

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): April 27, 2026

Compass Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-39696

(Commission File Number)

82-4876496

(I.R.S. Employer Identification No.)

**80 Guest Street, Suite 601
Boston, Massachusetts 02135**

(Address of Principal Executive Offices) (Zip Code)

(617) 500-8099

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	CMPX	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On April 27, 2026, Compass Therapeutics, Inc. (the “Company”) issued a press release announcing data related to a randomized Phase 2/3 study in patients with biliary tract cancer (“BTC”). The Company will host a webcast today, Monday, April 27, 2026 at 8:00 a.m. ET, to provide a review of the data. Interested parties may register for the call in advance via https://viavid.webcasts.com/starthere.jsp?ei=1761459&tp_key=efc315f5a6.

A copy of the full press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein. A copy of the presentation to be shown at the webcast on April 27, 2026, is attached as Exhibit 99.2 to this Current Report on Form 8-K and incorporated by reference herein. The presentation and a replay of the webcast will also be available on the investor relations section of the Company’s website at <https://investors.compasstherapeutics.com/>. Information contained on the Company’s website is not incorporated by reference into this Current Report on Form 8-K, and you should not consider any information on, or that can be accessed from, the Company’s website as part of this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibits 99.1 and 99.2 of this Current Report on Form 8-K are furnished and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. The information in this Item 7.01 and Exhibits 99.1 and 99.2 of this Current Report on Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report on Form 8-K, regardless of any general incorporation language in any such filing.

Item 8.01. Other Events.

Tovecimig results in Phase 2/3 Study in the Second Line Setting for Patients with BTC

On April 27, 2026, the Company announced data for COMPANION-002, the Company’s Phase 2/3 randomized trial of tovecimig (formerly CTX-009) in combination with paclitaxel in patients with advanced BTC. The study enrolled 168 adult patients, randomized in a 2:1 ratio to receive tovecimig plus paclitaxel (n=111) or paclitaxel alone (n=57). In April 2025, the Company announced that the study met its primary endpoint of overall response rate (“ORR”). Tovecimig in combination with paclitaxel achieved a 17.1% ORR, including one complete response, compared to a 5.3% ORR for paclitaxel alone, in patients with biliary tract cancer (“BTC”) treated in the second-line setting. The difference in ORR between the two treatment arms, the primary endpoint of the study, was statistically significant (p=0.031), and all responses were assessed by blinded independent central radiology (BICR) review.

The following additional information related to the study was announced on April 27, 2026:

Key Secondary Endpoints:

- Progression-Free Survival (PFS): Tovecimig in combination with paclitaxel demonstrated a statistically significant improvement in median PFS of 4.7 months compared to 2.6 months for paclitaxel alone (HR=0.44, p<0.0001). Progression was confirmed in each case by BICR.
- Overall Survival (OS): Tovecimig did not meet the OS secondary endpoint due to high crossover from the control arm (31 of 57 patients, or 54%) and prolonged survival of those crossover patients after receiving tovecimig, as further described below. As a result of this crossover, 85% (142 of 168) of patients in the study received tovecimig plus paclitaxel with a pooled OS in the study of 8.9 months.

In the ITT OS analysis, tovecimig in combination with paclitaxel had a median OS of 8.9 months compared to 9.4 months for the control arm, which included 26 patients (46%) who received paclitaxel alone and 31 patients (54%) who crossed over to receive tovecimig in combination with paclitaxel (HR=1.05, p=0.78). In the rank-preserving structural failure time (RPSFT) OS analysis, the combination also had a median OS of 8.9 months compared to 9.4 months for paclitaxel alone (HR=1.13, p=0.65). Though the RPSFT analysis is intended to adjust for crossover, its validity depends on certain assumptions that were not met in this study and thus its results here are largely uninterpretable.

- Progression-Free Survival of Crossover Patients (PFS2): An additional, pre-specified secondary endpoint analyzed PFS in the patients in the paclitaxel arm who crossed over to receive tovecimig plus paclitaxel. In this analysis, the pre-crossover PFS (PFS1) on paclitaxel alone was compared to PFS with tovecimig post-crossover (PFS2) in the same crossover patients (n=31). In this subset, tovecimig demonstrated a statistically significant improvement with median PFS2 of 3.5 months after treatment with tovecimig compared to median PFS1 of 1.9 months for paclitaxel (HR=0.36, p=0.0016).

Post Hoc Subset Analyses:

- OS of Paclitaxel Control Arm (Crossover vs. Non-Crossover): In an analysis of OS in all patients randomized to the paclitaxel control arm (n=57), crossover patients who subsequently received tovecimig demonstrated a statistically significant improvement in median OS of 12.8 months compared to 6.1 months for non-crossover patients who received only paclitaxel (HR=0.54, p=0.04).
- PFS of Paclitaxel Control Arm (Crossover vs. Non-Crossover): Another analysis of these same patients randomized to the paclitaxel control arm (n=57) demonstrated that the crossover patients initially progressed faster on paclitaxel monotherapy compared to the non-crossover patients, with a median PFS of 1.9 months versus 3.6 months (HR=2.31, p=0.007). Thus, notably, despite progressing more quickly on initial paclitaxel monotherapy, crossover patients still demonstrated a statistically significant median 12.8 months OS after being treated with tovecimig.

