

## **ORYZON presents new Phase II iadademstat efficacy data in AML at EHA-2020**

- ❖ **Robust signals of clinical efficacy, with ORR of 77%, of which 60% are CR/CRi**
- ❖ **Fast clinical responses, with mean time to response of 37 days**
- ❖ **Longest remission to date 488 days, still ongoing**
- ❖ **Iadademstat and azacitidine combination shows a good safety profile**
- ❖ **Results presented at 25th Congress of the European Hematology Association**

**MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, June 12<sup>th</sup>, 2020** –Oryzon Genomics, S.A. (ISIN Code: ES0167733015, ORY), a clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in diseases with strong unmet medical need, today presented positive new efficacy data from its ongoing Phase II ALICE trial, which is investigating iadademstat in combination with azacitidine in elderly patients with acute myeloid leukemia (AML). The data were presented at the ongoing virtual 25th Congress of the European Hematology Association, EHA-2020, in an e-poster entitled “Iadademstat Shows Efficacy in Combination with Azacitidine in Elderly AML Patients. ALICE Trial”.

The evidence of clinical efficacy is robust and consistent with previously reported data, with an objective response rate (ORR) of 77% (10 out of 13 evaluable patients); of these, 60% were complete remissions (6 CR/CRi), and 40% partial remissions (4 PR). Mean Time to Response (TTR) was only 37 days in those patients who responded. With historical response rates of 27% in this population when treated with azacitidine alone, these results suggest strong synergies between iadademstat and azacitidine when used in combination.

The longest remission (still ongoing) at the date of writing this poster was 488 days. The patient with the second longest remission died due to Covid-19 infection; another patient with stable disease abandoned the study, also due to Covid-19 infection. Several patients have also improved or overcome their dependency on blood transfusions (i.e., not requiring subsequent red cell / platelet transfusions).

Dr. Carlos Buesa, Oryzon’s CEO, said: “We are very pleased with these new data, which show a growing number of patients responding to iadademstat and contribute to a growing clinical data set which compares well with the most recent standard of care combination therapies for this type of elderly AML patient. Data continue to confirm initial observations as the study progresses, and have the potential to open new opportunities for the development of iadademstat in other leukemias.”

The combination of iadademstat with azacitidine continues to show a good safety profile in elderly AML patients, as reported previously at the American Hematology Association (ASH) meeting in December 2019.

Besides the reported hematological events, the combination appears to be safe and well tolerated, with no clinically relevant non-hematological adverse events reported to date.

The objective of the ALICE trial is to inform the broader evaluation of iadademstat in other leukemias. ALICE is designed as a single-arm, open-label study of iadademstat in combination with the standard of care treatment azacitidine in newly diagnosed elderly AML patients and is being carried out in five Spanish hospitals. The study is divided into two parts, the first optimizing the dose of the combination, and the second evaluating the combination's effectiveness. Efficacy endpoints include clinical response, as well as time to response, duration of response and average survival. At the time of writing the EHA-2020 poster, 18 patients had been enrolled in this trial; the study will recruit up to 36 patients. Following an interruption of two months due to the Covid-19 pandemic, recruitment has now resumed at the expected rate.

A copy of the poster is available [here](#)

For more information about EHA-2020, 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 neurological 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). In both studies, preliminary clinical results have been reported.

### **FORWARD-LOOKING STATEMENTS**

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