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Oryzon gets approval for conducting Phase IIa trial of Vafidemstat

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Spanish Medicines Agency has approved to carry out a Phase IIa trial with Vafidemstat. Vafidemstat exerts a holistic action on different types of alterations also seen in patients with Alzheimer's disease and other neurodegenerative disorders.



Oryzon Genomics, a public clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in diseases with strong unmet medical need, has announced the approval by the Spanish Medicines Agency of a clinical trial authorization to carry out a Phase IIa trial with Vafidemstat in patients with episodes of aggressiveness. The study, called REIMAGINE, is a "basket" trial to explore the safety and efficacy of Vafidemstat in patients with episodes of aggressiveness in two neurodegenerative disorders (Lewy Body Dementia (DLB) and Alzheimer's Disease and three psychiatric disorders (Autism Spectrum Syndrome (ASD), Borderline Personality Disorder (BPD) and adult Attention Deficit Hyperactivity disorder (ADHD).

This trial will include 6 patients per indication and will be conducted in Spain at the Valle de Hebrón hospital in Barcelona. REIMAGINE is designed as a single-arm, open-label, 8-weeks treatment study to evaluate safety and efficacy in aggression. Vafidemstat (ORY-2001) is an oral and brain penetrant drug that selectively inhibits LSD1 and MAOB. The molecule acts on several levels, reduces cognitive impairment, memory loss and neuroinflammation, and at the same time has neuroprotective effects. The company has recently reported in several scientific conferences that in preclinical models.

Vafidemstat exerts a holistic action on different types of alterations also seen in patients with AD and other neurodegenerative disorders. Different experiments suggest Vafidemstat may act as a disease modifying drug. In Alzheimer's Disease patients and other neurodegenerative disorders, cognitive deterioration is often accompanied by episodes of agitation, aggression, psychosis, apathy and depression. In preclinical studies, Vafidemstat not only restores memory but reduces the exacerbated aggressiveness of SAMP8 mice, a model for accelerated aging and Alzheimer’s disease, to normal levels and also reduces social avoidance and enhances sociability in various murine models. In addition, Vafidemstat exhibits fast, strong and durable efficacy in several preclinical models of multiple sclerosis (MS).

The company has already started Phase IIa clinical studies with Vafidemstat in patients with Relapse-Remitting and Secondary Progresive MS (SATEEN) and in patients with Mild to Moderate Alzheimer’s disease.

Roger Bullock, Oryzon’s Chief Medical Officer, commented: "This is a pioneering study borrowing cancer methodology for CNS research. Many behavior alterations like aggression are common across neurological and psychiatric disorders.

Preclinical work with Vafidemstat suggest that these behavior alterations may share common mechanisms, which potentially respond to epigenetic approaches. REIMAGINE is looking at aggression in response to stress across diverse CNS disorders and we are anticipating exciting discoveries. Further REIMAGINE studies will look at other behavior alterations in a series of ground breaking experiments to literally reimagine the treatment of CNS disorders."

Carlos Buesa, president and CEO of Oryzon, commented: "Vafidemstat is a first in class molecule and it is pioneering worldwide the epigenetic approach in the field of Nervous System diseases, not only neurodegenerative but also psychiatric.The molecule has shown a very good safety profile up to now, and in the preclinical studies it has shown a holisticaction on the different alterations observed in human patients. The results of this trial will give us valuable information about the future clinical development of Vafidemstat."