

A revolutionary step in diabetes care: Cipla receives approval for distribution and marketing of inhaled insulin in India

Redefining diabetes treatment with an innovative, needle-free alternative that is tailored to meet patient needs in India

Mumbai, December 11, 2024: Cipla Limited, hereafter referred to as "Cipla" (BSE: 500087; NSE: CIPLA EQ,) today announced that it has obtained regulatory approval from Central Drugs Standard Control Organisation (CDSCO) for the exclusive distribution and marketing of Afrezza® (insulin human) Inhalation Powder in India. Afrezza®, a product created and manufactured by MannKind Corporation (MannKind) USA, is used to improve glycemic control in adult patients with diabetes mellitus. By bringing a game-changing, patient-centered solution to diabetes management in India, Cipla will make this drug accessible to all and empower millions to take control of their health with greater ease.

Afrezza® is a rapid-acting insulin delivered through an inhaler as compared to current insulins which are given as injections. Taken at the beginning of a meal, Afrezza® dissolves rapidly upon oral inhalation into the lungs and delivers insulin quickly to the bloodstream. Afrezza® starts working in as early as 12 minutes and helps in reducing the rapid increase seen in sugar levels with meals. The effect of Afrezza® lasts for about 2-3 hours and it closely resembles the body's own response to insulin.¹ This is the first and only non-injectable insulin to be developed for patients of both type 1 and type 2 diabetes mellitus.

Mr. Umang Vohra, Managing Director and Global CEO, Cipla Limited, said, "Having pioneered inhalation therapy in India, we are proud to extend our innovation portfolio to diabetes management by partnering with MannKind for distribution of Afrezza®. Cipla at its core is committed to redefining patient experiences and this advancement reflects that vision. By reducing the need for multiple daily insulin injections, we are offering a convenient solution for people living with diabetes mellitus, particularly those who are uncomfortable with needles, helping them manage their condition more effectively."

Mr. Achin Gupta, CEO – One India Business, Cipla Limited, said, "The launch of Afrezza® reinforces our dedication towards making cutting-edge treatments available to patients. By harnessing our extensive distribution capabilities, we are committed to delivering this innovation to communities across India, fostering better health outcomes for all."

Dr. Jaideep Gogtay, Global Chief Medical Officer, Cipla Limited, said, "A phase 3 clinical trial conducted in 216 patients in India showed a significant reduction in HbA1c levels with Afrezza® when added to oral anti-diabetes medications. The availability of insulin to be inhaled through the lungs will provide a new and innovative option for patients with diabetes mellitus."

Afrezza® has been evaluated in over 70 clinical studies involving more than 3,000 patients overall. Afrezza® has been approved in the US for more than 10 years and has been prescribed for tens of thousands of patients. MannKind will supply Afrezza® to Cipla, who will be then responsible for sales and marketing activities in India.

About Cipla

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in our home markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, anti-retroviral, urology, cardiology, anti-infective and CNS segments are well-known. Our 46 manufacturing sites around the world produce 50+ dosage forms and 1,500+ products using cutting-edge technology platforms to cater to our 80+ markets. Cipla is ranked 3rd largest in pharma in India (IQVIA MAT Sep'24), largest in the pharma prescription market in South Africa (IQVIA MAT Aug'24), and 4th largest by prescription in the US Gx inhalation products (IQVIA MAT Aug'24). For over eight decades, making a difference to patients has inspired every aspect of Cipla's

¹ Afrezza (insulin human) Inhalation Powder Prescribing Information (as accessed from https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022472s023lbl.pdf; Rosenstock J. et. al., Diabetes Care. 2008; 31: 2177-82

work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS at less than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility, and affordability to the centre of the HIV movement. A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring for Life' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers and all stakeholders. For more, please visit www.cipla.com, or click on [Twitter](#), [Facebook](#), [LinkedIn](#).

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