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## Press Release

12 June 2019

### Immunicum AB (publ) Announces Positive Topline Results from the Phase I/II Clinical Trial in GIST

Immunicum AB (publ) announced today the completion and positive topline results from its Phase I/II clinical trial examining the safety and tolerability of Immunicum's lead candidate, ilixadencel, in combination with tyrosine kinase inhibitors (TKIs) in six patients with Gastrointestinal Stromal Tumors (GIST), a rare and difficult-to-treat disease indication. The trial showed that ilixadencel had a favorable safety profile, confirming similar data from past studies, in combination with several TKIs. In addition, analysis of the secondary clinical trial endpoints provided initial signals of clinical benefit in two patients that showed partial response to the treatment. The outcome of the GIST study, which Immunicum plans to publish in a peer-reviewed journal, contributes to the body of data supporting ilixadencel's potential as a safe and effective cell-based, off-the-shelf immune primer in a range of solid tumor cancers.

"Although this study was conducted in a small group of patients, it is important to note that they all were at an advanced disease stage, meaning that both the safety data and the signals of clinical response are encouraging. They support the continued evaluation of ilixadencel's role in the treatment of solid tumors and contribute to the growing body of data we will collect in our clinical development program this year," said Peter Suenart, MD, PhD, Chief Medical Officer at Immunicum.

#### Study Design

The Phase I/II open-label, single arm clinical trial conducted at the Karolinska University Hospital in Stockholm 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.

#### Results

Ilixadencel met the primary endpoint of safety, with no life-threatening treatment-related adverse events and no signs of autoimmunity. The secondary endpoint of efficacy was primarily evaluated based on tumor growth. The most positive outcome was seen in two patients where tumor growth halted and partially regressed for three and six months, respectively. These partial responses 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.

"As a disease with limited therapeutic options, it is a considerable achievement to see partial response in two out of six advanced-stage GIST patients as the disease at that point has developed resistance to standard of care treatment with TKIs," commented Principal Investigator, Robert Bränström, MD and Associate Professor at Karolinska University Hospital.

#### 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 GIST

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.

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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](http://www.immunicum.com)