NovaBridge Doses First Patient in Global, Randomized Phase 2 Study of Givastomig Combined with Immunochemotherapy in Patients with 1L Metastatic Gastric Cancer

February 17, 2026

- Global, randomized Phase 2 study to evaluate the addition of givastomig, a CLDN18.2 x 4-1BB bispecific antibody (8 mg/kg and 12 mg/kg) to standard of care immunochemotherapy in patients with first line (1L) metastatic gastric cancer
- Major milestone builds on positive Phase 1b combination data demonstrating that givastomig produced, best-in-class potential efficacy in 1L HER2-negative, metastatic gastric cancer patients in combination with nivolumab and chemotherapy (mFOLFOX6)
- Phase 1b results showed that patients treated with givastomig experienced an objective response rate (ORR) of 75%, median progression free survival (mPFS) of 16.9 months and 82% six-month landmark PFS
- Gastric cancer represents a $12 billion market opportunity by 2030
- Top line results from the Phase 2 study are expected in 2027

ROCKVILLE, Md., Feb. 17, 2026 (GLOBE NEWSWIRE) -- NovaBridge Biosciences (Nasdaq: NBP) (NovaBridge or the Company) a global biotechnology platform company committed to accelerating access to innovative medicines, today announced enrollment of the first patient in the global Phase 2 randomized combination study evaluating givastomig, a Claudin 18.2 (CLDN18.2) x 4-1BB bispecific antibody, in combination with nivolumab and chemotherapy (mFOLFOX6) in patients with HER2-negative, 1L metastatic gastric cancer. Positive Phase 1b data position givastomig to be a potential best-in-class CLDN18.2-directed therapy for gastric cancer with a projected $12 billion market opportunity by 2030[1]. Top line Phase 2 results are expected in 2027.

"We are pleased to be advancing givastomig one step closer towards commercialization, with the initiation of the global randomized Phase 2 study. The study builds on the compelling Phase 1b givastomig results, showing robust efficacy and favorable overall tolerability, and demonstrating a potential marked improvement relative to historical benchmarks for the standard of care. The Phase 2 study is designed to confirm these results in a broader setting and validate givastomig as a potential best in class therapy for 1L metastatic gastric cancer, with the potential for broad utilization across CLDN18.2 levels in PD-L1 positive patients," said **Phillip Dennis, MD, PhD, Chief Medical Officer of NovaBridge**. "We expect to present results from this study in 2027. In addition, we expect to present updated results from the Phase 1b dose expansion study in the second half of this year."

"We continue to be encouraged by givastomig's high response rate across a wide range of Claudin 18.2 and PD-L1 expression levels. The depth and duration of responses achieved with combination therapy coupled with the tolerability enabled the swift enrollment in the Phase 1b study and provides a strong basis to move to the next stage of development," said **Samuel J. Klempner, MD, Associate Professor of Medicine at Mass General Brigham Cancer Institute.** "We are hopeful that, with continued positive clinical results, givastomig will ultimately become a standard of care for gastric and esophageal cancer."

"Initiation of the Phase 2 study marks a pivotal moment for NovaBridge as we transition to a mid-stage clinical Company. Compelling Phase 1b efficacy and safety data validate givastomig's potential as a premier CLDN18.2-directed therapy for gastric cancer and beyond. The strong and durable response data underscore our conviction in givastomig's significant commercial potential," said **Sean Fu, PhD, MBA, Chief Executive Officer of NovaBridge**. "We remain focused on developing novel, differentiated therapies that can transform the treatment of patients worldwide and believe that givastomig will be a cornerstone of our future growth."

About the Givastomig Phase 1b Dose Escalation and Expansion Combination Study in 1L Gastric Cancer

The Phase 1b dose expansion data (per the January 6, 2026 press release and corporate presentation) showed that givastomig, dosed at 8 mg/kg every two weeks (Q2W) and 12 mg/kg Q2W, produced:

- Robust efficacy, with **75% ORR** (77% ORR observed at 8 mg/kg, 73% ORR observed at 12 mg/kg, n=52 evaluable)
- **Responses** observed **across a wide range of PD-L1 and CLDN18.2** expression levels
- Durable responses with **16.9-month mPFS and an 82% 6-month landmark PFS rate** (n=53 evaluable)
- **With good overall tolerability** in combination with immunochemotherapy, **without dose dependent toxicity**

Detailed Phase 1b expansion data are expected to be presented at a major medical conference in H2 2026

About the Global, Randomized Phase 2 Study of Givastomig in the Setting of 1L Gastric Cancer

The Phase 2 global, randomized study is evaluating the safety and efficacy of givastomig, used in combination with nivolumab and mFOLFOX6, as 1L therapy in patients with CLDN18.2-positive gastric cancer, including gastroesophageal cancer (GEC), gastroesophageal junction cancer (GEJ), gastroesophageal adenocarcinoma (GEA), with CLDN18.2 levels of ≥1+ immunohistochemistry (IHC) intensity on ≥1% of cells, and PD-L1 expression ≥1. The study is expected to enroll approximately 180 patients (randomized equally to 8mg/kg givastomig, 12 mg/kg givastomig or nivolumab+mFOLFOX6). The primary endpoint is progression free survival (PFS); secondary endpoints include objective response rate (ORR), overall survival (OS), duration of response (DoR) and disease control rate (DCR). The study will enroll patients globally.