Safety:

- Tovecimig was generally well tolerated and the safety profile was consistent with previously reported data from prior studies, with no new safety signals. The most commonly reported treatment emergent adverse events in the tovecimig combination arm were hypertension (69%) and fatigue (67%). The most common related treatment-emergent adverse events of Grade 3 or higher included hypertension (44%) and neutropenia (36%).

In the coming months, Compass intends to meet with the U.S. Food and Drug Administration (FDA) to discuss these data in advance of a planned BLA submission.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements. Statements that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, statements regarding Compass’s product candidates, including the potential of tovecimig to provide a treatment option for patients with BTC in the second-line setting, additional results of the COMPANION-002 study, and the timing and nature of any regulatory interactions and subsequent approval pathways, including Compass’s intention to discuss the data in the COMPANION-002 Randomized Phase 2/3 Study with the FDA in advance of a planned BLA submission, and the expectation to present the complete dataset at a medical conference this year. 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 Current Report on Form 8-K, 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 and subsequent filings with the SEC.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release dated April 27, 2026</u>
<u>99.2</u>	<u>Presentation dated April 27, 2026</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Compass Therapeutics, Inc.

Date: April 27, 2026

By: /s/ Neil Lerner
Neil Lerner
Chief Accounting Officer

Tovecimig Demonstrates Statistically Significant Benefit in COMPANION-002 Randomized Phase 2/3 Study in Patients with Biliary Tract Cancer

- Tovecimig (a DLL4 x VEGF-A bispecific antibody) in combination with paclitaxel demonstrated a highly statistically significant improvement versus paclitaxel alone in the key secondary endpoint of median progression-free survival (PFS) of 4.7 months versus 2.6 months, providing a 56% reduction in the risk of progression (hazard ratio=0.44, $p<0.0001$).
- Secondary endpoint analyses of overall survival (OS) were confounded by both high crossover (54%) and notably prolonged survival in crossover patients randomized to the control arm then treated with tovecimig and, therefore, did not meet statistical significance. In a subset analysis of the patients in the control arm, the median OS of the crossover patients was 12.8 months vs. 6.1 months in patients who did not crossover (hazard ratio=0.54, $p=0.04$).
- 85% of patients in the study received tovecimig with a pooled median OS of 8.9 months.
- As previously disclosed, tovecimig in combination with paclitaxel met the primary endpoint of overall response rate (ORR) in the study with an ORR of 17.1% vs. 5.3% in the paclitaxel control arm ($p=0.031$).
- The Company looks forward to meeting with FDA in advance of a planned Biologics License Application (BLA) submission.
- Company to host webcast today, April 27, 2026 at 8:00 a.m. ET.

BOSTON, April 27, 2026 (GLOBE NEWSWIRE) -- Compass Therapeutics, Inc. (Nasdaq: CMPX), a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics, today announced that it met the key secondary endpoint of PFS and showed additional compelling results in the randomized COMPANION-002 study, which evaluated tovecimig plus paclitaxel versus paclitaxel alone in patients with unresectable advanced, metastatic or recurrent biliary tract cancer (BTC) treated in the second-line setting. The complete dataset, including Duration of Response (DoR), will be presented at a medical conference later this year.

“In this study, tovecimig showed an impressive overall response rate which translated into a clinically meaningful and highly statistically significant improvement in PFS for patients with previously treated BTC. The remarkable 56% reduction in the risk of disease progression is unprecedented in this patient population without an actionable mutation in their tumor,” said Thomas Schuetz, MD, PhD, Chief Executive Officer of Compass. “It is also notable that the 31 crossover patients survived a median of 12.8 months, similar to the median OS seen in front-line studies in this setting. Including crossover, 85% of patients in the study received tovecimig in combination with paclitaxel and the pooled median OS for all patients in the study was 8.9 months, which is also substantially longer than chemotherapy benchmarks of approximately 6 months.”

“These findings reinforce our belief that tovecimig can address a significant unmet need for patients with limited and insufficient treatment options. We are immensely grateful to the patients, investigators, and clinical teams who made this study possible, and we look forward to presenting the full dataset at an upcoming medical meeting. We are now focused on engaging with the FDA to bring this much needed therapy to the cholangiocarcinoma community as quickly as possible.”

“Patients with advanced biliary tract cancer have an urgent need for better treatment options,” said Juan Valle, MD, Chief Medical Officer of the Cholangiocarcinoma Foundation. “These results are a significant step forward and I anticipate that, if approved, it will meaningfully change the way physicians care for these patients. I also applaud Compass for putting patients first in the design of this study by allowing patients to crossover to receive treatment with tovecimig. These patients clearly benefited from this innovative therapy. I look forward to supporting Compass as they work to bring tovecimig to patients with cholangiocarcinoma.”

