




## SHORT REPORT OPEN ACCESS

# Phase 2 Multi-Arm Study of Magrolimab Combinations in Patients With Acute Myeloid Leukaemia

Gabriel N. Mannis<sup>1</sup>  | Camille N. Abboud<sup>2</sup> | Naval G. Daver<sup>3</sup> | Guru Subramanian Guru Murthy<sup>4</sup> | Eunice S. Wang<sup>5</sup> | Terrence J. Bradley<sup>6</sup> | George Yaghmour<sup>7</sup>  | Pankit Vachhani<sup>8</sup> | Suresh Kumar Balasubramanian<sup>9</sup>  | Chong Chyn Chua<sup>10</sup> | Chun Yew Fong<sup>11</sup> | Adam S. Asch<sup>12</sup> | Mei Dong<sup>13</sup> | Shuang Li<sup>13</sup> | Taravat Bagheri<sup>13</sup> | Parul Doshi<sup>13</sup> | Paresh Vyas<sup>14</sup> | Monzr M. Al Malki<sup>15</sup>

<sup>1</sup>Stanford Cancer Institute, Stanford, California, USA | <sup>2</sup>Washington University School of Medicine, St. Louis, Missouri, USA | <sup>3</sup>The University of Texas MD Anderson Cancer Center, Houston, Texas, USA | <sup>4</sup>Froedtert & Medical College of Wisconsin, Milwaukee, Wisconsin, USA | <sup>5</sup>Roswell Park Comprehensive Cancer Center, Buffalo, New York, USA | <sup>6</sup>Sylvester Comprehensive Cancer Center, University of Miami Miller School of Medicine, Miami, Florida, USA | <sup>7</sup>University of Southern California Norris Comprehensive Cancer Center, Los Angeles, California, USA | <sup>8</sup>O'Neal Comprehensive Cancer Center, University of Alabama at Birmingham, Birmingham, Alabama, USA | <sup>9</sup>Karmanos Cancer Institute, Wayne State University, Detroit, Michigan, USA | <sup>10</sup>The Alfred Hospital, Melbourne, Victoria, Australia | <sup>11</sup>Austin Hospital and University of Melbourne, Melbourne, Victoria, Australia | <sup>12</sup>Stephenson Cancer Center, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, USA | <sup>13</sup>Gilead Sciences, Inc., Foster City, California, USA | <sup>14</sup>Weatherall Institute of Molecular Medicine, John Radcliffe Hospital, University of Oxford and Department of Haematology, Oxford University Hospitals NHS Trust, Oxford, UK | <sup>15</sup>City of Hope National Medical Center, Duarte, California, USA

**Correspondence:** Gabriel N. Mannis ([gmannis@stanford.edu](mailto:gmannis@stanford.edu))

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## ABSTRACT

**Introduction:** This phase 2 study evaluated magrolimab+venetoclax (VEN)+azacitidine (AZA) in untreated, unfit acute myeloid leukaemia (AML) and magrolimab+mitoxantrone+etoposide+cytarabine in relapsed/refractory (R/R) AML.

**Methods:** Endpoints included complete remission rate (CRR), overall response rate (ORR), overall survival (OS) and safety.

**Results:** Eighteen and 36 patients were enrolled into the unfit and R/R AML arms, respectively. CRR was 38.9% and 25.0%, ORR was 66.7% and 38.9%, and median OS was 15.3 and 10.5 months in the unfit AML and R/R AML arms, respectively. No dose-limiting toxicities or magrolimab-related deaths occurred.

**Conclusion:** Magrolimab was safely combined with existing AML therapies with no new safety signals.

**Clinical Trial Registration:** This trial was registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as NCT04778410.

## 1 | Introduction

Acute myeloid leukaemia (AML), an aggressive myeloid malignancy, is challenging to treat across the disease trajectory [1]. In patients with newly diagnosed AML unfit for intensive

chemotherapy (IC), the current standard of care, venetoclax (VEN) plus azacitidine (AZA), has a median overall survival (OS) of 14.7 months and a 24-month OS rate of 37.5% [2, 3]. Outcomes are worse for patients with relapsed/refractory (R/R) AML after IC, where the median OS for standard salvage chemotherapy

Affiliation at the time of study

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is 3.6–7.2 months [4, 5]. Thus, improved treatment options and clinical outcomes are needed for these challenging AML populations.

