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B+L/Novaliq Hope Miebo Can Stand Out In Crowded Dry Eye Field

Big Week For Bausch As Court Ruling Could Benefit Planned Spinoff

by Alaric DeArment

The companies got US FDA approval for the drug, which they said is the only approved medicine that targets tear evaporation rather than tear production, though its mechanism is not fully understood.

Bausch + Lomb Corporation and *Novaliq GmbH* hope to stand out in the crowded field of dry eye disease (DED) with their newly US Food and Drug Administration-approved Miebo (perfluorohexyloctane) based on its mechanism of action and a unique claim of direct effect on tear evaporation.

The commercial effort could be helped by Bausch + Lomb parent company *Bausch Health Companies Inc.*'s victory in federal court in a patent dispute, which may bode well for the planned spinoff of eye-care focused Bausch + Lomb.

More than a month ahead of the 28 June action date, the FDA approved Miebo for treating signs and symptoms of DED on 18 May, and Bausch + Lomb expects to launch the drug in the second half of the year. The two companies called the drug, formerly known as NOV03, the first and only FDA-approved treatment for DED that directly targets tear evaporation, often associated with meibomian gland dysfunction (MGD). The pivotal Phase III GOBI and MOJAVE trials enrolled 1,217 patients with a history of DED and signs of MGD, though the drug's label notes that the exact mechanism of action of Miebo in DED is not known.

GOBI, which enrolled 597 patients, was the first of the two trials to report a statistically significant improvement in signs and symptoms of DED, in April 2021, based on change from baseline in total corneal fluorescein staining (tCFS) at 15 and 57 days, as well as change from

baseline in dryness score, a symptom of dry eye disease. The measures at 57 days, or eight weeks, were the study's primary endpoints. (Also see "*Bausch + Lomb's Dry Eye Pivotal Data Pave The Way For Spinout*" - Scrip, 13 Apr, 2021.) Results from MOJAVE, published in the *American Journal of Ophthalmology* in March, likewise showed a statistically significant improvement on both sign and symptom of DED endpoints at eight weeks.

Differentiation In Crowded Field

The drug is targeted to a potentially large portion of the overall DED population, given that an estimated 86% of patients with the condition – of whom there are 17-18 million in the US – have excessive tear evaporation whereby MGD is the major contributor. Its purported mechanism of action could help it stand out on the market, according to Needham & Co. analyst David Saxon.

"While Miebo does not appear to be labeled specifically for meibomian gland dysfunction, we believe the mechanism of action, which targets tear evaporation vs. other drops that target tear production, could be a source of differentiation," Saxon said in an 18 May note.

The drug's label only mentions evaporation once, in the description of its mechanism of action, stating, "Perfluorohexyloctane forms a monolayer at the air-liquid interface of the tear film which can be expected to reduce evaporation," before stating that the exact mechanism of the drug in DED is not known. Likewise, MGD is mentioned only in describing the clinical trials, such as stating that the two Phase III clinical trials enrolled "a total of 1,217 patients with a history of DED and clinical signs of meibomian gland dysfunction."

Saxon noted that AbbVie Inc.'s Restasis (cyclosporine) currently leads the $2bn market for DED treatments, not to mention the multiple generic versions of the drug now available as well. He said that he initially expects ophthalmologists to reserve Miebo for patients who do not respond to Restasis, but over time they could use it alongside other drugs that target tear production. But it could take time for the drug to emerge as a driver of revenue growth and margin, as Bausch + Lomb will need time to ramp up sales, and the loss of exclusivity of the eye pain and swelling drug Prolensa (bromfenac) could offset revenues.

The market for DED has become rather crowded in recent years, with a March report from Datamonitor listing *Novartis AG*'s Xiidra (lifitegrast), *Viatris Inc.*'s Tyrvaya (varenicline) and *Alcon Inc.*'s Eysuvis (loteprednol etabonate) among FDA-approved agents, making differentiation important for Miebo. But H.C. Wainwright analyst Yi Chen said that could be a smooth process.

"Given the limitations of prescription DED drugs currently on the market, we believe Miebo could be easily adopted by eye care professionals once launched," Chen said in a 19 May note.

Court Ruling Bodes Well For Spinoff

Analysts said a recent positive court ruling in favor of Bausch Health Companies could have

positive implications for Bausch + Lomb as well, as Bausch Health announced plans to spin off Bausch + Lomb in August 2020, though it is not yet completed. (Also see "*Bausch + Lomb Taps A Familiar Face, Brent Saunders, As Next CEO*" - Scrip, 15 Feb, 2023.)

The US District Court of Delaware ruled on 17 May against Norwich Pharmaceuticals, which had tried to launch a generic version of Xifaxan (rifaximin) with a "skinny" label that would only cover irritable bowel syndrome with diarrhea, but not the other indication, prevention of hepatic encephalopathy. Norwich's rationale for the approach was the two different indications have different patents protecting them. The federal court's ruling means Bausch Health's exclusivity will last until late 2029. (Also see "*US Court Shoots Down Norwich In 'Unprecedented' Xifaxan 'Skinny Label' Claim*" - Generics Bulletin, 18 May, 2023.)

H.C. Wainwright's Chen said in his 19 May note that with Bausch Health still owning about 88.7% of Bausch + Lomb outstanding common shares as of mid-February and thus controlling the direction of the business, it has indicated that it plans to transfer all or a portion of its remaining direct or indirect equity interest in Bausch + Lomb to its shareholders. The ruling, he said, "significantly improves" Bausch Health's financial prospects and thus may increase the likelihood of that occurring.

Needham's Saxon similarly said in his 18 May note that the patent ruling "increases the probability that a [Bausch + Lomb] spin-off can be completed."