COMPANION-002 Data Summary:

Primary Endpoint (previously announced in April 2025):

- **Overall Response Rate:** 17.1% ORR for tovecimig in combination with paclitaxel (19 of 111 patients) including one complete response, compared to 5.3% for paclitaxel alone (3 of 57 patients), in patients with BTC in the second line setting. This 11.8% improvement in ORR for those receiving tovecimig was statistically significant ($p=0.031$). All responses were assessed by blinded independent central review (BICR).

Key Secondary Endpoints:

- **Progression-Free Survival (PFS):** Tovecimig in combination with paclitaxel demonstrated a statistically significant improvement in median PFS of 4.7 months compared to 2.6 months for paclitaxel alone ($HR=0.44$, $p<0.0001$). Progression was confirmed in each case by BICR.
- **Overall Survival (OS):** Tovecimig did not meet the OS secondary endpoint due to high crossover from the control arm (31 of 57 patients, or 54%) and prolonged survival of those crossover patients after receiving tovecimig, as further described below. As a result of this crossover, 85% (142 of 168) of patients in the study received tovecimig plus paclitaxel with a pooled OS in the study of 8.9 months.

In the ITT OS analysis, tovecimig in combination with paclitaxel had a median OS of 8.9 months compared to 9.4 months for the control arm, which included 26 patients (46%) who received paclitaxel alone and 31 patients (54%) who crossed over to receive tovecimig in combination with paclitaxel ($HR=1.05$, $p=0.78$). In the rank-preserving structural failure time (RPSFT) OS analysis, the combination also had a median OS of 8.9 months compared to 9.4 months for paclitaxel alone ($HR=1.13$, $p=0.65$). Though the RPSFT analysis is intended to adjust for crossover, its validity depends on certain assumptions that were not met in this study and thus its results here are largely uninterpretable.

- **Progression-Free Survival of Crossover Patients (PFS2):** An additional, pre-specified secondary endpoint analyzed PFS in the patients in the paclitaxel arm who crossed over to receive tovecimig plus paclitaxel. In this analysis, the pre-crossover PFS (PFS1) on paclitaxel alone was compared to PFS with tovecimig post-crossover (PFS2) in the same crossover patients ($n=31$). In this subset, tovecimig demonstrated a statistically significant improvement with median PFS2 of 3.5 months after treatment with tovecimig compared to median PFS1 of 1.9 months for paclitaxel ($HR=0.36$, $p=0.0016$).

Post Hoc Subset Analyses:

- **OS of Paclitaxel Control Arm (Crossover vs. Non-Crossover):** In an analysis of OS in all patients randomized to the paclitaxel control arm ($n=57$), crossover patients who subsequently received tovecimig demonstrated a statistically significant improvement in median OS of

12.8 months compared to 6.1 months for non-crossover patients who received only paclitaxel (HR=0.54, p=0.04).

- **PFS of Paclitaxel Control Arm (Crossover vs. Non-Crossover):** Another analysis of these same patients randomized to the paclitaxel control arm (n=57) demonstrated that the crossover patients initially progressed faster on paclitaxel monotherapy compared to the non-crossover patients, with a median PFS of 1.9 months versus 3.6 months (HR=2.31, p=0.007). Thus, notably, despite progressing more quickly on initial paclitaxel monotherapy, crossover patients still demonstrated a statistically significant median 12.8 months OS after being treated with tovecimig.

Safety:

- Tovecimig was generally well tolerated and the safety profile was consistent with previously reported data from prior studies, with no new safety signals. The most commonly reported treatment emergent adverse events in the tovecimig combination arm were hypertension (69%) and fatigue (67%). The most common related treatment-emergent adverse events of Grade 3 or higher included hypertension (44%) and neutropenia (36%).

BTC is estimated to affect approximately 26,500 patients annually in the United States. For the vast majority of patients with BTC whose tumors do not harbor an actionable mutation with an approved targeted therapy, there is currently no FDA-approved treatment in the second line setting. The therapeutics most commonly used in this setting, which are not labeled or approved by the FDA for the treatment of patients with BTC, generally have an ORR of ~5% or less and patients face a median OS of approximately six months.

In the coming months, Compass intends to meet with the U.S. Food and Drug Administration (FDA) to discuss these data in advance of a planned BLA submission.

Webcast Information

Compass will host a webcast today, Monday, April 27, 2026 at 8:00 a.m. ET to provide a review of the tovecimig secondary endpoints COMPANION-002 data. Interested parties may register for the call-in advance via https://viaavid.webcasts.com/starthere.jsp?ei=1761459&tp_key=efc315f5a6.

A replay of the webcast will be available via the Investors section of the Compass website at investors.compasstherapeutics.com.

About COMPANION-002

COMPANION-002 is a Phase 2/3 randomized, controlled study of tovecimig in patients with unresectable advanced, metastatic or recurrent biliary tract cancers who have received one prior systemic chemotherapy regimen (clinical trial information: [NCT05506943](https://clinicaltrials.gov/ct2/show/study/NCT05506943)). The study enrolled 168 adult patients, randomized in a 2:1 ratio to receive tovecimig plus paclitaxel (n=111) or paclitaxel alone (n=57). All patients were dosed with 80 mg/m² of paclitaxel on days 1, 8 and 15 of every 28-day cycle. Patients in the tovecimig arm were also dosed with 10 mg/kg of tovecimig on days 1 and 15 of each 28-day cycle. The primary endpoint of the trial is ORR as confirmed by blinded independent central radiology review and secondary endpoints include PFS, OS, and DoR, among others. Patients in the paclitaxel-only arm who progressed could cross over to the tovecimig plus paclitaxel arm after centrally confirmed progression if they also still met the enrollment criteria for the study.

