



PRESS RELEASE

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Hamlet BioPharma secures drug manufacturing at Phase III quality and release of Alpha1H for distribution to clinical trial sites

Hamlet BioPharma today announces the successful release of the Phase III quality batch of Alpha1H for use in clinical trials of bladder cancer in Europe and the US. Large-scale manufacturing of Alpha1H has been established since the start of the clinical program, with an increase in volumes and technical adjustments during successive phases of the program. The production at Phase III quality requires an extensive and complex development process, which now has been completed.

A Phase III trial requires increased production capacity, and advanced technical and drug quality control programs must be in place. Drug production at Phase III quality is therefore costly and extremely demanding. Hamlet BioPharma has completed the production of a first batch of Alpha1H at Phase III quality, which is now released for clinical use.

To meet the increased demand for Phase III-grade material, Hamlet BioPharma has also expanded its production of the Alpha1 peptide. The company has indentified Porton Pharmaceutical Chemicals GMBH as an advanced and cost effective pharmaceutical manufacturing infrastructure. The Alpha1 peptide production technology has been adjusted by Porton to meet the requirements of a Phase III trial and the production site has been extensively audited for alignment with international market requirements.

Hamlet BioPharma is continuing the successful collaboration with Rechon Life Science AB, a manufacturer approved for pharmaceutical supply worldwide, including the US. Together with Hamlet Pharma, Rechon has successfully produced and packaged Alpha1H at Phase III quality, for use at the clinical trial sites.

The timing of the Phase III adjusted manufacturing process is ideal for the start of the trials. In preparation for increased future demands, HAMLET is also producing additional Alpha1H batches in collaboration with Porton Pharmaceutical Chemicals GmbH and Rechon Life Science AB.

"Our strategy is to ensure that the drug is available for clinical use, and the timing is impeccable," says Catharina Svanborg, Founder and Chairman of the Board of Hamlet BioPharma.

“We are delighted to have reached this crucial point with our manufacturing partners” says Hans Wännman, CMC specialist assisting Hamlet BioPharma.

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