Supplemental Data

Phase III randomized trial of chemotherapy with or without oblimersen in older AML patients: CALGB 10201 (Alliance)

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Participating institutions

The following Cancer and Leukemia Group B (CALGB)/Alliance for Clinical Trials in Oncology (Alliance) institutional networks participated in this study and contributed at least five patients. For each of these institutions, the current or last principal investigator is listed as follows:

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Medical Center, Washington, DC, Minnetta C. Liu; NCORP of the Carolinas (Greenville Health System NCORP), Greenville, SC; Ki Y. Chung; Stony Brook University Medical Center, Stony Brook, NY; Michael M. Schuster; Via Christi Regional Medical Center, Wichita, KS, Shaker R. Dakhil; Eastern Maine Medical Center, Bangor, ME, Sarah J. Sinclair; Delaware/Christiana Care NCI Community Oncology Research Program, Newark, DE, Gregory A. Masters; Massachusetts General Hospital, Boston, MA, David Ryan and Justin Gainor; University of Minnesota/Masonic Cancer Center, Minneapolis, MN, Anne H. Blaes; Phoebe Putney Memorial Hospital, Albany, GA, Chirag R. Jani, Heartland Cancer Research NCORP, Decatur, IL, Bryan Faller; Missouri Cancer Associates, Columbia, MO, Mount Sinai Medical Center, Miami Beach, FL, Michael Swartz; National Capital Area Minority Underserved NCORP, Washington, DC, Marcus Noel; Nevada Cancer Research Foundation NCORP, Las Vegas, NV, John Ellerton; Northern Indiana Cancer ResearchConsortium, South Bend, IN; State University of New York Upstate Medical University, Syracuse, NY, Stephen Graziano; UC San Diego Moores Cancer Center, La Jolla, CA, Lyudmila Bazhenova; University of Missouri-Ellis Fischel, Columbia, MO, Puja Nistala;University of Nebraska Medical Center, Omaha, NE, Apar Ganti; and University of Oklahoma Health Sciences Center LAPS, Oklahoma City, OK, Adam Asch.

Supplemental Tables and Figures

Supplemental Table 1. Intent to treat response and survival by age group

End point	≥70 years			<70 years		
	Arm A: G3139	**Arm B: control**	***P***	**Arm A: G3139**	**Arm B: control**	***P***
Complete remission			.008			.52
Events/n	53/117	64/111		82/137	78/141	
Rate (95% CI)	0.45 (0.36-0.55)	0.58 (0.48-0.67)		0.60 (0.51-0.68)	0.55 (0.47-0.63)	
Overall survival			.55			.04
Events/n	110/117	103/111		118/137	134/141	
Median, months (95% CI)	7 (4.89-11.66)	9 (6.41-11.76)		10 (7.82-13.27)	9 (7.69-11.47)	
1-year OS rate (95% CI)	0.39 (0.31-0.49)	0.39 (0.31-0.50)		0.46 (0.38-0.55)	0.41 (0.33-0.50)	
2-year OS rate (95% CI)	0.21 (0.15-0.30)	0.22 (0.15-0.31)		0.23 (0.17-0.32)	0.15 (0.10-0.22)	
Event-free survival			.33			.19
Events/n	111/117	104/111		123/137	137/141	
Median, months (95% CI)	2 (1.41-3.29)	3 (2.04-5.85)		4 (2.33-6.67)	3 (2.37-5.65)	
1-year EFS rate (95% CI)	0.21 (0.15-0.30)	0.26 (0.19-0.36)		0.22 (0.16-0.30)	0.22 (0.16-0.30)	
2-year EFS rate (95% CI)	0.13 (0.08-0.21)	0.12 (0.07-0.20)		0.13 (0.09-0.20)	0.07 (0.04-0.13)	
Disease-free survival			.80			.16
Events/n	47/53	56/64		69/82	74/78	
Median, months (95% CI)	10 (7.39-19.09)	9 (7.10-15.77)		7 (5.98-11.30)	7 (6.21, 9.89)	
1-year DFS rate (95% CI)	0.45 (0.34-0.61)	0.47 (0.36-0.61)		0.36 (0.27-0.48)	0.28 (0.20-0.40)	
2-year DFS rate (95% CI)	0.28 (0.18-0.43)	0.22 (0.14-0.35)		0.21 (0.14-0.32)	0.12 (0.06-0.21)	
Early death rate during the first 30 days of induction therapy	0.19 (0.12-0.27)	0.17 (0.11-0.26)	.87	0.08 (0.04-0.14)	0.08 (0.04-0.14)	1.00