About Tovecimig (CTX-009)

Tovecimig is an investigational bispecific antibody that is designed to simultaneously block 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 clinical data of tovecimig 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.

About Compass Therapeutics

Compass Therapeutics, Inc. was founded in 2014 and is headquartered in Boston, MA. Compass is a clinical-stage, oncology-focused biopharmaceutical company discovering and developing proprietary antibody-based therapeutics to treat multiple diseases. The company's scientific focus is on the relationship between angiogenesis, the immune system and tumor growth. Compass has a robust pipeline of novel product candidates designed to target multiple key biological pathways to drive an effective anti-tumor response, including angiogenesis modulation, immune activation within the tumor microenvironment, and reduction of tumor-driven immunosuppression. The company is advancing discovery candidates through clinical development to commercial-stage assets. For more information, visit 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, statements regarding Compass's product candidates, including the potential of tovecimig to provide a treatment option for patients with BTC in the second-line setting, additional results of the COMPANION-002 study, and the timing and nature of any regulatory interactions and subsequent approval pathways, including Compass's intention to discuss the data in the COMPANION-002 Randomized Phase 2/3 Study with the FDA in advance of a planned BLA submission, and the expectation to present the complete dataset at a medical conference this year. 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 and subsequent filings with the SEC.

Investor Contact

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COMPANION-002: Secondary Endpoints

Corporate Presentation
Nasdaq: CMPX
April 27, 2026

DISCLAIMER

This presentation has been prepared by Compass Therapeutics, Inc. ("we," "us," "our," or the "Company"). Statements contained herein are made as of the date of this presentation unless stated otherwise, and this presentation shall not under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

This presentation contains forward-looking statements. Statements in this presentation 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 preclinical and clinical development, therapeutic potential and tolerability profile, estimates of the commercial opportunity and market size 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, initiate and 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 presentation, 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.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

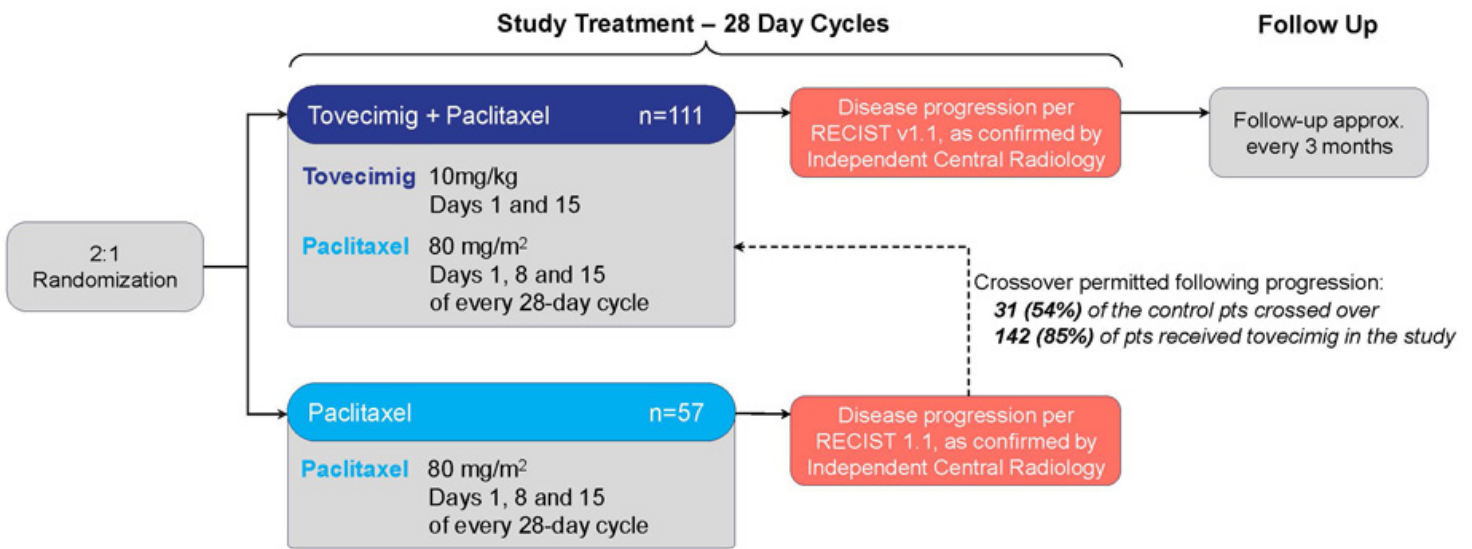
This presentation concerns drugs that are under clinical investigation, and which have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). It is currently limited by Federal law to investigational use, and no representation is made as to its safety or effectiveness for the purposes for which it is being investigated.

