MannKind Announces Ralinepag Dry Powder Inhalation (DPI) Program to be Pursued for Pulmonary Hypertension and Fibrotic Lung Diseases

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- *The formulation is being developed in collaboration with United Therapeutics Corporation*
- *United Therapeutics made an additional $5 million payment to MannKind to support the rapid advancement of ralinepag DPI*
- *United Therapeutics plans to be the primary manufacturer of ralinepag DPI*
- *MannKind eligible to receive up to $35 million in development milestones plus 10% royalties on net sales*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., May 06, 2026 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a company focused on the development and commercialization of inhaled therapeutic products, today announced that it has been developing a dry powder inhalation (DPI) formulation of ralinepag, known as ralinepag DPI (MNKD-1501), for United Therapeutics Corporation (Nasdaq: UTHR), under the companies' expanded license and collaboration agreement announcement from August 2025.

Ralinepag is an investigational prostacyclin receptor agonist that exhibits a long half-life and high potency in the pulmonary vasculature. In March 2026, United Therapeutics reported that its long-term pivotal phase 3 ADVANCE OUTCOMES study of ralinepag extended-release tablets in pulmonary arterial hypertension (PAH) met its primary endpoint with high statistical significance.

"Supported by the strength of the pivotal ADVANCE OUTCOMES results, we believe ralinepag has the potential to redefine the PAH treatment landscape, and we view ralinepag DPI as an important component of long-term success to help broaden real-world use and support patients over time," said Martine Rothblatt, Ph.D., Chairperson and Chief Executive Officer of United Therapeutics.

United Therapeutics believes the half-life of ralinepag may support once-daily dosing of ralinepag DPI. The companies are currently in the process of formulating ralinepag DPI for United Therapeutics' planned non-clinical studies and a subsequent phase 1 study in healthy volunteers to assess dosing and pharmacokinetic comparability with oral ralinepag tablets, which will then inform a pivotal study in PAH patients to further assess safety and PK comparability. United Therapeutics initially intends to seek approval of ralinepag DPI for PAH. The company also plans to develop the product for pulmonary hypertension associated with interstitial lung disease (PH-ILD), idiopathic pulmonary fibrosis (IPF), and progressive pulmonary fibrosis (PPF), which will require additional clinical studies assessing safety and efficacy in patients with these conditions. Ralinepag is currently not approved in any jurisdiction to treat any of these conditions, in any formulation.

"We have been working on the ralinepag DPI formulation for the past six months and are excited to finally be able to share this announcement," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "We are pleased to apply our dry powder development expertise to advance ralinepag DPI. This program further validates MannKind's role as a partner of choice for inhaled delivery of complex and high-value therapeutics."

Financial Terms and Collaboration Structure
Ralinepag DPI (MNKD-1501) is being advanced under the companies' existing worldwide collaboration agreement, pursuant to which United Therapeutics leads global development, regulatory, and commercialization activities and MannKind supports formulation and supply activities. United Therapeutics made an additional $5 million payment to MannKind in April 2026, to support the rapid advancement of ralinepag DPI. MannKind is eligible to receive up to $35 million in development milestone payments and 10% royalties on net sales of any resulting commercial product.

The original 2018 agreement with United Therapeutics led to the successful development and FDA approval of Tyvaso DPI® in May 2022. In 2025, United Therapeutics reported that Tyvaso DPI generated revenue of $1.3B.

About MannKind
MannKind Corporation (Nasdaq: MNKD) is a biopharmaceutical company dedicated to transforming chronic disease care through innovative, patient-centric solutions. Focused on cardiometabolic and orphan lung diseases, we develop and commercialize treatments that address serious unmet medical needs, including diabetes, pulmonary hypertension, and fluid overload in heart failure and chronic kidney disease. With deep expertise in drug-device combinations, MannKind aims to deliver therapies designed to fit seamlessly into daily life. Learn more at mannkindcorp.com and follow us on LinkedIn, Facebook, Instagram, and X.

Forward-Looking Statements
Statements in this press release that are not statements of historical fact are forward-looking statements that involve risks and uncertainties. These statements include, without limitation, statements regarding the potential development of an investigational product and receipt of milestone payments and royalties. Words such as "believes", "anticipates", "plans", "expects", "intends",

“will”, “goal”, “potential” and similar expressions are intended to identify forward-looking statements. These 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 an investigational drug product may not yield successful results or results that are consistent with earlier testing, and other risks detailed in MannKind’s filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2025 and subsequent periodic reports on Form 10-Q and current reports on Form 8-K. 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.

TYVASO DPI is a registered trademark of United Therapeutics Corporation.

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