REGULATORY NEWS – 3rd NOVEMBER 2021

FDA Fast Track Designation for Nemvaleukin Alfa in Combination With Pembrolizumab for the Treatment of Platinum-Resistant Ovarian Cancer

"This Fast Track designation in platinum-resistant ovarian cancer highlights the potential clinical utility of nemvaleukin in combination with pembrolizumab in this difficult-to-treat disease for which there is no approved immunotherapy and there remains significant need for new treatment options," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "We are excited to initiate our planned ARTISTRY-7 phase 3 trial in platinum-resistant ovarian cancer, as we advance nemvaleukin toward potential registration and seek to help patients living with this disease."

Positive EMA Scientific Advice Received for Further Clinical Development of Efti in MBC Including Ph 3

Immutep CEO, Marc Voigt, noted: "Receiving positive and constructive EMA advice on our clinical development program for efti, including the planned Phase III trial in metastatic breast cancer is an exciting achievement for Immutep. We now look forward to further engagement with the EMA and other regulators, including the US FDA to solidify our trial plans."

Priority review by US FDA and filing acceptance by EMA for Kymriah® to treat patients with relapsed or refractory follicular lymphoma

"This is an important milestone in our mission to bring Kymriah to adult patients with relapsed or refractory follicular lymphoma. Receiving orphan drug designation from the EC as well as priority review from the FDA underscores the unmet need and urgency for these patients. With Kymriah demonstrating impressive results in the ELARA trial, we are hopeful that we can offer a unique and potentially definitive treatment that minimizes the burden," said Jeff Legos, Executive Vice President, Global Head of Oncology & Hematology Development, Novartis.

IND Application for Ph 3 Clinical Study of Anti-HER2 Bispecific Antibody KN026 was Officially Accepted by CDE

- IND application for a Ph 3 clinical study of recombinant humanized anti-HER2 bispecific antibody KN026 (KN026-306) was officially accepted by Center for Drug Evaluation (CDE), and will initiate a pivotal clinical study of KN026 combined with chemotherapy in advanced gastric and gastroesophageal junction cancer (GC/GEJ) patients who progressed after first-line standard chemotherapy.
- Data from the Phase II clinical study of KN026 were published at the ASCO 2021, demonstrated favorable safety and promising efficacy in Chinese HER2 overexpressing GC/GEJ patients, either pretreated with or without anti HER2 treatments. In patients with high expression, the ORR was 55.6% and the DCR was 72.2%, and the 9-month PFS rate was 60.4%. Among patients receiving prior-HER2 treatment, the ORR was 44.4%, and the DCR was 66.7%.

- This is the second pivotal clinical study of KN026 after the first one combined with KN046 for the treatment of HER2-positive solid tumors. It is also the first phase III clinical study of KN026.

Independent DSMB Recommends to Advance SQZ-PBMC-HPV-101 Ph 1/2 trial In Combination With Checkpoint Inhibitors

"We are encouraged by our initial SQZ-PBMC-HPV-101 Phase 1/2 trial data and pleased to advance the highest dose of our SQZ™ APC clinical candidate into the combination stage of the trial," said Armon Sharei, Ph.D., Chief Executive Officer and Founder of SQZ Biotechnologies. "Based on our preclinical studies and available clinical trial data, we believe SQZ APCs could work synergistically with checkpoint inhibitors to provide additional clinical benefit to patients. Our clinical team and trial sites are ready to begin this important phase of the study."