

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): **January 13, 2025**

GALECTIN THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction of Incorporation)

001-31791
(Commission File Number)

04-3562325
(IRS Employer Identification No.)

4960 PEACHTREE INDUSTRIAL BOULEVARD, STE 240
NORCROSS, GA 30071
(Address of principal executive office) (zip code)

Registrant's telephone number, including area code: **(678) 620-3186**

N/A
(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 (see General Instruction A.2. below):

- 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))

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.

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

| Title of each class | Trading Symbol | Name of each exchange on which registered |
|--|----------------|---|
| Common Stock \$0.001 par value per share | GALT | The Nasdaq Stock Market |

Item 7.01 Regulation FD Disclosure.

On January 13, 2025, Galectin Therapeutics Inc. (the "Company") is making its updated corporate presentation available on its website. The Company intends to use the presentation at conferences and meetings with investors, shareholders and analysts. A copy of the presentation is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information furnished under this Item 7.01 of this Current Report on Form 8-K and the exhibits attached hereto are deemed to be "furnished" and shall not be deemed "filed" for the purpose of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall such information and exhibits be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

This Current Report on Form 8-K and Exhibit 99.1 hereto contain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Exhibit Description</u> |
|----------------------|---|
| 99.1 | Galectin Therapeutic Inc. Corporate Presentation, updated January 13, 2025 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

SIGNATURES

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

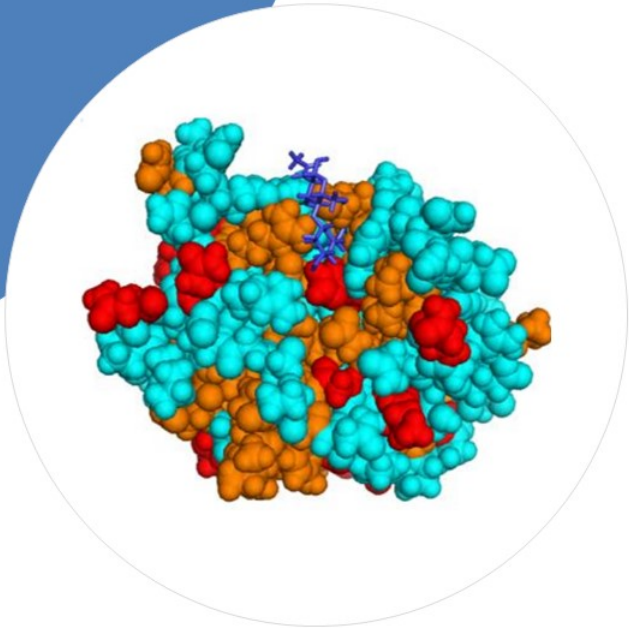
Galectin Therapeutics Inc.

Date: January 13, 2025

By: /s/ Jack W. Callicutt
Jack W. Callicutt
Chief Financial Officer

Galectin Therapeutics Corporate Overview

January 2025



Forward-Looking Statements

This presentation contains, in addition to historical information, forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future financial performance and use words such as “may,” “estimate,” “could,” “expect” and others. They are based on our current expectations and are subject to factors and uncertainties that could cause actual results to differ materially from those described in the statements.

These statements include those regarding potential therapeutic benefits of our drugs, expectations, plans and timelines related to our clinical trials, supporting activities, potential partnering opportunities and estimated spending for 2024 and beyond. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that our trials and supporting CMC information may be impacted by a resurgence of COVID-19 or a similar outbreak of an infectious disease.

We may experience delays in our trials, which could include enrollment delays. Future phases or future clinical studies may not begin or produce positive results in a timely fashion, if at all, and could prove time consuming and costly. Plans regarding development, approval and marketing of any of our drugs are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies. Strategies and spending projections may change. We may be unsuccessful in developing partnerships with other companies or obtaining capital that would allow us to complete our clinical trials or further develop and/or fund any future studies or trials.

To date, we have incurred operating losses since our inception, and our future success may be impacted by our ability to manage costs and finance our continuing operations. For a discussion of additional factors impacting our business, see our Annual Report on Form 10-K for the year ended December 31, 2023, and our subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause our views to change, we disclaim any obligation to update forward-looking statements.

Investment Highlights

Developing galectin-based therapeutics to improve the lives of patients with chronic liver diseases and cancer

Focused Pipeline

Belapectin is a novel, potent, galectin-3 inhibitor with Fast Track Designation
Low toxicity as a carbohydrate-based molecule which is degraded by natural processes
Patent protection through 2032

MASH Cirrhosis

Only company to exclusively focus on treatment for MASH cirrhosis and portal hypertension
Significant efficacy observed in cirrhotic patients without varices
Promising NAVIGATE topline results at 18 month read out, $\geq 40\%$ reduction in new varices vs placebo in ITT; significantly lower incidence of new varices in per protocol population

Oncology (Combination Therapy)

Encouraging clinical response in difficult-to-treat cancers in combination with checkpoint inhibitor
IND filed and approval to proceed received from FDA (Head & Neck cancer)

Highly Experienced Leadership Team



JOEL LEWIS
Chief Executive Officer &
President

Financial executive with over 25 years of management experience in a taxation, restructuring, acquisition, and private equity ventures.



JEFF KATSTRA
VP, CMC / Pharmaceutical
Development

Highly experienced in pharmaceutical development of novel formulations and medicines with advanced manufacturing techniques and bringing them to approval.



KHURRAM JAMIL, M.D.
Chief Medical Officer

Have two decades of experience leading drug development across various stages of clinical trials in the pharmaceutical industry. Led multiple new drug application filings and secured approvals from several regulatory agencies.



JESSICA KOPACZEWSKI
Senior Director, Clinical
Operations

Over 25 years diverse experience in the pharmaceutical research industry supporting global study operations from site to personnel management.



JACK W. CALLICUTT
Chief Financial Officer

Over 32 years of public and private company experience including more than a decade of audit, tax and SEC registrant experience with a major accounting firm.



SETH ZUCKERMAN
Senior Director,
Biostatistics

Over 28 years of experience working in the pharmaceutical industry in clinical data and trial management with 23 years as statistician.



