

2<sup>nd</sup> April 2020

(1) BSE Ltd  
Listing Department  
Phiroze Jeejeebhoy Towers,  
Dalal Street,  
Mumbai - 400 001

(2) National Stock Exchange of India Ltd  
Listing Department  
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Plot no. C/1, G Block,  
Bandra Kurla Complex,  
Bandra (East), Mumbai - 400 051

**Scrip Code: 500087**

**Scrip Code: CIPLA EQ**

(3) SOCIETE DE LA BOURSE DE LUXEMBOURG  
Societe Anonyme  
35A Boulevard Joseph II,  
L-1840 Luxembourg

**Sub: Press Release - Successful completion of Phase-3 clinical study for generic version of GSK's Advair Diskus®**

Dear Sir/Madam,

Please find enclosed press release dated 2<sup>nd</sup> April 2020 for the captioned subject.

Kindly acknowledge the receipt

Thanking you,

Yours faithfully,

**For Cipla Limited**

**Rajendra Chopra  
Company Secretary**

Encl: as above

Prepared by: Juzer Masta

**Cipla Ltd.**

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**Fax:** +9122 24826120 Website: [www.cipla.com](http://www.cipla.com) **Email:** [contactus@cipla.com](mailto:contactus@cipla.com) **Corporate Identity Number:** L24239MH1935PLC002380



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](#).

### **For queries, please contact:**

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