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Kabi Brings In Reddy's Rituximab As Biosimilar Breakeven Date Retreats

Indian Firm's Rituxan Biosimilar Added Amid Pegfilgrastim Frustrations

by Dean Rudge

The Fresenius group had much to say of Fresenius Kabi's biosimilar business during the firm's Q4 and year-end results call, which disclosed a US in-licensing deal for Dr Reddy's proposed rituximab biosimilar and suggested additional biosimilar manufacturing is among its top priorities.

Fresenius Kabi has in-licensed exclusive US commercialization rights to Dr Reddy's Laboratories proposed biosimilar Rituxan/MabThera (rituximab) product, as the German firm once again pushed back its expectations for its biosimilars business to break even at the EBITDA level.

The move broadens the German firm's pipeline and offers a further near-term opportunity, amid continued delays in the US for its proposed pegfilgrastim biosimilar, Stimufend, that have stymied the return on investment for Kabi's nascent biosimilars unit.

"Dr Reddy's is currently executing clinical trials," Kabi noted of the Indian firm's DRL_RI rituximab asset, ahead of a planned US Food and Drug Administration submission in 2023.

Kabi's frustrations for pegfilgrastim are well-documented. It was originally filed with the FDA in 2019 ahead of initial launch plans in 2020, the firm's senior vice president of US biosimilars, Ali Ahmed, underlined to *Generics Bulletin*

Fresenius Kabi Concedes On FDA Pegfilgrastim Chances

By Dean Rudge

04 Nov 2021
Fresenius Kabi is continuing to suffer from the longstanding effects of the US FDA backlog for onsite inspection reviews amid the

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during an exclusive interview last year.

"That was sort of our original launch timing, but unfortunately due to COVID-19, there has been some resource issues understandably, with the FDA not being able to conduct site inspections," Ahmed had summarized. (Also see "*Fresenius Delayed By FDA Inspection Uncertainty As It Works Towards US Pegfilgrastim Launch*" - Generics Bulletin, 12 Nov, 2021.)

coronavirus pandemic. Management discussed Kabi's latest prospects on its proposed pegfilgrastim biosimilar, as well as adalimumab and tocilizumab.

Read the full article here

"COVID, unfortunately, has created unexpected uncertainty related to the timelines of these health authority reviews," Kabi management had added in November last year. "We have low-to-no visibility when the required FDA pre-approval onsite inspection will actually take place" (*see sidebar*).

In an update coinciding with publication of its fourth-quarter and annual financial results, Kabi could only say that the approval was "pending due to a pre-approval inspection"; and that the firm was "committed to supporting the FDA in completing its assessment as soon as possible."

Bolstering Kabi's prospects, the European Medicines Agency's committee for medicinal products for human use had last month recommended that Stimufend should be issued a pan-European marketing authorization. (Also see "*Accord's Teriparatide And Fresenius Kabi's Pegfilgrastim Satisfy CHMP*" - Generics Bulletin, 31 Jan, 2022.)

EBITDA Breakeven Moves Back Once Again

The pegfilgrastim asset had passed into Kabi's hands as part of its September 2017 acquisition of Merck KGaA's biosimilar business. (Also see "*Fresenius Covers All Bases With Akorn Acquisition And Merck Biosimilar Buy*" - Generics Bulletin, 25 Apr, 2017.)

The deal, agreed in April of that year, eventually comprised a €156m ($177m) upfront payment; as well as up to €500m of milestone payments "strictly tied to achievements of development targets in the coming years."

Alongside pegfilgrastim, Kabi also obtained a biosimilar adalimumab product, named Idacio, that it has since launched in more than 30 countries and filed with the FDA.

A biosimilar tocilizumab asset is further back in development, with plans to launch in the US and EU in 2023. (Also see "*Fresenius Kabi Makes Progress On Tocilizumab*" - Generics Bulletin, 8 Sep, 2021.)

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“We expect EBITDA breakeven for 2022, and from the year after onwards, this investment is expected to become highly accretive to our earnings,” Kadi had spelled out of the acquired Merck business in April 2017.