SUE THORNTON
VP Regulatory Affairs

More than 20 years of domestic and international drug development experience encompassing all aspects of global Regulatory Affairs and Quality Assurance.



EZRA LOWE, Ph.D.
VP, Clinical and Preclinical
Pharmacology

Extensive experience in clinical pharmacology, drug metabolism, and pharmacokinetics with various drug formats and across therapeutic areas, leading to 10 different global drug approvals.

Laser-Focused Pipeline

| Clinical Program | | Development Stage | | | | |
|--|---|-------------------|-------------|---------|---------|---------|
| Drug | Indication | Discovery | Preclinical | Phase 1 | Phase 2 | Phase 3 |
| Fibrosis | | | | | | |
| Belapectin | MASH Cirrhosis and Portal Hypertension | | | | | |
| Cancer Immunotherapy (Combination therapy) | | | | | | |
| Belapectin + Keytruda | Melanoma + Head / Neck Cancer | | | | | |
| Oral Galectin-3 Inhibitors | | | | | | |
| Discovery program to identify subcutaneous forms of carbohydrates and oral small molecules | | | | | | |

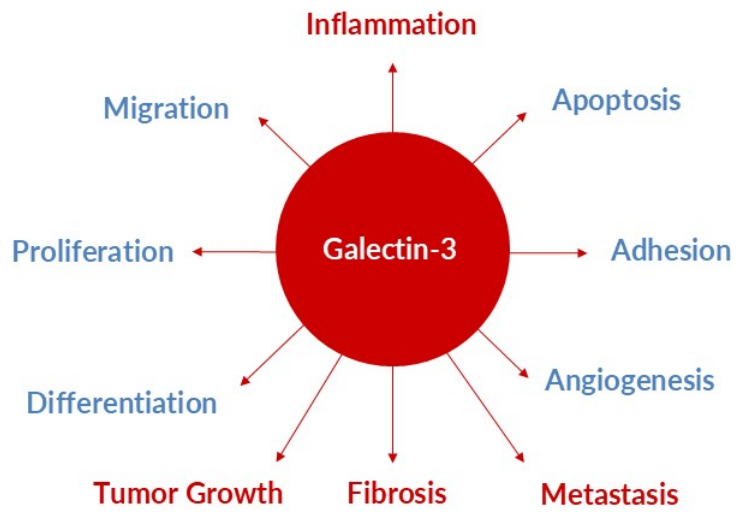
Galectin-3 is a Promising Therapeutic Target in Inflammatory and Fibrotic Diseases^{1,2}

Galectin 3 is part of the galectin family of sugar-binding proteins that act as a “molecular glue”, it is:

- Predominantly produced by activated macrophages
- Involved in a wide number of biological and pathological processes

Galectin-3 recruits macrophages to injury sites and promotes chronic inflammation by activating proinflammatory pathways

Galectin-3 drives many pathophysiological process in fibrotic diseases and cancer



1. Marino KV, et al. *Nat Rev Drug Discov.* 2023;22(4):295-316. 2. Henderson NC, et al. *Proc Natl Acad Sci U S A.* 2006;103(13):5060-5.

Belapectin: a Proprietary Galectin-3 Inhibitor with Low Toxicity and Anti-fibrotic Activity

Belapectin Preclinical Data:

In animal models of MASH (streptozotocin High-Fat Diet mice¹) and cirrhosis (thioacetamide treated rats²) belapectin was associated with decreased:

- Galectin-3 staining and galectin-3 expression in macrophages
- NAFLD Activity Scores
- Collagen-1 expression
- Hepatic collagen deposition
- Hepatic fibrosis
- Portal pressure

In toxicology studies, including monkeys, belapectin:

- Was well-tolerated even at high doses
- Accumulated in macrophages with a residence time longer than in plasma



Belapectin is a polysaccharide polymer comprising galacturonic acid, galactose, arabinose, rhamnose and smaller amounts of other sugars

MASH Cirrhosis

Galectin^{GT}
Therapeutics

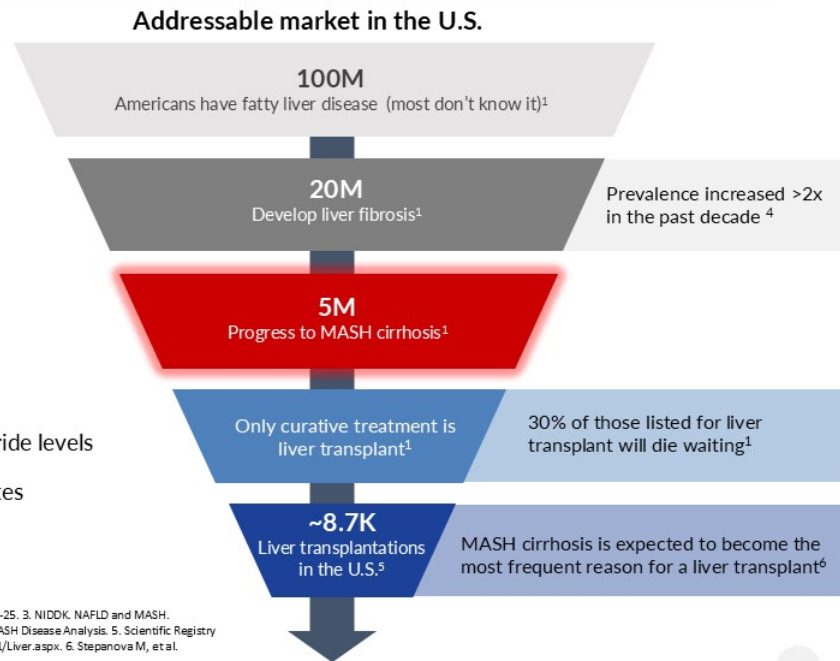
MASH Cirrhosis Represents a Significant Market Opportunity in the U.S. with No FDA-Approved Treatment

Metabolic dysfunction-associated steatohepatitis (MASH), previously known as non-alcoholic steatohepatitis (NASH), is characterized by fat accumulation, inflammation and fibrosis of the liver¹

