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): **September 9, 2024**

GALECTIN THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-31791**	**04-3562325**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 $0.001par value per share	GALT	The Nasdaq Stock Market

Item 7.01 Regulation FD Disclosure.

On September 9, 2024, 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.

Exhibit No.	Exhibit Description
99.1	Galectin Therapeutic Inc. Corporate Presentation, updated September 2024
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.

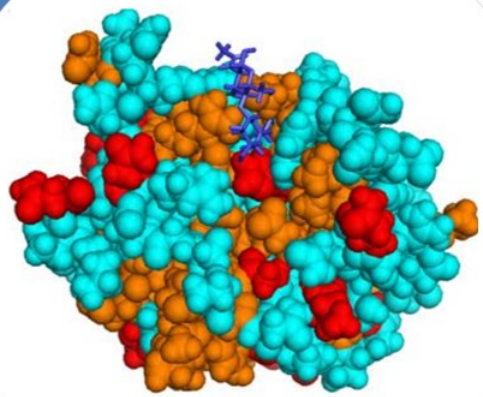
Date: September 9, 2024

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

Exhibit 99.1

Galectin Therapeutics Corporate Overview

August 2024



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 2035

MASH Cirrhosis

Only company to exclusively focus on treatment for the cirrhotic stage of MASH
Significant efficacy observed in cirrhotic patients without varices
Ongoing adaptively-designed pivotal Phase 2b/3 trial; interim readout expected in Q4 2024

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)

Finance

$23.6M* cash and $20M remaining under line of credit provided by GALT Chairman*
Cash runway expected through May 2025

*As of March 31, 2024.

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.

KHURRAM JAMIL, M.D.
Chief Medical Officer

Have two decades of expereince 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.

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.

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.

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.

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.

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.

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					
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						

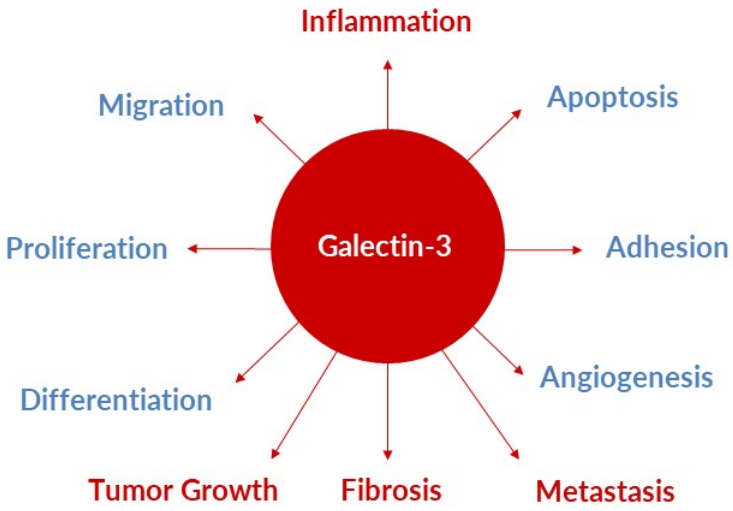
Galectin-3 is a Promising Therapeutic Target in Inflammatory and Fibrotic Diseases[1,2]

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 mice[1]) and cirrhosis (thioacetamide treated rats[2]) 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

1. Traber PG, et al. *PLoS One*. 2013;8(12):e83481. 2. Traber PG, et al. *PLoS One*. 2013; ;8(10):e75361.

MASH Cirrhosis

Galectin Therapeutics

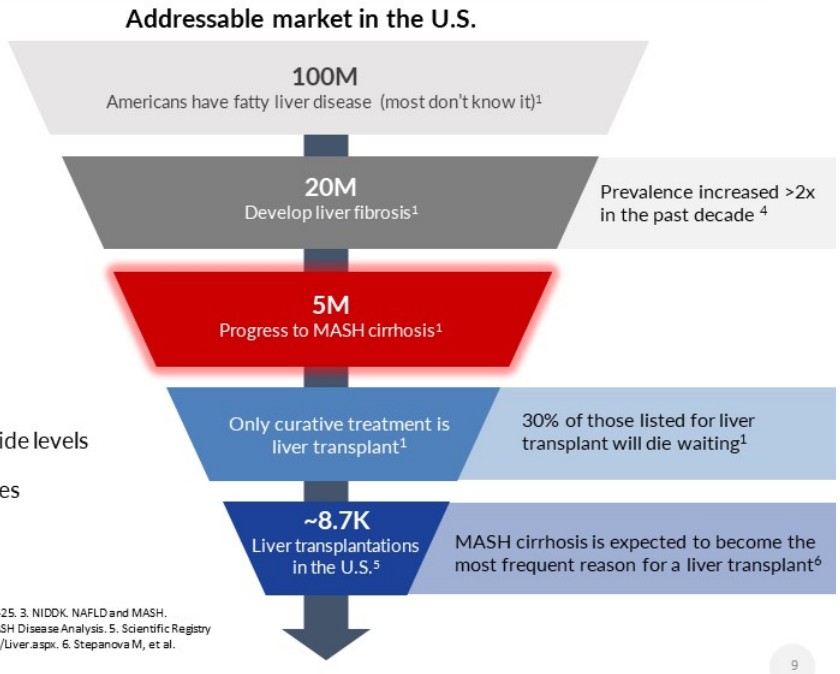
MASH Cirrhosis Represents a Significant Market Opportunity in the U.S. with No FDA-Approved Treatment