Supplemental Table 2. Intent to treat response and survival by AML type

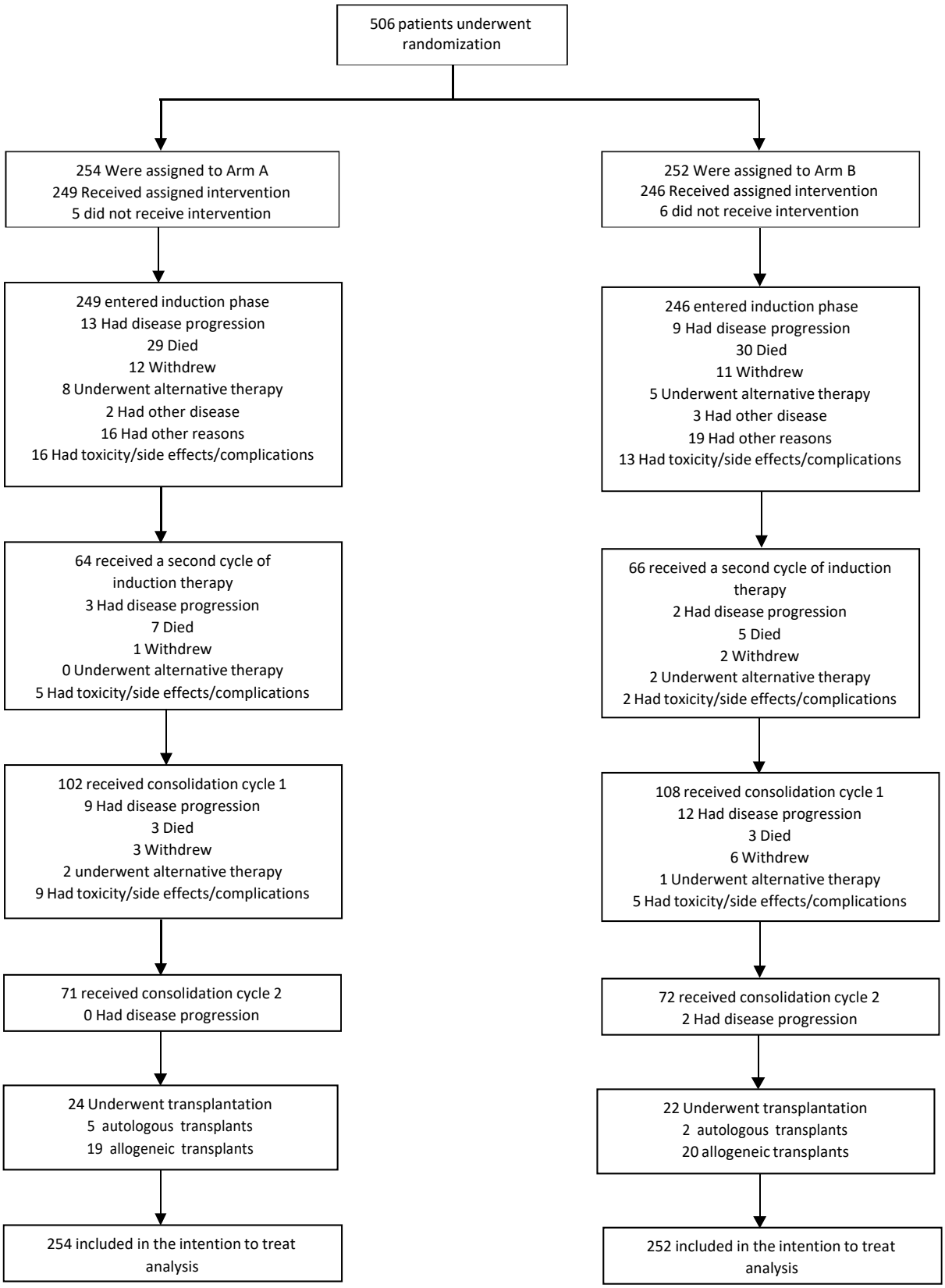
End point	AML de novo			Secondary AML		
	Arm A: G3139	Arm B: control	*P*	Arm A: G3139	Arm B: control	*P*
Complete remission			.76			.68
Events/n	104/186	112/193		31/68	30/59	
Rate (95% CI)	0.56 (0.49-0.63)	0.58 (0.51-0.65)		0.46 (0.34-0.58)	0.51 (0.38-0.64)	
Overall survival			.56			.15
Events/n	164/186	180/193		64/68	57/59	
Median, months (95% CI)	9.00 (7.23-10.91)	10 (7.92-12.84)		11 (6.57-14.36)	7 (5.65-10.32)	
1-year OS rate (95% CI)	0.41 (0.35-0.49)	0.44 (0.37-0.51)		0.47 (0.37-0.61)	0.27 (0.18-0.41)	
2-year OS rate (95% CI)	0.22 (0.17-0.29)	0.19 (0.14-0.26)		0.24 (0.15-0.36)	0.14 (0.07-0.26)	
Event-free survival			.81			.78
Events/n	169/186	183/193		65/68	58/59	
Median, months (95% CI)	3 (2.07-5.12)	4 (2.07-5.75)		2 (1.54-5.09)	3 (2.37-5.55)	
1-year EFS rate (95% CI)	0.23 (0.18-0.30)	0.26 (0.20-0.33)		0.19 (0.12-0.31)	0.17 (0.10-0.30)	
2-year EFS rate (95% CI)	0.14 (0.10-0.20)	0.10 (0.07-0.16)		0.10 (0.05-0.21)	0.05 (0.02-0.15)	
Disease-free survival			.69			.04
Events/n	88/104	101/112		28/31	29/30	
Median, months (95% CI)	7 (6.18-11.70)	9 (7.03-11.99)		10 (7.36-21.32)	6 (4.99-10.51)	
1-year DFS rate (95% CI)	0.38 (0.30-0.49)	0.39 (0.31-0.50)		0.45 (0.31-0.67)	0.27 (0.15-0.48)	
2-year DFS rate (95% CI)	0.24 (0.17-0.34)	0.19 (0.13-0.28)		0.23 (0.12-0.43)	0.07 (0.02-0.25)	
Early death rate during the first 30 days of induction therapy	0.14 (0.10-0.20)	0.12 (0.08-0.18)	.77	0.10 (0.05-0.21)	0.10 (0.04-0.22)	1.00

