Oryzon announces First-Patients-in in CLEPSIDRA: a Phase IIa clinical trial with Iadademstat (ORY-1001) in Small Cell Lung Cancer patients

- **In Second line patients in combination with Standard-of-Care**
- **Uses Proprietary Biomarkers as Inclusion Criteria**

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, December 3, 2018 – 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, has announced today the inclusion of the first two patients in a Phase IIa clinical study with Iadademstat (ORY-1001) in Small Cell Lung Cancer (SCLC) patients.

The study, named CLEPSIDRA ("*A **C**ombination trial of **L**SD1 and **E**top-**P**latinum in **S**mall Cell Lung Cancer in Biomarker-**ID** **R**elapsed p**A**tients),* is conducted at four Spanish hospitals in Madrid, Valencia and Barcelona. CLEPSIDRA will be performed on second line SCLC patients and is designed as a single-arm, open-label study of Iadademstat in combination with the standard of care treatment platinum/etoposide, in order to evaluate the safety and tolerability as well as the clinical effect (including time to response, duration of response, objective response and overall survival) of the combination. The study is divided into two parts, the first one to optimize the dose of the combination and the second one to evaluate the efficacy of the combination. Up to 36 patients are planned to be enrolled.

Iadademstat (ORY-1001) is a small oral molecule, which acts as a highly selective inhibitor of the epigenetic enzyme LSD1 and has a powerful differentiating effect in hematologic cancers (See Maes et al., Cancer Cell 2018 Mar 12; 33 (3): 495-511.e12.doi: 10.1016 / j.ccell.2018.02.002.). Inhibition of LSD1 has been proposed as a valid therapeutic approach in some solid tumors and, particularly, in SCLC. SCLC represents 15% of lung neoplasms and is an aggressive malignant tumor with very limited treatment options. Experiments done at the Fred Hutchinson Cancer center with Iadademstat (ORY-1001) show that some SCLC tumors display a high sensitivity to LSD1 inhibition. Oryzon has been working intensively on identifying tumor biomarkers that may be used to stratify those SCLC patients with increased likelihood of response to LSD1 inhibition. In CLEPSIDRA patients will be selected for inclusion based on the presence of these proprietary biomarkers in the primary tumor. Oryzon has recently started also another Phase IIa clinical trial of Iadademstat in combination with Azacitidine in elderly Acute Myeloid Leukemia (AML) patients not eligible for intensive chemotherapy. This study is already recruiting patients.

Roger Bullock, Oryzon's Chief Medical Officer commented: "The use of biomarkers in the inclusion criteria in a SCLC study is novel and if it produces positive results it would allow us to develop larger studies using this personalized approach in a disease that is extremely fast and aggressive".

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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