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Roche's Port Delivery System Approved, Paving The Way For Ophthalmology Expansion

by Jessica Merrill

Susvimo, a PDS version of the blockbuster Lucentis, is a refillable eye implant that will extend Roche's commercial opportunity in wet-AMD but presents training challenges. Pricing is slightly below Lucentis.

The US Food and Drug Administration's approval of Susvimo, a new port delivery system (PDS) for administration of a customized formulation of *Roche Holding AG*'s Lucentis (ranibizumab), will provide the company with a continued commercial opportunity in neovascular age-related macular degeneration (nAMD or wet AMD) as Lucentis biosimilars approach the market.

Roche's *Genentech, Inc.* subsidiary announced FDA approval of Susvimo (ranibizumab injection), a refillable eye implant for use with a customized formulation of the VEGF inhibitor ranibizumab, on 22 October. It is the first of two new commercial opportunities the company hopes to bring to the ophthalmology market in the next six months, with the other being the first bispecific antibody for nAMD, faricimab. *(Editor's Note: This story has been updated to reflect the correct date of approval and further highlight that it involves a customized formulation of ranibizumab).*

Roche will bring Susvimo to market with a list price of $17,250 in the first year and $16,000 annually thereafter. The first-year price, which is 26% less than the annual price of Lucentis eye injections if given 12 times per year as described on the product label, consists of $9,250 for the first six months – including the Susvimo implanted device and medicine – and $8,000 every six months thereafter.

Susvimo is a permanent refillable eye implant, about the size of a grain of rice, that can continuously deliver a formulation of ranibizumab over a period of months. It needs to be surgically implanted, but then it can be refilled in the clinic. The surgical requirements could

present some challenges to Roche when it comes to the commercial strategy, given the need for surgical training on the procedure and the specific safety issues posed by surgery.

The goal is to extend the length of time patients can go without needing treatment, avoiding burdensome regular eye injections and potentially improving vision outcomes as a result of continuous treatment. In the Phase III Archway study supporting the approval, more than 98% of patients treated with PDS were able to go six months without needing additional treatment prior to the refill and patients also achieved vision outcomes equivalent to patients receiving monthly ranibizumab eye injections. In clinical practice, many patients extend the duration of treatment beyond what is recommended because of the burdensome nature of the injections.

"When you have more than 98% of patients going out to six months without supplemental injections while maintaining their visual acuity and their retinal fitness, I think it is a great treatment option for patients," head of ophthalmology product development at Genentech Chris Brittain said in an interview.

Lucentis is a blockbuster drug for Roche, though it is maturing. The drug generated CHF1.02bn ($1.11bn) for Roche in the first nine months of 2021, but revenues declined 5% versus the first nine months of 2020. Roche only generates sales from Lucentis in the US, where it is responsible for commercialization, while *Novartis AG* sells Lucentis outside the US.

Roche is looking to expand its presence in ophthalmology with new options as the first biosimilar version of Lucentis is expected to launch by the end of the year. *Biogen, Inc.* and *Samsung Bioepis Co., Ltd.*'s biosimilar version was approved by the FDA in September under the brand name Byooviz (ranibizumab-nuna). (Also see "*FDA Approves First Ophthalmic Biosimilar With Samsung Bioepis' Lucentis Rival*" - Generics Bulletin, 20 Sep, 2021.) The launch of biosimilar versions of Lucentis and new innovative entries from Roche are poised to shake up the market.

Wet AMD Market Snapshot: A High-Growth Market Poised For Change

By Jessica Merrill

17 Sep 2021
Regeneron's Eylea and Roche's Lucentis currently dominate the treatment market for wet-AMD and diabetic eye disease, but biosimilar ranibizumab and new brand launches are on the horizon.

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Surgery Presents New Challenges

Because PDS is surgically implanted initially, it does pose some commercial obstacles – most notably because of the need to train surgeons on the procedure. Roche has already trained some surgeons on the procedure as part of the clinical trial program, which also includes Phase III trials ongoing in diabetic eye disease.

"The way that we are preparing for launch is similar in terms of the training that we've done, physician education, over our Phase II and Phase III programs," Brittain said. The company has developed virtual education modules as basic background and then provides peer-led surgical training for physicians. It has also established a specialized field force to walk surgeons through the procedure and even be present in the operating room.

"It's a real wrap-around. We recognize the need. The safety of the implantation procedure is absolutely critical here," Brittain said. The field force that has been hired includes representatives who have experience in the operating room, such as theater technicians or those with prior device experience.

"We've employed the right people and then we have a very robust surgical onboarding program for these individuals," he said.

PDS was generally well-tolerated in the Phase III clinical trial and represents a favorable benefit-risk profile, according to Roche. Nonetheless, there are specific risks that are associated with a surgical eye procedure, including hemorrhage, iritis, eye pain and endophthalmitis, a rare but serious infection within the eye.

Genentech noted that the Susvimo implant has been associated with a three-fold higher rate of endophthalmitis versus monthly intravitreal injections of ranibizumab. “Many of these events were associated with conjunctival retractions or erosions,” the company told *Scrip*. “Appropriate conjunctiva management and early detection with surgical repair of conjunctival retractions or erosions may reduce the risk of endophthalmitis. In clinical trials, 2% of patients receiving a ranibizumab implant experienced at least one episode of endophthalmitis.”

The Susvimo label’s warnings and precautions list several serious side effects that can be associated with inserting, filling, refilling and removing the implant: endophthalmitis, conjunctival erosion and conjunctival retraction (a missing layer or opening in the layer on top of the white part of the eye), rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage (bleeding), conjunctival bleb (a bump on the white part of the eye) and temporary decrease in vision after the implantation procedure.

Safety will be paramount to commercial success, given the widespread use of older VEGF drugs, including Lucentis and *Regeneron Pharmaceuticals, Inc.*'s Eylea (aflibercept). Novartis's launch of new ophthalmology drug Beovu (brolucizumab) has failed to gain commercial traction after safety issues emerged in the real-world setting, including retinal vasculitis. (Also see "*Blow For Novartis Eye Drug Beovu As Studies Stop On Safety Worries*" - Scrip, 1 Jun, 2021.)

Roche anticipates PDS will be used first in patients who have already demonstrated a response to anti-VEGF therapy. Treatment experienced patients are the ones who were included in the

clinical development program.

"For ongoing treatment, it's a patient choice," Brittain said. For example, it might not be the right fit for patients who are doing well on current treatment and able to get to their regular intravitreal injections, but for patients who are unable to get to the doctor regularly for treatment, it could be another option, he said.

Roche has other Phase III trials ongoing for Susvimo, including Portal, an extension study evaluating the long-term safety and efficacy in neovascular AMD; Pagoda evaluating Susvimo for the treatment of diabetic macular edema (DME); and Pavilion in diabetic retinopathy without DME. In addition, the company's bispecific antibody faricimab is pending at the FDA with action expected in 2022. It targets angiopoietin-2 (Ang-2) and VEGF-A. (Also see "*Roche Prepares Faricimab For Filing After Phase III AMD Data*" - Scrip, 26 Jan, 2021.)