Supplemental Table 3. Specific transplant type for patients who received hematopoietic cell transplantation

Transplant type	Arm A: G3139 (n=24)	Arm B: control (n=22)	Total (n=46)
BM from matched sibling, n (%)	4 (16.7)	5 (22.7)	9 (19.6)
PBSC from matched sibling, n (%)	10 (41.7)	6 (27.3)	16 (34.8)
BM from matched unrelated donor, n (%)	1 (4.2)	3 (13.6)	4 (8.7)
PBSC from matched unrelated donor, n (%)	2 (8.3)	5 (22.7)	7 (15.2)
Autologous BM, n (%)	2 (8.3)	1 (4.5)	3 (6.5)
Autologous PBSC, n (%)	3 (12.5)	1 (4.5)	4 (8.7)
Other, n (%)	2 (8.3)	1 (4.5)	3 (6.5)

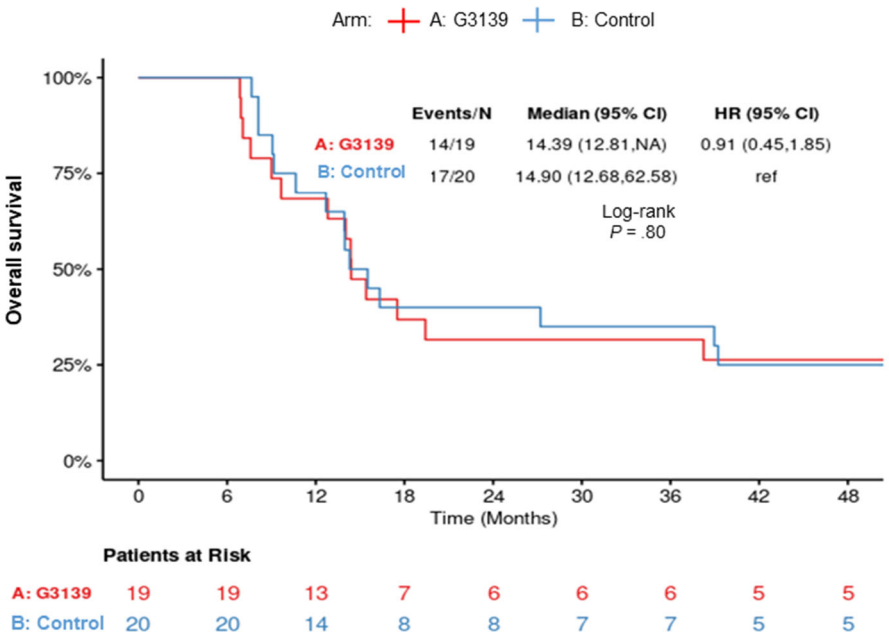
BM, bone marrow; PBSC, peripheral blood stem cells.

