Compass Therapeutics Announces Publication of Phase 2/3 COMPANION-002 Results for Tovecimig in the Journal of Clinical Oncology and Oral Presentation at ESMO 2026

October 24, 2026

- *As published in the Journal of Clinical Oncology (JCO) and presented at ESMO, COMPANION-002 met its primary endpoint of ORR and key secondary endpoint of PFS, with a 56% reduction in the risk of disease progression or death.*
- *Responses were durable, with a median duration of response (DOR) of 4.9 months, and disease control rate (DCR) was also significantly improved (62.2% vs. 36.8%).*
- *A new, post hoc analysis of overall survival (OS) included in the JCO publication uses the Two-Stage Estimation, an established method for adjusting for crossover, and demonstrates an OS hazard ratio of 0.85 (95% CI, 0.59–1.26; p=0.53).*
- *Safety profile was consistent with prior tovecimig studies and the anti-VEGF class, with no new safety signals identified.*

BOSTON, Oct. 24, 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 the publication of results from the positive Phase 2/3 COMPANION-002 study of tovecimig in combination with paclitaxel in patients with previously treated, advanced biliary tract cancer (BTC) in the *Journal of Clinical Oncology* (JCO). The results are also being presented today by Nilofer S. Azad, M.D., Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, at the 2026 European Society for Medical Oncology (ESMO) Congress in Madrid, Spain. The full publication is available via open access at https://ascopubs.org/toc/jco/0/ja.

COMPANION-002 is a randomized Phase 2/3 study that evaluated tovecimig plus paclitaxel versus paclitaxel alone in 168 patients with advanced BTC who had received one prior therapy. As previously reported, and now published following peer review, the study met its primary endpoint, with tovecimig plus paclitaxel demonstrating a statistically significant improvement in ORR of 18.0% vs. 5.3% with paclitaxel alone (p=0.0228) evaluated by blinded independent central review (BICR). The study also met its key secondary endpoint of PFS with a median PFS of 4.7 vs. 2.6 months (HR=0.44, p<0.0001), representing a 56% reduction in the risk of disease progression or death.

Key findings from COMPANION-002 include:

- **Duration of response and disease control:** Responses with tovecimig plus paclitaxel lasted a median of 4.9 months. The disease control rate, which includes patients whose cancer responded or remained stable, significantly improved at 62.2% vs. 36.8% with paclitaxel alone (p=0.0018).
- **Intrahepatic cholangiocarcinoma subgroup:** Patients with intrahepatic cholangiocarcinoma (cancer of the bile ducts inside the liver), a prespecified subgroup, made up more than half of the study population (92 of 168). In these patients, results were consistent with the overall study population, with an ORR of 15.3% vs. 0% (p=0.0258) and median PFS of 5.1 vs. 3.0 months (HR=0.32).
- **Overall survival (OS) and crossover-adjusted analysis:** Patients in the paclitaxel arm could cross over to tovecimig plus paclitaxel arm after BICR-confirmed progression. 31 of 57 (54%) patients crossed over, resulting in 85% of all patients in the study (142 of 168) ultimately receiving tovecimig. The intent-to-treat OS analysis was confounded by the high rate of crossover and no statistically significant difference in OS was observed. To estimate the treatment effect if crossover had not occurred, the JCO publication includes a post hoc exploratory analysis using the Two-Stage Estimation, an established method for adjusting for crossover, in which the OS hazard ratio was 0.85 (95% CI, 0.59–1.26; p=0.53).
- **Outcomes in crossover patients:** Among the 31 patients who crossed over, median PFS after the addition of tovecimig to paclitaxel, a prespecified secondary endpoint, was 3.5 months, compared with 1.9 months during their initial treatment with paclitaxel alone (HR=0.40, p=0.0035). In a post hoc exploratory analysis, these patients who crossed over to receive tovecimig had a median OS of 12.8 months, compared with 6.1 months for control-arm patients who did not cross over (HR=0.54, p=0.04), even though crossover patients had progressed more quickly on initial paclitaxel treatment. These crossover comparisons were not randomized and are exploratory.
- **Safety:** The safety profile was generally manageable and consistent with prior tovecimig studies and the anti-VEGF class, with no new safety signals identified. The most common treatment-emergent adverse events (TEAEs) in the combination arm were hypertension (69%) and fatigue (67%). Grade 3 or higher TEAEs occurred in 93.5% of patients in the combination arm and 64.2% of patients who received paclitaxel alone. TEAEs leading to overall treatment discontinuation occurred in 27.8% and 11.3%, respectively, and were mostly consistent with known anti-angiogenic and chemotherapy toxicities. No hypertensive crises or unexpected severe cardiovascular toxicities were observed. TEAEs leading to death occurred in 5.6% and 1.9% of patients, respectively.

“COMPANION-002 is an important, randomized study in patients with previously treated, advanced biliary tract cancer,” said Dr. Azad. “The significant

improvements in response rate and progression-free survival, together with the durability of responses and disease control, are encouraging for patients in this setting. We also saw activity in patients who switched to tovecimig after their disease progressed on paclitaxel alone, which is notable in a setting where disease often progresses quickly."

"Publication of the COMPANION-002 results in the *Journal of Clinical Oncology* following independent peer review is a significant milestone for patients with BTC," said Thomas Schuetz, M.D., Ph.D., Chief Executive Officer of Compass. "These data, including the new two-stage estimation adjusting for the crossover impact on overall survival, strengthen our conviction that tovecimig has the potential to make a meaningful difference for patients with previously treated, advanced biliary tract cancer who have few treatment options. We are determined to bring tovecimig to these patients and will continue working with the FDA toward that goal."

Additional analyses from COMPANION-002, including patient-reported quality of life and translational research, are ongoing and will be reported separately.

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. Tovecimig remains investigational and has not been approved by the FDA.

About Biliary Tract Cancer
BTC is an aggressive, life-threatening cancer 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 therapies 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 approximately 5% or less.

About COMPANION-002
COMPANION-002 (NCT05506943) is a randomized, controlled Phase 2/3 study of tovecimig in patients with unresectable advanced, metastatic or recurrent BTC who received one prior systemic chemotherapy regimen. The study randomized 168 patients 2:1 to tovecimig plus paclitaxel (n=111) or paclitaxel alone (n=57). The primary endpoint was ORR by blinded independent central review; secondary endpoints included PFS, OS and duration of response.

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 in clinical development 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 Compass's product candidates, including their development and clinical trial milestones such as the expected trial design, timing of enrollment, patient dosing and data readouts, regulatory plans with respect to Compass's product candidates 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.*

Investor Contact
ir@compasstherapeutics.com

Media Contact
Anna Gifford, Chief of Staff
media@compasstherapeutics.com
617-500-8099