

Cipla completes Phase-3 trials for generic version of GSK's Advair Diskus

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The product is indicated to treat asthma in patients 4 years and older



Cipla Limited has 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.