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Biocon a leading Indian play on global biosimilar scene

BIOCON/MYLAN today announced that US FDA accepted their biologics license application (BLA) for MYL-1401O,a proposed biosimilar trastuzumab, for filing through the 351(k) pathway.

Earlier, Biocon had submitted its BLA application in Nov 2016. The anticipated FDA goal date set under the Biosimilar User Fee Act (BsUFA) is Sept.3, 2017. This is Biocon's first regulatory submission in US through 351(k) pathway.

The BLA application includes analytical similarity, non-clinical and clinical data. We believe this has the potential to be the first submission of a proposed biosimilar trastuzumab in the US, ahead of all competition.

Total global sales for Herceptin in 2015 were $6.5-7 billion, of which the US accounted for roughly 35%, EU was 30%, RoW 29% and Japan 4%. Herceptin is used for adjuvant (early stage, 60% of sales) and metastatic (late stage) breast cancer. The compound patent for Herceptin expired in the EU in July 2014, and will expire in June 2019 in the US. Currently, four other trastuzumab biosimilars are under Phase III clinical development.

FDA is expected to give its decision by Sep 2017 and therefore Biocon may see possible approval in H2F17 assuming one review cycle.

We continue to position Biocon as a leading Indian play on the unfolding global biosimilar theme. While value creation in the biosimilar pipeline is under way, the base business is scalingup nicely with EM bio-similars (especially as Malaysian facility turns commercial in H2), contract research (Syngene) and US generics could gain some momentum (e.g.,gCopaxone 20mg).