



**ORYZON GENOMICS, S.A.**

Pursuant to the provisions of article 228 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

**SIGNIFICANT FACT**

ORYZON announces that it has received approval from the French Medicines Agency (ANSM) to conduct a Phase IIa clinical trial with ORY-2001 in patients of Alzheimer's Disease (AD).

The pressrelease that will be distributed today is attached.

Madrid, 8 May 2018

## ORYZON receives approval in France to start ETHERAL: a Phase IIa clinical trial in Alzheimer's Disease with ORY-2001

- ❖ Approval has been granted by the French Medicines Agency (ANSM)
- ❖ The trial received approval from the Spanish Medicines Agency in April
- ❖ ETHERAL is the second Phase II clinical trial in CNS with the drug

**MADRID, SPAIN and CAMBRIDGE, MA, May 8, 2018** – Oryzon Genomics (ISIN Code: ES0167733015, ORY), a public clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in diseases with strong unmet medical need, has announced today that it has received the approval from the Agence Nationale du Sécurité du Médicament et des Produits de Santé (ANSM), the French Medicines Agency, to conduct a Phase IIa trial with ORY-2001 in patients with mild and moderate Alzheimer's disease.

In addition to the approval from ANSM, the company has obtained the approval from the Ethics Committee to conduct this clinical trial in France. The trial will be conducted in different hospitals in Spain, France, and also in the UK once the corresponding approvals from the British regulatory authorities are obtained.

The study, named ETHERAL (Epigenetic **T**HERapy in **AL**zheimer's Disease), is designed as a randomised, double-blind, placebo-controlled, 3-arm, 26 weeks parallel-group study to evaluate the safety and tolerability of ORY2001 in patients with mild and moderate Alzheimer's disease. The study will involve 90 patients and incorporates measurements in the different domains of the disease as secondary endpoints, including memory and behavior alterations such as aggression and social withdrawal. It will also monitor the variations of several CSF biomarkers. The company is aiming to launch a twin study in the US in the coming months.

### **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. The company has one of the strongest portfolios in the field. Oryzon's LSD1 program has rendered two compounds in clinical trials. In addition, Oryzon has ongoing programs for developing inhibitors against other epigenetic targets. The company has a strong technological platform for biomarker identification and performs biomarker and target validation for a variety of malignant and neurodegenerative diseases. The company has offices in Spain and USA. For more information, visit [www.oryzon.com](http://www.oryzon.com).

### **FORWARD-LOOKING STATEMENTS**

This communication contains forward-looking information and statements about Oryzon Genomics, S.A., 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 Genomics, S.A. believes that the expectations reflected in such forward-looking statements are reasonable, investors and holders of Oryzon Genomics, S.A. 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 Genomics, S.A., 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 Genomics, S.A. to the *Comisión Nacional del Mercado de Valores*, which are accessible to the public. Forward-looking statements are not guarantees of future performance. The auditors of Oryzon Genomics, S.A. have not reviewed them. 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 Genomics, S.A. 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 Genomics, S.A. on the date hereof. Except as required by applicable law, Oryzon Genomics, S.A. 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. The Company's securities may not be offered or sold in the United States absent registration or an exemption from registration. Any public offering of the Company's securities to be made in the United States will be made by means of a prospectus that may be obtained from the Company or the selling security holder, as applicable, that will contain detailed information about the Company and management, as well as financial statements.

**US Contact:****The Trout Group****Thomas Hoffmann**

+1 646 378 2932

**thoffmann@troutgroup.com****Spain:****ATREVIA****Patricia Cobo/Luis Rejano**

+34 91 564 07 25

**pcobo@atrevia.com****lrejano@atrevia.com****The Company:****Emili Torrell****BD Director**

+34 93 515 13 13

**etorrell@oryzon.com**