

# FDA Clearance of IND Application for Alpha1H for the treatment of non-muscle invasive bladder cancer

Hamlet Pharma is proud to announce today that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for Alpha1H, a highly selective synthetic peptide for treatment of non-muscle invasive bladder (NMIBC). Working closely with their US based partner, Target Health LLC, a New Jersey-based, full-service CRO, the FDA's 'Study May Proceed' letter begins a hopeful new chapter for the treatment of NMIBC patients globally. Studies with Alpha1H show a combination of a lack of toxicity with a high selectivity for cancerous cells, resulting in massive cell shedding in solid tumors.

“ This milestone for Alpha1H underscores the urgency of our mission to bring this innovative therapy to unmet needs in the treatment of NMIBC patients. The FDA's clearance of the Hamlet IND bolsters our plans to expand clinical research in the future for this important compound.” says Catharina Svanborg, Chairman of the Board/Founder, Lead Researcher.

**About the Alpha1H Clinical Program** - The clinical trial, now open with the US FDA, clears the path to next phases with possible future trials in the US and other international markets.

Treatment of non-muscle-invasive bladder cancer includes transurethral resection of bladder tumor (TURBT) followed by intravesical BCG immunotherapy. Alpha1H treatment acts as an ablative-type treatment for early-stage patients and is administered during the period after diagnosis and prior to TURBT. This period is usually a non-interventional period, and Alpha1H would be considered an adjuvant treatment which could benefit patients awaiting TURBT and improve outcomes.

With no toxicity detected in studies to date, Alpha1H acts as an anti-cancer therapeutic, based on a synthetic-variant of the protein-lipid complex in human breast milk, alpha-lactalbumin and oleic acid. The alpha-lactalbumin protein, known to be essential for the survival of lactating mammals, targets and killing tumor cells with great precision, Hamlet Pharma is developing this peptide-based molecular approach as an effective cancer drug pipeline with a high degree of selectivity against a variety of cancers.

## For more information, please contact

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