

Japan Biosimilar- Active Players In Quest of a Specialty & Niche BS space

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Abstracts

Filgrastim BS and Lantus BS Approval- Encouraging uptake and a lesson to fast track JP approval based on Ex-Japan data!

Remicade biosimilar “NK” – A slow start does not pull back NK in starting PhIII for Herceptin BS in Japan

Active companies in Biosimilar Space: Local Japanese Generic Giants- Opening door for Biosimilars in Japan? - Will go for All or Niche in BS space???- Opportunities beyond 2020?

Encouraging Uptake of Filgrastim BS and Lantus BS in 2015 in Japan is indicative of Japan being a key important market after the EU for growth of Biosimilar players in the next five years. 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).

In contrast, there is a very slow uptake of Remicade Biosimilar post one year launch (~1% volume share). Biosimilars remains to be the key weapon to curb increasing healthcare cost in Japan & there is a forward pressure on Chuikyo (Central social Insurance Medical Council) by Zaimu-sho (Ministry of Finance- Japan) to increase use of biosimilars. We see that Abenomics measures and government involvement in biosimilar use would lead to the same type of progress for complex mAb Biosimilars in the coming times in Japan

The launch of Sandoz EU approved dosage form of Filgrastim BS in Japan, and Lantus BS based mainly on foreign studies (only one PhIII study involved JP patients from the eight studies submitted for approval) along with Celltrion-NK Remicade biosimilar in 2014/2015 in the Japan pharma market demonstrated more flexibility for EU- Ex-Japan data by JP regulatory authorities for a biosimilar approval and a less stringent path vs. US for BS approval.

Biosimilar of Complex mAb structure is an opportunity of cumulative market size of ¥300b in the next three years in Japan. It will open doors for first oncology biosimilar mAb in Japan after Remicade BS launch in 2014, while in next 7 years it is cumulative ¥600b market opportunity for biosimilar players.

While analyzing the launched biosimilar penetration since 2009 launch in Japan (Growth hormone, Erythropoietin, G-CSF), use of the product in DPC hospitals, simple protein moiety and product reimbursement under high cost medical care benefit programme of NHI/JP government are the key JP specific factors which decide uptake timeline and penetration of each biosimilar 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. 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)

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. It details 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

EXECUTIVE SUMMARY

Biosimilars (BS) – One of the key weapons for Government to curb healthcare cost in Japan

Uptake of Filgrastim and Lantus BS in Japan - Better than Small molecule generics—Key reasons

A slow start of Remicade BS “NK”- Will it change in near term or take time?

“Abenomics” initiatives to Promote BS use- How will it change the current scenario?

BS use must to curb healthcare cost- A forward Pressure on “Chukiyo”?- Japan early than US in approving “mAb” biosimilar- at What Price?

Upcoming next opportunities in biosimilar space in Japan beyond key Onco/RA drugs and Post 2020

Licensing activities in biosimilar space in Japan-

Current Status of pipeline of Each Active company in the BS space:

What is in and what is left?

Are some still in the dilemma of entering the BS space??

Most of the companies have cherry picked couple of biologics from the full basket

Launch timeline and Our view on Each potential key opportunity in Biosimilar space in Japan based on

Regulatory/Development investment - JP dosage strength of originator vs. US dosage strength of Originator

JP Market size and Reimbursement/NHI Price of Originator

Expected no. of players in the biosimilar space in Japan, Innovator strategy in Japan, Re-examination period expiry

Key challenges for each biosimilar opportunity in Japan

Niche BS opportunities in Japan

Factors driving biosimilar penetration in Japan – Government incentives to prescribe “BS” is key.

JP specific factor-

Use in DPC hospitals

Reimbursement under high cost medical care Government benefit programme.

Price difference for small molecule generic use vs. biologic - how big role it will play for biosimilar penetration?

Therapy Specific Factor-

Acute vs. Chronic/ Pediatric vs. Adult

Support therapy vs. treatment therapy

Physician experience of using class of therapy drugs

Table 1: Summary Table –Originator JP Dosage strength, Launch timeline and our view on each Potential biosimilar opportunity, Key players, and Key challenges

Table 2: Other Key JP Specific opportunities in Complex Mab biosimilar area

Table 3: Opening Opportunities in Biosimilar Space in Japan

Table 4: Japanese Companies in the Biosimilar Space

LAUNCHED BIOSIMILARS IN JAPAN:

FILGRASTIM (GRAN) BS:

Filgrastim biosimilar Japan - Neutropenia Market dynamics, Intensified Competition in Filgrastim Biosimilar Space?

