PRESS RELEASE

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Alpha1H treatment shows strong effects in patients with bladder cancer in final analysis published in Cancer Medicine

Hamlet BioPharma, the pharmaceutical company, specializing in the development of drugs for cancer and infections, announces that Hamlet BioPharma's drug candidate Alpha1H has shown potent treatment effects on the majority of tumors in patients with cancer of the urinary bladder. The final analysis from placebo-controlled and dose-escalation studies is now published in Cancer Medicine, https://doi.org/10.1002/cam4.70149. The paper entitled ''Clinical and molecular response to alpha1-oleate treatment in patients with bladder cancer'' presents data on all study endpoints, confirming the therapeutic effects against tumors compared to placebo, with a lack of drug-related side effects observed in these patients.

Clinical effects of alpha1-oleate were quantified in patients with non-muscle invasive bladder cancer (NMIBC), using a randomized, placebo-controlled study protocol. Patients with NMIBC were treated by intra-vesical instillation of increasing concentrations of alpha1-oleate (Alpha1H) and the treatment response was defined relative to the placebo group.

Strong, dose-dependent anti-tumor effects were detected in Alpha1H treated patients for a combination of molecular and clinical indicators. A complete or partial response was observed in 88% of the tumors in the 8.5 mM group, compared to 47% of tumors treated with 1.7 mM of Alpha1H. The frequency of tumors with a complete response increased from 27% in the 1.7 mM to 44% in the 8.5 mM group. The average size reduction was 59% in the 8.5 mM group compared to 30% in the 1.7 mM group and 5% in the placebo group.

Treatment further triggered rapid tumor cell death by apoptosis, which is a beneficial mechanism of cell death with low toxicity. Alpha1H reached tumor tissue where it was taken up, as shown by the increased detection of Alpha1H in tumor biopsies from patients treated with the higher treatment dose. Intravesical Alpha1H administrations were followed by rapid, dose-dependent

tumor cell shedding, resulting in increased cell numbers in the urine after each instillation, compared to each pre-instillation sample. The response was dose dependent, as defined by significantly higher cell numbers in patients receiving 8.5 mM compared to 1.7 mM of Alpha1H.

Alpha1H treatment further inhibited the expression of cancer gene networks, including bladder cancer genes. Tumor tissue that remained after treatment was changed in most patients, had lost tumor characteristics, and become more similar to healthy tissue. Drug-related side effects were not recorded, except for local irritation at the site of instillation.

These dose-dependent anti-tumor effects of Alpha1H are promising and support its potential in patients with NMIBC, initially as a neoadjuvant, targeting newly diagnosed tumors or recurrences. This potential has been acknowledged by the FDA (Food and Drug Administration, USA), which has awarded Alpha1H Fast Track status as a neoadjuvant for the treatment of bladder cancer.

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