



Press Release

Cipla files ANDA for generic version of GSK's Advair Diskus®

- **Phase-3 clinical study for generic version completed in first attempt**
- **Progresses towards strengthening respiratory franchise in the US market**

Mumbai, India; May 18, 2020: Cipla Limited (BSE: 500087; NSE: CIPLA EQ; and hereafter referred to as "Cipla") today announced its submission of an Abbreviated New Drug Application (ANDA) for Fluticasone propionate and Salmeterol inhalation powder (100/50 mcg, 250/50 mcg and 500/50 mcg) to the United States Food and Drug Administration (USFDA). The Company had recently announced the successful completion of its Phase-3 clinical end-point study for the product in the first attempt.

The product is the generic version of GSK's Advair Diskus®. According to IQVIA (IMS Health), Advair Diskus® and its generic equivalents had US sales of approximately US\$2.9bn for the 12-month period ending March 2020.

It is indicated as a twice-daily prescription medicine to treat asthma in patients aged four years and older. It is also used in the long term to treat chronic obstructive pulmonary disease (COPD), including chronic bronchitis, emphysema, or both, for better breathing and fewer flare-ups.

Commenting on the filing, Mr. Umang Vohra (MD and Global CEO, Cipla Limited) said, "We are pleased to announce the ANDA submission for generic Advair Diskus® to the USFDA. This marks a significant milestone and represents our commitment to increase patient access to complex treatment options in the respiratory space and will also play a major role in our strategy towards

building a respiratory franchise in the US. Our unparalleled range of offerings in this space has established our position as lung leaders in India and emerging markets and we intend to extend this offering to our developed markets.”

According to the IMS study (Dec 2019), Cipla ranked amongst the Top 2 companies globally for DPI and MDI devices*. Cipla's borderless respiratory program, a slew of new devices launches and the ANDA filing of generic Advair Diskus® are in line with its goal of becoming a global lung leader.

***Source: IMS (Dec 2019)**

(*) MDI volume are internal Cipla numbers

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 Mar'20), 3rd largest in the pharma private market in South Africa (IQVIA MAT Mar'20), and is among the most dispensed generic players in the U.S. For over eight decades, making a difference to patients has inspired every aspect of Cipla's 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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