ORYZON Files Clinical Trial Application in Spain for Phase I Study with ORY-2001 for Alzheimer’s Disease

BARCELONA, SPAIN and CAMBRIDGE, MA, December 16, 2015 - Oryzon Genomics - ORY (ISIN Code: ES0167733015), a clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in oncology and neurodegenerative diseases, today announced that a Clinical Trial Application (CTA), the European IND equivalent, has been filed with the Spanish Drug Agency (AEMPS) to conduct a Phase I clinical study with healthy volunteers as a first step to determine the potential of ORY-2001 for the treatment of Alzheimer’s disease (AD).

ORY-2001 is a highly selective dual LSD1-MAOB inhibitor. The molecule, which focuses on cognitive decline and memory loss, has a good safety profile and therapeutic index in preclinical trials. In non-transgenic AD mouse models, long-term treatments with the drug demonstrated a marked cognitive improvement. LSD1 is an epigenetic modulator, which regulates histone methylation. Epigenetic approaches to modify the progression of various neurodegenerative diseases focus on producing changes in patterns of gene expression in neurons and also in glia cells and are of interest for the pharmaceutical industry.

Oryzon is further exploring the potential of ORY-2001 in other neurodegenerative diseases, such as Huntington’s disease, Parkinson’s disease and other dementias. ORY-2001 is the second epigenetic drug that Oryzon is advancing into clinical trials.

The design of the Phase I clinical trial is a single center, double blind, parallel, ascending single and multiple dose program. The study will assess the safety, tolerability and pharmacokinetics of single and multiple oral doses of ORY-2001 in healthy male and female subjects and also in the elderly population. Hospital de Sant Pau in Barcelona, Spain will be the site center.

Cesar Molinero, Oryzon’s Chief Medical Officer commented, "In line with our expectations, the filing of the clinical trial application for ORY-2001 represents a significant milestone for the company. Preclinical studies validate the potential of ORY-2001 to treat cognitive defects resulting from neurodegenerative disorders and we look forward to advancing our development in this area."

Carlos Buesa, Oryzon’s Co-Founder, President and Chief Executive Officer, commented, "We are very excited that Oryzon has submitted a CTA for ORY-2001. Our lead CNS asset has the potential to be a first-in-class therapy for Alzheimer’s disease and other neurodegenerative disorders. The Company’s first clinical program with our LSD1 selective inhibitor, ORY-1001 for oncology, is also advancing satisfactorily and we are confident that the knowledge acquired during this Phase I/IIA study will be beneficial to our other clinical programs."

About Alzheimer’s disease
Alzheimer’s disease is the most common form of dementia in adults. It is estimated to affect 5.3 million Americans and over 30 million people worldwide with an average course of 8–12 years. It is projected that the disease prevalence will double over the next 20 years. Marketed products address some of the symptoms, but there are no treatments currently available. The economic cost of Alzheimer’s is expected to grow in the coming years. Projections of the direct cost of Alzheimer’s disease in adults over
PRESS RELEASE 2015

65 could balloon to $1.1 trillion in 2050 (in today’s dollars) with a total of $20.8 trillion in medical costs between 2015 and 2050, according to the Alzheimer’s Association.

**About Oryzon**
Founded in 2000 in Barcelona, Spain, Oryzon - ORY (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 19 patent families and has rendered one compound in clinical trials and another one is anticipated to enter clinical trials in early 2016. In addition, Oryzon has ongoing programs for developing inhibitors against other epigenetic targets. The company has also 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 out-license the compound for late stage development and commercialization. The company has offices in Barcelona and Cambridge, Massachusetts. For more information, visit 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.
US Contact: The Ruth Group
Lee Roth/Tram Bui
(646) 536-7012/7035
lroth@theruthgroup.com
tbui@theruthgroup.com

Spain:
ATREVIA
Ana Melgar/Patricia Cobo
+34 91 564 07 25
amelgar@atrevia.com
pcobo@atrevia.com

The Company:
Ms. Anna K Baran
IR Director
+44 (0) 752 1083 006
abaran@oryzon.com