Tovecimig (CTX-009) Meets Primary Endpoint in the Ongoing Randomized Phase 2/3 Study in Patients with Biliary Tract Cancer

April 1, 2025

- *Tovecimig (a DLL4 x VEGF-A bispecific antibody) in combination with paclitaxel achieved a 17.1% overall response rate (ORR), including one complete response, compared to 5.3% ORR for paclitaxel alone, in patients with biliary tract cancer (BTC) treated in the second-line setting.*
- *The difference in ORR between the two treatment arms, the primary endpoint of the study, was statistically significant (p=0.031), and all responses have been confirmed by blinded independent central radiology review.*
- *The study also showed differences between treatment arms for other efficacy measures, including progressive disease (PD) rates of 16.2% in patients on tovecimig in combination with paclitaxel versus 42.1% in patients on paclitaxel alone.*
- *The pre-specified number of events required to trigger the analyses of the secondary endpoints, including progression free survival (PFS), overall survival (OS) and duration of response (DoR), has not yet been met due to fewer of these events occurring than were originally modeled. The Company expects to report these endpoints in Q4 of this year.*
- *Company to host webcast today, April 1, 2025 at 8:00 a.m. ET.*

BOSTON, April 01, 2025 (GLOBE NEWSWIRE) -- Compass Therapeutics, Inc. (Nasdaq: CMPX), a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics, announced statistically significant top-line data on the primary efficacy endpoint for COMPANION-002, the Company's ongoing Phase 2/3 randomized trial of tovecimig (formerly CTX-009) in combination with paclitaxel in patients with advanced BTC.

"We are thrilled to share these positive primary endpoint data from the COMPANION-002 study of tovecimig in patients with advanced biliary tract cancer," said Thomas Schuetz, MD, PhD, CEO of Compass and Vice Chairman of the Board of Directors. "We would like to thank all of the patients and their caregivers who have participated and continue to participate in this study. We believe these findings highlight the potential of tovecimig to provide a much-needed treatment option for the majority of patients with BTC who have limited alternatives after first-line therapy. We look forward to discussing these data with regulatory authorities."

"As a treating clinician for over 20 years, I have seen firsthand how challenging a disease biliary tract cancer is. Patients currently have very limited treatment options, with the vast majority in the second-line setting having no approved therapeutic alternative whatsoever. For every statistic there is a person – a mother, father, relative, or friend – fighting for more time. Each investigative trial helps in this fight to advance new treatment options, and I look forward to following tovecimig's continued progress," said Juan Valle, MD, Chief Medical Officer of the Cholangiocarcinoma Foundation.

Biliary tract cancer is estimated to affect approximately 23,000 patients annually in the United States. For the approximately 85% 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 combinations of therapeutics used in this setting, which are not labeled for this indication, generally have an ORR of ~5% or less and patients face a median overall survival of approximately six months.

COMPANION-002 (tovecimig + paclitaxel versus paclitaxel alone): Top-Line Results

The trial 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. 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/m^2 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 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.

Top-line results of the study are summarized below, and the Company expects to announce additional data, including key secondary endpoints, in Q4 2025:

- **Primary Endpoint (ORR as confirmed by independent central radiology review).** 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% relative improvement in ORR for those receiving the combination was statistically significant (p=0.031).

		Tovecimig + Paclitaxel	Paclitaxel
Intent-to-Treat Population		n=111	n=57
Overall Response Rate (CR+PR)		19 (17.1%) (p=0.031)	3 (5.3%)
Best Overall Response n (%)	Complete Response (CR)	1 (0.9%)	0 (0.0%)
	Partial Response (PR)	18 (16.2%)	3 (5.3%)
	Stable Disease (SD)	49 (44.1%)	19 (33.3%)
	Non-CR / Non-PD*	9 (8.1%)	2 (3.5%)
	Progressive Disease (PD)	18 (16.2%)	24 (42.1%)
	Not Evaluable (NE)**	16 (14.4%)	9 (15.8%)

*Non-CR / Non-PD: patients enrolled based on local radiology scan results, but displayed no clearly definable target lesions as determined by independent central radiology.

** Not Evaluable: patients who did not receive a Week-8 scan.

- **Secondary Endpoints.** The COMPANION-002 study is ongoing and the data are not yet mature for the analyses of the secondary outcome measures (including PFS, OS and DoR). The trial requires a threshold of events in 80% of patients to trigger the secondary endpoint analyses. Based on current projections, the Company anticipates this pre-specified number of events to be reached in Q3 2025, and expects to report data from the secondary endpoints in Q4 2025.

- **Safety & Tolerability.** The safety profile of tovecimig in this study to date is consistent with prior studies of tovecimig. An independent Data Monitoring Committee (DMC) has reviewed safety data at four separate (pre-specified) DMC meetings and, after each meeting, recommended continuation of the study without modification. The Company expects to report detailed safety data with the analyses of secondary endpoints in Q4 2025.

Webcast Information
Compass Therapeutics will host a webcast today, Tuesday, April 1, 2025 at 8:00a.m. ET to provide a review of the tovecimig top-line COMPANION-002 data.

Interested parties may register for the call in advance via https://viavid.webcasts.com/starthere.jsp?ei=1712286&tp_key=3b05c5ebcd. A replay of the webcast will be available via the Investors section of the Compass website at investors.compasstherapeutics.com.

About Tovecimig (CTX-009)
Tovecimig is an investigational bispecific antibody that is designed to simultaneously blocks 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 early 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. Partial responses to tovecimig as a monotherapy have been observed in heavily pre-treated patients with cancer who were resistant to approved anti-VEGF therapies. COMPANION-002, a Phase 2/3 trial of tovecimig plus paclitaxel versus paclitaxel monotherapy in patients with previously treated, unresectable advanced metastatic or recurrent biliary tract cancers (BTC) is ongoing (clinical trial information: NCT05506943).

About Compass Therapeutics
Compass Therapeutics, Inc. is a clinical-stage oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics to treat multiple human diseases. Compass's scientific focus is on the relationship between angiogenesis, the immune system, and tumor growth. The Company's pipeline of novel product candidates is designed to target multiple critical biological pathways required for an effective anti-tumor response. These include modulation of the microvasculature via angiogenesis-targeted agents, induction of a potent immune response via activators on effector cells in the tumor microenvironment, and alleviation of immunosuppressive mechanisms used by tumors to evade immune surveillance. Compass plans to advance its product candidates through clinical development as both standalone therapies and in combination with proprietary pipeline antibodies based on supportive clinical and nonclinical data. 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, 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 and the timing of announcement of key secondary endpoints in the COMPANION-002 trial. 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.

Investor Contact

ir@compasstherapeutics.com

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