Compass Therapeutics Announces that the Phase 2 Data of CTX-009 in Combination with Paclitaxel in Patients with Biliary Tract Cancers (BTC) will be Presented at the ASCO GI Cancers Symposium on January 20, 2023

January 19, 2023

Compass to Host Investor Event on Monday, January 23rd at 8:30am ET

- CTX-009 in combination with paclitaxel demonstrated a 37.5% overall response rate (ORR) in 24 patients with BTC treated in the second- and third- line settings; at least one response was observed in each of the four anatomical subtypes of BTC
- Sub-group analysis showed that an ORR of 63.6% was observed in the 11 patients treated in the second-line setting compared with an ORR of 14.9% in the 13 patients treated in the third-line setting
- Median progression free survival (PFS) was 9.4 months and median overall survival (OS) was 12.5 months
- Safety and tolerability of CTX-009 were consistent with prior studies
- Compass has initiated a randomized Phase 2/3 trial of CTX-009 in combination with paclitaxel in the U.S. in patients with BTC. Depending on study results, this study may support a biologics license application (BLA) submission in 2024

BOSTON, Jan. 19, 2023 (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 presentation of data from a Phase 2 study of CTX-009 in combination with paclitaxel in patients with biliary tract cancers (BTC). These data will be presented at the 2023 American Society of Clinical Oncology Gastrointestinal Cancers (ASCO GI) Symposium taking place in San Francisco, CA on January 20, 2023.

Data highlights from the poster presentation include:

- In the primary analysis of all 24 patients participating in the study, CTX-009 with paclitaxel demonstrated a 37.5% ORR based on 9 patients with Partial Responses (PRs) that were confirmed by RECIST 1.1. Importantly, of the 11 patients who had received one prior systemic therapy, 7 patients achieved a PR, leading to an ORR of 63.6% in this sub-group.

- After a median follow up of approximately 12 months, the median PFS was 9.4 months, and the median OS was 12.5 months. For reference, one regimen that has been studied in patients with advanced BTC is FOLFOX, the regimen recommended in the guidelines of the National Comprehensive Cancer Network (NCCN) for patients with BTC treated in the second-line setting. FOLFOX demonstrated a median PFS of 4.0 months and a median OS of 6.2 months in a randomized study against best supportive care.

- As the data continue to mature, safety and tolerability of CTX-009 in combination with paclitaxel remain consistent with previous studies. Treatment emergent adverse events (TEAEs) were observed in all patients, including those TEAEs related to the patients' disease and the two study drugs in the treatment regimen, paclitaxel and/or CTX-009. Grade 3 or greater TEAEs were reported in 95.8% of patients, including decreased neutrophil count (83.3%), hypertension (16.7%), anemia (20.8%) and decreased platelet count (12.5%).

  The poster presentation will be available in the Pipeline section of the Compass Therapeutics website at www.compasstherapeutics.com.

"We are very pleased to see the maturing data from this study, particularly the median progression free survival of greater than 9 months and median overall survival of 12.5 months supporting the durable effect of CTX-009 in this patient population," said Thomas Schuetz, M.D., Ph.D., Chief Executive Officer and Scientific Founder of Compass. "Given that patients with advanced BTC have a poor prognosis, have been heavily pre-treated, and have few treatment options, we are particularly enthused with these results."

"The results from the Phase 2 trial in BTC continue to show the potential of CTX-009, which has demonstrated activity in a broad range of solid tumors. We are presently enrolling patients in two clinical studies of CTX-009 in the United States and expect to report initial data from the colorectal study in the second half of this year," added Vered Bisker-Leib Ph.D., President and Chief Operating Officer of Compass.

Investor Event Details

Compass will host a webcast on Monday, January 23rd at 8:30am ET. Registration for the webcast or access to a replay of the call is available on the Company's website or by clicking here.

CTX-009 Phase 2 BTC Study Design

The Phase 2 study is being conducted at four leading medical centers in Korea and has a Simon Two-Stage adaptive design.

As of November 9, 2022, the data cut-off date, 24 patients were enrolled and dosed with at least one cycle of CTX-009 and paclitaxel. Of these patients, 22 were evaluable for response. Nearly all patients (23/24) received gemcitabine plus cisplatin as a first-line treatment. Among patients enrolled in the study, 45.8% of patients received one prior therapy and 54.2% received at least two prior therapies. Patients with all four BTC subtypes were enrolled in the study: intrahepatic cholangiocarcinoma (37.5%), extrahepatic cholangiocarcinoma (12.5%), gallbladder cancer (29.2%) and ampullary cancer (20.8%). Patients had a median age of 62.1 years and an ECOG performance status of 0 (54.2%) or 1 (45.8%).

CTX-009 Phase 2/3 BTC Study Design

Compass has initiated a randomized Phase 2/3 study of CTX-009 in combination with paclitaxel in the United States in patients with advanced BTC. The study will enroll up to 150 patients with BTC who have received no more than one prior systemic therapy and those patients will be randomized to CTX-009 in combination with paclitaxel or paclitaxel alone in a 2:1 ratio. Based upon regulatory feedback and depending upon the study results, this study potentially could support a biologics license application (BLA) submission as soon as H2 2024. The primary endpoint of the study is ORR as measured by RECIST 1.1. Secondary endpoints of the study include PFS, OS, Quality of Life and other measures.

Study details are on www.clinicaltrials.gov Identifier: NCT05506943

About CTX-009

CTX-009 is a bispecific antibody that simultaneously blocks Delta-like ligand 4/Notch (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 currently approved anti-VEGF therapies.

Compass holds the global rights to CTX-009 (also known as ABL001) with the exception of rights in Korea, held by Handok, Inc. (https://www.handok.co.kr/eng/) and rights in China, which were out-licensed to Elpiscience Biopharma, Ltd. (https://www.elpiscience.com/).

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 18,400 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] **seer.cancer.gov/statfacts/html/livibd.html**
[2] **cancer.gov/types/liver/patient/bile-duct-treatment-pdq#_66**

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. Compass'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. Compass was founded in 2014 and is headquartered in Boston, Massachusetts. For more information, visit the Compass Therapeutics, Inc. 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 product candidate, CTX-009, its development, regulatory plans with respect thereto and 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 SEC available at www.sec.gov, including without limitation Compass's latest Form 10-Q and subsequent filings with the SEC.

Investor Contact
Mario Corso, Investor Relations
ir@compasstherapeutics.com

Media Contact
Anna Gifford, Communications Manager
media@compasstherapeutics.com
617-500-8099

Source: Compass Therapeutics