NovaBridge Biosciences Receives FDA Fast Track Designation for Givastomig in First-Line HER2-Negative Metastatic Gastric Cancer

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- Registrational Phase 3 Trial Expected to Begin as Early as Q4 2026
- Detailed Phase 1b Data Expected to be Presented at a Major Medical Conference in H2 2026

ROCKVILLE, Md., June 16, 2026 (GLOBE NEWSWIRE) -- NovaBridge Biosciences (Nasdaq: NBP) (NovaBridge or the Company) a global biotechnology platform company committed to accelerating access to innovative medicines that address significant unmet needs, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to givastomig in combination with nivolumab and chemotherapy for the treatment of patients with previously untreated HER2-negative advanced or metastatic gastroesophageal adenocarcinomas (GEA) whose tumors are both Claudin 18.2 (CLDN18.2) and PD-L1 positive. Givastomig is a novel CLDN18.2 x 4-1BB bispecific antibody.

Phase 1b data demonstrated compelling efficacy and tolerability for givastomig in combination with immunochemotherapy, supporting its potential as a premier CLDN18.2-directed therapy for gastric cancer. Fast Track Designation is intended to accelerate development and review of therapies for serious conditions with unmet medical need.

“Fast Track Designation is a valuable step forward for givastomig and for patients with first-line HER2-negative metastatic gastric cancer," said **Phillip Dennis, MD, PhD, Chief Medical Officer of NovaBridge**. "Phase 1b results demonstrate robust efficacy and favorable overall tolerability in combination with immunochemotherapy. Responses were deep and durable across a broad patient population, with marked improvement relative to historical benchmarks for the standard of care. Fast Track Designation, combined with FDA's prior confirmation of accelerated approval pathway eligibility, enables a more efficient path to a registrational Phase 3 trial, reflecting givastomig's promise as a first-in-class and best-in-class CLDN18.2-directed therapy for gastric cancer. We look forward to ongoing dialog with the FDA to bring givastomig to patients as quickly as possible.”

About Fast Track Designation

Fast Track Designation is an FDA process designed to facilitate the development and expedite the review of new therapies intended to treat serious or life-threatening conditions that demonstrate the potential to address an unmet medical need. Drugs receiving Fast Track Designation may benefit from more frequent interactions with the FDA throughout the development process. Programs receiving Fast Track Designation may also be eligible for Rolling Review of the regulatory submission, Priority Review, and Accelerated Approval, if relevant criteria are met.

About Givastomig

Givastomig (TJ033721 / ABL111) is a CLDN 18.2 X 4-1BB bispecific antibody targeting Claudin 18.2 (CLDN18.2)-positive (CLDN 18.2+) 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+ gastrointestinal malignancies. In Phase 1 trials, givastomig has shown promising anti-tumor activity attributable to a potential synergistic effect of the 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 first-in-class and best-in-class, Claudin 18.2 X 4-1BB bispecific antibody, and VIS-101, a purpose-designed, potential best-in-class, dual VEGF-A X ANG-2 inhibitor.

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 ulileDlimab, an anti-CD73 antibody that targets adenosine-driven immunosuppression in cancer.

VIS-101 targets VEGF-A and ANG-2 to provide more rapid, robust and durable treatment responses for patients with retinal vascular diseases including wet age-related macular degeneration, diabetic macular edema, and retinal vein occlusion. VIS-101 has completed a randomized, dose-ranging Phase 2a study for wet AMD and expects to initiate a dose-determining Phase 2b study in H2 2026. NovaBridge is the majority shareholder of Visara, Inc., 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," "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 strategy, clinical development, regulatory strategy and designations, including Fast Track Designation, plans, results, safety and efficacy for givastomig, VIS-101 and its other drug candidates; the strategic and clinical development of NovaBridge's drug candidates, including givastomig, VIS-101, ragistomig, and ulileDlimab; 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 or achievement of Accelerated Approval Pathway; 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 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

Bill Begien, VP, Investor Relations
+1-240-745-6330
bill.begien@novabridge.com
IR@novabridge.com

Jessica Zhang, Director, Public Relations
jessica.zhang@novabridge.com

NovaBridge