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New In Vitro Study Demonstrates Galimedix Therapeutics' Investigational Compound MRZ-99030 Neutralizes the Reproduction of Misfolded Amyloid-Beta, Thereby Potentially Reducing Synaptotoxic Effects

"Hot Topics" Poster at Society for Neuroscience Conference Suggests Even Highly Diluted Concentrations of MRZ-99030 Prevented Formation of Toxic Amyloid Beta Oligomers

KENSINGTON, Md. and SHORASHIM, Israel, Nov. 08, 2018 (GLOBE NEWSWIRE) -- Galimedix Therapeutics, which is developing new solutions for ophthalmic and neurodegenerative diseases, announced the results of a new study presented as a "Hot Topics" poster at the Society for Neuroscience conference demonstrating that a single application of the investigational compound MRZ-99030, also known as GAL-101, causes sustained prevention of misfolded amyloid beta molecules from aggregating into toxic forms *in vitro*, neutralizing their ability to be toxic to neural tissues.

"These results are groundbreaking in the prevention of misfolded amyloid beta from creating toxic oligomers and their effects within the body. While these results were presented at a neuroscience meeting, designed to bring additional light to new advances in neurodegenerative diseases, toxic oligomers of amyloid beta have been shown to play a significant role in the advancement of ophthalmic diseases, including glaucoma and dry age-related macular degeneration (dry AMD)," commented Dr. Christopher Parsons, co-author of the study, senior editor of the journal, *Neuropharmacology*, and co-founder of Galimedix. "This poster shows how powerful a compound MRZ-99030 may be. Even after a thousand-fold dilution below predicted therapeutic levels, it prevented the formation of these toxic oligomers and even reversed their toxic effects by rapidly capturing the misfolded proteins into harmless "blobs" that continued their work even after the drug dropped below minimal levels. In clinical use, this may prevent or reverse the development of these diseases."

Investigators had been aware that MRZ-99030 in low concentrations has proven to block the neural toxicity of amyloid beta in animal and *in vitro* models and was demonstrated safe in a Phase 1 study in 70 human subjects. In this study, a therapeutic concentration of MRZ-99030 was shown to rapidly clear the toxic molecules into "blobs," preventing further toxic effect on cells, and reversing the deficit in neural function caused by the toxic levels

of mis-formed amyloid beta. The “blobs” were collected and resuspended in solution with the original concentration of misfolded amyloid beta with ten times lower concentration of MRZ-99030, which still blocked the toxicity to cells and reversed deficit. The dilution step was then repeated four more times, ultimately resulting in a concentration of MRZ-99030 at least 1,000 times lower than the predicted therapeutic level, while misfolded amyloid beta was kept at original toxic levels. Even then, toxicity was again blocked and deficit to neural function was reversed. GAL-101 is currently advancing toward Phase 2 studies in both glaucoma and dry AMD.

“GAL-101 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,” added Dr. Andrew Pearlman, CEO and founder of Galimedix.

About MRZ-99030/GAL-101

MRZ-99030 (now 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, but not to the normally folded version, 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 and are thought to be cleared by the circulation. Interestingly, once formed, the “blobs” 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 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.

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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