ORYZON receives approval in the United Kingdom to start ETHERAL: a Phase IIa clinical trial in Alzheimer's Disease with ORY-2001

This trial was approved in the previous weeks in Spain and France

This approval concludes the regulatory start of this trial in Europe

This is the second Phase II study in CNS with the drug

MADRID, SPAIN and CAMBRIDGE, MA, May 29, 2018 – Oryzon Genomics (ISIN Code: ES0167733015, ORY), a public clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in diseases with strong unmet medical need, has announced today that it has received approval of a Clinical Trial Application (CTA), the European IND equivalent, from the Medicines & Healthcare products Regulatory Agency (MHRA) and also from the Ethics Committee to conduct a Phase IIa clinical study with ORY-2001 in patients of Alzheimer's disease (AD) in the UK. The trial had been previously approved in Spain and France. With this approval, the trial is now fully operationally deployed upon receipt from the corresponding regulatory authorities of all initially scheduled approvals.

The study, named ETHERAL (**E**pigenetic **THER**apy in **AL**zheimer's Disease), is being conducted in different European hospitals across Spain, France and UK, and is designed as a randomised, double-blind, placebo-controlled, 3-arm, 26 weeks parallel-group study to evaluate the safety and tolerability of ORY-2001 in patients with mild and moderate Alzheimer's disease. The study will involve 90 patients and incorporates measurements in the different domains of the disease as secondary endpoints, including memory and behavior alterations. It will also monitor the variations of diverse, yet significant CSF biomarkers. The company is aiming to launch a twin study in the US soon.

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 ORY-2001 exerts in preclinical models a holistic action on different types of alterations also seen in patients with AD and other neurodegenerative disorders. ORY-2001 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, ORY-2001 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, ORY-2001 exhibits fast, strong and durable efficacy in several preclinical models of multiple sclerosis (MS). The company has already started a Phase IIa clinical study with ORY-2001 in patients with MS.

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. The company 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. The company has a strong technological platform for biomarker identification and performs biomarker and target validation for a variety of malignant and neurodegenerative diseases. The company has offices in Spain and USA. For more information, visit www.oryzon.com.

FORWARD-LOOKING STATEMENTS

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