



MannKind and BIOMM Submit Registration Dossier to Brazilian Health Regulatory Agency (ANVISA)

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WESTLAKE VILLAGE, Calif. and BELO HORIZONTE, Brazil, Oct. 23, 2017 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq:MNKD) (TASE:MNKD) and BIOMM SA (B3:BIOM3) announced the submission of a registration dossier to ANVISA, seeking the approval of Afrezza® (insulin human) inhalation powder in Brazil.

The registration dossier includes recently updated prescribing information for Afrezza, incorporating new clinical data describing the rapid time-action profile of Afrezza.

"We are excited to file our first international application for approval of Afrezza in Brazil, which is in the top ten countries with the highest diabetes rates in the world according to the World Health Organization," said Michael Castagna, Chief Executive Officer of MannKind Corporation. "BIOMM's expertise in the diabetes market allowed the dossier to be updated quickly with the revised prescribing information, thereby providing physicians and patients, if and when Afrezza is approved in Brazil, with accurate information to achieve better glycemic control at mealtime."

BIOMM, the first Brazilian biopharmaceutical company, is responsible for registering the product with ANVISA. After approval, the drug will be submitted to CMED (the Brazilian drug price control agency) for release, after which MannKind will supply Afrezza to BIOMM, who will be responsible for the promotion, distribution and sales of Afrezza in Brazil.

"We intend to offer Brazilian patients an important technological innovation. Like all chronic diseases, diabetes needs prolonged adherence to treatment. Therefore, more comfortable and effective options may be a differentiating attribute that has the potential to contribute to the quality of life of the patient," said Heraldo Marchezini, Chief Executive Officer of BIOMM SA.

ABOUT MANNKIND CORPORATION

MannKind Corporation (NASDAQ:MNKD) (TASE: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.

ABOUT BIOMM SA

Biom SA (BOVESPA:BIOM3) is the first Brazilian biopharmaceutical company and the only human biotech company listed on the Brazilian BOVESPA Stock Exchange. The company is committed to making difficult-to-treat chronic diseases more cost-effective, thereby improving the quality of life for patients. With innovation in its DNA, Biom is pioneer in biotechnology and in the production of insulin in Brazil. For further information, please visit the web page: www.biom.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties, including statements regarding MannKind's and its partner's ability to directly commercialize pharmaceutical products. 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 the 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 these risks and uncertainties, which include, without limitation, the ability to obtain regulatory approvals, the ability to get satisfactory pricing terms from regulators and other risks detailed in MannKind's filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the year ended December 31, 2016 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.

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