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Pfizer's Essential Health Leadership On Why US Biosimilars Will Take Off – Eventually

by Jessica Merrill

Essential Health Group President Angela Hwang, Biosimilars President Richard Blackburn and US Biosimilars General Manager John Kennedy discuss the early challenges Pfizer has faced with Inflectra and optimism for the US biosimilars market over the long term.

Pfizer Inc. is in the biosimilar market for the long game, despite the commercial challenges it has faced with its first biosimilar to launch in the US – *Inflectra* (infliximab-dyyb). That was the message the company's Essential Health leadership set out during a briefing on the company's biosimilar strategy at Pfizer's New York headquarters April 10.

"The market for biosimilars is alive and it's real and it's here to stay," Essential Health Group President Angela Hwang said. Hwang took over the top leadership role for Pfizer's Essential Health business late last year, succeeding John Young in a broader leadership reorganization of Pfizer's top ranks. Young moved up to head Pfizer's Innovative Health business while Albert Bourla moved up to be chief operating officer. (Also see "*Appointments: Pfizer, Lilly, Theramex, Evox Therapeutics, Syros, Spruce Biosciences, Rexgenero*" - Scrip, 14 Nov, 2017.)

Hwang previously was global president and general manager of Pfizer's Inflammation & Immunology business, experience that suits her well now as Pfizer tries to get Inflectra off the ground in the nascent market for biosimilars in the US. Inflectra, which launched in late 2016, was the first biosimilar version of *Johnson & Johnson*'s *Remicade* (infliximab) to launch in the US. (Also see "*Pfizer Will Support Inflectra Launch With Dedicated Sales Force*" - Scrip, 14 Nov, 2016.)

Big Challenges And Big Opportunities

The early challenges Inflectra has faced have put a spotlight on what could be a big road block to the commercial uptake of biosimilars in the US. With no interchangeability requirements for biosimilars in the US, brand drug manufacturers have the leverage to simply lower the price of

their drug and negotiate preferred formulary access with payers for the brand product, which has substantially larger volumes and thus larger impact on payers' budgets. J&J has taken a hit on sales of Remicade in the last year because it is offering higher rebates, but it has effectively blocked Inflectra from the market. (Also see "*Payers Like Biosimilars, But Rebates Remain The Bottom Line (For Now)*" - Scrip, 29 Nov, 2017.) Inflectra generated $419m in 2017, whereas Remicade generated $6.3bn.

Pfizer has filed a lawsuit against J&J claiming the company's contracting strategy for Remicade is anti-competitive, alleging the company threatened to withhold rebates on Remicade if Inflectra was reimbursed. The outcome of that lawsuit could have implications for future biosimilar launches. (Also see "*Pfizer v. J&J Sets Stage For Biosimilar Showdown Over Exclusive Contracts*" - Pink Sheet, 20 Sep, 2017.)

Inflectra had a 5.6% share of the infliximab market by volume at the end of 2017, Pfizer said, with about half of that coming from highly-integrated payer systems like the Department of Veterans Affairs and Kaiser Permanente, which have been more receptive to providing access to Inflectra. *Aetna Inc.* added Inflectra to its commercial formulary effective Jan. 1, and Pfizer noted that it is making slow progress on the market access front.

Regardless of the slow launch of Inflectra, the long-term potential of biosimilars is too large to ignore, Global President-Europe, AfME and Biosimilars Richard Blackburn said.

"We are confident about the future," Blackburn said. That optimism is fueled by the increasing role of biologics in treating patients and increasing health care costs. Biologics are expected to represent global sales of roughly $360bn by 2025, with about one-third of those sales no longer subject to market exclusivity, according to Pfizer.

"As you get into the next decade you start to see the really big potential savings," Blackburn said. "We believe the market will form and we are optimistic."

But the US market for biosimilars is not going to take off without some nudging, he added. "There is a continued need for education," he said. "There's got to be fair and equal access to the medicines ... There needs to be a consensus around what is reasonable pricing."

"The sorts of savings that can be achieved in the solid oral generic space will not be achievable in this space, and if that's what stakeholders strive for we will find that companies are unable to make money, and we won't see the successive waves of new compounds coming to market."

Some payers have pointed out that one reason Inflectra has not been able to overcome the market access barrier is because the price is simply not low enough, though Pfizer disagrees with that view. The average sales price (ASP) of Inflectra in the US is about 17% lower than Remicade.

Average sales prices are what drug manufacturers report to the Centers for Medicare & Medicaid Services for drugs reimbursed under Medicare Part B and reflect the average prices including rebates and discounts. Pfizer also talked about offering discounts on the wholesale acquisition cost (WAC) of Inflectra of 25% to 40%.

US Biosimilars General Manager John Kennedy insisted the price of Inflectra is not the issue, since Pfizer has seen strong uptake of Inflectra in the closed payer systems that are reimbursing the drug.

"Anti-competitive tactics like J&J's exclusionary contracting need to be stopped," he said. "I'm convinced there is very significant long-term potential for biosimilars in the US, but now's the time to make sure there is a market that is receptive to them."

An Early Leader And Seven Clinical-Stage Biosimilars

Pfizer is an early leader in biosimilars, a position it acquired with the $17bn deal to buy *Hospira Inc.* in 2015. (Also see "*Hospira Bulks Up Pfizer's Established Products Unit, But Won't Speed A Split*" - Pink Sheet, 9 Feb, 2015.) Hospira had amassed one of the largest biosimilar pipelines in the industry at the time in part through a collaboration with South Korea's *Celltrion Inc.*, which gave it rights to several biosimilar drugs, including Inflectra. In addition to Inflectra in the US, Pfizer also markets *Nivestim*, biosimilar filgrastim, and *Retacrit*, biosimilar epoetin, in Europe.

Pfizer has a biosimilar version of Roche's breast cancer blockbuster *Herceptin* (trastuzumab) pending at the US FDA with action anticipated in the first half of 2018, and two other applications, for biosimilar *Epogen* (epoetin alfa) and *Neupogen* (filgrastim), that have been filed with the agency. The Neupogen application was accepted by FDA in November, while Pfizer resubmitted the Epogen application in November after receiving a complete response letter from the US regulator. Four other biosimilars are in late-stage development: *Humira* (adalimumab), *Rituxan* (rituximab), *Avastin* (bevacizumab) and *Neulasta* (pegfilgrastim). Five undisclosed biosimilars are in preclinical development, Pfizer said.

Humira is considered a golden ticket of sorts, given that *AbbVie Inc.*'s anti-TNF is the top-selling drug in the world six years running. The big question is when a biosimilar could enter the market, however, given AbbVie's strong patent estate on Humira. The company has settled two patent disputes now with *Amgen Inc.* and *Samsung Bioepis Co. Ltd.* that pave the way for biosimilar entry in Europe in October 2018 and in the US in 2023. (Also see "*End In Sight: Humira Stacks Up 20 Years Of US Market Exclusivity*" - Scrip, 5 Apr, 2018.)

Pfizer Essential Health Chief Counsel Eric Aaronson didn't sound particularly bullish about Pfizer's opportunity to launch a biosimilar version of Humira ahead of 2023 because of AbbVie's strong IP estate, though he said the launch timing ultimately would be decided by a court challenge. (Also see "*Humira's 'Unique' Number Of Patents Makes Biosimilar Entry Risky, Pfizer Says*

" - Pink Sheet, 10 Apr, 2018.)