Supplemental Figure 1. Screening, Randomization and Treatment



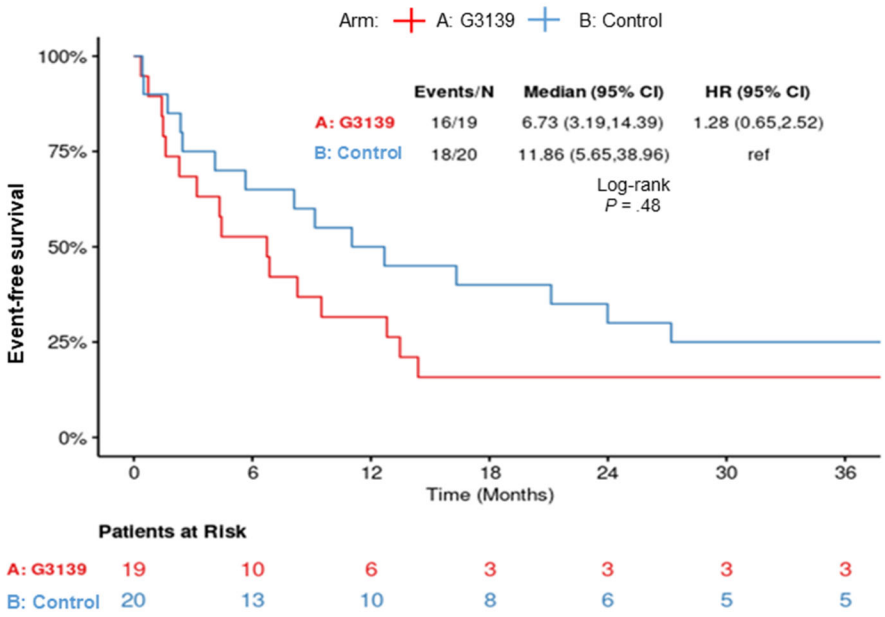
Supplemental Figure 1. Screening, Randomization, and Treatment. Eleven patients were registered in the trial and underwent randomization, but did not receive the trial treatment. In accordance with the rule for intention-to-treat, these patients were included in the primary analyses but excluded in the correlative analyses.

Supplemental Figure 2. Overall survival of AML patients who underwent allogeneic hematopoietic cell transplantation



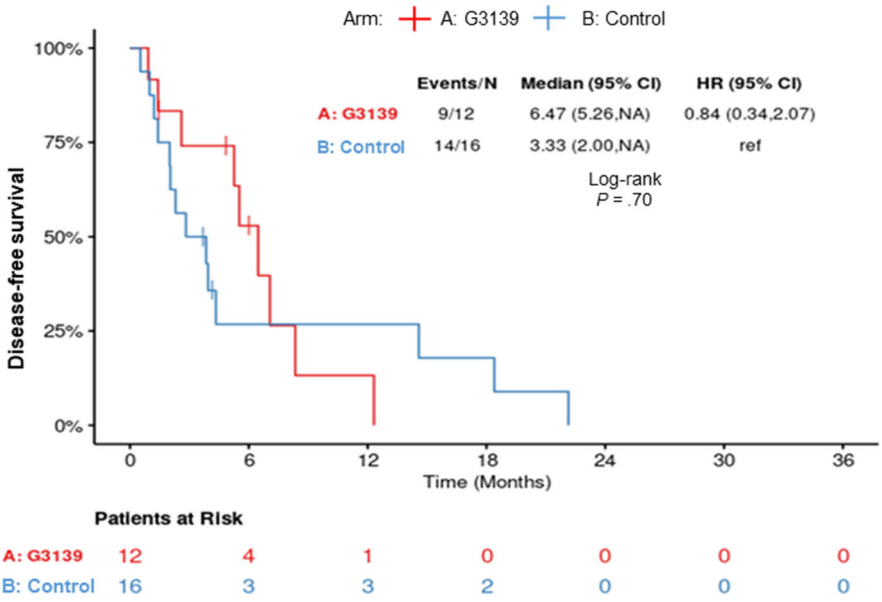
Supplemental Figure 2. Kaplan-Meier curves for overall survival in the G3139 group and the control group, among patients who underwent allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.

