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Physician Views: What Scope for the Next Oral RA Therapy?

https://marketpublishers.com/r/P6CBC31E32CEN.html
Date: March 2015
Pages: 0
Price: US$ 695.00 (Single User License)
ID: P6CBC31E32CEN

Abstracts

The rheumatoid arthritis (RA) market is one of the largest in the pharmaceutical sector and is dominated by biologic therapies, primarily the TNF inhibitors. The three largest products in this category – AbbVie's Humira, Johnson & Johnson and Merck & Co.'s Remicade, and Amgen and Pfizer's Enbrel – were positioned among the four biggest selling drug brands globally in 2014, generating combined sales of around $30 billion.

One of the key dynamics within this market is the emergence of biosimilar competition. Biosimilar versions of Remicade have already launched in Europe and are expected to debut in the US within in the next few years. How the availability of these products, and the pricing strategies attached to them, shape the broader market remains to be seen, but the value of the RA sector also continues to attract branded developers.

One such opportunity is focused on the continued development of small-molecule products that offer comparable efficacy and safety to the TNF inhibitors, but with the benefit of oral dosing. Pfizer has enjoyed a considerable first-to-market advantage here, having secured US approval for its Xeljanz franchise in 2012.

Xeljanz has largely failed to meet pre-launch revenue expectations, however, generating sales of $308 million in 2014, with this performance stemming partly from a delay to European approval. In addition, key opinion leaders (KOLs) interviewed by FirstWord for a new Therapy Trends report on the RAs market (for more details click HERE) also cite higher than expected pricing for Xeljanz as a notable barrier to usage.

With rebating flexibility in the US market already cited by analysts as a potential defensive strategy for the TNF inhibitor brands versus future biosimilar competition, it is perhaps not surprising that list pricing for Xeljanz almost on par with the TNF inhibitors

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has proven prohibitive in terms of uptake, particularly as many KOLs expected Pfizer's drug to be priced lower.

What does the performance and positioning of Xeljanz mean for other oral JAK inhibitors in development, such as Eli Lilly's baricitinib – for which Phase III data is expected imminently – or Galapagos' Phase II-stage filgotinib, which is currently partnered with AbbVie?

Baricitinib, the most advanced competitor to Xeljanz, benefits from a once-daily dosing profile (versus twice-daily for Pfizer's drug), but many KOLs expect pricing to play a key factor in driving uptake should Eli Lilly's product reach the market

To better understand how the market for oral RA therapies is likely to evolve assuming that baricitinib, as expected, demonstrates Phase III data broadly comparable with Xeljanz, we are polling US-based rheumatologists with the following questions this week…

> What is the most common reason for you not to prescribe Xeljanz in favour of a biologic RA therapy following methotrexate?
>
> Baricitinib (currently in Phase III studies) is expected to be the next oral RA drug to reach the market. Assuming efficacy, tolerability and side-effect profile are comparable to Xeljanz, how significant an advantage do you think once-daily dosing for baricitinib will be (versus current twice-daily dosing for Xeljanz)?
>
> Based on your experience in this market, what level of pricing discount versus Xeljanz do you think will be necessary to drive adoption of baricitinib in favour of Xeljanz?
>
> What impact do you think availability of a cheaper, once-daily oral treatment will have on overall uptake of oral RA therapies at the expense of biologic therapies?
>
> Do you think the availability of biosimilar anti-TNF products will have an impact in limiting the uptake of oral JAK inhibitors?

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