



CDSCO Approves Afrezza® (insulin human) Inhalation Powder in India

12/11/24

- *India has the 2nd highest burden of diabetes worldwide*
- *CDSCO decision follows existing approvals in the U.S.A. and Brazil*
- *MannKind expects to ship product for Cipla Ltd. by end of 2025*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Dec. 11, 2024 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a company focused on the development and commercialization of innovative inhaled therapeutic products and devices for patients with endocrine and orphan lung diseases, and Cipla Ltd. announced today that the Central Drugs Standard Control Organisation (CDSCO) in India has approved Afrezza (insulin human) Inhalation Powder in adults. The CDSCO decision follows existing approvals in the United States and Brazil.

“Achieving approval for Afrezza in India, a country with the second highest burden of diabetes worldwide, is an exciting milestone for MannKind and our partner Cipla,” said Michael Castagna, PharmD, Chief Executive Officer for MannKind Corporation. “We are excited for Cipla to market the first inhaled insulin treatment option for adults living with diabetes in India and expect to prepare product for export by the end of 2025.”

MannKind entered into an exclusive marketing and distribution agreement for Afrezza in India with Cipla Ltd., a global pharmaceutical company, in May 2018. Under the terms of the agreement, Cipla was responsible for obtaining regulatory approvals to distribute Afrezza in India as well as marketing and sales activities. MannKind is responsible for supplying Afrezza to Cipla.

“The availability of Afrezza has the potential to help so many people in India living with diabetes in improving glycemic control via a non-injectable and convenient delivery of inhaled insulin,” said Dr. Satish Garg, MBBS, DM, Professor of Medicine and Pediatrics at the Adult Clinic of the Barbara Davis Center for Diabetes of the University of Colorado School of Medicine in Denver.

The International Diabetes Federation (IDF) reported in 2021 that diabetes mellitus affects 537 million adults (20-79 years of age) worldwide, including more than 74 million people in India. IDF estimations are that the total number of people living with diabetes is projected to rise to 643 million by 2030 and 783 million by 2045.

About Afrezza

Afrezza (insulin human) Inhalation Powder is a rapid-acting inhaled human insulin indicated to improve glycemic control in adults with diabetes mellitus.

Limitations of Use: Not recommended for the treatment of diabetic ketoacidosis or in patients that smoke or have recently stopped smoking.

Important Safety Information

WARNING: RISK OF ACUTE BRONCHOSPASM IN PATIENTS WITH CHRONIC LUNG DISEASE

- Acute bronchospasm has been observed in Afrezza-treated patients with asthma and COPD.
- Afrezza is contraindicated in patients with chronic lung disease such as asthma or COPD.
- Before initiating Afrezza, perform a detailed medical history, physical examination, and spirometry (FEV₁) to identify potential lung disease in all patients.

Most common adverse reactions are hypoglycemia, cough, and throat pain or irritation.

Please see additional Important Safety Information, Full Prescribing Information, including BOXED WARNING, available on [Afrezza.com/safety](https://www.afrezza.com/safety).

About MannKind

MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of innovative inhaled therapeutic products and devices to address serious unmet medical needs for those living with endocrine and orphan lung diseases.

We are committed to using our formulation capabilities and device engineering prowess to lessen the burden of diseases such as diabetes, nontuberculous mycobacterial (NTM) lung disease, pulmonary fibrosis, and pulmonary hypertension. Our signature technologies – dry-powder formulations and inhalation devices – offer rapid and convenient delivery of medicines to the deep lung where they can exert an effect locally or enter the systemic circulation, depending on the target indication.

With a passionate team of Mannitarians collaborating nationwide, we are on a mission to give people control of their health and the freedom to live life.

Please visit mannkindcorp.com to learn more, and follow us on [LinkedIn](#), [Facebook](#), [X](#) or [Instagram](#).

Forward-Looking Statements

This press release contains forward-looking statements about the estimated shipment of product that involves 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, which include, without limitation, manufacturing risks that may adversely affect our ability to manufacture our products as well as 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, 2023, 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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The logo for MannKind, featuring the word "mannkind" in a lowercase, bold, pink font.

Source: MannKind