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ORYZON to Present Updated Positive Clinical Data for Iadademstat in Acute Myeloid Leukemia at EHA 2026

- **In first line, iadademstat with azacitidine and venetoclax continues to show favorable safety and 100% ORR, with a composite complete remission rate (CRc) of 93% (with 79% CR), and an estimated 12-month OS of 74%**
- **In FLT3-mutated refractory-relapsed setting, iadademstat with gilteritinib has shown favorable safety profile and a high CRc rate (67%)**

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, May 13, 2026 - Oryzon Genomics, S.A. (ISIN Code: ES0167733015, ORY), a clinical-stage biopharmaceutical company and a global leader in epigenetics, today announced that updated positive clinical data from two Phase Ib clinical trials evaluating its selective LSD1 inhibitor iadademstat in acute myeloid leukemia (AML) will be presented in two poster sessions at the European Hematology Association (EHA) Annual Congress, taking place June 11-14, 2026 in Stockholm, Sweden.

"We are encouraged by the updated findings from both the ALICE-2 and FRIDA trials, which continue to support the clinical activity and favorable safety profile of iadademstat-based combinations in AML," said Carlos Buesa, Chief Executive Officer of Oryzon. "We look forward to presenting updated data at EHA 2026 from a larger patient cohort in the ALICE-2 study, likely representing approximately 75–80% of the planned enrollment, which we believe will provide a more mature assessment of both safety and efficacy of the triplet combination. Based on the strength of the emerging data, the Company is envisaging an accelerated clinical development plan for iadademstat in the first-line AML setting."

Presentations details:

Title: Updated Safety and Efficacy Results of a Phase Ib Investigation of the LSD1 Inhibitor Iadademstat (ORY-1001) in Combination with Azacitidine and Venetoclax in Newly Diagnosed AML
Abstract ID: EHA-4924
Presenter: Curtis Lachowiez, MD, Oregon Health & Science University, Portland, United States of America
Presentation Date and Time: Saturday, June 13, 2026, 6:45-7:45 pm CEST.

As of the February 2026 data cutoff, the triplet combination of iadademstat, azacitidine and venetoclax evaluated in the ALICE-2 trial (NCT06357182) continues to demonstrate favorable safety and high response rates. Among evaluable patients (n=14/15) the overall response rate (ORR) was 100% with a complete response (CR) rate of 79% (n=11/14) and a composite complete remission (CRc: CR+CRh+CRi) rate of 93% (n=13/14). After a median follow-up of 6 months, the estimated 12-month OS rate was 74%. Updated data with additional patients and more mature responses will be presented at the meeting.

Title: Safety and Efficacy of Iadademstat Plus Gilteritinib in the FRIDA Expansion Cohort of FLT3-Mutated Relapsed/Refractory Acute Myeloid Leukemia
Abstract ID: EHA-5879
Presenter: Amir Fathi, MD, Massachusetts General Hospital, Boston, United States of America
Presentation Date and Time: Friday, June 12, 2026, 6:45-7:45 pm CEST

Updated data from a heavily pre-treated relapsed or refractory FLT3mut AML population in the FRIDA trial (NCT05546580) evaluating iadademstat plus standard of care treatment gilteritinib demonstrated a favorable safety profile and a CRc rate of 67% (n=12/18). Additional data will be presented at the conference.

The abstracts are available on the EHA 2026 website here

About Oryzon

Founded in 2000 and headquartered in Barcelona, Spain, Oryzon (ISIN: ES0167733015) is a clinical-stage biopharmaceutical company and a European leader in epigenetics, with a strong focus on personalized medicine for central nervous system (CNS) disorders and oncology. Oryzon's team comprises highly experienced pharmaceutical professionals based in Barcelona, Boston, and New Jersey. The Company has an advanced clinical portfolio built around two LSD1 inhibitors: iadademstat, its oncology/hematology program, with several ongoing Phase I and II studies and which has demonstrated strong preliminary clinical activity in acute myeloid leukemia (AML), including a 100% overall response rate (ORR) in first-line AML; and vafidemstat, its lead CNS program, which is Phase III–ready in Borderline Personality Disorder (BPD). In addition, Oryzon is advancing a broader epigenetics pipeline targeting other mechanisms, including HDAC6, for which the Company has nominated ORY-4001 as a clinical candidate for potential development in Charcot–Marie–Tooth disease (CMT), amyotrophic lateral sclerosis (ALS), and other neurological disorders. The Company also operates a robust platform for biomarker identification and target validation across malignant and neurological diseases. For more information, visit www.oryzon.com

About Iadademstat

Iadademstat (ORY-1001) is an oral, highly selective inhibitor of the epigenetic enzyme LSD1, with a potent differentiating effect in hematologic cancers. Iadademstat has shown encouraging safety and strong clinical activity in combination with azacitidine in a Phase IIa trial in elder 1L acute myeloid leukemia (AML) patients (ALICE trial). Iadademstat is currently being evaluated in combination with azacitidine and venetoclax in 1L AML in the ALICE-2 trial, an investigator-initiated study (IIS) led by OHSU, and in combination with gilteritinib in the company-sponsored Phase Ib FRIDA trial in relapsed/refractory FLT3-mutant AML, with highly encouraging preliminary safety and efficacy data in both trials: 100% overall response rate (ORR) and 93% composite complete remission rate (CRc), with 79% strict CR in 1L AML, and 67% CRc in R/R Flt3-mut AML. Additional studies in hematological malignancies include an IIS in myelodysplastic syndrome (MDS) and U.S. National Cancer Institute (NCI)-sponsored trials in myeloproliferative neoplasms and 1L AML conducted under the Cooperative Research and Development Agreement (CRADA) between Oryzon and the NCI. Beyond hematological cancers, iadademstat is being evaluated in extensive stage small cell lung cancer (ED-SCLC) in a Phase I/II randomized trial in 1L in combination with immune checkpoint inhibition (ICI) sponsored by the NCI and led by the Memorial Sloan Kettering Cancer Center, and an IIS trial in combination with ICI and radiotherapy. Oryzon has also expanded iadademstat into non-oncological hematology indications, with trials in sickle cell disease (approved by EMA, enrolling) and essential thrombocythemia (approved by EMA). Iadademstat has orphan drug designation for AML in the US and EU and for SCLC in the US.

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

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