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Abstracts

Pfizer has been granted FDA approval for Xeljanz (tofacitinib) 5 mg twice daily for the treatment of adults with moderate to severe active rheumatoid arthritis who had an inadequate response or is intolerant to methotrexate (MTX). FDA has asked for additional data to assess the risk and benefit of 10 mg twice daily dose. We do not see the advantage of oral delivery (twice daily) as important, when injectable drugs are administered once fortnightly (subcutaneous) or much less frequent than tofacitinib. Besides no differentiation from a clinical perspective over existing drugs which are well entrenched, we forecast a slow ramp up driven by penetration in, (i) an inadequate response or intolerant to MTX, biologic-naïve pts, and (ii) in non-responders to anti-TNF alpha therapy. Pfizer is also planning to discuss with FDA for the role of tofacitinib as first-line treatment option based on ORAL-Start two-year study which demonstrated superior efficacy (inhibiting structural damage) versus methotrexate with similar tolerability issues. Taken together, we project ww peak sales of $1.2b by 2017 for Xeljanz.

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