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FDA issues concerns about optimal baricitinib doses for the treatment of moderate-to-severe rheumatoid arthritis and delays drug approval

In a recent study, baricitinib 4 mg was compared with placebo or adalimumab in methotrexate-resistant RA patients (Taylor P. *et al.* Baricitinib versus Placebo or Adalimumab in Rheumatoid Arthritis N Engl J Med 2017; 376:652-662). In another study, baricitinib 4 and 2 mg was compared with placebo in DMARD-resistant RA patients (Dougados M. *et al.* Baricitinib in patients with inadequate response or intolerance to conventional synthetic DMARDs: results from the RA-BUILD study. Ann Rheum Dis 2017; 76:88-95). In both studies, baricitinib 4 mg was found superior in reaching an ACR 20 response, at the cost of limited infectious side effects. However, significant clinical results were also observed at the 2 mg dose, which might be the reason for the FDA concerns about optimal dosing described in the link here: http://www.prnewswire.com/news-releases/us-fda-issues-complete-response-letter-for-baricitinib-300439816.html.

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