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With Vuity Approval, AbbVie Continues Stepping Into Eye Care

Presbyopia Drug Carries On Allergan Legacy

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Executive Summary

AbbVie had no presence in ophthalmic medicine other than a single indication for Humira before the Allergan merger, but now has a growing eye care portfolio, including early FDA approval of Vuity for presbyopia.

ABBVIE HAS MORE OPHTHALMOLOGY PLANS BEYOND FIRST EYE DROP APPROVAL FOR PRESBYOPIA

Eye care was barely a blip on the radar at AbbVie Inc. when it acquired Allergan plc – a 2016 label expansion of top-seller Humira (adalimumab) into uveitis was AbbVie's only foray into ophthalmic medicine before the mega-merger that happened to bring it into the sector. Eye care R&D and product performance still may not be a central topic during AbbVie's quarterly earnings calls, but the recent approval of Vuity for presbyopia represents progress for the combined company's burgeoning eye care segment.

During its third quarter earnings call on 29 October, AbbVie noted that its eye care franchise – led by dry eye drug Restasis (cyclosporine) and prescription eye drop products for glaucoma Alphagan P (brimonidine tartrate) and Lumigan (bimatoprost), all legacy Allergan products – brought in aggregate sales revenue of $871m for the quarter, up 2.9%

AbbVie Pounces On Chance To Buy Revenues In $63bn Mega-Deal For Allergan

By Jessica Merrill

25 Jun 2019

year-over-year. (Also see "AbbVie Remains Confident About Rinvoq Despite Coming Safety Labeling Update" - Scrip, 29 Oct, 2021.)

On the same day, the company announced the early US Food and Drug Administration approval of Vuity, a 1.25% formulation of the glaucoma drug pilocarpine, as the first prescription eye drop product for presbyopia, or age-related blurry near vision. AbbVie estimates that as many as 128 million people in the US, approximately half the adult population, have presbyopia.

AbbVie will gain the $3.58bn Botox business, a women's health franchise and gastrointestinal products in an opportunistic acquisition intended to reduce the company's dependence on Humira.

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Michael Robinson, AbbVie's global therapeutic area head for eye care, told *Scrip* that Vuity's "secret sauce" is a formulation of pilocarpine that provides a fast-acting and comfortable product. The company said Vuity showed efficacy in improving near vision as early as 15 minutes, with the effect lasting up to six hours. In addition, AbbVie noted there were no serious adverse events in the pivotal Phase III GEMINI 1 and GEMINI 2 studies.

Improving Pilocarpine's Tolerability Profile

Pilocarpine is a miotic that works by draining excess fluid from the eye; higher concentrations used to treat glaucoma are commonly associated with side effects including stinging, burning, itching, redness and swelling of the eye, redness of eyelids, headache and blurry or dim vision, according to the US National Library of Medicine. AbbVie said the most commonly reported side effects in its clinical development program, occurring at a rate no greater than 5%, were headache and eye redness.

"All pilocarpine is stored at a very low pH in the bottle. It has to be a low pH around 4 in order to keep the molecules stable," Robinson noted. The Vuity formulation immediately adjusts to a pH physiologically around 7 when it gets into the eye, which "makes the eye drop more comfortable compared with the glaucoma formulation," he explained.

"Plus, when you go from a pH of 4 to a pH of 7, the pilocarpine molecule is in a non-protonated form and the bioavailability is much improved," he continued. "What that translates to is very rapid action of the pilocarpine, which essentially constricts the pupil and can also stimulate the ciliary muscle," thus improving visual acuity.

Realizing that many people with presbyopia already treat their symptoms with reading glasses or better lighting, Robinson said AbbVie's intent is not that Vuity will replace those remedies but complement them.

"In certain situations there are patients who don't want to wear glasses," he said. "Plus, the problem with reading glasses and with invisible bifocals is that it's very difficult to find a sweet spot. Here, with the mechanism of action of Vuity, you're able to increase the depth of focus and you have a more uninterrupted range of both near and intermediate vision, so the quality of vision for some patients can be improved."

AbbVie intends to make Vuity available before the end of the year and will announce product pricing at the time of launch.

AbbVie Could Create Market For Other Presbyopia Players

In a 1 November note, Cantor Fitzgerald analyst Kristen Kluska said AbbVie's size and commercial infrastructure could help create a market for presbyopia therapy that might benefit companies and products launching after Vuity. Looking specifically at Ocuphire Pharma, Inc. and its Phase II presbyopia candidate – a combination of low-dose pilocarpine and Nyxol (0.75% phentolamine), an alpha 1/2 adrenergic antagonist to smooth contraction of the iris – Kluska said the approval validates the concept of using pilocarpine in presbyopia.

