NovaBridge Presents Positive Givastomig Dose Expansion Data from the Phase 1b Combination Study in Patients with 1L Metastatic Gastric Cancer

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- Givastomig, a CLDN18.2 x 4-1BB bispecific antibody, continues to show robust efficacy when combined with nivolumab and chemotherapy (mFOLFOX6) in 1L HER2-negative, metastatic gastric cancer patients, with 77% ORR observed at 8 mg/kg and 73% ORR observed at 12 mg/kg, across a wide range of PD-L1 and CLDN18.2 expression levels
- The median PFS was 16.9 months at 8 mg/kg; 12 mg/kg is immature with approximately 4-month shorter median follow-up; data will be updated in 2026
- Six-month landmark PFS was 73% for 8 mg/kg, and 91% for 12 mg/kg cohorts
- Combination was well tolerated; safety is comparable to the current standard of care treatment
- Data demonstrate that givastomig is a potential best-in-class CLDN18.2 asset when added to 1L standard of care
- NovaBridge is on track to initiate enrollment in a global, randomized Phase 2 study, evaluating both doses against standard of care, in Q1 2026
- Detailed Phase 1b dose expansion data are expected to be presented at a medical conference later in 2026

ROCKVILLE, Md., Jan. 06, 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 positive updated results from the Phase 1b combination study of givastomig, a Claudin 18.2 (CLDN18.2) x 4-1BB bispecific antibody, in combination with nivolumab and chemotherapy (mFOLFOX6) in patients with HER2-negative, first line (1L) metastatic gastric cancer.

The results combine data from patients in the Phase 1b dose escalation and expansion cohorts treated with 8 mg/kg or 12 mg/kg of givastomig. An ORR of 77% (20/26) at the 8 mg/kg dose, and 73% (19/26) at the 12 mg/kg dose, confirms and extends positive signals observed in the dose escalation cohorts. Responses continue to be rapid and deepen over time, and were observed across all levels of CLDN18.2 and PD-L1 expression levels. The safety profile of the combination was similar to earlier observations, except for the emergence of immune-related gastritis, which correlated with improved clinical outcomes. These data, outlined in detail below, position givastomig as a potential best-in-class CLDN18.2-directed therapy for gastric cancer, a potential $12 billion market opportunity by 2030. The full data are intended to be presented at a medical meeting later in 2026.

The Phase 1b study (NCT04900818) is evaluating the safety, efficacy, pharmacokinetics (PK), and pharmacodynamics (PD) of givastomig, used in combination with nivolumab and mFOLFOX6, as 1L therapy in patients with CLDN18.2-positive gastric cancer (GC) (≥1+ immunohistochemistry (IHC) intensity in ≥1% of cells), and any level of PD-L1 expression. The primary endpoint is safety. Secondary endpoints include progression free survival (PFS). The study enrolled only patients in the U.S.

“The dose expansion data reinforce the strong signals we observed in dose escalation. The efficacy is clear at 8 mg/kg, with robust ORRs, including in subgroups defined by low PD-L1 and/or CLDN18.2 expression. The PFS data are very promising and continue to mature. Emerging efficacy data at 12 mg/kg are also strong and similar in terms of ORR. The 12 mg/kg cohort was enrolled after the 8 mg/kg cohort, so follow-up is shorter and PFS is less mature. We expect to report these data later in 2026. We remain enthusiastic about the 12 mg/kg dose because exposure analysis shows higher exposure is consistently associated with a higher probability of response, without a higher probability of toxicity,” said **Phillip Dennis, MD, PhD, Chief Medical Officer of NovaBridge**.

“I continue to be encouraged by givastomig’s high response rate across a wide range of Claudin 18.2 and PD-L1 expression levels, and the depth and duration of responses achieved with combination therapy. The development of gastritis was not predicted by the monotherapy study, and may be related to longer givastomig exposure duration, something that has been seen with some CLDN18.2-directed agents. Most gastritis cases were low grade and manageable, and interestingly appear to be associated with higher response rates and longer survival,” said **Samuel J. Klempner, MD, Associate Professor of Medicine at Massachusetts General Hospital**. “Givastomig’s favorable benefit-risk balance has the potential to offer real world benefit to patients and is planned to be investigated in a randomized trial.”

“Givastomig is a core program for NovaBridge,” said **Sean Fu, PhD, MBA, Chief Executive Officer of NovaBridge**. “The compelling Phase 1b data presented today have the potential to establish givastomig as the leading CLDN18.2-directed therapy

for 1L gastric cancer, where the unmet medical need remains high and the commercial opportunity is significant."

