MannKind Partners With NRx Pharmaceuticals To Explore A Dry Powder Formulation Of ZYESAMI™ (aviptadil) Based On The Technosphere® Platform

August 4, 2021

NRx was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for ZYESAMI™ (aviptadil) for the treatment of Critical COVID-19 with respiratory failure; currently in clinical trials

WESTLAKE VILLAGE, Calif., Aug. 4, 2021 /PRNewswire/ -- **MannKind Corporation** (Nasdaq: MNKD) has partnered with NRx Pharmaceuticals (Nasdaq: NRXP) (NRx) to evaluate the feasibility of formulating a dry powder formulation of ZYESAMI ™(aviptadil), a synthetic form of human Vasoactive Intestinal Peptide (VIP) – an endogenous substance produced by the body that helps protect cells against inflammatory conditions. An intravenous formulation of ZYESAMI is currently in clinical trials, having been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of Critical COVID-19 with Respiratory Failure.

"We continue to explore ways that our Technosphere technology can deliver unique compounds in a targeted and convenient manner for patients with serious lung diseases," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "The novel coronavirus continues to be a factor around the world, and we are just beginning to bear witness to its long-term effects on the lungs."

Rapid recovery from Critical COVID-19 with Respiratory Failure has been reported in patients treated with open label VIP under a Phase 2b/3 clinical trial and in an FDA Expanded Access Program. Emerging data indicates that VIP binds uniquely to receptors on Alveolar Type II cells preventing cell death, stopping replication of the coronavirus in the Type II cells and upregulating the production of surfactant – the loss of which is increasingly implicated in COVID-19 respiratory failure.

"As we continue to identify beneficial effects of VIP in treating various respiratory disorders, development of a convenient dosing method that offers stability at room temperature is key to long term success," said Prof Jonathan Javitt, MD, MPH, CEO and Chairman of the Board, of NRx. "We are pleased to be working with MannKind to develop an inhaled form of ZYESAMI which may offer patients an easier and more therapeutic option."

MannKind will begin exploring formulation potential at its research and manufacturing facility located in Danbury, Conn., which features a full range of development and manufacturing capabilities, including analytical, chemical, formulation, filling and packaging. It has sufficient filling capacity to produce more than 300 million cartridges of inhaled drug annually.

About MannKind Corporation
MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of inhaled therapeutic products for patients with endocrine and orphan lung diseases. MannKind is currently commercializing Afrezza® (insulin human) Inhalation Powder, the Company's first FDA-approved product and the only inhaled ultra-rapid-acting mealtime insulin in the United States, where it is available by prescription from pharmacies nationwide. Afrezza is also available by prescription in Brazil, where it is commercialized by the Company's partner, Biomm SA. MannKind was established in 1991, and is headquartered in Westlake Village, Calif., with a manufacturing and R&D facility based in Danbury, Conn. The Company also employs field sales and medical representatives across the U.S. Please visit mannkindcorp.com to learn more.

Forward-looking Statements
This press release contains forward-looking statements that involve risks and uncertainties. Words such as "plans," "expects," "intend," "will," "targeted," "potential" and similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements regarding the potential to create a dry powder formulation of a new compound and to treat certain diseases. Such forward-looking statements are based upon MannKind's current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the risk that continued testing of product candidates may not yield successful results. These and other risks are detailed in MannKind's filings with the Securities and Exchange Commission ("SEC"), including under the heading "Risk Factors" in MannKind's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 12, 2021. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.

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