

Immunicum updates safety and survival data in phase I/II liver cancer study with INTUVAX

GOTHENBURG, 24 August 2015 - Immunicum AB (publ) today released an updated report on safety and survival data from the ongoing phase I/II study with INTUVAX for patients with primary liver cancer. Of a total of seven fully treated patients, four showed a prolonged survival as compared to expected based on historical data. Two of the three patients that are still alive have not yet passed their expected median overall survival.

The update on safety and survival data for the ongoing phase I/II trial (IM-102), with INTUVAX for patients with primary liver cancer (NCT01974661), showed that no serious side effects have been attributed to the vaccine. The study's open design makes it possible to gather data continuously. A total of twelve liver cancer patients will be included in the study.

To date, nine (9) patients diagnosed with primary hepatocellular carcinoma (HCC) have been treated. Seven (7) patients have received all three planned INTUVAX doses. All patients had experienced tumor progression (tumor growth) on conventional first-line treatment before they were put on treatment with INTUVAX.

Noted is that out of the seven (7) patients who received all three planned INTUVAX doses, four (4) patients showed a survival that exceeded the expected median overall survival. Two of the seven fully treated patients who have not yet passed their expected median survival are still alive.

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.

- We are pleased that the survival data continues to progress well. Three patients remain to include in the study, even though we have screened many potential study candidates who have not been recruited to the study due to pre-defined inclusion criteria. We have been in close contact with the study center conducting the trial and have great confidence for the work they are doing to recruit patients to the study. A status update will be provided at the end of the year where we hope to announce more concrete plans on how we intend to pursue the continuation of the project, says Immunicum's CEO, Jamal El-Mosleh.

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 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 six months. The patient with bile duct cancer has now lived for 19 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.

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About INTUVAX

INTUVAX is an immunooncology product developed for the treatment of solid tumors. Its active ingredient comprises activated dendritic cells from healthy donors. INTUVAX is injected intratumorally and is supposed to cause an inflammatory reaction that ultimately leads to activation of tumor-specific cytotoxic T lymphocytes (CTLs) attacking cancer cells in the primary tumor and in metastases. In an ongoing phase II study in patients with metastatic renal cancer, the presence and infiltration of CD8+ T cells/CTLs in the primary tumor, metastases and in healthy tissue is evaluated.

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 – has been initiated. The project portfolio contains an additional clinical phase I/II project in liver cancer.

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