



NantKwest Announces FDA Authorization of IND Application for Mesenchymal Stem Cell Product for the Treatment of Severe COVID-19 Patients

May 18, 2020

- Preliminary data from NantKwest collaborators suggests mesenchymal stem cell treatments may benefit COVID-19 patients with acute respiratory distress syndrome and cytokine storm
- Trial anticipated to initiate in Los Angeles area hospitals in Q2
- Proprietary automated “GMP-in-a-Box”, an in-house manufacturing apparatus, enables rapidly scalable, off-the-shelf allogeneic mesenchymal stem cell product BM-Allo.MSC

EL SEGUNDO, Calif.--(BUSINESS WIRE)--May 18, 2020-- NantKwest, Inc. (NASDAQ: NK) today announced it has received authorization from the U.S. Food and Drug Administration (FDA) for an Investigational New Drug application to treat patients with acute respiratory distress syndrome (ARDS) caused by COVID-19 with BM-Allo.MSC, an allogeneic mesenchymal stem cell (MSC) product derived from human bone marrow. NantKwest has entered into an agreement with the National Marrow Donor Program (Be the Match) to provide donor material and has developed automated proprietary methods to expand and generate multiple dose forms utilizing a modular, closed system (GMP-in-a-box) from NantKwest affiliate ImmunityBio, Inc., to expand BM-Allo.MSCs, enabling the scalable manufacture and immediate distribution of cryopreserved BM-Allo.MSC product.

“There is an urgent need to develop broadly accessible treatment options for the devastating outcomes seen in the thousands of COVID-19 patients who are facing severe disease with ARDS and ‘cytopathic storm’,” said Patrick Soon-Shiong, M.D., Chairman and Chief Executive Officer of NantKwest and ImmunityBio. “While MSC-derived treatments have shown promise in treating patients with ARDS, including those with COVID-19, the ability to scale production to support the overwhelming patient need has been a challenge. Our proprietary GMP-in-a-Box enables the rapid and scalable manufacture of our fully human BM-Allo.MSC product, overcoming this previous limitation to advance a promising new treatment to those patients who are most in need. Due to our proprietary methods, we are well positioned to rapidly advance BM-Allo.MSC during the current wave of COVID-19, with an anticipated trial initiation in Q2.”

BM-Allo.MSC is a bone marrow-derived allogeneic MSC product being developed to attenuate the inflammatory processes that drive ARDS in severe COVID-19 patients. MSCs are multipotent progenitor cells that give rise to cell types responsible for tissue repair and may restore effective immune function and contribute to viral clearance. Prior work with allogeneic MSC products in patients with ARDS has shown that such treatment is safe and may reduce key markers of inflammatory processes.

Trial Design

The Phase 1b, randomized, double-blind, placebo-controlled study will evaluate the safety and efficacy of BM-Allo.MSC versus current supporting care in treating patients with severe disease and requiring ventilator support (IND 019735). The therapeutic will be administered to a total of 45 patients receiving care in the critical care or ICU setting. The primary objectives of the study include overall safety and reduction in time on ventilator. The secondary objective will focus on the efficacy of BM-Allo.MSC in reducing the number of days patients require oxygen, duration of hospitalization, and mortality.

About NantKwest

NantKwest (NASDAQ: NK) is an innovative, clinical-stage immunotherapy company focused on harnessing the power of the innate immune system to treat cancer and virally-induced infectious diseases. NantKwest is the leading producer of clinical dose forms of off-the-shelf natural killer (NK) cell therapies. The activated NK cell platform is designed to destroy cancer and virally-infected cells. The safety of these optimized activated NK cells—as well as their activity against a broad range of cancers—has been tested in Phase I clinical trials in Canada and Europe, as well as in multiple Phase I and II clinical trials in the United States. By leveraging an integrated and extensive genomics and transcriptomics discovery and development engine, together with a pipeline of multiple, clinical-stage, immuno-oncology programs, NantKwest's goal is to transform medicine by delivering off-the-shelf living drugs-in-a-bag and bringing novel NK cell-based therapies to routine clinical care. NantKwest is a member of the [NantWorks](#) ecosystem of companies. For more information, please visit www.nantkwest.com

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Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements concerning or implying that NantKwest will be successful in improving the treatment of cancer and/or Covid-19. Risks and uncertainties related to this endeavor include, but are not limited to, obtaining FDA approval of NantKwest's NK cells, as well as other therapeutics, as part of the NANT Cancer Vaccine platform as a cancer treatment and/or Covid-19 treatment.

Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements.

These and other risks regarding NantKwest's business are described in detail in its Securities and Exchange Commission filings, including in

NantKwest's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2020. These forward-looking statements speak only as of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

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