Launch of Pegfilgrastim by KHK in Japan- How will it impact market dynamics for Filgrastim biosimilar?

Dosage Strength: Comparison of each available BS vs. GRAN (Originator) – Does one need the photocopy of a JP originator product to get approval - A Myth?

What type of Bridging study was done by Sandoz for JP approval of its Ex-Japan approved Filgrastim BS?

INSIGHT FROM THE CLINICAL STUDIES SUBMITTED FOR REGULATORY APPROVAL OF GRAN BS

Dosage strength comparison of Filgrastim BS vs. GRAN BS-

Regulatory studies submitted for “Made in Japan” vs. “ Made for Japan” GRAN BS

Teva/NK's GRAN BS

Fuji Pharma/Mochida GRAN BS

Sandoz/Sawai GRAN BS

NHI reimbursement pricing – Trends for GRAN biosimilar

% price cut to Originator- Impact on NHI reimbursement price to biosimilar

For Sandoz, Late entry did not result in any NHI reimbursement price disadvantage???-Implications

Observed Impact Post tw years of Launch in Crowded Filgrastim BS market-

Estimated volume share vs. Gran - Same as the best-selling generic small molecule penetration in Japan.

Impact of “Made & Tested in Japan” vs. “Imported by Japan” on Filgrastim BS market share dynamics post tw years of launch

G-Lasta launch and uptake impact on Filgrastim BS market

Table 5: Local vs. Overseas Clinical Studies Submitted for JP approval by each BS player

Table 6: Mochida- Filgrastim BS studies submitted for Approval

Table 7: Nippon Kayaku- Filgrastim BS studies submitted for Approval

Table 8: Sandoz- JP Filgrastim BS – same as US dosage strength- Studies submitted for JP approval

Table 9: NHI REIMBURSEMENT pricing trend of GRAN, FILGRASTM BS and G-LASTA

Table 10: FILGRASTM BS – Competitive landscape – Market strategy of each player

Table 11: Sales Trend of Filgrastim BS/GRAN/G-LASTA

Chart 1: Japan Neutropenia Market dynamics- Change in last one year

Chart 2: Japan Neutropenia Market – Market share of each key player

Chart 3: Volume share trends of GRAN and Filgrastim BS

REMICADE BIOSIMILAR:

SLOW UPTAKE POST ONE YEAR IN MARKET BUT SWITCH DATA AND EXPECTED GOVERNMENT INCENTIVES FOR BS USE WILL CHANGE PICTURE IN NEXT TWO-THREE YEARS

Findings from JP approval of First complex mAb - Remicade biosimilar in Japan

Extrapolation of Indication expansion- possible or not? What studies needed/submitted?

Details of clinical studies submitted for Remicade biosimilar “NK” approval

PMS studies and label of Remicade BS

NHI reimbursement price to Remicade biosimilar-

Role of JP clinical studies

Originator NHI Price cut in Next NHI price revision (April-2016)

Table 12: Clinical development of Remicade biosimilar – Clinical studies data submitted for JP approval

REMICADE BIOSIMILAR JAPAN MARKET DYNAMICS- Role of PhIII study in respective indications- Only RA study carried out

Remicade use in hospitals

Remicade use in DPC hospitals

Remicade biosimilar use may reduce working capital of hospitals to some extent

Co-pay needed for Remicade treatment in Japan- High cost healthcare reimbursement benefit has a key role to play- Reforms under discussion-April-2016 price revision may change current co-pay benefit dynamics

Competitive landscape of Remicade biosimilar-

Nippon Kayaku's entry in RA market

Nichi-Iko's late entry

Table 13: Clinical Data Comparison of CT-P13 vs. INX in RA

LANTUS BIOSIMILAR- JAPAN PERSPECTIVE

Early uptake of LLY BS ENCOURAGING- FUJIFILM LANTUS BS- The first Insulin “Made in Japan” on the way

Regulatory studies submitted for Lantus BS approval in Japan- Only one Ph 3 study included JP patients, else all studies on Foreign patients submitted for approval.

