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 1, 2025

COMPASS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39696**	**82-4876496**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 1, 2025, Compass Therapeutics, Inc. (the "Company") issued a press release announcing that tovecimig met its primary endpoint in the ongoing randomized Phase 2/3 study in patients with biliary tract cancer ("BTC"). The Company will host a webcast today, Tuesday, April 1, 2025 at 8:00 a.m. ET, to provide a review of the data. Interested parties may register for the call in advance by visiting https://viavid.webcasts.com/starthere.jsp?ei=1712286&tp_key=3b05c5ebcd.

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 1, 2025, 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.

Top-line Data for Phase 2/3 Randomized Trial of Tovecimig in Combination with Paclitaxel in Patients with Advanced Biliary Tract Cancer

On April 1, 2025, the Company announced statistically significant top-line data on the primary efficacy endpoint for COMPANION-002, the Company's ongoing 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). 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 overall response rate ("ORR") as confirmed by independent central radiology review and secondary endpoints include progression-free survival ('PFS"), overall survival ("OS") and duration of response ("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.

Top-line results of the study are summarized below:

- **Primary Endpoint (ORR as confirmed by independent central radiology review).** 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% relative improvement in ORR for those receiving the combination was statistically significant (p=0.031).

		Tovecimig + Paclitaxel	**Paclitaxel**
Intent-to-Treat Population		n=111	n=57
Overall Response Rate (CR+PR)		19 (17.1%) (p=0.031)	3 (5.3%)
Best Overall Response n (%)	Complete Response (CR)	1 (0.9%)	0 (0.0%)
	Partial Response (PR)	18 (16.2%)	3 (5.3%)
	Stable Disease (SD)	49 (44.1%)	19 (33.3%)
	Non-CR / Non-PD*	9 (8.1%)	2 (3.5%)
	Progressive Disease (PD)	18 (16.2%)	24 (42.1%)
	Not Evaluable (NE)**	16 (14.4%)	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.

- **Secondary Endpoints.** The COMPANION-002 study is ongoing and the data are not yet mature for the analyses of the secondary outcome measures (including PFS, OS and DoR). The trial requires a threshold of events in 80% of patients to trigger the secondary endpoint analyses. Based on current projections, the Company anticipates this pre-specified number of events to be reached in the third quarter of 2025, and expects to report data from the secondary endpoints in the fourth quarter of 2025.
- **Safety & Tolerability.** The safety profile of tovecimig in this study to date is consistent with prior studies of tovecimig. An independent Data Monitoring Committee ("DMC") has reviewed safety data at four separate (pre-specified) DMC meetings and, after each meeting, recommended continuation of the study without modification. The Company expects to report detailed safety data with the analyses of secondary endpoints in the fourth quarter of 2025.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release dated April 1, 2025
99.1	Presentation dated April 1, 2025
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 1, 2025

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

Tovecimig (CTX-009) Meets Primary Endpoint in the Ongoing Randomized Phase 2/3 Study in Patients with Biliary Tract Cancer

- *Tovecimig (a DLL4 x VEGF-A bispecific antibody) in combination with paclitaxel achieved a 17.1% overall response rate (ORR), including one complete response, compared to 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 have been confirmed by blinded independent central radiology review.*
- *The study also showed differences between treatment arms for other efficacy measures, including progressive disease (PD) rates of 16.2% in patients on tovecimig in combination with paclitaxel versus 42.1% in patients on paclitaxel alone.*
- *The pre-specified number of events required to trigger the analyses of the secondary endpoints, including progression free survival (PFS), overall survival (OS) and duration of response (DoR), has not yet been met due to fewer of these events occurring than were originally modeled. The Company expects to report these endpoints in Q4 of this year.*
- *Company to host webcast today, April 1, 2025 at 8:00 a.m. ET.*

BOSTON, April 01, 2025 (GLOBE NEWSWIRE) -- Compass Therapeutics, Inc. (Nasdaq: CMPX), a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics, announced statistically significant top-line data on the primary efficacy endpoint for COMPANION-002, the Company's ongoing Phase 2/3 randomized trial of tovecimig (formerly CTX-009) in combination with paclitaxel in patients with advanced BTC.

"We are thrilled to share these positive primary endpoint data from the COMPANION-002 study of tovecimig in patients with advanced biliary tract cancer," said Thomas Schuetz, MD, PhD, CEO of Compass and Vice Chairman of the Board of Directors. "We would like to thank all of the patients and their caregivers who have participated and continue to participate in this study. We believe these findings highlight the potential of tovecimig to provide a much-needed treatment option for the majority of patients with BTC who have limited alternatives after first-line therapy. We look forward to discussing these data with regulatory authorities."