3%-5% of the global population is estimated to be affected by MASH, though the disease is considered to be underdiagnosed²

There are genetic predisposition to MASH, yet certain health conditions put patients at increased risk:³

- Being overweight or obese
- Having hypertension, high cholesterol or high triglyceride levels
- Having type 2 diabetes, insulin resistance or prediabetes



1. Fatty Liver Foundation. <https://www.fattyliverfoundation.org/#sec.tab=0>. 2. Sherif ZA, et al. *Dig Dis Sci*. 2016;61(5):1214-25. 3. NIDDK. NAFLD and MASH. <https://www.niddk.nih.gov/health-information/liver-disease/naflid-nash/symptoms-causes>. 4. Datamonitor Healthcare. MASH Disease Analysis. 5. Scientific Registry of Transplant Recipients. OPTN/SRTN 2021 Annual Data Report: Liver. https://str.transplant.hrsa.gov/annual_reports/2021/Liver.aspx. 6. Stepanova M, et al. *Hepatal Commun*. 2022;6(7):1506-1515.

Belapectin is a Novel Therapy with First- and Best-in-Class Potential in MASH Cirrhosis

United States Estimates¹

2.1M

Patients with compensated MASH cirrhosis in 2024

331K

Patients with compensated cirrhosis and portal hypertension with no varices in 2024

\$8.8B

Peak belapectin sales in U.S.

3rd Party Market Opportunity Assessment Suggests¹

Potential 50-100% Adoption Rate

Limited current treatment options:





- Cirrhotic management focuses on stabilization and delaying progression
- Management directed towards comorbidities

Highly favorable perception of belapectin indication, MoA and safety by HCPs

Payers believe in the high unmet need in MASH cirrhosis

A significant unmet need exists for MASH compensated cirrhosis patients with portal hypertension due to disease severity and risk of decompensation

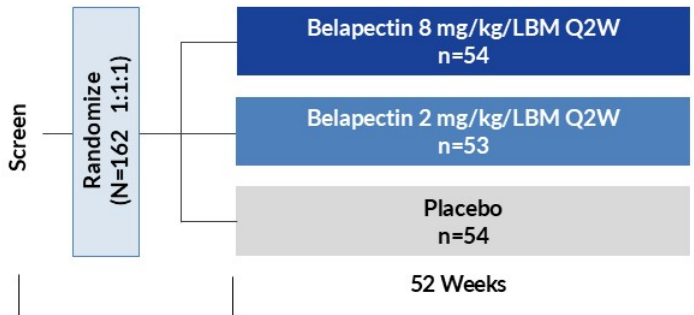
When to Intervene in Cirrhosis- before its too late!

| Compensated cirrhosis | | | Decompensated cirrhosis |
|---|---|--|---|
| No Portal Hypertension | Portal Hypertension | | |
| <i>No varices</i> | <i>No varices</i> | <i>Varices, small to large</i> | <i>Varices Bleeding, ascites, encephalopathy</i> |
|  |  |  |  |
| | ≥6 | HVPG ¹ mm Hg | >10 |
| | One year mortality 1-3% | | One year mortality ~50% |

There are no approved therapies to reverse portal hypertension once it develops in MASH Cirrhosis

HPVG=hepatic venous pressure gradient.

Phase 2b Study of Belapectin in Patients with MASH Cirrhosis: GT-026 Trial



Main inclusion criteria

- MASH cirrhosis (biopsy)
- Portal Hypertension: HVPG \geq 6 mmHg
- No cirrhosis complications
- No varices/varices (50:50)

HVPG = Hepatic Venous Pressure Gradient; LBM=lean body mass.
1. Chalasani N, et al. *Gastroenterol.* 2020;158:1334-45.

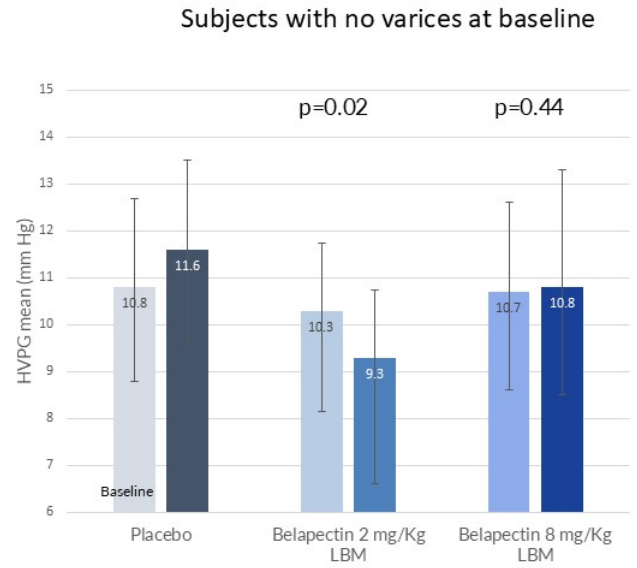
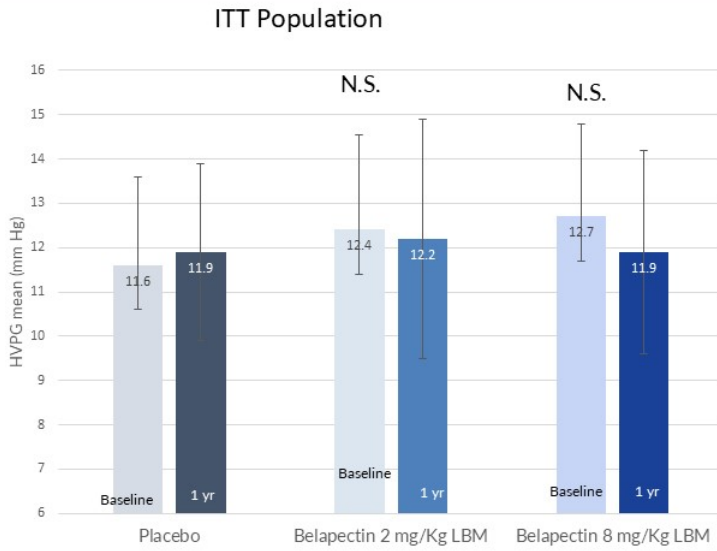
Primary endpoint