Metabolic dysfunction-associated steatohepatitis (MASH), previously known as non-alcoholic steatohepatitis (NASH), is characterized by fat accumulation, inflammation and fibrosis of the liver[1]

3%-5% of the global population is estimated to be affected by MASH, though the disease is considered to be underdiagnosed[2]

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/#gsc.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/nafld-nash/symptoms-causes. 4. Datamonitor Healthcare. MASH Disease Analysis. 5. Scientific Registry of Transplant Recipients. OPTN/SRTR 2021 Annual Data Report: Liver. https://srtr.transplant.hrsa.gov/annual_reports/2021/Liver.aspx. 6. Stepanova M, et al. *Hepatol Commun.* 2022;6(7):1506-1515.

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

United States Estimates[1]

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 Suggests[1]

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

1. LifeSci Consulting Belapectin Commercial Opportunity Assessment contracted by the Company. May 2024.

Intervention Before Escalation: When to Intervene in Cirrhosis

	Compensated Cirrhosis			Decompensated Cirrhosis
Liver Function	Despite histological findings, liver still able to function			Liver is **irreversibly failing**
Symptoms	Usually **no or minimal symptoms**		***Esophageal Varices*** *(first clinical expression of PH)*	**Varices Bleeding, ascites, encephalopathy**
Portal hypertension (PH)	No Portal Hypertension	Portal Hypertension	Portal Hypertension	
	HPVG < 6 mm Hg	6mm Hg < HPVG ≤ 10 mmHg	HPVG > 10 mmHg	
Mortality		**One year mortality 1-3%**		**One year mortality ~50%**

Ideal treatment timing

There are no specific therapies available for patients with portal hypertension who have not yet developed varices

HPVG=hepatic venous pressure gradient.

Belapectin Demonstrated Efficacy and Safety in Clinical Trials[1,2]

Efficacy

The Phase 2b MASH cirrhosis study provided a proof of concept for:

- Efficacy
- Choice of a relevant clinical outcome (prevention of varices)
- Dose range selection

Safety

Belapectin was well-tolerated and appeared safe in Phase 1 and Phase 2b clinical studies

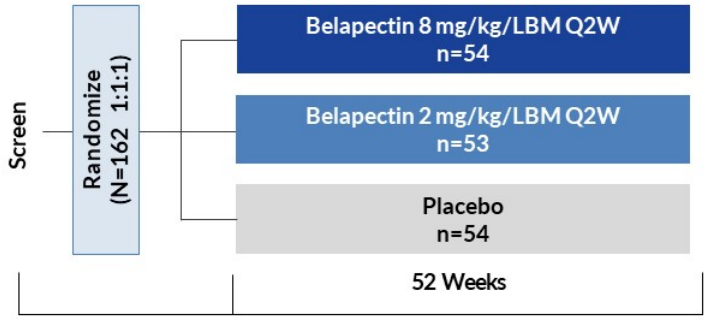
- No adverse safety signal identified
- Phase 2 study with one year of biweekly infusion:
  - Completion rate was 94%
  - Well-tolerated in doses up to 8 mg/kg LBM
- Belapectin exposure did not appear to increase with higher degree of hepatic insufficiency

Encouraging data from Phase 2 Study; Phase 2b/3 Adaptive Trial currently underway

LBM=lean body mass.

1. Chalasani N, et al. *Gastroentrol* 2020;158:1334-45. 2. Curti B. *J Immunother Cancer.* 2021;9:e002371.

Phase 2b Study of Belapectin in Patients with MASH Cirrhosis: Study Design[1]



