PRESS RELEASE

Lund, January 25, 2024

New analyses of clinical data from Alpha1H treated patients with bladder cancer detect a strong immune response with known anti-tumor effects

Hamlet BioPharma's drug candidate Alpha1H has been shown to affect a majority of tumors in treated patients with cancer of the urinary bladder. A new analysis now provides a further explanation for this strong effect, based on an immune response in the treated patients with known anti-tumor effects. Thus, in addition to killing tumor cells and inducing tumor cell shedding, Alpha1H activates a broad immune response, which adds a strong protective potential against cancer. The manuscript for this study has been submitted for publication.

Alpha1H complex kills several types of cancer cells *in vivo.* In clinical studies, the complex has shown therapeutic effects in a randomized, placebo-controlled study of patients with non-muscle invasive bladder cancer and increased effects in patients treated with higher doses, with almost no toxicity. Alpha1H-instillations in the bladder of the patients triggered a rapid tumor response, quantified as the shedding of tumor cells into the urine within two hours of treatment. Tumor cell death was accompanied by a strong apoptosis-like response in the tumor and shed cells contained large amounts of Alpha1H, identifying potent effects of the peptide-lipid complexes on bladder cancer tissue.

The new analysis detected an unexpected but very encouraging immune response in patients treated with Alpha1H, with strong anti-tumor potential. We found that this immune response was activated by Alpha1H immediately after the first treatment, and was sustained during the treatment period of one month. The immune response also increased with the treatment dose. The activation of the immune system adds power to the anti-tumor effects of Alpha1H and an additional way in which the tumor can be attacked and neutralized, as Alpha1H creates a multifunctional therapeutic environment.

Alpha1H treatment activates the immune response directly in the tumor area, resulting in a predominantly local effect. A further advantage of Alpha1H treatment is the lack of severe side effects in the treated patients, except for local irritation at the site of injection, which often accompanies local therapies.

The new analysis further shows that the immune response profile in Alpha1H treated patients with early tumors is rapid and at least as strong as that reported in of patients treated with BCG, which today is the drug of choice for many patients with more severe bladder cancer. Ongoing shortage of BCG supply in the USA and many countries, reported by the Food and Drug Administration, is expected to continue for years resulting in patients not getting full treatments, emphasizing the need for new alternative treatments. The publication will be evaluated during a review process before being considered for publication.

For further information, please contact:

Catharina Svanborg, Chairman and Founder of Hamlet BioPharma, +46-709 42 65 49
catharina.svanborg@hamletpharma.com

Martin Erixon, CEO Hamlet BioPharma, +46-733 00 43 77
martin.erixon@hamletpharma.com

www.hamletbiopharma.com