

Physician Views: What opportunity beyond the anti-TNFs in rheumatoid arthritis?

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Abstracts

Last week, FirstWord identified Bayer and Johnson & Johnson's anticoagulant Xarelto as the industry's leading product-level sales growth driver in 2013. Furthermore, in announcing its Q4 results, Bayer increased its own peak revenue forecast for the drug, from around \$2.7 billion to approximately \$5 billion.

Xarelto has defied commercial expectations, particularly regarding how it has fended off competition from Bristol-Myers Squibb and Pfizer's Eliquis, which is widely considered to have the best clinical profile among the new generation of anticoagulants.

FirstWord's recent list of the best-selling drugs in 2013 once again illustrated the commercial 'footprint' of the anti-TNF inhibitors, and in particular the three biggest-selling drugs in this class – Humira, Remicade and Enbrel. Positioned as three of the four best-selling drugs in 2013, they contributed combined revenue of around \$28 billion.

A key facet relating to both the commercial and clinical profiles of these products is their longevity, with Enbrel and Remicade both launched in 1998 and Humira launched in 2002.

From a clinical perspective, physicians have gained much experience in using these products, which has greatly helped to entrench them as the gold-standard second- and third-line therapy in rheumatoid arthritis (RA) patients behind methotrexate. Commercially speaking, the biologic status of these drugs has extended their lifecycles beyond those associated with a small-molecule product, indicating that impressive annual revenue expansion will be delivered for some time.

Herein lies something of a paradox for developers looking to access the RA market. To gain significant market share in the second- or even third-line settings a new treatment would be required to demonstrate notable superiority to the likes of Humira, Remicade and Enbrel that would need to be sufficient to trigger a paradigm shift in the way that rheumatologists treat RA.

Simultaneously, however, the scale of revenues generated by the anti-TNFs provides a tantalising commercial prospect for developers, albeit if a new product was to gain the majority of use in third-line RA patients.

But is the market opportunity for alternative biologic RA therapies – both already marketed (such as Bristol-Myers Squibb's Orencia and Roche's Actemra and Rituxan brands) and those in the late-stage pipeline (such as Eli Lilly's baricitinib, Regeneron Pharmaceuticals/Sanofi's sarilumab, Novartis' secukinumab or Johnson & Johnson's sirukumab) – likely to evolve significantly in the short to medium term?

The slower-than-expected launch of Pfizer's Xeljanz – touted as a potential anti-TNF competitor, but offering the convenience of oral availability – demonstrates just how entrenched the leading anti-TNFs are, particularly given the evidence to suggest that the injectable nature of these drugs is a notable barrier to even broader uptake.

To help answer these questions, this week's Physician Views poll asks rheumatologists based in the EU5 and US.

How many anti-TNF therapies an RA patient typically fails before they progress onto an alternative biologic therapy?

What their preferred non-anti-TNF therapy is in this instance?

What their primary reason is for selecting this product?

Based on their knowledge of the current treatment landscape and late-stage R&D how they expect the market for biologic RA therapies to develop over the next decade?

Excluding the emergence of a therapy that delivers a compelling efficacy/safety benefit over the anti-TNF products, what scenario they think would most likely see them increasingly usage of an alternative product in favour of an anti-TNF in RA patients progressing beyond methotrexate?

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