



## **Alector and GSK announce global collaboration in immuno-neurology for two clinical stage first-in-class monoclonal antibodies for neurodegenerative diseases**

July 2, 2021

- *Alector and GSK to co-develop progranulin-elevating monoclonal antibodies, AL001 and AL101, for a range of neurodegenerative diseases, including frontotemporal dementia, amyotrophic lateral sclerosis, Parkinson's disease and Alzheimer's disease*
- *Companies will co-commercialize and share profits in the US; GSK will retain exclusive commercialization rights outside the US*
- *Alector will receive \$700 million in upfront payments, up to \$1.5 billion in potential milestone payments, profit sharing and royalties*
- *Alector management to host conference call today at 8:30 a.m. ET*

SOUTH SAN FRANCISCO, Calif. and LONDON, July 02, 2021 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC) and GlaxoSmithKline plc (LSE/NYSE: GSK), today announced a strategic global collaboration for the development and commercialization of two clinical-stage, potential first-in-class monoclonal antibodies (AL001 and AL101) designed to elevate progranulin (PGRN) levels. PGRN is a key regulator of immune activity in the brain with genetic links to multiple neurodegenerative disorders, making it one of the most attractive genetically validated targets for the development of new immuno-neurology treatments.

The collaboration brings together Alector's leading immuno-neurology expertise with GSK's R&D focus on the science of the immune system and human genetics, proven late-stage drug development capabilities and global footprint. Enrollment is currently underway for a pivotal Phase 3 trial for AL001 in people at risk for or with frontotemporal dementia due to a progranulin gene mutation (FTD-GRN). FTD-GRN is a rapidly progressing and severe form of dementia found most frequently in people less than 65 years old at the time of diagnosis and has no approved treatments. AL001 is also currently in a Phase 2 study in symptomatic FTD patients with a mutation in the C9orf72 gene and is planned to enter Phase 2 development for amyotrophic lateral sclerosis (ALS) in the second half of 2021. AL101 is in a Phase 1a clinical trial and is designed to treat patients suffering from more prevalent neurodegenerative diseases, including Parkinson's disease and Alzheimer's disease.

**Dr Hal Barron, Chief Scientific Officer and President R&D, GSK, said:** "Our focus on human genetics and the science of the immune system gives us unique insights into the potential of targets such as progranulin to help patients with a number of neurodegenerative diseases. Working with Alector's world class scientists will allow us to investigate the potential of these immuno-neurology therapies to help patients with frontotemporal dementia, a devastating disease without any currently approved treatments, as well as explore the ability to help patients with other neurodegenerative diseases, such as ALS, Parkinson's and Alzheimer's."

**Arnon Rosenthal, Ph.D., Chief Executive Officer, Alector, said:** "This transformative collaboration brings together Alector's leading immuno-neurology expertise with GSK's commitment to immunology and human genetics, proven drug development capabilities and global footprint, to help expand and accelerate the development of our progranulin franchise into large indications, while bolstering the build out of our own late-stage development and commercial capabilities. Importantly, this collaboration is designed to fully support AL001 and AL101's development and to enable Alector to continue building a fully integrated company as we strive to address the high unmet medical need in patients suffering from neurodegenerative diseases. We are confident that GSK's extensive experience launching ground-breaking medicines at the intersection of immunology and human genetics, will ensure that AL001 and AL101 are developed to their full potential."

As part of the recent Investor Update day on 23 June 2021, GSK committed to an R&D approach focused on maximizing opportunities by leveraging an increased understanding of the science of the immune system and human genetics. The collaboration with Alector on AL001 and AL101, two antibodies designed to elevate PGRN levels and potentially slow the progression of FTD and other neurological disorders, provides GSK access to a promising clinical program in immuno-neurology.

### **Terms of the Collaboration**

Under the terms of the collaboration agreement, Alector will receive \$700 million in upfront payments. In addition, Alector will be eligible to receive up to an additional \$1.5 billion in clinical development, regulatory and commercial launch-related milestone payments.

Alector will lead the global clinical development of AL001 and AL101 through Phase 2 proof-of-concept. Thereafter, Alector and GSK will share development responsibilities for all late-stage clinical studies for AL001 and AL101 and all costs for global development will be divided between the two companies.