"As a treating clinician for over 20 years, I have seen firsthand how challenging a disease biliary tract cancer is. Patients currently have very limited treatment options, with the vast majority in the second-line setting having no approved therapeutic alternative whatsoever. For every statistic there is a person – a mother, father, relative, or friend – fighting for more time. Each investigative trial helps in this fight to advance new treatment options, and I look forward to following tovecimig's continued progress," said Juan Valle, MD, Chief Medical Officer of the Cholangiocarcinoma Foundation.

Biliary tract cancer is estimated to affect approximately 23,000 patients annually in the United States. For the approximately 85% 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 combinations of therapeutics used in this setting, which are not labeled for this indication, generally have an ORR of ~5% or less and patients face a median overall survival of approximately six months.

COMPANION-002 (tovecimig + paclitaxel versus paclitaxel alone): Top-Line Results

The trial 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. 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/m^2 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 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.

Top-line results of the study are summarized below, and the Company expects to announce additional data, including key secondary endpoints, in Q4 2025:

- **Primary Endpoint (ORR as confirmed by independent central radiology review).** 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% relative improvement in ORR for those receiving the combination was statistically significant (p=0.031).

		Tovecimig + Paclitaxel	**Paclitaxel**
Intent-to-Treat Population		n=111	n=57
Overall Response Rate (CR+PR)		19 (17.1%) (p=0.031)	3 (5.3%)
Best Overall Response n (%)	Complete Response (CR)	1 (0.9%)	0 (0.0%)
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*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.

- **Secondary Endpoints.** The COMPANION-002 study is ongoing and the data are not yet mature for the analyses of the secondary outcome measures (including PFS, OS and DoR). The trial requires a threshold of events in 80% of patients to trigger the secondary endpoint analyses. Based on current projections, the Company anticipates this pre-specified number of events to be reached in Q3 2025, and expects to report data from the secondary endpoints in Q4 2025.

- **Safety & Tolerability.** The safety profile of tovecimig in this study to date is consistent with prior studies of tovecimig. An independent Data Monitoring Committee (DMC) has reviewed safety data at four separate (pre-specified) DMC meetings and, after each meeting, recommended continuation of the study without modification. The Company expects to report detailed safety data with the analyses of secondary endpoints in Q4 2025.

Webcast Information
Compass Therapeutics will host a webcast today, Tuesday, April 1, 2025 at 8:00a.m. ET to provide a review of the tovecimig top-line COMPANION-002 data.

Interested parties may register for the call in advance via https://viavid.webcasts.com/starthere.jsp?ei=1712286&tp_key=3b05c5ebcd. A replay of the webcast will be available via the Investors section of the Compass website at investors.compasstherapeutics.com.

About Tovecimig (CTX-009)
Tovecimig is an investigational bispecific antibody that is designed to simultaneously blocks 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 early 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. Partial responses to tovecimig as a monotherapy have been observed in heavily pre-treated patients with cancer who were resistant to approved anti-VEGF therapies. COMPANION-002, a Phase 2/3 trial of tovecimig plus paclitaxel versus paclitaxel monotherapy in patients with previously treated, unresectable advanced metastatic or recurrent biliary tract cancers (BTC) is ongoing (clinical trial information: NCT05506943).

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 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, 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 and the timing of announcement of key secondary endpoints in the COMPANION-002 trial. 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.

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Developing next generation antibodies into transformative cancer therapies that improve patients' lives
COMPANION-002 Data Disclosure Presentation
Nasdaq: CMPX
April 1, 2025

