JANSSEN MIL Ex. 7
Pfizer Not Planning US Launch of its Second Remicade Biosimilar Approved by FDA

Posted 14 December 2017 | By Zachary Brennan
The US Food and Drug Administration (FDA) late Wednesday approved the ninth biosimilar in the US and the third for J&J’s Remicade (infliximab). But Pfizer said it will not launch Ixifi (infliximab-qbtx) in the US as the company already has another Remicade biosimilar on the market, known as Inflectra (infliximab-dyyb) (the third Remicade biosimilar is Merck and Samsung Bioepis’ Renflexis (infliximab-abda)).

Pfizer spokesman Thomas Biegi explained to Focus that Ixifi is the Remicade biosimilar that Pfizer developed on its own prior to the company’s acquisition of Hospira in 2015. Hospira and Celltrion had developed Inflectra, which is what the company has decided to market in the US and Europe.

So why go through the FDA approval process and not market an approved product?

Biegi declined to elaborate on the details of Pfizer’s plans, but he said the company is evaluating its strategic options and there are countries for which Pfizer and Celltrion have not brought Inflectra to market.

Meanwhile, Pfizer filed a lawsuit in September against J&J over exclusionary contracts that Pfizer said were limiting its ability to gain Remicade market share. J&J’s brand-name product still controls 96% of the market because of its effective strategies to stall competition.

And though the US District Court in Pennsylvania likely will not decide on whether to take up or dismiss Pfizer’s lawsuit until the beginning of the second quarter of 2018, J&J had to file its motion to dismiss Pfizer’s suit twice because the initial filing incorrectly defined average sales price (ASP). J&J did not respond to a request for comment.

The correction and second filing comes as, according to the Centers for Medicare and Medicaid’s (CMS) most recent ASP report released 5 December 2017, Inflectra’s average selling price (ASP) has declined in 2017 while Remicade’s ASP has increased.

<table>
<thead>
<tr>
<th>Product</th>
<th>Q1 17</th>
<th>Q2 17</th>
<th>Q3 17</th>
<th>Q4 17</th>
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<td>J&amp;J’s Remicade (infliximab)</td>
<td>$776</td>
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Pfizer’s Infliximab biosimilar

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<tr>
<th></th>
<th>$946*</th>
<th>$946*</th>
<th>$753</th>
<th>$738</th>
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*Q1 2017 and Q2 2017 reflect Wholesale Acquisition Cost (WAC) for Inflectra; Inflectra’s first ASP became available in Q3 2017.

Merck’s Renflexis hit the US market in July at a WAC of $753.39, which is lower than the WACs for Remicade or Inflectra, though it remains to be seen if that discount is enough to encourage further adoption of the biosimilar.

"Significant share of the market is tied up by payer contracts with J&J or bundled product at hospitals. To get that share, Merck will have to offer further discounts to the payers, which could be as high as a further 20%-40%," Bernstein analyst Ronny Gal wrote in a note to investors in July.

Tags: Pfizer, Inflectra, Remicade, J&J, Ixifi

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