Compass Therapeutics Receives FDA Fast Track Designation for the Investigation of CTX-009 in Combination with Paclitaxel for the Treatment of Patients with Metastatic or Locally Advanced Biliary Tract Tumors That Have Been Previously Treated

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- CTX-009, the Company's bispecific DLL4/VEGF-A antibody, in combination with paclitaxel, has shown promising clinical responses in patients with advanced biliary tract cancer (BTC) in its Phase 2 study
- Top-line data readout for COMPANION-002, the Company's randomized Phase 2/3 BTC U.S. study, is expected by the end of 2024

BOSTON, April 25, 2024 (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) has granted Fast Track Designation (FTD) to CTX-009, the Company's bispecific DLL4/VEGF-A antibody, in combination with paclitaxel for the treatment of patients with metastatic or locally advanced BTC that have been previously treated.

"We are delighted that CTX-009 has received FDA Fast Track Designation highlighting the large unmet need in patients with advanced BTC where current therapies have low, single digit response rates, and limited effect on patient survival," said Thomas Schuetz, MD, PhD, Co-founder, President of R&D, and Vice Chairman of the Compass board. "Our current study is evaluating the combination of CTX-009 with paclitaxel following the observation of nine partial responses in 24 patients treated in our Phase 2 study, leading to an overall response rate of 37.5% (n= 9/24), a median progression free survival of 9.4 months and a median overall survival of 12.5 months. Compass remains on track to complete enrollment by mid-year and reporting top-line data by year end."

About CTX-009

CTX-009 is a bispecific antibody that 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 CTX-009 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 CTX-009 as a monotherapy have been observed in heavily pre-treated patients with cancer who were resistant to approved anti-VEGF therapies.

About Biliary Tract Cancers

Biliary tract cancers (BTC) are a group of aggressive gastrointestinal (GI) cancers that form in the cells of the bile ducts (cholangiocarcinoma), gallbladder, or ampulla of Vater (where the bile duct and pancreatic duct connect to the small intestine).

In the United States approximately 23,000 cases of BTC are diagnosed annually,[1] including cholangiocarcinoma, gallbladder, and ampullary subtypes. Only 10% of these patients present at an early stage when they would be candidates for surgical resection. The vast majority present with locally advanced or metastatic BTC, for which there are very few therapeutic options.[2]

[1]Marcano-Bonilla, L. et al, Chin Clin Oncol. 2016 Oct; 5(5):61, p.1-31.
[2]cancer.gov/types/liver/patient/bile-duct-treatment-pdq#_66.

About FDA Fast Track Designation

FTD is designed to help drugs reach patients faster by facilitating the development and expediting the review of drugs with the potential to fill an unmet medical need by treating a serious or life-threatening condition. Fast Track addresses a broad range of serious conditions. Programs that receive FTD benefit from early and frequent interactions with the FDA during the clinical development process, more frequent written communication from the FDA, and, if relevant criteria are met, the FDA may consider reviewing portions of a marketing application before the sponsor submits the complete biologics license application.

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 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, 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.*

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