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Novartis Looking to Repurpose its Dangerous Beovu DrugBy **Ronald V. Miller, Jr.**

Beovu was supposed to be the big new revenue-making drug for pharmaceutical giant **Novartis** last year. Beovu was designed for the treatment of wet age-related macular degeneration (wet AMD), a common eye condition that can cause blindness if not treated. Novartis invested heavily in the development of Beovu and was counting on the drug's dosing advantages to help it tap into the massive market share currently held by the leading AMD drug – **Eylea**. But an onslaught of major safety concerns and anticipated **Beovu lawsuits** quickly crushed the money-making potential of Beovu. Rather than abandon its investment, Novartis is now trying to repurpose Beovu to treat other eye conditions.

Development of Beovu

The treatment of certain common eye conditions, particularly age-related macular degeneration, is big business in the pharmaceutical world. Really big. Age-related macular degeneration (AMD) comes in 2 forms (wet and dry) and it is the leading cause of blindness in the world today. An estimated 11 million people in the U.S. suffer from AMD. If not properly managed and treated, AMD can result in serious vision impairment or blindness.

Currently, the only effective treatment for AMD is with drugs that block the growth hormones that cause AMD. These drugs must be injected into the eye by a doctor on a fairly regular basis, but they are highly effective. They are also huge money makers for the drug companies.

For years the leading drug in the treatment of AMD has been Eylea. Eylea generates about \$5 billion in U.S. sales every year for its manufacturer (**Regeneron Pharmaceuticals**). This makes Eylea one of the top five most profitable drugs in the world. For several years many of Regeneron's competitors have been trying to develop drugs to challenge Eylea and earn a share of this massive revenue stream. Novartis has been one of the most active in this effort.

Novartis made a very substantial investment in the development of an Eylea competitor. Eventually, this investment led to the release of Beovu in October 2019. Beovu was similar to Eylea and it was designed and intended for the treatment of wet-AMD. Novartis had extremely high hopes for Beovu. Initial testing results showed that Beovu was just as effective as Eylea, but Beovu had a distinct advantage. Beovu required less frequent doses than Eylea.

Safety Problems Derail Beovu

When Beovu hit U.S. markets last year, Novartis was expecting it to make a big splash and become a major moneymaker for the company. Very soon after the release of Beovu, however, an alarming wave of reports starting coming in that Beovu was causing dangerous reactions in some patients.

It soon became apparent that Beovu was causing an inflammatory response in the retinas of some patients. These patients were eventually diagnosed with retinal vasculitis or retinal vascular occlusion. Both conditions can result in permanent vision loss or total blindness. Novartis eventually acknowledged the problem and added a new warning to the Beovu safety label.

Exhibit 2180

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Samsung v. Regeneron
IPR2023-00442
U.S. Pat. 10,130,681
Exhibit 2180

These concerning safety problems (along with the COVID-19 pandemic) crushed the market for Beovu. Sales of the drug dropped over 50% and even with the warning label change, lingering concerns about the safety of the drug remain. Not only is Beovu not going to be the big money drug Novartis was expecting, but we expect now a wave of Beovu lawsuits.

Novartis Looks to Salvage Beovu

To salvage the substantial investment they made, Novartis is now trying to find other potential applications for Beovu. Last month, the company announced that it was moving closer to getting Beovu approved for use in the treatment of diabetic macular edema (DME).

Expanding Beovu into treatment for DME and other conditions could help Novartis recover some massive costs spent on research and development. Of course, this effort to push Beovu into other areas of treatment may raise some eyebrows. After all, Novartis has yet to even complete its internal safety investigation of Beovu. Despite all the issues, the company continues to stand by its Beovu's potential and insist that the drug is safe.

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