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Merck - Celltrion filed first mAB Biosimilar in Europe: Remicade Challenged

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Abstracts

Celltrion filed infliximab biosimilar (CT-P13) in Europe and was accepted for review by EMA. It is the first biosimilar mAb to be filed for approval in Europe. The patent for Remicade is expected to expire by 2014 in Europe and Japan. According to EMEA recent guidelines, agency shall ensure that the Opinion of the CHMP is given within 210 days (not counting clock-stops within the procedure) and in accordance with the standard timetable. If the CHMP accepts the accelerated approval request by the filer, the timeframe for the evaluation will be reduced to 150 days. It is unclear whether Celltrion has submitted the application for accelerated approval. Celltrion conducted PhI and PhIII clinical trials with the duration of 12 months in more than 850 patients. It has already filed Infliximab biosimilar for approval with Korean FDA. Hospira has the European marketing deal with Celltrion.

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