Supplemental Figure 3. Event-free survival of AML patients who underwent allogeneic hematopoietic cell transplantation



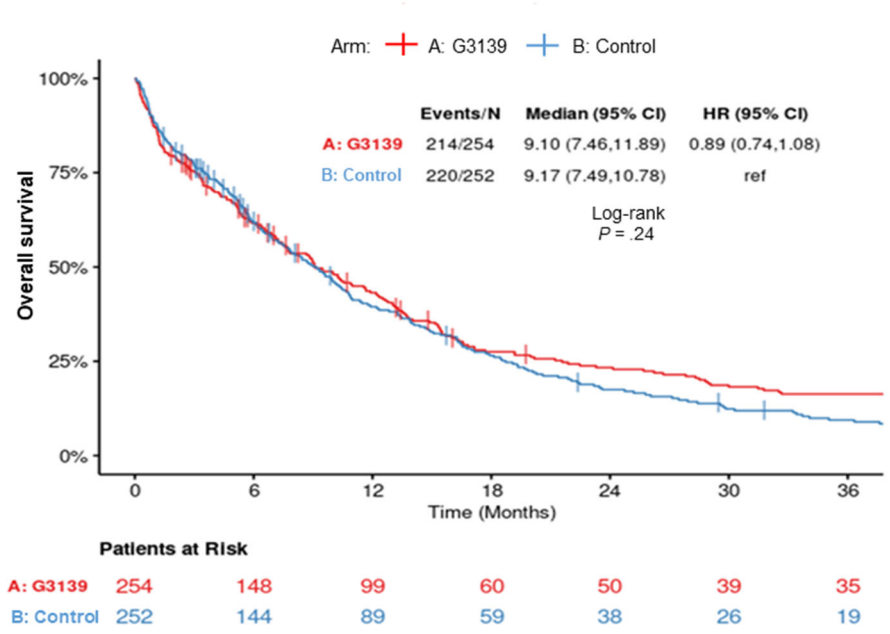
Supplemental Figure 3. Kaplan-Meier curves for event-free survival in the G3139 group and the control group, among patients who underwent allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.

Supplemental Figure 4. Disease-free survival of AML patients who underwent allogeneic hematopoietic cell transplantation



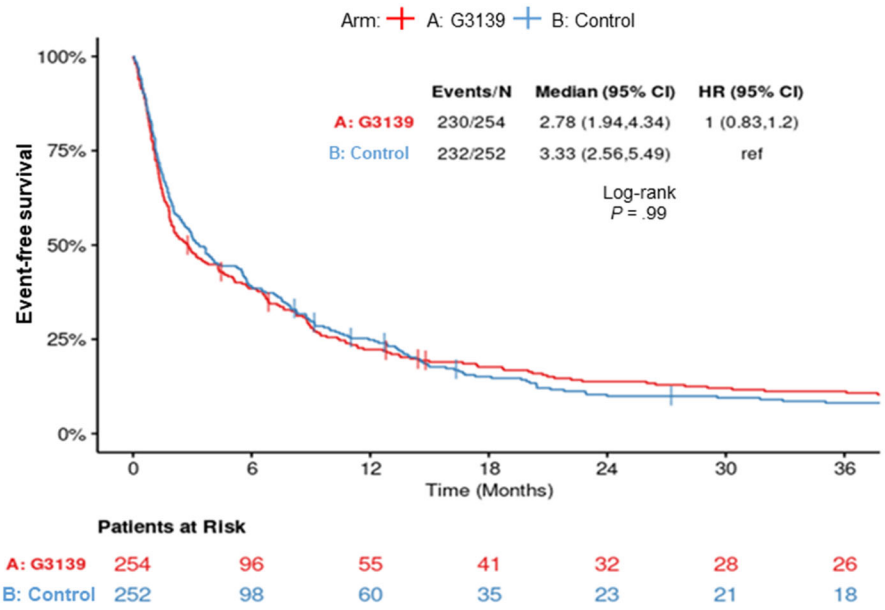
Supplemental Figure 4. Kaplan-Meier curves for disease-free survival in the G3139 group and the control group, among patients who underwent allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.

