NovaBridge Biosciences Reports Mature Phase 1b Data at ESMO 2026 Positioning Givastomig for Registrational Development

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Nearly 18 months of median follow-up, selection of the 8 mg/kg dose and FDA engagement strengthen the foundation for registrational development in first-line metastatic gastroesophageal adenocarcinoma

- Updated Phase 1b dataset provides nearly 18 months of median follow-up and shows the durability of clinical benefit observed with givastomig
- Clinical activity observed across CLDN18.2 expression levels, including in patients with lower-expression tumors not eligible for currently approved CLDN18.2-targeted therapies
- Totality of efficacy, safety and long-term follow-up data supports selection of the 8 mg/kg dose for registrational development
- Ongoing U.S. Food and Drug Administration (FDA) interactions, Orphan Drug Designation, Fast Track Designation and progress on Phase 3 planning further support a defined path towards registrational development
- NovaBridge to host investor webcast on November 2, 2026, to discuss the updated data and registrational development strategy

ROCKVILLE, Md., Oct. 25, 2026 (GLOBE NEWSWIRE) -- NovaBridge Biosciences (“NovaBridge” or “Company”) (Nasdaq: NBP) today announced the presentation of updated results from the ongoing Phase 1b study of givastomig, a CLDN18.2 x 4-1BB bispecific antibody, in combination with nivolumab and chemotherapy for patients with HER2-negative first-line metastatic gastroesophageal adenocarcinoma. The results were presented at the European Society for Medical Oncology (ESMO) Congress 2026 in Madrid, Spain.

Updated Clinical Dataset Strengthens Foundation for Registrational Development
The updated analysis includes data through August 6, 2026 and provides the most comprehensive assessment of givastomig generated to date. The dataset includes 71 patients across the 8 mg/kg and 12 mg/kg dose cohorts with nearly 18 months of median follow-up in the 8 mg/kg dose cohort and provides a more mature assessment of givastomig's clinical profile, substantially increasing confidence in the durability and consistency of clinical benefit while informing dose selection and registrational planning.

Among efficacy-evaluable patients treated at the selected 8 mg/kg dose:

- Objective response rate of 79% (23/29)
- Disease control rate of 97% (28/29)
- Median duration of response of 15.2 months
- Median progression-free survival of 16.9 months
- Median follow-up of 17.8 months

Clinical activity was observed across CLDN18.2 expression levels, including:

- Objective response rate of 82% in patients with CLDN18.2 expression ≥75%
- Objective response rate of 75% in patients with CLDN18.2 expression between 1% and 74%

“These updated data provide greater confidence in the durability of clinical benefit observed with givastomig and are encouraging given the persistent need for more effective first-line treatment options for patients with metastatic gastroesophageal adenocarcinoma,” said Samuel J. Klempner, M.D., Associate Professor of Medicine at Massachusetts General Hospital. “What stands out in the updated analysis is not only the durability of benefit with longer follow-up, but also the strength and consistency of efficacy results across a broad range of CLDN18.2 expression, including very low expression. The updated dataset provides a more mature view of givastomig’s activity and supports its continued advancement to a Phase 3 trial.”

Selected 8 mg/kg Dose Demonstrates Durable Activity and Manageable Safety
A key objective of the Phase 1b program was to identify the dose with the most appropriate overall benefit-risk profile for registrational development. Based on the totality of efficacy, safety and long-term follow-up data, NovaBridge selected the 8 mg/kg dose for the next stage of givastomig’s development.

The safety profile of givastomig in the updated analysis from the ongoing Phase 1b study remained manageable and generally

consistent with previous observations. No Grade 4 or Grade 5 treatment-related adverse events were attributed to givastomig. Immune-related adverse events were uncommon, other than gastritis, the majority of which were Grade 2 events. The selected 8 mg/kg dose demonstrated a favorable overall benefit-risk profile and provides a strong foundation for registrational development.

Mature Phase 1b Dataset and FDA Engagement Support Registrational Development
Over the past year, NovaBridge has substantially expanded the clinical dataset for givastomig, gained a more mature understanding of the durability and safety profile of givastomig, selected the 8 mg/kg dose for potential registrational development, and achieved alignment with the FDA on a global registrational study protocol. Combined with the program's Orphan Drug Designation and Fast Track Designation, these accomplishments support NovaBridge's view that givastomig has evolved into a registrational-ready program.

NovaBridge's engagement with the FDA has informed key elements of the planned Phase 3 strategy, including the intended patient population, dose, and primary endpoints. Together with the more mature clinical dataset and regulatory designations, NovaBridge believes this progress establishes a clear regulatory pathway for registrational development of givastomig.

