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Novartis hails Philippine FDA approval of brolucizumab treatment for age-related macular degeneration in time for Sight Saving Month

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- The Philippine Food and Drug Administration (FDA) has approved brolucizumab for the treatment of neovascular (wet) age-related macular degeneration (AMD).
- Wet AMD is the leading cause of severe vision loss and legal blindness in people over the age of 65 in North America, Europe, Australia and Asia, impacting an estimated 20 million people worldwide.
- Recognizing the ocular complications of diabetes mellitus, Novartis and the Vitreo-Retina Society of the Philippines (VRSP) launched the Mulat Mata program to promote patient education on diabetic retinopathy.

08 August 2022 – In a timely celebration of Sight Saving Month, the Philippine Food and Drug Administration (FDA) has approved brolucizumab for the treatment of neovascular (wet) age-related macular degeneration (AMD).

Affecting an estimated 20 million people globally, wet AMD is the leading cause of severe vision loss and legal blindness in people over the age of 65 in North America, Europe, Australia and Asia. In the Philippines, AMD is a major contributor to blindness.

"The Philippine FDA approval of brolucizumab brings us another step closer to providing wet AMD patients in the country with a new, effective, and affordable treatment option. At Novartis, we remain committed to reimagining treatments for patients suffering from wet AMD, a leading cause of blindness worldwide," said Mr. Joel Chong, Country President, Novartis Healthcare Philippines.

Wet AMD is caused by uncontrolled VEGF (vascular endothelial growth factor), a protein that promotes abnormal blood vessel formation underneath the macula, the area of the retina responsible for sharp, clear central vision. These blood vessels are fragile and leak fluid, disrupting the normal retinal architecture and ultimately causing damage to the macula.

By inhibiting VEGF, brolucizumab suppresses the growth of abnormal blood vessels and the potential for fluid leakage into the retina.

At present, the standard of care for wet AMD, not just in the Philippines but worldwide, is anti-VEGF treatment. The anti-VEGF drug is injected directly into the eye on a regular basis to control the growth of abnormal blood vessels under the retina. Dr. Marie Joan Loy, Immediate Past President of Vitreo-Retina Society of the Philippines (VRSP) and former member of the Executive Council of the Philippine Academy of Ophthalmology, emphasizes that there are still unmet needs and challenges in addressing wet AMD.

"Many of our patients experience improvement in their vision with appropriate and timely treatment. Unfortunately, some continue to have a progressive decline in their vision due to several factors, one of which is financial constraints preventing patients to continue the injections. The management of wet AMD in the Philippines is quite difficult to sustain because the cost of treatment is not subsidized by the government, so this accounts for high resource utilization on the part of the patient," Dr. Loy shared. "This is the reason why eye doctors are looking forward to have a new medication that will allow fewer injections and, hence, avoid treatment and monitoring fatigue."

Early symptoms of wet AMD include distorted vision (or metamorphopsia) and difficulty seeing objects clearly. If left unchecked, it can lead to cell damage, reduced vision quality, and, eventually, complete loss of central vision. The patient's vision can rapidly deteriorate without treatment, leaving them unable to read, drive, or recognize familiar faces.

For 75-year-old Renato Agbayani, who was diagnosed with wet AMD in 2013, early detection is crucial to preventing the rapid progression of the disease.

"The earlier you see your doctor and have the treatment done, the better; you save time," said Agbayani, who can now freely watch TV and read without visual distortion after undergoing years of treatment for wet AMD. "Lost time is lost time. The earlier you are treated, the lesser the damage in your eye."

Decades-long fight in preventing blindness among Filipinos

"VRSP welcomes the local introduction of brolucizumab into the Philippine market. This new medication is an additional treatment option that offers hope for preserving vision and may decrease the treatment burden for our senior patients and their families," said Dr. Harvey Uy, Clinical Associate Professor at the University of the Philippines-Philippine General Hospital (UP-PGH) Department of Ophthalmology and Visual Sciences, and President of the Vitreo Retina Society of the Philippines (VRSP).

"There is clearly an unmet need for more durable and longer-acting treatments against neovascular wet AMD. As such, the approval of new and effective treatments is certainly a welcome development and broadens the treatment options for this debilitating disease," Dr. Uy added.

Novartis first received the approval for brolucizumab in the treatment of wet AMD in 2019 through the US Food and Drug Administration.

Reference: <u>https://www.novartis.com/news/media-releases/novartis-receives-positive-chmp-opinion-beovu-brolucizumab-treatment-wet-amd</u>

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