

Therapeutic Class Overview: Emergence of Biogenerics Era in Japan - it's time to welcome Antibody Biosimilars of Foreign Origins Soon

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Abstracts

With three products and eight players already in market – Japan biosimilar market will enter new phase of biosimilars with first ‘mab’ approval expected in 2014. This approval (Remicade- FY03/13A sales ¥73.5, infliximab from Nippon Kayaku by YE 14) will be marked as a milestone development because – 1.) it will open antibody biosimilar market in Japan, and 2.) the approval will be based largely from overseas data. ~ ¥200b worth of biologic products is going off patent by 2015 and this value exceeds ~ ¥400b if we include products that will see their patent expiries by 2021 in Japan (Table 1). There are number of reasons to believe that follow-on-biologics or biosimilars will not replicate the lethargic growth story of generic – preliminary because the much higher cost of biologic therapy brings significant burden on patients despite relatively low co-pay in Japan – and this will push individuals and DPC Hospitals to use biogeneric products to a greater extent unlike generic drugs. Secondly, the regulatory supports are going to be stringent enough to ensure quality measures and minimizing the ‘not made in Japan’ factor from prescriber’s and user’s mindsets. Anticipating this opportunity and favorable macro forces as compared to generics, a number of companies aim to exploit this – Japan has seen a flood like consolidation and partnering activities in biosimilar space (Table 2, Annexure I). While a dozen+ companies have already laid their road map for biosimilars space, at this time we see Sandoz, JCR, Meiji Seika Pharma, Fuji Film Kyowa Kirin Biologics, Nippon Kayaku, Nichi Iko, Yoshindo etc. to be amongst the key players in biogenerics business in Japan. It is also noteworthy that large global player, which currently look silent in JapanIn this piece, we attempt to evaluate the future competitive landscape (Table 3) of the Biosimilars space in Japan, assess the overall attractiveness of the same, and try to identify the key determinates to succeed in this space. At this point, we do not arrive at any investment recommendations from the sector

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