CatalYm Starts First-in-Human Phase I Clinical Trial with GDF-15 Neutralizing Antibody CTL-002 to Treat Patients with Checkpoint-Inhibitor Refractory Cancer

Munich, Germany, January 28, 2021—CatalYm GmbH, a biopharmaceutical company developing novel cancer immunotherapies, announced today the start of clinical development of CTL-002, its proprietary GDF-15 neutralizing antibody designed to enhance effector T cell entry into the tumor microenvironment. The first patient was enrolled and treated safely in December 2020 in this first clinical trial with CTL-002, acronymed **GDFATHER** (**GDF**-15 **A**ntibody-media**T**ed **E**ffector cell **R**elocation, NCT04725474).

GDFATHER is an open-label, multicenter, Phase I clinical trial evaluating intravenous (IV) administration of CTL-002 as monotherapy and in combination with an anti-PD-1 checkpoint inhibitor. The trial is recruiting patients with advanced-stage, solid tumors, who have relapsed or are refractory to previous anti-PD-1/PD-L1 treatments. The trial is designed with two stages: Part A being a dose escalation study to MTD of CTL-002 in combination with a checkpoint inhibitor and part B expansion cohorts of dedicated GDF-15-dependent tumor indications that are checkpoint inhibitor relapsed/refractory. The trial is approved by regulators in Spain, Switzerland and Germany and may enroll up to 149 patients into part A and B combined.

“Our research has shown GDF-15 to be a malicious, tumor-produced factor that blocks immune effector cells from entering the tumor, thus interfering with immune cell activation and the killing of tumor cells. Blocking GDF-15 with CTL-002 should make modern immunotherapies more effective and potentially provide a major leap forward for the group of GDF-15-mediated checkpoint-inhibitor relapsed/refractory patients,” said Prof. Dr. Eugen Leo, Chief Medical Officer of CatalYm. “Moreover, we are delighted that regulators appreciated our efficient and tailored trial design that includes the immediate combination of CTL-002 with a checkpoint inhibitor allowing participating patients access to a promising, attractive antibody combination therapy from the very start of this clinical trial.”

Dr. Manfred Rüdiger, CEO of CatalYm, concluded: “We are proud of having achieved this important milestone, during this challenging time, that has involved great contributions from our team and our advisors. We look forward to delivering potentially better treatment options for patients failing on current checkpoint blocker treatment regimes.”

About CTL-002

CTL-002 is a humanized, monoclonal antibody designed to neutralize the tumor-produced Growth Differentiation Factor-15 (GDF-15). High concentrations of GDF-15 in the serum and tumor-microenvironment help the tumor evade the immune system and are associated with resistance to current therapies. [i]

CTL-002 addresses three of the tumor’s immune suppressive mechanisms all involving the inhibitory effect of GDF-15 on the immunostimulatory LFA-1/ICAM-1 interaction. By neutralizing GDF-15, CTL-002 is expected to enhance infiltration of immune cells into the tumor, improve priming of T cells by dendritic cells and improve tumor killing by T cells and NK cells.

About GDFATHER

The **GDFATHER** trial (**GDF**-15 **A**ntibody-media**T**ed **E**ffector cell **R**elocation) is a Phase I, first-in-human, multicenter, two-part (part A: dose escalation and part B: cohort expansion) clinical trial of

intravenous (IV) administration of CTL-002 as monotherapy and in combination with an anti-PD-1 checkpoint inhibitor in patients with advanced-stage, relapsed/refractory solid tumors, that relapsed post or were refractory to a prior anti-PD-1/PD-L1 therapy. The primary objectives of the study are to characterize the safety and tolerability of CTL-002 and to explore the preliminary anti-tumor activity of CTL-002 in the expansion cohorts. More information on trial can be found at https://www.clinicaltrials.gov.

About CatalYm

CatalYm is a biopharmaceutical company developing novel cancer immunotherapies targeting Growth-and-Differentiation Factor 15 (GDF-15). Apart from its established role in cachexia, GDF-15 has been associated with immunosuppression in tissues and tumors and a rapidly growing body of literature supports the concept that GDF-15 is a major T cell repellent. CatalYm aims to neutralize GDF-15 to turn "cold" tumors "hot" and thereby substantially improving the efficacy of established immunotherapy such as anti-PD1/-PD-L1 checkpoint inhibitors. The company's lead product candidate CTL-002, a neutralizing GDF-15 antibody, is currently under clinical evaluation in a two-part, open-label, multicenter, Phase I clinical trial (GDFATHER trial).

The Company was founded in 2016 as a spin-off from the Julius-Maximilians-University of Würzburg based on the innovative research work of Prof. Dr. Joerg Wischhusen. CatalYm is led by a seasoned senior executive team with substantial IO drug development as well as deal making experience and backed by international venture capital investors, e.g. Forbion and BioGeneration Ventures, Vesalius Biocapital III, Novartis Venture Fund, Wachstumsfonds Bayern and coparion. CatalYm also received financial support from the EIF via the EIB-EIF Co-investment Facility, backed by the European Union through the European Fund for Strategic Investments (EFSI).

Contact

CatalYm GmbH
Dr. Manfred Rüdiger, CEO
Am Klopferspitz 19
82152 Martinsried, Planegg
Germany
www.catalym.com
info@catalym.com

Media Inquiries

MC Services AG
Katja Arnold, Julia von Hummel, Shaun Brown
T: +49(0)89 2102280
catalym@mc-services.eu

References

[i] Front. Immunol. 11:951. doi: 10.3389/fimmu.2020.00951