ONO PHARMACEUTICAL CO.,LTD.

April 13, 2022

FDA Lifts Partial Clinical Hold on MDS and AML Magrolimab Studies

This information is intended to notify the press release issued on April 11 by Gilead Sciences Inc., our license partner for magrolimab. Please click https://www.gilead.com/news-and-press/press-room/press-releases/2022/4/fda-lifts-partial-clinical-hold-on-mds-and-aml-magrolimab-studies for the original press release by Gilead.

Subtitle of the press release:
- U.S. Pivotal Studies to Restart Enrollment Immediately
- Decision Based on Review of the Comprehensive Safety Data from Each Trial

1st paragraph of the press release:

FOSTER CITY, Calif.--(BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) lifted the partial clinical hold placed on studies evaluating its investigational agent magrolimab in combination with azacitidine. The FDA removed the partial clinical hold after a review of the comprehensive safety data from each trial.

*: Magrolimab is a development compound (development code: ONO-7913) by Ono in Japan.

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 hematologic cancers, including myelodysplastic syndrome (MDS), as well as solid tumor malignancies.

In Japan, Ono has been developing this compound under the development code of ONO-7913.

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), their monoclonal antibody against CD47, in Japan, South Korea, Taiwan and ASEAN countries.

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