In the GEMINI studies, Vuity achieved statistical significance in improving near vision in low light conditions without a loss of distance vision compared to vehicle on day 30 at three hours, the primary endpoint, measured by the percentage of patients who could read three additional lines or more on a chart without losing one line of distance vision acuity, AbbVie said. The firm presented data from the two Phase III trials at the American Academy of Optometry meeting on 3 November.

Kluska said Phase II data that Ocuphire reported in July suggest its candidate could differentiate from Vuity for magnitude of effect, durability, safety and onset of action. In the study, 61% of patients receiving the Nyxol/pilocarpine combination drop achieved three lines of benefit on a reading chart test at one hour compared to 28% who received placebo. "Even with multiple companies in development, we believe this is a market where multiple companies could be successful in generating high revenues," the analyst added.

In addition to the Ocuphire candidate, Eyenovia, Inc. also has a reformulation of pilocarpine called MicroLine in Phase III for presbyopia.

Robinson said AbbVie tested Vuity for efficacy up to 10 hours and may conduct future studies on the safety and efficacy of twice-daily dosing of the drop, but for now it is approved as a once-daily product. He predicted that as awareness of the product increases, discussions between patients with presbyopia and their eye specialists will become "extremely common."

AbbVie is not yet commenting on its marketing plans for the large potential patient base, but it will reach out to both ophthalmologists and optometrists.

"What optometrists and ophthalmologists are very good at is assessing a patient and looking at what their occupation is, what their typical reading habits are and then making the decision for that particular patient, asking what would suit them best," he explained. "Is it just a pair of readers, is it an invisible bifocal, is it the standard bifocal? Would it be Vuity?"

"With the large number of patients [we're] talking about, this is going to be an extremely common conversation when patients start getting into the presbyopic symptoms that begin around 40 years of age," he continued. "This is a conversation that both optometrists and ophthalmologists will have to have with their patients."

The Migration Of Allergan's Eye Portfolio To AbbVie

Robinson and his R&D team migrated from Allergan to AbbVie as part of the 2020 merger of the two firms. (Also see "AbbVie Will Use Allergan Revenue To Fund Combined Firm's Large R&D Pipeline" - Scrip, 27 Jun, 2019.) Then, as now, Restasis was the eye care portfolio's big earner – it brought in $319m – all but $14m in the US – during the third quarter, good for 6.7% year-over-year growth. Lumigan brought in $138m, a 7.5% decline, and Alphagan had 4.6% growth for $128m in Q3 sales– and the rest of the portfolio tallied $286m, up 6.4% from Q3 2020.

The wet age-related macular degeneration candidate abicipar pegol was seen as offering potential to help build out and grow the eye care unit at AbbVie, but the drug was shelved after an FDA complete response letter and its EU marketing authorization application was pulled in July 2020. (Also see "Allergan Pulls EU Filing For Abicipar Pegol" - Pink Sheet, 20 Jul, 2020.) Vuity was already in Phase III when the merger closed, Robinson noted.

In addition to presbyopia, glaucoma and dry eye disease, AbbVie's eye care R&D efforts also focus on retinal disease, the exec said. On 13 September, the pharma paid $370m up front to partner with Regenxbio Inc. on development and commercialization of RGX-314, the biotech's Phase II/III gene therapy candidate for wet AMD and diabetic neuropathy. (Also see "AbbVie Extends Reach Of Regenxbio's Wet AMD Program" - Scrip, 13 Sep, 2021.)

All legacy Allergan products, the eye care portfolio also includes Ozurdex (dexamethasone), an intravitreal injectable approved to treat uveitis, diabetic macular edema and macular edema resulting from retinal vein occlusion. For glaucoma, last year AbbVie launched Durysta, a sustained-release formulation of bimatoprost, Robinson said.

"It's a first-of-its-kind product that is applied to the front of the eye," he noted. "It's an extremely small implant that elutes drug for about four to six months. Then, we have follow-on programs for Durysta to make the implant smaller, the injection needle smaller and just gradually improve both the degree of intraocular pressure reduction in glaucoma patients and also the duration of action."

AbbVie's eye care pipeline also includes two Phase II dry eye candidates that could be follow-ons to Restasis, the exec said – AGN-231868 and AGN-242428. The company also has a potentially longer-acting presbyopia candidate – AGN-241622 – in Phase I. In addition, Robinson's unit is investigating a large library of proprietary drug candidates to see if they might be applicable to ophthalmic indications, Robinson added.

"The good thing about AbbVie is they have very large libraries of different compounds that my team is looking at to repurpose them for treating eye diseases," he said. "So, I think the combination of the smaller company Allergan that has eye care with AbbVie is definitely a plus."