Press Release

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Immunicum AB (publ) Announces Positive Preclinical Data on Ilixadencel in Combination with CTLA-4 Immune Checkpoint Inhibitor

Immunicum AB (publ) announced today results from a preclinical study examining ilixadencel, an off-the-shelf, cell-based immune primer, tested in combination with the immune checkpoint inhibitor CTLA-4. As Immunicum continues to advance ilixadencel in clinical trials, these preclinical studies allow the Company to identify potential synergistic combinations for ilixadencel in addition to gaining a stronger understanding of its effect on solid tumors. In this preclinical study, animals that were treated with the combination of ilixadencel and CTLA-4 showed a stronger anti-tumor response as compared to animals treated with PD-1 and CTLA-4, a well-known combination of checkpoint inhibitors (CPIs). The full results will be further analyzed for publication in a scientific journal or at a medical conference.

"Our preclinical findings indicate that the combination of ilixadencel with anti-CTLA-4 induces deeper and more durable responses than the well-known combination of anti-PD-1 and anti-CTLA-4 in this preclinical model. Part of the challenge for immunotherapy in solid tumors is to find the most effective and well-tolerated combinations. Therefore, we will continue to test ilixadencel in preclinical studies that will enable us to define and design the most beneficial treatment regimens that then could be tested in clinical trials," commented Associate Professor Alex Karlsson-Parra, Chief Scientific Officer of Immunicum.

The preclinical study used a CT26 tumor model (colon cancer cells injected subcutaneously) in mice with large established tumors (approximately 100 mm3 at the start of treatment) that are PD-1 resistant and only moderately responsive to CTLA-4 treatment (delayed tumor progression but no complete responses). One group of 10 mice received a combination of anti-CTLA-4 and anti-PD-1 antibodies, and another group of 10 mice received a combination of anti-CTLA-4 antibodies with mouse-ilixadencel. Survival was followed up to 44 days after treatment start. Six out of 10 mice (60%) in the ilixadencel/CTLA-4 group were still alive at the end of study, in which two out of six mice alive had a complete response and 3 had almost reached complete response at the end of study. Two out of 10 mice (20%) were still alive in the PD-1/CTLA-4 group, in which one out of two almost reached complete response at the end of the study. The study was conducted by the Charles River Laboratories in Morrisville, NC, USA.

"To date, ilixadencel has been tested in over 90 patients and has maintained an excellent safety profile and shown initial signs of efficacy as demonstrated most recently in the Phase II MERECA clinical study. As we continue to advance the development of this novel drug candidate, our goal is to continue to use preclinical studies to identify new opportunities for ilixadencel in which it could make a meaningful therapeutic impact for patients without adding toxicity when combined with standard cancer treatments," added Carlos de Sousa, CEO of Immunicum.

Novel combination approaches that combine durable response with an acceptable safety profile are critical to the growing field of immuno-oncology as current treatment options continue to remain highly toxic. CTLA-4 Yervoy® (ipilimumab) was one of the first CPIs to be successfully developed into an effective immunotherapy in melanoma and has also shown promise in combination with the PD-1 CPI Opdivo® (nivolumab) in other indications, including metastatic renal cell carcinoma. In contrast, the combination of CTLA-4 and PD-1/PD-L1 antibodies has recently failed in Phase III studies in non-small cell lung cancer and head and neck cancer, and the combination is known to have high toxicity. As such, Immunicum is committed to identifying where ilixadencel may enable better responses for immunotherapy combinations without adding unacceptable toxicity, especially in indications where the first generation of CPIs have yet to show positive results.

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.

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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. Immunicum has evaluated ilixadencel in several clinical trials including the recently completed exploratory Phase II MERECA study in kidney cancer and the Company is moving towards late-stage clinical development. Founded and based in Sweden, Immunicum is publicly traded on the Nasdaq Stockholm. **www.immunicum.com**