Magrolimab is a monoclonal antibody that blocks cluster of differentiation (CD) 47, an antiphagocytic signal overexpressed on cancer cells, including in AML [6]. Preclinically, magrolimab addition to VEN+AZA enhanced AML cell elimination by host macrophages [7]. Mitoxantrone and etoposide induce phagocytic calreticulin expression and may further enhance magrolimab antitumour activity [8, 9]. An early phase 1b study reported a complete remission rate (CRR) of 32% and acceptable safety for magrolimab+AZA in patients with previously untreated AML unfit for IC [10].

We present the final analysis results from a phase 2 study that evaluated the efficacy and safety of magrolimab combinations in adult patients with untreated AML ineligible for IC and with R/R AML after IC.

## 2 | Methods

### 2.1 | Study Design and Treatments

This phase 2, open-label, multicentre study (NCT04778410) enrolled patients diagnosed with AML (by World Health Organization classification 2016) and included three arms in its design.

- Arm 1 (first-line [1L] unfit AML): patients with newly diagnosed, previously untreated, histologically confirmed AML ineligible for IC due to age or significant comorbidities.
- Arm 2 (R/R AML): patients with histologically confirmed AML that was R/R after initial IC with or without consolidation therapy.
- Arm 3 (post-chemotherapy maintenance): patients with newly diagnosed AML with CR or CR with incomplete haematologic recovery and positive for minimal residual disease (MRD) after IC.

Each arm consisted of a safety run-in (SRI) cohort followed by an expansion cohort. Additional eligibility criteria are listed in the Supporting Information.

Patients in arm 1 were treated with magrolimab+VEN+AZA and those in arm 2 with magrolimab+(mitoxantrone+etoposide+cytarabine [MEC]). The planned treatment for arm 3 was magrolimab+CC-486 (oral AZA) as maintenance therapy but was discontinued. Dosing schedules are shown in Table S1. The duration of treatment is described in the Supporting Information.

Arm 1 was closed early, after enrolling 18 patients, due to the initiation of a competing phase 3 study in the same disease setting and treatment regimen. Arm 3 was closed due to a lack of patient enrolment.

All patients provided written informed consent before study participation. The study was conducted according to the Inter-

national Conference on Harmonisation Good Clinical Practice Guidelines, the Declaration of Helsinki and local Institutional Review Board requirements.

### 2.2 | Outcomes

Primary endpoints for SRI cohorts were dose-limiting toxicities (DLTs), treatment-emergent adverse events (TEAEs) and laboratory abnormalities.

The primary endpoint for expansion cohorts in arms 1 and 2 was investigator-assessed CRR. Selected secondary endpoints included overall response rate (ORR), duration of response (DOR), event-free survival (EFS), OS and safety. Endpoints are summarised in the Supporting Information.

### 2.3 | Statistical Analysis

The planned sample sizes were 46 patients each in arms 1 and 3 and 36 patients in arm 2 (power calculations are described in the Supporting Information). DLT definitions are provided in the Supporting Information. Efficacy and safety were assessed for each arm separately (SRI and expansion cohorts combined). Analysis sets and statistical methods are described in the Supporting Information.

## 3 | Results

### 3.1 | Patients

Between July 1, 2021, and October 7, 2022, 54 patients were enrolled (18 in arm 1; 36 in arm 2; 0 in arm 3). Patient demographics and baseline characteristics are reported in Table S2.

#### 3.1.1 | Arm 1: 1L Unfit AML (Magrolimab+VEN+AZA)

Median age (range) was 73 (62–84) years. Most patients (61.1%) had an Eastern Cooperative Oncology performance status (ECOG PS) of 2–3, and 27.8% of patients had a *TP53* mutation at screening. The median duration (range) of magrolimab exposure was 11.7 (0.1–86.1) weeks. In total, 66.7% of patients discontinued the study, mainly due to death (Figure S1), and 33.3% of patients received post-study treatment stem cell transplant (SCT).

#### 3.1.2 | Arm 2: R/R AML (Magrolimab+MEC)

Median age (range) was 52 (22–72) years. Most patients (88.9%) had ECOG PS 0–1 and primary refractory AML (61.1%); 19.4% of patients had a *TP53* mutation at screening. The median duration (range) of magrolimab exposure was 5.1 (1.1–17.1) weeks. In total, 75.0% of patients discontinued the study, primarily due to death (Figure S1), and 33.3% of patients received post-study treatment SCT.

### 3.2 | Efficacy

Response outcomes are reported in Table 1. Red blood cell and platelet transfusion independence rates are reported in Table S3.

