# CatalYm Presents Phase 2 Data Showing Visugromab Substantially Enhances the Clinical Benefit of PD-1 Inhibition in Neoadjuvant Bladder Cancer at ESMO 2026

- *Visugromab combined with PD-1 inhibitor nivolumab demonstrated higher response rates versus nivolumab alone across primary and secondary endpoints: pathologic Complete Response (pCR; 33% vs. 8%), radiographic Objective Response Rate (ORR; 60% vs. 15%) and Major Pathologic Response (MPR; 60% vs. 23%)*
- *Enhanced responses were associated with increased eligibility for bladder-sparing treatment approaches in cisplatin-ineligible or cisplatin-refusing patients with muscle-invasive bladder cancer (MIBC)*
- *Independent central assessment was largely concordant with the locally assessed pathologic and radiographic response results, reinforcing the robustness of the observed benefit in the visugromab treatment arm*
- *Visugromab combination was overall well tolerated, with no treatment-related discontinuations and no new safety signals*
- *Results were simultaneously published in Nature Medicine and support the ongoing late-stage clinical development of visugromab in early treatment lines for high-need solid tumor indications, including checkpoint-inhibitor-naïve cancers*

**MUNICH & SAN FRANCISCO--**CatalYm today announced final results from its randomized Phase 2 GDFATHER-NEO trial, which were presented in a rapid oral session at the European Society for Medical Oncology (ESMO) Congress 2026 and simultaneously published in *Nature Medicine*. The data showed that Growth Differentiation Factor-15 (GDF-15) blockade with visugromab substantially enhanced the anti-tumor activity of the PD-1 inhibitor nivolumab in the neoadjuvant treatment of patients with newly diagnosed, checkpoint-inhibitor-naïve muscle-invasive bladder cancer (MIBC). Visugromab is a humanized monoclonal antibody designed to neutralize the tumor-derived cytokine GDF-15, a key mediator of immune suppression and resistance to anti-PD-(L)1 therapies.

“With more than one year of follow-up and support from independent central assessment, these final results further strengthen the clinical evidence for visugromab and extend its potential into another high-need solid tumor indication,” **said Sujata Rao, MD, Chief Medical Officer at CatalYm.** “The improvements observed across key endpoints highlight the potential of visugromab to add meaningful benefit to PD-1 inhibition already in earlier treatment lines, providing further support for our ongoing Phase 2b programs in first- and second-line lung and liver cancer settings with high medical need.”

The *Nature Medicine* article, titled “Neoadjuvant nivolumab with visugromab versus placebo in patients with muscle-invasive bladder cancer: the GDFATHER-NEO phase 2 trial,” reports the final results from the study. Both the publication and the ESMO presentation highlight the efficacy benefits observed with the addition of visugromab to nivolumab in the neoadjuvant setting, including improvements in pathologic Complete Response (pCR), Major Pathological Response (MPR) and radiographic Objective Response Rate (ORR), while maintaining an overall well-tolerated safety profile comparable to nivolumab alone. Importantly, independent central assessment of the study endpoints was largely concordant with the locally assessed results, reinforcing the robustness of the overall treatment benefit observed in the visugromab combination arm.

“More than half of all patients with MIBC receiving neoadjuvant immune checkpoint therapy still fail to achieve meaningful responses, and opportunities for bladder preservation remain limited,” **said Prof. Dr. Andrea Necchi, Director of Genitourinary Medical Oncology at IRCCS San Raffaele Hospital, Principal Investigator of the study and first author of the Nature Medicine publication.** “The benefits observed across pathologic and radiographic assessments, including deeper responses and increased eligibility for bladder-sparing treatment approaches, support GDF-15 neutralization as a clinically relevant strategy to counteract or potentially prevent resistance to immunotherapy. Together, these findings highlight the broad potential of visugromab to enhance anti-tumor immunity and improve clinical outcomes for patients with localized immunoresponsive cancers.”

GDFATHER-NEO (NCT06059547) is a multicenter, stratified, single-blinded Phase 2 trial evaluating visugromab plus nivolumab vs. nivolumab plus placebo in cisplatin-ineligible or cisplatin-refusing patients with newly diagnosed, non-metastatic MIBC. Patients received neoadjuvant treatment every four weeks for three cycles before restaging by imaging and subsequent radical cystectomy (RC) or re-transurethral resection of the bladder tumor (re-TURBT), performed four to eight weeks after the final dose.

**Key trial results**

- A total of 31 patients were enrolled, with a median age of 76 years. At the data cut-off on July 15, 2026, 15 patients in the nivolumab + visugromab (N+V) arm and 13 patients in the nivolumab + placebo (N+P) arm were evaluable for local pathologic and radiographic primary endpoint analyses.
- N+V demonstrated higher response rates than N+P across multiple endpoints, including pCR (33% vs. 8%), MPR (60% vs. 23%) and ORR (60% vs. 15%; with 7/15 complete responses in the N+V arm), with findings supported by independent blinded central review.
- A greater proportion of patients in the N+V arm underwent bladder-sparing re-TURBT compared to the control arm (37.5% vs. 20.0%); 4/5 of the N+V patients with pCR retained their bladder after re-TURBT alone.
- At a median follow-up of 15.7 months, no recurrences were observed among patients who achieved a pCR (N+V = 5; N+P = 1)
- Median event-free survival (EFS) was not reached in either treatment arm, with follow-up limited to one year after surgery.
- Safety findings were consistent with previously reported data, with no new safety signals identified. Treatment with N+V was overall well-tolerated, with treatment-related adverse events predominantly mild to moderate and consistent with the known safety profile of checkpoint inhibitors. No treatment-related discontinuations or treatment-related delays to surgery were observed in the N+V arm.
- Baseline infiltration by proliferating CD8+ T cells correlated with response to nivolumab plus visugromab

Overall, the final results from the GDFATHER-NEO trial provide additional clinical evidence supporting CatalYm's strategy to investigate GDF-15 neutralization as a means of enhancing checkpoint inhibitor activity across multiple solid tumor settings. CatalYm is advancing visugromab through randomized Phase 2b trials in earlier lines of treatment, including ongoing randomized trials in first- and second-line non-small cell lung cancer (NCT07098988, NCT07246863), second-line hepatocellular carcinoma (NCT07219459), and cancer-associated cachexia (NCT07112196).

**About Visugromab**

Visugromab is a monoclonal antibody that neutralizes Growth Differentiation Factor-15 (GDF-15), a locally and systemically 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 deep and durable anti-tumor efficacy with long-lasting objective responses in relapsed and checkpoint 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 non-squamous NSCLC (NCT07098988), second-line metastatic non-squamous NSCLC (NCT07246863), second-line hepatocellular carcinoma (NCT07219459) 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, Omega Funds, Bioqube Ventures, Forbion, Jeito Capital, Brandon Capital, Gilde Healthcare, Novartis Venture Fund, Vesalius, Bayern Kapital, BioGeneration Ventures, and Coparion.

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