
Press Release

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Immunicum AB (publ) Announces Publication of Phase I/II Clinical Trial Results of Ilixadencel in Gastrointestinal Stromal Tumors (GIST) in *Cancer Immunology, Immunotherapy*

Immunicum AB (publ; IMMU.ST) announced today that the final data analysis from the clinical study of ilixadencel in patients with Gastrointestinal Stromal Tumors (GIST) has been published in the journal, *Cancer Immunology, Immunotherapy*. GIST is a rare and difficult-to-treat disease indication and the trial met the primary endpoint of safety showing that ilixadencel in combination with different tyrosine kinase inhibitors (TKIs) had a favorable safety profile with no treatment-related serious adverse events and no signs of autoimmunity. In addition, analysis of the secondary clinical trial endpoints provided initial signals of clinical benefit in two out of six patients that showed tumor shrinkage after adding ilixadencel treatment to TKI treatment despite previous tumor progression on the same TKI.

The final data analysis showed that two out of six patients exhibited partial tumor responses, according to the Choi response criteria (i.e. 33% objective response rate). The same two patients also exhibited stable disease for 9 months (on third line regorafenib) and 12 months (on second line sunitinib), respectively, based on the modified RECIST criteria. The partial responses observed indicate that ilixadencel contributed to therapeutic impact by overcoming resistance to TKIs in these two patients with metastatic disease whose disease previously progressed on second- and/or third-line TKI treatment.

“Although the GIST study was a trial with few patients enrolled, they were all at an advanced disease stage, meaning that both the safety data and the signals of clinical efficacy are encouraging and support ilixadencel’s potential as a safe and effective cell-based cancer immune primer. The publication of our clinical results in a peer reviewed journal further validates the quality of the data generated from our clinical study,” said Alex Karlsson-Parra, MD, PhD, CSO and interim CEO of Immunicum.

The full publication titled, "Phase 1 Trial Evaluating Safety and Efficacy of Intratumorally Administered Inflammatory Allogeneic Dendritic Cells (ilixadencel) in Advanced Gastrointestinal Stromal Tumors" can be accessed through the current online version of *Cancer Immunology, Immunotherapy* and through the following link: <https://bit.ly/37x0kVU>

About the GIST study

The GIST study, completed in June 2019, was a Phase I/II open-label, single arm clinical trial conducted at the Karolinska University Hospital in Stockholm that evaluated the safety and efficacy of ilixadencel in unresectable or metastatic GIST patients with tumor progression during ongoing second, third- or fourth-line treatment with TKI therapy. A total of six patients were enrolled. Patients were treated with two intratumoral doses of ilixadencel in combination with their ongoing TKI treatment, which continued for at least three months.

About Gastrointestinal Stromal Tumors

Gastrointestinal Stromal Tumors (GIST) is the most common sarcoma and is highly resistant to conventional radio- and chemotherapy. Although imatinib and other tyrosine kinase inhibitors (TKIs) have revolutionized the medical treatment of unresectable and/or metastatic GIST, TKI resistance still represents a major challenge as therapeutic options for advanced GISTs are limited when the disease progresses.

About ilixadencel

Ilixadencel is an off-the-shelf cell-based cancer immunotherapy developed for the treatment of solid tumors. Its active ingredient is activated allogeneic dendritic cells, derived from healthy blood donors. Injection of these cells in the patient’s tumor generates an inflammatory response which

in turns leads to tumor-specific activation of the patient's cytotoxic T cells. To-date ilixadencel has been tested in a range of clinical trials in various solid tumor indications including metastatic Renal Cell Carcinoma (mRCC), hepatocellular carcinoma (HCC) and gastrointestinal stromal tumors (GIST) and in combination with several standard-of-care cancer therapies such as the tyrosine kinase inhibitors Sutent® (sunitinib) and Stivarga® (regorafenib), and the checkpoint inhibitor Keytruda® (pembrolizumab). Ilixadencel has consistently maintained a positive safety and tolerability profile and demonstrated initial signs of efficacy as seen in the randomized Phase II MERECA trial. Ilixadencel is currently moving towards late-stage clinical development.

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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