

Cipla

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Completes Phase 3 studies for gAdvair in US

CMP: Rs 414
as of (April 2, 2020)

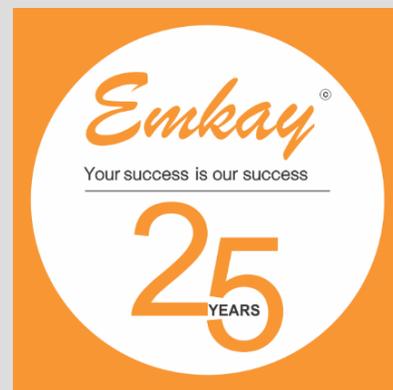
TP: Rs 522 (■)
12 months

Rating: BUY (■)

Upside: 26.2 %

- Cipla has successfully completed Phase 3 studies for gAdvair (Fluticasone propionate +Salmeterol inhalation powder) in the US. This was an extensive study conducted over 1400 asthma patients and showed therapeutic equivalence with no safety concern. Cipla believes that its product is substitutable to Advair.
- gAdvair is indicated for the treatment of Asthma in patients four years and older. It is also indicated to treat Chronic Obstructive Pulmonary Disorder in the long term, including chronic bronchitis, emphysema, or both, for better breathing and fewer flare-ups.
- Cipla will now file the product with the USFDA (another 3-4 months). Being a complex product and based on past experience with other players (Mylan, Hikma, Sandoz), it is highly likely that the approval pathway will be longer than the usual one-year cycle.
- As per IMS, Advair sales (brand + generic) are around USD2.9b (12M ending Feb-20) in the US. We do not expect gAdvair's launch by FY22 and hence, it is not a part of our estimates. Currently, Mylan's Wixela Inhub is the only generic in the market. Mylan received product approval in Jan-19 and launched the drug at a 70% discount. Sandoz has shelved off the gAdvair project after the USFDA rejected its application, while Hikma's (partnered with Vectura) application is currently under review (had received a CRL in the first review cycle). Among Indian generics, Lupin, partnered with Celon, is currently in the development stages.

Please see our sector model portfolio (Emkay Alpha Portfolio): [Pharmaceuticals](#)



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Praful Bohra

praful.bohra@emkayglobal.com

+91 22 6612 1254

Emkay Rating Distribution

Ratings	Expected Return within the next 12-18 months.
BUY	Over 15%
HOLD	Between -5% to 15%
SELL	Below -5%

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Emkay Global Financial Services Ltd.

CIN - L67120MH1995PLC084899

7th Floor, The Ruby, Senapati Bapat Marg, Dadar - West, Mumbai - 400028. India

Tel: +91 22 66121212 Fax: +91 22 66121299 Web: www.emkayglobal.com

SINGAPORE**DBS Bank Ltd**

Contact: Janice Chua
12 Marina Boulevard, Marina Bay Financial Centre Tower 3
Singapore 018982
Tel. 65-6878 8888
Fax: 65 65353 418
e-mail: equityresearch@dbs.com
Company Regn. No. 196800306E

THAILAND**DBS Vickers Securities (Thailand) Co Ltd**

Contact: Chanpen Sirithanarattanakul
989 Siam Piwat Tower Building,
9th, 14th-15th Floor
Rama 1 Road, Pathumwan,
Nagkok Thailand 10330
Tel. 66 2 857 7831
Fax: 66 2 658 1269
e-mail: research@th.dbs.com
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Contact: Maynard Priajaya Arif
DBS Bank Tower
Ciputra World 1, 32/F
Jl. Prof. Dr. Satrio Kav. 3-5
Jakarta 12940, Indonesia
Tel. 62 21 3003 4900
Fax: 62 21 3003 4943
e-mail: indonesiaresearch@dbs.com
