

ORYZON receives approval from AEMPS to start SATEEN: a Phase IIA clinical trial in Multiple Sclerosis with ORY-2001

The company expects to start enrollment before year's end

MADRID, SPAIN and CAMBRIDGE, MA, October 31, 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, today announced that it has received approval of a Clinical Trial Application (CTA), the European IND equivalent, from the Spanish Drug Agency (AEMPS) to conduct a Phase IIA clinical study with ORY-2001 in patients of Multiple Sclerosis (MS).

The study, named SATEEN (**SA**fety, **T**olerability and **E**fficacy in an **EPI**GENETIC approach to treat Multiple Sclerosis), will be conducted in different Spanish hospitals, and is designed as a randomised, double-blind, placebo-controlled, 3-arm, 36 weeks parallel-group study to evaluate the safety and tolerability of ORY-2001 in patients with Relapsing-Remitting Multiple Sclerosis (RRMS) and Secondary Progressive Multiple Sclerosis (SPMS).

In a recent Phase I trial carried out in 106 healthy volunteers, the drug proved to be safe and well tolerated. There were no adverse events related to the drug, neither significant side effects nor clinical changes detected. Importantly, at the doses to be applied in the Phase II no hematopoietic effects were observed. Brain penetrance was measured in 18 volunteers, and target engagement with the brain LSD1 enzyme was also established separately. These results were recently reported at the AAIC Conference in London.

ORY-2001 is a highly selective dual LSD1-MAOB inhibitor. The molecule has been shown to revert cognitive decline and memory loss, to decrease neuroinflammation and has also shown neuroprotection in a variety of preclinical models of AD, MS and ALS, suggesting that it might have a disease modifying potential. In different MS models, ORY-2001 reduces lymphocyte egress and demyelination and improves the clinical score of the animals, suggesting an epigenetic axis in MS.

Roger Bullock, Oryzon's Chief Medical Officer, commented, "In line with our expectations, the approval of SATEEN, the Phase IIA clinical trial for ORY-2001 in MS, represents a significant milestone for the company. Preclinical studies validate the potential of ORY-2001 to treat cognitive defects and neuroinflammation resulting from several neurodegenerative disorders and this is the first step in validating this novel approach in people who actually have a neurodegenerative disorder, namely MS. The entry of a safe, well tolerated, orally taken compound, that offers neuroprotection and reduces neuroinflammation, could be a significant step in our ongoing quest to impact on some of the most challenging disorders of our time, including MS, Alzheimer's disease and ALS. We are very pleased to have reached this landmark position and look forward to the results."

Carlos Buesa, Oryzon's President and Chief Executive Officer, commented, "We are really excited about Oryzon starting SATEEN with ORY-2001, whose properties might represent a clinical advantage for patients

with Multiple Sclerosis. We expect to be able soon to start another Phase II trial with ORY-2001 in Alzheimer's disease and we keep exploring other neurodegenerative disorders."

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 resulted in + 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 Spain and USA. For more information, visit www.oryzon.com.

FORWARD-LOOKING STATEMENTS

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