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Preclinical Studies Demonstrate Galimedix Therapeutics' Investigational Compound GAL-101 Shows Neuroprotective Effect from Toxic Amyloid-Beta in Dry AMD and Glaucoma Models

Poster Presented at the Association for Research in Vision and Ophthalmology Annual Meeting

KENSINGTON, Md. and SHORASHIM, Israel, May 08, 2019 (GLOBE NEWSWIRE) -- Galimedix Therapeutics, which is developing new solutions for ophthalmic and neurodegenerative diseases, today presented data demonstrating its novel, first-in-class, investigational compound GAL-101 provides neuroprotection from misfolded amyloid beta molecules aggregating into toxic forms *in vitro*, neutralizing their ability to be toxic to neural tissues. Further, investigators discovered that peak levels from a single delivery of the compound may provide sustained detoxification. The poster was presented at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in Vancouver, British Columbia, Canada from April 28 to May 2, 2019.

"The unique mechanism of action of GAL-101 has been shown to reduce the levels of amyloid beta present in the retina, thereby both preventing neurodegeneration and increasing the chances of preventing vision loss. However, this poster further demonstrates that a single peak administration of the compound by eye drops may also provide a sustained detoxifying effect in dry AMD and glaucoma patients," commented Dr. Hermann Russ, lead author of the paper and Chief Scientific Officer of Galimedix. "These preclinical data, combined with a positive result in the Phase 1 study have made it possible for us to move rapidly toward a Phase 2 program for which we will provide updates when available."

In the poster, investigators reported that eye drops of GAL-101 in repeated monkey models resulted in concentrations in the retina rapidly reaching levels far in excess of the threshold for initiating the peak-related pharmacological effect, and remained in those levels for at least four hours. Furthermore, in age-related macular degeneration (AMD) mouse models with substantial amyloid beta deposits in the retina accumulated during many months, GAL-101 eye drops when given for 1-3 months resulted in substantially less amyloid beta deposits, and simultaneously reduced the levels of C-complement response, which is considered a central factor leading to the progression of dry AMD.

About GAL-101
GAL-101 is a proprietary compound designed to prevent the formation of all forms of toxic amyloid beta oligomers, by binding with high affinity to the misfolded amyloid beta monomers before they can form toxic soluble oligomers. These then rapidly conglomerate into amorphous, non-beta-sheet formations, which we call "clusters," which are innocuous. Interestingly, once GAL-101 concentration reaches effective levels it "triggers" formation of the "clusters", which then have shown the capacity to collect additional misfolded amyloid beta monomers even in the absence of additional GAL-101 molecules, through a self-propagation mechanism. This novel "trigger effect," protected by Galimedix' patent portfolio, results in a sustained effect lasting far longer than the time a single administration of the drug remains at therapeutic levels in the retina, potentially allowing for a convenient interval application regimen for patients. Thus, GAL-101 drops may potentially provide sustained prevention of formation of toxic amyloid beta oligomers in the retina, leading to a reduction of complement response and their consequent damage. Thus GAL-101 could contribute to slowing or stopping progression, and possible restoration of neural function depressed by the chronic toxic attack.

About Galimedix
Based in the United States and Israel, Galimedix is a Phase 2 ready ophthalmic pharmaceutical company with a world class drug development team advancing a novel, patented small molecule drug with a novel MOA addressing glaucoma and dry AMD utilizing an eye drops delivery platform, which may offer significant safety and compliance advantages over commonly used direct ocular injections. Eye drops are used to deliver steroids and other small molecules, like GAL-101, to the retina, and studies with Galimedix's eye drops in monkeys have demonstrated therapeutic levels quickly reaching the retina of the closest model to humans. Compelling efficacy data from GAL-

101 eye drops in relevant animal models have demonstrated more than 90 percent neuroprotection, and the compound is supported by several leading experts in glaucoma and in dry AMD who also support the design of the company's proposed Phase 2 studies.

Galimedix has exclusive worldwide license from Tel Aviv University, following return of license by a German pharma (Merz) due to management change and strategic pivot away from neuroscience. The license also includes a next generation, potentially superior molecule intended for oral delivery, with potential to treat retinal and other CNS diseases.

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