https://www.biospace.com/article/releases/modag-initiates-first-in-patient-phase-1b-trial-for-anle138b-in-parkinson-s-disease/

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MODAG lance l'essai clinique de phase 1b de l'Anle138b sur des patients dans la maladie de Parkinson

WENDELSHEIM, Allemagne - (BUSINESS WIRE) - MODAG, une société de biotechnologie allemande axée sur le développement de traitements de fond à petites molécules pour les maladies neurodégénératives, a annoncé aujourd'hui le lancement du premier essai clinique sur des patients atteints de la maladie de Parkinson (MP) légère à modérée, étude de phase 1b del'anle138b. Anle138b est un candidat-médicament de fond des synucléinopathies, telles que l'atrophie multi-systématisée et la MP.

L'étude de phase 1b, d'une durée courte, avec des patients atteints de MP sera menée par Quotient Sciences à Nottingham, au Royaume-Uni, avec le soutien du département de neurologie de l'hôpital universitaire de Nottingham. Les principaux critères d'évaluation de l'étude comprennent l'innocuité, la tolérabilité et la pharmacocinétique de l'anle138b chez les patients atteints de MP afin d'établir le schéma posologique optimal pour les futurs essais d'efficacité à long terme. L'essai est financé par une subvention de 1,4 million de dollars de la Fondation Michael J. Fox pour la recherche sur la maladie de Parkinson.

«Après avoir terminé avec succès notre premier essai clinique de l'anle138b chez des volontaires en bonne santé en août, nous sommes ravis de lancer la première étude chez les patients, conformément avec les échéanciers de notre ambitieux plan de développement. Nous sommes fiers d'avoir atteint le stade important consistant à apporter l'anle138b aux patients pour la première fois et voyons cela comme une validation de notre capacité à agir conformément à nos visions et objectifs d'entreprise », a déclaré le Dr Torsten Matthias, PDG de MODAG.

Le professeur Armin Giese, responsable scientifique de MODAG, poursuit : *«Anle138b est une petite molécule capable de se lier aux structures oligomères toxiques de l'alpha-synucléine et de bloquer ainsi la progression de la maladie. L'étude de phase 1 récemment achevée a confirmé l'excellente innocuité et la tolérabilité de l'anle138b chez des volontaires humains en bonne santé. Depuis le développement initial de cette molécule, je suis très heureux de la voir atteindre si rapidement les patients avec cette première étude sur la maladie de Parkinson. "*

Le professeur Johannes Levin, responsable médical de MODAG, ajoute : *«Anle138b démontre son potentiel de devenir une option de traitement pour arrêter la progression de la maladie dans la MP et l'AMS. Les données recueillies dans cette étude serviront de base à son développement clinique continu et éclaireront la conception des futures études d'efficacité à long terme chez les patients. Je suis satisfait des progrès rapides que nous avons réalisés pour amener notre candidat principal auprès des patients.* »

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

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WENDELSHEIM, Germany--(BUSINESS WIRE)-- **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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Contacts

For MODAG:
Dr. Torsten Matthias, CEO
Website: www.modag.net
E-mail: info@modag.net
Phone: +49 6734 96 228000

For Media Inquiries:
Trophic Communications
Stephanie May or Valeria Fisher
E-mail: may@trophic.eu or fisher@trophic.eu
Phone: +49 171 185 56 82 or +49 175 804 1816

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