Topline Data from the Givastomig Phase 1b Dose Escalation and Expansion Combination Study in 1L Gastric Cancer

- 54 advanced metastatic gastric cancer patients (metastatic gastric, esophageal or gastroesophageal adenocarcinomas) were enrolled in cohorts across the 8 mg/kg (n=27), and 12 mg/kg (n=27) dose levels as of the December 2, 2025 data cutoff. 52 patients were efficacy evaluable
- Demographics show characteristics typical of metastatic gastric cancer in patients
- All patients were HER2-negative, CLDN18.2-positive (defined as ≥1+ IHC staining intensity in ≥1% of tumor cells), regardless of PD-L1 expression levels
- Enrolled at sites only within the United States
- Biomarker expression consistent with prevalence, noting that in efficacy evaluable patients:
    - 8 mg/kg cohort was over-represented with tumors expressing CLDN18.2 >75% (63%)
    - 12 mg/kg cohort was over-represented with tumors expressing PD-L1 <1% (34%)

Efficacy Results: 51/52 patients exhibited a reduction in the volume of target lesions per RECIST v1.1.

Phase 1b Combination Data Based on patients in the dose escalation and dose expansion cohorts		
Dose level	**8 mg/kg**	**12 mg/kg**
Enrolled patients	**27**	**27**
Efficacy evaluable patients (n)[1]	**26**	**26**
ORR: % (n)	**77 (20/26)**	**73 (19/26)**
• PR[2]	77 (20/26)	69 (18/26)
• CR	-	4 (1/26)
• SD	19 (5/26)	27 (7/26)
• PD	4 (1/26)	-
DCR[3] % (n)	**96 (25/26)**	**100 (26/26)**
Median time to onset of response (months, Min, Max)	**1.8** (1.3, 7.5)	**2.5** (1.5, 5.4)
Footnotes: 1. Efficacy evaluable patients defined as having had at least one evaluable on-treatment scan 2. The 12 mg/kg cohort includes three patients with unconfirmed partial responses, still on treatment 3. DCR defined as patients with a complete response (CR), partial response (PR) confirmed and unconfirmed, or stable disease (SD)		

Biomarker Expression

Phase 1b ORR Combination Data by Status Based on patients in the dose escalation and dose expansion cohorts		
Dose level	**8 mg/kg**	**12 mg/kg**
PD-L1 ≥1	74 (17/23)	75 (12/16)
PD-L1 <1	100 (3/3)	70 (7/10)
CLDN18.2 ≥75%	76 (13/17)	67 (8/12)
CLDN18.2 <75 %	78 (7/9)	79 (11/14)
Note: For patients with low PD-L1 and low CLDN18.2 the ORR was 83% (5/6)		

Durability of Response Data

Phase 1b PFS Combination Data in Efficacy Evaluable Patients Based on patients in the dose escalation and dose expansion cohorts		
Dose level	**8 mg/kg**	**12 mg/kg**
Enrolled patients	**27**	**27**
Efficacy evaluable patients (n)	**26**	**27[1]**
Median follow-up (month)	**10.7**	**6.8**
Events n (%)	12 (46%)	5 (19%)
Censored n (%)	14 (54%)	22 (81%)

Median PFS (mo., 95% CI)	**16.9 (6.8, NA)**	**7.7 (6.9, NA)**
6-month PFS rate (95% CI)	**73%** (51.7, 86.2)	**91%** (69.0, 97.7)
DOR (month, 95% CI)	**15.2** (5.6, NA)	NA
Patients remaining on study	**11**	**18**
Footnotes: 1. The 12 mg/kg cohort includes one additional patient for survival analysis who was ineligible for response analysis		

Safety: Consistent with previously reported results; incidence of TEAE, TRAE and SAE comparable to 1L combinations in relevant GC benchmark studies (CHECKMATE-649 and SPOTLIGHT), with no dose dependence in TRAE

- Common TRAEs (≥15% of patients in either dose) due to any drug were fatigue, nausea, neutropenia, observed in the majority of patients in each cohort. Grade 3 incidence was low in each cohort (listed as a percentage for 8 mg/kg and 12 mg/kg, respectively): fatigue (7%, 11%), nausea (7%, 4%), and neutropenia (26%, 26%)
- Most common givastomig-related TRAEs (>10% of patients in either dose): nausea, vomiting, and fatigue, all of which had a Grade 3 incidence of ≤11%
- Immune-related gastritis was observed in 33% of patients in each cohort (Grade 3 in 4% of patients dosed at 8 mg/kg and 15% of patients dosed at 12 mg/kg):
    - Gastritis was not observed in the monotherapy Phase 1 study of givastomig and infrequently observed with nivolumab and chemotherapy
    - Most commonly occurred after several cycles of therapy, was documented via endoscopy, and was managed with medications and treatment interruption
- Patients developing gastritis were observed to have improved ORR, PFS and OS compared to patients who did not develop gastritis
- Only Grade 4 TRAE was neutropenia (4% at 8 mg/kg and 7% at 12 mg/kg)
- No Grade 5 TRAEs were reported

Business Update with Leerink Partners
Leerink Partners (Leerink) will host a NovaBridge Business Update on Tuesday, January 6, 2026 at 8:30 AM ET. Interested investors should contact their Leerink representative to join.

Business Update with CITIC Securities
CITIC Securities (CITICS) will host a NovaBridge Business Update (in Chinese) on Wednesday, January 7, 2026 at 9:00 AM HKT. Interested investors should contact their CITICS representative to join.

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 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 large, randomized, dose-ranging Phase 2 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, ulileldimab, 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 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.

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