ONO PHARMACEUTICAL CO.,LTD.

January 28, 2022

Gilead Announces Partial Clinical Hold for Studies Evaluating Magrolimab in Combination with Azacitidine

This information is intended to notify the press release issued on January 25 by Gilead Sciences Inc., our license partner for magrolimab. Please click https://www.gilead.com/news-and-press/press-room/press-releases/2022/1/gilead-announces-partial-clinical-hold-for-studies-evaluating-magrolimab-in-combination-with-azacitidine for the original press release by Gilead.

Subtitle of the press release:
- Enrolled Patients in These Studies May Continue Receiving Study Medicine
- Studies Outside of Combination with Azacitidine Unaffected

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) has placed a partial clinical hold on studies evaluating the combination of magrolimab plus azacitidine due to an apparent imbalance in investigator-reported suspected unexpected serious adverse reactions (SUSARs) between study arms. While no clear trend in the adverse reactions or new safety signal has been identified by Gilead at this time, the partial clinical hold is being implemented by Gilead across all ongoing magrolimab and azacitidine combination studies worldwide in the best interests of patients as additional data is gathered and analyzed to address the concerns raised by FDA.

*: 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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