



Press Release

## **Cipla announces successful completion of Phase-3 clinical study for generic version of GSK's Advair Diskus®**

**Achieves a significant milestone towards strengthening its regulated markets**

**Respiratory franchise**

**Mumbai, India; April 02, 2020:** Cipla Limited (BSE: 500087; NSE: CIPLA EQ; and hereafter referred to as "Cipla") today announced the successful completion of Phase-3 clinical end-point study for fluticasone propionate and salmeterol inhalation powder (100/50 mcg).

Fluticasone propionate and salmeterol inhalation powder 100/50 mcg, 250/50 mcg and 500/50 mcg are generic versions of GSK's Advair Diskus®. The product is indicated to treat asthma in patients 4 years and older as a twice-daily prescription medicine and in long term to treat chronic obstructive pulmonary disease (COPD), including chronic bronchitis, emphysema, or both, for better breathing and fewer flare-ups.

The Phase-3 study, successfully completed in the first attempt, was conducted over a period of 15 months at over 100 sites in the US enrolling 1400 asthma patients. The study results demonstrate that Cipla's fluticasone propionate and salmeterol inhalation powder 100/50 mcg is therapeutically equivalent to Advair Diskus® 100/50mcg. The study demonstrated therapeutic equivalence by assessing the primary end points which is in accordance with regulatory recommendations and guidelines. There were no safety concerns identified during the trials.

Commenting on the trial completion, **Umang Vohra** (MD and Global CEO, Cipla, Limited) said "I am extremely pleased with the successful completion of the Phase-3 clinical study of generic Advair Diskus®. Considering the complexity of clinical endpoint study in the Fluticasone + Salmeterol combination, it is heartening to see that our study was successful in the first attempt. This is an important milestone and is a testament to Cipla's strong respiratory capabilities and will go a long way in strengthening our respiratory franchise in the US. Unmatched presence across the care continuum and the widest range of drug-device combinations has established Cipla's position as a lung leader in India and other key emerging markets. Our endeavour is to extend this expertise across developed markets through niche product development."

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 February 2020.

## **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 Feb'20), 3rd largest in the pharma private market in South Africa (IQVIA MAT Feb'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](http://www.cipla.com), or click on [Twitter](#), [Facebook](#), [LinkedIn](#).

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