078
Unstratified risk ratio[c]			2.422
(95% CI)			(0.882, 6.647)
p-value			0.086
Stratified risk ratio[b, c]			2.413
(95% CI)			(0.879, 6.620)
p-value			0.087
Absolute risk reduction			0.063

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(-0.006, 0.133)
p-value			0.083
Number of subjects reporting grade 3 and above fatigue (PT) - n (%)	6 (5.4)	4 (3.6)	1.83
(95% CI)	(2.01, 11.39)	(0.98, 8.89)	(-3.60, 7.27)
p-value[a, b]			0.48
Unstratified odds ratio[c]			1.543
(95% CI)			(0.423, 5.622)
p-value			0.51
Stratified odds ratio[b, c]			1.588
(95% CI)			(0.432, 5.841)
p-value			0.49
Unstratified risk ratio[c]			1.514
(95% CI)			(0.439, 5.218)
p-value			0.51

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified risk ratio[b, c]			1.508
(95% CI)			(0.441, 5.154)
p-value			0.51
Absolute risk reduction			0.018
(95% CI)			(-0.036, 0.073)
p-value			0.54
Number of subjects reporting grade 3 and above any infections and infestations (SOC) - n (%)	36 (32.4)	26 (23.2)	9.22
(95% CI)	(23.85, 41.97)	(15.76, 32.14)	(-2.49, 20.92)
p-value[a, b]			0.12
Unstratified odds ratio[c]			1.588
(95% CI)			(0.878, 2.870)
p-value			0.13
Stratified odds ratio[b, c]			1.597

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.888, 2.874)
p-value			0.12
Unstratified risk ratio[c]			1.397
(95% CI)			(0.908, 2.149)
p-value			0.13
Stratified risk ratio[b, c]			1.434
(95% CI)			(0.939, 2.191)
p-value			0.095
Absolute risk reduction			0.092
(95% CI)			(-0.025, 0.209)
p-value			0.14
Number of subjects reporting grade 3 and above device related infection (PT) - n (%)	12 (10.8)	6 (5.4)	5.45
(95% CI)	(5.71, 18.12)	(1.99, 11.30)	(-1.67, 12.58)
p-value[a, b]			0.14

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified odds ratio[c]			2.141
(95% CI)			(0.774, 5.924)
p-value			0.14
Stratified odds ratio[b, c]			2.103
(95% CI)			(0.765, 5.786)
p-value			0.15
Unstratified risk ratio[c]			2.018
(95% CI)			(0.785, 5.188)
p-value			0.14
Stratified risk ratio[b, c]			1.943
(95% CI)			(0.767, 4.927)
p-value			0.16
Absolute risk reduction			0.055
(95% CI)			(-0.017, 0.126)
p-value			0.15

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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-saf-mrdneg.sas
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Source data: adam.adsl, adampa.adae

Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting grade 3 and above sepsis (PT) - n (%)	15 (13.5)	11 (9.8)	3.69
(95% CI)	(7.77, 21.31)	(5.01, 16.89)	(-4.72, 12.11)
p-value[a, b]			0.41
Unstratified odds ratio[c]			1.435
(95% CI)			(0.628, 3.279)
p-value			0.39
Stratified odds ratio[b, c]			1.405
(95% CI)			(0.622, 3.175)
p-value			0.41
Unstratified risk ratio[c]			1.376
(95% CI)			(0.661, 2.862)
p-value			0.39
Stratified risk ratio[b, c]			1.413
(95% CI)			(0.681, 2.930)
p-value			0.35

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Absolute risk reduction			0.037
(95% CI)			(-0.047, 0.121)
p-value			0.41
Number of subjects reporting grade 3 and above any investigations (SOC) - n (%)	103 (92.8)	108 (96.4)	-3.64
(95% CI)	(86.29, 96.84)	(91.11, 99.02)	(-9.55, 2.28)
p-value[a, b]			0.25
Unstratified odds ratio[c]			0.477
(95% CI)			(0.139, 1.632)
p-value			0.24
Stratified odds ratio[b, c]			0.496
(95% CI)			(0.146, 1.686)
p-value			0.26
Unstratified risk ratio[c]			0.962

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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[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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.904, 1.025)
p-value			0.23
Stratified risk ratio[b, c, d]			0.959
(95% CI)			(0.867, 1.060)
p-value			0.41
Absolute risk reduction			-0.036
(95% CI)			(-0.095, 0.023)
p-value			0.25
Number of subjects reporting grade 3 and above alanine aminotransferase increased (PT) - n (%)	9 (8.1)	8 (7.1)	0.97
(95% CI)	(3.77, 14.83)	(3.13, 13.59)	(-6.00, 7.93)
p-value[a, b]			0.79
Unstratified odds ratio[c]			1.147
(95% CI)			(0.426, 3.089)

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.79
Stratified odds ratio[b, c]			1.143
(95% CI)			(0.431, 3.031)
p-value			0.79
Unstratified risk ratio[c]			1.135
(95% CI)			(0.454, 2.836)
p-value			0.79
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.010
(95% CI)			(-0.060, 0.079)
p-value			0.81

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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.
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Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting grade 3 and above aspartate aminotransferase increased (PT) - n (%)	6 (5.4)	3 (2.7)	2.73
(95% CI)	(2.01, 11.39)	(0.56, 7.63)	(-2.43, 7.89)
p-value[a, b]			0.31
Unstratified odds ratio[c]			2.076
(95% CI)			(0.506, 8.517)
p-value			0.31
Stratified odds ratio[b, c]			2.034
(95% CI)			(0.500, 8.266)
p-value			0.32
Unstratified risk ratio[c]			2.018
(95% CI)			(0.518, 7.869)
p-value			0.31
Stratified risk ratio[b, c, e]			NE

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.027
(95% CI)			(-0.024, 0.079)
p-value			0.33
Number of subjects reporting grade 3 and above lymphocyte count decreased (PT) - n (%)	38 (34.2)	31 (27.7)	6.56
(95% CI)	(25.49, 43.84)	(19.64, 36.93)	(-5.55, 18.66)
p-value[a, b]			0.32
Unstratified odds ratio[c]			1.360
(95% CI)			(0.769, 2.405)
p-value			0.29
Stratified odds ratio[b, c]			1.325
(95% CI)			(0.760, 2.310)

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.32
Unstratified risk ratio[c]			1.237
(95% CI)			(0.833, 1.836)
p-value			0.29
Stratified risk ratio[b, c]			1.253
(95% CI)			(0.844, 1.859)
p-value			0.26
Absolute risk reduction			0.066
(95% CI)			(-0.056, 0.187)
p-value			0.31
Number of subjects reporting grade 3 and above neutrophil count decreased (PT) - n (%)	97 (87.4)	106 (94.6)	-7.26
(95% CI)	(79.74, 92.93)	(88.70, 98.01)	(-14.71, 0.20)
p-value[a, b]			0.073

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified odds ratio[c]			0.392
(95% CI)			(0.145, 1.061)
p-value			0.065
Stratified odds ratio[b, c]			0.412
(95% CI)			(0.153, 1.115)
p-value			0.081
Unstratified risk ratio[c]			0.923
(95% CI)			(0.850, 1.004)
p-value			0.061
Stratified risk ratio[b, c, d]			0.958
(95% CI)			(0.864, 1.063)
p-value			0.42
Absolute risk reduction			-0.073
(95% CI)			(-0.147, 0.002)
p-value			0.065

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting grade 3 and above platelet count decreased (PT) - n (%)	78 (70.3)	87 (77.7)	-7.41
(95% CI)	(60.85, 78.57)	(68.84, 85.00)	(-18.89, 4.07)
p-value[a, b]			0.22
Unstratified odds ratio[c]			0.679
(95% CI)			(0.372, 1.241)
p-value			0.21
Stratified odds ratio[b, c]			0.682
(95% CI)			(0.371, 1.255)
p-value			0.22
Unstratified risk ratio[c]			0.905
(95% CI)			(0.774, 1.058)
p-value			0.21
Stratified risk ratio[b, c, d]			0.918

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.797, 1.058)
p-value			0.24
Absolute risk reduction			-0.074
(95% CI)			(-0.189, 0.041)
p-value			0.22
Number of subjects reporting grade 3 and above white blood cell count decreased (PT) - n (%)	60 (54.1)	74 (66.1)	-12.02
(95% CI)	(44.33, 63.55)	(56.52, 74.75)	(-24.78, 0.74)
p-value[a, b]			0.074
Unstratified odds ratio[c]			0.604
(95% CI)			(0.352, 1.037)
p-value			0.068
Stratified odds ratio[b, c]			0.615
(95% CI)			(0.360, 1.050)

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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Output: t14-06-006-007-teae-soc-pt-gr3-ge5pct-saf-mrdneg.rtf (Date generated: 11MAY2024:00:01)
Source data: adam.adsl, adampa.adae

Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.075
Unstratified risk ratio[c]			0.818
(95% CI)			(0.659, 1.016)
p-value			0.070
Stratified risk ratio[b, c, d]			0.847
(95% CI)			(0.692, 1.036)
p-value			0.11
Absolute risk reduction			-0.120
(95% CI)			(-0.248, 0.007)
p-value			0.076
Number of subjects reporting grade 3 and above any metabolism and nutrition disorders (SOC) - n (%)	21 (18.9)	19 (17.0)	1.95
(95% CI)	(12.11, 27.45)	(10.53, 25.22)	(-8.12, 12.02)
p-value[a, b]			0.68

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified odds ratio[c]			1.142
(95% CI)			(0.576, 2.265)
p-value			0.70
Stratified odds ratio[b, c]			1.154
(95% CI)			(0.588, 2.265)
p-value			0.68
Unstratified risk ratio[c]			1.115
(95% CI)			(0.636, 1.957)
p-value			0.70
Stratified risk ratio[b, c]			1.139
(95% CI)			(0.651, 1.995)
p-value			0.65
Absolute risk reduction			0.020
(95% CI)			(-0.081, 0.120)
p-value			0.73

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting grade 3 and above hyperglycaemia (PT) - n (%)	12 (10.8)	9 (8.0)	2.78
(95% CI)	(5.71, 18.12)	(3.74, 14.71)	(-4.89, 10.44)
p-value[a, b]			0.50
Unstratified odds ratio[c]			1.387
(95% CI)			(0.560, 3.437)
p-value			0.48
Stratified odds ratio[b, c]			1.364
(95% CI)			(0.553, 3.363)
p-value			0.50
Unstratified risk ratio[c]			1.345
(95% CI)			(0.591, 3.065)
p-value			0.48
Stratified risk ratio[b, c]			1.359
(95% CI)			(0.601, 3.074)
p-value			0.46

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Absolute risk reduction			0.028
(95% CI)			(-0.049, 0.104)
p-value			0.50
Number of subjects reporting grade 3 and above hypertriglyceridaemia (PT) - n (%)	4 (3.6)	6 (5.4)	-1.75
(95% CI)	(0.99, 8.97)	(1.99, 11.30)	(-7.18, 3.67)
p-value[a, b]			0.56
Unstratified odds ratio[c]			0.661
(95% CI)			(0.181, 2.407)
p-value			0.53
Stratified odds ratio[b, c]			0.678
(95% CI)			(0.185, 2.485)
p-value			0.56
Unstratified risk ratio[c]			0.673

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.195, 2.319)
p-value			0.53
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.018
(95% CI)			(-0.072, 0.037)
p-value			0.75
Number of subjects reporting grade 3 and above any musculoskeletal and connective tissue disorders (SOC) - n (%)	6 (5.4)	7 (6.3)	-0.84
(95% CI)	(2.01, 11.39)	(2.55, 12.45)	(-6.99, 5.30)
p-value[a, b]			0.81
Unstratified odds ratio[c]			0.857
(95% CI)			(0.279, 2.636)

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.79
Stratified odds ratio[b, c]			0.875
(95% CI)			(0.291, 2.635)
p-value			0.81
Unstratified risk ratio[c]			0.865
(95% CI)			(0.300, 2.492)
p-value			0.79
Stratified risk ratio[b, c]			0.852
(95% CI)			(0.296, 2.449)
p-value			0.77
Absolute risk reduction			-0.008
(95% CI)			(-0.070, 0.053)
p-value			>0.999

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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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting grade 3 and above any nervous system disorders (SOC) - n (%)	27 (24.3)	11 (9.8)	14.50
(95% CI)	(16.68, 33.38)	(5.01, 16.89)	(4.80, 24.20)
p-value[a, b]			0.005
Unstratified odds ratio[c]			2.951
(95% CI)			(1.382, 6.301)
p-value			0.005
Stratified odds ratio[b, c]			2.860
(95% CI)			(1.337, 6.120)
p-value			0.007
Unstratified risk ratio[c]			2.477
(95% CI)			(1.293, 4.744)
p-value			0.006
Stratified risk ratio[b, c]			2.465

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(1.289, 4.713)
p-value			0.006
Absolute risk reduction			0.145
(95% CI)			(0.048, 0.242)
p-value			0.004
Number of subjects reporting grade 3 and above aphasia (PT) - n (%)	7 (6.3)	0 (0.0)	6.31
(95% CI)	(2.57, 12.56)	(0.00, 3.24)	(1.78, 10.83)
p-value[a, b]			0.008
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

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.063
(95% CI)			(0.018, 0.108)
p-value			0.007
Number of subjects reporting grade 3 and above headache (PT) - n (%)	5 (4.5)	7 (6.3)	-1.75
(95% CI)	(1.48, 10.20)	(2.55, 12.45)	(-7.66, 4.17)
p-value[a, b]			0.55
Unstratified odds ratio[c]			0.708
(95% CI)			(0.218, 2.300)
p-value			0.57

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified odds ratio[b, c]			0.700
(95% CI)			(0.218, 2.254)
p-value			0.55
Unstratified risk ratio[c]			0.721
(95% CI)			(0.236, 2.203)
p-value			0.57
Stratified risk ratio[b, c]			0.733
(95% CI)			(0.243, 2.216)
p-value			0.58
Absolute risk reduction			-0.017
(95% CI)			(-0.077, 0.042)
p-value			0.77
Number of subjects reporting grade 3 and above any psychiatric disorders (SOC) - n (%)	10 (9.0)	2 (1.8)	7.22

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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-saf-mrdneg.sas
Output: t14-06-006-007-teae-soc-pt-gr3-ge5pct-saf-mrdneg.rtf (Date generated: 11MAY2024:00:01)
Source data: adam.adsl, adampa.adae

Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)	(4.41, 15.94)	(0.22, 6.30)	(1.36, 13.09)
p-value[a, b]			0.012
Unstratified odds ratio[c]			5.446
(95% CI)			(1.165, 25.452)
p-value			0.031
Stratified odds ratio[b, c]			6.111
(95% CI)			(1.278, 29.213)
p-value			0.023
Unstratified risk ratio[c]			5.045
(95% CI)			(1.131, 22.505)
p-value			0.034
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.072

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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[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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.014, 0.131)
p-value			0.019
Number of subjects reporting grade 3 and above any respiratory, thoracic and mediastinal disorders (SOC) - n (%)	8 (7.2)	4 (3.6)	3.64
(95% CI)	(3.16, 13.71)	(0.98, 8.89)	(-2.28, 9.55)
p-value[a, b]			0.22
Unstratified odds ratio[c]			2.097
(95% CI)			(0.613, 7.176)
p-value			0.24
Stratified odds ratio[b, c]			2.131
(95% CI)			(0.615, 7.383)
p-value			0.23
Unstratified risk ratio[c]			2.018
(95% CI)			(0.626, 6.510)
p-value			0.24

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.036
(95% CI)			(-0.023, 0.095)
p-value			0.25
Number of subjects reporting grade 3 and above any vascular disorders (SOC) - n (%)	19 (17.1)	10 (8.9)	8.19
(95% CI)	(10.63, 25.43)	(4.36, 15.81)	(-0.59, 16.96)
p-value[a, b]			0.059
Unstratified odds ratio[c]			2.107
(95% CI)			(0.932, 4.763)
p-value			0.074
Stratified odds ratio[b, c]			2.180

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.957, 4.967)
p-value			0.064
Unstratified risk ratio[c]			1.917
(95% CI)			(0.934, 3.936)
p-value			0.076
Stratified risk ratio[b, c]			1.883
(95% CI)			(0.918, 3.863)
p-value			0.084
Absolute risk reduction			0.082
(95% CI)			(-0.006, 0.170)
p-value			0.076
Number of subjects reporting grade 3 and above hypertension (PT) - n (%)	12 (10.8)	3 (2.7)	8.13
(95% CI)	(5.71, 18.12)	(0.56, 7.63)	(1.63, 14.64)
p-value[a, b]			0.013

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified odds ratio[c]			4.404
(95% CI)			(1.207, 16.064)
p-value			0.025
Stratified odds ratio[b, c]			4.671
(95% CI)			(1.258, 17.342)
p-value			0.021
Unstratified risk ratio[c]			4.036
(95% CI)			(1.171, 13.914)
p-value			0.027
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.081
(95% CI)			(0.016, 0.146)
p-value			0.017