COMPANION-002: Executive Summary

- **Primary endpoint (previously reported):** significant improvement in ORR
 - 17.1% vs. 5.3% BICR-assessed ORR ($p=0.031$)
- **Key secondary endpoint:** highly significant improvement in PFS
 - 4.7 vs. 2.6 months median BICR-assessed PFS ($HR=0.44$, $p<0.0001$)
- **Key secondary endpoint:** OS analyses confounded by crossover and were not met
 - 54% of control patients crossed over; 85% of patients in the study received tovecimig
- **Subset analysis:** crossover patients from the control arm had significantly improved OS than non-crossover patients
 - 12.8 vs. 6.1 months median OS ($HR=0.54$, $p=0.04$)
- **Safety profile:** generally consistent with prior studies and well tolerated
- **Next steps:** meet with FDA in advance of a planned BLA submission

COMPANION-002: Phase 2/3 U.S. BTC Study

Registrational-intent study in patients who have received one prior line of therapy



Primary Endpoint: **ORR**

Key Secondary Endpoints: **PFS, OS, DoR**

COMPANION-002: Baseline Demographics

Baseline characteristics were well balanced

		Tovecimig + Paclitaxel n=111	Paclitaxel n=57
Age	Median (years)	65.0	63.0
Sex	Male	53 (47.7)	24 (42.1)
	Female	58 (52.3)	33 (57.9)
Race	Asian	17 (15.3)	10 (17.5)
	White	84 (75.7)	40 (70.2)
	African American	4 (3.6)	6 (10.5)
	Unknown/Other	6 (5.4)	1 (1.8)
Primary Location	Intrahepatic	62 (55.9)	30 (52.6)
	Other (extrahepatic, gallbladder, ampullary)	49 (44.1)	27 (47.4)
ECOG	0	53 (47.7)	27 (47.4)
	1	58 (52.3)	30 (52.6)
Disease Status	Locally advanced	12 (10.8)	5 (8.8)
	Metastatic	99 (89.2)	52 (91.2)

COMPANION-002: Significant Improvement in Primary Endpoint of ORR

COMPANION-002 Study (BTC)	Tovecimig + Paclitaxel	Paclitaxel
Intent-to-Treat Population	n=111	n=57
Overall Response Rate (CR+PR)	19 (17.1%)	3 (5.3%)
Two-Sided p-value	p=0.031	
Best Overall Response RECIST v1.1 by blinded independent central review (BICR)	Complete Response (CR)	0 (0.0%)
	Partial Response (PR)	3 (5.3%)
	Stable Disease (SD)	19 (33.3%)
	Non-CR / Non-PD*	2 (3.5%)
	Progressive Disease (PD)	24 (42.1%)
	Not Evaluable (NE)**	9 (15.8%)

*Non-CR / Non-PD: patients enrolled based on local radiology scan results, but displayed no clearly definable target lesions as determined by independent central radiology.

** Not Evaluable: patients who did not receive a Week-8 scan; these patients are not evaluable for response only, but will be evaluable for PFS/OS analyses.

Safety Data: The safety profile of tovecimig in this study to date has been consistent with prior studies.

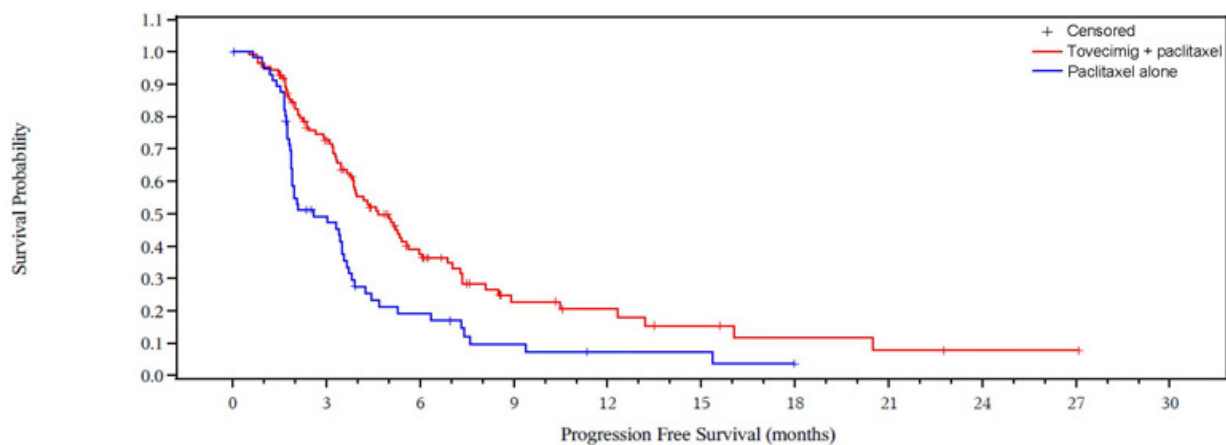
Safety Monitoring: An independent Data Safety Monitoring Committee reviewed safety data at four separate (pre-specified) meetings and recommended continuation of the study with no modification after each meeting.