**TABLE 1** | Investigator-assessed responses.

<b>Response outcomes</b>	<b>1L unfit AML: Magrolimab+VEN+AZA (n = 18)</b>	<b>R/R AML: Magrolimab+MEC (n = 36)</b>
Best overall response, n (%)		
CR	7 (38.9)	9 (25.0)
CR without MRD	3 (16.7)	3 (8.3)
CRi and CRh	0	1 (2.8)
CRi only	2 (11.1)	1 (2.8)
CRh only	0	1 (2.8)
MLFS	3 (16.7)	2 (5.6)
PR	0	0
SD	3 (16.7)	18 (50.0)
PD	0	3 (8.3)
No assessment	3 (16.7)	1 (2.8)
ORR <sup>a</sup> [95% CI], %	66.7 [41.0–86.7]	38.9 [23.1–56.5]
CR rate [95% CI], %	38.9 [17.3–64.3]	25.0 [12.1–42.2]
CR without MRD rate [95% CI], %	16.7 [3.6–41.4]	8.3 [1.8–22.5]
CR/CRi/CRh rate [95% CI], %	50.0 [26.0–74.0]	33.3 [18.6–51.0]
Median duration of CR [95% CI], months	15.9 [6.7–NE]	8.7 [2.3–NE]
Median time to response (range), months	1.0 (0.9–3.0)	1.0 (0.8–1.5)
Median DOR [95% CI], months	15.9 [2.2–NE]	8.7 [6.3–NE]

Abbreviations: 1L, first-line; AML, acute myeloid leukaemia; AZA, azacitidine; CR, complete remission; CRh, CR with partial haematologic recovery; CRi, CR with incomplete haematologic recovery; DOR, duration of response; MEC, mitoxantrone + etoposide + cytarabine; MLFS, morphologic leukaemia-free state; MRD, minimal residual disease; NE, not estimable; ORR, overall response rate; PD, progressive disease; PR, partial remission; R/R, relapsed or refractory; SD, stable disease; VEN, venetoclax.

<sup>a</sup>ORR was defined as the proportion of patients who achieved CR, CRh, CRi, PR or MLFS.

### 3.2.1 | Arm 1: 1L Unfit AML (Magrolimab+VEN+AZA)

CRR (95% confidence interval [CI]) was 38.9% (17.3%–64.3%), ORR (95% CI) was 66.7% (41.0%–86.7%) and median DOR (95% CI) was 15.9 (2.2–not estimable [NE]) months. Median EFS (95% CI) was 3.8 (0.0–16.8) months, and median OS (95% CI) was 15.3 (3.1–NE) months (Figure S2).

### 3.2.2 | Arm 2: R/R AML (Magrolimab+MEC)

CRR (95% CI) was 25.0% (12.1%–42.2%), ORR (95% CI) was 38.9% (23.1%–56.5%) and median DOR (95% CI) was 8.7 (6.3–NE) months. Median EFS (95% CI) was 0.0 (NE–NE) months, and median OS (95% CI) was 10.5 (7.1–15.4) months (Figure S2).

## 3.3 | Safety

No patients in the SRI cohorts experienced DLTs.

### 3.3.1 | Arm 1: 1L Unfit AML (Magrolimab+VEN+AZA)

Any grade, grade  $\geq 3$  and serious TEAEs occurred in all patients (Table 2). The most common any-grade TEAEs were nausea (61.1%), thrombocytopenia (55.6%), anaemia (50.0%) and

diarrhoea (50.0%). The most common grade  $\geq 3$  TEAEs were thrombocytopenia (50.0%), anaemia (44.4%) and neutropenia (38.9%) (Table S4). Magrolimab-related TEAEs occurred in 77.8% of patients.

TEAEs led to magrolimab discontinuation in 38.9% of patients; no TEAEs led to magrolimab dose reduction. TEAEs leading to death were sepsis ( $n = 2$ ), genital haemorrhage ( $n = 1$ ) and dyspnoea ( $n = 1$ ); none of the fatal TEAEs was magrolimab related; 1 TEAE was related to AZA. Overall, 2 deaths (progressive disease and TEAE,  $n = 1$  each) occurred within 30 days of treatment initiation.

