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Celltrion files for Remsima approval in Japan

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Singapore: Korea-based Celltrion has completed filing procedure of biosimilar drug Remsima to obtain Japan's Ministry of Health, Labour and Welfare (MHLW) approval.

Remsima is a biosimilar treatment akin to rheumatoid-arthritis drug Remicade and is the world's first biosimilar mAb to receive European Medicines Agency (EMA) approval with global clinical trial results.

Celltrion jointly conducted clinical trial in Japan with its partner company, Nippon Kayaku. Last July, Celltrion officially completed these clinical trials in Japan. Celltrion expects to launch Remsima in the Japanese market within 2014 as approval procedure usually takes around a year in Japan.

Remicade, the originator product of Remsima, is a TNF antagonist treatment antibody in terms of market share in Japan. Japan is the second largest market for Remicade following the USA.

An official from Nippon Kayaku elaborated, "The Japanese approval for Remsima will be good news not only for patients in Japan who previously had limited access to advanced therapeutics, but also for their families and their healthcare providers. As Remsima has already successfully received approval from the EMA, the approval process in Japan is expected to proceed smoothly."