

## **Immunicum reports positive phase I/II-data for the therapeutic cancer vaccine INTUVAX® in the treatment of kidney cancer**

**Immunicum® AB (publ), a Swedish listed company on NASDAQ OMX First North, developing therapeutic cancer vaccines, today announces positive survival data from a clinical phase I/II-study with the therapeutic cancer vaccine INTUVAX® for the treatment of metastatic renal cancer. A presentation will be held today by the Company's Chief Scientific Officer, Associate Professor Alex Karlsson-Parra, at Informa's Immunotherapy Conference in Brussels.**

The clinical phase I/II-study, initiated in February 2012, includes a total of 12 patients, each treated with two intratumoral injections/vaccinations with INTUVAX®, two weeks apart, after which their cancer affected kidney, as part of the standard treatment, was surgically removed.

Vaccination with INTUVAX® did not have any negative impact on patients' general condition and no serious vaccine-related adverse events have been reported.

Median overall survival after vaccination for the subgroup of 5 patients with poor prognosis (subgrouping according to generally accepted so-called Heng-criteria) is currently at 8 months and has thus already exceeded the expected median overall survival of 5 months with interferon treatment and 7.8 months with modern targeted therapies.

Three of the five patients in the poor prognosis group also have an unusual tumor type, so called extensive sarcomatoid tumor transformation, which impairs the prognosis further. Median survival in these 3 patients is currently at 6 months from the time of diagnosis compared to the expected 3 months.

Noteworthy is that 2 of 5 patients (40%) in the poor prognosis group currently have survived for more than 15 months after vaccination, and both are still alive. These figures can be compared with an expected 15-month survival rate of approximately 15 % in patients with poor prognosis who are treated with interferon and about 25 % in patients treated with targeted therapies.

The observation period is still too short to draw any conclusions about how the median overall survival in the subgroup with intermediate prognosis (7 patients) stands in relation to the expected median. Two patients have already passed the expected median survival of 14 months for patients treated with interferon. The first patient treated has now survived for almost 22 months after vaccination and has not required any further treatment.

Looking at the entire patient population of 12 patients, 10 patients are still alive. The Company will continue to monitor survival data after the final study report has been submitted to the Medical Products Agency, which is expected in Q1 2014.

- The vaccine-related increases in circulating tumor-specific lymphocytes in 9 of 11 examined patients, as well as the massive intratumoral infiltration of potentially tumor killing CD8 + T-cells, noted in 5 of 12 analyzed primary tumors, also give good support to the expected mechanism of action, said Immunicum's Chief Scientific Officer, Associate Professor Alex Karlsson-Parra. According to available scientific publications, the intratumoral infiltration of CD8 + T-cells in the 5 patients is the most massive ever reported in therapeutic cancer vaccination, in animal studies as well as in human studies. In addition, massive intratumoral infiltration of CD8 + T-cells seems to correlate with prolonged survival in our patients with sarcomatoid tumor transformation.

- Even if we have only treated a limited number of patients, with no control arm, all these results are very encouraging, especially as current therapies are often associated with severe side effects. We therefore look forward to test our vaccine in a larger phase II-study that we plan to launch during next year, says CEO, Jamal El-Mosleh.

Immunicum's vaccine cells are comprised of so-called allogeneic dendritic cells, which through a unique processing system are developed into effective immune activating cells. Immunicum's unique vaccine concept is based on over 30 years of research in the field of transplantation immunology and, by use of a new method, activates the body's own immune system to attack tumor cells. Immunicum's shares have been traded since April 22, 2013 on NASDAQ OMX First North under the ticker IMMU.

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### **About Immunicum AB (publ):**

Immunicum AB (publ) develops cancer immunotherapies. Its two main groups of therapeutic cancer vaccines, SUBCUVAX<sup>®</sup> and INTUVAX<sup>®</sup>, and the method of expansion of tumor-specific T-cells (CD70) is based on the Nobel prize awarded discovery of the dendritic cell and its central role in the activation of the specific immune response. Since the raw material consists of allogeneic dendritic cells, Immunicum's products can be produced in large scale. The vaccines are now undergoing clinical trials in renal cell carcinoma and hepatocellular carcinoma.

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