DISCLAIMER

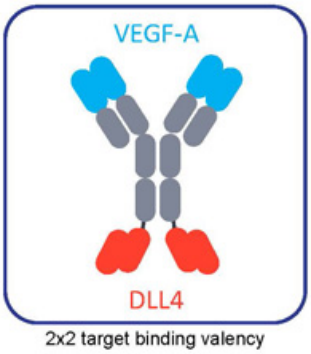
This presentation has been prepared by Compass Therapeutics, Inc. ("we," "us," "our," or the "Company"). Statements contained herein are made as of the date of this presentation unless stated otherwise, and this presentation shall not under any circumstances create an implication that the information 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 includes forward-looking statements regarding our drug candidates, the timing and outcome of regulatory decisions, future availability of clinical trial data, our collaborations for our product candidates and the maintenance of those collaborations, business and results from operations, and other matters. Actual results could differ materially from those contained in any forward-looking statements as a result of various factors, including without limitation: that our drug candidates do not advance in development or result in approved products on a timely or cost effective basis or at all; the cost, timing and results of clinical trials; that many drug candidates that have completed early-stage trials do not become approved drugs on a timely or cost effective basis or at all; the ability to enroll patients in clinical trials; possible safety and efficacy concerns; regulatory developments; our ability to protect our intellectual property rights, and unexpected costs, charges or expenses that reduce cash runway. Our pipeline programs are in various stages of pre-clinical and clinical development, and the process by which such pre-clinical or clinical therapeutic candidates could potentially lead to an approved therapeutic is long and subject to significant risks and uncertainties. These and other risks and uncertainties that we face are described in our most recent Annual Report on Form 10-K, and in other filings that we make with the Securities and Exchange Commission from time to time. We undertake no obligation to update forward-looking statements as a result of new information or otherwise.

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.

Tovecimig: Bispecific with Compelling MOA (DLL4 x VEGF-A)



2x2 target binding valency

Anti-VEGF-A MAb
VEGF/VEGF-R signaling

→ **Disrupts tumor vessel formation**
(proven anti-angiogenic mechanism)

Anti-DLL4 MAb
DLL4-Notch-1 signaling

→ **Targets tumor DLL4 expression and alters perfusion in tumor vessels**
(novel angiogenesis target)

- Dual blockade: **VEGF-A** – validated target for blockbuster oncology therapeutics (e.g.: Avastin®)
  DLL4 (Notch-1 ligand) – mediates resistance to anti-VEGF therapies
- Bispecific anchors in tumor microenvironment (DLL4) to disrupt angiogenesis
- Only DLL4 X VEGF bispecific to demonstrate monotherapy activity in patients with CRC and GC[1]

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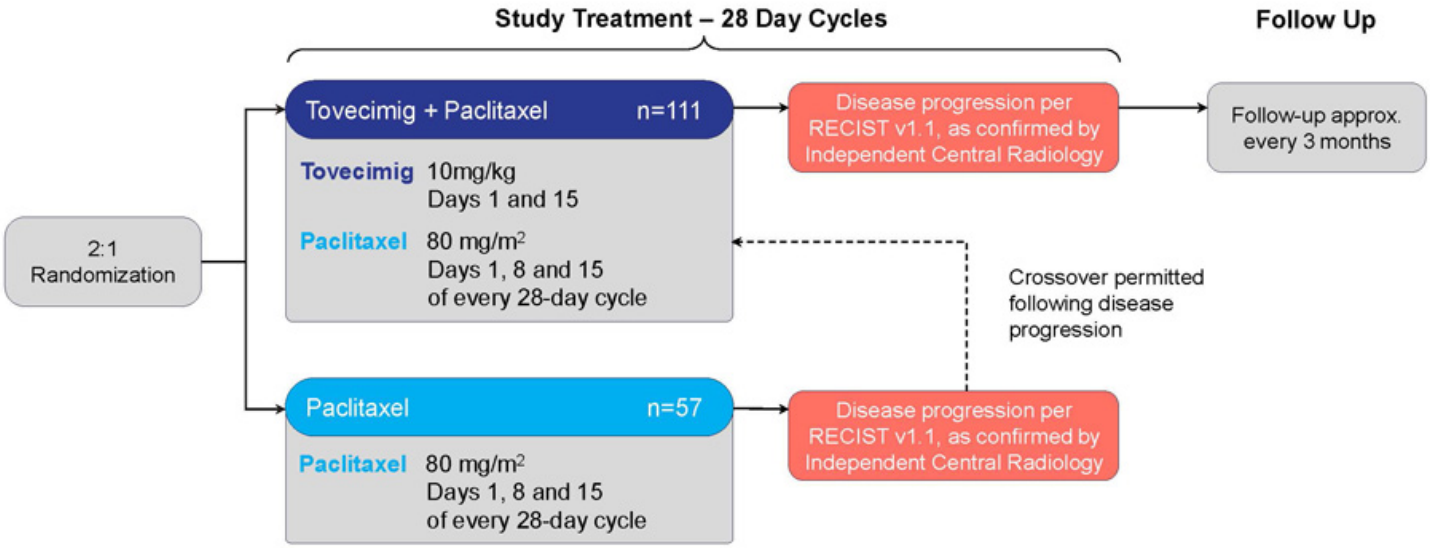
1. Lee, J et. al. 2021, October 7-10. Plenary Presentation AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics.

