Press Release

ADVANCED BIODESIGN RECEIVES AUTHORIZATION FROM ANSM FOR ITS "ODYSSEY" CLINICAL TRIAL IN ACUTE MYELOID LEUKAEMIA

ODYSSEY is the Phase I First-in-Human clinical trial of drug candidate ABD-3001 in Acute Myeloid Leukaemia (AML)

Lyon, 26th January 2022 – Advanced BioDesign, a French biotechnology company specializing in the development of a new group of targeted cancer therapies, has announced that it has received authorization from ANSM (National Agency for Medicinal Safety) and from the CPP (Committee for People Protection) to start its first clinical trial phase for its drug candidate ABD-3001 (a clinical formulation of DIMATE), in Acute Myeloid Leukaemia (AML) and in patients with Myelodysplastic Syndrome (MDS). AML is one of the most common leukaemia among adults, with an occurrence rate in Western countries between 3.7 and 6 per 100,000 inhabitants. Today, the 5-year survival rate among patients over the age of 20 is around 25%, a figure which illustrates the unmet medical needs in this indication.

Entitled "ODYSSEY", the aim of this study is to assess the safety, tolerance, pharmacokinetics, and pharmacodynamics of ABD-3001 as monotherapy in patients whose therapeutic options are limited and prognoses unfavourable, and in refractory patients or patients relapsing to reference treatments.

ODYSSEY will follow an adaptive protocol and will involve a first stage lasting 12 months with a single increasing dosage given to 6 cohorts of patients, followed by a second stage over an identical time scale, with multiple doses, where 3 cohorts of patients will receive a full four-week treatment cycle. Through this design, the first efficacy results of the treatment can be obtained, and the best treatment regimen can be determined. The patient cohort will be increased for the last stage in order to confirm the estimated effective dose (6 to 9 additional patients). The medical protocol will ensure that all patients who participated to the second stage of the clinical study will be offered a complete treatment cycle in addition to their initial treatment.

Professor Régis COSTELLO (Hospital la Conception, Marseille) will coordinate the clinical trial, collaborating with Professor Pierre FENAUX (Hospital Saint-Louis, Paris) and Doctor Maël HEIBLIG (Hospital Lyon Sud, Lyon). Together they represent three of the largest oncology departments treating leukaemia in France.

Professor Régis Costello, **Principal Investigator** (APHM-Head of Haematology Department, Hospital la Conception, Marseille) states: "*We are very happy to have received approval and eager to begin this clinical trial soon. During the last seven years of collaboration with Advanced BioDesign, we have obtained very encouraging results in vitro but also on in vivo models* with the DIMATE, the active ingredient of ABD3001. *I am delighted to be able to finally move on to patient trials in order to assess the effectiveness of this innovative therapeutic approach in treating the most serious forms of acute myeloid leukaemia, namely relapsed or refractory leukaemia that cannot benefit from standard remedial treatment. DIMATE represents a real hope for patients who could benefit from compassionate drug use or early access to medication at the end of this clinical trial*", he specifies.

Ismail Ceylan, **founder and CEO of Advanced BioDesign**, says that he is very proud "*of this new step, which is greatly important for Advanced BioDesign, since it is the first time that a therapeutic alternative based on inhibiting the activity of Aldehydes Dehydrogenases (ALDH) will be investigated in humans. This approval and recognition from ANSM and CPP are a testimony of the rigorous work of*

our team, which I would like to thank and warmly congratulate, as well as of the credibility of our research work. This major advance underlines the importance we confer to every project that we undertake, each of which aims to better understand and overcome resistant cancers. This approval is certainly the most significant step we have taken since Advanced BioDesign's creation in 2010. We would like to thank Xerys Invest for its unfailing support and financial backing since 2013, which has enabled us to continue our research and development programs.", he adds.

Olivier Ossipoff, President of Xerys Invest: "*I am delighted by the news and would like to congratulate Advanced BioDesign for receiving the green light from ANSM to begin the ODYSSEY clinical trial. This crucial step shows the pertinence of the research and development work undertaken by the company. We are confident in the ambitious projects it is developing. Xerys Invest's commitment to Advanced BioDesign has been strengthened by this achievement and it will continue after this major phase and in the years to come.*"

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About Advanced BioDesign

Advanced BioDesign is a French biotechnology company developing an innovative approach to the treatment of resistant cancers, with a first indication in acute myeloid leukaemia (AML). Its main anti-cancer compound, DIMATE (ABD-3001), is a first-in-class suicide inhibitor of aldehyde dehydrogenases 1 & 3 (ALDH1 & 3). The ALDH enzyme allows cancer cells to detoxify themselves by recycling potentially damaging molecules. By inhibiting this enzyme, DIMATE induces apoptosis of the cancer cell without damaging healthy cells at therapeutic doses. Founded in 2010 and based in Saint-Priest, near Lyon (France), Advanced BioDesign has benefited from the strategic and financial support of Xerys Invest since 2013. As part of the continued funding of its research and development programs, Advanced BioDesign raised €16 million from Xerys Invest.
www.a-biodesign.com

About ABD-3001

ABD-3001 is the pharmacological form of DIMATE that targets and inhibits a detoxification system present within cancer cells. This detoxification is strongly active in most tumour or leukemic cells, enabling them to survive the inevitable metabolic disorders that occur during the cancer process. By inhibiting this cellular protection system, DIMATE poisons and kills off cancer cells, without harming healthy ones. In most cancers, there is also a population of cells, so called "cancer stem cells", which are most often highly resistant to the cytotoxic effects of current anti-cancer drugs. This resistance to treatment appears to be the main cause of regular relapses of cancer. In studies carried out by the Advanced BioDesign team, DIMATE also destroys these cancer stem cells. Because of this specific property, which is a result of its molecular mechanism of action, DIMATE could be a particularly important drug in preventing cancers from recurring. DIMATE's active mechanisms should enhanced the anti-tumor action of all drugs and therapies activating the redox system, such as platinum salts and gamma rays, and therefore overcome primary resistance to these treatments.

About Xerys Invest

Xerys Invest is a French private equity firm that invests mainly in today's leading sectors such as Health & Life Sciences and GreenTech. Xerys Invest supports companies in industrial sectors that are undergoing major transformations in response to economic, environmental, and societal challenges that have strong ambitions of development and international expansion. Xerys Invest stands out in the market both through its modus operandi and its long-term strategic and operational support for portfolio companies, as well as through its offer of traced or mutualised investment opportunities to investors and its relationship with them. Lastly, Xerys Invest has genuine sectoral expertise, supported by a strategic committee made up of specialists and recognised experts in key sectors. For more information, please visit: https://xerys.com; LinkedIn

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