Kieger – Thoughts from the Street

Biosimilars Congress 2017

Zurich, September 26-27, 2017

Market anticipation of profitability in biosimilars is likely set for a steep disappointment

We attended the Biosimilars Global Congress held in London and happened to be one of the few participants from the financial community.

After two days, our most important observations from the congress were 1) Biosimilars were likely to be more intensely competitive than what we thought or market is pricing currently 2) Regulators are likely to amend current guidances or show flexibility without compromising on quality to approve biosimilars

Biosimilars have been an important topic of debate over the recent few years, more from a regulatory and legal perspective than a clinical perspective. With almost all of the top selling blockbuster drugs currently being biologics, and accounting for nearly USD 240 bn of global pharma sales, the need for a clearer or easier biosimilar pathway was always clear though. In this context, the European regulatory agencies have definitely taken significant strides compared to the US FDA.

Competitive intensity in biosimilars is likely to be high

Apart from firms which are well established in the biosimilars field, we met a few other firms which are actively working on this area in Europe & Asia. The discussions around the evolution of this space points us to a level of competitive intensity which is higher than what we believe market is forecasting. We concluded that for most biologics, there were more than just the 2-3 biosimilars that is generally priced in; e.g., Filgrastim has currently five different biosimilar versions.

Eventually, regulators are likely to show flexibility around discussions

What emerged from the discussions was that the European regulators have not only led the way ahead with clear guidances, but also recognize that case-by-case flexibility has its merits. This is because of their view that non-identicality is a normal feature of all biologics (even innovators). We discussed the case of a biosimilar application for Eculizumab where regulator needed just Pharmacokinetic (PK) studies as comparable PK dynamics at population level would mean it was unlikely that biosimilars will behave differently at the patient level. Similarly, the distinction between Interchangeability and Substitutability being at the regulators and the pharmacies jurisdiction respectively were also made. Switching was relevant for chronic conditions and it would be unlikely to see random switching every few months just due to a lower price. Hence, in chronic conditions, the first or second biosimilar would have an advantage.

Biosimilar companies should brace in for complexities in pricing

Over the past decade, we have noted firms stating the cost of getting a biosimilar to the market being around USD 100-$150 mn per product. However, with the current competitive landscape, the planned return on their investments may not materialize. One speaker told of how the cost of APIs for biologics have declined by 20X in the last few years. Thus, with both production and developmental costs falling, there is likely a strong negative bearing on pricing. Lastly, the power of single purchasers (like the Government) or few (large Insurance companies) in bringing down the pricing is still very high. Poland was discussed as an example where a biosimilar completely replaced the brand. The Norwegian regulator spoke of getting 'remarkable' discounts on biosimilar Infliximab, which could likely be a barometer for future launches. Thus, all new patients are directly started on biosimilar Infliximab. In our view, these factors would mean that the pricing dynamics will likely get materially demanding, and also that pricing of newer Biologics could face a 'chilling' effect due to this.

Conclusion: access is easier, profitability in question, Innovators exposed

In conclusion, we felt that as the initial hiccups around approvability, interchangeability, immunogenicity, CQA, Drug Characterization gets resolved, the road for Biosimilars will be easier. However, these would also have the dynamics of impacting profitability more. The innovators, in our view, stand most exposed, as more biosimilar versions at lower prices leaves the innovators on a weaker competitive footing.

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