AML-542

GO-First: Real-world data of front line gemtuzumab ozogamicin in intermediate and favorable risk AML patients in a multicenter retrospective chart review

Wolfgang R. Sperr[1], Ann De Becker[2], Johan Maertens[3], Alexander Schauwvlieghe[4], Tom Bailey[5], Lucinda Camidge[5], Alexander Russell-Smith[6], Stephanie Dorman[7], Maja Strecker[8], Carla Al Assaf[9], Maik Scherholz[10], Wei Jiang[11], Alexander Ford[5], Chloe Middleton-Dalby[5], Teresa Taylor-Whiteley[5], Florian Kron[12], Peter Valent[1], Karl-Anton Kreuzer[13].

[1]Medizinische Universität Wien, Vienna, Austria; [2]Vrije Universiteit Brussel, Brussels, Belgium; [3]Universitair Ziekenhuis Leuven, Leuven, Belgium; [4]AZ Sint-Jan Brugge-Oostende, Bruges, Belgium; [5]Adelphi Real World, Bollington, United Kingdom; [6]Pfizer UK Ltd, Sandwich, United Kingdom; [7]Pfizer Canada, Quebec, Canada; [8]Pfizer Germany, Berlin, Germany; [9]Pfizer Belgium, Brussels, Belgium; [10]Pfizer Austria, Vienna, Austria; [11]Pfizer US, New York, NY, USA; [12]VITIS Healthcare, Cologne, Germany; [13]Universität zu Köln, Cologne, Germany

INTRODUCTION

- AML is the most common acute leukemia in adults, characterized by abnormal proliferation and differentiation of myeloid cells. The incidence of AML is increasing globally and is linked to aging, high body mass index (BMI), and smoking[1].
- Standard induction chemotherapy achieves complete remission (CR) in many patients, but relapse is common, and five-year overall survival remains low[2].
- The ALFA-0701 clinical trial demonstrated the efficacy of GO when added to standard chemotherapy in patients with favorable or intermediate risk AML (CR rate: 70.4%; median EFS and RFS: 17.3 and 15.6 months in the GO arm vs. 9.5 and 9.7 months in the control arm, respectively). Based on results from ALFA-0701 GO was approved for newly-diagnosed, CD33-positive AML by FDA (in 2017) and EMA (in 2018)[3,4].
- Real-world evidence of GO treatment patterns and effectiveness remains limited. This study ('GO-First') retrospectively collected real-world data on treatment patterns and efficacy of first-line (1L) therapy with GO combined with chemotherapy.

OBJECTIVE

To evaluate the real-world treatment patterns and efficacy of gemtuzumab ozogamicin (GO) in newly-diagnosed acute myeloid leukemia (AML).

METHODS

- Retrospective, observational study using real-world data from five hospital sites in Austria, Belgium, and Germany.
- Adult patients with *de novo* AML that:
  - Received 1L induction with GO between 1st April 2018 (EMA approval and the start of real-world use) and 31st May 2023 in a combination chemotherapy treatment.
  - Favorable or intermediate risk karyotype.
  - Follow-up time of three months to allow for assessment of efficacy outcomes.
- Data included patient demographics, clinical characteristics, treatment patterns and treatment outcomes, including overall survival (OS), relapse-free survival (RFS) and event-free survival (EFS)).

Statistical Analysis

- Descriptive statistics were used to summarise patient demographics, disease characteristics, and treatment patterns.
- Survival outcomes OS, RFS, EFS were calculated using the method of Kaplan-Meier.
- Subgroup analyses were performed based on cytogenetic risk category (favorable or intermediate).
- All analyses were conducted using Stata 17.

RESULTS

- Data from 89 patients were collected.
- 37.1% (n=33) of the sample had favorable risk karyotype and 62.9% (n=56) intermediate risk karyotype.
- The median BMI was 26.1 and 52.8 % of patients were male.
- The median observation time was 2.4 years (**Table 1**).
- Following 1L induction therapy, for those with a recorded response, a complete remission (CR) was achieved in 70.7% of patients (n=58), 14.6% (n=12) achieved CR with incomplete haematologic recovery (CRi), 13.4% (n=11) had no CR. Within the study, 2.2% (n=2) patients died within 30 days.

