

ORYZON Announces End of Patient Recruitment for its Phase IIa trials in aggression with vafidemstat: REIMAGINE and REIMAGINE-AD

- ❖ **REIMAGINE has recruited 30 patients in three psychiatric disorders: Borderline personality disorder (BPD), Attention deficit and hyperactivity disorder (ADHD) and Autism Spectrum Disorder (ASD)**
- ❖ **REIMAGINE-AD has recruited 12 patients in Alzheimer's disease**

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, July 29th, 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 the company has recruited all the planned patients in the ongoing Phase IIa REIMAGINE trials, with a total of 42 patients recruited.

REIMAGINE is a Phase IIa "basket" clinical trial programme to evaluate the safety, tolerability and efficacy of vafidemstat in aggression. The initial study concept evolved in to the recruiting of 30 participants from three adult populations with psychiatric disorders (BPD, ADHD, ASD) after the trial reported positive preliminary efficacy data in two 6 patients-cohorts in BPD and ADHD at the 27th European Congress of Psychiatry (EPA 2019) in Warsaw and the 7th World Congress on ADHD in Lisbon in April. Data with a third 6-patient cohort in ASD will be presented at ECNP in Copenhagen in September. The company has now finalized the recruitment of these 30 patients, from which 12 have ADHD, 11 have BPD and 7 have ASD. This novel study of a new approach to treating aggression is being conducted in Spain at the Vall d'Hebrón hospital in Barcelona. REIMAGINE (EudraCT Number 2018-002140-88) is designed as a single-arm, open-label, 8-weeks treatment study.

Because REIMAGINE became focused on psychiatric indications, a trial in neurodegenerative conditions is being conducted separately, under the same name and using the same design. REIMAGINE-AD (EudraCT Number 2019-001436-54) is interrogating aggression in a moderate Alzheimer's disease population. Besides memory loss, the most impairing alterations in AD patients are aggression and apathy, where aggression is the leading reason for AD patients being institutionalized. This study, again a single-arm, open-label, 8-weeks treatment study, has recruited its intended 12 patients. The study is also being conducted in Spain, at the Fundació ACE in Barcelona. The company expects to present data of REIMAGINE-AD in December at CTAD-2019 in San Diego.

Dr. Roger Bullock, Medical Director of the company, said: "Aggression is a very debilitating feature across different CNS diseases, often associated with accelerated speed of progression of that CNS disorder. In AD, with over 45 million patients, more than 20% of the outpatients and 40% of long-term care residents

exhibit disrupted behavior, particularly agitation and aggression. Current anti-psychotics have limited activity and are associated with serious adverse effects including sedation, cerebrovascular accidents and increased mortality. Vafidemstat could provide a safer alternative therapeutic option for these patient groups if we continue to get positive results in these ongoing trials”.

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, vafidemstat and iadademstat, 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

About Vafidemstat

Vafidemstat (ORY-2001) is an oral, brain penetrant drug that selectively inhibits LSD1 and MAOB. The molecule acts on several levels: it reduces cognitive impairment, including 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). Vafidemstat is in Phase IIa clinical studies in patients with Relapse-Remitting and Secondary Progressive MS (SATEEN), in patients with Mild to Moderate Alzheimer's disease (ETHERAL) and in aggressiveness in patients with different psychiatric or neurodegenerative disorders (REIMAGINE, a basket trial).

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