Press Release

16 November 2018

Immunicum AB (publ) Announces Collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer to Evaluate Ilixadencel in Combination with Avelumab in Multi-Indication Phase Ib/II Study

Immunicum AB (publ; IMMU.ST) announced today that it has entered into a collaboration agreement with Merck KGaA, Darmstadt, Germany, and Pfizer to evaluate its lead product, ilixadencel, an off-the-shelf cell-based cancer immune primer, in combination with avelumab*, a human anti-PD-L1 monoclonal antibody, in a planned multi-indication Phase Ib/II clinical trial.

Immunicum will initiate a study of ilixadencel in the fourth quarter of 2018. Following completion of the Ib portion of the study, a Phase II study will be conducted using the checkpoint inhibitor avelumab in combination with ilixadencel to evaluate the safety and efficacy of the combination in patients with advanced head and neck cancer and gastric adenocarcinoma. Immunicum will be responsible for conducting the study and continues to retain all commercial rights to ilixadencel.

“We are delighted to work with Merck KGaA, Darmstadt, Germany, and Pfizer to further establish ilixadencel’s potential as a backbone component of combination cancer therapies in different forms of solid tumors where there is a high unmet medical need,” said Carlos de Sousa, CEO of Immunicum. “This collaboration will greatly benefit the study by providing access to avelumab and represents our first corporate agreement that supports the development of ilixadencel.”

“Building on our progress with avelumab as a monotherapy, our key focus is to evaluate the potential of combination therapy in the treatment of solid tumors,” said Kevin Chin, Vice President, Global Clinical Development, Immuno-Oncology at the biopharma business of Merck KGaA, Darmstadt, Germany, which in the US and Canada operates as EMD Serono. “We believe the next wave of innovation is with combination approaches to support patients with hard-to-treat cancers.”

“We look forward to working with Immunicum to assess ilixadencel with avelumab. As part of our clinical development program for avelumab, this collaboration can help advance our understanding of the potential of immunotherapy combination regimens,” said Chris Boshoff, M.D., Ph.D., Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology, Pfizer Global Product Development.

Avelumab has received accelerated approval** by the US Food and Drug Administration (FDA) for the treatment of patients with metastatic Merkel cell carcinoma (MCC) and previously treated patients with locally advanced or metastatic urothelial carcinoma (mUC), and is under further clinical evaluation across a range of tumor types under a global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer.

*Avelumab is under clinical investigation for the treatment of various solid tumors and has not been demonstrated to be safe and effective for these indications. There is no guarantee that avelumab will be approved for specific solid tumors by any health authority worldwide

About ilixadencel

Ilixadencel, a cell therapy product, is an off-the-shelf cancer immune primer, developed for the treatment of solid tumors. Its active ingredient is activated allogeneic dendritic cells, derived from healthy blood donors. Intratumoral injection of these cells generates an inflammatory response which in turn leads to tumor-specific activation of the patient's cytotoxic T-cells.

About Avelumab

Avelumab is a human anti-programmed death ligand-1 (PD-L1) antibody. Avelumab has been shown in preclinical models to engage both the adaptive and innate immune functions. By blocking the interaction of PD-L1 with PD-1 receptors, avelumab has been shown to release the suppression of the T cell-mediated antitumor immune response in preclinical models.[1-3] Avelumab has also been

shown to induce NK cell-mediated direct tumor cell lysis via antibody-dependent cell-mediated cytotoxicity (ADCC) *in vitro*.[3-5] In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

Avelumab is currently being evaluated in the JAVELIN clinical development program, which involves at least 30 clinical programs, including eight Phase III trials, and more than 9,000 patients across more than 15 different tumor types. For a comprehensive list of all avelumab trials, please visit clinicaltrials.gov.

Indications in the US**

The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Important Safety Information from the US FDA Approved Label

The warnings and precautions for avelumab (BAVENCIO®) include immune-mediated adverse reactions (such as pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions), infusion-related reactions and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with BAVENCIO for mMCC and patients with locally advanced or metastatic UC include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash.

For full prescribing information and medication guide for BAVENCIO, please see www.BAVENCIO.com.

Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

The information is such information that Immunicum is obliged to make public pursuant to EU Market Abuse Regulation. The information was released for public disclosure through the contact persons detailed below on 16 November 2018 at 8.30 am CET.

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ABOUT IMMUNICUM AB (PUBL)

Immunicum is establishing a unique immuno-oncology approach through the development of allogeneic, off-the-shelf cell-based therapies. Our goal is to improve survival outcomes and quality of life by priming the patient's own immune system to fight cancer. The company's lead product ilixadencel, consisting of pro-inflammatory allogeneic dendritic cells, has the potential to become a backbone component of modern cancer combination treatments in a variety of solid tumor indications. Founded and based in Sweden, Immunicum is publicly traded on the Nasdaq Stockholm. www.immunicum.com