New Phase of Mab Biosimilar Knocks the Door - Biosimilar Opportunities In Japan

Description: The launch of Remicade biosimilar in Dec-2014 in the Japan pharma market demonstrated its changing regulatory environment; it is faster than U.S. in adapting to biosimilar use. After nine years of continuous efforts by the JP government to promote increased use of generics (started in 2006 by launching various benefits for GE use at Pharmacy, hospital level) – now in 2014, Generic penetration of small molecules is changing the trend line and moving towards faster market penetration. While for biosimilars since their launch from 2009- various Japan specific factors has played role for each of them varied market penetration (Growth hormone, Erythropoietin, G-CSF).

2015 will be a litmus test for the next five years cumulative ¥400b biosimilar opportunity in Japan and will give clarity on the importance of "Made in Japan" (Filgrastim biosimilar competition amongst six players) and "Tested by Japan" (NK's Remicade biosimilar) factor for biosimilar penetration. It remains to be seen whether Japan will repeat the story of EU uptake (likes of Norway) for Remicade biosimilar or will follow any of the JP trend line of launched biosimilar (Growth hormone, Erythropoietin, G-CSF launched since 2009) for market penetration.

Approval of Remicade biosimilar with broader label (RA,UC,CD-PMS required for UC/CD) based on PhIII data of EU/Korean RA (Rheumatoid Arthritis) patients and PhI/IIb data in JP patients depict Japanese regulators to be less stringent than US and more or less similar to EU regulators for biosimilar approval requirements and provides ease on regulatory front for entering in Japan biosimilar market.

Consolidation activities are in place for biosimilar entry by a couple of big players (Daiichi-Sankyo, KHK), JP Innovator+ GE companies (Meiji, Fujifilm, Nippon Kayaku, Mochida, and Kissei), Global Multinationals (Pfizer, Sandoz) and some rising star JP local companies (Yoshindo, Gene Techno Science, Sanwa Kagaku). Recent learning suggests that expectations from partnering are not met at many places. This report provides a crisp summery on activities and plans of ~19 Japanese companies venturing in bio-similar space and ~6 multi-national companies that are going to play important role in the space. It also highlights how the consolidations activities are rapping up currently in biosimilar space, JP companies interest in hedging risk of biosimilar development by partnering with more than one company and where the opportunities are left unexplored for each RA and Oncology mAb.

In this report, along with JP regulatory/IP landscape for each mAb biosimilar opportunity, we attempt to evaluate the future competitive landscape in Japan, and assess the overall attractiveness of the same for market penetration (JP specific factor/Therapy specific factor). Considering NHI reimbursement bracket for each product, current market size of originator, expected no. of biosimilar players, JP biosimilar local companies key strength in specific therapy area/market (Hospital/GP/DP/DPC) etc.. - We try to identify the key determinates to succeed for each of the biosimilar opportunity in Japan.

Contents:

EXECUTIVE SUMMARY
2015- A year of litmus test for complex mab biosimilar penetration in Japan??
Upcoming next five year opportunities in biosimilar space in Japan
Factors driving biosimilar penetration in Japan - What will weigh more? - JP specific factor or Therapy specific factor or else??
JP specific factor-
Use in DPC hospitals
Price difference for small molecule generic use vs. biologic- how big role it will play for biosimilar penetration
Reimbursement under high cost medical care Government benefit programme
Therapy Specific Factor-
Acute vs. Chronic/ Pediatric vs. Adult
Support therapy vs. treatment therapy
Physician experience of using class of therapy drugs....
Consolidation activities in biosimilar space in Japan-
Alliance done by JP innovator, JP Innovator+ Generic, JP generic companies –
Most of companies have cherry picked couple of biologics from full basket
Some are still in dilemma for entering
Launch timeline and Our view on Each potential key opportunity in Biosimilar space in Japan based on JP Market size, Expected no of players in biosimilar space in Japan, Innovator strategy in Japan, Re-examination period expiry
Key challenges for each biosimilar opportunities in Japan

Table 1: Summary Table – Launch timeline and our view on each Potential biosimilar opportunity, Key players, and Key challenges
Table 2: Opening Opportunities in Biosimilar Space in Japan
Table 3: Japanese Companies in the Biosimilar Space

LESSONS FROM LAUNCHED BIOGENERIC PROGRESS IN JAPAN SINCE 2009
Launched biosimilar in Japan- Uptake Varies per Therapy area
Growth Hormone, Erythropoietin, Filgrastim- Uptake vs. which opportunity poised best for highest penetration?
EPO- Do market forces allow this biosimilar market to grow like EU??
Japan – Anemia market Dynamics- Trend of market share of key EPO in 2014
Filgrastim biosimilar- Japan- Neutropenia Market dynamics, Intensified Competition In Filgrastim Biosimilar Space?
Launch of Pegfilgrastim by KHK in Japan- How it will impact market dynamics for Filgrastim biosimilar?
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
Table 4: Launched biosimilar in Japan- Uptake Varies per Therapy Area
Table 5: Filgrastim/Gran biosimilar- Competitive landscape- Market strategy of each player
Table 6: NHI Reimbursement Price- Gran Biosimilar Pricing Trend

REGULATORY APPROVAL REQUIREMENT AND REIMBURSEMENT SCENARIO FOR COMPLEX MAB BIOSIMILAR IN JAPAN
Japan biosimilar Regulatory Guidelines: Key Take away
- JP Requirement: PMS for Biosimilar

Somatropin BS
Epoetin Alfa BS
Filgrastim
Remicade
- Label for biosimilar in Japan

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

NHI reimbursement price to Remicade biosimilar-
- Role of JP clinical studies
- What to foresee for the next two biosimilars expected to get an approval in 2016?
- Table 7: Clinical development of Remicade biosimilar – Clinical studies data submitted for JP approval

REMICADE (INFLIXIMAB) BIOSIMILAR – JAPAN MARKET DYNAMICS- For volume market share- Does it repeat the story of Norway? Or market penetration like Epoetin/Filgrastim biosimilar in Japan?? Various factors to account....
Role of PhIII study in respective indications- Only RA study is 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
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