PRESS RELEASE

Lund, June 22th, 2026

Clinical trial expansion in the US, in collaboration with the University of Iowa, to treat high-risk, resistant, non-muscle-invasive bladder cancer (NMIBC)

Hamlet BioPharma AB (publ) today announced the signing of a clinical trial agreement with the University of Iowa, one of the leading U.S. centers for bladder cancer research and therapy. The new study advances the clinical development of Alpha1H, a human breast milk derived treatment for bladder cancer, to include Carcinoma In Situ (CIS); a severe surface-spreading and therapy-resistant form of bladder cancer where patients may need to remove their bladders to avoid systemic disease.

Professor O'Donnell, a key opinion leader and driver of the international bladder cancer therapy field, has identified a significant unmet medical need among patients with CIS and initiated discussions with Hamlet BioPharma and scientists at Lund University, regarding this clinical expansion of the Alpha1H drug development program. This collaboration follows an extensive scientific and clinical evaluation of Alpha1H by the University of Iowa, including review of published clinical data and the mechanism of action described in peer-reviewed publications.

Bladder cancer is one of the most common urological malignancies worldwide. A substantial proportion of patients experience recurrence following treatment, creating a significant need for new therapies that can reduce recurrence rates and preserve bladder function. The clinical study is planned to be conducted under Hamlet BioPharma's existing Investigational New Drug (IND) application for Alpha1H in the United States through submission of a new clinical protocol amendment to the U.S. Food and Drug Administration (FDA).

"The signing of this agreement establishes a collaboration with the University of Iowa group, led by Professor O'Donnell, who are pioneers in the field and have defined multiple novel therapies in bladder cancer. Expanding the clinical indications to include CIS allows us to evaluate Alpha1H in a patient population with severe and resistant disease and a substantial unmet medical need," says Catharina Svanborg, Professor at Lund University and Chairman of the Board of Hamlet BioPharma.

"Despite advances in bladder cancer treatment, high recurrence rates remain a major challenge. Many patients with CIS have exhausted all available treatments, without a cure, and are faced with the prospect of bladder removal. Based on our evaluation of Alpha1H and the clinical results generated to date, we believe the Alpha1H treatment warrants further investigation in this patient group. We look forward to working with Hamlet BioPharma and the scientists at Lund University to explore the potential of Alpha1H in patients with treatment

resistant CIS," says Michael O'Donnell, Professor and Director of Urologic Oncology at the University of Iowa.

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About BCG-Unresponsive Carcinoma In Situ

Carcinoma in situ of the bladder is a high-grade, flat urothelial tumor that, while non-muscle-invasive, carries significant risk of progression to muscle-invasive disease if inadequately treated. Intravesical Bacillus Calmette-Guérin (BCG) immunotherapy is the standard of care for high-risk NMIBC including CIS, yet a substantial proportion of patients — estimated at 30 to 50 percent — fail to achieve or sustain a complete response. The FDA defines BCG-unresponsive disease as persistent or recurrent CIS within 12 months of adequate BCG therapy, a designation that has become the regulatory benchmark for trials in this indication. Patients meeting this definition who are unwilling or medically unfit for radical cystectomy represent a vulnerable population with urgent unmet needs.

The University of Iowa's Bladder Cancer Program is one of the highest-volume centers for the diagnosis and management of non-muscle-invasive bladder cancer in the United States. The program's research activities encompass doublet intravesical drug delivery, urothelial tumor immunology, biomarker discovery, personalized medicine and health outcomes research. Faculty investigators have contributed to hundreds of peer-reviewed publications in the field over the past decade. The University of Iowa maintains an annotated biorepository of bladder cancer tissue and urine specimens collected under IRB-approved protocols, and its dedicated phase I/II clinical trials unit has enrolled patients in multiple prior NMIBC studies.

This research is funded in part by Hamlet BioPharma under a sponsored research agreement with the University of Iowa. The financial terms of the agreement have been reviewed and disclosed in accordance with the University of Iowa's institutional conflict-of-interest policies. No investigator holding a financial interest in Hamlet BioPharma will serve in a patient-facing role in this study. Results of the pilot study will be submitted for publication in a peer-reviewed journal regardless of outcome.

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