Data cutoff from COMPANION-002 as of March 2025.

COMPANION-002: Tovecimig Significantly Improves PFS (BICR)

ITT Analysis: HR=0.44, $p < 0.0001$, 4.7 vs. 2.6 months median PFS



	Number at Risk:									
Tovecimig + paclitaxel	111	73	30	11	8	5	3	2	1	1
Paclitaxel alone	57	25	9	4	2	2				

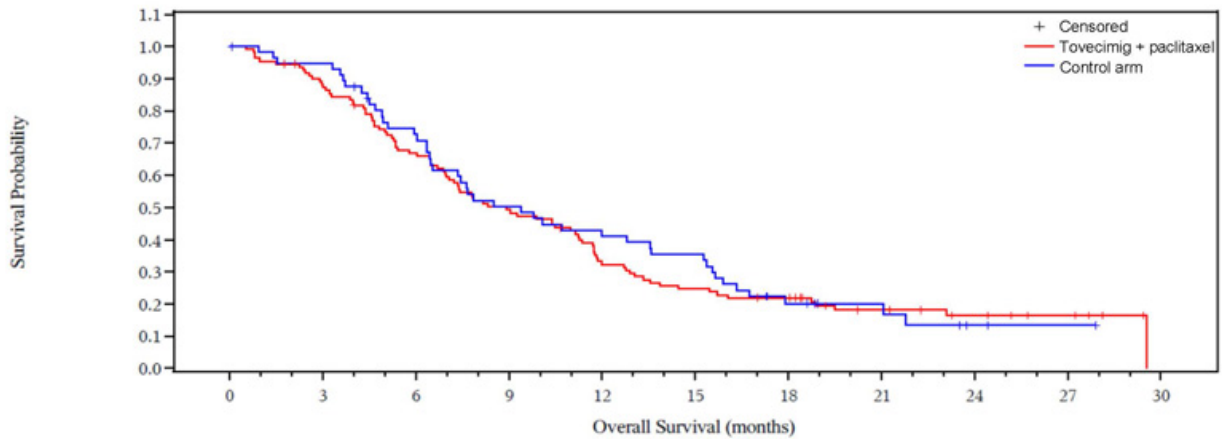


Data cutoff from COMPANION-002 as of April 2026.

COMPANION-002: OS Analysis Confounded by Crossover

ITT analysis: HR=1.05, p=0.78, 8.9 vs. 9.4 months median OS

Control arm includes 31 patients (54%) who crossed over and received tovecimig plus paclitaxel and 26 patients (46%) who received paclitaxel alone



	Number at Risk:										
Tovecimig + paclitaxel	111	95	72	53	34	26	22	13	9	5	2
Paclitaxel alone	57	53	39	27	22	19	9	6	2	1	



Data cutoff from COMPANION-002 as of April 2026.

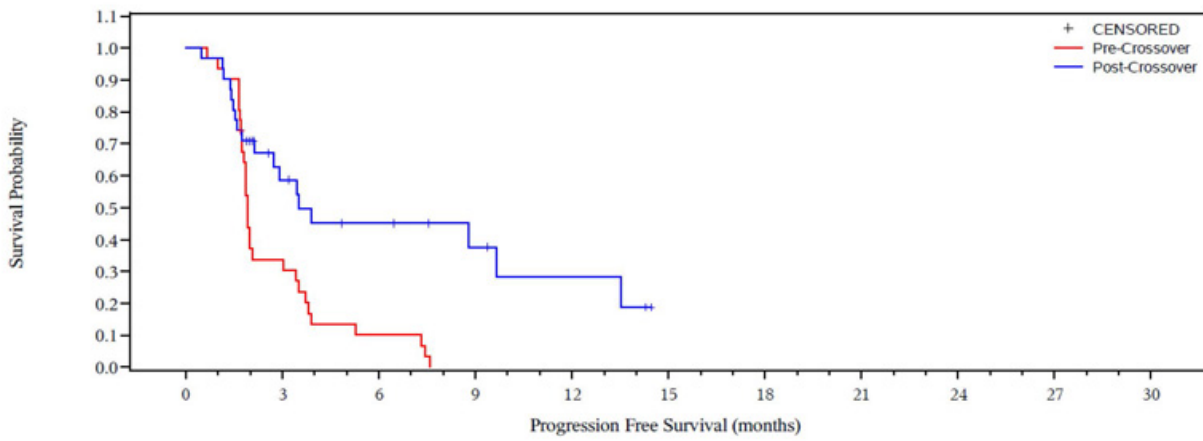
Phase 2/3 COMPANION-002: Efficacy Results

Endpoint	Tovecimig + Paclitaxel (n=111)	Paclitaxel (n=57)	Two-Sided p-value	Hazard Ratio
Primary Endpoint				
Overall Response Rate	19 (17.1%)	3 (5.3%)	p=0.031	–
Key Secondary Endpoints (months)				
Progression Free Survival	4.7	2.6	p<0.0001	0.44
Overall Survival (RPSFT–crossover adjusted)*	8.9	9.4	p=0.65	1.13
Overall Survival (intent-to-treat)	8.9	9.4	p=0.78	1.05

*Although this was a prespecified analysis, statistical assumptions for the RPSFT were not met.