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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.
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Table 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting grade 3 and above hypotension (PT) - n (%)	6 (5.4)	3 (2.7)	2.73
(95% CI)	(2.01, 11.39)	(0.56, 7.63)	(-2.43, 7.89)
p-value[a, b]			0.30
Unstratified odds ratio[c]			2.076
(95% CI)			(0.506, 8.517)
p-value			0.31
Stratified odds ratio[b, c]			2.089
(95% CI)			(0.511, 8.537)
p-value			0.30
Unstratified risk ratio[c]			2.018
(95% CI)			(0.518, 7.869)
p-value			0.31
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.7. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Absolute risk reduction			0.027
(95% CI)			(-0.024, 0.079)
p-value			0.33

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting grade 3 and above any blood and lymphatic system disorders (SOC) - n (%)	14 (38.9)	9 (56.3)	-17.36
(95% CI)	(23.14, 56.54)	(29.88, 80.25)	(-46.42, 11.70)
p-value[a, b]			0.39
Unstratified odds ratio[c]			0.495
(95% CI)			(0.150, 1.633)
p-value			0.25
Stratified odds ratio[b, c]			0.528
(95% CI)			(0.120, 2.315)
p-value			0.40
Unstratified risk ratio[c]			0.691
(95% CI)			(0.381, 1.254)
p-value			0.22

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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.
[g] The number of events in one group is zero 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-saf-mrdpos.sas
Output: t14-06-006-008-teae-soc-pt-gr3-ge5pct-saf-mrdpos.rtf (Date generated: 11MAY2024:00:01)
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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, d]			0.769
(95% CI)			(0.359, 1.651)
p-value			0.50
Absolute risk reduction			-0.174
(95% CI)			(-0.464, 0.117)
p-value			0.36
Number of subjects reporting grade 3 and above anaemia (PT) - n (%)	9 (25.0)	8 (50.0)	-25.00
(95% CI)	(12.12, 42.20)	(24.65, 75.35)	(-53.29, 3.29)
p-value[a, b]			0.044
Unstratified odds ratio[c]			0.333
(95% CI)			(0.097, 1.148)
p-value			0.082
Stratified odds ratio[b, c]			0.195

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.035, 1.075)
p-value			0.060
Unstratified risk ratio[c]			0.500
(95% CI)			(0.237, 1.057)
p-value			0.070
Stratified risk ratio[b, c, d]			0.491
(95% CI)			(0.162, 1.486)
p-value			0.21
Absolute risk reduction			-0.250
(95% CI)			(-0.533, 0.033)
p-value			0.11
Number of subjects reporting grade 3 and above febrile neutropenia (PT) - n (%)	9 (25.0)	5 (31.3)	-6.25
(95% CI)	(12.12, 42.20)	(11.02, 58.66)	(-33.01, 20.51)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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.
[g] The number of events in one group is zero 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-saf-mrdpos.sas
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Source data: adam.adsl, adampa.adae

Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value[a, b]			0.93
Unstratified odds ratio[c]			0.733
(95% CI)			(0.200, 2.687)
p-value			0.64
Stratified odds ratio[b, c]			1.066
(95% CI)			(0.240, 4.732)
p-value			0.93
Unstratified risk ratio[c]			0.800
(95% CI)			(0.318, 2.010)
p-value			0.63
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(-0.330, 0.205)
p-value			0.74
Number of subjects reporting grade 3 and above any cardiac disorders (SOC) - n (%)	3 (8.3)	1 (6.3)	2.08
(95% CI)	(1.75, 22.47)	(0.16, 30.23)	(-12.82, 16.99)
p-value[a, b]			0.50
Unstratified odds ratio[c]			1.363
(95% CI)			(0.131, 14.209)
p-value			0.80
Stratified odds ratio[b, c]			2.285
(95% CI)			(0.191, 27.269)
p-value			0.51
Unstratified risk ratio[c]			1.333
(95% CI)			(0.150, 11.857)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.80
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.021
(95% CI)			(-0.128, 0.170)
p-value			>0.999
Number of subjects reporting grade 3 and above cardiac arrest (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.48
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.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	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, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting grade 3 and above any gastrointestinal disorders (SOC) - n (%)	5 (13.9)	4 (25.0)	-11.11
(95% CI)	(4.67, 29.50)	(7.27, 52.38)	(-35.15, 12.93)
p-value[a, b]			0.67
Unstratified odds ratio[c]			0.484
(95% CI)			(0.111, 2.113)
p-value			0.33
Stratified odds ratio[b, c]			1.535
(95% CI)			(0.219, 10.766)
p-value			0.67
Unstratified risk ratio[c]			0.556
(95% CI)			(0.171, 1.800)
p-value			0.33

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.111
(95% CI)			(-0.351, 0.129)
p-value			0.43
Number of subjects reporting grade 3 and above anal inflammation (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.32
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c]			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above colitis (PT) - n (%)	2 (5.6)	1 (6.3)	-0.69
(95% CI)	(0.68, 18.66)	(0.16, 30.23)	(-14.72, 13.33)

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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.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value[a, b]			0.49
Unstratified odds ratio[c]			0.882
(95% CI)			(0.074, 10.496)
p-value			0.92
Stratified odds ratio[b, c]			2.406
(95% CI)			(0.189, 30.680)
p-value			0.50
Unstratified risk ratio[c]			0.889
(95% CI)			(0.087, 9.109)
p-value			0.92
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.007

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(-0.147, 0.133)
p-value			>0.999
Number of subjects reporting grade 3 and above diarrhoea (PT) - n (%)	3 (8.3)	1 (6.3)	2.08
(95% CI)	(1.75, 22.47)	(0.16, 30.23)	(-12.82, 16.99)
p-value[a, b]			0.32
Unstratified odds ratio[c]			1.363
(95% CI)			(0.131, 14.209)
p-value			0.80
Stratified odds ratio[b, c]			3.169
(95% CI)			(0.296, 33.881)
p-value			0.34
Unstratified risk ratio[c]			1.333
(95% CI)			(0.150, 11.857)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.80
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.021
(95% CI)			(-0.128, 0.170)
p-value			>0.999
Number of subjects reporting grade 3 and above nausea (PT) - n (%)	2 (5.6)	1 (6.3)	-0.69
(95% CI)	(0.68, 18.66)	(0.16, 30.23)	(-14.72, 13.33)
p-value[a, b]			>0.999
Unstratified odds ratio[c]			0.882
(95% CI)			(0.074, 10.496)
p-value			0.92

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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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Data cut-off date: 23JUN2023

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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified odds ratio[b, c]			1.000
(95% CI)			(0.045, 22.175)
p-value			>0.999
Unstratified risk ratio[c]			0.889
(95% CI)			(0.087, 9.109)
p-value			0.92
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.007
(95% CI)			(-0.147, 0.133)
p-value			>0.999
Number of subjects reporting grade 3 and above oral pain (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25

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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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, g]			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, f]			NE
(95% CI)			(NE, NE)
p-value			NE

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above stomatitis (PT) - n (%)	2 (5.6)	3 (18.8)	-13.19
(95% CI)	(0.68, 18.66)	(4.05, 45.65)	(-33.73, 7.34)
p-value[a, b]			0.46
Unstratified odds ratio[c]			0.255
(95% CI)			(0.038, 1.704)
p-value			0.16
Stratified odds ratio[b, c]			0.322
(95% CI)			(0.016, 6.513)
p-value			0.46
Unstratified risk ratio[c]			0.296

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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.055, 1.605)
p-value			0.16
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.132
(95% CI)			(-0.337, 0.073)
p-value			0.16
Number of subjects reporting grade 3 and above any general disorders and administration site conditions (SOC) - n (%)	3 (8.3)	2 (12.5)	-4.17
(95% CI)	(1.75, 22.47)	(1.55, 38.35)	(-22.72, 14.38)
p-value[a, b]			0.82
Unstratified odds ratio[c]			0.636

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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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.096, 4.235)
p-value			0.64
Stratified odds ratio[b, c]			0.740
(95% CI)			(0.056, 9.721)
p-value			0.82
Unstratified risk ratio[c]			0.667
(95% CI)			(0.123, 3.611)
p-value			0.64
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.042
(95% CI)			(-0.227, 0.144)
p-value			0.64

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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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting grade 3 and above chills (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, g]			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, f]			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.
Treatment-emergent adverse event is any AE recorded during any treatment period.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above fatigue (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.025
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, g]			NE
(95% CI)			(NE, NE)

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
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			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above pain (PT) - n (%)	1 (2.8)	1 (6.3)	-3.47
(95% CI)	(0.07, 14.53)	(0.16, 30.23)	(-16.49, 9.55)
p-value[a, b]			0.48

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			0.429
(95% CI)			(0.025, 7.313)
p-value			0.56
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			0.444
(95% CI)			(0.030, 6.670)
p-value			0.56
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.035
(95% CI)			(-0.165, 0.095)

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[g] The number of events in one group is zero 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-saf-mrdpos.sas
Output: t14-06-006-008-teae-soc-pt-gr3-ge5pct-saf-mrdpos.rtf (Date generated: 11MAY2024:00:01)
Source data: adam.adsl, adampa.adae

Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.52
Number of subjects reporting grade 3 and above any immune system disorders (SOC) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			0.32
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)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999
Number of subjects reporting grade 3 and above cytokine release syndrome (PT) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			0.32
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
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, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting grade 3 and above any infections and infestations (SOC) - n (%)	6 (16.7)	5 (31.3)	-14.58
(95% CI)	(6.37, 32.81)	(11.02, 58.66)	(-40.35, 11.19)
p-value[a, b]			0.20
Unstratified odds ratio[c]			0.440
(95% CI)			(0.111, 1.737)
p-value			0.24
Stratified odds ratio[b, c]			0.315
(95% CI)			(0.050, 1.981)
p-value			0.22
Unstratified risk ratio[c]			0.533
(95% CI)			(0.190, 1.495)
p-value			0.23

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.146
(95% CI)			(-0.404, 0.112)
p-value			0.28
Number of subjects reporting grade 3 and above bacteraemia (PT) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			0.13
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c]			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999
Number of subjects reporting grade 3 and above clostridium difficile infection (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value[a, b]			0.37
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, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above device related infection (PT) - n (%)	1 (2.8)	2 (12.5)	-9.72
(95% CI)	(0.07, 14.53)	(1.55, 38.35)	(-26.79, 7.35)
p-value[a, b]			0.013
Unstratified odds ratio[c]			0.200
(95% CI)			(0.017, 2.386)
p-value			0.20
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			0.222
(95% CI)			(0.022, 2.277)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.21
Stratified risk ratio[b, c, d]			0.043
(95% CI)			(0.000, 13.489)
p-value			0.28
Absolute risk reduction			-0.097
(95% CI)			(-0.268, 0.073)
p-value			0.22
Number of subjects reporting grade 3 and above pneumonia (PT) - n (%)	1 (2.8)	1 (6.3)	-3.47
(95% CI)	(0.07, 14.53)	(0.16, 30.23)	(-16.49, 9.55)
p-value[a, b]			>0.999
Unstratified odds ratio[c]			0.429
(95% CI)			(0.025, 7.313)
p-value			0.56

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified odds ratio[b, c]			1.000
(95% CI)			(0.045, 22.175)
p-value			>0.999
Unstratified risk ratio[c]			0.444
(95% CI)			(0.030, 6.670)
p-value			0.56
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.035
(95% CI)			(-0.165, 0.095)
p-value			0.52
Number of subjects reporting grade 3 and above sepsis (PT) - n (%)	0 (0.0)	2 (12.5)	-12.50

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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Data cut-off date: 23JUN2023

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Source data: adam.adsl, adampa.adae

Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)	(0.00, 9.74)	(1.55, 38.35)	(-28.70, 3.70)
p-value[a, b]			0.013
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

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Absolute risk reduction			-0.125
(95% CI)			(-0.287, 0.037)
p-value			0.090
Number of subjects reporting grade 3 and above upper respiratory tract infection (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.32
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

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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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above any investigations (SOC) - n (%)	29 (80.6)	15 (93.8)	-13.19
(95% CI)	(63.98, 91.81)	(69.77, 99.84)	(-30.74, 4.35)
p-value[a, b]			0.50

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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			0.276
(95% CI)			(0.031, 2.458)
p-value			0.25
Stratified odds ratio[b, c]			0.438
(95% CI)			(0.037, 5.225)
p-value			0.51
Unstratified risk ratio[c]			0.859
(95% CI)			(0.700, 1.054)
p-value			0.15
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.132
(95% CI)			(-0.307, 0.044)

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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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.41
Number of subjects reporting grade 3 and above lymphocyte count decreased (PT) - n (%)	3 (8.3)	4 (25.0)	-16.67
(95% CI)	(1.75, 22.47)	(7.27, 52.38)	(-39.72, 6.39)
p-value[a, b]			0.093
Unstratified odds ratio[c]			0.273
(95% CI)			(0.053, 1.401)
p-value			0.12
Stratified odds ratio[b, c]			0.144
(95% CI)			(0.012, 1.657)
p-value			0.12
Unstratified risk ratio[c]			0.333
(95% CI)			(0.084, 1.320)

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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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.12
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.167
(95% CI)			(-0.397, 0.064)
p-value			0.18
Number of subjects reporting grade 3 and above neutrophil count decreased (PT) - n (%)	28 (77.8)	13 (81.3)	-3.47
(95% CI)	(60.85, 89.88)	(54.35, 95.95)	(-26.93, 19.98)
p-value[a, b]			0.91
Unstratified odds ratio[c]			0.808
(95% CI)			(0.184, 3.552)

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.78
Stratified odds ratio[b, c]			0.881
(95% CI)			(0.109, 7.131)
p-value			0.91
Unstratified risk ratio[c]			0.957
(95% CI)			(0.714, 1.283)
p-value			0.77
Stratified risk ratio[b, c, d]			1.069
(95% CI)			(0.741, 1.543)
p-value			0.72
Absolute risk reduction			-0.035
(95% CI)			(-0.269, 0.200)
p-value			>0.999

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting grade 3 and above platelet count decreased (PT) - n (%)	24 (66.7)	14 (87.5)	-20.83
(95% CI)	(49.03, 81.44)	(61.65, 98.45)	(-43.19, 1.52)
p-value[a, b]			0.23
Unstratified odds ratio[c]			0.286
(95% CI)			(0.056, 1.467)
p-value			0.13
Stratified odds ratio[b, c]			0.351
(95% CI)			(0.061, 2.032)
p-value			0.24
Unstratified risk ratio[c]			0.762
(95% CI)			(0.567, 1.024)
p-value			0.072

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, d]			0.886
(95% CI)			(0.527, 1.489)
p-value			0.65
Absolute risk reduction			-0.208
(95% CI)			(-0.432, 0.015)
p-value			0.18
Number of subjects reporting grade 3 and above white blood cell count decreased (PT) - n (%)	14 (38.9)	7 (43.8)	-4.86
(95% CI)	(23.14, 56.54)	(19.75, 70.12)	(-33.92, 24.20)
p-value[a, b]			0.30
Unstratified odds ratio[c]			0.818
(95% CI)			(0.248, 2.699)
p-value			0.74

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified odds ratio[b, c]			0.392
(95% CI)			(0.064, 2.383)
p-value			0.31
Unstratified risk ratio[c]			0.889
(95% CI)			(0.446, 1.773)
p-value			0.74
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.049
(95% CI)			(-0.339, 0.242)
p-value			0.77

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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Source data: adam.adsl, adampa.adae

Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting grade 3 and above any metabolism and nutrition disorders (SOC) - n (%)	3 (8.3)	4 (25.0)	-16.67
(95% CI)	(1.75, 22.47)	(7.27, 52.38)	(-39.72, 6.39)
p-value[a, b]			0.27
Unstratified odds ratio[c]			0.273
(95% CI)			(0.053, 1.401)
p-value			0.12
Stratified odds ratio[b, c]			0.319
(95% CI)			(0.040, 2.520)
p-value			0.28
Unstratified risk ratio[c]			0.333
(95% CI)			(0.084, 1.320)
p-value			0.12

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.167
(95% CI)			(-0.397, 0.064)
p-value			0.18
Number of subjects reporting grade 3 and above decreased appetite (PT) - n (%)	2 (5.6)	2 (12.5)	-6.94
(95% CI)	(0.68, 18.66)	(1.55, 38.35)	(-24.79, 10.90)
p-value[a, b]			0.46
Unstratified odds ratio[c]			0.412
(95% CI)			(0.053, 3.219)
p-value			0.40
Stratified odds ratio[b, c]			0.322

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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.016, 6.513)
p-value			0.46
Unstratified risk ratio[c]			0.444
(95% CI)			(0.069, 2.882)
p-value			0.40
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.069
(95% CI)			(-0.248, 0.109)
p-value			0.58
Number of subjects reporting grade 3 and above glucose tolerance impaired (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.32
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, f]			NE
(95% CI)			(NE, NE)
p-value			NE

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above hyperglycaemia (PT) - n (%)	2 (5.6)	3 (18.8)	-13.19
(95% CI)	(0.68, 18.66)	(4.05, 45.65)	(-33.73, 7.34)
p-value[a, b]			0.40
Unstratified odds ratio[c]			0.255
(95% CI)			(0.038, 1.704)
p-value			0.16
Stratified odds ratio[b, c]			0.345
(95% CI)			(0.027, 4.393)
p-value			0.41
Unstratified risk ratio[c]			0.296

