MODAG Initiates First-in-Human Phase 1 Clinical Trial for Anle138b

-- Worldwide patent for anle138b secured --

Wendelsheim, Germany – December 18, 2019 – MODAG, a German biotechnology company focused on the development of disease-modifying small molecule therapeutics for neurodegenerative diseases, today announced the clinical trial initiation of, and recruitment for, a first-in-human Phase 1 study of lead candidate, anle138b in healthy volunteers. The compound is initially being developed for the treatment of Multiple System Atrophy (MSA), with the potential to be applied to other synucleinopathies, such as Parkinson's disease, in the future. MODAG also recently secured a U.S. patent for anle138b, expanding the Company's patent estate for anle138b to exclusive, worldwide coverage.

"Obtaining global patent protection for anle138b while beginning clinical testing in healthy individuals not only marks a significant strategic progression of our pipeline, but also emphasizes our ability to act on our corporate vision and goals. With the start of this trial, we are on track to run the tests necessary to bring anle138b one step closer to patients," said Dr. Torsten Matthias, CEO of MODAG.

Anle138b is a small molecule compound that specifically binds toxic oligomeric structures of alpha-synuclein, the core aggregating protein in Parkinsonian disorders, preventing new oligomers from forming and blocking the aggregation process from advancing. As a primary objective, the study will evaluate the safety and tolerability of the compound in healthy volunteers. Secondary objectives include the analysis of the pharmacokinetic profile as well as dose-finding evaluations of single and multiple ascending doses of anle138b. Recruitment into the trial, which will be conducted by Quotient Sciences in Nottingham, UK, is underway. Anle138b will be administered orally as a single agent to healthy volunteers.

"Anle138b has the potential to become a tangible treatment option to stop MSA, a highly underserved indication, in its tracks. MSA patients are severly impacted by progressing movement, balance and autonomic function impairments and as with many neurodegenerative diseases, there are no disease-halting treatment options available. If successful, the Phase 1 trial also opens the opportunity for MODAG to investigate anle138b in other Parkinsonian disorders and Parkinson's itself," added Dr. Johannes Levin, CMO of MODAG.

About anle138b

MODAG's lead candidate, anle138b, is a small molecule compound that specifically binds toxic oligomeric structures of alpha-synuclein, the core aggregating protein in Parkinsonian disorders. Through the binding, anle138b dissolves toxic oligomers and prevents new oligomers from forming, addressing the diseases at the core. Pre-clinical animal model studies in Parkinson's disease and MSA have demonstrated the ability to halt disease progression and alleviate symptoms *in vivo*, effectively preventing further damage by stopping the accumulation of pathological protein aggregates in the brain. In contrast to antibodies, anle138b can be administered orally, efficiently passing the blood-brain-barrier, while directly acting on toxic intracellular oligomers.

About MSA

Multiple System Atrophy (MSA) is a currently non-curable neurological disorder characterized by neurodegeneration in several parts of the brain including the basal ganglia and the cerebellum. It is characterized by a build-up of pathologically aggregated alpha-synuclein proteins in neuronal and glial cells. Patients experience an array of symptoms, including movement, balance and autonomic function disorders. Current drugs do not address the cause of the disease and are only capable of treating symptoms which progress alongside the disease. MSA is classified as a rare disease with an incident rate of approximately 0.6 cases per 100,000 people annually in the European Union. In Europe/United States/Japan, there are approximately 50,000 MSA patients. The mean age of onset of the disease is in the sixth decade of life. The mean survival period after the onset of the disease is 6-10 years.

About Parkinson's disease

Parkinson's disease (PD) is one of the most common diseases of the central nervous system. It is usually diagnosed between the ages of 50 and 79, with increasing incidences at an advanced age; men are affected more often than women. Drugs and supportive therapies can alleviate motor symptoms, but to date, there is no cure for PD. PD belongs to the group of synucleinopathies, diseases that are characterized by the abnormal deposition of the α-synuclein protein in the central and peripheral nervous system. In PD, α-synuclein accumulates predominantly in neurons, resulting in the formation of so-called Lewy bodies and Lewy neurites, which can be detected microscopically in neuropathological examinations. The typical motor symptoms that afflict PD patients include tremors, muscle stiffness and slowness of movements. They are mainly caused by a lack of the neurotransmitter, dopamine, which is produced by certain nerve cells in the midbrain. In PD, the dopamine-producing nerve cells in the substantia nigra exhibit pronounced synuclein deposits.

About MODAG

MODAG, a privately held German biotech company, aims to provide a novel approach for treating neurodegenerative diseases by combining targeted small molecule therapeutics with the right diagnostic tools. Our first objective is to demonstrate clinical proof-of-concept with our lead compound anle138b in Multiple System Atrophy (MSA), seeking to halt the progression and provide a first disease-modifying therapeutic. This success will allow us to apply our technology to similar diseases such as Parkinson's disease and other synucleinopathies with the goal of dissolving disease-related intra-cellular oligomers, thereby reducing their toxic properties. The Company was founded in 2013 based on research conducted by Prof. Dr. Giese (Ludwig Maximilian University of Munich) and Prof. Dr. Griesinger (Max-Planck-Institute for Biophysical Chemistry) examining protein aggregation and its toxic properties in neurodegenerative diseases to develop therapeutic options for conditions without available disease-modifying treatments. MODAG has been supported by grants from leading patient organizations including the Michael J Fox Foundation for Parkinson's Research, the Cure Parkinson's Trust, and the Parkinson's UK. For more information see www.modag.net

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