

COMPANY STATEMENT

Merck KGaA, Darmstadt, Germany Statement on Phase II Study of Bintrafusp Alfa in First-Line Treatment of Biliary Tract Cancer

Darmstadt, Germany, August 23, 2021 – Based on a review of data conducted by the Independent Data Monitoring Committee (IDMC), Merck KGaA, Darmstadt, Germany has decided to discontinue the Phase II INTR@PID BTC 055 study evaluating bintrafusp alfa with gemcitabine plus cisplatin in the first-line treatment of patients with locally advanced or metastatic biliary tract cancer (BTC), as the study is unlikely to achieve the primary objective of overall survival. No new safety signals were identified.

Health authorities and trial investigators are being notified of the decision and patients currently receiving bintrafusp alfa in the trial will be advised about next steps by their investigators.

Merck KGaA, Darmstadt, Germany thanks the investigators and the patients and their families who participated in this clinical trial. We will share the data and analyses from this study with the scientific community in the future.

Bintrafusp alfa (M7824), discovered in-house at Merck KGaA, Darmstadt, Germany, is currently in clinical development through a strategic alliance with GSK.

**Bintrafusp alfa is not approved for any use anywhere in the world.*