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Planned Phase 2 Trial of Visual Function Improvement in iAMD Gains Support From Novel Analysis Of Microperimetry Endpoints

Galimedix Therapeutics, Inc. To Present Poster at the 2021 ARVO Annual Meeting

KENSINGTON, Md. and SHORASHIM, Israel, April 12, 2021 -- Galimedix Therapeutics, which is developing new solutions for ophthalmic and neurodegenerative diseases, announced today that Chief Medical Officer, Yaniv Barkana, MD, will present a poster titled "Improved sensitivity of microperimetric outcomes for clinical studies in age-related macular degeneration" at the 2021 ARVO Annual Meeting on May 1, 2021 from 10:15 AM to 12:00 PM EDT.

The presentation will provide an original analysis of microperimetry data in eyes with iAMD, conducted in collaboration with leading KOLs from the University Eye Clinic in Bonn, Germany. The analysis shows that such a functional outcome measure in clinical trials of iAMD is more sensitive and therefore more likely to show an effect of a therapeutic intervention if it is based exclusively on grid points which are abnormal at baseline, rather than the commonly used index of mean sensitivity or mean deviation of all the points in the exam grid. This is particularly useful in a study that seeks to show improvement in retinal function, so called "neuro-enhancement", since points which are statistically normal at baseline are unlikely to improve with the intervention, and therefore "dilute" the intervention's effect on the diseased points and lower the sensitivity of the outcome measure.

The analysis is based on mesopic MAIA microperimetry data of 25 eyes of 25 subjects with iAMD. Abnormal points were defined as having sensitivity lower than 1.65 SD (5%) or 2 SD (2.5%) than the expected threshold in healthy eyes according to the MAIA internal normative database. The novel outcome measure provides a significantly greater mean defect compared with that of all the grid points, allowing more potential for improvement. It also significantly reduces SD of the mean defect in the study population providing a more homogenous dataset, and improves test-retest repeatability, two factors that allow a more efficient clinical trial design requiring a smaller sample size and fewer microperimetry exams. The analysis provides support for the novel primary outcome measure chosen for Galimedix's planned Phase 2 trial of GAL-101 for visual function improvement in eyes with iAMD.

This analysis is detailed in a Scientific Reports publication now e-published at https://rdcu.be/cfR8y.

About Galimedix Therapeutics, Inc.

Based in the United States and Israel, Galimedix is a Phase 2/3-ready pharmaceutical company with a world-class drug development team advancing a novel, patented small molecule drug with a unique MOA addressing glaucoma, dry AMD. The company's most advanced compound, GAL-101, which utilizes an eye drop delivery platform, is expected to provide an effective, convenient and safe treatment for two of the leading causes of blindness. Studies with Galimedix's eye drops in monkeys, the closest model to humans, have demonstrated that therapeutic levels are quickly reached in the retina. Compelling efficacy data from GAL-101 eye drops in relevant animal models have demonstrated more than 90 percent neuroprotection, and *in vitro* studies in neuronal cells that have lost function have shown that GAL-101 can restore the neural function, suggesting it could potentially improve visual function in patients. The Company has successfully completed Phase 1 studies in 70 subjects, including 30 glaucoma patients. The compound is supported by many of the world's leading experts in glaucoma and in dry AMD, who also support the design of the company's proposed Phase 2 and Phase 3 studies.

GAL-101 is also potentially capable for oral delivery and is in active development towards Phase 1 studies with the oral formulation. In this oral formulation GAL-101 can be developed as treatment of Alzheimer's disease.

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