



PRESS RELEASE

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Pre-initiation visit in Prague, for the Phase III trial of Alpha1H in bladder cancer

Hamlet BioPharma AB (publ) today conducted a pre-initiation visit at the Department of Urology at Charles University, Prague, led by Professor Marek Babjuk, a key international opinion leader in bladder cancer therapy. Prague is an important center for bladder cancer research and trials of novel therapies, and the trial technology and collaboration with Hamlet BioPharma and Lund University is established. Professor Babjuk's group conducted the recently completed, successful Phase II study of Alpha1H in patients with non-muscle invasive bladder cancer (NMIBC). The Phase III study strengthens the commercial potential of Alpha1H and the future market opportunities for the drug.

Bladder cancer is a significant unmet medical need and the costliest cancer form in the USA, due to high recurrence rates and cancer progression. Despite available treatments, patient remain at risk of recurrence, creating a need for less toxic therapies. The Phase III study is based on an extensive scientific and clinical evaluation of Alpha1H by the FDA (Food and Drug Administration, USA), including reviews of published clinical data and the mechanism of action described in peer-reviewed publications.

“Despite advances in bladder cancer treatment, recurrence remains a major challenge for many patients. Based on our evaluation of Alpha1H and the clinical results generated to date, we believe the treatment warrants further investigation in the neo-adjuvant setting. We look forward to exploring the potential of Alpha1H to improve outcomes for patients with bladder cancer”, says Marek Babjuk, Professor of Urology and Dean of the Medical School at the Charles University in Prague.

“The Phase III trial represents an important step in our clinical and commercial development. The Phase III study collaboration with the Prague team and Professor Babjuk allows us to evaluate Alpha1H in this patient population with longer follow up and comparisons to the standard of care”, says Catharina Svanborg, Professor at Lund University and Chairman of the Board of 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