



Afrezza® (insulin human) Inhalation Powder Approved in Brazil

06/03/19

Afrezza® is the only orally inhaled ultra rapid-acting mealtime insulin approved by ANVISA in Brazil. The innovative delivery system reduces injections while improving glycemic control in adult patients with diabetes

WESTLAKE VILLAGE, Calif. and BELO HORIZONTE, Brazil, June 03, 2019 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq:MNKD) and BIOMM SA (BVMF:BIOM3) today announced that Afrezza® (insulin human) Inhalation Powder, an ultra rapid-acting mealtime insulin to improve glycemic control in adult patients with diabetes mellitus, has been registered by the Brazilian Health Regulatory Agency (ANVISA). The commercialization of Afrezza in Brazil is expected to begin in the fourth quarter this year, subject to the pricing registration process by Câmara de Regulação do Mercado de Medicamentos (CMED).

"The regulatory approval of Afrezza in Brazil is an important milestone for MannKind and our partner Biomm. It not only represents our first international approval of Afrezza, but more importantly, we now have the opportunity to bring a novel mealtime insulin therapy to patients in a country with one of the highest prevalence of diabetes in the world, according to the International Diabetes Federation," said Michael Castagna, Chief Executive Officer of MannKind Corporation.

Afrezza is an ultra rapid-acting orally inhaled insulin therapy indicated to improve glycemic control in adult patients with diabetes mellitus. Afrezza consists of a dry powder formulation of human insulin delivered using a small, discreet and easy-to-use inhaler. Administered at the start of a meal, Afrezza dissolves rapidly upon inhalation to the deep lung and passes quickly into the bloodstream (in less than one minute). Glucose-lowering effects are achieved within minutes of administration, and clinical data with Afrezza demonstrates proven efficacy and safety in the treatment of both type 1 and type 2 diabetes.

"Insulin was first isolated and purified for clinical use in 1923 and now, almost 100 years later, we are excited that patients in Brazil are expected to soon have access to Afrezza, the only non-injectable oral insulin available in the market," said Heraldo Marchezini, President Director/CEO of Biomm SA. "We believe that Afrezza, with its distinct time-action profile and route of administration, will address many of the unmet needs for mealtime insulin therapy and has the potential to change the way that diabetes is treated. As a pioneering biotechnology company, we are proud to leverage our portfolio of diabetes products and offer another option to treat the significant and growing numbers of patients with diabetes in Brazil."

Currently, diabetes mellitus affects 425 million adults worldwide, including more than 12 million in Brazil, according to the International Diabetes Federation. Diabetes mellitus is characterized by the body's inability to regulate levels of blood glucose properly. Insulin, a hormone produced by the pancreas, normally regulates the body's glucose levels, but in people with diabetes mellitus insufficient levels of insulin are produced or the body fails to respond adequately to the insulin it produces.

ABOUT MANNKIND CORPORATION

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 orally inhaled ultra 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 and research facility in Danbury, Connecticut. The Company also employs field sales and medical representatives across the U.S. For further information, visit www.mannkindcorp.com.

ABOUT BIOMM SA

Biomm's mission is to develop, produce and market global competitive biomedicines with quality and accessibility. The company's focus is developing biological products, aiming to guarantee national self-sufficiency. Due to its innovator DNA, the company is pioneer in biotechnological drugs in Brazil. Founded in 2002, Biomm's headquarters and factory are in Nova Lima (MG), with capacity to produce 20 million vials of insulin per year, based on advanced and innovative technologies that guarantee the medicines quality. The company is listed on the Brazilian stock exchange (BVMF: BIOM3). For further information access www.biomm.com.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements that involve risks and uncertainties. Words such as "believes", "anticipates", "plans", "expects", "intend", "will", "goal", "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon MannKind's and Biomm'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 these risks and uncertainties, which include, without limitation, the risks detailed in MannKind's filings with the Securities and Exchange Commission. 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 neither MannKind nor Biomm undertakes any obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.

MannKind Corporation

Rose Alinaya
Investor Relations
818-661-5000
ir@mannkindcorp.com

Biommm S/A

Bruna Sales - +55 11 3147 7423 | c: +55 11 94836 6956
bruna.sales@maquinacohnwolfe.com

Raquel Tomacelli - +55 11 3147-7906 | +55 11 98048-8022
raquel.tomacelli@maquinacohnwolfe.com

Nancy Campos - + 55 (11) 3147-7900 | + 55 11 97574-9149
nancy.campos@maquinacohnwolfe.com

The logo for MannKind, featuring the word "mannkind" in a bold, lowercase, sans-serif font. The letters are a vibrant magenta color. The letter 'i' in "kind" has a small dot above it.

Source: MannKind