

ORYZON announces First Patients in the UK in ETHERAL: a Phase IIa clinical trial in Alzheimer's Disease with ORY-2001

MADRID, SPAIN and CAMBRIDGE, MA, June 25, 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 enrolled the first patients in the UK, at St Pancras Clinical Research, in its Phase IIa clinical study with ORY-2001 in patients of Alzheimer's disease (AD). The study, named ETHERAL (Epigenetic THERapy in ALzheimer's Disease), is being conducted in different European hospitals, and is designed as a randomised, double-blind, placebo-controlled, 3-arm, 26 weeks parallel-group study to evaluate the safety and tolerability of ORY2001 in patients with mild and moderate Alzheimer's disease. The study incorporates as secondary endpoints measurements in the different dimensions of the disease, including memory and behavior alterations.. The study will also monitor the variations of diverse CSF biomarkers. This study will enroll 90 patients, and the FPIs in Spain were enrolled in May. The company is looking to launch a twin study in the US soon with a, yet to be determined, number of additional patients.

ORY-2001 is also in another Phase IIa clinical study in patients of Multiple Sclerosis (MS). The study, named SATEEN, is currently being conducted in nine different Spanish hospitals, and is designed as a randomised, double-blind, placebo-controlled, 3-arm, 36 weeks parallel-group study to evaluate the safety and tolerability of ORY2001 in patients with Relapsing-Remitting Multiple Sclerosis (RRMS) and Secondary Progressive Multiple Sclerosis (SPMS). The FPI was enrolled in January and the recruitment is proceeding.

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 ORY-2001 exerts a holistic action on different types of alterations also seen in patients with AD and other neurodegenerative disorders. Different experiments suggest that 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 to normal levels and also reduces social avoidance and enhances sociability in various murine models.

Roger Bullock, Oryzon's Chief Medical Officer, commented, "This heralds an important landmark, as the UK contribution to this trial is going to be crucial to achieve the planned timings. UK clinical specialists have a solid tradition to be at the forefront of innovative clinical investigation, particularly in neurodegenerative diseases like Alzheimer's. We expect that the seven UK clinical sites will play a central role in the execution and in the analysis of the results of this study. We now await commencement of recruitment in our final country, France, after which the study will be fully operational and on course to have results in this innovative paradigm for CNS disorders".

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.

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