

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

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 (Nichilko 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

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 trial data, 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.

Contents

CHAPTER 1: EXECUTIVE SUMMARY

CHAPTER 2: JAPANESE GOVERNMENT AND “CHUIKYO” INITIATIVES TO INCREASE BIOSIMILAR PENETRATION IN JAPAN

JBSA- How it will play important role for biosimilar penetration in Japan and overcome BS penetration related issues?

CHAPTER 3: LESSONS FROM LAUNCHED BIOGENERIC PROGRESS IN JAPAN SINCE 2009

Encouraging uptake for Filgrastim, Insulin glargine, Rituximab and Eterncept BS, while sluggish start for Infliximab demonstrates variable market for each BS – Highly depends on the reimbursement status and front-end presence

CHAPTER 4: GROWTH HORMONE MARKET (SOMATROPIN) IN JAPAN

Despite being the first biosimilar to hit the Japan market, low uptake reported due to the brand loyalty by pediatrician; Long acting growth hormone entry is the upcoming threat

CHAPTER 5: ANEMIA MARKET IN JAPAN

EPO- After an initial struggle, biosimilar of EPO is steadily growing
NESP “Biosame” vs. NESP BS uptake - key to watch in 2020

CHAPTER 6: FILGRASTIM (GRAN) BS

G-LASTA uptake squeeze the market for GRAN BSs - Entry of G-lasta biosimilars expected to change the game

CHAPTER 7: REMICADE (INFLIXIMAB) BS

High cost healthcare system and impact of competing products like Simponi in the RA market, key hurdles for the slower biosimilar uptake

CHAPTER 8: LANTUS (INSULIN GLARGINE) BIOSIMILAR

One of the most successful BS launch in Japan –now facing challenges from next generation Lantus (Lantus-XR)

CHAPTER 9: ENBREL (ETANERCEPT) BIOSIMILAR

First Etanercept BS had encouraging early uptake as provides co-pay difference due to low cost vs. other approved Mabs, available in both formulations and strong front end of the commercial partner

CHAPTER 10: ONCOLOGY BIOSMILARS ERA STARTS WITH RITUXAN (RITUXIMAB) BIOSIMILAR

Rituxan biosimilar take off strongly captured major shares from the originator; Gazyva (obinutuzumab) to replace Rituxan is the major threat

CHAPTER 11: HERCEPTIN (TRASTUZUMAB) BIOSIMILAR

Now with approval of all dosing schedules and indications as the originator, three BS players ready to take the market share- Approval of fixed-dose combination of Roche's Herceptin/Perjeta and new competitors can change the game

CHAPTER 12: AVASTIN (BEVACIZUMAB) BIOSIMILAR

Japan's best selling drug with sizable market to attract more biosimilar players in the coming future without "Biosame" threat

CHAPTER 13: FABRAZYME (AGALSIDASE BETA) BIOSIMILAR

Niche opportunity captured by Japanese biosimilar rising star, difficulties ahead with the entry of Japan's first oral treatment for Fabry disease (Galafold)

CHAPTER 14: FORTEO (TERIPARATIDE) BIOSIMILAR

Entry of Evenity –create a headwind despite lower copay & strong front end by Mochida

CHAPTER 15: NEXT WAVE OF BIOSIMILAR OPPORTUNITIES IN JAPAN

Actemra BS a more attractive opportunity in Japan vs. Humira
Avastin biosimilar uptake and Ophthalmology BS development are key to watch

CHAPTER 16: BIOSIMILAR/BIOPHARMA CMO OPPORTUNITY

Would Japanese conglomerates cater the global market?