NHI reimbursement pricing of Lantus BS in Japan

Early uptake encouraging and better than EU- Probable reasons??

Competitive Landscape in Japan

Change in Market dynamics of Lantus in Japan- DPC use of Lantus.

Table 14: Lantus, Lantus XR and Insulin Glargine “BS”- Dosage Strength/NHI Price

Table 15: Lantus BS Estimated Volume share in Japan/EU market post Launch

Table 16: Clinical studies submitted for Lantus BS approval in Japan

Table 17: Other Key Biosimilar Opportunities in Insulin area in Japan

LESSONS FROM OTHER LAUNCHED BIOGENERICS PROGRESS IN JAPAN SINCE 2009 & OTHER POTENTIAL NICHE BS OPPORTUNITIES

Launched biosimilar in Japan- Uptake Varies per Therapy area

Growth Hormone - Erythropoietin (EPO) - Uptake vs. which opportunity poised best for highest penetration?

EPO- Dmarket forces allow this biosimilar market to grow like EU??

Japan – Anemia market Dynamics- Trend of market share of key EPO in 2014

Table 18: Launched biosimilar in Japan- Uptake Varies per Therapy Area

Table 19: Anemia Market- Market share and sales of Erythropoietin

Table 20: Niche opportunities other than complex mAb

Chart 4: Japan Anemia market- Trends of Market share of each player

Chart 5: Japan Anemia market – 12 month cumulative market share

AUTOIMMUNE AND ONCOLOGY BIOSIMILARS: JP Specific Opportunity other than key complex MAB

AUTOIMMUNE BIOSIMILARS: RA Market – Share of KEY RA mAb DIFFER in Japan vs. WW Market

Enbrel BS – Next opportunity in RA space after Remicade

Humira -a limited n of players in Japan? - Probable Reasons

Actemra and Cimzia- Opportunities beyond 2020 and more attractive?

Patent expiry (Indication wise JP patents, Reexamination period expiry) and

Competitive Landscape of Autoimmune biosimilar in Japan- Market dynamics will be

different for Remicade/Humira/Enbrel biosimilar despite targeting similar key markets

Table 21: RA Biologics sales Trend Japan 2010-2014

Chart 6: RA biologics Market share

ONCOLOGY BIOSIMILAR IN JAPAN - HERCEPTIN followed by AVASTIN will be the first in the market

Herceptin Biosimilar- CLEOPATRA success and MARINE failure makes it an interesting opportunity- A Next mAb opportunity to watch out for in Japan

Big Oncology Focused Japanese Pharma Giants- D they follow AZN type of product specific BS deal- to strengthen their Oncology NCE franchisee?

Patent expiry (Indication wise JP patents, Reexamination period expiry) and

Competitive Landscape of Oncology biosimilar in Japan- Era starts with Expected launch of Herceptin biosimilar in 2016/2017 in Japan

OTHER NICHE OPPORTUNITIES IN AUTOIMMUNE THERAPY AREA

Table 22: Other Niche Opportunities in Onco/Autoimmune therapy area

Table 23: Japan IP landscape of Key biosimilars focusing on autoimmune Disease

Table 24: Japan competitive landscape of key biosimilars focusing on autoimmune disease

Table 25: Japan IP landscape of key biosimilars focusing on oncology disease

Table 26: Japan competitive landscape of key biosimilars focusing on oncology disease

REGULATORY APPROVAL REQUIREMENT FOR COMPLEX MAB BIOSIMILAR IN JAPAN

Japan biosimilar Regulatory Guidelines: Key Take away

JP Requirement: Reference Product, Interchangeability/Substitution, Pharmacovigilance

JP Requirement: PMS for Biosimilar

Somatropin BS

Epoetin Alfa BS

Filgrastim

Remicade

Label for biosimilar in Japan

Annexure-3: Biosimilar Guidelines Adopted By Various Countries

LICENSING/CONSOLIDATION ACTIVITIES IN BIOSIMILAR SPACE IN JAPAN-

Current Status of pipeline of Each Active Company in BS space:

What is in and what is left?

Some are still in a dilemma whether to enter?

