Compass Therapeutics Provides Regulatory Update on Tovecimig in Biliary Tract Cancer Following FDA Feedback

September 22, 2026

- *The FDA recommended that Compass conduct a trial to demonstrate a survival benefit prior to submitting a BLA for tovecimig.*
- *Compass does not believe that a new trial is warranted prior to submitting a BLA based on the data from the Phase 2/3 COMPANION-002 study and the urgent unmet medical need for patients with BTC.*
- *Compass intends to further engage with the FDA as we continue to prepare a BLA submission for tovecimig.*
- *Compass remains confident in tovecimig based on the positive results from COMPANION-002, including the statistically significant improvements in ORR and PFS.*

BOSTON, Sept. 22, 2026 (GLOBE NEWSWIRE) -- Compass Therapeutics, Inc. (Nasdaq: CMPX), a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics to treat multiple human diseases, today announced that the U.S. Food and Drug Administration (FDA) recommended that Compass conduct a trial demonstrating a survival benefit before proceeding with a Biologics License Application (BLA) submission for tovecimig in patients with previously treated, advanced biliary tract cancer (BTC).

BTC is an aggressive, life-threatening cancer with poor survival outcomes, and effective options remain limited for patients who have received prior treatment, underscoring the urgent need for new approaches.

As previously disclosed, in the positive Phase 2/3 COMPANION-002 study, tovecimig plus paclitaxel demonstrated a statistically significant improvement in the primary endpoint of objective response rate (ORR) of 18.0% vs. 5.3% with paclitaxel alone (p=0.0228) and a highly significant improvement in progression-free survival (PFS) in patients with BTC who had received prior treatment. Median PFS was 4.7 vs. 2.6 months with a hazard ratio of 0.44 (p<0.0001), representing a compelling 56% reduction in the risk of disease progression. Overall survival (OS) analyses were confounded by both high crossover and notably prolonged survival in crossover patients randomized to the control arm then treated with tovecimig and, therefore, did not meet statistical significance. The safety profile was generally consistent with previously reported data from prior tovecimig studies.

“While this is not the response we expected, we respect the FDA’s feedback and our priority is to work with the Agency to determine the best path forward to support our planned BLA submission and address this pressing unmet need,” said Thomas Schuetz, M.D., Ph.D., Chief Executive Officer of Compass. “We remain confident that the COMPANION-002 findings, including the statistically significant improvements in PFS and ORR combined with subset analyses on survival, demonstrate clinically meaningful activity in patients with previously treated, advanced BTC.”

About Tovecimig
Tovecimig is an investigational DLL4 x VEGF-A bispecific antibody designed to block two angiogenic pathways simultaneously, representing a first-in-class approach to disrupting tumor angiogenesis. In COMPANION-002, tovecimig was evaluated in combination with paclitaxel in patients with previously treated, advanced biliary tract cancer. Tovecimig has received Fast Track and Orphan Drug Designation from the U.S. Food and Drug Administration.

About Compass Therapeutics
Compass Therapeutics is a clinical-stage, oncology-focused biopharmaceutical company dedicated to transforming the standard of care for patients with cancer through the discovery and development of innovative antibody-based therapeutics. The company leverages deep expertise in tumor biology and proprietary antibody engineering technologies to develop differentiated therapies that target the intersection of angiogenesis, immune activation, and tumor-driven immunosuppression. Compass has a robust pipeline of novel product candidates designed to address significant unmet needs and improve outcomes for patients with cancer. The Company was founded in 2014 and is headquartered in Boston, Massachusetts. For more information, visit the Compass Therapeutics website at https://www.compasstherapeutics.com

Forward-Looking Statements
This press release contains forward-looking statements. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to Compass’s financial position to continue advancing its product candidates, expectations about cash runway, business and development plans, and statements regarding tovecimig, the results of the COMPANION-002 study, and the associated regulatory feedback, plans, and timelines, and the therapeutic potential thereof. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, Compass’s ability to raise the additional funding it will need to continue to pursue its business and product development plans, the inherent uncertainties associated with developing product candidates and operating as a development stage company, Compass’s ability to identify additional product candidates for development, Compass’s ability to develop, complete clinical trials for, obtain approvals for and commercialize any of its product candidates, competition in the industry in which Compass operates and market conditions. These forward-looking statements are made as of the date of this press release, and Compass assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents Compass files with the U.S. Securities and Exchange Commission (SEC) available at www.sec.gov, including without limitation Compass’s latest Annual Report on Form 10-K, Quarterly Report on Form 10-Q and subsequent filings with the SEC.

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