Compass Therapeutics Provides Corporate Update and Announces Advancement of a New Drug Candidate

January 8, 2025

- Top-line Phase 2/3 data readout for CTX-009, now named tovecimig (a DLL4 x VEGF-A bispecific), in patients with biliary tract cancer (BTC) is on track for end of Q1 2025.
- CTX-10726 (a novel PD-1 x VEGF-A bispecific) is advancing as a new drug candidate after a year of preclinical development, with YE 2025 IND expected.
- Two Phase 2 biomarker trials are expected to initiate in mid-2025: tovecimig (in DLL4-positive colorectal cancer) and CTX-471 (in NCAM/CD56 expressing tumors).
- Fully enrolled the third dosing cohort of the Phase 1 dose-escalation study of CTX-8371 (PD-1 x PD-L1 bispecific) with preliminary data expected in the second half of 2025.
- Estimated $127 million in cash and marketable securities at YE 2024, which is expected to provide cash runway into Q1 2027.

BOSTON, Jan. 08, 2025 (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 a corporate and financial update.

“We are approaching a key catalyst for the company with the top-line data readout at the end of the first quarter for our Phase 2/3 combination study of tovecimig, which is our new nonproprietary name for CTX-009, in patients with advanced BTC,” said Thomas Schuetz, MD, PhD, CEO of Compass and Vice Chairman of the Board of Directors. “In addition, we are very excited to announce our new drug candidate, CTX-10726, a novel PD-1 x VEGF-A bispecific antibody. CTX-10726 builds on our deep VEGF-IO expertise and our research team has been rigorously advancing this candidate for the past year. We expect to submit an IND by year-end with initial proof-of-concept clinical data in 2026.”

“Finally, we are making good progress on designing our two new Phase 2 biomarker studies with tovecimig and CTX-471 and continue to expect initiation of these clinical trials in mid-2025.”

DEVELOPMENT PIPELINE UPDATES:

Tovecimig (CTX-009 - DLL4 x VEGF-A bispecific antibody)

- Top-line data readout in the U.S. on track for the end of Q1 2025 for COMPANION-002, the Company’s Phase 2/3 randomized trial of tovecimig in combination with paclitaxel in patients with advanced BTC (see press release).
- Continuing to design and plan a Phase 2 study in patients with DLL4-positive colorectal cancer in the second-line setting in combination with chemotherapy, which is expected to initiate in mid-2025.
- An IST (investigator sponsored study) of tovecimig in patients with BTC in the first-line setting at The University of Texas MD Anderson Cancer Center is being initiated in Q1 2025. Tovecimig will be added to the standard first-line regimen of gemcitabine, cisplatin, and durvalumab (see press release).

CTX-471 (CD137 agonist antibody)

- Phase 2 trial initiation of CTX-471 in patients with tumors expressing neural cell adhesion molecule (NCAM or CD56) is expected in mid-2025.
- Presented CTX-471 clinical data at multiple scientific meetings in 2024, including data demonstrating durable clinical responses in Phase 1 presented at the American Society of Clinical Oncology (ASCO) Annual Meeting and data showing a correlation between levels of NCAM (CD56) expression and disease control presented at the 39th Society for Immunotherapy of Cancer 2024 Annual Meeting.

CTX-8371 (PD-1 x PD-L1 bispecific antibody)

- CTX-8371 is a next generation bispecific checkpoint inhibitor that simultaneously targets PD-1 and PD-L1 and exhibits a unique mechanism-of-action that involves cleavage of cell surface PD-1.

- The third dosing cohort in the Phase 1 dose-escalation study of CTX-8371 is fully enrolled; no dose limiting toxicities (DLTs) have been observed to date.

CTX-10726 (PD-1 x VEGF-A bispecific antibody)

- CTX-10726 is a tetravalent PD-1 x VEGF-A bispecific antibody discovered and engineered at Compass. CTX-10726 is designed to synergistically deliver VEGF-A blockade and checkpoint inhibition, potentially applicable to multiple solid tumor indications.

- The bispecific antibody demonstrates a highly stable structure with high affinity target binding. CTX-10726 exhibits more potent PD-1 blockade compared with data reported for other drugs in the class.

- IND-enabling studies have been ongoing, and we expect to submit an IND by the end of 2025.

- Compass's deep experience in discovery, pre-clinical, and clinical work focused on complementary bispecific approaches that simultaneously target angiogenesis and immuno-oncology uniquely positions us to rapidly progress this candidate to an IND filing and Phase 1 clinical development.

In addition, the Company had an estimated $127 million in cash and marketable securities as of December 31, 2024, which is expected to provide cash runway into Q1 2027.

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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