# Compass Reports the Advancement of CTX-009, a Bispecific Antibody, to Phase 2a Development in Patients with Biliary Tract Cancers (BTC), and the Clearance of a Key Clinical Hurdle

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- Phase 2a study was initiated by Handok Pharmaceuticals in Q1 2021 in patients with Biliary Tract Cancers (cholangiocarcinoma).
- Enrollment in the first part of the study has been completed and the criteria to advance to the second part of the study have been met.
- Notably, five partial responses have already been observed among the first 17 patients evaluated leading to a preliminary overall response rate of 29% (ORR=29%), and all patients evaluated have had stable disease or better with a decline in tumor burden observed in 16 of the 17 patients leading to a Clinical Benefit Rate of 100% (CBR=100%).
- Compass plans to submit an Investigational New Drug (IND) application to the United States Food and Drug Administration (FDA) this quarter, and subject to the IND clearance with the FDA, to initiate a Phase 2 study in Q2 2022.

BOSTON--(BUSINESS WIRE)-- Compass Therapeutics, Inc. (OTC:CMPX) today provided an update on the clinical development of CTX-009 (also known as ABL001), a dual anti-angiogenic bispecific antibody targeting DLL4 and VEGF-A.

A Phase 2a study for CTX-009 in combination with paclitaxel was initiated by Handok Pharmaceuticals, Inc. (KOSDAQ: 002390) in Q1 2021 in patients with BTC and the enrollment in the first part of the study has been completed. The study has been enrolling patients who have unresectable advanced, metastatic, or relapsed BTC's who have received one or two prior systemic therapies. The Phase 2a design was informed by the CTX-009 Phase 1b study, where CTX-009 in combination with either paclitaxel or irinotecan led to an overall response rate of 23.5% and a clinical benefit rate of 76.5%, including two confirmed and durable partial responses among four patients with advanced cholangiocarcinoma (clinicaltrials.gov Identifier: NCT04492033).

The Phase 2a study utilizes a Simon Two-Stage adaptive design where the criteria to advance to the second stage of the study is three or more partial responses observed in 21 patients. So far, there have been five partial responses observed among the first 17 patients evaluated, which is an overall response rate of 29%, and accordingly, the criteria to advance to the second part of the study has been met. In the second part of the Phase 2a study, 45 additional patients will be enrolled. The preliminary adverse event profile of CTX-009 in this Phase 2a study is consistent with prior studies of CTX-009 with hypertension and neutropenia being the most common events related to CTX-009 and paclitaxel, respectively. Handok initiated the study in Q1 2021 at four leading medical centers in South Korea. Compass plans on submitting an IND for CTX-009 in the United States later this quarter and subject to the IND going into effect with the FDA, plans on initiating a Phase 2 study in the United States in Q2 2022.

"Patients with cholangiocarcinoma have limited treatment options following front line combination chemotherapy. In the Phase 1b and Phase 2a studies, we have seen a total of seven partial responses in 21 total patients evaluated. Impressively, there have been measurable tumor declines in 19 of the 21 advanced patients treated across both studies. We are looking forward to filing our IND in the United States this quarter and pursuing the global development of CTX-009," said Thomas Schuetz, M.D., Ph.D., CEO and scientific founder of Compass. Compass holds the global rights to CTX-009 with the exception of South Korea rights, which are held by Handok, and China rights, which were out-licensed to Elpiscience Biopharma.

**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. Phase 1b and Phase 2a combination studies are ongoing.

**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.

**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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