Investigational Magrolimab in Combination With Azacitidine Demonstrates Durable Activity in Previously-Untreated Myelodysplastic Syndrome and Acute Myeloid Leukemia

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-- Phase 1b Findings Presented in Oral Session at 2020 American Society of Clinical Oncology Annual Meeting Further Support CD47 as a Promising Target in First-line Higher-Risk MDS and Intensive Chemo-Ineligible AML --

-- 91 Percent of Patients with Higher-Risk MDS Treated with Magrolimab Plus Azacitidine Achieved an Objective Response and 42 Percent Achieved a Complete Response --

-- 64 Percent of Patients with Intensive Chemo-Ineligible AML Treated with Magrolimab Plus Azacitidine Achieved An Objective Response and 56 Percent Achieved a Complete Response or Complete Response with Incomplete Hematological Recovery --

FOSTER CITY, Calif.--(BUSINESS WIRE)--May 29, 2020-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced updated results from a single-arm, open-label Phase 1b trial of magrolimab, an investigational anti-CD47 monoclonal antibody, in combination with azacitidine in previously untreated patients with higher-risk myelodysplastic syndrome (MDS) and previously untreated patients with acute myeloid leukemia (AML) who are ineligible for intensive chemotherapy, including patients with TP53-mutant AML, a high unmet need population. Results continue to support the clinical activity of magrolimab and azacitidine. The data were presented during an oral session at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting held from May 29-31 (Abstract #7057).

At the time of the data cut-off, 68 patients had been treated with magrolimab plus azacitidine, including 39 patients with previously untreated higher-risk MDS and 29 patients with previously untreated AML. Of 33 MDS patients who were evaluable for efficacy, 91 percent (n=30/33) achieved an objective response (response assessments per 2006 IWG MDS criteria) including 42 percent (n=14/33) with a complete response (CR). Responses to magrolimab and azacitidine also deepened over time, as the CR rate with at least six months of follow-up was 56 percent in MDS patients.

In AML, 64 percent (n=16/25) of patients evaluable for efficacy achieved an objective response (response assessments per 2017 AML ELN criteria), including 56 percent (n=14/25) with a CR or a CR with incomplete blood count recovery (CRI). Notably in TP53-mutant AML (n=12), a treatment refractory and poor prognosis population, 75 percent achieved a CR or CRI.

Median duration of response and median overall survival have not yet been reached in MDS, AML or TP53-mutant AML, with a median follow-up of 5.8 (range: 2.0-15.0 months), 9.4 (range: 1.9-16.9 months) and 8.8 months (range: 1.9-16.9 months), respectively.

The safety profile of the combination of magrolimab plus azacitidine was generally consistent with prior reports with no maximum tolerated dose reached. Common all-grade treatment-related adverse events (AEs) among 68 patients with MDS or AML were anemia (38 percent), fatigue (21 percent), neutropenia (19 percent), thrombocytopenia (18 percent) and infusion reaction (16 percent). Treatment-related febrile neutropenia occurred in 1.5 percent of patients. Only one patient (1.5 percent) discontinued the trial due to a treatment-related AE.

“We continue to be encouraged by the response rates observed with magrolimab and azacitidine in first-line, high-risk MDS and AML,” said David Sallman, MD, H. Lee Moffitt Cancer Center and Research Institute, an investigator for the clinical trial. “Particularly impressive are the responses in some of the most difficult-to-treat patients, including AML patients with a TP53 mutation. This patient group suffers from a lack of effective treatment options. These results support further study in these patients and provide hope for a potentially meaningful clinical advance.”

“Results presented at ASCO reinforce the clinical potential of CD47 inhibition with magrolimab in high risk, difficult-to-treat hematologic malignancies,” said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. “We look forward to initiating additional trials in MDS and TP53-mutant AML, which will be a significant step forward for this exciting next-generation cancer immunotherapy.”

Magrolimab is investigational and not approved anywhere globally. Its efficacy and safety have not been established. More information about clinical trials with magrolimab is available at www.clinicaltrials.gov (NCT03248479).

About Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML)

Myelodysplastic syndromes (MDS) are a type of cancer caused by poorly formed or dysfunctional blood cells in the bone marrow. Approximately 15,000 people are diagnosed with MDS in the U.S. each year, and no new treatments have been approved in 14 years.

Acute myeloid leukemia (AML) is a type of cancer which begins in the bone marrow and can quickly move to the blood and other parts of the body. AML most often develops from cells that would turn into white blood cells, but can also develop from other types of blood-forming cells. Cancers such as MDS can also develop into AML. Approximately 20,000 Americans will be diagnosed with AML each year.

About the Phase 1b Trial

The Phase 1b trial, which is being funded in part by the California Institute of Regenerative Medicine (CIRM), is designed to evaluate the safety, tolerability and efficacy of magrolimab in combination with azacitidine in untreated patients with higher-risk MDS or with AML who are ineligible for induction chemotherapy. All patients in the trial received a 1 mg/kg priming dose of magrolimab, coupled with intrapatient dose escalation, to mitigate on-target anemia. Patients were then treated with full doses of azacitidine and a magrolimab maintenance dose of 30 mg/kg once weekly (QW) or every two weeks (Q2W). Based on pharmacokinetics and CD47 receptor occupancy data in the bone marrow from the ongoing trial, Q2W dosing has been selected to optimize patient convenience.

This trial, which is ongoing, aims to enroll up to a total of 257 patients.

About Magrolimab
Magrolimab is an investigational monoclonal antibody against CD47 that is designed to interfere with recognition of CD47 by the SIRPα receptor on macrophages, thus blocking the “don't eat me” signal used by cancer cells to avoid being ingested by macrophages. Forty Seven, Inc. developed magrolimab and was recently acquired by Gilead. Magrolimab is initially being studied in patients with MDS and AML, and additional studies are ongoing in non-Hodgkin lymphoma (NHL) and solid tumors. Magrolimab has been granted Fast Track designation by the FDA for the treatment of MDS and AML, and for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma, two forms of B-cell non-Hodgkin's lymphoma. Magrolimab has also been granted Orphan Drug designation by the U.S. Food and Drug Administration for AML and MDS and by the European Medicines Agency for the treatment of AML.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company’s website at www.gilead.com.

Gilead Forward-Looking Statement

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the possibility of unfavorable results from ongoing and additional clinical studies involving magrolimab, including in combination with azacitidine, and the possibility that Gilead may be unable to initiate and complete future studies involving magrolimab in the anticipated timelines or at all. Further, it is possible that Gilead may make a strategic decision to discontinue development of magrolimab. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information about Gilead, please visit the company’s website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.