Press release

Immunicum presents safety and survival data from a clinical phase I/II study with INTUVAX in patients with liver cancer

GOTHENBURG, December 3, 2014. Immunicum AB (publ) today published an interim report on the safety and survival data from the ongoing phase I/II study with INTUVAX in patients with primary liver cancer. Based on the results achieved so far, an independent safety committee has approved that the next six patients may receive a higher dose of the vaccine, with 20 million vaccine cells on three occasions.

Six patients to date have been treated of which five have been vaccinated on three occasions with INTUVAX at a dose of 10 million vaccine cells. All of these five patients had experienced progression of their tumor disease after previous conventional first-line treatment. No serious vaccine-related adverse events have so far been reported for INTUVAX.

The expected median survival after completion of first-line treatment is highly variable, depending on the individual patient's residual liver function at baseline. The limited number of patients in the current study, and the current short observation time, makes it impossible to draw any reliable statistical conclusions about the effectiveness of the vaccine. It should however be noted that three of the five patients who received all three doses of INTUVAX already have surpassed the expected median survival time. One patient, who did not receive the usual standard treatment before vaccination, experienced very rapid disease progression already prior to the first vaccination and deceased before the third vaccination could be implemented.

Through a protocol amendment, approved by the Medical Products Agency, Immunicum has also been able to include a patient with bile duct cancer, which was first interpreted as primary liver cancer, in the ongoing liver cancer study. The patient received three doses of INTUVAX (10 million cells/dose), and showed no signs of serious side effects. Since the patient showed signs of tumor progression at a computed tomography (CT) scan six months after vaccination, the patient was treated with gemcitabine (which is known to inhibit the immunosuppressive cells in tumors) in combination with cisplatin. Renewed CT scans three months later showed a clear regression of the tumor mass. The patient has now lived for 10 months post the first vaccine dose compared with the expected median survival of about 11 months in newly diagnosed patients with bile duct cancer who are treated with gemcitabine combined with cisplatin.

- We now look forward to the opportunity to evaluate a higher dose of INTUVAX in patients with primary liver cancer as this tumor type is associated with massive inherent immunosuppression. We are also encouraged by the response shown by the patient with bile duct cancer following add-on treatment with established drugs and see this as further signs of synergistic effect between INTUVAX and treatments that

are capable of fighting immunosuppression, says Immunicum's Chief Scientific Officer, Alex Karlsson-Parra.

– It is reassuring that no severe side effects of INTUVAX have been noted in this safety study so far, and that we see preliminary signs of prolonged survival in some of these critically ill patients. However, we must keep in mind that these are interim data from a limited study, says Immunicum's CEO, Jamal El-Mosleh.

The clinical study is conducted on patients with primary liver cancer (hepatocellular carcinoma) and is implemented in collaboration with the Transplant Center at Sahlgrenska University Hospital in Gothenburg. Principal investigator is Dr. Magnus Rizell, who is also chairman of the Swedish national health care program for liver cancer and chairman of the Swedish tumor registry of cancer of the liver and bile ducts. The first patient was treated during the fourth quarter of 2013 and the study is expected to close in 2015. The goal is to treat a total of 12 patients.

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About Immunicum AB (publ)

Immunicum AB (publ) develops vaccines for the treatment of tumor diseases. A phase II study of the company's most advanced project - INTUVAX® against renal cancer - is expected to start in early 2015. The project portfolio contains three further projects against various tumor diseases, including liver cancer.

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