### 3.3.2 | Arm 2: R/R AML (Magrolimab+MEC)

Any-grade, grade  $\geq 3$  and serious TEAEs occurred in 97.2%, 88.9% and 58.3% of patients, respectively (Table 2). The most common any-grade TEAEs were pyrexia (55.6%), febrile neutropenia (52.8%) and nausea (50.0%). The most common grade  $\geq 3$  TEAEs were febrile neutropenia (47.2%), anaemia (38.9%) and thrombocytopenia (36.1%; Table S4). Magrolimab-related TEAEs occurred in 58.3% of patients.

TEAEs led to magrolimab discontinuation in 2.8% of patients; no TEAEs led to magrolimab dose reduction. Two patients

**TABLE 2** | Overall summary of treatment-emergent adverse events (TEAEs) in the safety analysis set.

Patients, <i>n</i> (%)	1L unfit AML: Magrolimab+VEN+AZA	R/R AML: Magrolimab+MEC
	( <i>n</i> = 18)	( <i>n</i> = 36)
Any-grade TEAE	18 (100)	35 (97.2)
Related to any study drug	15 (83.3)	31 (86.1)
Related to magrolimab	14 (77.8)	21 (58.3)
Grade $\geq 3$ TEAE	18 (100)	32 (88.9)
Related to any study drug	14 (77.8)	24 (66.7)
Related to magrolimab	12 (66.7)	16 (44.4)
Serious TEAE	18 (100)	21 (58.3)
Related to any study drug	10 (55.6)	12 (33.3)
Related to magrolimab	3 (16.7)	2 (5.6)
TEAE leading to dose reduction		
Of any study drug	4 (22.2)	1 (2.8)
Of magrolimab	0	0
TEAE leading to discontinuation		
Of any study drug	7 (38.9)	3 (8.3)
Of magrolimab	7 (38.9)	1 (2.8)
TEAE leading to death	4 (22.2)	2 (5.6)
Related to any study drug	1 (5.6)	0
Related to magrolimab	0	0

Abbreviations: 1L, first-line; AML, acute myeloid leukaemia; AZA, azacitidine; MEC, mitoxantrone + etoposide + cytarabine; R/R, relapsed or refractory; TEAE, treatment-emergent adverse event; VEN, venetoclax.

had TEAEs leading to death (acute respiratory failure and febrile neutropenia, *n* = 1 each); neither were related to any study drugs. No deaths occurred within 30 days of treatment initiation.

## 4 | Discussion

Combination therapies building off existing therapies are of interest in AML. In this phase 2 study, magrolimab combined with VEN+AZA or MEC had manageable toxicity in two difficult-to-treat AML populations. Overall, safety was consistent with previous reports, with no new safety signals detected [10, 11].

The phase 3 VIALE-A and ENHANCE-3 trials provide safety and efficacy benchmarks for VEN+AZA with or without magrolimab in the 1L unfit AML setting. In the 1L unfit AML arm of our study, the rates of both anaemia (50%) and magrolimab discontinuations due to TEAEs (39%) were higher than those reported for VEN+AZA in VIALE-A (anaemia: 28%; VEN/AZA discontinuations: 24%) [2]. Anaemia is a known on-target effect of magrolimab and was mitigated by magrolimab priming doses and haemoglobin monitoring. With respect to efficacy, the CRR with magrolimab+VEN+AZA (38.9%) in our study was modest and similar to that reported for VEN+AZA alone in VIALE-A and ENHANCE-3 (36.7%–42.9%) [2, 12]. Since this study was designed and conducted, ENHANCE-3 has further clarified the

magrolimab+VEN+AZA efficacy profile, showing that it did not improve CRR or OS compared to VEN+AZA alone. CRR for magrolimab+VEN+AZA was consistent with ENHANCE-3; however, the median OS differed: 15.3 months in this study and not reached in another phase 2 study (NCT04435691) [11] compared with 11.7 months (ENHANCE-3) [12]. The cross-trial comparisons made here should be interpreted with caution due to inherent variation across randomized vs. single-arm studies and patient populations.

In R/R AML, the CRR with magrolimab+MEC (25%) was within the range of previous studies of MEC (23%–52% [4, 5, 13]). In previous MEC studies, the median OS was 3.6–7.2 months [4, 5, 13], whereas this study reports a median OS of 10.5 months. We hypothesise that the relatively long median OS observed here may be due to no early mortality (none within 30 days) and a high proportion of patients receiving post-study treatment SCT (33.3%), the only curative option in R/R AML. In previous studies of MEC in R/R AML, only 8%–25% of patients received post-study SCT [4, 5, 13]. However, caution is warranted when interpreting these OS results given the relatively low CRRs and the cross-trial nature of the comparison.

