ORYZON announces enrollment of first patient in ESCAPE: a Phase II clinical trial with vafidemstat in severely ill COVID-19 patients

❖ ESCAPE study to recruit 40 patients

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, May 18th, 2020 - 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 the enrollment of the first patient in its Phase II clinical trial with vafidemstat in seriously ill COVID-19 patients.

The study, named ESCAPE (Nº EudraCT: 2020-001618-39), is an open-label, randomized, double arm Phase II trial to assess the efficacy and tolerability of vafidemstat in combination with standard of care, to prevent progression to Acute Respiratory Distress Syndrome (ARDS). The study has two treatment arms: in one the patients will receive standard of care and in the other the standard of care in combination with vafidemstat. Each of the study arms will include 20 patients. The endpoints of the study will be assessed at days 5, 14 and 28.

If positive clinical signs are identified, additional centers and patients may be added. Given the current epidemiological dynamics of the pandemic in Spain and elsewhere in Europe, the company expects to be able to report initial efficacy data before the end of the year.

Carlos Buesa, President and CEO of Oryzon, said: "We at Oryzon are very proud to be playing our part in the fight against COVID-19 with this study. While our business remains focused on epigenetics, it is essential to do everything we can to address the greatest threat to public health of our times."

ESCAPE (*Efficacy and Safety of a Combined treatment with vafidemstat to prevent ARDS in adult Patients with severE COVID-19*) (EudraCT No.: 2020-001618-39) aims to explore a therapeutic intervention to prevent progression of severely ill COVID-19 patients with pneumonia to ARDS, one of the main causes of death in this disease, by reducing the patient's inflammatory response to the infection. For more details, please visit https://www.oryzon.com/sites/default/files/PRESS_RELEASE_10-2020.pdf

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 neurological 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, CNS optimized LSD1 inhibitor. 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 (AD), 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 performed a Phase IIa clinical trial in aggressiveness in patients with different psychiatric disorders (REIMAGINE) and in aggressive/agitated patients with moderate or severe AD (REIMAGINE-AD), with positive preliminary clinical results reported. Additional Phase IIa clinical trials with vafidemstat are ongoing in patients with Mild to Moderate AD (ETHERAL), where a significant reduction of the inflammatory biomarker YKL40 has been observed after 6 months of treatment, and in Relapse-Remitting and Secondary Progressive MS (SATEEN).

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