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New Phase of Mab biosimilar knocks the door Biosimilar Opportunities In Japan

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Abstracts

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

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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.

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COMPANIES MENTIONED:

Chugai
Kyowa Hakko Kirin
Toray
Kissei
JCR
Abbott JP
Mitsubishi Tanabe

Takeda
Zenyaku Kogyo
Eisai
Aska
Daiichi Sankyo
Fuji Pharma
Fujifilm Pharma
JCR
Meiji Seika Pharma
Mochida
Nichi-Iko
Nippon Kayaku
Nipro Pharma
Sawai
Towa
Taiyo
Toyobo biologics
UMN Pharma
Yoshindo
Gene Techno Science
Sandoz Japan K.K.
Symphogen A/S
Dong-A
LG lifesceinces
Celtrion
Daiichi Sankyo Espha
Catalent Pharma Solution
UNIGEN

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