CHAPTER 17: REGULATORY APPROVAL REQUIREMENT FOR COMPLEX MAB BIOSIMILAR IN JAPAN

Key take away of JP biosimilar guideline when compared to EU/US requirement
JP requirements for the approval of biosimilars

CHAPTER 18: LICENSING/CONSOLIDATION ACTIVITIES IN BIOSIMILAR SPACE IN JAPAN

CHAPTER 19: JAPANESE COMPANIES ACTIVE INTO BIOGENERICS SPACE

Aska Pharmaceuticals - No major progress on the biobetter

Asahi Glass –Entering in Biopharma CDMO Business for Global Market

Chugai Pharmaceuticals- Entry to Authorised Biosimilar unlikely - Fighting for originator rights

Daiichi Sankyo –Potential to be a front runner in the biosimilar space with Amgen Partnership

Fuji Film Kyowa Kirin Biologics (FF-KKB) – Looking beyond domestic opportunities to capture global biosimilar business

Fuji Pharma – Alvotech partnership to bolster biosimilar business as its new core in the home ground

Gene Techno Science – JP Biopharma rising star - A reliable partner for Developing Biosimilar in Japan by Japanese Front End Companies

Itochu Chemical Frontier Corporation – A trading house with new role in biosimilar value chain

JCR Pharmaceuticals –A pioneer for biosimilars -now thrive in regenerative medicine & fast tracking NESP biosimilar

Kissei – Timely launch of NESP biosimilar – Next to watch! Focus to be a niche player in BS space

Kyowa Hakko Kirin – Tapping biosimilar market through “Biosame” launch –Taking advantage of front end leadership for Anemia and Hematology therapy area

Meiji Seika Pharma (MSP) –Trastuzumab biosimilar launch awaited in Japan- Tough competition with already approved other players!

Mochida – Enbrel BS- first to file for Japan, now equipped with full basket for being one

of the top biosimilar player in Japan

Mitsubishi Tanabe –Not in biosimilars area yet

MGC Pharma (now as Cultivec) – A Bio-pharmaceutical CMO- leveraging the findings gained through developing the mass-culture technology to develop biosimilars!

Nichi-Iko – Aspiring to capture overseas markets, committed to the biosimilar business in the US

Nipro Pharma – Not much development after Somatropin BS

Nippon Kayaku – Pioneering ‘New Age’ of biosimilars: After Remicade- now launch of Herceptin BS is key

Sawai – Intends to establish sales team in biosimilar field in next few years

Towa – Still waiting for Government right policy pitch for biosimilar

Toyobo Biologics - Eying at biosimilars CMO Business

Takeda Teva Pharmaceuticals – No clarity on biosimilar launch plan in Japan

UMN Pharma – Transforming vaccines heritage into new generation biologics- but no major progress in last couple of years in biosimilar area

Yoshindo – A steady progress for Enbrel biosimilar- “Three step” approach to build a Bio Company

Sanwa Kagaku – NESP biosimilar – a therapy focus biosimilar entry for Japan market

Amgen – Timely launch is key through Daiichi Sankyo Partnership in Japan

Chong Kun Dang – With Fuji Pharma entering in NESP BS market

Tables

TABLES

- 1 TABLE 1: JP BIOSIMILAR COMPETITIVE LANDSCAPE (A)
- 2 TABLE 2: OPENING OPPORTUNITIES - EARLY WAVE BIOSIMILARS (B)
- 3 TABLE 2: OPENING OPPORTUNITIES - NEXT WAVE BIOSIMILARS (C)
- 4 TABLE 3: CO-PAY SLABS IN JAPAN
- 5 TABLE 4: LAUNCHED BIOSIMILARS IN JAPAN- UPTAKE VARIES FOR EACH BIOSIMILARS
- 6 TABLE 5: APPROVED BIOSIMILARS IN JAPAN
- 7 TABLE 6: DATA PACKAGE OF SOMATROPIN BIOSIMILAR APPROVAL
- 8 TABLE 7: DATA PACKAGE OF EPOETIN ALFA BIOSIMILAR APPROVAL
- 9 TABLE 8: ANEMIA MARKET DYNAMICS: REPORTED SALES FOR FY2017, FY2018 & FY2019
- 10 TABLE 9: DARBOPOETIN ALFA: BIOSIMILARS AND BIOSAME
- 11 TABLE 10: FILGRASTIM BS - LOCAL VS. OVERSEAS CLINICAL STUDIES SUBMITTED FOR JP APPROVAL BY EACH PLAYER
- 12 TABLE 11: MOCHIDA FILGRASTIM BS - CLINICAL STUDIES SUBMITTED FOR JP APPROVAL
- 13 TABLE 12: NIPPON KAYAKU FILGRASTIM BS – DETAIL STUDIES SUBMITTED FOR JP APPROVAL
- 14 TABLE 13: SANDOZ – JAPAN FILGRASTIM “BS” - DETAIL STUDIES SUBMITTED FOR JP APPROVAL
- 15 TABLE 14: SANDOZ – JAPAN FILGRASTIM “BS” - OVERSEAS STUDIES SUBMITTED FOR JP APPROVAL
- 16 TABLE 15A: FILGRASTIM/GRAN, COMPETITIVE LANDSCAPE- MARKET STRATEGY OF EACH PLAYER
- 17 TABLE 15B: FILGRASTIM/GRAN/G-LASTA- SALES TREND OF EACH NEUTROPENIADRUG IN JAPAN
- 18 TABLE 16: DATA PACKAGE OF INFLIXIMAB BS
- 19 TABLE 17: CLINICAL DATA SUBMITTED FOR JP APPROVAL OF REMICADE BIOSIMILAR
- 20 TABLE 18: CLINICAL DATA COMPARISON OF CT- P13 VS. INX IN RA
- 21 TABLE 19: CLINICAL STUDIES SUBMITTED FOR ELI-Lilly LANTUS BS APPROVAL IN JAPAN
- 22 TABLE 20: CLINICAL STUDIES SUBMITTED FOR FUJIFILM-BIOCON LANTUS BS APPROVAL IN JAPAN
- 23 TABLE 21: OTHER KEY BIOSIMILAR OPPORTUNITIES IN INSULIN AREA IN