Supplemental Figure 5. Overall survival of AML patients, censoring at the time of allogeneic hematopoietic cell transplantation



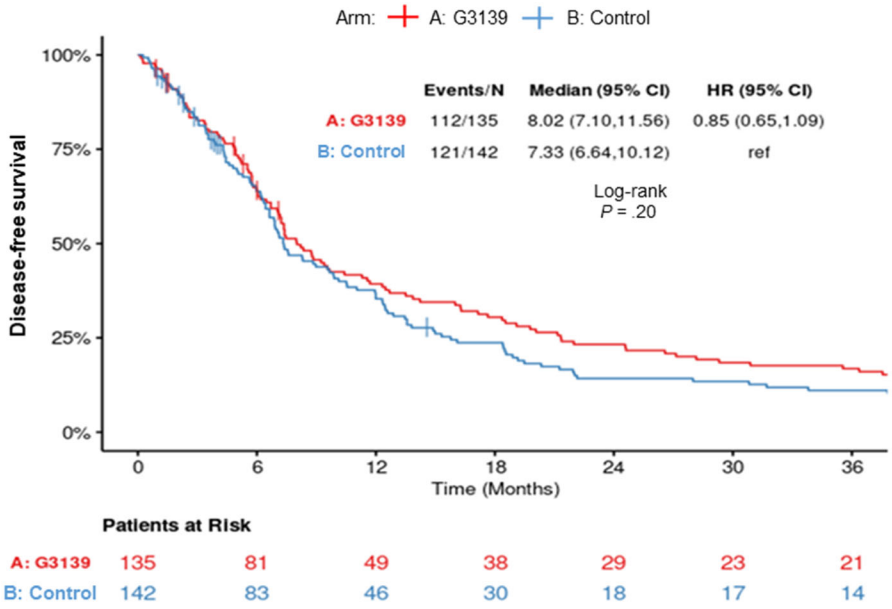
Supplemental Figure 5. Kaplan-Meier curves for overall survival (OS) in the G3139 group andthe control group. OS was censored at the time of allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.

Supplemental Figure 6. Event-free survival of AML patients, censoring at the time of allogeneic hematopoietic cell transplantation



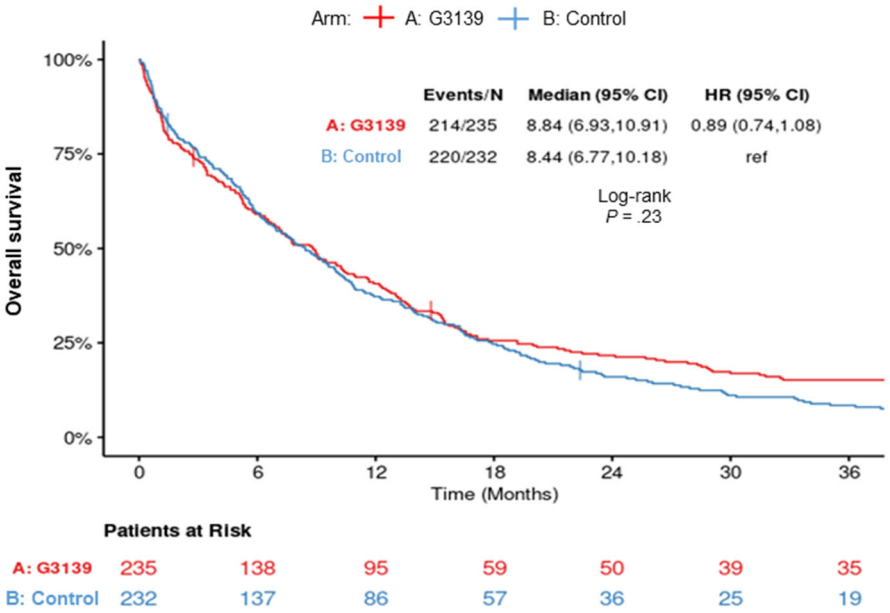
Supplemental Figure 6. Kaplan-Meier curves for event-free survival (EFS) in the G3139 group and the control group. EFS was censored at the time of allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.