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**

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Tovecimig: Ongoing Phase 2/3 Summary - Primary Endpoint

COMPANION-002 Study (BTC)		Tovecimig + Paclitaxel	Paclitaxel
Intent-to-Treat Population		n=111	n=57
Overall Response Rate (CR+PR)		**19 (17.1%)**	5.3%
Two-Sided p-value		**p=0.031**	
Best Overall Response (RECIST v1.1 by blinded independent radiology review)	Complete Response (CR)	**1 (0.9%)**	0 (0.0%)
	Partial Response (PR)	**18 (16.2%)**	3 (5.3%)
	Stable Disease (SD)	49 (44.1%)	19 (33.3%)
	Non-CR / Non-PD*	9 (8.1%)	2 (3.5%)
	Progressive Disease (PD)	**18 (16.2%)**	24 (42.1%)
	Not Evaluable (NE)**	16 (14.4%)	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.

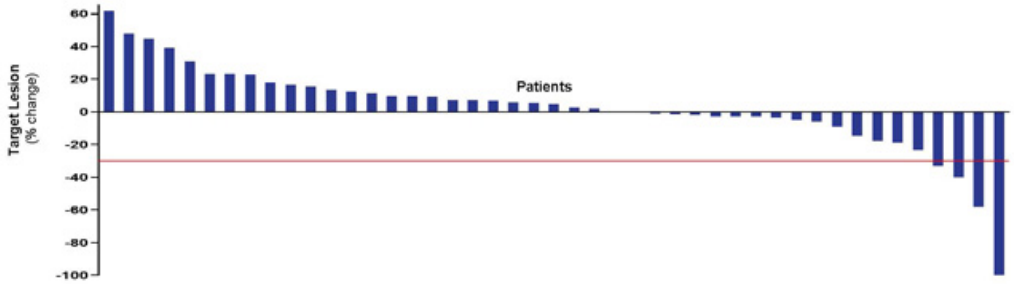
Safety Data: The safety profile of tovecimig in this study to date has been consistent with prior studies.

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.

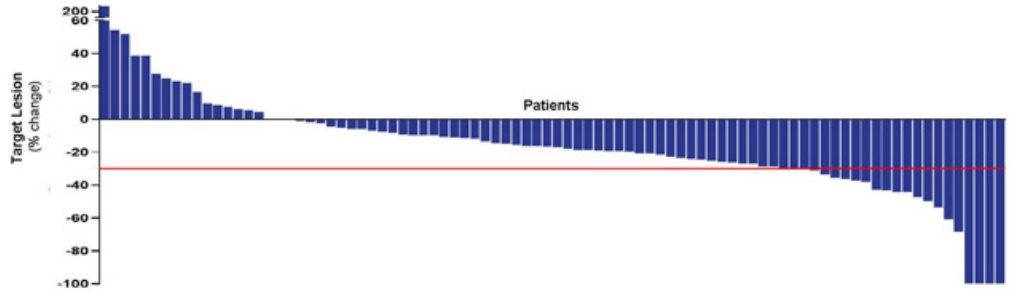
COMPASS THERAPEUTICS

Tovecimig: Top-line Ph 2/3 Activity in Patients with BTC (2L)

