MODAG Successfully Completes Phase 1 Study of their Lead Candidate Anle138b and Receives Additional USD 1.4 Million from Michael J. Fox Foundation

WENDELSHEIM, Germany, August 5, 2020 – MODAG, a German biotechnology company focused on the development of disease-modifying small molecule therapeutics for neurodegenerative diseases, today announced the successful completion of its first clinical trial of anle138b (NCT04208152) in healthy volunteers. The Company's lead candidate, which was administered in doses of up to 300 mg daily, demonstrated excellent safety and tolerability profiles at all dose levels and reached significantly higher plasma levels in humans than those required for full therapeutic efficacy in animal models. Anle138b was initially developed for the treatment of Multiple System Atrophy (MSA) and has the potential to be applied to other synucleinopathies, such as Parkinson's disease. Based on the positive Phase 1 study results, MODAG was also able to obtain additional funding of USD 1.4 million from The Michael J. Fox Foundation for Parkinson's Research.

"The successful completion of our first clinical trial with anle138b is an important step toward beginning further evaluation in neurodegenerative diseases and underscores our expertise in drug development," commented Dr. Torsten Matthias, CEO of MODAG. "The fact that we were able to carry out this study in a timely manner despite the COVID-19 pandemic, is largely due to the tireless efforts and commitment of the MODAG team. I would also like to thank our Phase 1 study partners, Quotient Sciences, Aptuit and Granzer Consulting."

Professor Armin Giese, CSO of MODAG, continued, "Anle138b is a small molecule that specifically binds to toxic oligomeric structures of alpha-synuclein, the core aggregating protein in Parkinson's disease. This prevents the formation of new oligomers and thereby blocks the disease-specific aggregation process from advancing. In the recently completed Phase 1 study, safety, tolerability and pharmacokinetic properties of anle138b known from animal models were confirmed in humans. Already at a 100 mg dose-level, anle138b plasma levels that were significantly above the threshold dose effective in animal experiments could be achieved. Furthermore, no therapy-specific side effects were observed. The plasma half-life of anle138b after oral administration in capsule form was about 12 hours, which is ideal for this application. Furthermore, it could be shown that the uptake of the substance was not significantly altered by parallel food intake."

Professor Johannes Levin, CMO of MODAG, added: "The data from this Phase 1 study will serve as the foundation for the further clinical development of our lead candidate. We are diligently working on the next step: a first-in-patient study investigating safety, tolerability and pharmacokinetics in Parkinson's patients which is planned to start by the end of this year. MODAG already received a $1.26 million grant from The Michael J. Fox Foundation in 2015 toward pre-clinical optimization of anle138b and biomarker assay development and now the foundation will support this first-in-patient study. The reviewers of The Michael J. Fox Foundation are among the world's leading experts on Parkinson's disease, so the funding for this study from this highly recognized organization adds further validation to our approach and its potential. In my clinical work with MSA and Parkinson's patients, I am confronted with the urgent need for disease-modifying treatments on a daily basis. Thus, I am pleased that we have made such rapid progress towards the first potential tests in patients."

Following the first-in-patient study, MODAG plans to conduct long-term clinical trials investigating the efficacy of anle138b in MSA and Parkinson's disease patients. These studies are anticipated to begin at the end of 2021.

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 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, 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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