Press release

Immunicum updates safety and survival data in liver cancer study with INTUVAX

GOTHENBURG, April 23, 2015. – Immunicum AB (publ) today reported updated safety and survival data in the ongoing phase I/II study with INTUVAX in patients with primary liver cancer. Six out of eight included liver cancer patients were able to receive all three vaccine doses with encouraging survival data for four of these six fully vaccinated patients.

The interim update on safety and survival data from the phase I/II study with INTUVAX in patients with primary liver cancer (clinicaltrials.gov identifier NCT01974661), an open-label study with the primary purpose of studying patient safety and immunological response, shows that no serious vaccine-related adverse events have been observed so far. The study is planned to include a total of twelve patients and final data is expected to be reported by the end of this year.

To date, eight (8) patients diagnosed with primary hepatocellular carcinoma (HCC) have been treated in addition to one patient with bile duct cancer. Of the HCC-patients, six (6) have been given all three INTUVAX doses (five at 10 million vaccine cells/dose and one at 20 million vaccine cells/dose). All patients had experienced progression of their tumor disease after conventional first-line treatment before being assigned to INTUVAX.

The expected median survival after completion of first-line treatment in HCC is highly variable, depending on the individual patient's residual liver function at baseline. The limited number of patients in the current safety evaluation study will not allow for a definitive conclusion on the therapeutic efficacy of the vaccine.

However, it is noted that out of the six (6) patients who have received all three scheduled doses of INTUVAX, four (4) have surpassed their expected median survival time. All patients are classified at baseline according to the Child-Pugh (CP) liver function score with a median survival for patients with CP scores 5 and 6 of 8.3 and 4.3 months respectively (Shao et al, Journal of Hepatology 2014; 60: 313). In the ongoing study, three (3) of these four (4) patients are still alive 5.5 months and 10 months (both CP score 6) and 13 months (CP score 5) after vaccination. The fourth patient with a CP score of 6 lived for 7.3 months.

Two (2) patients experienced a very rapid disease progression already prior to the first vaccination and deceased before the second and third vaccination, respectively, could be implemented.

Through a study protocol amendment, approved by the Swedish Medicinal Products Agency, Immunicum has also been allowed to include a patient with bile duct cancer, which was first interpreted as primary liver cancer. The patient received three doses of INTUVAX (10 million cells/dose) and showed no signs of serious side effects. When tumor progression was observed at a computed tomography (CT) scan six

months after full vaccination, treatment with gemcitabine (which is known to inhibit the immunosuppressive cells in tumors) in combination with cisplatin was initiated. Renewed CT scans three months after initiation of the treatment showed a clear regression of the tumor mass and regression was still evident after 6 months. The patient with bile duct cancer has now lived for 15.2 months post the first vaccine dose compared with an expected median survival of 11.7 months (Valle et al N Engl J Med 2010: 362:1273) for patients with bile duct cancer who are treated with gemcitabine combined with cisplatin.

Only four patients so far have been evaluated with regard to immunological response, including the patient diagnosed with bile duct cancer. Two patients have shown an increased number of tumor specific circulating CD8+ T cells after third vaccination compared to before vaccination. No evaluation of intratumoral infiltration of CD8+ T cells has been done as no biopsies have been taken.

– Liver cancer is associated with massive inherent immunosuppression, making it a highly appropriate target for treatment with INTUVAX. We now look forward to continue the evaluation of the higher dose of INTUVAX in the remaining four HCC patients to be included, says Immunicum's Chief Scientific Officer, Alex Karlsson-Parra.

– We are also really 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 a synergistic effect between INTUVAX and established treatments capable of fighting immunosuppression, Karlsson-Parra continues.

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About INTUVAX

INTUVAX is a therapeutic cancer vaccine being developed for treatment of solid tumors. Its active ingredient is processed dendritic cells from healthy donors. In short, dendritic cells are a type of withe blood cells with an antigen-presenting function in the body’s adaptive immune defense. INTUVAX is believed to cause an inflammatory reaction at the vaccine site that subsequently leads to activation of tumor-specific cytotoxic T lymphocytes (CTLs) attacking cancer cells. In a phase II study in patients with metastatic renal cell carcinoma, the infiltration of CD8 positive CTLs will be documented in primary tumors, metastases, and healthy tissue.

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 – started in the first half of this year. The project portfolio contains three further projects against various tumor diseases, including liver cancer.

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