Paclitaxel Monotherapy



Tovecimig + Paclitaxel



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

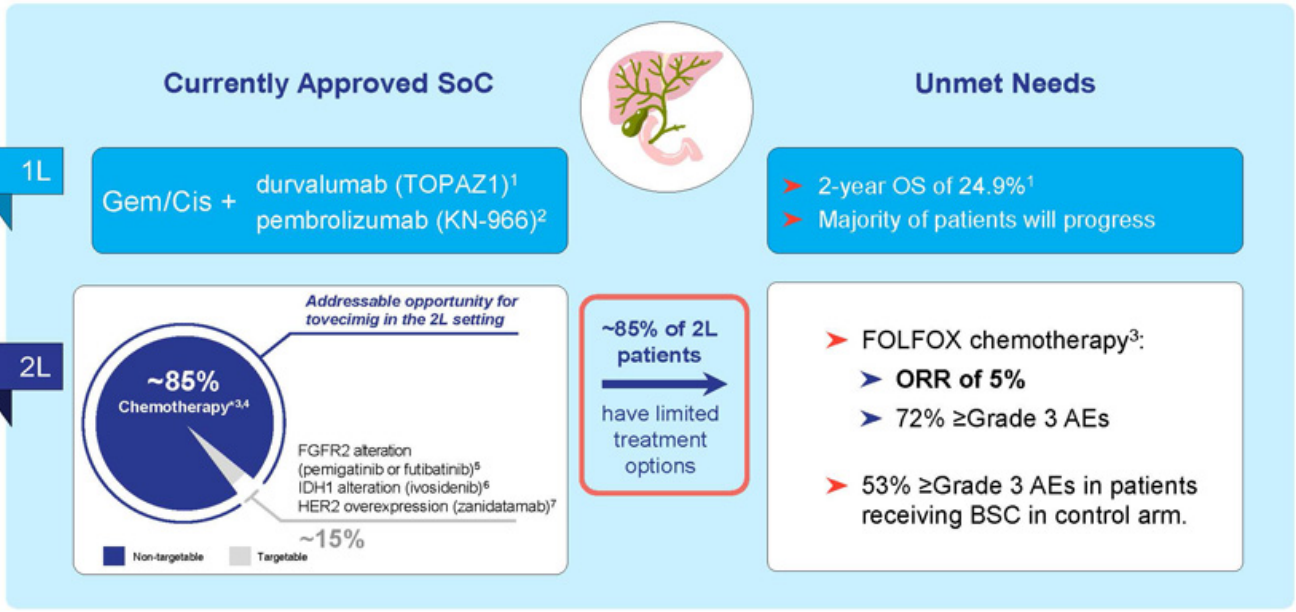
Line	Program	N	ORR	Progression Free Survival / Overall Survival (Months: 0, 2, 4, 6, 8, 10, 12, 14)
First Line				
1L	Gem/Cis + Durv[1]	341	26.7%	7.2 m; 12.8 m
1L	Gem/Cis + Pembro[2]	533	28.7%	6.5 m; 12.7 m
Second Line				
2L	ABC-06[3]	81 BSC	0%	5.3 m
		81 FOLFOX	5%	4.0 m; 6.2 m
Tovecimig* in 2L				
2L	Tovecimig + Paclitaxel[4]	111	**17.1%** **(p=0.031)**	**PFS, OS and DoR Data Expected Q4 2025**

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

COMPASS THERAPEUTICS

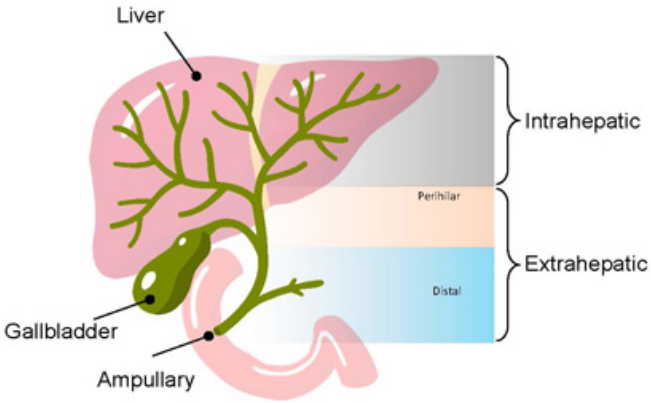
1. PMID: 38319896; 2. PMID: 37075781; 3. PMID: 33798493; 4. DOI: 10.1200/JCO.2023.41.4_suppl.540

Significant Unmet Needs in Current Treatments for BTC



1. PMID: 38319896; 2. PMID: 37075781; 3. PMID: 33798493; 4. NCCN (2024). Biliary Tract Cancers (version 4.2024); 5. PMID: 37017301; 6. PMID: 33182517; 7. PMID: 38266541

Incidence of BTC is Significant and Not Fully Appreciated



Cancer site	Epidemiology-based Approach (SEER)	Claims-based Approach (ICD)
Liver & intrahepatic bile duct	15%[2] of 42,240[1]	---
Gallbladder & other biliary	12,610[1]	---
Other & unspecific primary sites	11%[3] of 37,370[1]	---
Incidence	**~23,000**[1]	**~22,800**[4]

Projected ~100,000 incidence of liver and intrahepatic bile duct cancer by 2040 (making it third most common cause of cancer-related deaths)[5]

1. PMID: 39817679; 2. Lowe, R, et al. Epidemiology, risk factors, anatomy, and pathology of cholangiocarcinoma. UpToDate, Inc. (2022); 3. PMID: 35484217; 4. Worrall S, Komodo Health x Cholangiocarcinoma Foundation. (2023); 5. PMID: 33825840

Key Upcoming Milestones