Advanced Biodesign Announces First Patient Dosed in ODYSSEY

Lyon (France), March 4, 2025 - Advanced BioDesign, a clinical-stage pharmaceutical company specializing in the development of new therapeutic approaches to resistant cancers, is pleased to announce that the first patient has been successfully treated for 3 cycles of treatment in the ODYSSEY trial. This trial is designed to evaluate the tolerability of ABD-3001, a first-in-class ALDH1 inhibitor, in monotherapy in relapse/refractory hematological malignancies. Based on encouraging results from the dose escalation part of ODYSSEY, Advanced Biodesign initiated in December 2024 a randomized regimen optimization cohort evaluating three regimens of ABD-3001 in Acute Myeloid Leukemia (AML) patients resistant to standard therapies.

"With the accomplishment of this first patient in the second part of the study, we are confirming the preliminary data gathered in the dose escalation part. First, related adverse events seem to be manageable minor and do not compromise the fulfill of the treatment. Second, we confirmed that even at the lowest dose selected in this part, we have gathered positive result with a complete response observed after the first cycle of treatment and a transfusion independency", **said Professor Régis COSTELLO, Head of the Hematology and Cell Therapy in Oncology Department in Marseille (CEPCM, Timone Hospital), and principal investigator and coordinator of the ODYSSEY study.**

"The initiation of this trial marks a pivotal moment in the development of this new therapy class", **added Ismail CEYLAN, CEO of Advanced BioDesign.** *"This trial is a crucial step in our mission to bring innovative therapies to patients in need. We are optimistic about the potential of ABD-3001 to make a meaningful impact on patient outcomes."*

The ODYSSEY trial is being conducted at 3 sites across France, with Paris (APHP), Lyon (HCL) and Marseille (APHM). In total 36 patients will be recruited during 2025.

The multi-center ODYSSEY trial is the only Phase I/II first-in-human study in France targeting a treatment for AML. Initiated in 2024, its primary objective is to assess the safety of ABD-3001, as well as to collect pharmacokinetic and pharmacodynamic data to define a treatment regimen for future studies in patients with acute myeloid leukemia, for whom therapeutic options are limited and prognosis unfavorable. The study follows an adaptive design, with an initial single ascending dose in six patient cohorts.

Acute Myeloid Leukemia (AML) is one of the most frequent and severe leukemias affecting adults over 60. The incidence of this form of cancer in Western countries is around 5 per 100,000 inhabitants, and survival at 5 years is no more than 20%. Today, 150,000 patients a year around the world have reached a therapeutic impasse.

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About Xerys Invest

Xerys is a portfolio management company specializing in private equity with an approach that places the entrepreneur's vision at the heart of its investment philosophy. It aims to support the managers of the companies within Xery's fund portfolios at every stage of their growth, from venture capital to maturity.
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About the ODYSSEY clinical trial

ODYSSEY is a Phase I/II clinical trial for the treatment of acute myeloid leukemia (AML). It is a multicenter study, with centers in Paris, Lyon and Marseille, designed to assess the safety and tolerability of the drug candidate ABD-3001.

Organized according to an adaptive design, this study integrates a first part with a single ascending dose, on six cohorts of patients, followed by a second part, during which three cohorts of patients will receive complete treatment cycles of 3 months, thus allowing initial efficacy results to be obtained.

Fully funded by Advanced BioDesign, the ODYSSEY clinical trial is coordinated by Professor Régis COSTELLO (Hôpital de la Conception, Marseille), in collaboration with Doctor Lina BENAJIBA (Hôpital Saint-Louis, Paris), and Doctor Maël HEIBLIG (Hôpital Lyon Sud, Lyon).

About Advanced BioDesign

Advanced BioDesign is a French biotechnology company developing an innovative new therapeutic approach against resistant cancers, with a first indication in acute myeloid leukemia (AML). Its first drug candidate, ABD-3001, is a first-in-class "suicide" inhibitor of class 1 aldehyde dehydrogenases (ALDH1). In January 2022, Advanced BioDesign obtained authorization from the French Agence Nationale de Sécurité du Médicament (ANSM) to launch its first human clinical trial, ODYSSEY, which began in November 2022. Based in Lyon, Advanced BioDesign is supported and accompanied by Xerys Invest funds, which have been financing its research and development programs since 2013.

For more information: https://www.a-biodesign.com; LinkedIn @Advanced BioDesign

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