JAPAN

- 24 TABLE 22: ETANERCEPT COMPETITIVE LANDSCAPE
- 25 TABLE 23: ORIGINATOR'S APPROVED INDICATION AND DOSING SCHEDULE
- 26 TABLE 24: COMPETITIVE LANDSCAPE WITH DETAILS OF THE CLINICAL STUDIES SUBMITTED FOR HERCEPTIN BIOSIMILAR
- 27 TABLE 25: AVASTIN BIOSIMILARS–LAUNCHED & PIPELINE
- 28 TABLE 26: KEY RA BIOLOGICS SALES TREND JAPAN 2014-2019
- 29 TABLE 27: HUMIRA BIOSMILAR COMPETITATIVE LANDSCAPE
- 30 TABLE 28: OTHER NICHE OPPORTUNITIES IN OPHTHALMIC/ONCO/AUTOIMMUNE THERAPY AREA
- 31 TABLE 29: MAJOR BIO-CMO COMPANIES IN THE WORLD AND THEIR ACTIVITIES IN JAPAN
- 32 TABLE 30: MAJOR BIO-CMO COMPANIES IN JAPAN
- 33 TABLE 31: FUJI FILM KYOWA KIRIN BIOLOGICS- BIOSIMILAR PIPELINE
- 34 TABLE 32: GENE TECHNO SCIENCE-BIOGENERICS STATUS
- 35 TABLE 33: JCR -APPROVED PRODUCTS
- 36 TABLE 34: MSP - BIOSIMILAR PIPELINE
- 37 TABLE 35: MOCHIDA -BIOSIMILARS - MARKETED PRODUCTS AND PIPELINE
- 38 TABLE 36: NICHI- IKO - BIOSIMILARS -MARKETED PRODUCTS AND PIPELINE
- 39 TABLE 37: NIPPON KAYAKU - BIOSIMILAR STATUS
- 40 TABLE 38: AMGEN/DAIICHI SANKYO - BIOSIMILARS–LAUNCHED & PIPELINE

CHARTS AND ANNEXURE:

- 1 CHART 1: ANEMIA DYNAMIC MARKET IN JAPAN (2017-2019)
- 2 CHART 2: NEUTROPENIA MARKET DYNAMICS
- 3 ANNEXURE: - I YEAR WISE PARTNERSHIP IN BIOSIMILAR SPACE IN JAPAN
- 4 ANNEXURE: - II BIOSIMILAR GUIDELINES ADOPTED BY VARIOUS COUNTRIES
- 5 ANNEXURE:-III ACTIVE FOREIGN COMPANIES IN BIOSIMILAR SPACE- JAPAN

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