- Portal pressure (HPVG) change from baseline to Week 54

Secondary endpoints at Week 54

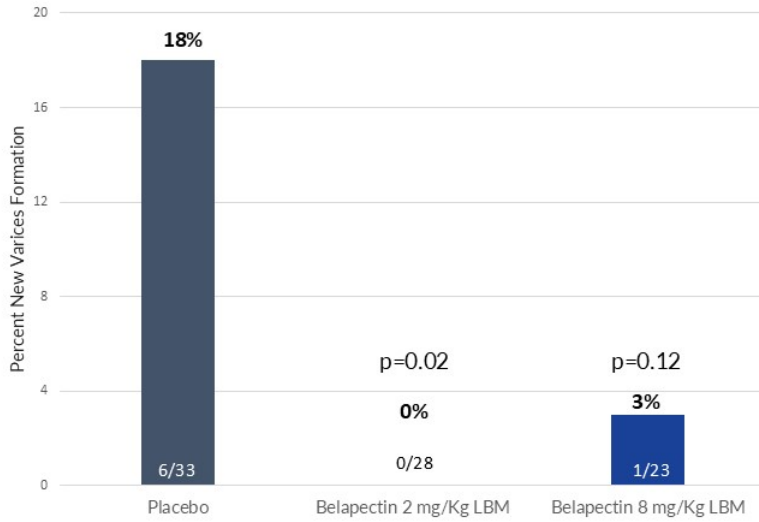
- Liver biopsy
- Varices (esophago-gastric endoscopy)
- Cirrhosis decompensation

Belaepectin Impact on HPVG at One Year^{1,*}



HPVG = Hepatic Venous Pressure Gradient; LBM=lean body mass, N.S.=non significant.
^{*}ITT with LOCF, ANCOVA with baseline as covariate and treatment as factors, Bonferroni-Holm.
¹. Chalasani N, et al. *Gastroenterol*. 2020;158:1334-45.

Belapectin Reduces Emergence of Varices in Patients with MASH Cirrhosis^{1,*}



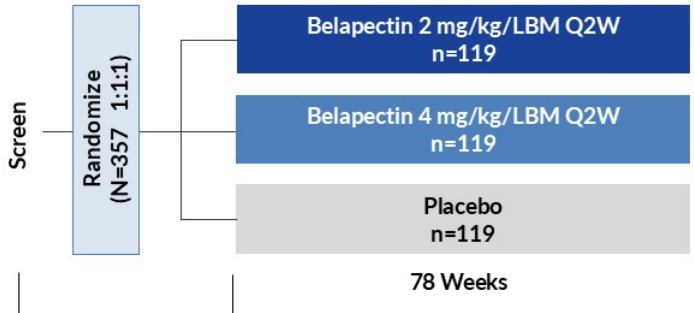
Significantly fewer new varices on belapectin vs placebo

No patients on 2 mg/kg/LBM developed new varices

Belapectin demonstrated efficacy on a clinically-meaningful endpoint where no current therapies exist

LBM=lean body mass.
*Chi square
1. Chalasani N, et al. *Gastroenterol.* 2020;158:1334-45.

NAVIGATE Trial: Belaepectin for Prevention of Varices in Patients with MASH cirrhosis and Portal Hypertension



Patient Population

- MASH cirrhosis
- Diagnosis of Portal Hypertension using Baveno criteria
(via non-invasive markers as per latest guidelines)
- EGDs assessed via central review by multiple blinded reviewers.

Originally the NAVIGATE trial was designed as an adaptive Phase 2b/3 trial for 36-month duration. However, based on FDA feedback, the Company made the decision to analyze the stage 1 (18 month) as stand-alone clinical trial.

LBM- Lean body mass; EGD=Esophagogastroduodenoscopy

NAVIGATE Study: Patient Population and Efficacy Endpoints

Key inclusion criteria

- MASH cirrhosis
- No varices on EGD
- CTP Scores <7
- Portal hypertension:
 - Thrombocytopenia or at least
 - AST/ALT > 1
 - Spleen ≥ 14 cm
 - Collaterals by imaging
 - Stiffness ≥ 20 kPa

Primary endpoint

- Development of new varices (composite strategy) in ITT population-
 1. Number of subjects with varices
 2. Subject with intercurrent events (ICE*)
 3. Subject with missing EGDs and no ICE
- Pre-defined per protocol population-
 - Development of new varices per protocol

Secondary endpoint

- Hepatic decompensation events
- All-cause mortality
- Proportion of patients with large varices or red wales
- Varices requiring treatment
- MELD ≥ 15
- Liver transplant
- Non-invasive biomarkers

ALT=alanine aminotransferase ; AST=aspartate transaminase; CTP=Child-Turcotte-Pugh; MELD=model for end-stage liver disease.

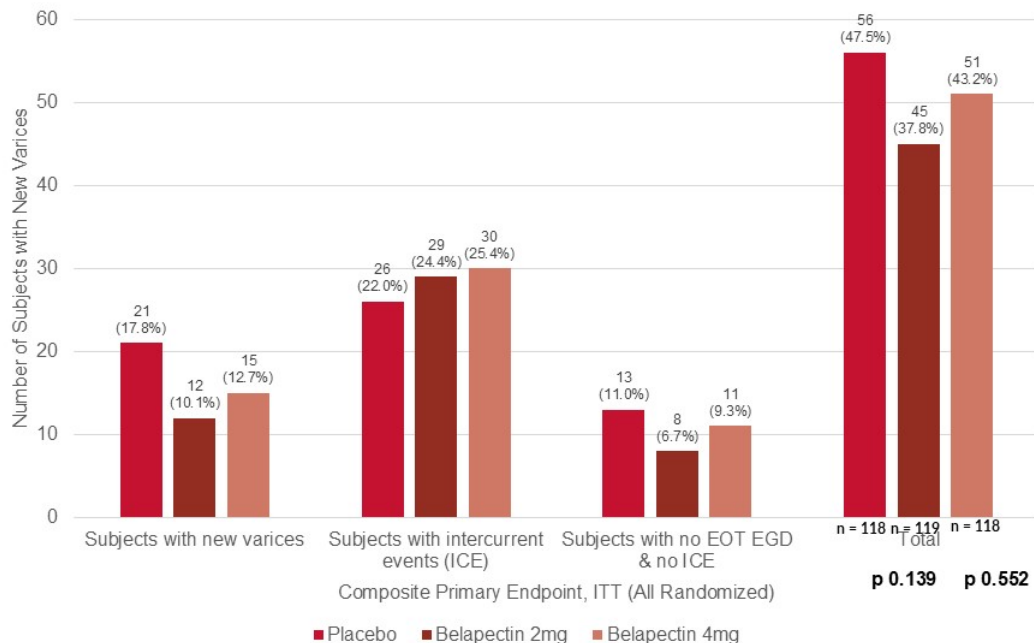
*Intercurrent events include; Liver related clinical events, any AE leading to discontinuation, TIPS; ≥12-month use of GLP-1 or NSBB

