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Japan Biosimilars – A start of Authorized Biosimilar Era? Biosimilar/BioPharma CMO opportunities – JP Conglomerates – A definite role to play for Global Market!

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Abstracts

In 2016, encouraging uptake of Lantus BS in Japan confirms strong foothold of the marketer, product mix targeted to DPC hospitals (Diagnostic Procedure Combination hospitals- ~4000) and early entry of the player are critical factors to decide biosimilar penetration and market share dynamics of Japan Biosimilar Market. While ongoing discussion of local originators to launch authorized generic BS in a way indicate cost pressure & threat on the originators by payers(Chuikyo), but put pause on attractiveness of developing BS for a mid size & generic pharma players. Small molecule authorized generics launch in Japan (Blopress- Aska, Plavix-Nichi Iko.) in last few years took major market share amongst generic players (>50%).

On the contrary, Biologics contribute significant part of the current healthcare spend (17% of total healthcare spend) by government in Japan. As the growth rate of drug cost are higher than the growth rate of the overall health care costs in Japan, and biologics are one of the major contributor to that- to reduce healthcare burden, a biosimilar weapon is a must need in Japan. As per the recent survey of RA market in Japan amongst patient and Prescribers, ~40% of the patients/prescribers not used biologics to treat RA as it is expensive. To address these challenges and to make biosimilar development/use friendly environment, initiative to form JBSA (Japan biosimilar Association) has been in place in 2016. Separately, Government recent “Honebuto” Policy aims to double Biosimilar API by 2020 from Current (5 to 10), again confirms JP Government stands to aggressively push biosimilars use in Japan.

JBSA has done on the ground survey to handle Biosimilar penetration challenges and

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we expect this to result in government definite direction for efficient biosimilar development in Japan around 2018 with institutional reforms. This may include remunerating prescribers/pharmacy/hospitals to use biosimilar, removing high cost medical care benefit system for increasing biosimilar penetration in Japan. High cost medical care benefit programme and various Government public Insurance programmes minimize the benefits of “co-pay difference” associated with biosimilar use. We expect evident change in these programmes in next NHI price revision to push prescribers/DPC hospitals to increase use for biosimilar in Japan.

Globally, a definite positive directions from USFDA to approve Biosimilars in US, recent success of Immuno Oncology Mabs on Innovation front and a steep uptake of these drugs in the Japan market, increased confidence of Japanese giants for more biopharma success in the coming time vs. small molecule to get breakthrough to grow. These has allowed Japanese conglomerates to venture in global biologics CMO space in recent times (Asahi-Kasei – CMC biologics) and more M & A is expected in this direction to fulfill the gap of Biopharma-MAb technology platforms amongst Japanese Players.

Based on the FY2016 sales reported by major biopharma drugs in Japan- Biosimilars are an opportunity of cumulative market size of ¥630b (Table 3) in next few years for Japan biosimilar players.

In this report, we attempt to evaluate key upcoming opportunity for Japan BS market, its competitive landscape, and current trend of biosimilars use in Japan. It also details Japanese “Chuikyo” (Central and Social Regulatory Council) stand for Biosimilar penetration and regulatory approval requirement for non- JP specific dosage strength or/has clinical data from Ex-Japan clinical trial. The report provide all the Japanese/Global players’ activities in biosimilar space for Japan market along with their pipeline deal history, current Mab tech platforms, alliances and deal structure. It details crisp summary on strategies of each key player (~36 JP local companies, multinational companies), their interest & focus for future collaboration in biosimilar space.

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