Most of the companies have cherry picked couple of biologics from a full basket

In place for most of the JP Innovator + GE companies- Local GE companies still under dilemma of entering.

JP specific hurdles and drivers-

Govt. measures to increase use of generics comes under high cost medical care benefit system- What to expect in next scheduled NHI price revision???

DPC hospitals- Changing scenario

Table 27: Co-pay Slabs in Japan

Table 28: Revised Pricing of key biologics in Japan

Companies Covered: SELECT JAPANESE COMPANIES ACTIVE IN THE BIOGENERICS SPACE

JCR Pharmaceuticals: A Pioneer in Space with Healthy Partners. Now thrives in Regenerative Medicine (Table 29,30)

Meiji Seika Pharma (MSP) – Trastuzumab Race- May not be the first one (Table 31)

Fuji Film - Kyowa Kirin Biologics (FF-KKH) - Looking beyond Domestic Opportunities, First step in that direction by FKB238 JV with Astrazeneca (Table 32)

Nichi-Ik- Aspiring to Capture Overseas Markets As Well, Plans to file Remicade BS in US in 2018 (Table 33)

Mochida: Now Equipped with Full Basket for Being a Top Biosimilar Player in Japan (Table 34)

NiprPharma: Not Much Development Following First Success

Yoshindo: A 'Three Step' Approach to Build a 'BioCompany'

Nippon Kayaku - Pioneering 'New Age' Of Biosimilars by First launching Remicade BS in Japan- A slow start but situation will change soon (Table 35)

Mitsubishi Tanabe: Late Entrant But With Many Strengths

Sawai: Intends to Establish Sales team in Biosimilar Field in next few years

Towa: May Venture in the Biosimilar Space in near term

Daiichi Sankyo- Premium Generics Business. Will Prioritize Biosimilars- Ph III for Enbrel BS started in 2014

UMN Pharma - Transforming Vaccines Heritage into New Generation Biologics but N major progress in recent past

Kissei: Focus to be a Niche Player in BS space

Kyowa HakkoKirin: Gearing up for Bigger Pie- AZN JV is the first step

Aska Pharmaceuticals - Barriers to Gain from Partner's Pipeline

ToyoboBiologics - Eying Biosimilars CMO Business

Gene Techn Science- JP Rising star in biosimilar and biobetter space (Table 36)

Fuji Pharma- Dynamic Specialty Pharma Focusing on Biosimilars

Itochu Chemical Frontier- A trading house with New role in Biosimilar value chain

MGC Pharma- A Bio-pharmaceutical CMO

Annexure-1: Active companies in biosimilar Space in Japan -Domestic JP Cos, Foreign Companies in Japan

Annexure-2: Year wise Partnership in Biosimilar Space in Japan

Annexure-3: Biosimilar Guidelines Adopted by Various Countries

Tables

TABLES

- 1 Summary Table 1: Originator JP Dosage strength, Launch timeline and our view on each Potential biosimilar opportunity, Key players, and Key challenges
- 2 Table 2: Other Key JP Specific opportunities in Complex Mab biosimilar area
- 3 Table 3: Opening Opportunities in Biosimilar Space in Japan
- 4 Table 4: Japanese Companies in the Biosimilar Space
- 5 Table 5: Local vs. Overseas Clinical Studies Submitted for JP approval by each BS player
- 6 Table 6: Mochida- Filgrastim BS studies submitted for Approval
- 7 Table 7: Nippon Kayaku- Filgrastim BS studies submitted for Approval
- 8 Table 8: Sandoz- JP Filgrastim BS – same as US dosage strength- Studies submitted for JP approval
- 9 Table 9: NHI REIMBURSEMENT pricing trend of GRAN, FILGRASTM BS and G-LASTA
- 10 Table 10: FILGRASTM BS – Competitive landscape – Market strategy of each player
- 11 Table 11: Sales Trend of Filgrastim BS/GRAN/G-LASTA
- 12 Table 12: Clinical development of Remicade biosimilar – Clinical studies data submitted for JP approval
- 13 Table 13: Clinical Data Comparison of CT-P13 vs. INX in RA
- 14 Table 14: Lantus, Lantus XR and Insulin Glargine “BS”- Dosage Strength/NHI Price
- 15 Table 15: Lantus BS Estimated Volume share in Japan/EU market post Launch
- 16 Table 16: Clinical studies submitted for Lantus BS approval in Japan
- 17 Table 17: Other Key Biosimilar Opportunities in Insulin area in Japan
- 18 Table 18: Launched biosimilar in Japan- Uptake Varies per Therapy Area
- 19 Table 19: Anemia Market- Market share and sales of Erythropoietin
- 20 Table 20: Niche opportunities other than complex mAb
- 21 Table 21: RA Biologics sales Trend Japan 2010-2014
- 22 Table 22: Other Niche Opportunities in Onco/Autoimmune therapy area
- 23 Table 23: Japan IP landscape of Key biosimilars focusing on autoimmune Disease
- 24 Table 24: Japan competitive landscape of key biosimilars focusing on autoimmune disease
- 25 Table 25: Japan IP landscape of key biosimilars focusing on oncology disease
- 26 Table 26: Japan competitive landscape of key biosimilars focusing on oncology disease
- 27 Table 27: Co-pay Slabs in Japan