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.055, 1.605)
p-value			0.16
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.132
(95% CI)			(-0.337, 0.073)
p-value			0.16
Number of subjects reporting grade 3 and above any musculoskeletal and connective tissue disorders (SOC) - n (%)	3 (8.3)	1 (6.3)	2.08
(95% CI)	(1.75, 22.47)	(0.16, 30.23)	(-12.82, 16.99)
p-value[a, b]			0.29
Unstratified odds ratio[c]			1.363

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.131, 14.209)
p-value			0.80
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			1.333
(95% CI)			(0.150, 11.857)
p-value			0.80
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.021
(95% CI)			(-0.128, 0.170)
p-value			>0.999

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting grade 3 and above back pain (PT) - n (%)	1 (2.8)	1 (6.3)	-3.47
(95% CI)	(0.07, 14.53)	(0.16, 30.23)	(-16.49, 9.55)
p-value[a, b]			0.48
Unstratified odds ratio[c]			0.429
(95% CI)			(0.025, 7.313)
p-value			0.56
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			0.444
(95% CI)			(0.030, 6.670)
p-value			0.56
Stratified risk ratio[b, c, f]			NE

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.035
(95% CI)			(-0.165, 0.095)
p-value			0.52
Number of subjects reporting grade 3 and above any nervous system disorders (SOC) - n (%)	6 (16.7)	2 (12.5)	4.17
(95% CI)	(6.37, 32.81)	(1.55, 38.35)	(-16.10, 24.43)
p-value[a, b]			0.30
Unstratified odds ratio[c]			1.400
(95% CI)			(0.250, 7.828)
p-value			0.70
Stratified odds ratio[b, c]			0.310

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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.032, 2.958)
p-value			0.31
Unstratified risk ratio[c]			1.333
(95% CI)			(0.301, 5.904)
p-value			0.70
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.042
(95% CI)			(-0.161, 0.244)
p-value			>0.999
Number of subjects reporting grade 3 and above headache (PT) - n (%)	4 (11.1)	2 (12.5)	-1.39
(95% CI)	(3.11, 26.06)	(1.55, 38.35)	(-20.57, 17.79)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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.
[g] The number of events in one group is zero 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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value[a, b]			0.30
Unstratified odds ratio[c]			0.875
(95% CI)			(0.143, 5.346)
p-value			0.89
Stratified odds ratio[b, c]			0.310
(95% CI)			(0.032, 2.958)
p-value			0.31
Unstratified risk ratio[c]			0.889
(95% CI)			(0.181, 4.367)
p-value			0.88
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.014

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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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(-0.206, 0.178)
p-value			>0.999
Number of subjects reporting grade 3 and above tremor (PT) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999
Number of subjects reporting grade 3 and above any psychiatric disorders (SOC) - n (%)	3 (8.3)	0 (0.0)	8.33
(95% CI)	(1.75, 22.47)	(0.00, 20.59)	(-0.70, 17.36)
p-value[a, b]			0.48
Unstratified odds ratio[c]			NE
(95% CI)			(NE, 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.
Treatment-emergent adverse event is any AE recorded during any treatment period.
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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
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			0.083
(95% CI)			(-0.007, 0.174)
p-value			0.54

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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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting grade 3 and above confusional state (PT) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, g]			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

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999
Number of subjects reporting grade 3 and above any renal and urinary disorders (SOC) - n (%)	2 (5.6)	1 (6.3)	-0.69
(95% CI)	(0.68, 18.66)	(0.16, 30.23)	(-14.72, 13.33)
p-value[a, b]			0.94
Unstratified odds ratio[c]			0.882
(95% CI)			(0.074, 10.496)
p-value			0.92
Stratified odds ratio[b, c]			1.118

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(0.070, 17.952)
p-value			0.94
Unstratified risk ratio[c]			0.889
(95% CI)			(0.087, 9.109)
p-value			0.92
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.007
(95% CI)			(-0.147, 0.133)
p-value			>0.999
Number of subjects reporting grade 3 and above acute kidney injury (PT) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)

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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.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value[a, b]			0.26
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, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(-0.019, 0.130)
p-value			>0.999
Number of subjects reporting grade 3 and above haematuria (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.32
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)

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above any respiratory, thoracic and mediastinal disorders (SOC) - n (%)	2 (5.6)	4 (25.0)	-19.44
(95% CI)	(0.68, 18.66)	(7.27, 52.38)	(-41.94, 3.05)
p-value[a, b]			0.15
Unstratified odds ratio[c]			0.176
(95% CI)			(0.029, 1.090)
p-value			0.062

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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.
[g] The number of events in one group is zero 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-saf-mrdpos.sas
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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified odds ratio[b, c]			0.185
(95% CI)			(0.016, 2.127)
p-value			0.18
Unstratified risk ratio[c]			0.222
(95% CI)			(0.045, 1.092)
p-value			0.064
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.194
(95% CI)			(-0.419, 0.031)
p-value			0.064
Number of subjects reporting grade 3 and above dyspnoea (PT) - n (%)	0 (0.0)	2 (12.5)	-12.50

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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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)	(0.00, 9.74)	(1.55, 38.35)	(-28.70, 3.70)
p-value[a, b]			0.033
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

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Absolute risk reduction			-0.125
(95% CI)			(-0.287, 0.037)
p-value			0.090
Number of subjects reporting grade 3 and above epistaxis (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.32
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

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above oropharyngeal pain (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Stratified odds ratio[b, c, g]			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, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting grade 3 and above pulmonary oedema (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.32
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, f]			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above any skin and subcutaneous tissue disorders (SOC) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, g]			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above dry skin (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, g]			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, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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[g] The number of events in one group is zero 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-saf-mrdpos.sas
Output: t14-06-006-008-teae-soc-pt-gr3-ge5pct-saf-mrdpos.rtf (Date generated: 11MAY2024:00:01)
Source data: adam.adsl, adampa.adae

Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above any vascular disorders (SOC) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, g]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[f] 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.
[g] The number of events in one group is zero resulting in proc genmod failing to converge. Setting the result to NE.
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Table 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting grade 3 and above hypertension (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.8. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Stratified odds ratio[b, c, g]			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, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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[e] The negative of the Hessian is not positive definite. The convergence is questionable.
[f] 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.
[g] The number of events in one group is zero 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 ≥ 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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Table 14-6.6.9. Summary of Severe (Grade ≥3) Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an Incidence ≥ 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

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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 ≥ 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)

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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 ≥ 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.
[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 ≥ 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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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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.
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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 ≥ 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)

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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 ≥ 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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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.
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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 ≥ 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.
[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.
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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 ≥ 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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Treatment period includes 3 distinct periods: blinatumomab (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 ≥ 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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Treatment period includes 3 distinct periods: blinatumomab (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 ≥ 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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Treatment period includes 3 distinct periods: blinatumomab (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 ≥ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction			0.044
(95% CI)			(-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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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and 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 ≥ 5% (Step 3 Safety Analysis Set)

	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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Treatment period includes 3 distinct periods: blinatumomab (up to 4 cycles), chemotherapy consolidation (up to 4 cycles) and 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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	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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Treatment period includes 3 distinct periods: blinatumomab (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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	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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	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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	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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	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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[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
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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 ≥ 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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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 ≥ 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-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 ≥ 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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Treatment-emergent adverse event is any AE recorded during any treatment period.
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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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Treatment period includes 3 distinct periods: blinatumomab (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 ≥ 5% (Step 3 Safety Analysis Set)

	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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[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 ≥ 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 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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Treatment period includes 3 distinct periods: blinatumomab (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
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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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)			(0.474, 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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Treatment-emergent adverse event is any AE recorded during any treatment period.
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	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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Treatment-emergent adverse event is any AE recorded during any treatment period.
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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction			-0.001
(95% CI)			(-0.058, 0.056)
p-value			>0.999
Number of subjects reporting grade 3 and above any nervous system disorders (SOC) - n (%)	33 (22.4)	13 (10.2)	12.29
(95% CI)	(15.98, 30.06)	(5.52, 16.74)	(3.76, 20.83)
p-value[a, b]			0.021
Unstratified odds ratio[c]			2.561
(95% CI)			(1.282, 5.116)
p-value			0.008
Stratified odds ratio[b, c]			2.228
(95% CI)			(1.112, 4.464)
p-value			0.024

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	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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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 ≥ 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

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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.
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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 ≥ 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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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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 ≥ 5% (Step 3 Safety Analysis Set)

	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

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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.
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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 ≥ 5% (Step 3 Safety Analysis Set)

	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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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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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[d] The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.
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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 ≥ 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 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

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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 ≥ 5% (Step 3 Safety Analysis Set)

	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

Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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.
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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 ≥ 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.
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1 Post-hoc Analysen Studie E1910; Primärer Datenschnitt vom 23.06.2023

