CatalYm Announces Initial Data from Ongoing Phase 2a Trial Evaluating GDF-15-targeting Antibody Visugromab in Combination with Nivolumab at ASCO 2023

- Oral presentation highlights first data from the GDFATHER-2a trial demonstrating lasting and confirmed responses (as per RECIST criteria) following treatment with visugromab and the anti-PD-1 inhibitor nivolumab in, advanced-stage solid tumor patients that were relapsed/refractory to prior anti-PD1/-L1 treatment
- Promising early responses in major cancer indications, including non-small cell lung cancer (NSCLC), bladder cancer and hepatocellular carcinoma (HCC).
- Treatment with visugromab and nivolumab continues to demonstrate overall very good safety and tolerability profile
- Evaluation of potentially response-predictive biomarkers continued
- Totality of updated data from Phase 1 and emerging 2a further underscores the potential of neutralizing GDF-15 as a novel treatment strategy in combination with PD-1 inhibition in advanced-stage solid tumor patients

Munich, Germany, June 6, 2023 – CatalYm today announced first Phase 2a data from its ongoing GDFather-2 trial (**GDF**-15 **A**ntibody-media**T**ed **H**uman **E**ffector Cell **R**elocation Phase 2) (NCT04725474) at the American Society of Clinical Oncology (ASCO) Annual Meeting 2023 in Chicago, Illinois. The early data presented during today's oral "Developmental Therapeutics-Immunotherapy" session revealed lasting and confirmed responses in several solid tumor types investigated following treatment with visugromab and the anti-PD-1 inhibitor nivolumab. In addition, the combination continues to demonstrate a good safety and tolerability profile across all cohorts. CatalYm's lead candidate, visugromab, is a humanized, monoclonal antibody designed to neutralize the tumor-produced Growth Differentiation Factor-15 (GDF-15), a central regulator of tumor resistance development.

"These early data from our Phase 2a cohorts corroborate the encouraging anti-tumor-response we have seen in the Phase 1 study and further elucidate the considerable therapeutic potential of visugromab in very advanced and anti-PD1/PD-L1 relapsed/refractory solid tumor patient populations. They also confirm and further refine our scientifically guided indication selection to identify the solid tumor patients that would most benefit from a GDF-15 modulating approach," said **Prof. Dr. Eugen Leo, Chief Medical Officer at CatalYm**.

The presentation at ASCO by International Coordinating Investigator Prof. Dr. Ignacio Melero Bermejo, MD, Co-Director of Immunology and Immunotherapy (CIMA) at the Universidad de Navarra, Pamplona/Spain, builds on the further matured Phase 1 trial data announced in September 2022 which showed a significant clinical benefit in last line tumor patients that were anti-PD1/-L1 relapsed or refractory with an overall response rate of 17% in an advanced-stage mixed tumor population (RECIST, all responses confirmed). The Phase

2a study cohorts were selected based on a translational research program and include several major solid tumor types identified in Catalym's translation research program as potentially being GDF-15 influenced.

The emerging phase 2a efficacy data further extend the initial encouraging data from Phase 1 with durable, confirmed responses as per RECIST criteria in several major tumor indications. Furthermore, investigation of potentially response-predictive biomarkers identified during phase 1 dose-escalation are ongoing through tumor biopsy analyses. The cumulative safety and tolerability profile for the Phase 1/2a study confirmed, so far, a well-acceptable safety profile when treating advanced-stage cancer patients, an important aspect for combination therapy in this critically ill patient population and earlier treatment lines.

Dr. Phil L'Huillier, Chief Executive Officer at CatalYm added: "The data revealed in today's presentation illustrate the strides we have made in developing a completely novel treatment option by neutralizing GDF-15 in a variety of indications. We will continue in our broad multi-arm Phase 2 development program (GDFATHER-2) in 2023 and anticipate sharing more data and an update on our late-stage clinical development strategy later this year. I am grateful for the study patients and dedicated clinicians who have been a part of our clinical development program to this stage."

The Phase 2a GDFATHER-2 program was initiated in March 2022. The ongoing study consists of two segments with up to seven cohorts, expected to enroll a total of over 200 patients in Simon-2-stage designs and in a biomarker-evaluation directed cohort.

Mature data readouts for efficacy and safety data of the core phase 2a program as well as main biomarker-correlations are expected to become available before the end of 2023.

About the GDFATHER-2 Trials

The GDFATHER-2a trial (**GDF**-15 **A**ntibody-media**T**ed **H**uman **E**ffector Cell **R**elocation Phase 2) (NCT04725474) is an ongoing Phase 2a trial with several cohorts investigating the effect of visugromab (CTL-002) as monotherapy and/or in combination with a PD-1 checkpoint inhibitor in patients in various advanced-stage, relapse/refractory solid tumor types and a biomarker-selected cohort. The study can enroll > 200 patients in Simon-2-stage designs and a biomarker-evaluation directed cohort to confirm certain response rates and potential biomarker-based responder patient selection.

About Visugromab (CTL-002)

Visugromab is a humanized monoclonal antibody that neutralizes the tumor-derived Growth Differentiation Factor-15 (GDF-15). GDF-15 is an essential player in feto-maternal tolerance, a powerful mechanism that cancer cells hijack to create an immunosuppressive environment to evade destruction. By neutralizing GDF-15, visugromab reverses the immunosuppressive effects that block an efficient anti-tumor immune response in the tumor microenvironment and the draining lymph nodes. Visugromab drives an activated and differentiated immune cell infiltration into the solid tumor as well as enables priming

of T cells and enhances the tumor killing effects of T cells and NK cells. GDF-15 is currently investigated in an ongoing Phase 2 program that includes confirmatory studies in multiple solid tumor indications and the analysis of a predictive response biomarker to better identify the patients benefiting from this new class of immunotherapy.

About CatalYm

CatalYm is pioneering a novel immuno-oncology therapy that safely overcomes GDF-15-mediated immunosuppression in the tumor microenvironment. Our lead product, visugromab, a first-in-class GDF-15 neutralizing antibody, has demonstrated potent and durable anti-tumor efficacy with multiple, long-lasting objective responses in combination with anti-PD-1 treatment in phase 1/2 studies in advanced cancer patients. CatalYm is focused on maximizing visugromab's potential as a new class of cancer immunotherapy with a clinically distinct profile in a range of solid tumor indications.

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