Press Release

MonTa Biosciences starts collaboration with the National Cancer Institute in the US through its Nanotechnology Characterization Laboratory to strengthen development of its lead candidate MBS8 for cancer treatment

September 8, 2020.

MonTa Biosciences, a Danish biotech company located in Copenhagen, today announced that the company has entered into collaboration with the Nanotechnology Characterization Laboratory (NCL) of Frederick National Laboratory for Cancer Research on behalf of the National Cancer Institute (NCI). The NCL, located in Maryland, USA, will perform preclinical characterization of MonTa Biosciences' lead candidate, a nanotechnology-based cancer immunotherapy product. The collaboration aims to advance the science which facilitates more efficient translation to clinical studies.

MonTa Biosciences lead candidate MBS8 has demonstrated superior preclinical data in mouse models of cancer and a favorable safety profile, as compared to other products. MBS8 is a nanoparticle formulation that boosts the immune system to fight cancer. MBS8 is active as monotherapy treatment with strong antitumor activity in a majority of tumor models, in some cases with complete cure of all mice. In combination with PD-1 treatment, MBS8 is able to rescue PD-1 resistance and show a strong synergistic activity in a number of models. MBS8 also show strong synergy when combined with chemotherapy or radiotherapy, with many mice in complete remission and ability to resist subsequent re-challenge, demonstrating generation of protective immunity in these mice. In addition, MBS8 production has been scaled to large amounts with long stability properties. The NCL has reviewed this encouraging preliminary data and found them satisfactory to meet the acceptance criteria of the NCL assay cascade and enable the entry of MBS8 into the NCL's preclinical characterization program to produce further knowledge about MBS8 as it translates towards clinical trials. MonTa Biosciences will file a Clinical Trial Application in Europe in Q4, 2020, and start a phase I/IIA study in patients with advanced solid tumors in Q1, 2021.

The NCL was founded in 2004 by the Food and Drug Administration (FDA), National Institute of Standards and Technology (NIST) and the National Cancer Institute (NCI), to improve the knowledge on nanomaterials used in medicine and enable their informed clinical translation. NCL's "assay cascade" is an exclusive and attractive program for companies to engage with due to their depth of experience in the characterization and development of nanoparticles for cancer treatment. Access to the NCL program is granted via a competitive application process, and selected characterization is provided free of charge for partners that are selected.

NCL is run by the Frederick National Laboratory for Cancer Research, Contractor, operated by Leidos Biomedical Research Inc., on behalf of the National Cancer Institute (NCI) under contract 75N91019D00024, task order 75N91019F00129.

MonTa Biosciences CEO, Simon S Jensen said “We are very excited to have the support of NCL to develop our lead candidate product MBS8 into clinical trials”, and continues “NCL is one of the most experienced laboratories in the world characterizing nanomedicine products, and it is a great honor for MonTa Biosciences to be enrolled in this program”.

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About Monta Biosciences

MonTa Biosciences is a biotech company located in Copenhagen, Denmark, and work with a cancer immunotherapy nanoparticle called micelles, which incorporates a TLR7 agonist. Our lead candidate MBS8 has shown superior antitumor activity in mouse models of cancer, and a favorable safety profile. MBS8 is unique compared to other innate immune stimulators through the micelle formulation that targets specific immune cells after intravenous administration, but with reduced risk of systemic cytokine release. The MBS8 formulation activates certain immune cells that migrate into the tumor tissue shortly after treatment, leading to immediate tumor cell death. This is followed on a longer timescale by invasion of cells from the adaptive immune system, leading to protective immunity. Furthermore, MBS8 has a favorable kinetic profile after multiple administrations compared to other nanoparticles, with nearly identical half-life and PK parameters at multiple injections.

MonTa Biosciences start clinical phase I/IIA in Q1, 2021 at clinical sites in Europe, in cancer patients with advanced solid tumors. The trial is designed with a dose escalation phase and an expansion phase to provide safety data for a phase IIB trial in monotherapy and combination with existing cancer therapies.

The MBS8 micelles were developed at The Danish Technical University using a TLR7 agonist developed by University of California San Diego and is covered by two strong IP positions.

MonTa Biosciences is privately owned and has recently raised a series A investment to complete its phase I /IIA study.

Read more about MonTa Biosciences here

Read more about NCL here