REGULATORY NEWS – 18th MAY 2022

Breakthrough Therapy Designation Granted for Repotrectinib Treatment in Patients With One Prior ROS1 Tyrosine Kinase Inhibitor and no Prior Chemotherapy

"We are excited to receive our third BTD and eighth overall FDA regulatory designation for repotrectinib in an indication where there are no approved targeted therapies," said Mohammad Hirmand, M.D., Chief Medical Officer. "We are encouraged by the continued momentum in TRIDENT-1 with enrollment targets achieved in cohorts EXP-1, EXP-4 and EXP-6. We look forward to continuing to progress repotrectinib toward registration with our first pre-NDA meeting with the FDA to discuss the topline data by blinded independent central review from the ROS1-positive advanced NSCLC cohorts of the TRIDENT-1 study expected later this quarter."

Imfinzi plus chemotherapy granted Priority Review in the US for patients with locally advanced or metastatic biliary tract cancer based on TOPAZ-1 Ph 3 trial

Susan Galbraith, Executive Vice President, Oncology R&D, AstraZeneca, said: "People with advanced biliary tract cancer have faced poor outcomes and limited treatment options for too long, and today's news for the TOPAZ-1 trial underscores the urgency to deliver new, effective therapies in this setting. We are working closely with the FDA to bring the first immunotherapy-based option to patients with this devastating cancer and potentially set a new standard of care with Imfinzi plus chemotherapy."

Fast Track Designation for HM43239 in R/R AML Patients and FLT3 Mutation

"Fast Track status acknowledges HM43239's potential to fill an unmet need for AML patient populations and supports our efforts as we advance it towards a potential registration study," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "HM43239, which potently inhibits all tested forms of FLT3 and the SYK and JAK driven pathways, already has delivered complete remissions in a broad diversity of relapsed or refractory AML patients in an ongoing Phase 1/2 clinical trial, including patients with prior failure of other FLT3 inhibitor agents. Fast Track designation will help facilitate the drug's development."

FDA clears IND of ES014 for Patients with Advanced Solid Tumors

"We are delighted that our IND for ES014 was cleared by FDA," said Steve Chin, Chief Medical Officer of Elpiscience. "ES014 is a first-in-class anti-CD39xTGF-β bispecific antibody. In preclinical studies, ES014 demonstrated significant anti-tumor activity in a PD-1 resistant in vivo efficacy model. We look forward to starting the Phase 1 study soon."

Complete Response Letter from the U.S. FDA for Surufatinib for the Treatment of Advanced Neuroendocrine Tumors

Dr Weiguo Su, Chief Executive Officer and Chief Scientific Officer of HUTCHMED, commented: "Although this decision from the FDA is disappointing, we remain confident about the clinical value of surufatinib for NET patients and committed to making surufatinib available to patients globally. We look forward to working with the Agency to evaluate its feedback. Throughout the duration of the U.S. review process, we have been transparent and collaborative with the FDA. There are very few treatments approved and used in these rare diseases, and patients and physicians would benefit from more options to address the

unmet medical need. We look forward to continued engagement with the FDA on developing a plan to bring surufatinib to patients in the U.S."

Complete Response Letter from U.S. FDA for Toripalimab BLA

"We will continue to work closely with our partner, Junshi Biosciences, to facilitate the completion of the FDA's review of the toripalimab BLA. In late April, we responded quickly to an FDA request for a quality process change and implemented required actions," said Denny Lanfear, CEO of Coherus. "We plan to first meet with the FDA and directly thereafter to resubmit the BLA. The FDA has indicated that the existing toripalimab clinical data are supportive of the BLA submission, and we eagerly await scheduling and completion of the required inspections in China that have been impeded to date by COVID-related travel restrictions. We believe toripalimab addresses an important unmet need for patients with NPC for whom there are currently no approved immunotherapies in the United States, and the FDA has stated that this indication warrants regulatory flexibility with respect to the sufficiency of single country clinical data."

sNDA accepted and Priority Review granted for NUBEQA® (darolutamide) in Combination with Docetaxel for mHSPC

"Bayer remains dedicated to addressing unmet needs in prostate cancer treatment for various stages of the disease," said Christine Roth, Member of the Executive Committee of Bayer's Pharmaceutical Division and Head of the Oncology SBU at Bayer. "Today's sNDA acceptance, confirmation of Priority Review and participation in Project Orbis, bring us closer to adding a new indication for NUBEQA in combination with docetaxel to benefit men with mHSPC."