ORYZON presents data on the Phase I trial with ORY-2001 at the 13th International Conference on Alzheimer's and Parkinson's diseases

Data allows establishment of a safe administration scheme for long term efficacy studies

BARCELONA, SPAIN and CAMBRIDGE, MA, April 3rd, 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, presented last Friday preliminary data on the First in Human clinical trial of ORY-2001 at the 13th international Conference on Alzheimer's and Parkinson's disease celebrated in Vienna, Austria.

ORY-2001, a dual LSD1/MAO-B inhibitor, is a novel epigenetic drug for the treatment of neurodegenerative diseases and the second compound the company has moved into clinical trials. ORY-2001 has provided robust preclinical therapeutic activity, restoring memory and other parameters in SAMP-8 mice, a model for accelerated aging and Alzheimer's disease, as well as in other models. LSD1 is a protein that participates in transcription regulation complexes; its modulation can be used to tweak transcriptional imbalances in neurodegenerative disease and redress neuroinflammation and cognitive deficit.

The objective of the Phase I study, performed at the Center of Investigation of Medicines of the Sant Pau Hospital in Barcelona, was to assess safety, tolerability, pharmacokinetics and pharmacodynamics of ORY-2001. The originally planned single and multiple ascending dose (SAD and MAD) study has been successfully finalized. It has shown that orally administered ORY-2001 is well tolerated and does not provoke clinically significant changes in laboratory tests, vital signs, ECGs, physical findings, or relevant adverse events. As the maximum tolerated dose (MTD) was not reached, the company, with the approval of the Spanish Medicines Agency (AEMPS), decided to incorporate an additional cohort of volunteers to be administered at a higher dose, as well as an additional cohort to determine the level of the drug in cerebrospinal fluid and to confirm that ORY-2001 passes the human blood brain barrier. These additional cohorts are still ongoing.

The pharmacodynamics of peripheral target engagement of ORY-2001 to LSD1, analyzed using a patented proprietary assay developed by the company, showed a time and dose dependent profile that can be correlated to the pharmacokinetics data.

The Phase I study has provided detailed information that allows modeling of the dose response in human vs preclinical species and the establishment of a safe administration scheme for long term Phase II efficacy studies of ORY-2001 in patients with neurodegeneration and neuroinflammation. The company aims to file the corresponding CTA/INDs in the second semester of 2017.

Dr. César Molinero, Chief Medical Officer of ORYZON commented: "The results of the study have so far fulfilled our expectations, and are informative to define the doses to be used in our future Phase IIs. Taking into account the differences between species, we have found an excellent correlation between First in Human and pre-clinical data and are excited to take this important step forward in the clinical

development of ORY-2001." "We know that neurodegenerative diseases have an important epigenetic component, and ORY-2001 has demonstrated its potential in a variety of preclinical models" said Dr. Tamara Maes, Vice President of the company and Chief Scientific Officer. "The recent capital increase announced by the company also provides us with the resources to undertake Phase II clinical trials and place the company in a position of great relevance in the field."

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.

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US Contact:
The Trout Group
Maria Kelman
+1 646 378 2932
mkelman@troutgroup.com

Spain:
ATREVIA
Patricia Cobo/Luis Rejano
+34 91 564 07 25
pcobo@atrevia.com
lrejano@atrevia.com

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