Supplemental Figure 7. Disease-free survival of AML patients, censoring at the time of hematopoietic cell transplantation



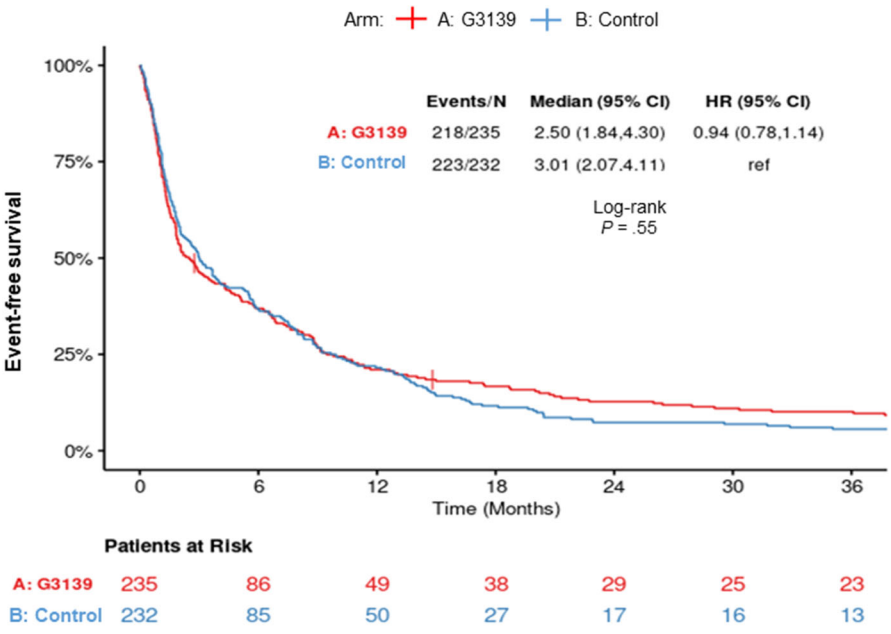
Supplemental Figure 7. Kaplan-Meier curves for disease-free survival (DFS) in the G3139 group and the control group. DFS was censored at the time of allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.

Supplemental Figure 8. Overall survival of AML patients who did not undergo hematopoietic cell transplantation



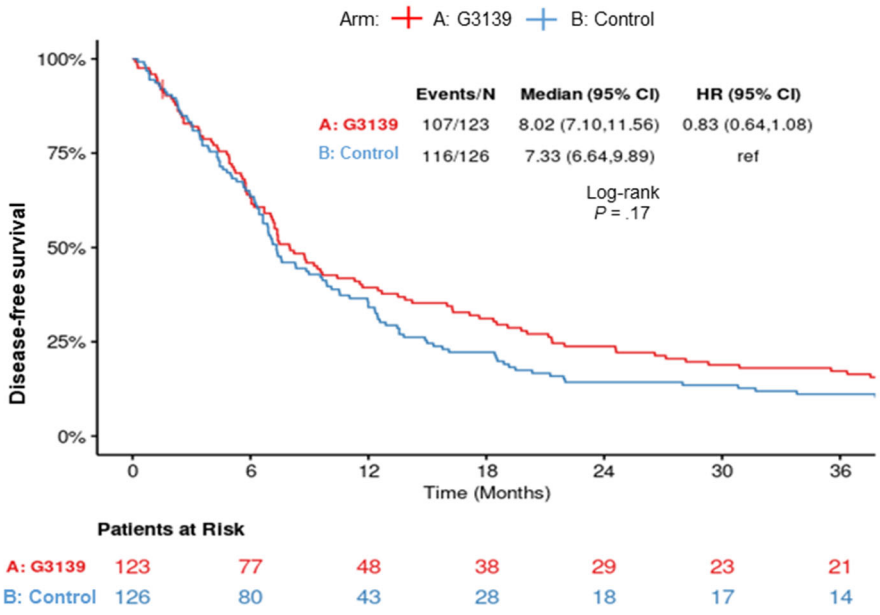
Supplemental Figure 8. Kaplan-Meier curves for overall survival in the G3139 group and thecontrol group, among patients who did not undergo allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.

