PRESSRELEASE

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Hamlet BioPharma receives U.S. FDA Fast Track designation for Alpha 1H for the treatment of non-muscle invasive bladder cancer

Lund, Sweden, November 29, 2023. Hamlet BioPharma AB (publ), the pharmaceutical company with a strong portfolio of projects for the treatment of cancer and infections, announces today that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for its drug candidate Alpha1H for the treatment of non-muscle invasive bladder cancer. The U.S. FDA Fast Track Designation accelerates the approval process for Alpha 1H and potential for reaching the US market.

Hamlet BioPharma has been working closely together with its US partner Target Health, receiving the FDA's 'Fast Track Granted' letter, which adds this latest important milestone in the development of Alpha1H following last June's FDA clearance of the investigational new drug application (IND) for this compound. Fast Track Designation conveys eligibility to Sponsors to aid in their development program such as more frequent meetings and communication with FDA regarding Accelerated Approval and Priority Review in later development stages if relevant criteria are met.

With no severe toxicity detected in studies to date, Alpha1H acts as an anti-cancer therapeutic, based on a synthetic-variant of the protein-lipid complex. Targeting and killing tumor cells with great precision, Hamlet BioPharma is developing this peptide-based molecular approach as an effective cancer drug pipeline with a high degree of selectivity against a variety of cancers. The Fast track status will also be essential for the dialogue with potential commercial partners.

"We are excited to receive Fast Track Designation from the US FDA as a wonderful affirmation of the results generated to date for Alpha1H aligning with the aims *of the program to positively impact patients with an early Non-Muscle-Invasive-Bladder-Cancer treatment option."* comments Catharina Svanborg, Chairman of the Board, Founder and Lead Researcher.

"I'm very proud of the studies performed by our team and the recognition we have received for the quality of our work validated by major international authorities, including the European commission earlier this year and now the FDA, through this Fast track designation."

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