

Gemtuzumab ozogamicin in children with relapsed or refractory acute myeloid leukemia: a report by Berlin-Frankfurt-Münster study group

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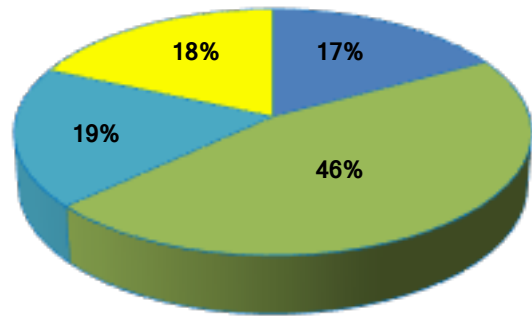
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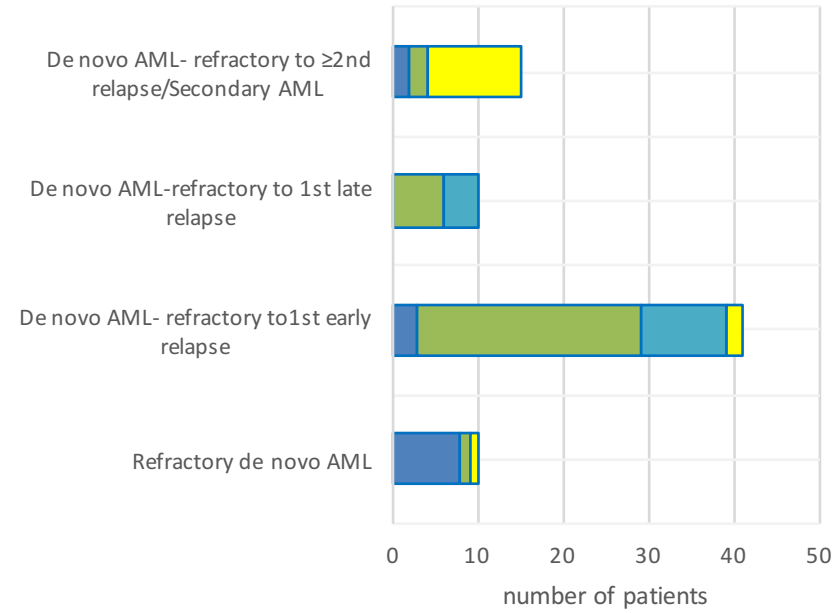
Table S1. Active Clinical trials with Gemtuzumab Ozogamicin Intervention Listed in ClinicalTrials.gov by September 2017

N	Title	Study Type	Phase	Status	TG	Target Disease Status	N	Trial Number	Sponsor	Collaborator(s)
1	International Randomised Phase III Clinical Trial in Children With Acute Myeloid Leukaemia (Myechild01)	Interventional	III	Recruiting	Child	De-novo AML MDS with ≥10% Myeloblasts at Dx	700	NCT02724163	University of Birmingham	Assistance Publique - Hôpitaux de Paris, Cancer Research UK, National Cancer Institute, FRA., Pfizer
2	A Pilot Study of Gemtuzumab Ozogamicin in Combination With Busulfan and Cyclophosphamide (Immunochemotherapy) and Allogeneic Stem Cell Transplantation in Patients With High Risk Acute Myelogenous Leukemia and Myelodysplastic Syndrome	Interventional	II	Recruiting	Child Adult	Relapsed/Refractory AML MDS with ≥ 6% Myeloblasts at Dx	25	NCT02221310	New York Medical College	N/I
3	Allogeneic Stem Cell Transplantation Following by Targeted Immune Therapy) (Gemtuzumab Ozogamicin) in Average Risk Acute Myelogenous Leukemia and Myelodysplastic Syndrome (AML/MDS)(IND 111024)	Interventional	II	Recruiting	Child Adult	Relapsed/Refractory AML MDS with ≥ 5% Myeloblasts at Dx	26	NCT02117297	New York Medical College	N/I
4	Acute Promyelocytic Leukemia (APL) Treated With ATRA, Arsenic Trioxide and Gemtuzumab Ozogamicin	Interventional	II	Recruiting	Child Adult Senior	De-novo APL	100	NCT01409161	M.D. Anderson Cancer Center	Pfizer
5	Expanded Access /Compassionate Use Protocol For Relapsed Or Refractory CD33 Positive AML Patients In The USA Without Access To Comparable Or Alternative Therapy	Expanded Access	N/I	Recruiting	Child Adult Senior	Relapsed/Refractory AML or APL	NA	NCT02312037	Pfizer	N/I
6	Gemtuzumab Ozogamicin in Treating Patients With Relapsed or Refractory Acute Myeloid Leukemia or Acute Promyelocytic Leukemia	Interventional	N/I	Recruiting	Adult Senior	Relapsed/Refractory AML, biphenotypic acute leukemia, or APL	30	NCT01869803	Wake Forest University Health Sciences	National Cancer Institute (NCI)
7	Gemtuzumab Ozogamicin+Cytarabine vs Idarubicin+Cytarabine in Elderly Patients With AML.Mylofrance 4	Interventional	II/III	Recruiting	Adult Senior	De-novo AML	225	NCT02473146	Versailles Hospital	N/I
8	Study of Chemotherapy in Combination With All-trans Retinoic Acid (ATRA) With or Without Gemtuzumab Ozogamicin in Patients With Acute Myeloid Leukemia (AML) and Mutant Nucleophosmin-1 (NPM1) Gene Mutation	Interventional	II	Recruiting	Adult Senior	De-novo AML	588	NCT00893399	University of Ulm	N/I
9	Trial to Test the Effects of Adding 1 of 2 New Treatment Agents to Commonly Used Chemotherapy Combinations	Interventional	III	Recruiting	Adult Senior	De-novo primary or secondary AML MDS with ≥ 10% Myeloblasts at initial diagnosis	1600	NCT02272478	Cardiff University	Cancer Research UK

