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2 important triggers for biocon to watch now

Biocon (BION.BO)

Open a Positive Catalyst Watch: Glargine Interchangeability and Aspart Approval are Big Events to Watch Out For

CITI'S TAKE

We open a 90 day +ve catalyst watch as Biocon has two major catalyst in July 2021 – a) USFDA's decision on Insulin Glargine interchangeability status and b) USFDA approval of Insulin Aspart. On Glargine, the company remains confident of getting a favorable outcome as it has submitted robust analytical and comparability data. Biocon's Aspart filing is also for an interchangeable product and given that this is going to be the first biosimilar of Insulin Aspart, the company also stands to gain from the first mover advantage. Risk-reward is positive as favorable outcome(s) can result in c10-20% increase in our FY23E EPS (we also expect consensus upgrades); however, if there is any delay (given that USFDA hasn't approved intercheangeable biosimilars so far), it is unlikely to have any material downside as they don't seem to be there in the current stock price in our view.

Interchangeability status on Glargine can be a big booster — If USFDA grants interchaengeability status to Insulin Glargine, it will not only help in the market share accelaration of the product (Semglee), but also enhance the the value of the company's overall insulin franchise. In the revised guidelines, USFDA has done away with requirement of "***comparative immunogenecity or switching studies***" making the path easier for interchangeable insulins. As insulins are outpatient, self-administered products, interchangeability can significantly accelerate market share.

Aspart approval is next in line — Approval for biosimilar Aspart (bNovolog) is next in line for Biocon and USFDA action date in July 2021 (next month). According to the company, the filing for Insulin Aspart is also for an interchangeable one and if the company gets approval on expected lines it can be a material event as this is a large product with cUS$2bn market size in US. The filing of this product is from the Malaysia facility from which the company's Glargine filing is approved and therefore a pre approval insection (PAI) may not be required as per the company. However, if the USFDA requires PAI before approving this drug, approval of the product can be delayed and therefore our model assumes a very low market share in FY22 (c2-3%).