

## Immunicum in collaboration with Karolinska Institute submits an application for starting a clinical study with INTUVAX® in GIST

**GOTHENBURG, September 17, 2015 - Immunicum AB (publ) today announced that it, together with Karolinska Institute and Karolinska University Hospital, has filed an application with the Swedish Medical Products Agency to start a phase I/II study with the Company's therapeutic cancer immune primer INTUVAX®. The safety and efficacy of INTUVAX® in combination with *sunitinib* in patients with incurable Gastrointestinal Stromal Tumor (GIST) will be examined.**

"The first observations of INTUVAX® in humans looks promising and have made our research group wanting to look closely at INTUVAX's effect on critically ill GIST patients. As far as we know, there are only very few studies looking at how a cancer immune primer can improve the prognosis for this patient population", said principal investigator, MD and Associate Professor Robert Bränström, Division of Endocrine and Sarcomas Surgery, Karolinska University Hospital.

The study is expected to start at the end of the year and will be conducted at the Karolinska University Hospital during about a year. This is the fourth clinical study with INTUVAX®. The Company's most advanced clinical trial is an ongoing phase II study in patients with metastatic renal cell cancer (mRCC). Immunicum also has an ongoing phase I/II study in patients with primary liver cancer and a completed phase I/II study in mRCC where the Company continues to follow overall survival.

"We are very proud that the Karolinska University Hospital wants to start this collaboration with Immunicum. The study's focus goes well together with our hypothesis that INTUVAX among other things, can act as potentiating add-on treatment of cancers where certain types of established treatments begin to falter. The Karolinska University Hospital gives us the opportunity to quickly and cost-effectively determine the effect of INTUVAX since, this time, our primary measure of efficacy is tumor response. If the study delivers positive data, we will seek orphan drug designation for INTUVAX for the treatment of GIST, "says Immunicum's CEO, Jamal El-Mosleh.

### Study details

Up to 12 patients with GIST, showing signs of progression with established second-line treatment with *sunitinib* (Sutent®, Pfizer) will be included in the study. The patients will obtain two or three doses of INTUVAX. The study design gives Immunicum the opportunity to compare the effect of two and three vaccine doses (for the first six respectively the last six patients in the study). Since Immunicum's completed phase I/II

study in patients with metastatic renal cell carcinoma, including patients with so-called sarcomatoid tumor development, showed signs of synergy between INTUVAX and *sunitinib*, the GIST patients who progress despite ongoing treatment with *sunitinib* will remain on *sunitinib* treatment during at least three months.

The study's primary objective is to determine safety and the most important secondary objective is to study whether patients showing progression and resistance to existing treatment after INTUVAX treatment show objective tumor response.

Immunicum expects the Company's existing cash to cover the financing of the GIST study and that the study will not affect the timing of a potential future fundraising.

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**About INTUVAX**

INTUVAX is a therapeutic cancer immune primer, developed for the treatment of solid tumors. Its active ingredient is activated white blood cells, so called dendritic cells, derived from healthy blood donors. Intratumoral injection of these cells is expected to lead to an inflammatory response which in turn leads to tumor-specific activation of the patient's cytotoxic T lymphocytes.

**About GIST**

Gastrointestinal Stromal Tumor (GIST) is a tumor arising from Cajals interstitial cells in the gastrointestinal tract. GIST belongs to the group sarcoma cancer, cancers originating in the soft tissues. Every year about 200 new cases of GIST are diagnosed in Sweden.

First-line treatment for patients with so-called KIT-positive, non-operable GIST, is the tyrosine kinase inhibitor *imatinib* (Glivec® Novartis). Half of *imatinib*-treated patients show signs of progressive disease (progression) after two years<sup>1</sup>.

**About Immunicum AB (publ)**

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<sup>1</sup> Gastrointestinal Stromal Tumor Meta-Analysis Group, 2010

Immunicum AB (publ) develops cancer immune primers for the treatment of tumor diseases. A phase II clinical trial for the Company's most advanced project - INTUVAX® against kidney cancer - has been initiated. The project portfolio contains four other projects against various tumor diseases, including a clinical study in patients with liver cancer.