**Press release**

# Immunicum reports updated data from the INTUVAX phase I/II study in liver cancer and announces plan for the continuation of the study

**Gothenburg, Sweden, November 25 2015. - Immunicum AB (publ) today reported an update on the safety and survival data from the ongoing phase I/II study with INTUVAX in patients with primary liver cancer. Currently, ten patients have received at least one dose of INTUVAX and an additional patient is scheduled to begin treatment before year-end. Of the seven patients who have so far received all three doses of INTUVAX, five have exhibited a prolonged survival compared to expected based on historical data. Immunicum also announces plan for an extension of the study where INTUVAX will be combined with first-line treatments.**

The update of the safety and survival data for the ongoing phase I/II trial (IM-102) with INTUVAX for patients with primary liver cancer (NCT01974661) showed that no serious side effects have been related to the vaccine. To date, ten (10) patients with the diagnosis primary hepatocellular carcinoma (HCC) have been treated.

Seven (7) patients have received their three scheduled INTUVAX doses. Two (2) of the patients suffered a very rapid progression of the disease already before treatment could start and passed away before the second and third doses could be given. One (1) patient has received the first of three planned treatment doses and one (1) patient is expected to start treatment before the year-end.

All patients had demonstrated tumor progression (tumor growth) after conventional first-line treatment (local chemoembolization or systemic treatment with Nexavar) before start of INTUVAX-treatment.

It can be noted that out of the seven (7) patients who received all three planned INTUVAX doses, five (5) patients exhibited a survival that exceeded the expected median overall survival. Two (2) of the fully treated patients are still alive and one (1) of these have not yet passed the expected median overall survival.

An amendment to the study protocol, approved by the Swedish Medical Products Agency, gave Immunicum the possibility to include a patient with bile duct cancer, which initially was thought to be primary liver cancer. The patient has been treated with three doses of INTUVAX and also received standard treatment with gemcitabine (G) which is known to inhibit immunosuppressive cells in tumors in combination with cisplatine (C). This patient is still alive approximately 22 months after the first vaccine dose, compared with an expected median overall survival of 11.7 months for patients with bile duct cancer that are treated with G/C (Valle et al N Engl J Med 2010: 362: 273). Three months after the initiation of G/C treatment, the patient showed an objective response (November 2014) which is still ongoing (recent CT performed in November 2015) despite the fact that G/C treatment was discontinued six months ago.

Immunicum also announced that the Company has submitted an application to the Medical Products Agency to extend the study by inclusion of up to an additional six (6) patients that will receive INTUVAX as first-line therapy in combination with local chemoembolization of the tumor or the tyrosine kinase inhibitor Nexavar.

- The good safety profile that INTUVAX has demonstrated in liver cancer now makes it possible for us to target a patient population that can get INTUVAX at an earlier stage of the disease, in this case as first-line treatment in combination with either local chemoembolization or with the tyrosine kinase inhibitor Nexavar. Thus, the study gives us the opportunity to investigate the potential synergistic effect of INTUVAX in combination with local chemoembolization or with systemic treatment with Nexavar. Regarding combination with local chemoembolization, we expect a synergistic effect with INTUVAX since local chemoembolization is expected to increased the amount of dying tumor cells which can subsequently be taken up by locally recruited dendritic cells. The expected synergy with Nexavar is based on Nexavar's proven ability to reduce the immunosuppression inherent in tumors, says Immunicum's Chief Scientific Officer, professor Alex Karlsson-Parra.

- By including up to six new patients under the frames of the current study, we save time and money compared to starting a new safety study on INTUVAX in combination with first-line therapy in primary liver cancer. The new setup will give us important information for a possible future phase II/III trial in that indication, says Immunicum's CEO Jamal El-Mosleh.

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**About INTUVAX**

INTUVAX is a 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 Immunicum AB (publ)**

Immunicum AB (publ) develops cancer immune primers for the treatment of tumor diseases. A clinical phase II trial for the Company's most advanced product - INTUVAX® against kidney cancer - has been initiated. The project portfolio contains an

additional clinical phase I/II study in liver cancer and an upcoming clinical phase I/II study in gastrointestinal stromal tumors (GIST).

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