Abbreviations: TG, target group; N, number of patients; N/I, not indicate; MDS, myelodysplastic syndrome; APL, acute promyelocytic leukemia; FRA, France; UK, United Kingdom of Great Britain.

A

■ 2nd treatment attempt ■ 3rd treatment attempt
■ 4th treatment attempt ■ ≥ 5th treatment attempt

B

■ 2nd treatment attempt ■ 3rd treatment attempt
■ 4th treatment attempt ■ ≥ 5th treatment attempt

Figure S1. (A) Distribution Rank of treatment with Gemtuzumab Ozogamicin in the total cohort. **(B)** Rank of treatment with Gemtuzumab Ozogamicin in different groups of patients.

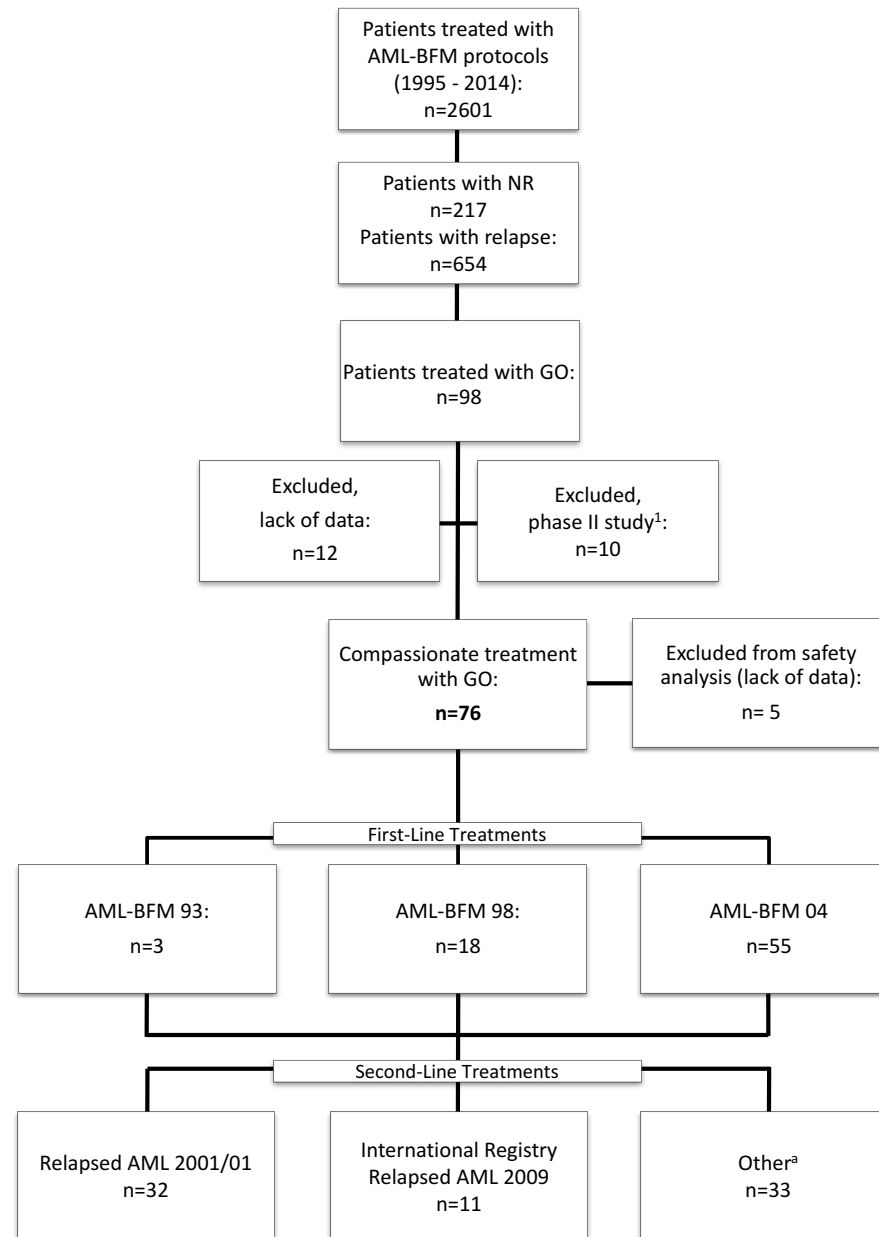


Figure S2. Flow chart of the study design and first/second line treatments before administration of Gemtuzumab Ozogamicine. Abbreviations: n, number of patients; AML, acute myeloid leukemia; BFM, Berlin-Frankfurt-Münster; NR, non-response; GO, Gemtuzumab Ozogamicin. ^aPatients were treated with diverse treatment attempts.

