

# MITSUBISHI TANABE - Remicade Biosimilar in Japan: Rapid Movements in Competitive Landscape!

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## Abstracts

On September 11th, Nippon Kayaku (NK) has filed BLA for Remicade biosimilar in Japan (CT-P13, partnered with Celtrion). If approved, it will be the first mab biosimilar to be launched in the Japan. NK's BLA filing is based on the EU clinical data provided by Celtrion and some clinical studies done in Japan. Based on reported positive PhIII data of CT-P13 in European RA patients against originator Infliximab (Table 2- CT-P13 Global PhIII data), we expect it to get an approval in Japan within standard review timeline and launch by FY2014. Currently, Remicade is growing at ~7% YoY and posted ~¥73b in 03/13. Other than NK - Nichi-ikko (Aprogen/Sanofi-Table 3) is also preparing to launch biosimilar of Remicade by 2014/2015. As Nippon Kayaku.....Remicade in Japan is more used by.....2014 NHI Price Revisions More Crucial than Remicade Biosimilar For Remicade! In the next NHI price revision due in April -2014 - mainly four topics under consideration by CSIMC are of great importance. These are.....

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