Tovecimig Demonstrates Statistically Significant Benefit in COMPANION-002 Randomized Phase 2/3 Study in Patients with Biliary Tract Cancer

April 27, 2026

- *Tovecimig (a DLL4 x VEGF-A bispecific antibody) in combination with paclitaxel demonstrated a highly statistically significant improvement versus paclitaxel alone in the key secondary endpoint of median progression-free survival (PFS) of 4.7 months versus 2.6 months, providing a 56% reduction in the risk of progression (hazard ratio=0.44, p<0.0001).*
- *Secondary endpoint analyses of overall survival (OS) were confounded by both high crossover (54%) and notably prolonged survival in crossover patients randomized to the control arm then treated with tovecimig and, therefore, did not meet statistical significance. In a subset analysis of the patients in the control arm, the median OS of the crossover patients was 12.8 months vs. 6.1 months in patients who did not crossover (hazard ratio=0.54, p=0.04).*
- *85% of patients in the study received tovecimig with a pooled median OS of 8.9 months.*
- *As previously disclosed, tovecimig in combination with paclitaxel met the primary endpoint of overall response rate (ORR) in the study with an ORR of 17.1% vs. 5.3% in the paclitaxel control arm (p=0.031).*
- *The Company looks forward to meeting with FDA in advance of a planned Biologics License Application (BLA) submission.*
- *Company to host webcast today, April 27, 2026 at 8:00 a.m. ET.*

BOSTON, April 27, 2026 (GLOBE NEWSWIRE) -- Compass Therapeutics, Inc. (Nasdaq: CMPX), a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics, today announced that it met the key secondary endpoint of PFS and showed additional compelling results in the randomized COMPANION-002 study, which evaluated tovecimig plus paclitaxel versus paclitaxel alone in patients with unresectable advanced, metastatic or recurrent biliary tract cancer (BTC) treated in the second-line setting. The complete dataset, including Duration of Response (DoR), will be presented at a medical conference later this year.

“In this study, tovecimig showed an impressive overall response rate which translated into a clinically meaningful and highly statistically significant improvement in PFS for patients with previously treated BTC. The remarkable 56% reduction in the risk of disease progression is unprecedented in this patient population without an actionable mutation in their tumor,” said Thomas Schuetz, MD, PhD, Chief Executive Officer of Compass. “It is also notable that the 31 crossover patients survived a median of 12.8 months, similar to the median OS seen in front-line studies in this setting. Including crossover, 85% of patients in the study received tovecimig in combination with paclitaxel and the pooled median OS for all patients in the study was 8.9 months, which is also substantially longer than chemotherapy benchmarks of approximately 6 months.”

“These findings reinforce our belief that tovecimig can address a significant unmet need for patients with limited and insufficient treatment options. We are immensely grateful to the patients, investigators, and clinical teams who made this study possible, and we look forward to presenting the full dataset at an upcoming medical meeting. We are now focused on engaging with the FDA to bring this much needed therapy to the cholangiocarcinoma community as quickly as possible.”

“Patients with advanced biliary tract cancer have an urgent need for better treatment options,” said Juan Valle, MD, Chief Medical Officer of the Cholangiocarcinoma Foundation. “These results are a significant step forward and I anticipate that, if approved, it will meaningfully change the way physicians care for these patients. I also applaud Compass for putting patients first in the design of this study by allowing patients to crossover to receive treatment with tovecimig. These patients clearly benefited from this innovative therapy. I look forward to supporting Compass as they work to bring tovecimig to patients with cholangiocarcinoma.”

COMPANION-002 Data Summary:

Primary Endpoint (previously announced in April 2025):

- **Overall Response Rate:** 17.1% ORR for tovecimig in combination with paclitaxel (19 of 111 patients) including one complete response, compared to 5.3% for paclitaxel alone (3 of 57 patients), in patients with BTC in the second line setting. This 11.8% improvement in ORR for those receiving tovecimig was statistically significant (p=0.031). All responses were assessed by blinded independent central review (BICR).

Key Secondary Endpoints:

- **Progression-Free Survival (PFS):** Tovecimig in combination with paclitaxel demonstrated a statistically significant improvement in median PFS of 4.7 months compared to 2.6 months for paclitaxel alone (HR=0.44, p<0.0001). Progression was confirmed in each case by BICR.
- **Overall Survival (OS):** Tovecimig did not meet the OS secondary endpoint due to high crossover from the control arm (31 of 57 patients, or 54%) and prolonged survival of those crossover patients after receiving tovecimig, as further described below. As a result of this crossover, 85% (142 of 168) of patients in the study received tovecimig plus paclitaxel with a

pooled OS in the study of 8.9 months.

In the ITT OS analysis, tovecimig in combination with paclitaxel had a median OS of 8.9 months compared to 9.4 months for the control arm, which included 26 patients (46%) who received paclitaxel alone and 31 patients (54%) who crossed over to receive tovecimig in combination with paclitaxel (HR=1.05, p=0.78). In the rank-preserving structural failure time (RPSFT) OS analysis, the combination also had a median OS of 8.9 months compared to 9.4 months for paclitaxel alone (HR=1.13, p=0.65). Though the RPSFT analysis is intended to adjust for crossover, its validity depends on certain assumptions that were not met in this study and thus its results here are largely uninterpretable.

