

# **ORYZON Announces First Patient Dosed in Phase 1 Trial of the LSD1 inhibitor RG6016 in Small Cell Lung Cancer (SCLC)**

## **Second clinical trial with RG6016, while the first one in Acute Leukemia is almost completed**

**BARCELONA, SPAIN and CAMBRIDGE, MA, January 9<sup>th</sup>, 2017** – Oryzon Genomics (ISIN Code: ES0167733015, ORY), a public clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in diseases with strong unmet medical need, announced that the first patient has been treated in the Phase I study of RG6016, a LSD1 inhibitor, in small cell lung cancer (SCLC). This clinical trial is executed by Roche.

Roche has started a dose finding and expansion study of RG6016 administered orally in participants with relapsed, extensive-stage disease small cell lung cancer (ED SCLC). The study initially will be conducted in several European countries and Canada. (ClinicalTrials.gov Identifier: NCT02913443)

This is a Phase I, open-label, multicenter study designed to assess the safety and tolerability of RG6016 in participants with relapsed ED SCLC. This dose escalation and expansion study plans to determine the maximum tolerated dose and/or optimal biological dose as a recommended Phase 2 dose for RG6016, based on the safety, tolerability, pharmacokinetic and pharmacodynamic profiles observed after oral administration of the drug.

Roche licensed in the global development and commercial rights to RG6016, previously known as ORY-1001 in 2014. After completion of the first trial in Acute Leukemia, sponsored by Oryzon and currently in the process of final data analysis and closing, Roche is solely responsible for the further clinical development of RG6016. Preliminary efficacy data obtained in the Phase IIA arm of this first clinical study in Leukemia was presented at the ASH meeting in San Diego last December.

### **About RG6016**

RG6016, previously known as ORY-1001, is a highly potent and selective oral epigenetic inhibitor that modulates LSD1, a histone demethylase that removes (“erases”) signals in the histone, provoking changes in the reading context of the chromosome and turning off genes. Aberrant “erasing” activity may lead to disease. LSD1 has been related with several malignancies such as solid tumours and haematological diseases. In Leukemia RG6016 affects AML stem cells, a sub-population of cancer cells that has been proposed to be responsible for frequent relapses of the disease. RG6016 also significantly reduces tumour cell load and increases survival time in mouse models of Acute Lymphoblastic Leukaemia. LSD1 inhibition has been proposed as a meaningful therapeutic option, alone or in combination, in several solid tumors such as SCLC. RG6016 is part of the worldwide collaboration signed between Oryzon and Roche on April 2014.

### **About Small Cell Lung Cancer (SCLC)**

Small cell lung cancer is an aggressive form of cancer that accounts for approximately 15 percent of all lung cancers. SCLC is a difficult to treat cancer and the five-year survival rate for extensive-stage SCLC is

less than 5 percent. Current treatment options are unfortunately limited for the more than 234,000 people diagnosed annually and survival in refractory settings is typically less than one year, exemplifying the need for more effective therapeutics.

#### **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 and a clinical asset already partnered with Roche. Oryzon's LSD1 program is currently covered by +20 patent families and 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. Oryzon's strategy is to develop first in class compounds against novel epigenetic targets through Phase II clinical trials, at which point it is decided on a case-by-case basis to either keep the development in-house or to partner or outlicense the compound for late stage development and commercialization. The company has offices in Barcelona and Cambridge, Massachusetts. 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**  
**Maria Lomaka**  
+1 646 378 2932  
[mkelman@troutgroup.com](mailto:mkelman@troutgroup.com)

#### **Spain:**

**ATREVIA**  
**Patricia Cobo/Luis Rejano**  
+34 91 564 07 25  
[pcobo@atrevia.com](mailto:pcobo@atrevia.com)  
[lrejano@atrevia.com](mailto:lrejano@atrevia.com)

#### **The Company:**

**Anna K Baran**  
**IR Director**  
+44 (0) 752 1083 006  
[abaran@oryzon.com](mailto:abaran@oryzon.com)