28 October 2025 • Press Release

ORYZON strengthens regulatory strategy with the appointment of Dr. Iman Barilero as Senior Advisor for Regulatory Affairs

- **To enhance and accelerate regulatory dialogue with the FDA**
- **To provide strategic guidance across clinical development programs**
- **To bring deep expertise in CNS and immuno-oncology**

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, October 28, 2025 — Oryzon Genomics, S.A. (ISIN Code: ES0167733015, BME: ORY), a clinical-stage biopharmaceutical company and global leader in epigenetics, is pleased to announce the strategic collaboration with Dr. Iman Barilero, PharmD, PhD, as Senior Advisor for Regulatory Affairs to support the advancement of its Phase III clinical program with vafidemstat in Borderline Personality Disorder (BPD).

Dr. Barilero brings over 30 years of global regulatory leadership across CNS, neuropsychiatry, immuno-oncology, and rare diseases, with a proven track record in guiding Phase II–III programs, securing global approvals, and developing innovative regulatory pathways. Her expertise includes direct engagement with major health authorities including the FDA (CBER & CDER), EMA, PMDA, CFDA, Health Canada, ANVISA, and other.

Her career spans academia, big pharma, and emerging biotechs, with a key highlight being her tenure as Vice President, Head of Global Regulatory Science for CNS at Lundbeck, where she led global regulatory strategies for breakthrough therapies targeting depression, bipolar disorder, schizophrenia, stroke, Alzheimer's disease, Parkinson's disease, and alcohol dependence. She played a pivotal role in securing first-in-class label claims for cognition in major depressive disorder (Brintellix/Trintellix), and approvals across the US, EU, Japan, China, and other major markets, demonstrating her strategic leadership in global regulatory engagement.

"This new collaboration forms part of Oryzon's strategic reinforcement of its Medical, Regulatory, and Strategic functions," said Dr. Carlos Buesa, CEO of Oryzon. "Dr. Barilero's deep expertise in CNS drug development and global regulatory strategy will be invaluable as we advance vafidemstat into Phase III and address all areas identified by the FDA. Her leadership will help ensure the company is fully prepared to advance its late-stage pipeline in BPD and Schizophrenia, and well as our early-stage program in ASD."

"I'm thrilled to join Oryzon at this pivotal moment as Senior Advisor for Regulatory Affairs," said Dr. Iman Barilero, Founder of Kulli Global Development consultancy. "Vafidemstat holds significant promise for patients with CNS disorders, and I look forward to contributing my experience in global regulatory strategy to help advance its development and ensure strategic alignment with FDA."

Oryzon's ambitious CNS pipeline also includes programs in schizophrenia and Autistic Spectrum Disorder (ASD). Vafidemstat is currently being evaluated in EVOLUTION, a double-blind, randomized, placebo-controlled Phase IIb trial assessing its potential to improve negative symptoms in schizophrenia. Additionally, a clinical trial in ASD is also in preparation.

About Oryzon

Founded in 2000 in Barcelona, Spain, Oryzon (ISIN Code: ES0167733015) is a clinical stage biopharmaceutical company and the European leader in epigenetics, with a strong focus on personalized medicine in CNS disorders and oncology. Oryzon's team is composed of highly qualified professionals from the pharma industry located in Barcelona, Boston, and San Diego. Oryzon has an advanced clinical portfolio with two LSD1 inhibitors, vafidemstat in CNS (Phase III-ready) and iadademstat in oncology (Phase II). The company has other pipeline assets directed against other epigenetic targets like HDAC-6 where a clinical candidate, ORY-4001, has been nominated for its possible development in CMT and ALS. In addition, Oryzon has a strong platform for biomarker identification and target validation for a variety of malignant and neurological diseases. For more information, visit www.oryzon.com

About Vafidemstat

Vafidemstat (ORY-2001) is an oral, CNS-optimized LSD1 inhibitor. The molecule acts on several levels: it reduces cognitive impairment, including memory loss and neuroinflammation, and at the same time has neuroprotective effects. In animal studies vafidemstat not only restores memory but reduces the exacerbated aggressiveness of SAMP8 mice, a model for accelerated aging and Alzheimer's disease (AD), to normal levels and also reduces social avoidance and enhances sociability in murine models. In addition, vafidemstat exhibits fast, strong, and durable efficacy in several preclinical models of multiple sclerosis (MS). Oryzon has performed two Phase IIa clinical trials in aggressiveness in patients with different psychiatric disorders (REIMAGINE, see Ferrer et al, Psychiatry & Clin Neurosci, 2025, doi.org/10.1111/pcn.13800) and in aggressive/agitated patients with moderate or severe AD (REIMAGINE-AD), with positive clinical results reported in both. Additional finalized Phase IIa clinical trials with vafidemstat include the ETHERAL trial in patients with Mild to Moderate AD, where a significant reduction of the inflammatory biomarker YKL40 was observed after 6 and 12 months of treatment, and the pilot, small-scale SATEEN trial in Relapse-Remitting and Secondary Progressive MS, where anti-inflammatory activity was also observed. Vafidemstat has also been tested in a Phase II in severe Covid-19 patients (ESCAPE) assessing the capability of the drug to prevent ARDS, one of the most severe complications of the viral infection, where it showed significant anti-inflammatory effects in severe Covid-19 patients. Following completion of the global, randomized, double blind Phase IIb PORTICO trial in Borderline Personality Disorder (BPD), with final data presented at ECNP-2024, vafidemstat is advancing as a Phase III-ready asset for agitation/aggression in BPD (PhIII protocol submitted). Vafidemstat is also being investigated in a double-blind, randomized, placebo-controlled Phase IIb trial in negative symptoms of schizophrenia (EVOLUTION trial, recruitment ongoing). The company is also deploying a CNS precision medicine approach with vafidemstat in genetically defined patient subpopulations of certain CNS disorders, as well as in neurodevelopmental syndromes, and is preparing a clinical trial in aggression in autistic conditions like Phelan-McDermid syndrome.

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 document does not constitute an offer or invitation to purchase or subscribe shares in accordance with the provisions of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017, and/or the restated text of the Securities Market Law, approved by Law 6/2023 of 17 March, and its implementing regulations. Nothing in this document constitutes investment advice. In addition, this document does not constitute an offer of purchase, sale or exchange, nor a request for an offer of purchase, sale or exchange of securities, nor a request for any vote or approval in any jurisdiction. The shares of Oryzon Genomics, S.A. may not

be offered or sold in the United States of America except pursuant to an effective registration statement under the Securities Act of 1933 or pursuant to a valid exemption from registration..

Spain

Patricia Cobo/Mario Cordera
Atrevia
+34 91 564 07 25
+34 673 33 97 65
pcobo@atrevia.com
mcordera@atrevia.com

Oryzon

Emili Torrell
Chief BD Officer
+34 93 515 1313

etorrell@oryzon.com

IR & Media, Europe & US

Sandya von der Weid
LifeSci Advisors, LLC
+41 78 680 05 38

svonderweid@lifesciadvisors.com