Baseline demographics

Table 14.1.3.1

Baseline Demographics and Clinical Characteristics (n=355)

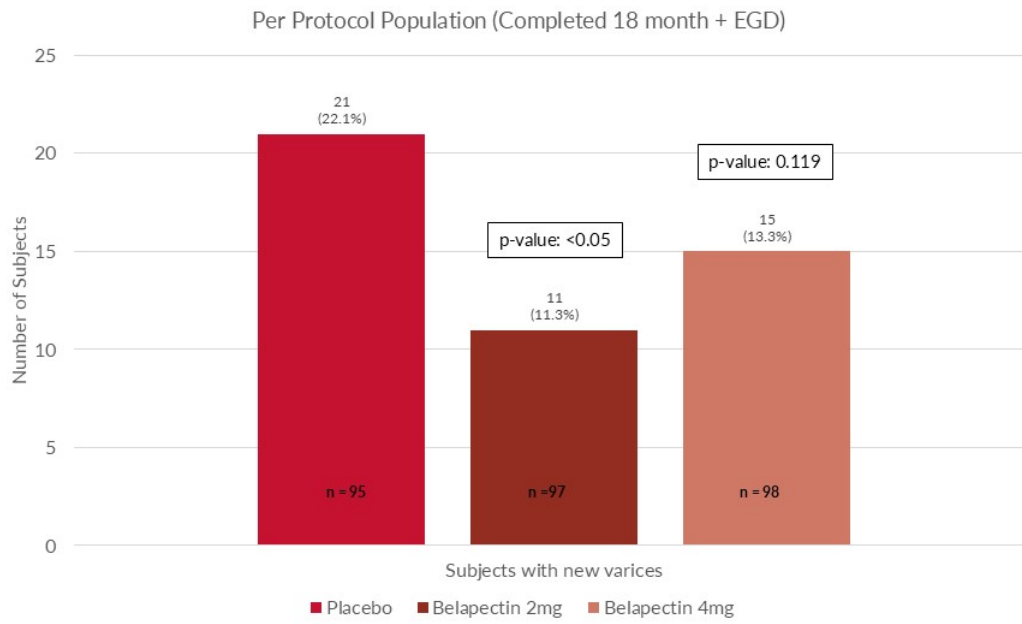
| | Placebo (N = 118) | 2mg/kg LBM (N = 119) | 4mg/kg LBM (N = 118) |
|---------------------------------------|---------------------------|---------------------------|---------------------------|
| | Mean (Standard Deviation) | Mean (Standard Deviation) | Mean (Standard Deviation) |
| Age (years) | 60.4 (8.50) | 60.6 (8.82) | 59.0 (9.14) |
| Gender (female), n | 72 (61.0) | 75 (63.0) | 83 (70.3) |
| Ethnicity (Hispanic), n | 34 (28.8) | 39 (32.8) | 33 (28.0) |
| Race (white), n | 104 (88.1) | 107 (89.9) | 111 (94.1) |
| Weight (kg) | 94.2 (21.68) | 98.1 (24.30) | 94.6 (20.95) |
| BMI (Kg/m ²) | 33.82 (6.467) | 34.88 (6.683) | 34.53 (6.223) |
| Hypertension | 89 (75.4) | 89 (74.8) | 82 (69.5) |
| Type 2 Diabetes | 80 (67.8) | 79 (66.4) | 79 (66.9) |
| HbA1C % | 6.4 (1.27) | 6.3 (1.13) | 6.4 (1.09) |
| Alanine Aminotransferase (ALT), U/L | 46.3 (29.92) | 38.9 (26.88) | 39.7 (20.22) |
| Aspartate Aminotransferase (AST), U/L | 46.7 (23.52) | 41.8 (24.40) | 43.6 (21.90) |
| Platelets (per μ L) | 130.1 (39.66) | 127.6 (48.39) | 136.4 (53.62) |
| Liver Stiffness Measurement (kPa) | 24.22 (12.179) | 24.63 (13.548) | 25.67 (13.196) |
| Spleen (cm) | 13.79 (2.750) | 13.97 (2.602) | 13.87 (2.436) |
| MELD Score | 7.6 (1.65) | 7.9 (2.46) | 7.5 (1.55) |
| Child Pugh Score | 5.1 (0.29) | 5.1 (0.31) | 5.0 (0.18) |
| Statins (n) | 49 (41.5) | 55 (46.2) | 47 (39.8) |
| GLP-1 agonist (n) | 24 (20.3) | 26 (21.8) | 27 (22.9) |



- ITT: All randomized subjects
- Primary end point composite strategy i.e. new varices and or intercurrent events or drop out
- ICEs (intercurrent events) include; Liver related clinical events, AE leading to discontinuation, TIPS; ≥12-month use of GLP-1 or NSBB
- Overall Target Significance level – 2-sided p value of 0.05; p: 0.048, using CMH test, stratified by Type 2 diabetes status at randomization.
- The categories are not mutually exclusive.