While the sponsor is no longer developing magrolimab, these results suggest magrolimab was safely combined with standard-of-care agents in AML. Although insights into the factors influencing the efficacy of anti-CD47 therapy are growing [14,

15], they are not fully understood. The potential for anti-CD47-based therapies to improve AML outcomes requires further investigation.

### Author Contributions

Gabriel N. Mannis, Camille N. Abboud, Naval G. Daver, Guru Subramanian, Guru Murthy, Eunice S. Wang, Terrence J. Bradley, George Yaghmour, Pankit Vachhani, Suresh Kumar Balasubramanian, Chong Chyn Chua, Chun Yew Fong, Adam S. Asch, Taravat Bagheri, Parul Doshi, Paresh Vyas and Monzr M. Al Malki contributed to the study design and data collection; Mei Dong and Shuang Li performed statistical analysis. All authors read, provided critical revisions and approved the manuscript.

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### Ethics Statement

This study was conducted according to the International Conference on Harmonisation Good Clinical Practice Guidelines, the Declaration of Helsinki and local Institutional Review Board requirements.

### Consent

All patients provided written informed consent before study participation.

### Conflicts of Interest

Gabriel N. Mannis reports institutional research funding from Jazz, Astex, Glycomimetics, Syndax, ImmuneOnc, Forty-Seven, Aptose and BMS/Celgene; consulting or advisory roles for Abbvie, Agios, Pfizer, Servier and Stemline; participation on a data safety monitoring board or advisory board for Abbvie, Agios, Astellas, BMS/Celgene, Genentech Stemline, Rigel, Wugen and Immunogen. Naval G. Daver reports grants or contracts from Daiichi-Sankyo, Bristol-Meyers Squibb, Pfizer, Gilead Sciences, Inc., Servier, Genentech, Astellas, AbbVie, ImmunoGen, Amgen, Trillium, Hanmi, Trovogene, FATE Therapeutics, Novimmune, Glycomimetics and Kite; consulting or advisory roles for Daiichi-Sankyo, Bristol-Meyers Squibb, Pfizer, Gilead Sciences, Inc., Servier, Genentech, Astellas, AbbVie, ImmunoGen, Amgen, Trillium, Arog, Novartis, Jazz, Celgene, Syndax, Shattuck Labs, Agios, Kite and Stemline/Menarini. Guru Subramanian, Guru Murthy reports institutional research funding from Xencor Inc., Zentalis Inc., Beigene, Lilly/LOXO, Oryzon Genomics, Merck and Schrodinger; consulting or advisory roles for Amgen Inc., BeiGene, Gilead/Kite, Pfizer, BMS, Rigel, Stemline Therapeutics, Cardinal Health, Servier, DAVA Oncology, Aptitude Health, Curio Science and Autolus Therapeutics; payment/honoraria for lecturing, presentations, serving on speaker bureaus, writing manuscripts or educational events from Rigel, Stemline Therapeutics, Cardinal Health, DAVA Oncology, Aptitude Health, Curio Science and Amgen. Eunice S. Wang reports consulting or advisory roles for AbbVie, Blueprint, Daiichi Sankyo, Immunogen, Kite, Kura, Novartis, Qiagen, Rigel, Ryvu, Schrodinger, Servier, Stemline, Syndax and Takeda; speaker bureau participation for Astellas, Dava and Pfizer; serving on data safety and monitoring committees for AbbVie and Gilead Sciences, Inc; and serving as Section Editor for UpToDate (Wolters Kluwer). Terrence J. Bradley reports consulting or advisory roles for Novartis and Morphosys; participation on a data safety monitoring board or advisory board for KaryoPharm, Morphosys, Servier and Sobi. George Yaghmour reports receiving payment/honoraria for lecturing, presentations, serving on speaker bureaus, writing manuscripts

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### Data Availability Statement

Gilead Sciences shares anonymised individual patient data upon request or as required by law or regulation with qualified external researchers on the basis of submitted curriculum vitae and reflecting non-conflict of interest. The request proposal must also include a statistician. Approval of such requests is at the discretion of Gilead Sciences, Inc., and is dependent on the nature of the request, the merit of the research proposed the availability of the data and the intended use of the data. Data requests should be sent to [datarequest@gilead.com](mailto:datarequest@gilead.com).

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## Supporting Information

Additional supporting information can be found online in the Supporting Information section.