Hamlet BioPharma Receives European Regulatory Approval for Phase III Study of Alpha1H in Bladder Cancer

Hamlet BioPharma, a pharmaceutical company specializing in the development of novel treatments for cancer and infectious diseases, today announces regulatory approval from the European Medicines Agency (EMA) for its Phase III clinical study of Alpha1H in bladder cancer. The approval represents a milestone crucial for the clinical development of Alpha1H and provides a clear regulatory path toward a potential future marketing application in Europe.

The submission documents including the study protocol were based on the prior scientific dialogue with the Czech State Institute for Drug Control (SÚKL) during the Phase II program and further refined in close collaboration with the U.S. Food and Drug Administration (FDA), supported by regulatory experts at InClino in Europe and Target Health in the USA. Hamlet BioPharma is pleased to acknowledge the constructive and efficient review process of the Regulatory Authority and Ethics Committee, who contributed to a high-quality submission and smooth approval process.

The European Phase III study will be conducted in partnership with the group of Professor Marek Babjuk at the Second Faculty of Medicine, Charles University in Prague. The same team recently completed the successful Phase II study of Alpha1H in patients with non-muscle invasive bladder cancer (NMIBC), which demonstrated promising anti-tumor activity and a favorable safety profile. As a result of this approval, patients with low- to intermediate-risk NMIBC will now have access to Alpha1H treatment within the framework of the clinical study.

"Receiving regulatory approval in Europe for our Phase III study is a defining step for the Alpha1H development program, required to support a future marketing application. The approval recognizes the quality of our work and supports the progression of our clinical development. We look forward to initiating patient recruitment without delay," says Catharina Svanborg, Chairman of Hamlet BioPharma.

''We are proud of the rapid approval process and the productive dialogue between the EMA and the study organization'' says Petr Bouska, expert advisor to Hamlet Biopharma.

For further information, please contact

Catharina Svanborg, Chairman of the Board, Hamlet BioPharma AB, +46 709 42 65 49

catharina.svanborg@hamletpharma.com

Jakob Testad, CEO, Hamlet BioPharma AB, +46 708 48 42 10

jakob.testad@hamletbiopharma.com

www.hamletbiopharma.com