The companies will be jointly responsible for commercialization in the U.S. and will share profits and losses. Alector will lead commercial efforts associated with AL001 in orphan indications and GSK will lead the commercialization of AL101 in Alzheimer's and Parkinson's disease. Outside the U.S., GSK will be responsible for commercialization of AL001 and AL101 and Alector will be eligible for tiered royalties.

The collaboration agreement is conditional upon customary conditions including review by the appropriate regulatory agencies under the Hart-Scott-Rodino Act.

### **About the Progranulin-Elevating Monoclonal Antibodies - AL001 and AL101**

Decreased levels of PGRN, a key regulator of immune response, lysosomal function, and neuronal survival in the brain, are genetically linked to many neurodegenerative disorders. AL001 and AL101 are novel human monoclonal antibodies that elevate levels of progranulin by blocking the sortilin receptor responsible for progranulin degradation. AL001 is currently in a pivotal Phase 3 clinical study in people at risk for or with frontotemporal dementia due to a progranulin gene mutation (FTD-GRN). AL001 is also currently in a Phase 2 study in symptomatic FTD patients with a C9orf72 mutation, with another Phase 2 study in patients with ALS planned to begin in the second half of 2021. AL101, is designed to treat people suffering from more prevalent neurodegenerative diseases and is currently in a Phase 1a study in healthy volunteers. AL101 is intended to be developed for treatment of Parkinson's disease and Alzheimer's disease.

#### **About Frontotemporal Dementia (FTD)**

Frontotemporal dementia is a rapidly progressing and severe form of dementia. It affects 50,000 to 60,000 people in the United States and roughly 110,000 in the European Union, with potentially higher prevalence in Asia and Latin America. There are currently no FDA-approved treatment options for FTD.

There are multiple heritable forms of FTD. In one form, FTD-GRN, people have a mutation in the progranulin gene. This population represents 5% to 10% of all people with FTD. Mutations in a single copy of a progranulin gene leads to a 50% or greater decrease in the level of progranulin protein and invariably leads to development of FTD. In another form, people with mutations in the chromosome 9 open reading frame 72 (C9orf72) gene can develop FTD. FTD-C9orf72 is associated with abnormal accumulation of the protein TDP-43, which is also a hallmark in FTD-GRN. To date researchers have identified more than 120 inherited loss of function mutations in the progranulin gene that lead to FTD.

#### **Alector Conference Call Information**

Alector management will host a conference call to discuss the collaboration today at 8:30 a.m. ET. Analysts and investors are invited to participate in the conference call by dialling (888) 705-0365 from the U.S. and Canada or (415) 817-9241 internationally and using the conference ID 9476664. The live webcast can be accessed on the investor page of Alector's website at [investors.alector.com](http://investors.alector.com). A replay of the webcast will be available on Alector's website approximately two hours after the completion of the event and will be archived for up to 30 days.

#### **About GSK**

GSK is a science-led global healthcare company. For further information please visit [www.gsk.com/about-us](http://www.gsk.com/about-us).

#### **About Alector**

Alector is a clinical stage biotechnology company pioneering immuno-neurology, a novel therapeutic approach for the treatment of neurodegenerative diseases. The Company is developing a broad portfolio of innate immune system programs, designed to functionally repair genetic mutations that cause dysfunction of the brain's immune system and enable the rejuvenated immune cells to counteract emerging brain pathologies. Immuno-neurology targets immune dysfunction as a root cause of multiple pathologies that are drivers of degenerative brain disorders. The Company's immuno-neurology product candidates are supported by biomarkers and target genetically defined patient populations in frontotemporal dementia and Alzheimer's disease. This scientific approach is also the basis for the Company's immuno-oncology programs. Alector is headquartered in South San Francisco, California. For additional information, please visit [www.alector.com](http://www.alector.com).

#### **GSK Cautionary Statement Regarding Forward-Looking Statements**

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

#### **Alector Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on the current expectations and beliefs of Alector. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs, including but not limited to the outcome, benefits and synergies of the proposed collaboration with GSK, the anticipated completion of the proposed transaction and risks and uncertainties related to market conditions, Alector and its business as set forth in Alector's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 25, 2021, as well as the other documents Alector files from time to time with the SEC. These documents contain and identify important factors that could cause the actual results for Alector to differ materially from those contained in Alector's forward-looking statements. Any forward-looking statements contained in this press release speak only as of the date hereof, and Alector specifically disclaims any obligation to update any forward-looking statement, except as required by law.

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