REGULATORY NEWS – 22nd SEPTEMBER 2021

U.S. FDA Accepts Biologics License Application for Tislelizumab in Esophageal Squamous Cell Carcinoma

"Our uniquely designed anti-PD-1 antibody tislelizumab has been shown to significantly improve survival compared to chemotherapy for people with a variety of solid tumors and hematologic malignancies. We previously shared the compelling results at ASCO 2021 with tislelizumab significantly prolonging survival and demonstrating a favorable safety profile over chemotherapy in patients with locally advanced or metastatic ESCC, a devastating disease with an average five-year survival rate of just five percent. This BLA acceptance brings us closer to potentially providing tislelizumab as a treatment for these patients in the United States," said Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. "Tislelizumab is already approved in five indications in China and has the potential to become a preferred immunotherapy option there. We look forward to continued collaboration with Novartis to work to bring access to tislelizumab to patients around the world."

Positive EU CHMP Opinion for KEYTRUDA® (pembrolizumab) + Chemotherapy for Certain Patients With Locally Recurrent Unresectable or mTNBC with PD-L1 (CPS ≥10)

"Triple-negative breast cancer grows and spreads faster than other types of breast cancer and consequently has a worse prognosis," said Dr. Vicki Goodman, vice president, clinical research, Merck Research Laboratories. "This positive CHMP opinion is an important step forward in bringing a new immunotherapy treatment option with KEYTRUDA to appropriate patients in Europe with metastatic triple-negative breast cancer. Importantly, this treatment regimen can be used in combination with different chemotherapy agents. We look forward to the European Commission's decision in the coming months."

CHMP recommendations for approval at September 2021 meeting

CHMP recommends Brukinsa* (zanubrutinib) in Waldenström's macroglobulinaemia, Qinlock* (ripretinib) in advanced GIST for marketing authorization and conditional marketing approval for Gavreto (pralsetinib) in NSCLC.

Positive CHMP opinion for Gavreto® (pralsetinib) for the treatment of adults with RET fusion-positive advanced NSCLC

"This positive CHMP opinion for Gavreto represents another important step towards our goal of providing effective therapeutics that target genomic drivers of disease for as many cancer patients as possible," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Advances in personalised medicine also underscore the importance of tumour genomic profiling to identify patients who may benefit from targeted therapies."