

ORYZON announces FDA Approval of IND for ETHERAL, a Phase IIa trial of the epigenetic drug Vafidemstat in Patients with mild to moderate Alzheimer's disease

Recruitment is ongoing in Europe

The European and US Study will recruit a total of 150 patients

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, March 11, 2019 – Oryzon Genomics, S.A. (ISIN Code: ES0167733015, ORY), a public clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in diseases with strong unmet medical need, announced today that Oryzon has received confirmation from the U.S. Food and Drug Administration (FDA) that its Investigational New Drug application (IND) is now open for vafidemstat (ORY-2001) for the treatment of mild to moderate Alzheimer's disease (AD) patients. Oryzon submitted its IND for this Phase IIa clinical trial of vafidemstat in patients with Alzheimer's disease to the FDA on February 6, 2019.

ETHERAL (Epigenetic THERapy in ALzheimer's Disease) is already recruiting across different European hospitals. It is planned that the European sites will contribute approximately 125 participants to the study and the US arm will contribute the remainder for a total of 150 participants. With the FDA approval, the trial is now fully operational in the EU and US.

ETHERAL is a Phase IIa randomised, double-blind, placebo-controlled, 3-arm, 24 weeks parallel-group study to evaluate the safety and tolerability of vafidemstat in patients with mild-to-moderate Alzheimer's disease. Secondary endpoints include measures of cognition, function and behavior. Finally, ETHERAL will measure and monitor several traditional and novel CSF biomarkers.

"The FDA's timely acceptance of our IND application and Phase IIa protocol is an important milestone for Oryzon," said Dr. Michael Ropacki, Oryzon's Vice President of Clinical and Product Development. "Vafidemstat has a unique epigenetic mechanism of action targeting neuroinflammation and gene expression. Previous preclinical research strongly suggests that it may decrease patients and caregiver burden in several CNS diseases including Alzheimer's disease. Epigenetics provides a tremendous opportunity to meaningfully impact patients' lives.", Dr. Ropacki added. Dr. Carlos Buesa, Oryzon's CEO, said "This is our first US clinical trial and represents a qualitative step forward in the company strategy. For Oryzon, the progressive deployment of clinical and market US operations are of the utmost importance"

About Vafidemstat

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. In animal 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 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 study), in patients with Mild to Moderate Alzheimer's disease (ETHERAL study) and in aggressiveness in patients with different psychiatric or neurodegenerative disorders (basket trial REIMAGINE).

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 has offices in Spain and the United States. For more information, visit www.oryzon.com

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US Contact:

The Trout Group
Thomas Hoffmann
+1 646 378 2932
thoffmann@troutgroup.com

Spain:

ATREVIA
Patricia Cobo/Idoia Revuelta
+34 91 564 07 25
pcobo@atrevia.com
irevuelta@atrevia.com

Oryzon:

Emili Torrell
BD Director
+34 93 515 13 13
etorrell@oryzon.com