

ORYZON enters cooperative research and development agreement (CRADA) with U.S. National Cancer Institute to develop iadademstat in different cancers

❖ Oryzon and NCI will collaborate to assess the safety and efficacy of iadademstat in oncology patients with different hematological and solid tumors

MADRID, SPAIN and BOSTON, MA, UNITED STATES, July 19, 2022 - Oryzon Genomics, S.A. (ISIN Code: ES0167733015, ORY), a clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in diseases with strong unmet medical need, announced today that it has entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. National Cancer Institute (NCI), part of the National Institutes of Health. Under the terms of the agreement, Oryzon and the NCI will collaborate on potential further clinical development of Oryzon's clinical stage LSD1 inhibitor, iadademstat, in different types of solid and hematological cancers.

Dr. Carlos Buesa, President and CEO of Oryzon, said: "This research and development agreement with the NCI is, first, a strong validation of iadademstat, probably the most potent and selective LSD1 inhibitor currently in clinical development, and will also allow us to significantly expand our clinical development program for this compound."

Dr Douglas V. Faller, Oryzon's Global Chief Medical Officer said: "This collaboration with the NCI on the development of iadademstat will allow us to work with some of the world's leading oncology researchers to further expand its therapeutic potential. This collaboration also dramatically expands our ability to conduct clinical trials in a wide number of indications, and in combination with other novel or established therapies such as immuno-oncology and molecularly-targeted agents."

iadademstat is an orally active, highly potent and selective inhibitor of the epigenetic enzyme LSD1 and has a powerful differentiating effect in hematologic cancers. More than 100 cancer patients have been treated with iadademstat in several trials. In a still ongoing Phase IIa trial (ALICE trial) in elderly 1L acute myeloid leukemia (AML) patients (ALICE trial), iadademstat has shown encouraging safety and efficacy data in combination with azacitidine. The company is now starting a Phase Ib trial of iadademstat in combination with gilteritinib in FLT3 mutant relapsed/refractory AML patients, which recently received IND approval by the FDA. Beyond hematological cancers, the inhibition of LSD1 has been proposed as a valid therapeutic approach in some solid tumors such as small cell lung cancer (SCLC), neuroendocrine tumors, medulloblastoma and others. In a Phase IIa trial in combination with platinum/etoposide in second line ED-SCLC patients (CLEPSIDRA trial, finalized), preliminary efficacy results have been reported. iadademstat has recently received orphan drug designation from the FDA for SCLC and has now orphan drug status in the US for SCLC and AML.

About Oryzon

Founded in 2000 in Barcelona, Spain, Oryzon (ISIN Code: ES0167733015) is a clinical stage biopharmaceutical company considered as the European leader in epigenetics. Oryzon has one of the strongest portfolios in the field, with two LSD1 inhibitors, iadademstat and vafidemstat, in Phase II clinical trials, and other pipeline assets directed against other epigenetic targets. In addition, Oryzon has a strong platform for biomarker identification and target validation for a variety of malignant and neurological diseases. For more information, visit www.oryzon.com

About iadademstat

iadademstat (ORY-1001) is a small oral molecule, which acts as a highly selective inhibitor of the epigenetic enzyme LSD1 and has a powerful differentiating effect in hematologic cancers (see Maes et al., Cancer Cell 2018 Mar 12; 33 (3): 495-511.e12.doi: 10.1016 / j.ccell.2018.02.002.). A FiM Phase I/IIa clinical trial with iadademstat in R/R AML patients demonstrated the safety and good tolerability of the drug and preliminary signs of antileukemic activity, including a CRi (see Salamero et al, J Clin Oncol, 2020, 38(36): 4260-4273. doi: 10.1200/JCO.19.03250). In an ongoing Phase IIa trial in elder 1L-AML patients (ALICE trial), iadademstat has shown encouraging safety and efficacy data in combination with azacitidine (see Salamero et al., ASH 2021 poster). The company has recently obtained approval from the U.S. FDA for its IND for FRIDA, a Phase Ib trial of iadademstat plus gilteritinib in patients with relapsed/refractory AML with FLT3 mutations. Beyond hematological cancers, the inhibition of LSD1 has been proposed as a valid therapeutic approach in some solid tumors such as small cell lung cancer (SCLC), neuroendocrine tumors (NET), medulloblastoma and others. In a Phase IIa trial in combination with platinum/etoposide in second line ED-SCLC patients (CLEPSIDRA trial), preliminary activity and safety results have been reported (see Navarro et al., ESMO 2018 poster). New trials in combination in SCLC and NET are under preparation. In total iadademstat has been dosed so far to more than 100 cancer patients in four clinical trials.

FORWARD-LOOKING STATEMENTS

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