Amid its delays for pegfilgrastim and lower-than-anticipated prices for adalimumab in Europe, however, Kabi had in February 2020 pushed back by one year the proposed EBITDA breakeven date, to 2023. (Also see "*Emerging Markets Help Fresenius Kabi Offset US Pressures*" - Generics Bulletin, 28 Feb, 2020.)

But even that will not happen now, Kabi concedes. “We now expect the EBITDA breakeven in our biosimilars business to be in 2024,” the Fresenius group’s chief financial officer Rachel Empey commented, speaking during Fresenius’ year-end earnings call.

Meanwhile, she added, Kabi in 2022 “expects to roughly double our sales, which were a mid-double digit absolute million-euro number last year.”

Given their growing importance to Kabi and its financials, biosimilars sales are to be reported separately by the firm, beginning in the first quarter of 2022.

€1.4bn Investment Ceiling ‘Tighter Than I Ever Thought’

Upon the Merck deal’s agreement, Kabi had envisioned a €1.4bn investment ceiling. The figure was to include 100% of potential payments to Merck, as well as the ramp-up of R&D and marketing and sales expenses, until the projected EBITDA breakeven in 2022.

Considering its challenges for the biosimilars business, the Fresenius group’s chairman of the management board, Stephan Sturm was asked, was Kabi approaching the initial €1.4bn investment ceiling?

“Given the various delays that we’re suffering right now, it’s going to be tight, much tighter than I had ever thought,” Sturm acknowledged. Pushed further, Sturm could not offer precise financial information, stating: “This is going to be tight for 2023/2024.”

“But frankly, given the progress that we have made, I continue to believe now that we are on the right track.”

He also made clear that the €1.4bn investment ceiling related to the original Merck portfolio only and did not consider any bolt-on deals like the Reddy’s agreement for rituximab.

“On the one hand, I believe it does make sense to broaden the portfolio,” Sturm said. “On the other hand, I am acutely aware of that self-imposed ceiling, and I was wary [not to be] accused of muddying the waters unnecessarily.”

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"I think," he noted, "it would be fair that for any further development projects, we have to start a separate calculation."

Will Kabi Become A 'Master Of Its Own Destiny'?

Talk also turned to biosimilar manufacturing capacity and cost-effectiveness. Its importance continues to grow, especially ahead of biosimilar adalimumab debuting in the US next year.

Consistent, reliable supply has been identified as one of the market's most important factors for biosimilar sponsors. (Also see "*Humira One Year Out: The Largest LOE Event In US Pharma History*" - Generics Bulletin, 31 Jan, 2022.)

Kabi's acquisition agreement with Merck had provided for "reserved and guaranteed access to its manufacturing," and Kabi "at least at this point in time, [has] no intention to build our own manufacturing capacities," it had said almost five years ago.

"Specifically, with Idacio (adalimumab), but also with future molecules, we are taking an end-to-end view in terms of the overall processes that we have: all the way through from the very beginning in R&D, and specifically through the development, testing and final manufacturing processes," Empey had commented in October 2020.

Kabi, she had underlined, was continually looking "at how we can optimize, how we can ramp up the volumes that are going to be required in the most effective and efficient way to really truly drive the highest quality and most efficient processes throughout that full supply chain."

As Kabi continued to weigh up its capital allocation priorities, was the Merck manufacturing agreement sufficient? Sturm was asked. Or did Kabi need to think about a larger scale?

In response, Sturm acknowledged that manufacturing had "been under review right from the beginning of entering into that agreement."

"It is an option for us to use Merck's facilities rather than an obligation," Sturm pointed out. While volume demand continued to be good, "pricing pressure – at least on the margin – has been a bit more pronounced than we had originally assumed."

"This is down to becoming more efficient on the cost of manufacturing," Sturm said. "Therefore, we continue to evaluate whether we may not all be better off focusing those manufacturing capacities on something that Merck truly needs; whereas we should be masters of our own destiny."

However, a decision had not been taken, he underlined. "But, in general, that is the direction that we're headed," Sturm revealed.

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