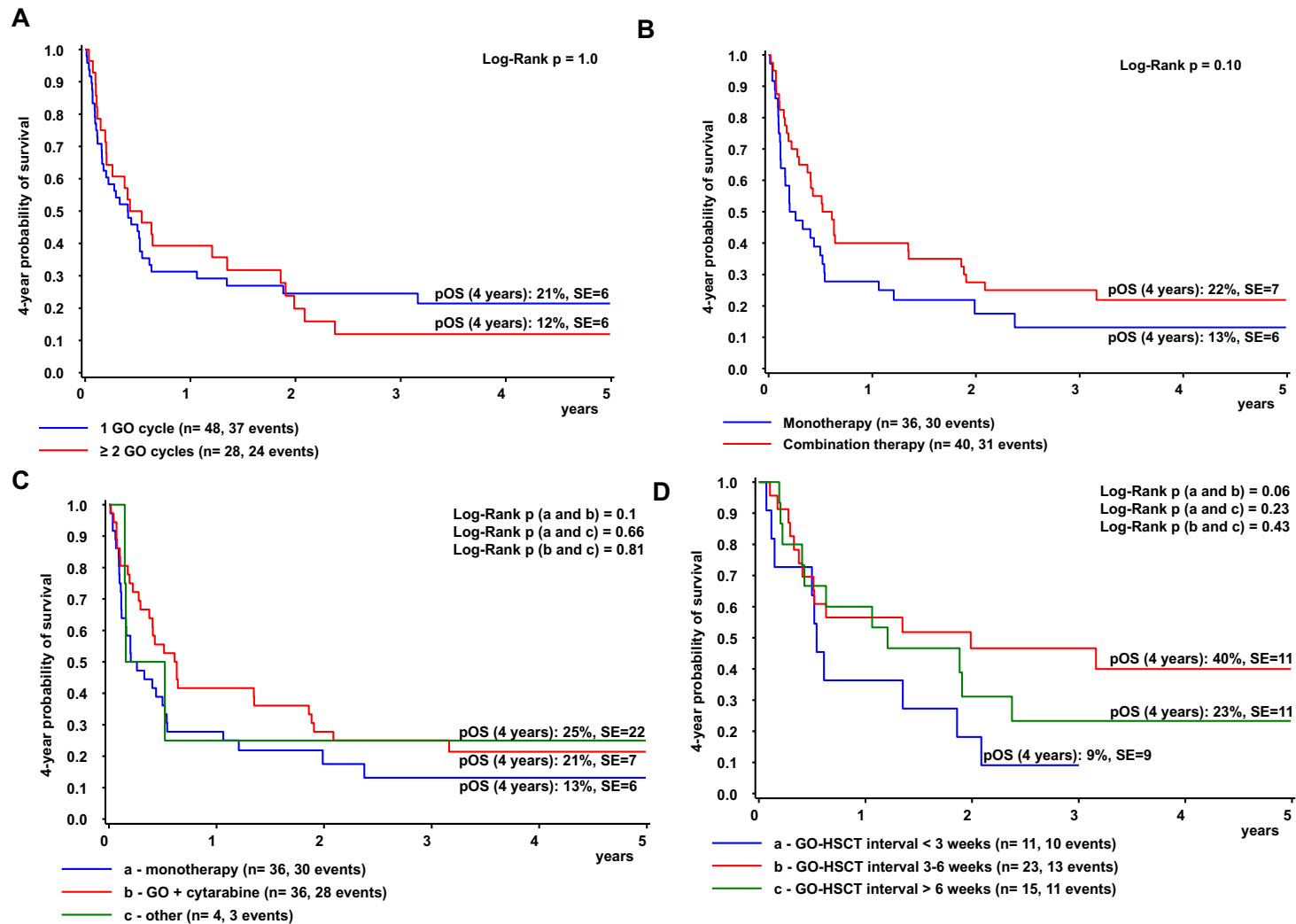


Figure S3. (A) 4-year probability of survival based on cycles of treatment. (B) 4-year probability of survival based on monotherapy or combined treatment. (C) 4-year probability of survival based on monotherapy or combined treatment in detail. (D) 4-year probability of survival based on the interval between GO treatment and HSCT. Abbreviations: pOS, probability of overall survival; n, number of patients; HSCT, hematopoietic stem cell transplantation; AML, acute myeloid leukemia; GO, Gemtuzumab Ozogamicin.

References

1. Zwaan CM, Reinhardt D, Zimmerman M, et al. Salvage treatment for children with refractory first or second relapse of acute myeloid leukaemia with gemtuzumab ozogamicin: results of a phase II study. *Br J Haematol.* 2010;148(5):768-776.