PFS2: Tovecimig Significantly Improves PFS Post-Crossover

Prespecified secondary analysis (n=31): HR=0.36, p=0.0016, 3.5 vs. 1.9 months median PFS



Number at Risk:

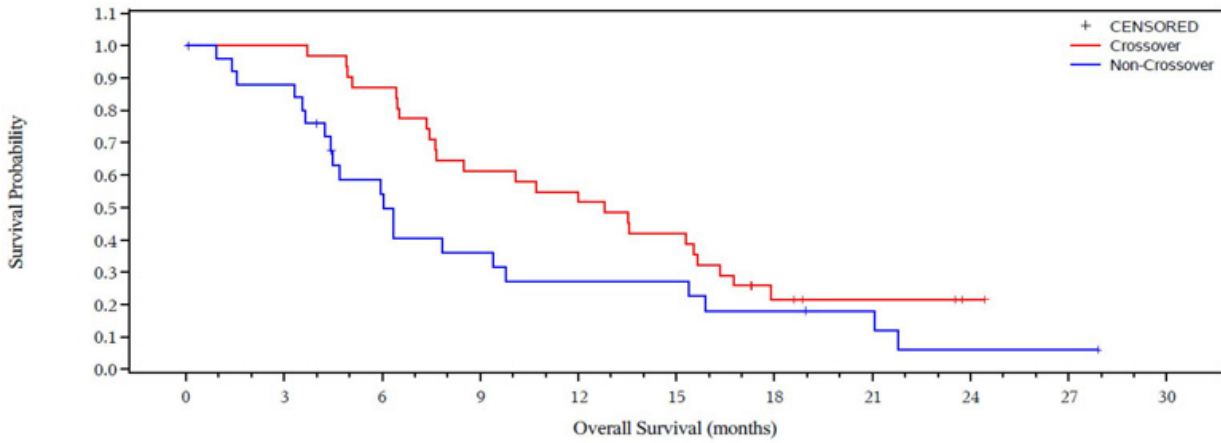
Pre-Crossover	31	10	3		
Post-Crossover	31	14	9	5	3



Data cutoff from COMPANION-002 as of April 2026.

Tovecimig Significantly Improved OS in Crossover Patients

Post hoc subset analysis (n=31 vs. n=26): HR=0.54, p=0.04, 12.8 vs. 6.1 months median OS



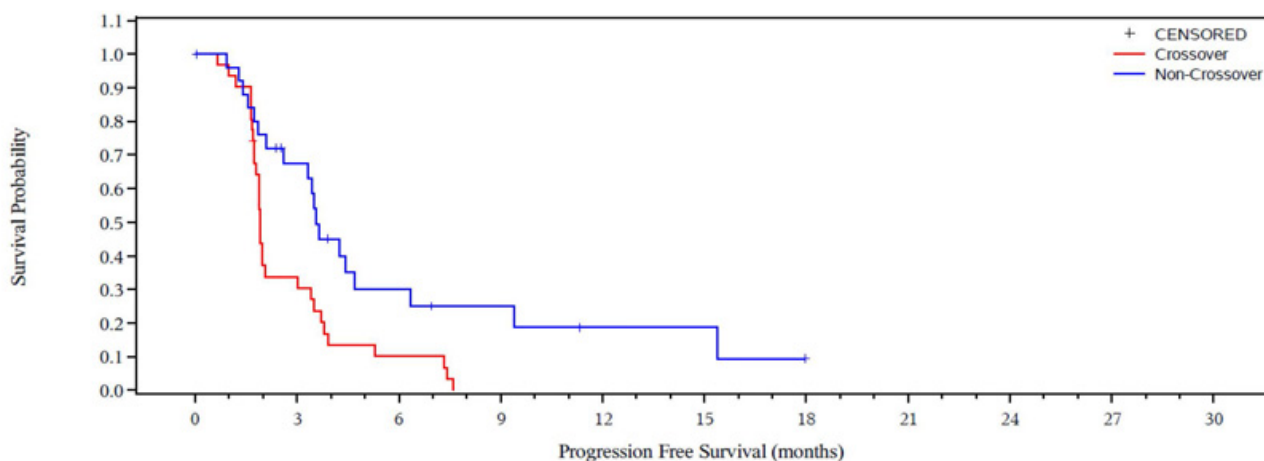
	Number at Risk:									
Crossover	31	31	27	19	16	13	5	3	1	
Non-Crossover	26	22	12	8	6	6	4	3	1	1



Data cutoff from COMPANION-002 as of April 2026.

Crossover Patients Progressed Faster on Paclitaxel Monotherapy

Post hoc subset analysis (n=31 vs. n=26): 1.9 vs. 3.6 months median PFS, p=0.007



Number at Risk:

	0	3	6	9	12	15	18
Crossover	31	10	3	4	2	2	
Non-Crossover	26	15	6	4	2	2	



Data cutoff from COMPANION-002 as of April 2026.