"The updated dataset provides a more mature view of givastomig's clinical profile, including longer follow-up, greater insight into durability and safety, and increased confidence in the 8 mg/kg dose, which has been selected for registrational development," said Phillip Dennis, M.D., Ph.D., Chief Medical Officer of NovaBridge. "Over the past year, we have significantly strengthened the clinical and regulatory foundation for the program through continued dataset maturation, dose selection, and productive engagement with the FDA, culminating in alignment on a Phase 3 study design. Together with the program's Orphan Drug and Fast Track Designations, we believe these advances position givastomig as a registrational-ready program."

"The maturation of the givastomig dataset over the past year has significantly increased our confidence in the program," said Srishti Gupta, M.D., M.P.P., Chief Executive Officer of NovaBridge. "The updated efficacy, durability and safety findings, together with productive interactions with the FDA and important regulatory milestones, have advanced givastomig into a late-stage development program. We believe this represents an important inflection point for givastomig and its potential to make a meaningful difference for patients with metastatic gastroesophageal adenocarcinoma."

ESMO Congress 2026 Presentation Materials and Supplemental Data
The ESMO Congress 2026 poster presentation and supplemental analyses based on the August 2026 data cutoff are available on NovaBridge's investor relations website and can be accessed here.

NovaBridge to Host Webcast to Discuss Updated Givastomig Data and Path to Registrational Development
NovaBridge will host a webcast on November 2, 2026, at 8:00 a.m. ET to discuss the updated results presented at ESMO, the clinical rationale for selection of the 8 mg/kg dose and the implications of the mature Phase 1b dataset for givastomig's registrational readiness. The event will feature Samuel J. Klempner, M.D., Associate Professor of Medicine at Massachusetts General Hospital, who will discuss the clinical significance of the updated data, the unmet need in first-line gastric and gastroesophageal cancers, and the potential role of givastomig in CLDN18.2-positive disease. Company management will also discuss the maturation of the clinical dataset, regulatory progress, ongoing FDA interactions and the considerations informing future development planning for the program. A question-and-answer session will follow the formal presentations.

Webcast Details
Title: Givastomig: Mature Clinical Data and Path to Registrational Development
Date: November 2, 2026
Time: 8:00 a.m. EST
Featured Speaker: Samuel J. Klempner, M.D., Associate Professor of Medicine at Massachusetts General Hospital and lead investigator of the Phase 1b givastomig study
Format: Live webcast followed by Q&A
Registration and webcast details are available on the Investor Relations section of the NovaBridge website and can be accessed here.

About Givastomig
Givastomig (TJ033721 / ABL111), a potential first-in-class Conditional T-cell Engager and Immune Amplifier (CTIA), is a Claudin 18.2 x 4-1BB bispecific antibody. 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 for the potential treatment of gastroesophageal carcinoma, its current lead indication. Givastomig also has potential applicability across other Claudin 18.2-positive gastrointestinal malignancies, including biliary tract cancer and pancreatic ductal adenocarcinoma.

Givastomig is being evaluated in a global, randomized Phase 2 study (NCT07432295), following positive topline results from a Phase 1b, multicenter, open-label study in first-line metastatic gastroesophageal carcinoma. The U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to givastomig for the treatment of previously untreated HER2-negative advanced or metastatic gastroesophageal adenocarcinoma in combination with nivolumab and chemotherapy.

About NovaBridge Biosciences
NovaBridge Biosciences ("NovaBridge") (NASDAQ: NBP) is a global biotechnology company focused on identifying, developing and maximizing the value of differentiated therapeutic assets. The Company advances programs through clinical development and pursues the financing and partnering strategies best suited to each opportunity.

NovaBridge's portfolio is led by givastomig, a Claudin 18.2 × 4-1BB bispecific antibody being developed for the potential treatment of gastrointestinal malignancies, and Visara, its majority-owned ophthalmology subsidiary. Through Visara, NovaBridge is building a diversified ophthalmology franchise designed to address unmet needs across diseases of the front and back of the eye.

NovaBridge's objective is to build a sustainable biotechnology company by repeatedly identifying differentiated innovation, advancing it efficiently, and bringing novel therapies to patients through the path best suited to each opportunity.

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," "look forward to," 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 potential benefits of givastomig, including the reproducibility and durability of any favorable results initially seen in patients dosed to date in clinical trials; the potential of FDA interactions, Orphan Drug Designation, Fast Track Designation and progress on Phase 3 planning for givastomig to result in a defined path towards registrational development; the selection of the 8 mg/kg dose and its implications for registrational development; NovaBridge's engagement with the FDA, including alignment on a global registrational study protocol and Phase 3 study design;; and 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 or eligibility for accelerated approval pathway or receipt of accelerated approval; the content and timing of decisions made by the relevant regulatory authorities, including the FDA, 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; the impact of macroeconomic conditions, including inflation, tariffs, volatile interest rates, regulatory uncertainty, potential government shutdowns, volatility in the capital markets, and regional and other global events, including ongoing armed conflicts in different regions of the world; 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 7, 2026, and amended on June 16, 2026, 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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