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Rheumatoid Arthritis [2017]: Bulletin #1

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Abstracts

This edition presents key opinion leader (KOL) views on recent developments in the treatment of rheumatoid arthritis (RA). Topics covered include; KOL views on the Food and Drug Administration's issuance of a complete response letter, in April 2017, regarding Elli Lilly's Janus-kinase inhibitor Olumiant (baricitinib), requesting additional dosing and safety data; the European approval, in March 2017, of Pfizer's Janus-kinase inhibitor, Xeljanz (tofacitinib), following the product's delayed entry to this market; the FDA's approval, in May 2017, of Sanofi and Regeneron's second-in-class, anti-interleukin-6 (IL-6) inhibitor, Kevzara (sarilumab), for the treatment of moderate to severely active RA.

Business Questions

In April 2017, the FDA issued a complete response letter in respect of Elli Lilly's Janus-kinase inhibitor Olumiant (baricitinib), but what was the reason for this given that European approval for the product was granted in February 2017? What is the future of this product in the US market?

How will Olumiant compete with first-in-class Xeljanz (tofacitinib), which is well established in the US market?

With a batch of biosimilar anti-TNF products already on the market, and more in pre-registration and late-stage development, how successfully can the newer and more expensive Janus-kinase inhibitors compete with these more cost-effect therapies?

How can Kevzara (sarilumab) differentiate itself from first-in-class Actemra/RoActemra (tocilizumab; Roche)? How well does Kevzara compare in terms of safety and efficacy?

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As the number of marketed therapies for RA expands, where in the treatment paradigm will the anti-IL-6 drugs fit?

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