NAVIGATE 18-month Primary Analyses Result

Per protocol population



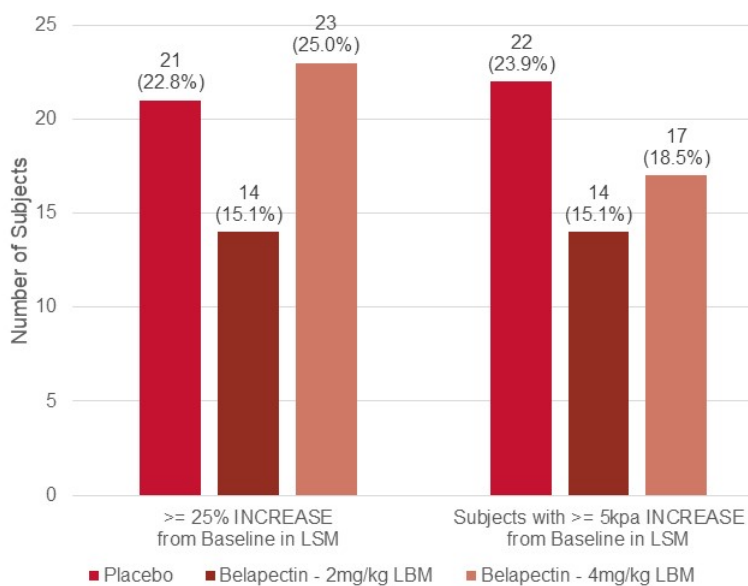
- Per Protocol: All ITT subjects who completed 18 months of treatment and an end of treatment (EOT) EDG
- Overall Target Significance level - 2-sided p value of 0.05; using CMH test, stratified by Type 2 diabetes status at randomization.

**Categorical Changes in Liver Stiffness Measure LSM (kPa)
Baseline to 18 month Per-Protocol (N = 277)**

Table 14.2.5.1.1.3

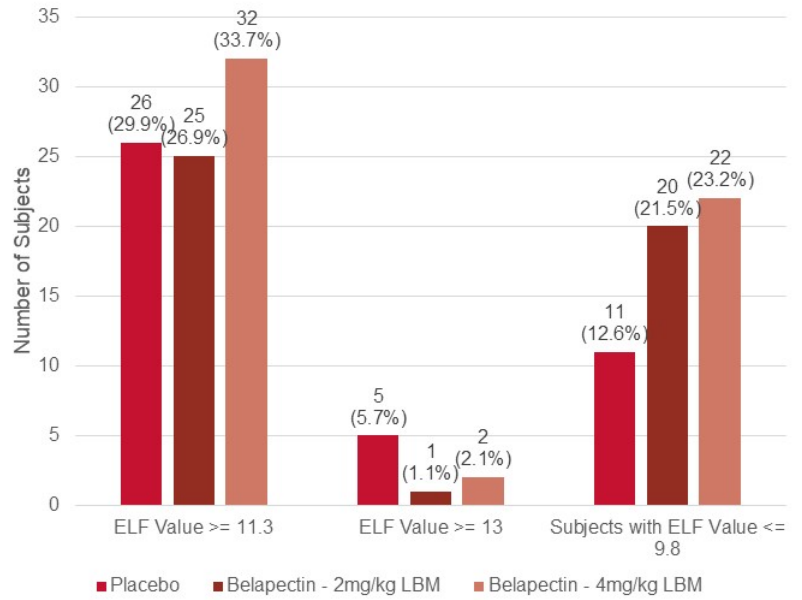
| | Belapectin | | |
|--|---------------------|------------------------|------------------------|
| | Placebo (N = 92) | 2mg/kg LBM (N = 93) | 4mg/kg LBM (N = 92) |
| Baseline LSM Value (kPa) | | | |
| Mean (SD) | 23.3 (11.1) | 22.9 (10.6) | 24.4 (11.8) |
| Median | 22.4 | 21.5 | 23.4 |
| W78/EOT LSM Value (kPa) | | | |
| Mean (SD) | 22.5 (13.6) | 21.2 (12.9) | 22.8 (13.8) |
| Change from Baseline in W78/EOT LSM Value (kPa) | | | |
| Mean (SD) | -0.8 (11.8) | -1.7 (9.7) | -1.5 (12.6) |
| % Change from Baseline in W78/EOT LSM Value (kPa) * | | | |
| Mean % | 9.9 | -4.3 | 9.3 |

* Percentage change calculated for each individual subject



Categorical Changes in ELF Score- Baseline to 18 months
Per-Protocol Table 14.2.5.1.2.2 (N: 275)

| | Placebo | Belapectin | |
|---------------------------|-----------|------------|------------|
| | | 2mg/kg LBM | 4mg/kg LBM |
| Baseline ELF Value | | | |
| N | 87 | 93 | 95 |
| Mean | 10.68 | 10.55 | 10.58 |
| SD | 1.1621 | 0.9608 | 1.0433 |

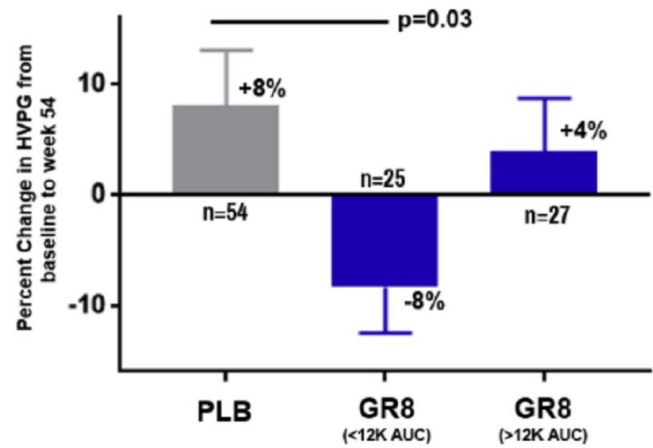


ELF Enhanced Liver Fibrosis Score- combined for HA, PIIINP and TIMP-1

ELF: Risk of disease progression. < 9.8 Low risk, ≥11.3 mid risk, highest risk ≥13

Lack of Dose Response at Higher Doses of Belapectin in GT-026 were also observed in NAVIGATE trial

