Merck KGaA
Darmstadt, Germany

March 18, 2020 | Darmstadt, Germany

COMPANY STATEMENT

Merck KGaA, Darmstadt, Germany, statement on upcoming clinicaltrials.gov updates for the INTR@PID Lung 037 clinical study

In February 2019, we entered into a global strategic alliance with GSK to jointly develop and commercialize bintrafusp alfa*, an investigational asset discovered in-house at Merck KGaA, Darmstadt, Germany. In the U.S. and Canada, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, operates as EMD Serono.

Together with GSK, we have decided to proactively amend the protocol of the INTR@PID Lung 037 study versus pembrolizumab.

As a reminder, these changes, soon to be reflected on clinicaltrials.gov, will include:

- An adaptive trial design based on pre-specified rules to determine whether to expand to Phase III or stay as Phase II
- A change to study endpoints from ORR/PFS to PFS/OS, thus confirming the registrational intent and incorporating the guidance from health authorities

Please note that these changes are not data-driven as no results are available for the 037 study at this time.

Bintrafusp alfa is being studied in a variety of solid tumors, including non-small cell lung cancer (INTR@PID LUNG 005, INTR@PID LUNG 024, INTR@PID LUNG 037), biliary tract cancer (INTR@PID BTC 055, INTR@PID BTC 047) and HPV-associated tumors, such as cervical cancer (INTR@PID CERVICAL 017). Additional studies, including in triple negative breast cancer (TNBC), are in planning and will be communicated in the upcoming months. In December 2018, bintrafusp alfa was granted orphan drug designation by both the US Food and Drug Administration as well as the European Medicines Agency in biliary tract cancer.

**Bintrafusp alfa is currently under clinical investigation and not approved for any use anywhere in the world.*

About Bintrafusp Alfa
Bintrafusp alfa (M7824), discovered in-house at Merck KGaA, Darmstadt, Germany, is a potential first-in-class investigational bifunctional fusion protein designed to simultaneously block two immunosuppressive pathways, TGF-β and PD-L1, within the tumor microenvironment. This bifunctional approach is thought to control tumor growth by potentially restoring and enhancing anti-tumor responses. In preclinical studies, bintrafusp alfa has demonstrated antitumor activity both as monotherapy and in combination with chemotherapy. Based on its mechanism of action, bintrafusp alfa offers a potential targeted approach to addressing the underlying pathophysiology of difficult-to-treat cancers.

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