

CatalYm to Present Primary Results From Phase 2 Neoadjuvant Bladder Cancer Trial in Late-breaking Oral Presentation at ESMO

- Second oral presentation will provide updated data from GDFATHER-01 trial demonstrating deep and durable remissions in heavily pretreated patients

MUNICH & SAN FRANCISCO--(BUSINESS WIRE), September 23, 2025 – [CatalYm](#), a world-leader in neutralizing GDF-15 in cancer and cachexia, today announced two upcoming oral presentations highlighting the company's lead-candidate visugromab at the European Society of Medical Oncology (ESMO) Congress, being held October 17th - 21st, 2025, in Berlin, Germany. Visugromab is a humanized, monoclonal antibody designed to neutralize the tumor-derived cytokine Growth Differentiation Factor-15 (GDF-15) that plays a central role in immune suppression and anti-PD(L)-1 treatment resistance.

A late-breaking abstract featuring first results from the Phase 2 GDFATHER-NEO trial ([NCT06059547](#)) was accepted for oral presentation. The trial investigates visugromab as neoadjuvant treatment in combination with nivolumab in patients with muscle-invasive bladder cancer (MIBC) compared to nivolumab administered with placebo.

In addition, a second oral presentation will cover long-term follow-up data from the GDFATHER-01 Phase 1/2 trial ([NCT04725474](#)) demonstrating deep and durable remissions in heavily pretreated, anti-PD1/-L1 relapsed/refractory non-squamous non-small cell lung cancer (NSCLC), urothelial cancer (UC) and hepatocellular cancer (HCC) patients.

Presentation Details

Late-breaking Oral Presentation

Abstract Title: A blinded, exploratory phase 2 trial of nivolumab and the GDF-15 neutralizing antibody visugromab or placebo as neoadjuvant treatment of patients with muscle-invasive bladder cancer (MIBC): Primary results of the GDFATHER-NEO trial

Session Category & Title: Proffered Paper session 1: GU tumours, renal & urothelial

Presentation Date & Time: October 17, 2025; 3:00 – 3:10 pm CEST

Presenter: Prof. Andrea Necchi, MD, Vita-Salute San Raffaele University, IRCCS San Raffaele Hospital

Location: Dortmund Auditorium - Hall 7.1a

Proffered Paper Presentation

Abstract Title: Long-term follow-up GDFATHER-01 trial: GDF-15 neutralization combined with nivolumab can enable deep, long-term remission in heavily pretreated, anti-PD1/-L1 relapsed/refractory non-squamous non-small cell lung cancer (NSCLC), urothelial cancer (UC) and hepatocellular cancer (HCC)

Session Category & Title: Proffered paper session: Investigational immunotherapy

Presentation Date & Time: October 20, 2025; 10:55 – 11:05 am CEST

Presenter: Prof. Ignacio Melero, MD, PhD, Co-Director of Immunology and Immunotherapy (CIMA) at the Universidad de Navarra, Pamplona/Spain

Location: Hanover Auditorium - Hall 7.2c

About Visugromab

Visugromab is a monoclonal antibody that neutralizes Growth Differentiation Factor-15 (GDF-15), a locally acting immunosuppressant produced by tumors which fosters immunotherapy resistance and drives cachexia in people with cancer. Neutralizing GDF-15 with visugromab reverses key cancer resistance mechanisms to reinstate an efficient anti-tumor response by re-enabling immune cell activation, proliferation and induction of interferon- γ . In addition, visugromab also mitigates cancer cachexia, a severe condition affecting a significant number of advanced cancer patients by inhibiting the activation of the GFRAL pathway in the brainstem, a key driver of weight loss and appetite suppression in cancer patients.

About CatalYm

CatalYm is developing visugromab, a first-in-class anti-GDF-15 antibody, in solid tumors and cachexia. In its first-in-human Phase 1/2a study, visugromab demonstrated durable anti-tumor efficacy with long-lasting objective responses in relapsed and refractory metastatic solid tumor patients in combination with anti-PD-1 treatment. In addition, data from the same study demonstrated that visugromab can significantly counteract the effects of cachexia in these patients. This data was published in Nature and presented at the International Conference on Sarcopenia, Cachexia & Wasting Disorders. CatalYm is now advancing visugromab into multiple Phase 2b studies including first-line metastatic NSCLC ([NCT07098988](#)) and cachexia ([NCT07112196](#)).

Founded in 2016 and based in Munich, Germany and San Francisco, USA, CatalYm is backed by leading international investors including Canaan Partners, Bioqube Ventures, Forbion, Omega Funds, Gilde Healthcare, Jeito Capital, Novartis Venture Fund, Vesalius, Brandon Capital, Bayern Kapital, BioGeneration Ventures, and Coparion.

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