- Based on findings from preclinical and clinical trials to date, Belapectin likely demonstrates target-mediated drug disposition (TMDD)
- Once Galectin-3 binding sites within macrophages are saturated, additional drug molecules do not enhance efficacy
- Higher doses may exceed the macrophage-specific uptake mechanisms, resulting in altered drug distribution and clearance
- Higher drug concentrations have been associated with reduced efficacy, as observed in the GT-026 cohort, where subjects receiving 8 mg/kg (with higher AUC) exhibited lower pharmacodynamic (PD) effects.
- Similar PK profile shown by monoclonal antibodies and interferon among other agents.
- 2 mg/kg dose demonstrated consistent and most optimum efficacy response
- Similar PK-PD effects were observed across the GT-026 trial and the NAVIGATE 18-month results



Pharmacokinetic-Pharmacodynamic (PK-PD)

Chalasani et al. *Gastroenterology* 2020; 158: 1334-1345

- Similar proportion of subjects discontinued the study treatment in each arm due to Adverse Events: 7 (5.9%) in the Placebo arm, 6 (5.0%) in the Belapectin 2 mg/Kg arm and 9 (7.5%) in the Belapectin 4 mg/Kg arm.
- Similar proportion of subjects discontinued the study due to Adverse Events: 7 (5.9%) in the Pbo, 5 (4.2%) in 2 mg/Kg arm and 8 (6.7%) in the Belapectin 4 mg
 - One subject in each arm discontinued the study due to death
- No Adjudicated Drug-Induced Liver Injury (DILI) Events.
- Similar proportion of subjects reported **Treatment-Emergent Adverse Events TEAEs** across 3 cohorts: 112 (94.9%) in Pbo, 116 (97.5%) in 2 mg and 116 (96.7%) in 4 mg
- Similar proportion of subjects reported **Treatment-Emergent Serious Adverse Events (TESAEs)** across 3 cohorts: 23 (19.5%) in Pbo, 27 (22.7%) 2 mg and 25 (20.8%) 4 mg

- Belapectin 2 mg reduced varices incidence by 43.2% compared to placebo in the overall population; results were not statistically significant (ITT).
- In the per-protocol population (18-month treatment + end-of-treatment EGD), the reduction was **48.9%**.
 - Initial sample size assumed **52.5%** lower varices incidence with Belapectin vs. placebo.
 - Per-protocol population (18-month treatment + EGD) parallels evaluable biopsy results in MASH trials.
 - Non-diabetic subjects showed better responses, aligning with trends in MASH interventions (Belapectin 2 mg: 11.1% vs. placebo: 29.4%, n=70).
- Following reasons likely contributed to missing statistical significance;
 - Fewer recorded varices than expected; mid-study sample size re-estimation based on composite endpoint, not varices.
 - Shorter treatment duration; primary analysis at 18 months instead of 36 months.
 - Higher dropout rate (18.3% observed vs. 10% expected), mostly during COVID and first 4 months.
- These risks were accepted, leading to unblinding at 18 months instead of completing the 36-month trial.

**Power of a trial roughly equates to the probability of seeing a statistically significant result - all else being equal*

- 2 mg dose demonstrated a meaningful reduction in the development of new esophageal varices in patients with MASH cirrhosis and portal hypertension validating the findings observed in GT-026 trial.
- Non-invasive markers provide supportive evidence showing a lower incidence of disease progression 36-month categorical changes in the 2 mg group compared to placebo in LSM and ELF data.
- Belapectin exhibits a clean and favorable safety profile; low rate of discontinuation due to AEs, no drug related SAEs.
- Analyses for 18-month data ongoing; 36-month data from available patients; biomarker data expected by end of first quarter.
- Prevention of varices in this high-unmet-need population is a recognized clinical need, and we believe an acceptable regulatory endpoint; FDA accepted central EGD reading.
- The distinct MOA of belapectin as Galectin 3 inhibitor positions it as a favorable and complementary candidate for combination therapy in MASH cirrhosis.
- Exploring partnership opportunities

. Chalasani N, et al. *Gastroenterol.* 2020;158:1334-45

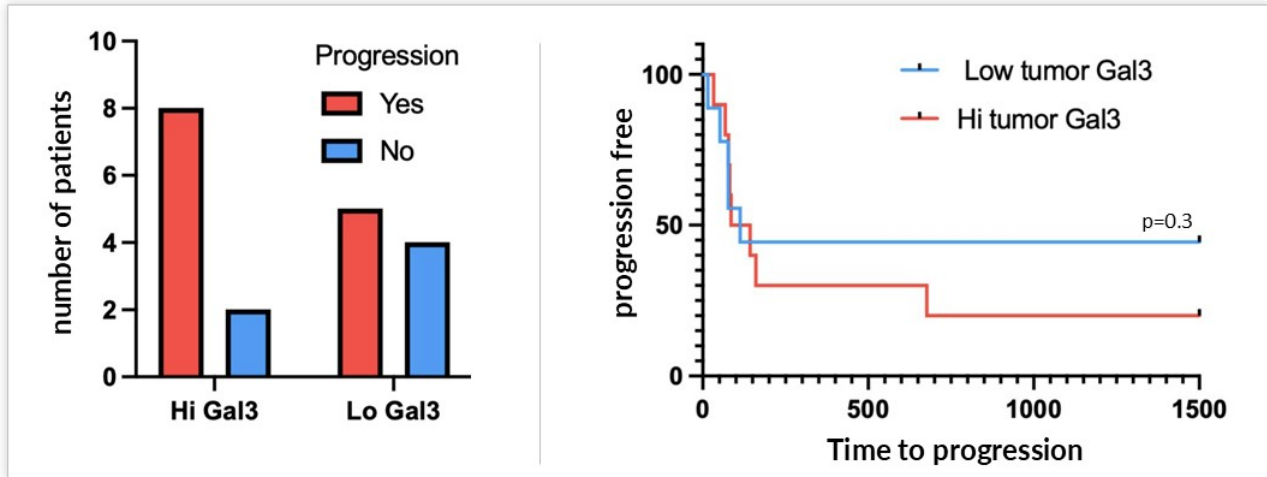


Cancer Immunotherapy Program (Belapectin + checkpoint inhibitor)

