REGULATORY NEWS - 20th October 2021

Deficiencies raised in the CRL addressed and potential regulatory path forward for Oral Paclitaxel in mBC in the U.S. discussed

"We had an informative meeting with the FDA, which was an important step to assessing the U.S. regulatory pathway for Oral Paclitaxel in mBC," said Dr. Johnson Lau, Chief Executive Officer of Athenex. "After careful consideration of the FDA feedback, we have determined to redeploy our resources to focus on other ongoing studies of Oral Paclitaxel and our promising CAR-NKT and TCR-T cell therapies to maximize value for all stakeholders. We also remain committed to serving patients utilizing products manufactured by our specialty pharmaceutical business (APS and APD)."

Positive CHMP Opinion for RYBREVANT® (amivantamab) for Patients with Advanced NSCLC with EGFR Ex 20 Insertion Mutations, After Failure of Platinum-based Therapy

"Following the U.S. FDA approval of RYBREVANT® earlier this year, we are extremely pleased that the CHMP has granted Janssen a positive opinion for amivantamab, the first such opinion for a product created using Genmab's DuoBody technology platform. We are hopeful that this opinion will lead to an approval and to the first treatment option for European patients with advanced NSCLC with activating EGFR exon 20 insertion mutations," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Positive EU CHMP Opinions for KEYTRUDA® + LENVIMA® (lenvatinib) in advanced RCC and Endometrial Carcinoma

"We appreciate the positive opinions rendered by the EU CHMP recommending approval of KEYTRUDA plus LENVIMA in advanced renal cell carcinoma and advanced endometrial carcinoma, underscoring the potential significance of the outcomes observed in the CLEAR/KEYNOTE-581 and KEYNOTE-775/Study 309 trials," said Dr. Takashi Owa, President, Oncology Business Group at Eisai. "We are grateful to the patients who participated in these studies, their families and clinicians. Their commitment made these meaningful milestones possible."

Anti-TROP-2 ADC with a drug payload SN38 (ESG-401) received FDA authorization to begin clinical trials in the US

- Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) approved the Application for Clinical Trial (Acceptance No. CXSL2101069) of Recombinant Humanized Anti-Trop2 Mab-SN38 Conjugate.
- US FDA also gave clearance to proceed with clinical trials in cancer patients with relapsed or refractory solid tumors.