GILEAD'S MAGROLIMAB, AN INVESTIGATIONAL ANTI-CD47 MONOCLONAL ANTIBODY, RECEIVES FDA BREAKTHROUGH THERAPY DESIGNATION FOR TREATMENT OF MYELODYSPLASTIC SYNDROME

- Ongoing Clinical Program Includes the Phase 3 ENHANCE Study in MDS -

- Additional Studies Are Evaluating Magrolimab in Both Hematologic and Solid Tumors -

Foster City, Calif., September 15, 2020 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for magrolimab, a first-in-class, investigational anti-CD47 monoclonal antibody for the treatment of newly diagnosed myelodysplastic syndrome (MDS).

MDS is 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. The average survival rate for those with lower-risk MDS is six years and approximately 18 months for those with higher-risk MDS.
Breakthrough Therapy designation is designed to expedite the development and regulatory review of investigational treatments for serious or life-threatening conditions that, based on preliminary clinical evidence, have the potential to substantially improve clinical outcomes compared with available therapy.

The FDA granted Breakthrough Therapy designation for magrolimab based on positive results of an ongoing Phase 1b study, which evaluated magrolimab in combination with azacitidine in previously untreated intermediate, high and very high-risk MDS. In data presented at the 2020 European Hematology Society Congress, 91 percent of evaluable patients (n=33) treated with magrolimab plus azacitidine achieved an objective response, with 42 percent achieving a complete remission (CR). The combination of magrolimab plus azacitidine was generally well-tolerated. No maximum tolerated dose was reached and no MDS patients discontinued treatment due to a treatment-related adverse event.

"The Breakthrough Therapy designation recognizes the potential for magrolimab to help address a significant unmet medical need for people with MDS and underscores the transformative potential of Gilead's immuno-oncology therapies in development," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences.

Magrolimab is currently being studied in the double-blind, placebo-controlled, randomized Phase 3 ENHANCE trial in previously untreated higher risk MDS. The trial will evaluate the safety and efficacy of magrolimab, in combination with azacitidine, as measured by CR and duration of CR.

Magrolimab is an investigational agent and has not been approved anywhere globally. Its safety and efficacy have not been established.

About Magrolimab

Magrolimab is a first-in-class investigational monoclonal antibody against CD47 and macrophage checkpoint inhibitor 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. Magrolimab is being developed in several hematologic and solid tumor malignancies,

including MDS. Magrolimab has been granted Fast Track Designation by the FDA for the treatment of MDS, acute myeloid leukemia (AML), diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma. Magrolimab has also been granted Orphan Drug Designation by the FDA for MDS and AML and by the European Medicines Agency for AML.
Additional information on magrolimab clinical trials is available on www.clinicaltrials.gov.