- **Progression-Free Survival of Crossover Patients (PFS2):** An additional, pre-specified secondary endpoint analyzed PFS in the patients in the paclitaxel arm who crossed over to receive tovecimig plus paclitaxel. In this analysis, the pre-crossover PFS (PFS1) on paclitaxel alone was compared to PFS with tovecimig post-crossover (PFS2) in the same crossover patients (n=31). In this subset, tovecimig demonstrated a statistically significant improvement with median PFS2 of 3.5 months after treatment with tovecimig compared to median PFS1 of 1.9 months for paclitaxel (HR=0.36, p=0.0016).

Post Hoc Subset Analyses:

- **OS of Paclitaxel Control Arm (Crossover vs. Non-Crossover):** In an analysis of OS in all patients randomized to the paclitaxel control arm (n=57), crossover patients who subsequently received tovecimig demonstrated a statistically significant improvement in median OS of 12.8 months compared to 6.1 months for non-crossover patients who received only paclitaxel (HR=0.54, p=0.04).
- **PFS of Paclitaxel Control Arm (Crossover vs. Non-Crossover):** Another analysis of these same patients randomized to the paclitaxel control arm (n=57) demonstrated that the crossover patients initially progressed faster on paclitaxel monotherapy compared to the non-crossover patients, with a median PFS of 1.9 months versus 3.6 months (HR=2.31, p=0.007). Thus, notably, despite progressing more quickly on initial paclitaxel monotherapy, crossover patients still demonstrated a statistically significant median 12.8 months OS after being treated with tovecimig.

Safety:

- Tovecimig was generally well tolerated and the safety profile was consistent with previously reported data from prior studies, with no new safety signals. The most commonly reported treatment emergent adverse events in the tovecimig combination arm were hypertension (69%) and fatigue (67%). The most common related treatment-emergent adverse events of Grade 3 or higher included hypertension (44%) and neutropenia (36%).

BTC is estimated to affect approximately 26,500 patients annually in the United States. For the vast majority of patients with BTC whose tumors do not harbor an actionable mutation with an approved targeted therapy, there is currently no FDA-approved treatment in the second line setting. The therapeutics most commonly used in this setting, which are not labeled or approved by the FDA for the treatment of patients with BTC, generally have an ORR of ~5% or less and patients face a median OS of approximately six months.

In the coming months, Compass intends to meet with the U.S. Food and Drug Administration (FDA) to discuss these data in advance of a planned BLA submission.

Webcast Information
Compass will host a webcast today, Monday, April 27, 2026 at 8:00 a.m. ET to provide a review of the tovecimig secondary endpoints COMPANION-002 data. Interested parties may register for the call-in advance via https://viavid.webcasts.com/starthere.jsp?ei=1761459&tp_key=efc315f5a6.

A replay of the webcast will be available via the Investors section of the Compass website at investors.compasstherapeutics.com.

About COMPANION-002
COMPANION-002 is a Phase 2/3 randomized, controlled study of tovecimig in patients with unresectable advanced, metastatic or recurrent biliary tract cancers who have received one prior systemic chemotherapy regimen (clinical trial information: NCT05506943). The study enrolled 168 adult patients, randomized in a 2:1 ratio to receive tovecimig plus paclitaxel (n=111) or paclitaxel alone (n=57). All patients were dosed with 80 mg/m2 of paclitaxel on days 1, 8 and 15 of every 28-day cycle. Patients in the tovecimig arm were also dosed with 10 mg/kg of tovecimig on days 1 and 15 of each 28-day cycle. The primary endpoint of the trial is ORR as confirmed by blinded independent central radiology review and secondary endpoints include PFS, OS, and DoR, among others. Patients in the paclitaxel-only arm who progressed could cross over to the tovecimig plus paclitaxel arm after centrally confirmed progression if they also still met the enrollment criteria for the study.

About Tovecimig (CTX-009)
Tovecimig is an investigational bispecific antibody that is designed to simultaneously block Delta-like ligand 4 (DLL4) and vascular endothelial growth factor A (VEGF-A) signaling pathways, which are critical to angiogenesis and tumor vascularization. Preclinical and clinical data of tovecimig suggest that blockade of both pathways provides robust anti-tumor activity across several solid tumors, including colorectal, gastric, cholangiocarcinoma, pancreatic and non-small cell lung cancer.

About Compass Therapeutics
Compass Therapeutics, Inc. was founded in 2014 and is headquartered in Boston, MA. Compass is a clinical-stage, oncology-focused biopharmaceutical company discovering and developing proprietary antibody-based therapeutics to treat multiple diseases. The company's scientific focus is on the relationship between angiogenesis, the immune system and tumor growth. Compass has a robust pipeline of novel product candidates

designed to target multiple key biological pathways to drive an effective anti-tumor response, including angiogenesis modulation, immune activation within the tumor microenvironment, and reduction of tumor-driven immunosuppression. The company is advancing discovery candidates through clinical development to commercial-stage assets. For more information, visit 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, statements regarding Compass's product candidates, including the potential of tovecimig to provide a treatment option for patients with BTC in the second-line setting, additional results of the COMPANION-002 study, and the timing and nature of any regulatory interactions and subsequent approval pathways, including Compass's intention to discuss the data in the COMPANION-002 Randomized Phase 2/3 Study with the FDA in advance of a planned BLA submission, and the expectation to present the complete dataset at a medical conference this year. 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 and subsequent filings with the SEC.

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