1.1 Sicherheit

1.1.3 UE nach SOC/PT

1.1.3.3 Expedited UE nach SOC/PT bei ≥ 5 % der Patientinnen und Patienten

Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting expedited any blood and lymphatic system disorders (SOC) - n (%)	15 (13.5)	14 (12.5)	1.01
(95% CI)	(7.77, 21.31)	(7.01, 20.08)	(-7.82, 9.84)
p-value[a, b]			0.77
Unstratified odds ratio[c]			1.094
(95% CI)			(0.501, 2.388)
p-value			0.82
Stratified odds ratio[b, c]			1.121
(95% CI)			(0.516, 2.435)
p-value			0.77
Unstratified risk ratio[c]			1.081
(95% CI)			(0.548, 2.133)
p-value			0.82
Stratified risk ratio[b, c]			1.098

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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.
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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.558, 2.161)
p-value			0.79
Absolute risk reduction			0.010
(95% CI)			(-0.078, 0.098)
p-value			0.84
Number of subjects reporting expedited febrile neutropenia (PT) - n (%)	14 (12.6)	14 (12.5)	0.11
(95% CI)	(7.07, 20.26)	(7.01, 20.08)	(-8.59, 8.81)
p-value[a, b]			0.94
Unstratified odds ratio[c]			1.010
(95% CI)			(0.458, 2.231)
p-value			0.98
Stratified odds ratio[b, c]			1.032
(95% CI)			(0.471, 2.263)
p-value			0.94

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified risk ratio[c]			1.009
(95% CI)			(0.505, 2.017)
p-value			0.98
Stratified risk ratio[b, c]			1.024
(95% CI)			(0.514, 2.038)
p-value			0.95
Absolute risk reduction			0.001
(95% CI)			(-0.086, 0.088)
p-value			>0.999
Number of subjects reporting expedited any gastrointestinal disorders (SOC) - n (%)	8 (7.2)	3 (2.7)	4.53
(95% CI)	(3.16, 13.71)	(0.56, 7.63)	(-1.14, 10.19)
p-value[a, b]			0.11
Unstratified odds ratio[c]			2.822
(95% CI)			(0.729, 10.928)

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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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-saf-mrdneg.sas
Output: t14-06-006-013-teae-sum-exp-soc-pt-ge5pct-saf-mrdneg.rtf (Date generated: 10MAY2024:23:43) Source data: adam.adsl, adampa.adae

Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.13
Stratified odds ratio[b, c]			2.892
(95% CI)			(0.747, 11.197)
p-value			0.12
Unstratified risk ratio[c]			2.691
(95% CI)			(0.733, 9.880)
p-value			0.14
Stratified risk ratio[b, c]			2.760
(95% CI)			(0.764, 9.975)
p-value			0.12
Absolute risk reduction			0.045
(95% CI)			(-0.011, 0.102)
p-value			0.14
Number of subjects reporting expedited nausea (PT) - n (%)	6 (5.4)	0 (0.0)	5.41
(95% CI)	(2.01, 11.39)	(0.00, 3.24)	(1.20, 9.61)

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value[a, b]			0.013
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)			(0.012, 0.096)

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.014
Number of subjects reporting expedited any general disorders and administration site conditions (SOC) - n (%)	18 (16.2)	2 (1.8)	14.43
(95% CI)	(9.90, 24.41)	(0.22, 6.30)	(7.15, 21.71)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			10.642
(95% CI)			(2.407, 47.054)
p-value			0.002
Stratified odds ratio[b, c]			11.048
(95% CI)			(2.493, 48.951)
p-value			0.002
Unstratified risk ratio[c]			9.081
(95% CI)			(2.158, 38.217)

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.003
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.144
(95% CI)			(0.071, 0.217)
p-value			<0.001
Number of subjects reporting expedited pyrexia (PT) - n (%)	13 (11.7)	1 (0.9)	10.82
(95% CI)	(6.39, 19.19)	(0.02, 4.87)	(4.59, 17.05)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			14.724
(95% CI)			(1.892, 114.608)
p-value			0.010
Stratified odds ratio[b, c]			14.334
(95% CI)			(1.853, 110.886)

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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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 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.011
Unstratified risk ratio[c]			13.117
(95% CI)			(1.745, 98.579)
p-value			0.012
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.108
(95% CI)			(0.046, 0.170)
p-value			<0.001
Number of subjects reporting expedited any infections and infestations (SOC) - n (%)	30 (27.0)	15 (13.4)	13.63
(95% CI)	(19.04, 36.28)	(7.69, 21.13)	(3.24, 24.03)
p-value[a, b]			0.011
Unstratified odds ratio[c]			2.395

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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 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(1.206, 4.758)
p-value			0.013
Stratified odds ratio[b, c]			2.375
(95% CI)			(1.201, 4.696)
p-value			0.013
Unstratified risk ratio[c]			2.018
(95% CI)			(1.151, 3.538)
p-value			0.014
Stratified risk ratio[b, c]			2.101
(95% CI)			(1.210, 3.647)
p-value			0.008
Absolute risk reduction			0.136
(95% CI)			(0.032, 0.240)
p-value			0.013

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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.
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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting expedited device related infection (PT) - n (%)	11 (9.9)	3 (2.7)	7.23
(95% CI)	(5.05, 17.04)	(0.56, 7.63)	(0.92, 13.54)
p-value[a, b]			0.026
Unstratified odds ratio[c]			3.997
(95% CI)			(1.084, 14.740)
p-value			0.037
Stratified odds ratio[b, c]			3.973
(95% CI)			(1.082, 14.592)
p-value			0.038
Unstratified risk ratio[c]			3.700
(95% CI)			(1.061, 12.904)
p-value			0.040
Stratified risk ratio[b, c]			3.586

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(1.037, 12.404)
p-value			0.044
Absolute risk reduction			0.072
(95% CI)			(0.009, 0.135)
p-value			0.029
Number of subjects reporting expedited sepsis (PT) - n (%)	13 (11.7)	8 (7.1)	4.57
(95% CI)	(6.39, 19.19)	(3.13, 13.59)	(-3.08, 12.22)
p-value[a, b]			0.27
Unstratified odds ratio[c]			1.724
(95% CI)			(0.685, 4.340)
p-value			0.25
Stratified odds ratio[b, c]			1.667
(95% CI)			(0.671, 4.144)
p-value			0.27
Unstratified risk ratio[c]			1.640

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(0.707, 3.801)
p-value			0.25
Stratified risk ratio[b, c]			1.692
(95% CI)			(0.732, 3.910)
p-value			0.22
Absolute risk reduction			0.046
(95% CI)			(-0.031, 0.122)
p-value			0.26
Number of subjects reporting expedited any investigations (SOC) - n (%)	18 (16.2)	6 (5.4)	10.86
(95% CI)	(9.90, 24.41)	(1.99, 11.30)	(2.83, 18.88)
p-value[a, b]			0.006
Unstratified odds ratio[c]			3.419
(95% CI)			(1.303, 8.974)
p-value			0.013

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified odds ratio[b, c]			3.599
(95% CI)			(1.365, 9.489)
p-value			0.010
Unstratified risk ratio[c]			3.027
(95% CI)			(1.248, 7.341)
p-value			0.014
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.109
(95% CI)			(0.028, 0.189)
p-value			0.010
Number of subjects reporting expedited alanine aminotransferase increased (PT) - n (%)	9 (8.1)	0 (0.0)	8.11
(95% CI)	(3.77, 14.83)	(0.00, 3.24)	(3.03, 13.19)

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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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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-saf-mrdneg.sas
Output: t14-06-006-013-teae-sum-exp-soc-pt-ge5pct-saf-mrdneg.rtf (Date generated: 10MAY2024:23:43) Source data: adam.adsl, adampa.adae

Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value[a, b]			0.002
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			0.081
(95% CI)			(0.030, 0.132)

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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

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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.002
Number of subjects reporting expedited neutrophil count decreased (PT) - n (%)	9 (8.1)	2 (1.8)	6.32
(95% CI)	(3.77, 14.83)	(0.22, 6.30)	(0.68, 11.96)
p-value[a, b]			0.021
Unstratified odds ratio[c]			4.853
(95% CI)			(1.024, 22.995)
p-value			0.047
Stratified odds ratio[b, c]			5.397
(95% CI)			(1.121, 25.988)
p-value			0.036
Unstratified risk ratio[c]			4.541
(95% CI)			(1.004, 20.544)
p-value			0.049

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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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 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.063
(95% CI)			(0.007, 0.120)
p-value			0.034
Number of subjects reporting expedited any metabolism and nutrition disorders (SOC) - n (%)	8 (7.2)	3 (2.7)	4.53
(95% CI)	(3.16, 13.71)	(0.56, 7.63)	(-1.14, 10.19)
p-value[a, b]			0.12
Unstratified odds ratio[c]			2.822
(95% CI)			(0.729, 10.928)
p-value			0.13
Stratified odds ratio[b, c]			2.810
(95% CI)			(0.717, 11.018)

