

Immunicum announces phase I/II data showing tumor specific immune responses that directly correlate with prolonged survival rates for the majority of liver cancer patients treated with INTUVAX

Gothenburg, Sweden, April 18, 2016 - Immunicum AB (publ), pursuing to develop sophisticated, safe and efficient therapeutic cancer treatments with powerful and long lasting immune responses, today announced new immunological phase I/II data showing that the majority of liver cancer patients that received full treatment with INTUVAX experience increases in the frequency of tumor-specific CD8 + T cells and that these increases directly correlate with prolonged survival rates.

Highlights of the current data results:

- Of the eleven evaluated liver cancer patients treated with INTUVAX, nine received full treatment with three doses of INTUVAX.
- Five of the nine fully-treated patients have surpassed their expected median overall survival while two of three patients still alive have yet to surpass their expected median overall survival.
- Assays were performed that compared the frequency of interferon-producing CD8 + T cells in the blood, indicating that the T cells have a killing function, by stimulation with two different tumor-associated antigens (antigens that can be expressed in primary liver tumors) before first INTUVAX-dose and one week after the third and final dose.
- Six of the nine fully-treated patients showed an increased frequency of these interferon-producing CD8 + T cells in the blood, reactive against at least one of the two tumor-associated antigens for liver cancer, after treatment with INTUVAX. For five of these six patients, an increase in the frequency of CD8+ T cells reactive against at least one of the two tumor-associated antigens for liver cancer remained at renewed analysis six weeks after the third and final INTUVAX-dose.
- Four of the six patients that showed an increased frequency of these tumor-specific CD8 + T cells have surpassed their expected median overall survival and the other two patients are still alive and have not yet surpassed the expected median overall survival.
- Two of three fully-treated patients who did not exhibit an increased frequency of tumor-specific T cells in the blood after full INTUVAX treatment passed away before they could pass their expected median overall survival.

- One patient with bile duct cancer was also treated with three doses of INTUVAX and showed an increased frequency of CD8 + T cells in the blood, reactive against the two different tumor associated antigens (which may also be expressed in bile duct cancer) after full INTUVAX-treatment. The patient also received standard treatment with gemcitabin (G), which is known to inhibit the immunosuppressive cells in tumors, in combination with cisplatin (C). This patient is still alive 26 months after the first vaccination, compared with an expected average median overall survival of 11.7 months in patients with bile duct cancer treated with G/C (Valle et al N Engl J Med 2010: 362:1273).

"These results are very positive as they not only show that INTUVAX induces a higher frequency of tumor specific CD8 + T cells in the peripheral blood in the majority of the fully-treated patients, but also that these CD8 + T cells produce interferon-gamma which is a proinflammatory factor that is associated with the T cells' ability to function as a tumor killing cell. Moreover, we see a clear correlation between the increased incidence of these tumor-specific CD8 + T cells and prolonged survival, which speaks in favor of an INTUVAX-related clinical effect", says Immunicum's Chief Scientific Officer, Professor Alex Karlsson-Parra.

"The correlation between prolonged survival rates and tumor specific immune responses as a result of receiving INTUVAX in the treatment of liver cancer is extremely encouraging and meaningful. In addition, we now have clear signs of INTUVAX-related tumor-specific immune responses in two different indications and the data we continue to collect further strengthens our faith in INTUVAX's potential as a future standard treatment for cancer", says Immunicum's CEO, Jamal El-Mosleh.

About the liver cancer study (IM-102)

As has been previously announced, Immunicum initiated a phase I/II study (IM-102) in liver cancer in October 2013. Patients that previously failed on first-line treatments began second-line treatment with the cancer immune primer INTUVAX. No serious side effects have been related to the vaccine. All patients had experienced tumor progression (tumor growth) after conventional first-line treatment (local chemoembolization or systemic treatment with Sorafenib) before they were put on treatment with INTUVAX. Two of the study patients, however, had a very rapid disease-progression before the first vaccine dose and, as a result, died before the second respectively the third dose could be given.

Additionally, as has been previously announced, Immunicum received approval from the Medical Products Agency to expand the study by including up to an additional six patients. These patients are approved to receive INTUVAX as first-line treatment, in combination with local chemoembolization of the tumor or the tyrosine kinase inhibitor Sorafenib.

For further information, please contact:

Jamal El-Mosleh, CEO, Immunicum
Phone: +46 (0) 31 41 50 52
jamal.el-mosleh@immunicum.com

Immunicum's Certified Adviser is Redeye AB
Phone: +46 (0) 8 545 013 31. www.redeye.se

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).

www.immunicum.com