Special Reports

Beovu, Novartis

by Noah Higgins-Dunn | Oct 25, 2021 3:00am

Beovu has generated a mere $87 million in sales so far this year, a 16% decline compared with the same period a year prior. (Novartis)

Drug name: Beovu

First approval: October 2019, U.S. FDA

Indication: Wet age-related macular degeneration (AMD)

Past sales estimate: $4.38 billion by 2021

2020 sales: $190 million

When Novartis' wet age-related macular degeneration (AMD) med Beovu crossed the FDA's finish line, it seemed to pose a formidable threat to Regeneron's megablockbuster Eylea and Roche's Lucentis. But its foes had one card left to play: Beovu carried greater safety risks. And that hampered its highly anticipated rollout.

Market watchers held high expectations for Beovu when it scored the agency's go-ahead in October 2019. The drug was priced on par with its rivals and could be used to treat AMD patients on a longer quarterly or every-other-month basis.

At the time, Wall Street analysts expected Novartis' new eye med to top the market by 2026, earning roughly $4.38 billion by the end of 2021, according to consensus estimates. Novartis execs **talked up** the less-frequent dosing schedule, encouraging patients to spend more time focusing "on what's important in their lives."

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But convenience has proven to be a less-than-enticing sales pitch. Beovu has generated a mere $87 million in sales so far this year, a 16% decline compared with the same period a year prior.

When Beovu first entered the scene, Novartis touted head-to-head data showing it could topple market giant Eylea on some metrics. Eylea has been a massive hit for Regeneron, **ranking** among the world's best-selling drugs last year.

In two late-stage clinical trials, Beovu matched Eylea on efficacy, as measured by best-corrected visual acuity. Beovu even beat out the anti-VEGF med at reducing retinal fluid and central subfield thickness, a measure of abnormal fluid accumulation and edema that can result in vision loss.

Meanwhile, Roche's Lucentis has faced copycat competition in the U.S. and Europe following a key patent expiration. Those biosimilars, notably one from Samsung Bioepis that scored an FDA nod just weeks ago, are set to chip away at the entire AMD market. Still, Beovu had an impressive enough resume to spell blockbuster sales, analysts figured.

But Beovu had a chink in its armor from the get-go. SVB Leerink analysts speculated that Regeneron could take advantage of Beovu's "higher safety liabilities," namely that in late-stage trials, Beovu patients were four times as likely to report intraocular inflammation than were those on Eylea.

Turns out, that's exactly what happened. The American Society of Retina Specialists (ASRS) **issued** a warning in February 2020 pinning Beovu to cases of retinal vasculitis, or eye inflammation. Eleven of the 14 cases of ASRS detected at the time were serious enough to raise the risk of vision loss.

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Novartis later confirmed that Beovu carries greater risks of side effects and asked the FDA for a label update. RBC Capital Markets analyst Kennen MacKay at that time suspected that a revision would end up with a black box warning, which would

The COVID-19 pandemic shutdowns swept in shortly after, posing a particularly bleak challenge to Novartis given that physicians were advised to monitor patients following their Beovu injections. As Bernstein analyst Ronny Gal put it, that meant "adoption of Beovu has been essentially stopped," according to the BioPharma Dive report.

That gave Regeneron and its partner Bayer the opportunity to tout Eylea's own safety data and an extended dosing schedule that allows the product to be administered every 4, 8 or 12 weeks. In 2020, Eylea sales **grew** 7% year over year to $8.36 billion.

As for Beovu, its safety troubles have only grown worse. In June, Novartis **called off** three trials testing a four-week dosing of the VEGF inhibitor after one of them turned up higher rates of eye inflammation compared with Eylea. The company still hasn't identified the root cause of the issue.

Editor's Note: *A previous version of the article mistakenly stated that Novartis had asked the FDA to include a black box warning on Beovu. The company has asked for a label update.*

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