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Théa Open Innovation and Galimedix announce strategic partnership to develop and commercialize GAL-101, a Phase 2/3-ready small molecule, to treat ophthalmic indications with high unmet medical need

- **Galimedix eligible for upfront payment plus various success-based milestone payments and royalties on future net sales**
- **Equity investment by Théa Open Innovation into Galimedix supports further Galimedix pipeline development**
- **In parallel, Galimedix will continue to extend its pipeline, particularly in Alzheimer's disease**

CLERMONT FERRAND, France and KENSINGTON, Md., March 29, 2023 (GLOBE NEWSWIRE) -- Théa Open Innovation ("TOI"), a sister company of ophthalmic specialty pharmaceutical company Laboratoires Théa, and Galimedix Therapeutics, Inc. ("Galimedix"), a clinical-stage biotechnology company addressing the cause of neurodegenerative diseases of the eye and central nervous system, announced today that they have signed a licensing agreement. Galimedix will grant TOI exclusive rights for the development and commercialization of GAL-101, Galimedix's lead disease-modifying compound, for the topical and oral treatment of dry age-related macular degeneration (AMD), glaucoma and other ophthalmic indications with high unmet medical need, in Europe, the Americas, the Middle East and Africa.

Under the terms of the agreement, Galimedix will receive an upfront technology access fee and is eligible to receive further success-based milestone payments as well as royalties on net sales. While TOI will fully fund the remaining development of GAL-101 in dry AMD and take charge of the registration and commercialization of the drug, Galimedix will remain responsible for the mid-stage clinical trials, leveraging their respective expertise and familiarity with the compound, which has a unique first-to-market mechanism of action. Furthermore, TOI will invest into Galimedix, thereby demonstrating its strong interest in the Galimedix pipeline, including in Alzheimer's disease (AD).

"Through the partnership with Galimedix, Théa will be among the few companies globally that are working on an innovative drug for the treatment of dry AMD patients who are currently at risk of going blind," said **Jean-Frédéric Chibret, President of the Théa Group**. "We are excited to be working with Galimedix, as this collaboration supports our continued commitment to building a strong cutting-edge and diversified ophthalmological portfolio for eye care specialists around the world and their patients."

GAL-101: Eye drops and tablets – the first drug candidate for disease-modification of dry AMD is also designed to be patient friendly

GAL-101 is Galimedix's most advanced compound, ready to enter clinical Phase 2/3 trials. Delivered topically as an eye drop, it is expected to provide a convenient and safe treatment for two of the leading causes of blindness – dry AMD and glaucoma, including normo-tension glaucoma, an indication not addressed by any of the approved glaucoma drugs. GAL-101 was designed to target β -amyloid ($A\beta$) aggregates, the underlying cause of distinct neurodegenerative diseases of the eye and the central nervous system (CNS).

Preclinically, GAL-101 demonstrated compelling efficacy, protecting neuronal retinal cells from toxic damage in relevant ophthalmic models.

In clinical Phase 1 testing, Galimedix has successfully demonstrated GAL-101's excellent safety and tolerability profile. Also, the company has received supportive FDA feedback to continue the development through Phase 2 or Phase 2/3. The first patient is planned to be enrolled in 2024, with initial clinical efficacy results expected about 18 months later. Based on convincing results in animals, it is also planned to develop GAL-101 as an oral formulation to offer another convenient treatment alternative to patients.

"We are excited to partner our front-runner program, GAL-101, in ophthalmology with TOI, a company highly respected in and fully dedicated to the challenging field of ophthalmology already for several generations. This collaboration is an important milestone for Galimedix, as it further validates our technology and is critical to bringing GAL-101 through clinical development and approval to help patients who are currently at risk of gradually going blind," said **Alexander Gebauer, MD, Executive Chairman of Galimedix Therapeutics, Inc** "In addition, we are gratified by the strong support TOI has shown towards Galimedix by way of its equity investment in the company. This will enable us to move forward with our development plans for GAL-201, our next-generation oral compound for Alzheimer's disease."

Age-related macular degeneration (AMD) – leading cause of adult blindness

AMD is a neurodegenerative disease of the retina and is classified as either "wet" or "dry". Dry AMD is the most common form of the condition. In dry AMD, toxic $A\beta$ aggregates cause retinal cells in the central area (the macula) to slowly degenerate and die. The result is progressive loss of vision. Currently, there is no approved treatment for dry AMD. AMD affects about one in four adults over the age of 65. It is estimated that there are currently around 200 million patients globally suffering from AMD, which is the leading cause of adult blindness in the U.S. and other industrialized countries.

Additional information

About β -amyloid ($A\beta$) aggregation and GAL-101

β -amyloid ($A\beta$) aggregations occur when $A\beta$ monomers are misfolded. These aberrant structures form toxic $A\beta$ oligomers and protofibrils, and finally insoluble $A\beta$ aggregates which are deposited. Comprehensive scientific evidence has shown that $A\beta$ aggregations can be highly toxic to retinal cells and brain neurons and are likely to play an important role in the progressive loss of neurons.

Striking similarities link the underlying neurodegenerative pathology in ocular neurodegenerative diseases, such as glaucoma and age-related macular degeneration

(AMD), with the central nervous system disorder, Alzheimer's disease (AD). This suggests that elimination of toxic A β oligomers and protofibrils could be a promising therapeutic approach to slowing or halting retinal neurodegeneration. GAL-101 is designed to bind to a specific motif from A β , which is only exposed in the misfolded form of the A β monomer and can, therefore, be targeted. This ultimately leads to the elimination of all toxic species of A β from the retina while leaving normal A β intact and could potentially slow, halt or even reverse neurodegeneration and progression in AMD and glaucoma.

About Galimedix Therapeutics, Inc.

Galimedix Therapeutics, Inc. was founded by bio-entrepreneur Dr. Andrew Pearlman, neuroscientist Prof. Hermann Russ, Dr. Alexander Gebauer and others based on technology invented by Prof. Ehud Gazit and licensed from Tel Aviv University, Israel. Galimedix is a clinical-stage biotechnology company focused on developing innovative small molecule medicines addressing the cause of Alzheimer's disease, glaucoma, dry AMD, and other neurodegenerative disorders. The Company's pipeline includes the pre-clinical candidate GAL-201 for the treatment of patients with Alzheimer's disease and GAL-101 for patients with glaucoma and dry AMD. GAL-101 is about to enter Phase 2/3 clinical development. Galimedix is a U.S. Delaware corporation with operations in Europe, Israel, and the U.S. The company's neuropharma team has extensive experience in successful industrial drug development. They and their global network of collaborators are among the world leaders in the field of A β toxicity and A β aggregation modulation. Galimedix's success was facilitated by seed funding from InFocus Capital Partners and Rimongi Capital, two VC investors highly specialized in vision science technologies.

About Théa and Théa Open Innovation

Théa is the leading independent European pharmaceutical company specialized in the research, development, and commercialization of eye-care products. Based in Clermont-Ferrand, France, this family-owned company has continued to expand by opening more than 35 affiliates and offices in Europe, North Africa, North and South America, the Middle East. Its products are available in 75 countries. Théa Open Innovation (TOI) is a sister company of Théa. TOI's mission is to set up partnerships with companies and universities to help bring the most innovative products in ophthalmology to the market.

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