REGULATORY NEWS – 27th October 2021

Development of Pepaxto® (INN melphalan flufenamide) in the US to be discontinued following the Ph 3 OCEAN study results

“The decision to withdraw Pepaxto from the market has been a difficult decision, that has been made with great consideration and with the best intentions for patients and shareholders," says Marty J Duvall, Chief Executive Officer at Oncopeptides. “The Company now needs to refocus its resources and energy on R&D and remain true to its mission of bringing hope to patients through science. We believe that this is the only viable path forward to accomplish this goal.”

FDA Pre-IND Meeting of Proposed Ph 2 Trial for ENKASTIM™ autologous NK cell therapy with Advanced (stage III & Stage IV) NSCLC Patients completed

“We are delighted with the outcome of the Pre-IND meeting with the US FDA which was supported by clinical data from a prior Phase II Clinical Trial involving patients with advanced (stage IIIb) NSCLC in Germany. Although the number of patients was small, the prior Phase II Clinical Trial demonstrated the therapy was safe and had promising signs of efficacy in the most commonly diagnosed cancer and the leading cause of cancer deaths worldwide.” said A. Graham Pockley, PhD, Chief Scientific Officer of Alphageneron. ”Based upon our recent FDA interaction, we are working diligently to finalize the protocol design to initiate our first multi-site Phase II Clinical Trial to treat patients with advanced (stage III and IV) NSCLC in 2022, an important milestone for the company.” added Robert K. Brooks, JD, Chairman and Chief Executive Officer of Alphageneron.

Dual FDA Fast Track Designation granted for UV1 in Advanced Malignant Melanoma

“We are delighted UV1 has received the Fast Track designation and look forward to working more closely with the FDA to bring UV1 to melanoma patients as soon as possible,” said Carlos de Sousa, Chief Executive Officer of Ultimovacs. “The FDA’s decision recognizes the potential synergy of UV1 and checkpoint inhibitors and will greatly encourage physicians and patients involved in our Phase II clinical trial INITIUM. We remain committed to progressing UV1 in our four ongoing Phase II clinical studies and assessing development of UV1 with pembrolizumab in advanced melanoma.”

PD-L1 IHC 28-8 pharmDx Receives CE-IVD Mark as a Companion Diagnostic Test in Advanced or Metastatic Gastric, GEJ, or Esophageal Adenocarcinoma

"The added indication of PD-L1 IHC 28-8 pharmDx will give physicians in Europe important information to inform first-line treatment decisions for patients with these common and potentially deadly cancers," said Sam Raha, president of the Agilent’s Diagnostics and Genomics Group. "Agilent values opportunities such as this to partner with pharmaceutical companies in the development of clinically relevant IHC-based or NGS-based diagnostics that enhance confidence in targeted cancer therapy."