



CatalYm Presents Expanded Clinical and New Preclinical Data from GDF-15-targeting Program CTL-002 at SITC Conference

- First four dose escalation levels completed showing excellent tolerability for CTL-002 as monotherapy and in combination with PD-1
- Preliminary pharmacodynamic analyses at early dose levels indicate CTL-002-mediated selective T cell shift into the tumor microenvironment
- Preclinical *in vivo* study validates relevance of GDF-15 as an exciting novel immunology target

Munich, Germany, November 12, 2021 – [CatalYm](#) today announced the presentation of expanded clinical and new preclinical data for its lead candidate CTL-002, an antibody targeting the novel cancer target GDF-15, at the 36th Society for Immunotherapy of Cancer (SITC) Annual Meeting. The results will be presented in two poster presentations on November 13, 2021 and will include data from the ongoing first-in-human trial “GDFather” (*GDF-15 Antibody-mediated Effector cell Relocation*) as well as preclinical data characterizing the potential of GDF-15 as a therapeutic target for the treatment of multiple solid tumor indications. The conference is taking place, both in person (Washington, D.C.) and virtually, from November 10 - 14, 2021.

“Based on GDF-15’s overexpression in a wide variety of tumors and strong correlation with poor survival, we are making it our mission to develop a therapy to neutralize GDF-15 to make a positive impact for the large population of patients unresponsive to checkpoint inhibitors. The data presented today are really interesting based on the demonstration of CTL-002-mediated GDF-15 neutralization and T cell activity in patients, further strengthening our therapeutic concept,” commented Prof. Dr. Eugen Leo, Chief Medical Officer at CatalYm.

Dr. Phil L’Huillier, Chief Executive Officer at CatalYm added, “GDFather is the most advanced clinical trial of a GDF-15-targeting therapeutic, and we are delighted to further update the scientific community on our rapid progress with our unique approach. With the enrollment in all dose levels of the escalation part now completed, we look forward to providing first efficacy read-outs in the near term.”

The poster titled “A phase I, first-in-human clinical trial of the GDF-15 neutralizing antibody CTL-002 in subjects with advanced stage solid tumors (Acronym: GDFATHER)” provides an update on the ongoing Phase 1 trial assessing CTL-002 as a monotherapy or in combination with nivolumab. Dose levels 1-4 have been completed safely with excellent tolerability and no adverse effects. Preliminary pharmacodynamics for dose levels 1-3 are indicative of CTL-002-mediated GDF-15 neutralization, as well as a tumor-selective influx of T cells in the majority of enrolled patients.

The second poster, “Tumor-derived GDF-15 prevents therapy success of checkpoint inhibitors by blocking T-lymphocyte recruitment”, describes the preclinical validation of GDF-15 as a druggable therapeutic target and CatalYm’s lead candidate CTL-002, a



monoclonal antibody designed to neutralize GDF-15. The results further strengthen the pivotal role GDF-15 plays in preventing effective immune cell infiltration. CTL-002 is shown to restore the ability of immune cells to enter the tumor microenvironment *in vivo* validating the GDF-15-specific antibody as a strong candidate for cancer treatment.

All posters presented in the poster hall will be made available as virtual ePosters throughout the SITC 36th Annual Meeting and can be accessed in the “Science” section on [CatalYm’s website](#) under publications.

About the GDFather Trial

The [GDFather trial](#) (GDF-15 antibody-mediated effector cell relocation) is an ongoing first-in-human study and consists of two parts. In the dose escalation phase (Part A), up to 24 patients will receive escalating doses of CTL-002 in a “3+3” manner with the lead candidate given as a monotherapy and followed by combination with an anti-PD-1 checkpoint inhibitor. In the second dose expansion phase (Part B, phase 2a), several cohorts with tumors identified to be GDF-15-dependent will be treated to further evaluate safety and preliminary efficacy of CTL-002 treatment.

About CTL-002

CTL-002 is a humanized, monoclonal antibody designed to neutralize the tumor-produced Growth Differentiation Factor-15 (GDF-15). GDF-15 secretion by the tumor has been shown to prevent T cell migration into the tumor and suppresses T cell function and the adaptive immune response in the tumor microenvironment. This enables the tumor to evade the immune system and become resistant to standard of care and current immunotherapy approaches such as checkpoint inhibitors. CTL-002 counteracts these immuno-suppressive mechanisms by neutralizing GDF-15, enhancing the infiltration of immune cells into the tumor, improving both priming of T cells by dendritic cells and tumor killing by T cells and NK cells.

About CatalYm

CatalYm has identified GDF-15 as a central regulator of the immune system in the tumor microenvironment. We are pioneering the reversal of GDF-15-mediated immunosuppression to induce a potent antitumoral immune reaction in non-responsive tumors. CatalYm’s lead program CTL-002 is poised to demonstrate clinical proof-of-concept in multiple solid tumor indications which will expand the treatment horizon for current and future immunotherapies.

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