

FDA Accepts ACTEMRA sBLA for 1st- Line – A Step Closer Towards Approaching Full Market Potential!

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Abstracts

FDA accepted Actemra's application for 1st-line biologic for RA patients. The development brings Actemra a step closer to its likely full market potential where it will be used at par with anti-TNF therapies in US and can generate additional \$1b+ sales. Its data from head-to-head trial vs. Enbrel and approval as SC formulation are also crucial in determining sales ramp of Actemra and are due by 1H 2012 and 2014 respectively. We see a fair possibility of Actemra eventually being approved for 1st-line biologic before PDUFA action date. Non-availability of 1st-line data on US population would be the weakest part of data submitted. However, as data accumulate from European population, data from head-to-head trial vs. Enbrel will be available; Actemra will come in front with a stronger claim for its use as 1st-line.

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COMPANIES MENTIONED

CHUGAI, ROCHE

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