Lund May 10th, 2021

Press Release

Marked increase in tumor response with higher doses of Alpha1H

Hamlet Pharma is proud to announce the successful outcome of the dose-escalation study, which is an extension of the Phase I/II trial. Patients with bladder cancer were treated with increasing doses of Alpha1H, following a dose-escalation protocol. The initial data analysis has revealed a dramatic increase in the tumor response to Alpha1H, measured both as shedding of tumor fragments into the urine and as changes in remaining tumor tissue.

Hamlet Pharma has previously reported the successful completion of the Phase I/II bladder cancer study using a 1.7 mM dose of Alpha1H. We have now performed a dose-escalation study, using 8.5 or 17 mM, i.e. five or ten times higher doses in patients with superficial bladder cancer.

Alpha1H triggered massive shedding of tumor cells and tumor fragments into patient urine. A dose-dependent increase was demonstrated, resulting in significantly higher shedding than in the first study ($P<0.0001$). As shown earlier, significant cell shedding did not occur in the placebo group, supporting a treatment effect.

Major effects on tumor tissue were detected by histopathology of tumor biopsies, obtained at surgery after the end of treatment. Tumor fragmentation and shedding of tumor fragments was visible and the remaining tumor showed a loss of viability, with large areas of cells undergoing apoptosis or necrosis.

Apoptosis is a beneficial, non-toxic form of cell death, and a desirable outcome to limit the side effects of cancer therapy. In addition to the apoptotic changes in the tumors, a pronounced apoptotic response was detected in cells and tumor fragments shed by the treated patients, confirming that Alpha1H accelerates cell death in the tumor.

Furthermore, the tumor fragments in urine were shown to contain large amounts of Alpha1H, confirming the efficiency with which the higher doses of Alpha1H reach tumor tissue. The results suggest that uptake of Alpha1H by the tumor triggers apotosis, tumor fragmentation and release of the affected tumor fragments by shedding into the urine.

"'The dose-dependet increase in tumor response is dramatic and provides further motivation to develop Alpha1H for therapeutic use in bladder cancer," says Catharina Svanborg, founder and chairman of the board of Hamlet Pharma Ltd.

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"The results support our strategy to develop Alpha1H for Phase III trials" says Mats Persson, CEO of Hamlet Pharma Ltd.

For more information, please contact

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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. Alpha1H is the synthetic variant of HAMLET, which has enabled development of the agent for clinical trials. Alpha1H kills different types of tumour cells and has demonstrated therapeutic effects on bladder cancer in animal models. Hamlet Pharma has one ongoing Phase I/II clinical trial with Alpha1H in patients with bladder cancer, a costly form of cancer that is difficult to treat, and intends to expand its activities into other types of cancer. The first results from the ongoing clinical Phase I/II study shows no side effects of Alpha1H, indicating that the treatment is safe and well tolerated. Alpha1H also demonstrated clinical efficacy compared with patients who received placebo. In addition, Hamlet Pharma develops BAMLET, which is a molecular complex formed by bovine α-lactalbumin and oleic acid. Data from animal models suggest that local BAMLET treatment may be effective against colon cancer.

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 May 10, 2021 at 10.25 CET.

The project is coordinated by Prof. Catharina Svanborg and CEO Mats Persson of Hamlet Pharma. This project is funded from the European Union's Horizon 2020 research and innovation programme under grant agreement No 954360.