



**ORYZON GENOMICS, S.A.**

Pursuant to the provisions of article 227 of the Restated Text of the Securities Market Act approved by Royal Legislative Decree 4/2015 of 23 October, ORYZON GENOMICS, S.A. ("**ORYZON**" or the "**Company**") hereby gives notice of the following

### **MATERIAL FACT**

ORYZON announces that it will present today at the 24<sup>th</sup> Congress of the European Hematology Association (EHA) preliminary human efficacy data with iadademstat from its ALICE Phase IIa clinical trial in acute myeloid leukemia.

These results are summarized in the attached pressrelease that will be distributed today.

Madrid, 14 June 2019

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

- ❖ Results presented at 24<sup>th</sup> 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 24<sup>th</sup> 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<sup>2</sup>.

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](http://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. Oryzon 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).

### **FORWARD-LOOKING STATEMENTS**

This communication contains, or may contain, forward-looking information and statements about Oryzon, including financial projections and estimates and their underlying assumptions, statements regarding plans, objectives and expectations with respect to future operations, capital expenditures, synergies, products and services, and statements regarding future performance. Forward-looking statements are statements that are not historical facts and are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates" and similar expressions. Although Oryzon believes that the expectations reflected in such forward-looking statements are reasonable, investors and holders of Oryzon shares are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Oryzon that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include those discussed or identified in the documents sent by Oryzon to the Spanish Comisión Nacional del Mercado de Valores (CNMV), which are accessible to the public. Forward-looking statements are not guarantees of future performance and have not been reviewed by the auditors of Oryzon. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date they were made. All subsequent oral or written forward-looking statements attributable to Oryzon or any of its members, directors, officers, employees or any persons acting on its behalf are expressly qualified in their entirety by the cautionary statement above. All forward-looking statements included herein are based on information available to Oryzon on the date hereof. Except as required by applicable law, Oryzon does not undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. This press release is not an offer of securities for sale in the United States or any other jurisdiction. Oryzon's securities may not be offered or sold in the United States absent registration or an exemption from registration. Any public offering of Oryzon's securities to be made in the United States will be made by means of a prospectus that may be obtained from Oryzon or the selling security holder, as applicable, that will contain detailed information about Oryzon and management, as well as financial statements.

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