

Lund July 18th, 2019

Press Release

HAMLET Pharma Announces Results of First Major Clinical Trial for a New Cancer Killing Molecule

Successful clinical trial – Alpha1H shows high efficacy without toxicity

Hamlet Pharma is proud to announce the successful outcome of the Phase I/II trial, aimed at studying the safety and efficacy of **Alpha1H** in patients with bladder cancer. The first data analysis has revealed highly significant differences between the **Alpha1H** treated patients and the placebo group, for several crucial efficacy variables. Treatment was also shown to be safe, as no drug-related side effects were observed.

Alpha1H triggered significant shedding of cells in all tumor patients, who received the treatment ($p < 0.0001$). In addition, **Alpha1H** triggered the excretion of whole tumor fragments into the urine ($p < 0.0001$), illustrating the potent effect compared to the placebo group.

Alpha1H triggered cell death in the tumor, as shown by cytolysis and apoptosis, a beneficial form of cell death. These findings support the key mechanisms of action of **Alpha1H** discovered in the laboratory and the successful translation from the laboratory to the clinic.

Carefully selected safety variables were recorded according to safety guidelines. The effects of **Alpha1H** occurred without drug-related side effects in the patients, consistent with the lack of toxicity observed in animal models of bladder cancer.

The clinical trial of 40 patients (20 placebo and 20 with treatment who received 6 infusions over 22 days) has been a technical success, due to the competence and commitment of the different study teams involved. A team of experts at the Motol University Hospital in Prague handled patient enrolment, clinical care, pathology assessments and treatment. The study was monitored by a highly renowned, clinical trial CRO in Prague. Scientific coordination was from Lund University, where research sample analysis was handled and molecular information obtained. Additional study variables will be communicated as soon as data is available.

*“This is a bench-to-bedside moment and we are grateful to all, who have made this possible. The results inspire us to continue the efforts making **Alpha1H** available to cancer patients”*
says Catharina Svanborg, founder, CMO and chairman of the board of Hamlet Pharma Ltd.

“This is a very important milestone for the company. We need more evidence but hopefully this could be the gentle chemotherapy of the future,” says Mats Persson, CEO of Hamlet Pharma Ltd.

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Notes to Editors

A research group in Lund led by Professor Catharina Svanborg discovered in 1995 that a component of human breast milk kills tumour cells without harming mature, healthy cells. Further experiments and studies have shown that the effect is due to the most common protein in human milk, alpha-lactalbumin, but in a new shape, bound to oleic acid. This new biological complex was called Human Alpha-lactalbumin Made Lethal to tumour cells, abbreviated HAMLET, and is a tumoricidal protein-lipid complex, formed by two GRAS (generally regarded as safe) molecules present in human milk. The novel therapeutic entity HAMLET is formed specifically when the human milk protein alpha-lactalbumin undergoes a conformational change and binds to oleic acid.

HAMLET Pharma plans to conduct further studies in bladder cancer and several other cancer indications, such as colon cancer and brain tumors; all hard to cure with current therapies. HAMLET Pharma has 35 patents for the manufacturing and use of HAMLET as well as the second-generation Alpha1H derivative of the HAMLET molecule. HAMLET has been found to kill more than forty types of cancer cells to date in laboratories. The work has been published in leading international journals like The New England Journal of Medicine, GUT commented in Nature Reviews Gastroenterology and PNAS (Proceedings of the National Academy of Science, USA).

About HAMLET Pharma

HAMLET Pharma, listed on Spotlight, develops drugs based on the unique tumoricidal protein-lipid complex, HAMLET, formed by two natural and harmless molecules found in breast milk. Development focuses primarily on drugs, for the treatment and prevention of cancer. HAMLET kills tumour cells and has proven safe in proof-of-concept studies in animal models. HAMLET has also shown therapeutic efficacy on skin papillomas in a placebo-controlled clinical trial and caused shedding of dead cancer cells, after injection into the bladders of patients with bladder cancer. A phase I/II clinical trial was recently concluded in patients with bladder cancer, using the synthetic peptide-based compound Alpha1H. HAMLET is a registered trademark of HAMLET Pharma.

This information is insider information that Hamlet Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication through the agency of the contact persons set out above, on July 18, 2019.