Oryzon announces First-Patient-in in ALICE: a Phase IIa clinical trial with Iadademstat (ORY-1001) in Acute Myeloid Leukemia patients

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, November 12, 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 patient in a Phase IIa clinical study with Iadademstat (ORY-1001) in elderly Acute Myeloid Leukemia (AML) patients not eligible for intensive chemotherapy.

The study, named ALICE ("An **A**ML trial with **L**SD1**i** in **C**ombination with azacitidine in the **E**lderly"), is conducted at two Spanish hospitals, "La Fe" in Valencia and "Valle de Hebrón" in Barcelona. ALICE will be performed on newly diagnosed AML patients and is designed as a single-arm, open-label study of Iadademstat in combination with the standard of care treatment Azacitidine, 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. 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.). A first Phase I/IIa clinical trial with Iadademstat in refractory and relapsed acute leukemia patients demonstrated the safety and good tolerability of the drug and preliminary signs of antileukemic activity including a CRi (manuscript in preparation). Beyond hematological cancers, the inhibition of LSD1 has been proposed as a valid therapeutic approach in some solid tumors such as small cell lung cancer (SCLC). SCLC represents 15% of lung neoplasms and is an aggressive malignant tumor with very limited treatment options. Oryon has recently received approval from the Spanish Medicines Agency to conduct a Phase IIa clinical trial of Iadademstat in combination with platinum/etoposide in SCLC (CLEPSIDRA study). Recently, it has also been published that the inhibition of LSD1 improves the antitumor response of the immune system and, in melanoma models, eliminates resistance to therapy with PDL-1 antibodies, a stellar agent of the immuno-oncology field already approved for use in various types of tumors (see Sheng et al., Cell 2018 Jun 18. pii: S0092-8674 (18) 30715-3.doi: 10.1016 / j.cell.2018.05.052. [Epub ahead of print]).

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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