Sources:

1. Markets include U.S., five E.U. countries, and Japan by 2030 for potential sales based on Data Monitor Biomed Tracker

About Givastomig

Givastomig (TJ033721 / ABL111) is a bispecific antibody targeting Claudin 18.2 (CLDN18.2)-positive tumor cells. It conditionally activates T cells through the 4-1BB signaling pathway in the tumor microenvironment where CLDN18.2 is expressed. Givastomig is being developed for potential treatment of gastric cancer and other Claudin 18.2-positive gastrointestinal malignancies. In Phase 1 trials, givastomig has shown promising anti-tumor activity attributable to a potential synergistic effect of proximal interaction between CLDN18.2 on tumor cells and 4-1BB on T cells in the tumor microenvironment, while minimizing toxicities commonly seen with other 4-1BB agents.

Givastomig is being jointly developed through a global partnership with ABL Bio, in which NovaBridge is the lead party and shares worldwide rights, excluding Greater China and South Korea, equally with ABL Bio.

About NovaBridge

NovaBridge is a global biotechnology platform company committed to accelerating access to innovative medicines. The Company combines deep business development expertise with agile translational clinical development to identify, accelerate, and advance breakthrough assets. By bridging science, strategy, and execution, NovaBridge enables transformative therapies to progress rapidly from discovery toward patients in need.

The Company's differentiated pipeline is led by givastomig, a potential best-in-class, Claudin 18.2 x 4-1BB bispecific antibody, and VIS-101, a second-in-class, potentially best-in-class bifunctional biologic, targeting VEGF-A and ANG2.

Givastomig conditionally activates T cells via the 4-1BB signaling pathway in the tumor microenvironment where Claudin 18.2 is expressed. Givastomig is being developed to treat Claudin 18.2-positive gastric cancer and other gastrointestinal malignancies. The product candidate is being evaluated in a global, randomized Phase 2 study, following the recent announcement of positive topline results from a Phase 1b, multi-center, open label study in first line gastric cancer. The Company is also collaborating with its partner, ABL Bio, for the development of ragistomig, a bispecific antibody integrating PD-L1 as a tumor engager and 4-1BB as a conditional T cell activator, in solid tumors. Additionally, NovaBridge owns worldwide rights outside of China to ulilediimab, an anti-CD73 antibody that targets adenosine-driven immunosuppression in cancer.

VIS-101 targets VEGF-A and ANG-2 to provide more potent and durable treatment benefits for patients with wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME). VIS-101 is currently completing a randomized, dose-ranging Phase 2a study for wet AMD. NovaBridge is the majority shareholder of Visara, and Visara controls global rights to VIS-101, outside of Greater China and certain countries in Asia.

For more information, please visit www.novabridge.com and follow us on LinkedIn.

Forward Looking Statements

This announcement contains forward-looking statements. These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as "will", "expects", "believes", "designed to", "anticipates", "future", "intends", "plans", "potential", "estimates", "confident", and similar terms or the negative thereof. NovaBridge may also make written or oral forward-looking statements in its periodic reports to the U.S. Securities and Exchange Commission (the SEC), in its annual report to shareholders, in press releases and other written materials and in oral statements made by its officers, directors or employees to third parties. Statements that are not historical facts, including statements about the Company's beliefs and expectations, are forward-looking statements. Forward-looking statements in this press release include, without limitation, statements regarding: the strategy, clinical development, plans, results, safety and efficacy of givastomig and VIS-101 and its other drug candidates; the strategic and clinical development of NovaBridge's drug candidates, including givastomig, ragistomig, ulilediimab, and VIS-101; anticipated clinical milestones and results, and related timing. Forward-looking statements involve inherent risks and uncertainties that may cause actual results to differ materially from those contained in these forward-looking statements, including but not limited to the following: the Company's ability to demonstrate the safety and efficacy of its drug candidates; the Company's ability to enroll patients and complete clinical

studies on the timelines contemplated; the clinical results for its drug candidates, which may or may not support further development or New Drug Application/Biologics License Application (NDA/BLA) approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of the Company's drug candidates; the Company's ability to achieve commercial success for its drug candidates, if approved; the Company's ability to obtain and maintain protection of intellectual property for its technology and drugs; the Company's reliance on third parties to conduct drug development, manufacturing and other services; the Company's limited operating history and the Company's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; and those risks more fully discussed in the "Risk Factors" section in the Company's annual report on Form 20-F filed with the SEC on April 3, 2025 as well as the discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the SEC. All forward-looking statements are based on information currently available to the Company. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law.

NovaBridge Investor & Media Contacts

PJ Kelleher
LifeSci Advisors
+1-617-430-7579
pkelleher@lifesciadvisors.com

NovaBridge Biosciences
+1-240-745-6330
IR@novabridge.com

Source: NovaBridge Biosciences