



February 7, 2024

**Re: Discontinuation of ENHANCE-3 study in AML (Acute Myeloid Leukaemia) due to futility and FDA Clinical Hold for magrolimab in AML & MDS – Update to the Magrolimab Compassionate Use Program, also referred to as Named Patient Compassionate Use (NPCU)**

Dear Magrolimab Compassionate Use Investigator,

Gilead Sciences, Inc. today announced it has discontinued the Phase 3 ENHANCE-3 study of magrolimab in acute myeloid leukemia (AML) and that the U.S. Food and Drug Administration (FDA) placed all magrolimab studies in myelodysplastic syndromes (MDS) and AML, including related expanded access programs, on full clinical hold. These decisions follow the recommendation of an independent Data Monitoring Committee which reviewed top-line data from a planned interim analysis of ENHANCE-3 for overall survival (OS). In that analysis, magrolimab in combination with azacitidine plus venetoclax demonstrated futility and an increased risk of death was observed, primarily driven by infections and respiratory failure.

Based on these results, as well as data from two other clinical studies in higher-risk MDS (ENHANCE) and AML with TP53 mutations (ENHANCE-2) where the primary analyses also demonstrated futility with an increased risk of death in the magrolimab-treatment arm, Gilead will not pursue further development of magrolimab in hematologic cancers.

In light of this information, Gilead will discontinue the Named Patient Compassionate Use (NPCU) program for patients with AML and no new unsolicited requests will be approved. HCPs with patients currently enrolled in the program should discontinue magrolimab treatment and patients should transition to an alternative treatment that does not include magrolimab.

Please see the attached Dear Investigator Letter (DIL) that was sent to ENHANCE-3 investigators with additional information.

On behalf of the Oncology Expanded Access team and Gilead, we would like to thank you and your staff for your understanding. Please reach out to [OncologyExpandedAccess@gilead.com](mailto:OncologyExpandedAccess@gilead.com) if you have any questions.

Kind regards,

Luciana Preger, MD

Vice-President & Head of Global Medical Affairs Oncology

Gilead Sciences, Inc