Supplemental Figure 9. Event-free survival of AML patients who did not undergo hematopoietic cell transplantation



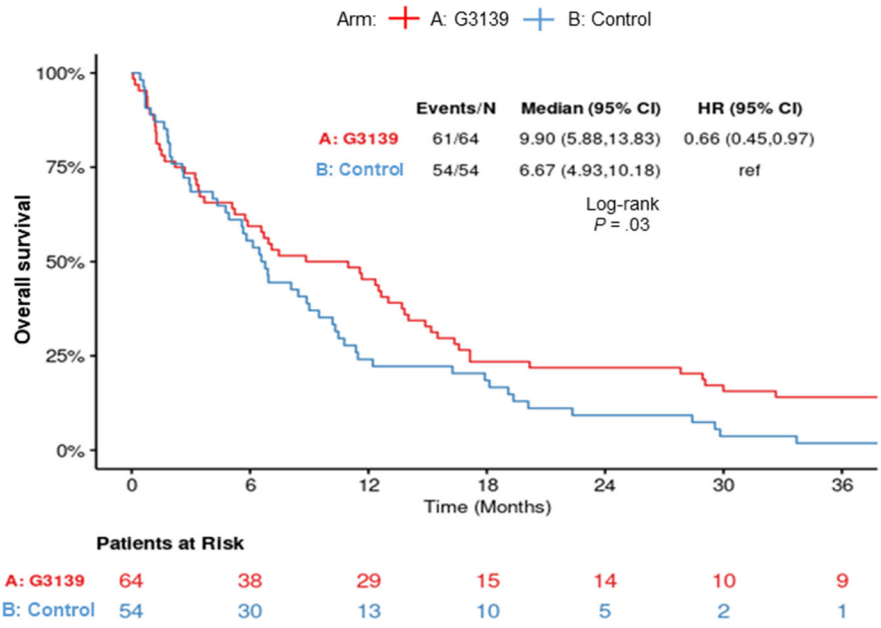
Supplemental Figure 9. Kaplan-Meier curves for event-free survival in the G3139 group and the control group, among patients who did not undergo allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.

Supplemental Figure 10. Disease-free survival of AML patients who did not undergo allogeneic hematopoietic cell transplantation



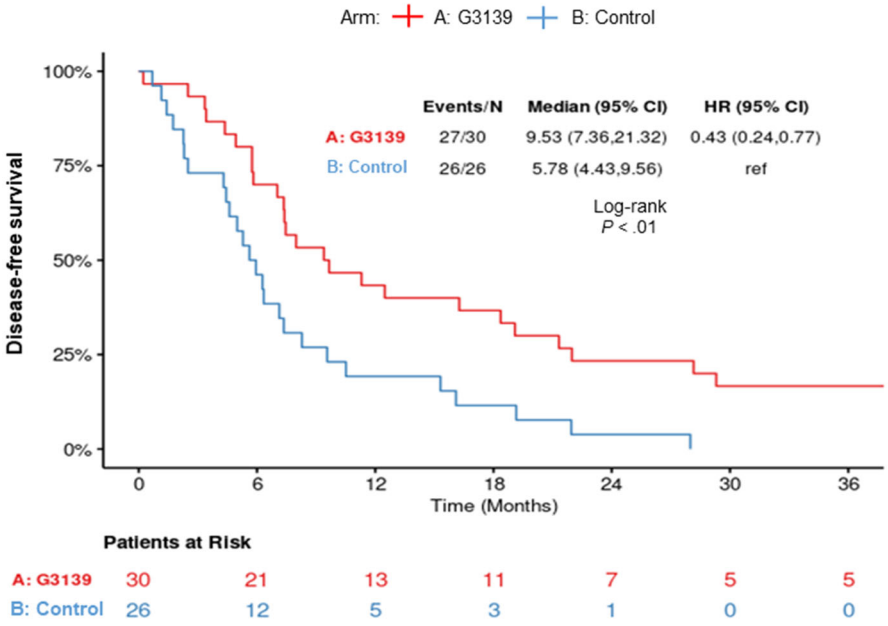
Supplemental Figure 10. Kaplan-Meier curves for disease-free survival in the G3139 group and the control group, among patients who did not undergo allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.

Supplemental Figure 11. Overall survival of patients with secondary AML who did not undergo allogeneic hematopoietic cell transplantation



Supplemental Figure 11. Kaplan-Meier curves for overall survival in the G3139 group and the control group, among secondary AML patients who did not undergo allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.

Supplemental Figure 12. Disease-free survival of patients with secondary AML who did not undergo allogeneic hematopoietic cell transplantation



Supplemental Figure 12. Kaplan-Meier curves for disease-free survival in the G3139 group and the control group, among secondary AML patients who did not undergo allogeneic hematopoietic cell transplantation. CI=Confidence Interval. Median survival in months.