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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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] 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 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.14
Unstratified risk ratio[c]			2.691
(95% CI)			(0.733, 9.880)
p-value			0.14
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.045
(95% CI)			(-0.011, 0.102)
p-value			0.14
Number of subjects reporting expedited any musculoskeletal and connective tissue disorders (SOC) - n (%)	6 (5.4)	1 (0.9)	4.51
(95% CI)	(2.01, 11.39)	(0.02, 4.87)	(-0.04, 9.07)
p-value[a, b]			0.057

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Unstratified odds ratio[c]			6.343
(95% CI)			(0.751, 53.573)
p-value			0.090
Stratified odds ratio[b, c]			6.182
(95% CI)			(0.734, 52.060)
p-value			0.094
Unstratified risk ratio[c]			6.054
(95% CI)			(0.741, 49.471)
p-value			0.093
Stratified risk ratio[b, c]			6.087
(95% CI)			(0.753, 49.194)
p-value			0.090
Absolute risk reduction			0.045
(95% CI)			(-0.000, 0.091)
p-value			0.065

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Number of subjects reporting expedited any nervous system disorders (SOC) - n (%)	19 (17.1)	0 (0.0)	17.12
(95% CI)	(10.63, 25.43)	(0.00, 3.24)	(10.11, 24.12)
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

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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.
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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.171
(95% CI)			(0.101, 0.241)
p-value			<0.001
Number of subjects reporting expedited aphasia (PT) - n (%)	8 (7.2)	0 (0.0)	7.21
(95% CI)	(3.16, 13.71)	(0.00, 3.24)	(2.40, 12.02)
p-value[a, b]			0.004
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

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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.
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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.072
(95% CI)			(0.024, 0.120)
p-value			0.003
Number of subjects reporting expedited any psychiatric disorders (SOC) - n (%)	8 (7.2)	1 (0.9)	6.31
(95% CI)	(3.16, 13.71)	(0.02, 4.87)	(1.20, 11.43)
p-value[a, b]			0.013
Unstratified odds ratio[c]			8.620
(95% CI)			(1.060, 70.103)
p-value			0.044

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.
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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified odds ratio[b, c]			9.099
(95% CI)			(1.118, 74.038)
p-value			0.039
Unstratified risk ratio[c]			8.072
(95% CI)			(1.027, 63.474)
p-value			0.047
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.063
(95% CI)			(0.012, 0.114)
p-value			0.019
Number of subjects reporting expedited any respiratory, thoracic and mediastinal disorders (SOC) - n (%)	8 (7.2)	2 (1.8)	5.42
(95% CI)	(3.16, 13.71)	(0.22, 6.30)	(0.02, 10.82)

Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value[a, b]			0.049
Unstratified odds ratio[c]			4.272
(95% CI)			(0.886, 20.587)
p-value			0.070
Stratified odds ratio[b, c]			4.335
(95% CI)			(0.895, 20.991)
p-value			0.068
Unstratified risk ratio[c]			4.036
(95% CI)			(0.876, 18.585)
p-value			0.073
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.054
(95% CI)			(0.000, 0.108)

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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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-saf-mrdneg.sas
Output: t14-06-006-013-teae-sum-exp-soc-pt-ge5pct-saf-mrdneg.rtf (Date generated: 10MAY2024:23:43) Source data: adam.adsl, adampa.adae

Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
p-value			0.059
Number of subjects reporting expedited any vascular disorders (SOC) - n (%)	7 (6.3)	1 (0.9)	5.41
(95% CI)	(2.57, 12.56)	(0.02, 4.87)	(0.57, 10.26)
p-value[a, b]			0.023
Unstratified odds ratio[c]			7.471
(95% CI)			(0.904, 61.757)
p-value			0.062
Stratified odds ratio[b, c]			8.093
(95% CI)			(0.976, 67.119)
p-value			0.053
Unstratified risk ratio[c]			7.063
(95% CI)			(0.883, 56.467)
p-value			0.065

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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

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Table 14-6.6.13. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Safety Analysis Set - MRD Negative)

	SOC Chemotherapy+ Blinatumomab (N = 111)	SOC Chemotherapy (N = 112)	Treatment Difference
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.054
(95% CI)			(0.006, 0.103)
p-value			0.035

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Safety analysis set includes all Step 3 randomized subjects who are assessed as MRD negative centrally after induction and intensification chemotherapy who take at least 1 dose of protocol-specified therapies using 10^{-4} cut-off.
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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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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[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 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting expedited any blood and lymphatic system disorders (SOC) - n (%)	5 (13.9)	1 (6.3)	7.64
(95% CI)	(4.67, 29.50)	(0.16, 30.23)	(-8.74, 24.02)
p-value[a, b]			0.24
Unstratified odds ratio[c]			2.419
(95% CI)			(0.259, 22.583)
p-value			0.44
Stratified odds ratio[b, c]			3.736
(95% CI)			(0.371, 37.580)
p-value			0.26
Unstratified risk ratio[c]			2.222
(95% CI)			(0.282, 17.517)

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[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.
[f] The number of events in one group is zero resulting in proc genmod failing to converge. Setting the result to NE.
Data cut-off date: 23JUN2023

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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			0.45
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.076
(95% CI)			(-0.087, 0.240)
p-value			0.65
Number of subjects reporting expedited febrile neutropenia (PT) - n (%)	4 (11.1)	1 (6.3)	4.86
(95% CI)	(3.11, 26.06)	(0.16, 30.23)	(-10.83, 20.55)
p-value[a, b]			0.43
Unstratified odds ratio[c]			1.875
(95% CI)			(0.193, 18.249)
p-value			0.59

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[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.
[f] The number of events in one group is zero resulting in proc genmod failing to converge. Setting the result to NE.
Data cut-off date: 23JUN2023

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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified odds ratio[b, c]			2.619
(95% CI)			(0.222, 30.869)
p-value			0.44
Unstratified risk ratio[c]			1.778
(95% CI)			(0.215, 14.674)
p-value			0.59
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.049
(95% CI)			(-0.108, 0.205)
p-value			>0.999

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[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 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting expedited any cardiac disorders (SOC) - n (%)	1 (2.8)	2 (12.5)	-9.72
(95% CI)	(0.07, 14.53)	(1.55, 38.35)	(-26.79, 7.35)
p-value[a, b]			0.23
Unstratified odds ratio[c]			0.200
(95% CI)			(0.017, 2.386)
p-value			0.20
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			0.222
(95% CI)			(0.022, 2.277)
p-value			0.21

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.097
(95% CI)			(-0.268, 0.073)
p-value			0.22
Number of subjects reporting expedited cardiac arrest (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.48
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	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, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting expedited sinus tachycardia (PT) - n (%)	1 (2.8)	1 (6.3)	-3.47

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)	(0.07, 14.53)	(0.16, 30.23)	(-16.49, 9.55)
p-value[a, b]			0.32
Unstratified odds ratio[c]			0.429
(95% CI)			(0.025, 7.313)
p-value			0.56
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			0.444
(95% CI)			(0.030, 6.670)
p-value			0.56
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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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 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Absolute risk reduction			-0.035
(95% CI)			(-0.165, 0.095)
p-value			0.52
Number of subjects reporting expedited any gastrointestinal disorders (SOC) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			0.32
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

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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[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.
[f] The number of events in one group is zero 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-saf-mrdpos.sas
Output: t14-06-006-014-teae-sum-exp-soc-pt-ge5pct-saf-mrdpos.rtf (Date generated: 10MAY2024:23:43) Source data: adam.adsl, adampa.adae

Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999
Number of subjects reporting expedited any general disorders and administration site conditions (SOC) - n (%)	2 (5.6)	1 (6.3)	-0.69
(95% CI)	(0.68, 18.66)	(0.16, 30.23)	(-14.72, 13.33)
p-value[a, b]			0.81

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			0.882
(95% CI)			(0.074, 10.496)
p-value			0.92
Stratified odds ratio[b, c]			0.707
(95% CI)			(0.042, 11.786)
p-value			0.81
Unstratified risk ratio[c]			0.889
(95% CI)			(0.087, 9.109)
p-value			0.92
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-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.
Treatment-emergent adverse event is any AE recorded during any treatment period.
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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(-0.147, 0.133)
p-value			>0.999
Number of subjects reporting expedited influenza like illness (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.32
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

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting expedited any infections and infestations (SOC) - n (%)	3 (8.3)	4 (25.0)	-16.67
(95% CI)	(1.75, 22.47)	(7.27, 52.38)	(-39.72, 6.39)
p-value[a, b]			0.026

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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 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			0.273
(95% CI)			(0.053, 1.401)
p-value			0.12
Stratified odds ratio[b, c]			0.094
(95% CI)			(0.009, 1.002)
p-value			0.050
Unstratified risk ratio[c]			0.333
(95% CI)			(0.084, 1.320)
p-value			0.12
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.167

