

Lund 4th November, 2016

Press Release

Agreement with Production Partner for HAMLET Peptide

Hamlet Pharma reaches the important goal of establishing large-scale production of the drug candidate for Phase II clinical trials. For this purpose, Hamlet Pharma now signs a production and development agreement with PolyPeptide Laboratories Holding (PPL) AB. PPL is part of the PolyPeptide Group - one of the largest contract manufacturers of peptides and peptide-related molecules in the world. PolyPeptide is represented globally with manufacturing facilities in the US, Europe and India that have been approved by the FDA.

The implementation of Phase II clinical studies requires large quantities of the drug candidate, produced in accordance with Good Manufacturing Practices (GMP). Hamlet Pharma has therefore finalised an agreement with PPL to manufacture the HAMLET Peptide α 1 for production of the peptide-lipid complex α 1H. The contract also includes Ready-to-file documentation in the so-called CTD format for the drug substance, according to the guidelines of the European authorities and the American FDA.

This production method offers significant advantages compared to other alternatives, as the peptide can be produced at a much lower cost and with a less complex process for GMP approval. Moreover, recently issued patents significantly extend the patent life of the HAMLET peptide complex. It is important to note that the efficiency of the peptide-oleate complex as a killer of tumour cells is similar to HAMLET.

We envisage that peptide production will make it possible for the company to also explore additional clinical indications as well as new out-licensing strategies in selected therapeutic areas.

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About Hamlet Pharma

Hamlet Pharma AB owns and develops a new technology to kill cancer cells without harming healthy tissues. The HAMLET technology is focused around the HAMLET family of tumoricidal protein-lipid complexes, formed by naturally occurring molecules from human milk and extended to include recombinant variants of the natural substance. HAMLET has validated therapeutic efficacy in clinical studies and animal models, and in many different cellular models of human cancer. HAMLET will now be developed further for Phase II clinical trials, to verify the positive proof of concept studies. Hamlet Pharma AB shares are listed at AktieTorget. HAMLET is an abbreviation for Human Alpha-lactalbumin Made LEthal to Tumor cells.