Compass Therapeutics Reports Positive Interim Phase 2 Data of CTX-009 in Combination with Paclitaxel in Biliary Tract Cancers

May 4, 2022

*CTX-009 Demonstrated a **42% Overall Response Rate (ORR) Based on 10 Partial Responses (PRs)** in 24 Enrolled Patients*

CTX-009 Continues to be Well Tolerated, Consistent with the Phase 1 Studies

Compass Plans to Initiate Stage 2 of the Phase 2 Study in the U.S. in Q3 2022

Compass to Host Key Opinion Leader Webinar on May 4, 2022 at 8:00 a.m. ET

BOSTON, May 04, 2022 (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 reported additional interim results from a Phase 2 study of CTX-009 in combination with paclitaxel in patients with biliary tract cancers (BTC). The data show that:

- CTX-009 demonstrated a 42% overall response rate (ORR) based on 10 patients with Partial Responses (PRs), including 9 PRs confirmed by RECIST 1.1 and 1 PR pending confirmation
- CTX-009 demonstrated anti-tumor activity in previously treated patients with a clinical benefit rate (CBR) of 92% based on 22 patients with a PR or stable disease (SD) out of 24 enrolled patients
- CTX-009 was well-tolerated and preliminary safety profile is consistent with prior studies

Thomas Schuetz, M.D., Ph.D., Chief Executive Officer, and Scientific Founder of Compass, said “We are excited by these impressive interim Phase 2 results and believe CTX-009 is a promising investigational drug. In the initial data review of this trial, reported in November 2021, CTX-009 exhibited a 29% ORR and a 100% CBR. We are very encouraged by the performance of CTX-009 across a larger patient population, particularly the maturing of the dataset, with the ORR moving from 29% in 17 evaluable patients to 42% in all 24 patients enrolled.”

Dr. Schuetz continued, “The findings reported today suggest that CTX-009, if approved, may represent a novel therapeutic option for patients with BTC who have limited treatment choices and poor prognoses. We are very pleased to see the strategy of blocking both DLL4 and VEGF-A in a bispecific antibody continue to yield positive data.”

Vered Bisker-Leib, Ph.D., President and Chief Operating Officer of Compass said “CTX-009 demonstrated responses across all of the four BTC subtypes enrolled in the trial and good overall tolerability. These are very encouraging aspects of the Phase 2 results and mark an important step forward in the ongoing development of CTX-009 as a potential new treatment for patients with BTC. We look forward to studying CTX-009 further in Phase 2 trials, which we expect to begin in the U.S. in the third quarter.”

CTX-009 Phase 2 Study Overview

The Phase 2 study has a Simon Two-Stage adaptive design where three PRs among the first 21 patients enrolled in the first stage of the study will advance the study to the second stage. In November 2021, Compass reported that there were five PRs observed among the first 17 evaluable patients, and therefore, the criteria to advance the study to its second stage was met. The study is currently being conducted at four leading medical centers in Korea. In the United States, an IND was opened in January of 2022 and first patient dose is projected to take place in early Q3 2022.

Enrollment

All patients enrolled in the study had BTC, classified into four subgroups: intrahepatic cholangiocarcinoma (37.5%), extrahepatic cholangiocarcinoma (12.5%), gallbladder cancer (29.2%) and ampullary cancer (20.8%).

As of the data cut-off date April 14, 2022, 24 patients were enrolled and dosed with at least one cycle of CTX-009 and paclitaxel, and 22 were evaluable for response. All patients enrolled in the study have advanced BTC; 45.8% of the patients received one prior therapy and 54.2% of the patients received at least two prior therapies. Almost all patients (95.8%) received gemcitabine/cisplatin.

Patients had a median age of 61.5 years, an ECOG performance status of 0 (54.2%) or 1 (45.8%).

Preliminary Activity Data

CTX-009 exhibited a 42% ORR based on 10 patients with PRs, including nine confirmed PRs by RECIST 1.1 and one PR pending confirmation.

Two patients were not evaluable for the purpose of efficacy, and 22 of the 24 patients have had stable disease or better observed leading to a CBR of 92%. As of the cutoff date, seven patients were continuing to receive treatment, including five patients who had been on treatment for over nine months.

Preliminary Safety Data

CTX-009, in combination with paclitaxel, continues to be well tolerated, consistent with the Phase 1 studies, with hypertension and neutropenia being the most common events related to CTX-009 and paclitaxel, respectively.

Of the 24 subjects enrolled in the study, all subjects had at least one AE related to CTX-009 and/or paclitaxel. The most common adverse events (all Grades) occurring in at least three patients were anemia (12.5%), asthenia (25.0%), fatigue (16.7%), edema (16.7%), pyrexia (16.7%), neutropenia (54.2%), thrombocytopenia (20.8%), headache (16.7%), proteinuria (20.8%), dysphonia (12.5%), dyspnea (25%), epistaxis (33.3%), pulmonary hypertension (16.7%, all Grade 1) and hypertension (50.0%).

Grade 3 or greater treatment-emergent adverse events (TEAE) occurring in more than one patient include neutropenia (n=12; 50.0%), hypertension (n=4; 16.7%), anemia (n=3; 12.5%) and thrombocytopenia (n=2; 8.3%); all TEAEs were manageable with standard treatment.

About the Trial

The Phase 2 trial was designed as a prospective, multi-center, open-label, Simon Two-Stage adaptive design trial to evaluate the use of CTX-009 in combination with paclitaxel for the treatment of patients with BTC. The study enrolled patients with advanced, unresectable, metastatic or recurrent biliary tract cancer with an ECOG performance status of 0 or 1.

The initial phase of the trial was conducted in Korea and enrolled 24 subjects at four leading medical centers. All subjects received bi-weekly doses of 10 mg/kg of CTX-009, and paclitaxel, dosed at 80 mg/m^2 weekly every three out of four weeks.

The primary endpoint for the study is ORR, based on the proportion of subjects whose best overall response is assessed to be Complete Response (CR) or Partial Response (PR) per Independent Radiology review. Secondary outcome measures include assessments of several standard measures of disease progression.

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 cancer patients who were resistant to currently approved anti-VEGF therapies. CTX-009 has completed a Phase 1 monotherapy dose escalation and dose expansion study and a Phase 2 combination study is ongoing. Initiation of a Phase 2 trial in the U.S. is planned for Q3 2022.

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 Compass out-licensed to Elpiscience Biopharma, Ltd. (https://www.elpiscience.com/).

About Biliary Tract Cancers

Biliary tract cancers (BTC) are a group of rare and 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 18,300 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. The company's pipeline of novel product candidates was 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 and selected targeted therapies based on supportive clinical and nonclinical data. The company was founded in 2014 and is headquartered in Boston, Massachusetts. The Company's website is www.compasstherapeutics.com.

Webinar Information

Compass will host a webcast on Wednesday, May 4th at 8:00 a.m. ET

Registration for the webcast or access to a replay of the call is available by **clicking here.**

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 our 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 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.

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