Safety: Treatment Emergent Adverse Events $\geq 20\%$

Safety profile generally consistent with previously reported data

n (%)	Tovecimig + Paclitaxel n=108				Paclitaxel n=53			
	Overall	Related	\geq Grade 3	Related \geq Grade 3	Overall	Related	\geq Grade 3	Related \geq Grade 3
Fatigue	72 (67)	66 (61)	16 (15)	12 (11)	24 (45)	23 (43)	3 (6)	2 (4)
Hypertension	75 (69)	65 (60)	56 (52)	48 (44)	10 (19)	2 (4)	3 (6)	1 (2)
Neutropenia	59 (55)	58 (54)	40 (37)	39 (36)	20 (38)	20 (38)	14 (26)	14 (26)
Diarrhea	51 (47)	38 (35)	6 (6)	6 (6)	15 (28)	11 (21)	1 (2)	1 (2)
Anemia	48 (44)	42 (39)	23 (21)	20 (19)	17 (32)	11 (21)	5 (9)	3 (6)
Alopecia	32 (30)	31 (29)	-	-	28 (53)	25 (47)	-	-
Nausea	43 (40)	36 (33)	2 (2)	-	17 (32)	13 (25)	-	-
Decreased appetite	44 (41)	32 (30)	2 (2)	1 (1)	11 (21)	7 (13)	-	-
Vomiting	36 (33)	30 (28)	1 (1)	1 (1)	13 (25)	12 (23)	1 (2)	1 (2)
Abdominal pain	35 (32)	6 (6)	9 (8)	2 (2)	13 (25)	2 (4)	4 (8)	-
Dyspnea	32 (30)	8 (7)	5 (5)	-	13 (25)	2 (4)	-	-
Peripheral edema	35 (32)	20 (19)	-	-	7 (13)	3 (6)	-	-
Peripheral Neuropathy	29 (27)	28 (26)	2 (2)	2 (2)	13 (25)	11 (21)	1 (2)	1 (2)
Proteinuria	37 (34)	30 (28)	3 (3)	2 (2)	5 (9)	-	-	-
Thrombocytopenia	33 (31)	30 (28)	7 (7)	7 (7)	6 (11)	3 (6)	-	-
Constipation	30 (28)	17 (16)	-	-	8 (15)	3 (6)	-	-
Epistaxis	32 (30)	23 (21)	-	-	4 (8)	2 (4)	-	-
Headache	25 (23)	10 (9)	-	-	7 (13)	4 (8)	-	-
Arthralgia	25 (23)	18 (17)	-	-	6 (11)	3 (6)	-	-

COMPANION-002: Study Summary and Next Steps

	Endpoint / Analysis	Results
ORR	Primary	<ul style="list-style-type: none"> • Significant improvement: 17.1% vs 5.3% BICR-assessed ORR (p=0.031)
PFS	Key Secondary	<ul style="list-style-type: none"> • Significant improvement: 4.7 vs 2.6 months median PFS (HR=0.44, p<0.0001)
OS	Key Secondary	<ul style="list-style-type: none"> • OS was not met: 8.9 vs 9.4 months median OS (HR=1.05, p=0.78) • Analyses confounded by crossover (54% crossover rate; 85% of all patients received tovecimig)
Crossover Arm PFS1 / PFS2	Prespecified Secondary	<ul style="list-style-type: none"> • Significant improvement: 3.5 vs 1.9 months median PFS (HR=0.36, p=0.0016) (post-crossover PFS2 with tovecimig vs initial PFS1 on paclitaxel alone)
Crossover Arm OS	Post Hoc Subset	<ul style="list-style-type: none"> • Significant improvement: 12.8 vs 6.1 months median OS (HR=0.54, p=0.04) (post-crossover patients vs patients who did not cross over)
Safety / Tolerability	AEs	<ul style="list-style-type: none"> • Generally consistent with prior studies; no new safety signals

Longer OS despite faster initial progression on paclitaxel for these patients

Next Steps:
Meet with FDA to discuss these data in advance of a BLA submission

Tovecimig: Potential to Become Standard of Care in 2L BTC

Analysis	Program	N	ORR	Months		
				Median Progression Free Survival	Median PFS2 (post-crossover progression)	Median Overall Survival

Tovecimig COMPANION-002 Study in 2L*

ITT	Tovecimig + Paclitaxel	111 Combo	17.1% (p=0.031)	4.7 m	8.9 m
		57 Control	5.3%	2.6 m	9.4 m
Subset	Patients Initially Randomized to Paclitaxel	31 Crossover		1.9 m → 3.5 m → 5.4 m (total)	12.8 m
		26 Paclitaxel		3.6 m	6.1 m

Other Second Line*

2L	Choi-2021 ¹	59 FOLFIRI	4.0%	2.1 m	5.7 m
		59 FOLFOX	5.9%	2.8 m	6.2 m



*Historical data presented. Tovecimig is investigational, and no head-to-head studies have been conducted.

1. PMID: 34303287



Compass Therapeutics

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Nasdaq: CMPX
