

## **Immunicum receives approval to start phase II study with the therapeutic cancer vaccine INTUVAX**

**Gothenburg, 17 February 2015. Immunicum AB (publ) today announced that the Swedish Medical Products Agency has granted the Company's application to commence a phase II clinical trial in patients with renal cell carcinoma with the therapeutic cancer vaccine INTUVAX in Sweden. In addition to an approval from the Ethics Committee to start the trial in Sweden, Immunicum will also need clearance from a number of other European regulatory authorities to start enrollment of patients in more countries during spring 2015.**

INTUVAX is a therapeutic cancer vaccine being developed to treat solid tumors such as kidney cancer and liver cancer. The upcoming phase II trial has been designed based on the promising results obtained in a phase I/II trial in patients with metastatic renal cell carcinoma. A follow-up of this study shows that the median survival in a subgroup of five high-risk patients is over 22 months, which compares with an expected median survival of nine months, with current standard treatments.

- With the Medical Products Agency's approval in place, we are now approaching the start of the extensive phase II study, which we hope will further highlight the efficacy and safety of INTUVAX as treatment for metastatic renal cell cancer - a disease for which there is a great need for better therapies, says Jamal El-Mosleh, CEO of Immunicum.

In an unblinded, randomized, multicentre study (MERECA-study), the efficacy and safety of INTUVAX, and INTUVAX in combination with the tyrosine kinase inhibitor sunitinib, will be compared with only sunitinib treatment.

INTUVAX will be injected into the primary tumors on two occasions before surgical removal of the kidney. For patients with poor prognosis, combination therapy with sunitinib is initiated six weeks after surgery, whereas patients with intermediate prognosis receive sunitinib only if the disease shows signs of progression. This approach makes it possible to evaluate the effect of INTUVAX as monotherapy, but also the potentially synergistic effect in combination with a drug that inhibits immunosuppression.

- The reason we want to study the effect of INTUVAX in combination with sunitinib is that this drug inhibits the immunosuppression that is associated with most cancers, including renal cell cancer. It should make it easier for

CD8-positive T cells to exert their cancer-inhibiting effect, which we have seen signs of in the completed phase I/II trial, says Immunicum's Chief Scientific Officer, Dr. Alex Karlsson-Parra.

Immunicum plans to include a total of 90 patients at around twenty hospitals in Europe. Patients will be randomized 2:1 and the aim is to include 60 % of the patients with intermediate risk prognosis and 40 % of the patients with high-risk prognosis. Patients will be followed for 18 months with the primary objective to evaluate the median overall survival for high-risk patients treated with INTUVAX in combination with sunitinib. CD8-positive T-cells' ability to fight cancer cells is central to the INTUVAX-concept. Therefore, emphasis will be placed on documenting the infiltration of such cells in primary tumors, metastases and healthy tissue. The trial is expected to be completed by the end of 2017 but the study design gives Immunicum ongoing valuable information that – assuming that the data is positive - both can facilitate the planning of future studies and increase the possibilities of out-licensing of the project.

**For further information, please contact:**

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**About Immunicum**

Immunicum AB (publ) develops therapeutic cancer vaccines. A phase II study of the Company's most advanced project - INTUVAX® against renal cancer - has been approved by the Swedish Medical Products Agency and is expected to start in spring 2015. The project portfolio contains three additional projects against various tumors, including an ongoing clinical study in patients with liver cancer.

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