- 28 Table 28: Revised Pricing of key biologics in Japan
- 29 Table 29: JCR Pharmaceuticals: A Pioneer in Space with Healthy Partners. Now thrives in Regenerative Medicine
- 30 Table 30: Meiji Seika Pharma (MSP) – Trastuzumab Race- May not be the first one
- 31 Table 31: Fuji Film - Kyowa Kirin Biologics (FF-KKH) - Looking beyond Domestic Opportunities, First step in that direction by FKB238 JV with Astrazeneca
- 32 Table 32: Nichi-Iko- Aspiring to Capture Overseas Markets As Well, Plans to file Remicade BS in US in 2018
- 33 Table 33: Mochida: Now Equipped with Full Basket for Being a Top Biosimilar Player in Japan
- 34 Table 34: Nipr Pharma: Not Much Development Following First Success
Yoshindo: A 'Three Step' Approach to Build a 'BioCompany'
Nippon Kayaku - Pioneering 'New Age' Of Biosimilars by First launching Remicade BS in Japan- A slow start but situation will change soon
- 35 Table 35: Mitsubishi Tanabe: Late Entrant But With Many Strengths
- 36 Table 36: Sawai: Intends to Establish Sales team in Biosimilar Field in next few years
- 37 Table 37: Towa: May Venture in the Biosimilar Space in near term
- 38 Table 38: Daiichi Sankyo- Premium Generics Business. Will Prioritize Biosimilars- Ph III for Enbrel BS started in 2014
- 39 Table 39: UMN Pharma - Transforming Vaccines Heritage into New Generation Biologics but N major progress in recent past
- 40 Table 40: Kissei: Focus to be a Niche Player in BS space
- 41 Table 41: TaKyowa HakkoKirin: Gearing up for Bigger Pie- AZN JV is the first step
- 42 Table 42: Aska Pharmaceuticals - Barriers to Gain from Partner's Pipeline
- 43 Table 43: ToyoboBiologics - Eying Biosimilars CMO Business
- 44 Table 44: Gene Techn Science- JP Rising star in biosimilar and biobetter space
- 45 Table 45: Fuji Pharma- Dynamic Specialty Pharma Focusing on Biosimilars
- 46 Itochu Chemical Frontier- A trading house with New role in Biosimilar value chain
- 47 MGC Pharma- A Bio-pharmaceutical CMO

CHARTS

- 1 Chart 1: Neutropenia Market Dynamics Change in Last One Year
- 2 Chart 2: Japan Neutropenia Market – Market share of each key player
- 3 Chart 3: Volume share trends of GRAN and Filgrastim BS
- 4 Chart 4: Japan Anemia market- Trends of Market share of each player
- 5 Chart 5: Japan Anemia market – 12 month cumulative market share Partners. Now thrives in Regenerative Medicine

6 Chart 6: RA biologics Market share

ANNEXURE:

- 1 Annexure-1: Active companies in biosimilar Space in Japan Domestic JP Cos,
Foreign Companies in Japan
- 2 Annexure-2: Year wise Partnership in Biosimilar Space in Japan
- 3 Annexure-3: Biosimilar Guidelines Adopted by Various Countries

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