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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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Expedited adverse event: A serious adverse event meeting requiring expedited reporting via CTEP AERS is called an expedited adverse event.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(-0.397, 0.064)
p-value			0.18
Number of subjects reporting expedited device related infection (PT) - n (%)	1 (2.8)	2 (12.5)	-9.72
(95% CI)	(0.07, 14.53)	(1.55, 38.35)	(-26.79, 7.35)
p-value[a, b]			0.013
Unstratified odds ratio[c]			0.200
(95% CI)			(0.017, 2.386)
p-value			0.20
Stratified odds ratio[b, c]			NE
(95% CI)			(NE, NE)
p-value			NE

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified risk ratio[c]			0.222
(95% CI)			(0.022, 2.277)
p-value			0.21
Stratified risk ratio[b, c, d]			0.043
(95% CI)			(0.000, 13.489)
p-value			0.28
Absolute risk reduction			-0.097
(95% CI)			(-0.268, 0.073)
p-value			0.22
Number of subjects reporting expedited pneumonia (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.32
Unstratified odds ratio[c]			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(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, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting expedited sepsis (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.025
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, f]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31
Number of subjects reporting expedited upper respiratory tract infection (PT) - n (%)	0 (0.0)	1 (6.3)	-6.25
(95% CI)	(0.00, 9.74)	(0.16, 30.23)	(-18.11, 5.61)
p-value[a, b]			0.32
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE

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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.
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.
[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.
[f] The number of events in one group is zero 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-saf-mrdpos.sas
Output: t14-06-006-014-teae-sum-exp-soc-pt-ge5pct-saf-mrdpos.rtf (Date generated: 10MAY2024:23:43) Source data: adam.adsl, adampa.adae

Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	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, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			-0.063
(95% CI)			(-0.181, 0.056)
p-value			0.31

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[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.
[f] The number of events in one group is zero resulting in proc genmod failing to converge. Setting the result to NE.
Data cut-off date: 23JUN2023

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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Number of subjects reporting expedited any investigations (SOC) - n (%)	5 (13.9)	0 (0.0)	13.89
(95% CI)	(4.67, 29.50)	(0.00, 20.59)	(2.59, 25.19)
p-value[a, b]			0.13
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

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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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.
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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.139
(95% CI)			(0.026, 0.252)
p-value			0.31
Number of subjects reporting expedited neutrophil count decreased (PT) - n (%)	3 (8.3)	0 (0.0)	8.33
(95% CI)	(1.75, 22.47)	(0.00, 20.59)	(-0.70, 17.36)
p-value[a, b]			0.48
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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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.
[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.
[f] The number of events in one group is zero resulting in proc genmod failing to converge. Setting the result to NE.
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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	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, d]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.083
(95% CI)			(-0.007, 0.174)
p-value			0.54
Number of subjects reporting expedited platelet count decreased (PT) - n (%)	2 (5.6)	0 (0.0)	5.56

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
[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 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			0.16
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)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
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[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 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999
Number of subjects reporting expedited any musculoskeletal and connective tissue disorders (SOC) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
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)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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.
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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999
Number of subjects reporting expedited any nervous system disorders (SOC) - n (%)	3 (8.3)	0 (0.0)	8.33
(95% CI)	(1.75, 22.47)	(0.00, 20.59)	(-0.70, 17.36)
p-value[a, b]			<0.001

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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[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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[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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	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, f]			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			0.083

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)			(-0.007, 0.174)
p-value			0.54
Number of subjects reporting expedited tremor (PT) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified odds ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Unstratified risk ratio[c]			NE
(95% CI)			(NE, NE)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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 = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Stratified risk ratio[b, c, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999
Number of subjects reporting expedited any renal and urinary disorders (SOC) - n (%)	2 (5.6)	0 (0.0)	5.56
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			0.26
Unstratified odds ratio[c]			NE
(95% CI)			(NE, NE)
p-value			NE

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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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.
[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.
[f] The number of events in one group is zero 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-saf-mrdpos.sas
Output: t14-06-006-014-teae-sum-exp-soc-pt-ge5pct-saf-mrdpos.rtf (Date generated: 10MAY2024:23:43) Source data: adam.adsl, adampa.adae

Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	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, e]			NE
(95% CI)			(NE, NE)
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999
Number of subjects reporting expedited acute kidney injury (PT) - n (%)	2 (5.6)	0 (0.0)	5.56

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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[d] The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.
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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
(95% CI)	(0.68, 18.66)	(0.00, 20.59)	(-1.93, 13.04)
p-value[a, b]			0.26
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, e]			NE
(95% CI)			(NE, NE)

Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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Table 14-6.6.14. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 5% (Step 3 MRD Positive Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 36)	SOC Chemotherapy (N = 16)	Treatment Difference
p-value			NE
Absolute risk reduction			0.056
(95% CI)			(-0.019, 0.130)
p-value			>0.999

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Step 3 MRD positive safety analysis set includes all subjects from Step 3 safety analysis set that are MRD positive at Step 3 using the protocol-specified 10^{-4} cut-off.
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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[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 14-6.6.15. Summary of Expedited Treatment-emergent Adverse Events by System Organ Class and Preferred Term with an incidence ≥ 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:
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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 ≥ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction			0.019
(95% CI)			(-0.060, 0.097)
p-value			0.72
Number of subjects reporting expedited febrile neutropenia (PT) - n (%)	18 (12.2)	15 (11.7)	0.53
(95% CI)	(7.42, 18.66)	(6.71, 18.59)	(-7.16, 8.22)
p-value[a, b]			0.77
Unstratified odds ratio[c]			1.051
(95% CI)			(0.506, 2.182)
p-value			0.89
Stratified odds ratio[b, c]			1.116
(95% CI)			(0.537, 2.322)
p-value			0.77
Unstratified risk ratio[c]			1.045
(95% CI)			(0.549, 1.987)
p-value			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.
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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] 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 ≥ 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. ≥ 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 ≥ 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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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 ≥ 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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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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.
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	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.
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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 ≥ 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.
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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

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/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 ≥ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction			0.076
(95% CI)			(-0.015, 0.167)
p-value			0.12
Number of subjects reporting expedited device related infection (PT) - n (%)	12 (8.2)	5 (3.9)	4.26
(95% CI)	(4.29, 13.83)	(1.28, 8.88)	(-1.30, 9.81)
p-value[a, b]			0.16
Unstratified odds ratio[c]			2.187
(95% CI)			(0.749, 6.384)
p-value			0.15
Stratified odds ratio[b, c]			2.101
(95% CI)			(0.723, 6.106)
p-value			0.17
Unstratified risk ratio[c]			2.090
(95% CI)			(0.757, 5.772)
p-value			0.16

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	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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	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) - n (%)	23 (15.6)	6 (4.7)	10.96
(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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	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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	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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	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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	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction			0.066
(95% CI)			(0.017, 0.115)
p-value			0.014
Number of subjects reporting expedited any metabolism and nutrition disorders (SOC) - n (%)	8 (5.4)	3 (2.3)	3.10
(95% CI)	(2.38, 10.44)	(0.49, 6.70)	(-1.41, 7.61)
p-value[a, b]			0.19
Unstratified odds ratio[c]			2.398
(95% CI)			(0.622, 9.238)
p-value			0.20
Stratified odds ratio[b, c]			2.404
(95% CI)			(0.619, 9.339)
p-value			0.21
Unstratified risk ratio[c]			2.322
(95% CI)			(0.629, 8.568)
p-value			0.21

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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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	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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	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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[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] 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 ≥ 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			0.054
(95% CI)			(0.018, 0.091)
p-value			0.008

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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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.
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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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Step 3 safety analysis set includes all subjects in the Step 3 analysis set who take at least 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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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.
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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 ≥ 5% (Step 3 Safety Analysis Set)

	SOC Chemotherapy+ Blinatumomab (N = 147)	SOC Chemotherapy (N = 128)	Treatment Difference
Absolute risk reduction			0.053
(95% CI)			(0.012, 0.095)
p-value			0.022
Number of subjects reporting expedited any respiratory, thoracic and mediastinal disorders (SOC) - n (%)	9 (6.1)	2 (1.6)	4.56
(95% CI)	(2.84, 11.30)	(0.19, 5.53)	(0.13, 8.99)
p-value[a, b]			0.051
Unstratified odds ratio[c]			4.109
(95% CI)			(0.871, 19.379)
p-value			0.074
Stratified odds ratio[b, c]			4.207
(95% CI)			(0.888, 19.939)
p-value			0.070
Unstratified risk ratio[c]			3.918
(95% CI)			(0.862, 17.804)
p-value			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.
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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			0.046
(95% CI)			(0.001, 0.090)
p-value			0.067

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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