

ORYZON's iadademstat shows efficacy signs in relapsed SCLC

- ❖ Preliminary data from CLEPSIDRA Phase II trial presented at WCLC 2019
- ❖ Case study showing a 86% tumor reduction
- ❖ Additional data will be presented late September at ESMO-2019

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, September 9th, 2019 - Oryzon Genomics, S.A. (ISIN Code: ES0167733015, ORY), a public clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in diseases with strong unmet medical needs, today presents the first preliminary data from CLEPSIDRA, a Phase II trial investigating iadademstat in combination with standard-of-care in relapsing small cell lung cancer (SCLC) patients.

The company will present a poster, at the IASLC 20th World Conference on Lung Cancer (WCLC), being held in Barcelona, Spain, entitled "*iadademstat shows preliminary efficacy signals in relapsed ED-SCLC patients: A case report within CLEPSIDRA, a Phase II trial of iadademstat in combination with platinum-etoposide in biomarker-positive patients*".

The preliminary data, corresponding to the patient with the longest treatment period in the study, show that:

- Administration of the combination of iadademstat with standard-of-care during the first 6 cycles produced a tumor reduction of 78.7%, as defined by RECIST criteria
- The only toxicity of the combination was hematological
- Subsequent administration of iadademstat alone for four consecutive cycles proved to be safe and well tolerated without producing any hematological toxicity
- Reduction of main lesions and metastasis continues with iadademstat in monotherapy, reaching an overall tumor reduction of 86.3% by RECIST criteria according to CT scan evaluation in Cycle 8.

Dr. Roger Bullock, Oryzon's Chief Medical Officer stated "Although this Phase II trial is just starting and we have only a limited number of patients in the study, the impressive tumor reduction observed in this first patient is very promising. These data show that iadademstat has the potential to make a difference to patients with SCLC, and we are looking forward to presenting more data from the trial with this exciting drug candidate in the coming weeks."

The company plans to present additional data from the first 10 patients of the CLEPSIDRA study during the ESMO-2019 International Conference, to be held from September 27 to October 1 in Barcelona.

CLEPSIDRA ("A *Combination trial of LSD1 and Etop-Platinum in Small Cell Lung Cancer in Biomarker-ID Relapsed pAtients*") is a Phase IIa trial of iadademstat, being conducted in several hospitals in Spain. CLEPSIDRA is enrolling relapsed ED-SCLC patients and is designed as a single-arm, open-label study of iadademstat in combination with the standard of care treatment with platinum/etoposide, in order to evaluate the safety and tolerability as well as the clinical effect (including time to response, duration of response, objective response and overall survival) of the combination. Patients are stratified by certain proprietary biomarkers characterized by their ability to identify LSD1i-sensitive SCLC tumors. The study is divided into two parts, the first one to optimize the dose of the combination, and the second one to evaluate the combination's efficacy. The study is designed to recruit up to 36 patients.

WCLC 2019 is held from September 7 to 10. For more info about the congress, please visit [WCLC 2019's website](#)

A copy of the poster is available [here](#)

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. Oryzon has one of the strongest portfolios in the field. Oryzon's LSD1 program has rendered two compounds, vafidemstat and iadademstat, in clinical trials. In addition, Oryzon has ongoing programs for developing inhibitors against other epigenetic targets. Oryzon has a strong technological platform for biomarker identification and performs biomarker and target validation for a variety of malignant and neurodegenerative diseases. Oryzon has offices in Spain and the United States. 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 first Phase I/IIa clinical trial with iadademstat in refractory and relapsed acute leukemia patients demonstrated the safety and good tolerability of the drug and preliminary signs of antileukemic activity, including a CRi. 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), medulloblastoma and others. Oryzon is conducting two Phase IIa clinical trials of iadademstat in combination; the first one in combination with azacitidine in elderly AML patients (ALICE study) and the second one in combination with platinum/etoposide in second line SCLC patients (CLEPSIDRA study).

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