It appears that the next biological agent is soon to fall to US lookalike competition. Johnson & Johnson’s Remicade looks likely to have to vie with Pfizer and Celltrion’s biosimilar form of infliximab in rheumatoid arthritis and other autoimmune disorders.

The approaching competition has caused a commotion among follow-up rivals, with Pfizer having now sold to Novartis European rights to a second infliximab project that emerged from its own laboratories. The realities of biosimilar competition are becoming more visible, making an investment environment already shaken by fears about pricing pressure still less certain.

If the FDA approves it in April as expected, the lead Remicade biosimilar, widely known as Remsima but code-named CT-P13 in the US, would become the second biosimilar but the first lookalike monoclonal antibody to be launched in the world’s biggest drug market. The first biosimilar was Zarxio, a copy of the protein Neupogen, which is not an antibody.

CT-P13 received the backing of an advisory committee last week. Moreover, the Arthritis Advisory Committee voted 21-3 in support of using data from rheumatoid arthritis and ankylosing spondylitis trials to extrapolate to four other autoimmune conditions in which Remicade is approved – and two of those who voted against did so raised concerns only about long-term safety in Crohn’s disease.

This was an important hurdle for the project to leap. Companies with biological products under threat would obviously prefer that biosimilars show efficacy in every indication, allowing them to preserve their intellectual property estates. In this way the CT-P13 vote might very well have set a precedent.

If this precedent supports the growth of biosimilars, one other stands in its way – namely, a court’s decision that the 2010 law establishing the regulatory track requires the copycat drugs to wait six months after approval before they can be launched (End of the patent dance leaves Sandoz with six-month delay, July 22, 2015). Assuming an April approval, CT-P13 will not be on the market until the fourth quarter of the year.

Rationalising

Meanwhile, Pfizer appears to be trying to rationalise an embarrassment of riches in its biosimilars pipeline. It gained US rights to Remsima with its takeout of the injectables specialist Hospira, which had agreed to collaborate with Celltrion in 2009.

With the Celltrion asset so far advanced it makes sense for Pfizer to begin thinking about how it prioritises its biosimilars pipeline – and a major sign of how it intends to do so came with news that it had sold European rights to an internally developed infliximab called PF-06438179 to Novartis’s Sandoz generics division for an undisclosed amount.

Celltrion’s infliximab is already on the market in Europe, where one of the stranger aspects of the legacy tie-up with Hospira is that it is separately marketed as competing assets – as Remsima by Celltrion or Inflectra by Pfizer (Interview – Celltrion measures up US biosimilar outlook, March 4, 2015).

Three separate marketing efforts was undoubtedly one too many for collaborating companies to assimilate, and Pfizer found a buyer eager for a late-stage infliximab in Sandoz, which has biosimilar antibodies in the form of its Enbrel, Rituxan and Humira lookalikes.

It would not be too surprising to see Pfizer take a similar path in the US should CT-P13 win approval, not to mention needing to make a decision on the two Avastin biosimilars that Celltrion and Pfizer hold. As biosimilars by definition offer no differentiation apart from their price, it does not seem sensible for a single company to try to market more than one.

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