

Lund October 29, 2021

Press Release

Hamlet Pharma secures Alpha1H production for continued clinical trials

It is a great pleasure to announce that Hamlet Pharma has secured the production of larger quantities of Alpha1H, using a stable, large scale manufacturing process. The new batches will be essential to extend the clinical trial program in patients with bladder cancer.

The clinical trial program in bladder cancer is proceeding according to plan, using Alpha1H secured from previous production rounds. Larger amounts of Alpha1H will be needed moving forward, as the clinical trial program is expanding to involve larger patient numbers.

As previously announced, Hamlet Pharma is collaborating with Rechon Life Science for the production and formulation of the drug candidate Alpha1H. Rechon Life Science AB is a manufacturer approved for pharmaceutical supply worldwide, including the US. Together with Hamlet Pharma, Rechon has now successfully established large scale Alpha1H production technology. Production is carried out in accordance with Good Manufacturing Practice (GMP) and Alpha1H, packaged for clinical use, will be distributed to the clinical trial site.

“Scaling up the production of Alpha1H is essential for the growth of Hamlet Pharma and for future clinical trials” says Catharina Svanborg, CMO and chairman of the board of Hamlet Pharma Ltd.

“Securing a robust production of our drug candidate is an important milestone for the company”, says Mats Persson, CEO of Hamlet Pharma Ltd.

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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 October 29, 2021 at 12.55 CET.

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.



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.