CatalYm Receives FDA IND Clearance to Expand Development of Visugromab in Advanced Cancer Patients into the U.S.

Munich, Germany, September 26, 2022 – CatalYm today announced that it has received Investigational New Drug (IND) clearance from the United States Food and Drug Administration (FDA) to expand its ongoing Phase 2 clinical program to include clinical trial centers in the U.S. The ongoing GDFATHER-2 program (**GDF**-15-neutralizing **a**ntibody-media**t**ed **h**uman **e**ffector cell **r**elocation) is evaluating the company's lead candidate, visugromab in combination with an anti-PD1 antibody in patients with advanced solid tumors that are relapsed/refractory to prior anti-PD1/-PD-L1 treatment. Visugromab is a monoclonal antibody that neutralizes GDF-15, a key immunosuppressor, which has been shown to prevent T cell migration into tumors, enabling cancerous cells to evade the immune system.

"Adding trial sites in the U.S. is a critical component of our clinical development strategy for visugromab and we appreciate receiving this IND approval," **said Prof. Dr. Eugen Leo, Chief Medical Officer at CatalYm**. "Our focus is to rapidly advance the GDFATHER-2 program and we have now gained the opportunity to enroll a more diverse set of cancer patients. We are planning to further maximize the potential of this program with additional cohorts and trial modalities in the future."

Dr. Phil L'Huillier, Chief Executive Officer at CatalYm added: "The IND clearance demonstrates our ability to execute on our clinical objectives and heralds the next stage of our journey toward developing visugromab as a new class of anti-cancer immunotherapeutic treatment. We look forward to working with our clinical partners in the United States and to announcing initial results from the first ongoing Phase 2a cohorts by mid 2023."

The multi-center, open-label, cohort expansion GDFATHER-2 trial (NCT04725474) investigates the treatment of advanced stage cancer patients that are relapsed/refractory to prior anti-PD-1/-PD-L1 treatment with the GDF-15 neutralizing antibody, visugromab, in combination with the anti-PD-1 checkpoint inhibitor nivulomab. The GDFATHER-2a program will enroll up to 164 participants aged 18 years or older, who are relapsed or refractory to prior anti-PD-1/-PD-L1 treatment, at clinical centers across Europe and the United States. Phase 2a is currently recruiting at locations in Germany, Spain and Switzerland. Recruitment in the United States is expected to begin before end of 2022.
The full data readout from the visugromab Phase 1 trial, GDFATHER-1, was recently presented at the European Society for Medical Oncology (ESMO) Congress 2022 and demonstrated encouraging signs of efficacy in a last-line patient setting with a favorable safety profile.

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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

visugromab is poised to demonstrate clinical proof-of-concept in multiple solid tumor indications which will expand the treatment horizon for current and future immunotherapies.

About the GDFATHER-2 Trials

The **GDFATHER-2** trials (**GDF**-15 **A**ntibody-media**T**ed **H**uman **E**ffector cell **R**elocation Phase 2) (NCT04725474) are ongoing first-in-human Phase 2a cohorts investigating the effect of visugromab (CTL-002) as monotherapy and/or in combination with a PD-1 checkpoint inhibitor in patients with various advanced-stage, relapse/refractory solid tumors. The study consists of two segments with a total of six cohorts, enrolling up to 164 patients in Simon-2-stage designs to confirm a certain response rate within each tumor type. Five cohorts are within tumor types with anti-PD1/-L1 label, recruiting patients that either were refractory to or relapsed post prior anti-PD1/-L1 treatment. One cohort entails treatment of an anti-PD1/-L1 naïve tumor type in an indication without anti-PD1/-L1 approval. Main data read-outs from Phase 2a are expected by mid 2023. Additional cohorts are in planning.

About Visugromab (CTL-002)

Visugromab, formerly known as 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. Visugromab 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.

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