FDA Determines that Afrezza REMS Communication Plan Has Met Goals and REMS No Longer Necessary

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WESTLAKE VILLAGE, Calif., April 25, 2018 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq:MNKD), focused on the development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension, today announced that the Food and Drug Administration (FDA) has completed its review of a supplemental New Drug Application (sNDA) for Afrezza (insulin human) inhalation powder and has determined that the Risk Evaluation and Mitigation Strategy (REMS) communication plan regarding the risks of Afrezza has been completed and has met its goals. As a result, the FDA has decided that a REMS is no longer required for Afrezza.

“We are pleased that the FDA determined that a communication plan is no longer necessary to ensure the benefits of Afrezza outweigh its risks and that a REMS is no longer required,” stated Dr. David Kendall, Chief Medical Officer of MannKind. “We are grateful for the FDA’s guidance and expediency in this process, and we look forward to advancing our goal of establishing inhaled insulin as a preferred treatment option for individuals with diabetes who require mealtime glucose control.”

The FDA approved the original REMS for Afrezza in June 2014, and a REMS modification took effect in April 2015. The REMS consisted of a communication plan intended to inform prescribers of Afrezza of the potential risks associated with the use of Afrezza as described in the boxed warning. Two subsequent REMS assessments were conducted following Afrezza’s approval, and both assessments found that the communication plan met its goals.

The release of the REMS means that no further assessments are necessary; had it not been released, additional assessments would have been conducted at seven years post-approval. The Afrezza website, www.afrezzarems.com, will be inactivated, and the Company will no longer be required to distribute the Afrezza fact sheet at scientific meetings.

About Afrezza®
Available by prescription, Afrezza® (insulin human) inhalation powder is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. Afrezza consists of a dry powder formulation of human insulin delivered from a small and portable inhaler. Administered at the beginning of a meal, Afrezza dissolves rapidly upon inhalation to the lung and passes quickly into the bloodstream (in less than one minute). This rapid absorption allows Afrezza to begin reducing blood sugar levels within about 12 minutes of administration. Afrezza is available in 4-unit, 8-unit and 12-unit single-dose cartridges of insulin powder that can be used, as prescribed by a health care professional, in combination with other diabetes medications to achieve target blood sugar levels. For Afrezza doses exceeding 12 units, patients may use a combination of existing cartridge strengths. For more information on Afrezza, please visit www.afrezza.com.

About MannKind
MannKind Corporation (NASDAQ:MNKD) focuses on the development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension. MannKind is currently commercializing Afrezza® (insulin human) inhalation powder, the Company's first FDA approved product and the only inhaled rapid-acting mealtime insulin in the United States, where it is available by prescription from pharmacies nationwide. MannKind is headquartered in Westlake Village, California, and has a state-of-the art manufacturing facility in Danbury, Connecticut. The Company also employs field sales and medical representatives across the U.S. For further information, visit www.mannkindcorp.com.

Forward-Looking Statements
This press release contains forward-looking statements that involve risks and uncertainties. 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 detailed in MannKind's filings with the SEC, including its annual report on Form 10-K for the year ended December 31, 2017. 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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