

MODAG Initiates First-in-Patient Phase 1b Trial for Anle138b in Parkinson's Disease

Wendelsheim, Germany – December 23, 2020 – 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 a first-in-patient Phase 1b study for anle138b in patients with mild to moderate Parkinson's Disease (PD). Anle138b is a disease-modifying treatment option for synucleinopathies, such as Multiple System Atrophy (MSA) and PD.

The short-term Phase 1b study with PD patients will be conducted by Quotient Sciences in Nottingham, UK, supported by the Neurology Department of Nottingham University Hospital. The study's primary endpoints include safety, tolerability and pharmacokinetics of anle138b in PD patients in order to establish the optimal dosing scheme for future long-term efficacy trials. The trial is supported by a grant of USD 1.4 million from The Michael J. Fox Foundation for Parkinson's Research.

"After successfully completing our first-in-human clinical trial for anle138b in healthy volunteers in August, we are excited to launch the first-in-patient study in line with our ambitious development plan timelines. We are proud to have reached the significant milestone of bringing anle138b to patients for the first time and see this as a validation of our ability to act on our corporate visions and goals," said Dr. Torsten Matthias, CEO of MODAG.

Professor Armin Giese, CSO of MODAG, continued, "Anle138b is a small molecule capable of binding to alpha-synuclein's toxic oligomeric structures and thereby blocking disease-progression. The recently completed Phase 1 study confirmed excellent safety and tolerability of anle138b in healthy human volunteers. From initially developing this molecule I am very excited to see it reach patients so rapidly with this first study in Parkinson's disease."

Professor Johannes Levin, CMO of MODAG, added: "Anle138b demonstrates the potential to become a tangible treatment option for halting disease progression in PD and MSA. The data collected in this study will serve as the foundation for its continued clinical development and will inform the design of future long-term efficacy studies in patients. I am pleased with the rapid progress we have made in bringing our lead candidate to patients."

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 Parkinson's disease

Parkinson's disease (PD) is one of the most common diseases of the central nervous system with an estimated 10 million patients worldwide. 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) and Parkinson's disease (PD), seeking to halt the progression and provide a first disease-modifying therapeutic. This success will allow us to apply our technology to similar diseases with protein aggregation including Alzheimer's disease and tauopathies such as PSP, with the goal of dissolving disease-related intra-cellular oligomers, thereby reducing their toxic properties. The Company was founded based on research conducted by scientists at the Ludwig Maximilian University of Munich and the Max-Planck-Institute for Biophysical Chemistry in Göttingen and 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 Parkinson's UK. For more information see www.modag.net

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