LumiThera Announces Sustained Vision Improvement for 24 months in Dry Age-Related Macular Degeneration Subjects from US LIGHTSITE III Clinical Trial Data

SEATTLE, March 15, 2023 (BUSINESS WIRE) -- LumiThera Inc., a medical device company offering photobiomodulation (PBM) treatment for ocular damage and disease, today announced the 24-month data from its LIGHTSITE III, multi-center clinical trial which demonstrated sustained vision improvement in dry Age-Related Macular Degeneration (AMD) subjects treated with the Valeda® Light Delivery System.

LIGHTSITE III, a prospective, double-masked, randomized, multi-center clinical trial, was conducted at ten leading US retinal centers and enrolled 100 subjects with early to intermediate dry AMD. Eyes were treated with the Valeda system every four months. The last treatment was administered at 21 months and the last follow-up visit was at 24 months. The primary efficacy endpoint was best corrected visual acuity (BCVA). At 24 months there were minimal safety risks and high patient compliance; 80% of the patients completed the trial. In the PBM-treated arm there was a statistically significant visual acuity improvement at month 21 following the last treatment with sustained vision benefits throughout the trial including the 24-month trial end.

The analysis included 91 eyes in the PBM treatment group and 54 eyes in the sham-treatment group in the modified intent to treat population with at least 1 post-treatment visit. The trial initially demonstrated sustained and statistically significant improvement in the primary endpoint, BCVA, at 13 months in the PBM treatment group when compared to the sham-treatment group ($p = 0.02$). Now, a sustained, mean increase in ETDRS letter score >5.0 letters from baseline is reported at both the 13- and 21-month timepoints in the PBM-treated subjects BCVA ($p < 0.0001$). The improvement from baseline in BCVA at 24 months in the PBM treatment group was significantly greater than in the sham group, 5.9 vs 1.0 letters ($p = 0.0015$). Approximately 58% of the PBM-treated eyes had $\geq$5 letter gain with a mean of 8.5 $\pm$ 0.5 letter gain.

“Previously, the LIGHTSITE III trial results demonstrated sustained improvements of visual benefits with PBM treatments out to 13 months,” stated René Rückert, MD, MBA, Chief Medical Officer, LumiThera. “The trial results confirm the multi-center European LIGHTSITE II trial and extend the improvements to two years. We have been treating patients for about 4 years in Europe and Latin America in over 9,000 estimated patients. The sustained $\geq$5 letter improvement for 24 months was outstanding considering the earlier stage of AMD disease and the good BCVA at baseline in these patients.”

“The patients further underwent a detailed retinal morphology analysis using optical coherence tomography (OCT) during the course of the trial. Fewer eyes progressed to new geographic atrophy (GA), a later disease stage that is associated with permanent loss of retinal tissue. The 24-month OCT data indicated that 5 of 88 eyes (5.7%) in the PBM group had progressed to new GA, whereas 11 of 51 eyes (21.6%) in the sham arm developed new GA,” stated Glenn Jaffe, MD, Duke University, Duke Reading Center. “PBM treatment showed a statistically significant ($p = 0.003$) slowing of disease progression in patients with early to intermediate dry AMD.”

“These final results from the LIGHTSITE III trial are indeed very exciting and encouraging,” said Diana V. Do, MD and Quan Dong Nguyen, MD, MSc. Both are professors of ophthalmology and members of the Retina Division at the Byers Eye Institute at Stanford University, which is one of the clinical sites for the LIGHTSITE III trial. “PBM is a non-invasive therapy that can improve and sustain vision and slow the progression of disease. PBM is a significant advancement in saving sight for AMD patients. We are in urgent need of therapy for our patients with dry AMD, especially if the treatment is non-invasive such as the Valeda Light Delivery System.”

“Valeda’s multi-wavelength device is an unprecedented treatment option for dry AMD patients. PBM can offer a non-invasive treatment that can improve vision and potentially address the disease earlier, before we see permanent vision loss,” stated Clark Tedford, Ph.D., President and CEO. “Reductions in the number of eyes that progress to GA were seen at the 13-month and now further extended at the 24-month timepoints.”

The initial, first presentation worldwide of the top line data will be presented at the 2023 Sonoma Eye Meeting (March 17 to 19, San Diego, California) by one of the LIGHTSITE III trial investigators, Dr. Diana V. Do, Byers Eye Institute, Stanford University on Saturday, March 18, 2023.

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 a medical device company focused on diagnosing, treating, and monitoring ocular disease and damage including dry age-related macular degeneration (AMD), a leading cause of blindness in adults over 65.

LumiThera’s flagship product, the Valeda® Light Delivery System, uses multiwavelength photobiomodulation to treat dry AMD patients. Valeda is CE Marked in the EU and is available in Europe and in countries in Latin America. Valeda is not yet approved by the Food & Drug Administration (FDA).

AdaptDx Pro® dark adaptation functional testing technology enables eye care professionals to detect and monitor AMD three years before clinical presentation. AdaptDx Pro is listed on the FDA’s Establishment Registration & Device Listing.

Diopsys ERG and VEP systems help eye care professionals analyze the entire pathway for visual and neuro-visual disorders. VEP is FDA-cleared. ERG and VEP are available in select countries outside of the USA.

LumiThera’s AMD Excellence Program® provides customer implementation, training, best practices, and ongoing support across all brands.

For more information on the Valeda® Light Delivery System please visit www.lumithera.com. The AdaptDx Pro and Diopsys ERG and VEP systems are available separately through LumiThera Diagnostics, Inc. and Diopsys, Inc.