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Galimedix Therapeutics Presents Data Showing Safety, Tolerability and Potential for Efficacy of Its Investigational Eyedrops Containing GAL-101 at Glaucoma 360 Conference

KENSINGTON, Md. and SHORASHIM, Israel, Feb. 06, 2019 (GLOBE NEWSWIRE) -- Galimedix Therapeutics, which is developing new solutions for ophthalmic and neurodegenerative diseases, presented an overview of data disclosed to date on its novel, first-in-class, investigational compound GAL-101, which, in animal models caused sustained prevention of misfolded amyloid beta molecules from aggregating into toxic forms *in vitro*, neutralizing their ability to be toxic to neural tissues. The presentation also included positive safety and tolerability data from the company's Phase 1 study in both healthy and glaucoma patients. These data were presented at the Glaucoma 360 conference on February 1, 2019 in San Francisco by the company's chief scientific officer, Hermann Russ, M.D., Ph.D.

"Misfolded monomers of amyloid beta have been shown to rapidly form toxic oligomers that play a significant role in the advancement of ophthalmic diseases, including glaucoma and dry age-related macular degeneration (dry AMD). The unique mechanism of action of GAL-101 has been shown to prevent this advancement and instead, form amorphous assemblies, or blobs, that are benign in the eye," commented Dr. Russ. "These preclinical data, combined with a positive result in the Phase 1 study have made it possible for us to develop a Phase 2 program, for which we are currently in the planning and fundraising stage."

In preclinical data, GAL-101 was shown to reach the retina with a greater than 30-fold therapeutic threshold within 5 minutes of eye drop application, and lasting for multiple hours, into sustained effect for weeks. Furthermore, the data showed more than 90 percent survival of retinal ganglion cells compared to controls ($p<0.05$), with the experiment being repeated multiple times. In addition, the company conducted Phase 1 trials demonstrating safety and tolerability in both health subjects (n=40) and glaucoma patients (n=30).

About GAL-101
MRZ-99030 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 "blobs." These "blobs" are innocuous. Interestingly, once formed, the "blobs" have shown the capacity to collect additional misfolded amyloid beta monomers even in the absence of additional MRZ-99030 molecules, through a self-propagation mechanism. This novel "trigger effect," protected by Galimedix' patent portfolio, results in a sustained action 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 sustained inter-treatment interval application regimen for patients. Thus MRZ-99030 eye drops may potentially provide sustained prevention of formation of toxic amyloid beta oligomers, clearing the system of these pathological factors, which has been shown in animal studies to lead to gradual removal of toxic beta amyloid deposits, and which the current "Hot Topic" poster has shown could potentially reduce neural deficit and improve function.

About Galimedix
Based in the United States and Israel, Galimedix is a phase 2 ophthalmic pharmaceutical company with 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 often used to deliver steroids and other small molecules, like GAL-101, in retinal disease, and studies with Galimedix' eye drops in monkeys have demonstrated more than 30 times predicted 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. In the meantime, key members of

the Merz Pharma team that developed the compound are now working with or for the company. The license also includes a next generation, potentially superior version, intended for oral delivery, with potential to treat retinal and other CNS diseases.

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