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Press Release

Ethical approval for the bladder cancer clinical study

Hamlet Pharma takes a further step towards the start of the clinical study in patients with bladder cancer. The company has received ethical approval of the clinical study protocol and the study organization. Ethical approval is required to start the clinical study and to evaluate the effects of Alpha1H in this patient group.

It is essential that new drugs undergo rigorous scrutiny by relevant authorities. This includes strict rules for production of GMP drug substance, proper testing for possible toxic effects and ethical committee approval. As recently announced, HAMLET Pharma has successfully completed GMP production of the Alpha1 peptide as well as toxicology studies, showing no evidence of bladder toxicity. We can now add approval of the study protocol by the ethical authority at the study site in Prague.

The clinical study is designed as a placebo-controlled study, in patients diagnosed with bladder cancer. This Phase I / II study will be conducted according to Good Clinical Practice (GCP), applicable guidelines and regulatory requirements. Hamlet Pharma has prepared the protocol for the clinical trial in collaboration with a highly competent clinical trial organization in Prague, together with the researchers at Lund University, who have extensive experience in this field.

"Ethical committee approval is a prerequisite for starting clinical studies and we are pleased that the ethics committee in Prague shares our view on the design of the study" says Professor Catharina Svanborg, Chairman of the Board.

"Together with the Prague clinic we have developed a study protocol that will address the safety profile and the effect of Alpha1H" says Mats Persson, CEO.

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Hamlet Pharma company listed on AktieTorget, is a company engaged in drug development based on a tumoricidal protein-lipid complex, HAMLET, formed by two natural and harmless molecules found in breast milk. The development aims to develop drugs that primarily will be used for the treatment and prevention of cancer. HAMLET effectively kills tumor cells but have also proven to be safe in the proof-of-concept studies done on humans. The substance has demonstrated therapeutic effect on skin papillomas in a placebo-controlled clinical trial and causes shedding of dead cancer cells by injection into the bladder in patients with bladder cancer. Hamlet Pharma intends to initiate a phase II study with Alpha1H in patients with bladder cancer, a difficult and costly cancer form. HAMLET is a registered trademark of Hamlet Pharma.