ONO PHARMACEUTICAL CO.,LTD.

August 22, 2023

Ono Pharmaceutical Co., Ltd

Gilead Announces Partial Clinical Hold for Magrolimab Studies in AML

This information is intended to notify the press release issued on August 21 by Gilead Sciences Inc., our license partner for magrolimab. Please click https://www.gilead.com/news-and-press/press-room/press-releases/2023/8/gilead-announces-partial-clinical-hold-for-magrolimab-studies-in-aml for the original press release by Gilead.

Subtitle of the press release:
- Enrolled Patients May Continue Receiving Study Medicine
- Studies in Solid Tumors Unaffected

1st and 2nd paragraphs of the press release:
Foster City, Calif., August 21, 2023 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on the initiation of new patients in U.S. studies evaluating magrolimab to treat acute myeloid leukemia (AML).

The FDA action follows the previously announced discontinuation of the Phase 3 ENHANCE study of magrolimab in higher-risk myelodysplastic syndromes (HR-MDS).

*: Magrolimab is a development compound (development code: ONO-7913) by Ono in Japan, South Korea and Taiwan.

About Magrolimab (ONO-7913)

Magrolimab is a potential, first-in-class investigational monoclonal antibody against CD47 and a macrophage checkpoint inhibitor that is designed to interfere with recognition of CD47 by the SIRPα receptor on macrophages, with the goal of blocking the “don’t eat me” signal used by cancer cells to avoid being ingested by macrophages. Magrolimab is being developed in several hematological malignancies, as well as solid tumors.

In Japan, South Korea and Taiwan, Ono has been developing this compound as ONO-7913 (development code).

About Ono and Gilead Collaboration

In July 2019, Ono entered into a license agreement with Forty Seven, Inc. (which became a wholly owned subsidiary of Gilead in April 2020) to exclusively develop, manufacture and commercialize 5F9 (magrolimab), the monoclonal antibody against CD47, in Japan, South Korea, Taiwan and ASEAN countries.

Contact:
Ono Pharmaceutical Co., Ltd.
Corporate Communications
public_relations@ono-pharma.com