

Oryzon announces first patient enrolled in REIMAGINE: a Phase IIa clinical trial with Vafidemstat (ORY-2001) in aggressiveness

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, October 9, 2018 – Oryzon Genomics S.A. (ISIN Code: ES0167733015, ORY), (“Oryzon”), a public clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in diseases with strong unmet medical need, has announced today that the first patient has been enrolled in the REIMAGINE Phase IIa trial with Vafidemstat (ORY-2001) in patients with episodes of aggressiveness.

The REIMAGINE study 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 (AD)) 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 of Vafidemstat in aggression.

Vafidemstat is an oral, brain penetrant drug that selectively inhibits LSD1 and MAOB. The molecule acts on several levels: it reduces cognitive impairment, memory loss and neuroinflammation, and at the same time has neuroprotective effects. Oryzon 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 AD 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). Oryzon has already started Phase IIa clinical studies with Vafidemstat in patients with Relapse-Remitting and Secondary Progressive MS (SATEEN) and in patients with Mild to Moderate Alzheimer’s disease (ETHERAL).

Dr. José Antonio Ramos-Quiroga, head of the Psychiatry Service of the Valle-Hebrón hospital and Principal Investigator of the study, said: "Vafidemstat, with its novel mechanism of action and the results obtained in animal models, raises hopes for its application in humans. If the preclinical results are replicated in the REIMAGINE study, this drug will be a great help for patients and their families."

Roger Bullock, Oryzon’s Chief Medical Officer, commented: "Behavior alterations like aggression are common across neurological and psychiatric disorders. REIMAGINE paves a new way for assessing epigenetic applications in human diseases."

Carlos Buesa, president and CEO of Oryzon, commented: "This is a new clinical trial we are starting in collaboration with the Hospital Valle de Hebrón, a European leading site in clinical research, with which Oryzon maintains a long and very fruitful relationship. This long partnership shows the vigorous Spanish biomedical ecosystem that has been set up in the last few years and allows Spanish researchers to develop new first-in-class experimental drugs."

About Oryzon

Founded in 2000 in Barcelona, Spain, Oryzon (ISIN Code: ES0167733015) is a clinical stage biopharmaceutical company considered as the European champion in Epigenetics. Oryzon has one of the strongest portfolios in the field. Oryzon's LSD1 program has rendered two compounds in clinical trials. In addition, Oryzon has ongoing programs for developing inhibitors against other epigenetic targets. Oryzon has a strong technological platform for biomarker identification and performs biomarker and target validation for a variety of malignant and neurodegenerative diseases. Oryzon is publicly traded on the Spanish Automated Quotation System (Continuous Market) that includes the Madrid, Barcelona, Bilbao and Valencia Stock Exchanges. Oryzon has offices in Spain and the United States. For more information, visit www.oryzon.com.

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