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Japan Biosimilars- Landscape Today Outlook Tomorrow

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Abstracts

“Biosame” entry, uninterrupted supply and companies’ strong front-end footprint requirement makes it distinct

After a decade, JP Biosimilar guideline’s first revision expected in FY2020 –Demonstrate Chuikyo need of biosimilar tool to curb healthcare cost

Biosimilars uptake varies as per each opportunity, Remicade BS vs. Rituxan BS- Two poles of the curve

A few skipping NHI listing due to manufacturing issues associated with constantsupply need, Japanese CDMO imminent to seal this local need

Since 2009, 25 biosimilars of 12 originator products are approved in Japan and have yielded mixed performances and attained annual sales of ~?32.4b ($300m). Unique biosimilars landscape with the entry of NESP “biosame” by originator Kyowa Hakko Kirin through its subsidiary, co-promotion/marketing collaboration with local companies for the front-end skill sets (Ayumi, Kyowa Hakko Kirin, Teijin) and few skipped listing to better manage constant supply (Pfizer), a key requirement by MHLW, makes Japan a distinct market vs. US and EU. Less stringent regulatory environment vs. US for approval, increasing healthcare burden and strong foothold of the marketers have played key roles in this early uptake which is at par to one of the best generic small molecule penetration in Japan in a short time (Filgrastim BS-volume share~45% in two years, Lantus BS- ~9% in 2 months vs. Lipitor generics ~50% volume share).

While analyzing the launched biosimilar penetration since 2009 in Japan, bolstering

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uptake of Enbrel, Rituxan, and Lantus biosimilar vs. very slow uptake of Remicade BS mainly been attributed with the use of biosimilars in DPC hospitals,product reimbursement under high cost medical care benefit system and front end presence of the local partner. Despite the string of recent biosimilars approvals, healthcare professionals still harbor concerns over the quality of biosimilars. MHLW's announcement to update a decade back biosimilars guideline by FY2020 to reduce cost of development as well as to increase confidence of physician on quality, is indicative of biosimilar as important weapon for Chuikyo(Central social Insurance Medical Council) to curb healthcare cost. Further, "Biosame" pricing game will play a major role in the future for biosimilar penetration. We see that Abenomics measures and government involvement in biosimilars use would lead to the Biosimilars promotions in the coming times in Japan.

Mixed strategies by originator for "Bio-same" launch (Kyowa Hakko Kirin to launch "Biosame" vs. Chugai said not to launch "Biosame"), therapy area wise biosimilars cherry picking by mid-size Japanese companies, and different strategies by local generic companies (NichiIko heading for global market vs. Sawai testing through co-promotion and Towa yet not decided to enter), demonstrates each company's different need and approach to cater biosimilar opportunities in Japan.

Since the last five years, most of the companies have some alliance in place for biosimilars, with most of the Japanese companies undertaking pacts with South Korean companies to ride on their back of biosimilar mAb expertise. There is a trend of doing product specific alliance by most of the JP companies active in BS space and to go step by step on this high risk/high return opportunities. Against this backdrop, multinational companies like Pfizer are setting their sights on this market without local partnership taking advantage of pro-biosimilar environment to capture decent biosimilar market share. Overall, in the Japan market, each opportunity has a different competitive landscape for itself, and some companies are looking for niche opportunities in biosimilar space as per their specialty therapy area- like ophthalmology BS (Lucentis), Enzyme therapy BS (JCR)

While launched biosimilars now generates ~?32b ($300m) sales and its penetration is accelerating, MHLW's approval of "Biosame" of NESP based on same clinical data as the originator NESP, and current ongoing dialogs to price "Biosame" higher than biosimilars, indicative of Biosame to be the key hurdle in the future for mid-size biosimilar companies in Japan. In the year 2020, MHLW's stand on Biosame, will be important to decide future of theses mid-size /generic biosimilar developers. Around ~?550b opportunity is opening for biosimilar in the next 7 years in Japan due to patent

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expiry of Wave 2-3 biologics.

In this report, we attempt to analyze trend/requirement of regulatory approval of biosimilars based on Ex-Japan clinical trialdata, factors responsible for each key launched biosimilar penetration (“Made in Japan” vs. “Tested by Japan”), and the future competitive landscape in the biosimilars space in Japan. We also attempt to analyze detail BS market of EPO, Filgrastim/Pegfilgrastim/ Insulin/Lantus apart from other key complex Mab Biosimilar opportunities and list out niche opportunities in biosimilar space in Japan. Details of all major consolidation activities done by JP/Foreign companies in biosimilar space in the last five years and crisp summary on strategies of each key player (~21 JP local companies, multinational companies), their interest & focus for future collaboration in biosimilar space.

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