LumiThera Obtains FDA Authorization of Valeda Treatment for Dry AMD Patients to Improve Vision

November 04, 2024 05:18 PM Eastern Standard Time

SEATTLE--(BUSINESS WIRE)--LumiThera Inc., a medical device company offering photobiomodulation (PBM) treatment for ocular damage and disease, today announced the U.S. Food & Drug Administration (FDA) has authorized marketing of Valeda® Light Delivery System for treatment of patients with dry age-related macular degeneration (AMD), a leading cause of central vision loss in people over 55 in developed countries.

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The Valeda therapy is the first ever authorized treatment by the FDA for vision loss in dry AMD patients. Valeda provides an improvement in best corrected visual acuity (BCVA) over 24 months of >5 letters or equivalent to a line on the eye chart. In the pivotal U.S. LIGHTSITE III trial, the Valeda treatment met its primary endpoint and was shown to be safe and effective in increasing and maintaining improved visual acuity.

LumiThera submitted the US LIGHTSITE III clinical data as part of a technical package to the FDA under a De Novo request with special controls.

“The De Novo authorization established Valeda as the first device for treatment of dry AMD patients with vision loss and creates a threshold for this novel class of PBM devices that must show similar clinical and nonclinical performance controls equivalent to the Valeda Light Delivery System,” stated Lori Holder, Vice President, Regulatory Affairs, LumiThera, Inc.

“The RCT results demonstrated clinical benefits in early to intermediate dry AMD patients out to 24 months and an excellent safety profile,” stated David Boyer, MD, Retina Vitreous Associates Medical Group, Beverly Hills, CA. “Patients will now be able to try a non-invasive treatment that can help improve their vision earlier in the disease process. This is an exciting option for patients and something doctors and patients have been waiting for.”

“The primary endpoint for the study was visual acuity gain,” indicated Glenn Jaffe, MD, Duke Reading Center. However, we also followed multiple anatomical endpoints from BL throughout the 24-month study to determine whether PBM helped to preserve retinal anatomy. The PBM treatment had a beneficial effect on multiple anatomic biomarkers. For example, we looked at whether PBM affected progression to geographic atrophy and found that incident geographic atrophy was reduced in the PBM-treated eyes compared to the sham treated eyes respectively, 6.8% versus

24%. Although incident GA was not a prespecified clinical endpoint, the results supported overall safety benefits of treating earlier in dry AMD disease.

“We have been working hard to bring Valeda, a multiwavelength photobiomodulation device to our U.S. patients for several years. We now have a non-invasive treatment option for dry AMD patients that may improve vision and address the disease earlier, before permanent vision loss,” stated Clark Tedford, Ph.D., President and CEO. “The FDA authorization of the Valeda treatment to improve vision in dry AMD now provides a significant option for our US patients.”

About AMD

AMD is a leading cause of vision loss for people aged 65 and older. Losing central vision can make it harder to see faces, drive, or do close-up work like cooking or fixing things around the house. The overall prevalence of AMD is estimated to increase 7-fold with age, from 4.2% in those aged 45–49 years, to 27.2% in those aged 80–85 years. Globally, the prevalence is estimated to increase by 20% between 2020 (195.6 million) and 2030 (243.3 million).

About LumiThera

LumiThera, Inc. is an ophthalmic medical device company that is Harnessing the Power of Light® to offer a comprehensive approach for detecting, treating, and monitoring retinal diseases, particularly dry AMD.

LumiThera is the leader in ophthalmic photobiomodulation (PBM) innovation with its flagship product, the Valeda® Light Delivery System. Multiwavelength Valeda treatments are for patients suffering from dry AMD. The Food & Drug Administration (FDA) has authorized marketing of Valeda Treatment for dry AMD Patients to Improve Vision. Valeda is CE Marked in the EU and is available in select countries in Latin America.

AdaptDx Pro® is a portable dark adaptometer that utilizes AI to deliver a uniform patient experience. Impaired dark adaptation is the earliest biomarker of dry AMD and can be detected three years before clinical presentation. AdaptDx Pro is available in the U.S. and Canada.

NOVA Vision Testing System is a comprehensive electrophysiology platform that provides objective assessment of the entire pathway for visual and neuro-visual disorders. VEP is available in the U.S. and select countries outside of the U.S. ERG is only available outside of the U.S.

For more information on Valeda, visit www.lumithera.com. AdaptDx Pro and NOVA are available through LumiThera Diagnostics, Inc. and Diopsys, Inc., respectively.

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