ORYZON presents preliminary dose finding results of Phase II trial with iadademstat in AML

- **Results presented at 24th Congress of EHA in Amsterdam**
- **Combination of iadademstat and azacitidine shows good safety profile in elderly AML patients**
- **Recommended dose for Phase II established with only six patients**
- **Quick onset of response and preliminary clinical efficacy results also positive**

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, June 14th 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, today presents preliminary data from Part I (dose finding) of the Phase II trial ALICE, which investigates iadademstat in combination with azacitidine in elderly patients with acute myeloid leukemia (AML), at the 24th Congress of the European Hematology Association (EHA-2019) in Amsterdam.

In Part I of the ALICE study, which has been completed, the combination of iadademstat with azacitidine demonstrated a good safety profile in the first six patients. The full target engagement at the initial planned dose allows to determine the recommended dose of iadademstat for the continuation of the Phase II trial at 90 ug/m^2.

The preliminary clinical efficacy results are also positive. The drug produces a clear differentiation effect in the blasts of patients and the clinical efficacy responses are encouraging, with 80% of objective responses in the five patients who were evaluable. Of these, 75% were complete remissions with incomplete hematologic recovery (CRi) and 25% were partial remissions (PR) (3/5 CRi and 1/5 PR). Interestingly, the observed clinical responses appear rapidly with a median time of 1.5 months.

The objective of the ALICE trial is to set the stage for the broader application of iadademstat in other leukemias. It is being carried out in two Spanish hospitals, “La Fe” in Valencia and “Valle de Hebrón” in Barcelona, on newly diagnosed elderly AML patients and is designed as a single-arm, open-label study and in combination with the standard of care treatment azacitidine. The study is divided into two parts, the first one optimizing the dose of the combination, and the second one to evaluate the combination’s effectiveness. The study will recruit up to 36 patients. In the trial, clinical responses are measured, as well as time to response, duration of response and average survival.

Dr. Carlos Buesa, CEO of Oryzon, said: "Although the total number of patients is still small, we are cautiously optimistic about these promising results and are continuing our development of iadademstat, which has a powerful differentiating effect in hematologic cancers. In particular, we are pleased to observe the high percentage of complete remissions, the quick onset of response, and the tolerability of

the combination with azacitidine. We aim to present a significant update in December at the American Society of Hematology Meeting in Orlando."

The poster presentation on the data takes place June 14, 17:30-19:00, at the Conference Center. A complete view of the poster is available here

For more information about the congress please visit EHA's website

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 Iadademstat

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. 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), medulloblastoma and others. Oryon is conducting two Phase IIa clinical trials of iadademstat in combination; the first one in combination with azacitidine in elderly AML patients (ALICE study) and the second one in combination with platinum/etoposide in second line SCLC patients (CLEPSIDRA study).

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