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## **PRESS RELEASE**

Lund, April 3, 2024

## Immune responses in patients treated with Alpha1H - results published in the journal Cancer Medicine

Hamlet BioPharma announced on January 25 that clinical data showed a strong immune response with anti-tumor potential in Alpha1H-treated patients with bladder cancer. The submitted manuscript has now been approved and published in Cancer Medicine.

http://doi.org/10.1002/cam4.7091

The analysis shows an unexpectedly strong immune response in patients treated with Alpha1H. The rapid immune response was activated after the first Alpha1H treatment and persisted during the treatment period. The immune response increased with the treatment dose and has a strong anti-tumor potential. The results show that Alpha1H creates a multifunctional treatment environment in the tissue, with direct killing of tumor cells, secretion of tumor cells and bits of tumor, and an immune response that can attack the tumor.

Alpha1H treatment also activates the immune response directly in the tumor area, resulting in a predominantly local effect. An additional benefit of Alpha1H treatment is that treated patients do not experience serious side effects, except for local irritation at the injection site, which often accompanies local treatments.

It is interesting to note that the immune response profile in Alpha1H-treated patients with early tumors is rapid and at least as strong as in patients treated with BCG (Bacillus Calmette-Guerin), which is the drug of choice for many patients with more severe bladder cancer. The current shortage of BCG in the U.S. and other countries, reported by the Food and Drug Administration<sup>1</sup>, is expected to continue for several years, emphasizing the need for new alternative treatments.

<sup>&</sup>lt;sup>1</sup> <u>https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages</u>

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