RESULTS (continued)

- Most patients (68.5% [n=61]) received consolidation (**Figure 1**) with cytarabine. 38 (42.7%) patients received haematopoietic stem cell transplant (HSCT) (**Figure 1**).
- Median EFS was 4.4 years for the favorable risk group and 4.9 years for the intermediate risk group (**Figure 2A**).
- Median RFS was not reached for the favorable risk group. RFS for the intermediate group was 4.7 years (**Figure 2B**).
- Median OS was not reached.

Table 1. Patient Demographics and Clinical Characteristics.

	Overall (n=89)	Favorable (n=33)	Intermediate (n=56)
Follow-up (years), median (IQR)	2.4 (1.0-3.7)	3.0 (0.8-3.9)	2.4 (1.2-3.6)
Age, median (IQR)	60 (44-67)	61 (42-66)	59.5 (45-68)
Patient sex, n (%)			
Female	42 (47.2)	14 (42.4)	28 (50.0)
Male	47 (52.8)	19 (57.6)	28 (50.0)
BMI, median (IQR)	26.1 (22.8-30.1)	25.3 (22.7-30.1)	26.8 (23.0-29.5)
ECOG PS*			
0 Asymptomatic	52 (75.4)	19 (82.6)	33 (71.7)
1 Symptomatic but completely ambulatory	15 (21.7)	4 (17.4)	11 (23.9)
2 Symptomatic, <50% in bed during the day	2 (2.9)	0 (0.0)	2 (4.3)
Missing, n	20	10	10

ECOG PS=Eastern Cooperative Oncology Group performance status

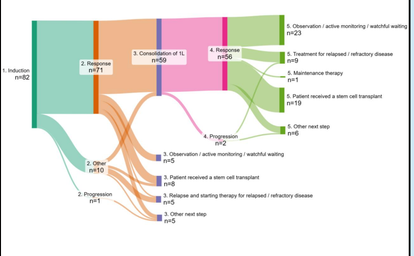
GO Treatment Patterns

- In 1L induction, all patients received cytarabine together with daunorubicin (91.0%) or idarubicin (10.1%) and GO.
- In 80.9% (n=72), three doses of GO were given (median dose of 5mg).
- 78.7% of consolidations (n=61) included GO. Where dose was recorded, patients had 1 dose: 43.8% (n=21), 2 doses: 50.0% (n=24) and 3 doses: 6.2% (n=3).

Veno-occlusive disease (VOD)

- Four patients developed signs of VOD after induction therapy or HSCT (n=2)
- Death during follow up was recorded in 29.2% (n=26) of patients. Of those, n=3 were diagnosed with VOD; one had VOD following HSCT.

Figure 1. Treatment Patterns Across 1L Induction and Consolidation.



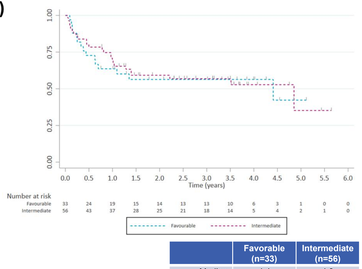
Response: Patients with a recorded response of CR, CRi, or CRp after either induction (2. Response) or consolidation (4. Response).

Other: Patients with a recorded response of partial remission, stable disease, or uncertain response after induction (2. Other).

Progression: Patients with a recorded response of progressive disease after induction (2. Progression) or consolidation (4. Progression).

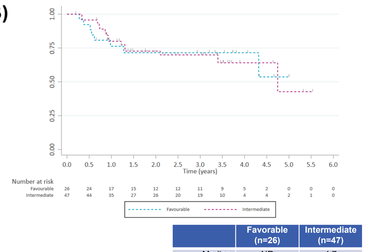
Figure 2. (A) Event-Free Survival by Risk Status (B) Relapse-Free Survival by Risk Status.

(A)



	Favorable (n=33)	Intermediate (n=56)
Median	4.4	4.9
SE	0.1	1.0
95% CI	0.6, NR.	1.3, NR.

(B)



	Favorable (n=26)	Intermediate (n=47)
Median	NR	4.7
SE	NR	0.1
95% CI	1.3, NR	3.4, NR.

SE= standard error, CI= confidence interval, NR= not reached.

CONCLUSIONS

- **Treatment with intensive chemotherapy and GO was an effective 1L therapy in both favorable and intermediate risk groups in the real-word setting.**
- **Event- and relapse-free survival exceeded data observed in the pivotal trial ALFA-0701.**
- **The survival data and acceptable safety profile of GO reinforce the role GO has in the treatment of AML.**

References

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Disclosures

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Presenting author: Wei Jiang

wei.jiang@pfizer.com

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