Galectin^{GT}
Therapeutics

Higher Galectin-3 Tumor Levels are Associated with Metastatic Melanoma Progression

Number of patients with or without progressive disease in hi/lo Galectin-3 expression in metastatic melanoma



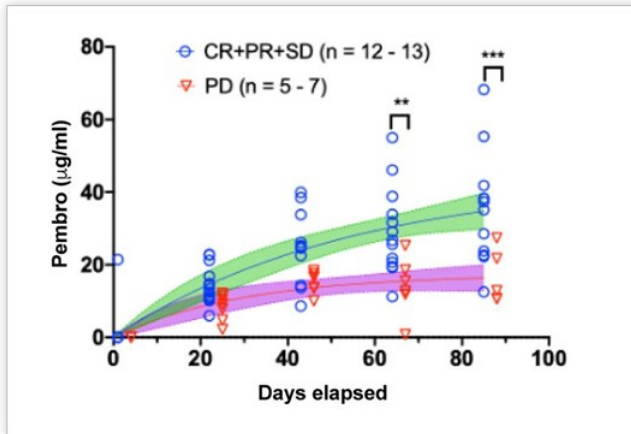
p<0.01, *p<0.001.

CR=complete response; HNSCC=head and neck squamous cell carcinoma; MM=metastatic melanoma; PD=progressive disease; PR=partial response; SD=stable disease.

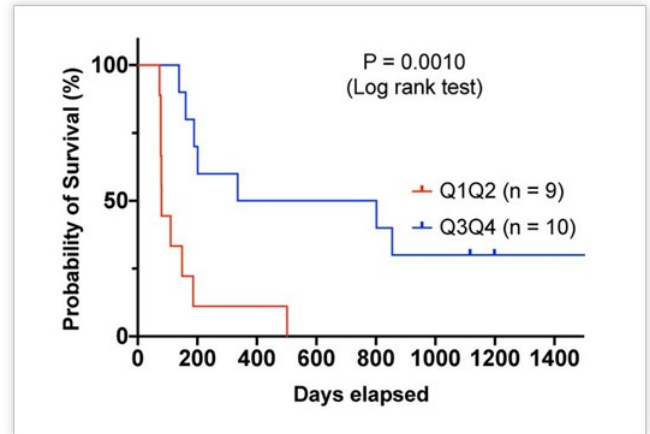
1. Greisen SR, et al. *J Immunother Cancer*. 2024;12(10):e009952.

Reduced PD-1 Clearance Correlates with Better Survival in Patients with MM and HNSCC

Serum trough levels of pembrolizumab in patients with disease control or progressive disease¹



Increased progression-free survival in patients with higher trough level of pembrolizumab^{1,*}



Increased trough levels of belapectin and pembrolizumab correlated with better clinical outcome including progression free survival in patients with MM and HNSCC

*Patients were grouped based on the trough levels of pembrolizumab at day 43: Q1Q2 (below population mean) and Q3Q4 (above population mean).

p<0.01, *p<0.001.

CR=complete response; HNSCC=head and neck squamous cell carcinoma; MM=metastatic melanoma; PD=progressive disease; PR=partial response; SD=stable disease.

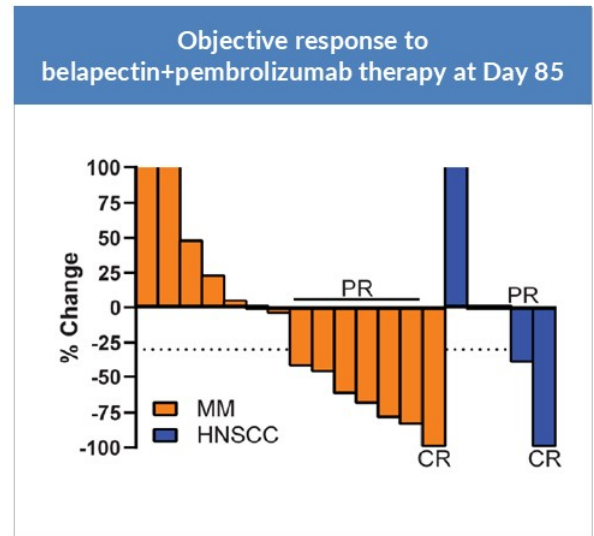
1. Curti B. *J Immunother Cancer*. 2021;9:e002371.

Belapectin in Combination with Pembrolizumab Showed Clinical Efficacy and Safety in Phase 1¹

Phase 1 (Investigator-Initiated) of belapectin + pembrolizumab (Keytruda®)

- Objective response observed in 50% of MM (7/14) and 33% of HNSCC (2/6) patients
- Extension in more advanced patients showed stable disease in 56% MM (5/9) and 40% in HNSCC (2/5)
- Combination treatment was well tolerated with no dose-limiting toxicity observed
- Fewer immune adverse events than expected
- Increased baseline expression of Gal3⁺ tumor cells, periphery PD-1⁺CD8⁺ T cells and reduced clearance of pembrolizumab correlated with clinical response

IND filed and approval to proceed received from FDA (Head and Neck cancer)



HNSCC=head and neck squamous cell carcinoma; MM=metastatic melanoma.
1. Curti B. *J Immunother Cancer*. 2021;9:e002371.

Investment Highlights

Developing galectin-based therapeutics to improve the lives of patients with chronic liver diseases and cancer

Focused Pipeline

Belapectin is a novel, potent, galectin-3 inhibitor with Fast Track Designation
Low toxicity as a carbohydrate-based molecule which is degraded by natural processes
Patent protection through 2032

MASH Cirrhosis

Only company to exclusively focus on treatment for MASH Cirrhosis and Portal Hypertension
Consistent and promising results for prevention of varices in 2 mg dose across GT-026 and NAVIGATE trials
Biomarker data and longer-term outcomes data (36-month data) from available patients expected by end of Q1 2025

Oncology (Combination Therapy)

Encouraging clinical response in difficult-to-treat cancers in combination with checkpoint inhibitor
IND filed and approval to proceed received from FDA (Head & Neck cancer)

Thank you!

