Hamlet BioPharma Receives FDA Pivotal-Study Feedback for Novel Neoadjuvant Therapy in Non–Muscle Invasive Bladder Cancer

HAMLET BioPharma, a clinical-stage biopharmaceutical company advancing targeted oncological and other therapies, today announced it has received written feedback from the U.S. Food and Drug Administration (FDA) supporting a pivotal development path for Alpha1H, a first-in-class neoadjuvant therapy for patients with low-risk non–muscle invasive bladder cancer (NMIBC).

This latest interaction with the US FDA follows the previous successful face-to-face interaction with the Agency last June 2025. FDA's letter, specific and helpful, evidenced both serious and enthusiastic support for the program. Alpha1H has so far exhibited little to no toxicity in the clinic and offers low-risk NMIBC patients treatment in the neoadjuvant phase of disease, for which currently there are no therapy options available.

Helpful in advancing Hamlet's marketing objectives for Alpha1H, the FDA's comments focused on a pivotal clinical design. Next steps for Hamlet BioPharma and their partners will be to put these collaborative fruits to good use with the full protocol development.

Highlights from the FDA Interaction

- The FDA's written feedback supports the overall pivotal study design framework proposed by Hamlet BioPharma, including patient population, key efficacy endpoints, and statistical approach.
- The Agency provided guidance on primary and key secondary endpoints appropriate for low-risk NMIBC, including complete response (CR) rate and duration of response and event-free survival, along with the safety database size.
- FDA aligned on Hamlet's plan to utilize central pathology review, blinded independent review (as applicable), and standardized cystoscopic assessment intervals.

- Hamlet intends to incorporate the Agency's recommendations and initiate enrollment in the next stage of the clinical program pending completion of routine CMC activities and institutional review board (IRB) approvals.

Next Milestones

- Finalize protocols and engage first study sites Q1 – Q2 2026.
- Complete CMC readiness packages, including process and formulation optimization, stability testing, and pharmaceutical development plans.
- Evaluate potential expedited-program designations with FDA.

"The Oncology Division at FDA has been extraordinarily helpful and collaborative, and we celebrate this latest interaction as a major step forward for the Alpha1H program, getting us closer than ever to making this therapy available to patients in the shortest time possible. We are grateful for the FDA's support and look forward to next steps, to implement this feedback into the clinical program and begin study enrollment team she has assembled, with the consultants Target Health in the US and InClino un Europe."says Hamlet CEO, Catharina Svanborg.

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