Main inclusion criteria

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

Primary endpoint

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

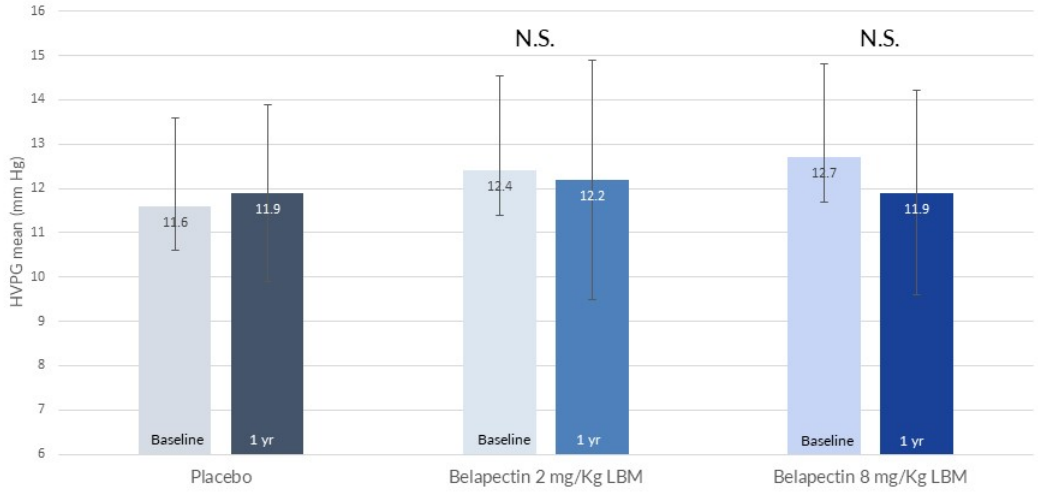
Secondary endpoints at Week 54

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

HVPG = Hepatic Venous Pressure Gradient; LBM=lean body mass.

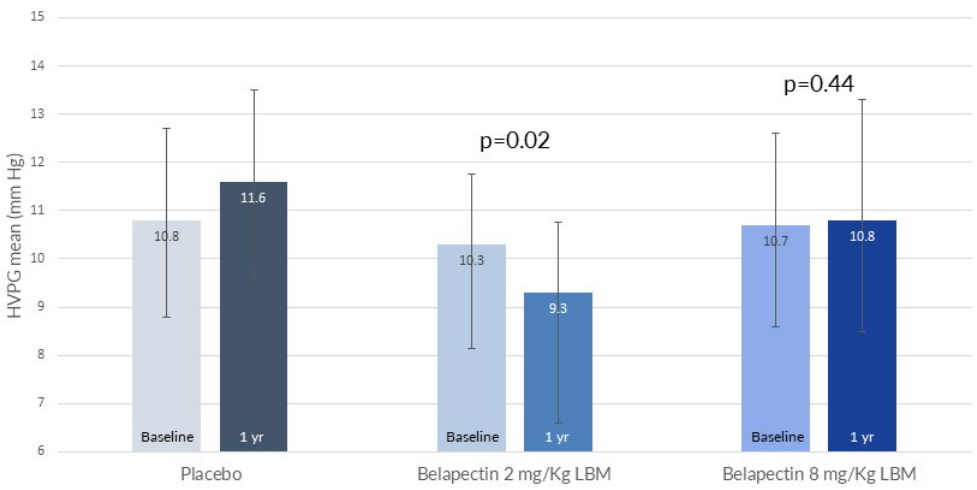
1. Chalasani N, et al. *Gastroentrol.* 2020;158:1334-45.

Total Patient Population: Belapectin Impact on HPVG at One Year[1,*]



HVPG = 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. *Gastroentrol.* 2020;158:1334-45.

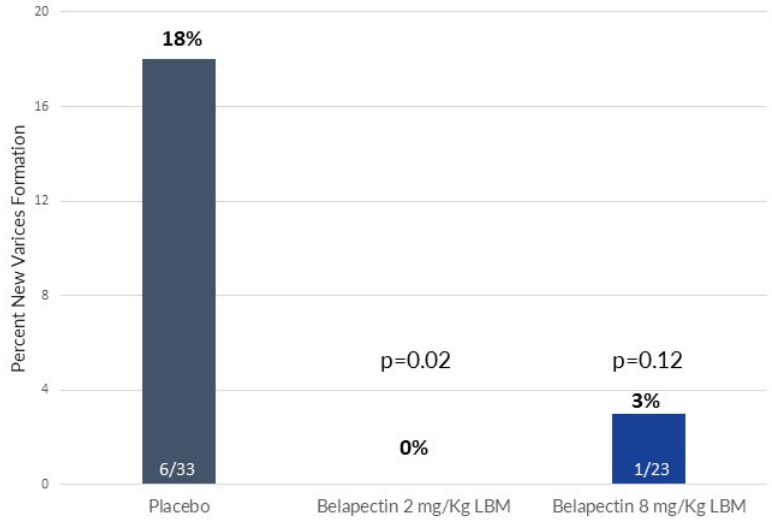
Patients without Varices: Belapectin Significantly Reduced HVPG at One Year[1,*]



Statistically significant effect of 2 mg/kg/LBM dose on change in HVPG from baseline at 1 year

HVPG = Hepatic Venous Pressure Gradient; LBM=lean body mass.
*ITT with LOCF, ANCOVA with baseline as covariate and treatment varices, and treatment/varices interaction as factors, LOCF, Bonferroni-Holm
1. Chalasani N, et al. *Gastroentrol.* 2020;158:1334-45.

Belapectin Reduces Emergence of Varices[1,*]



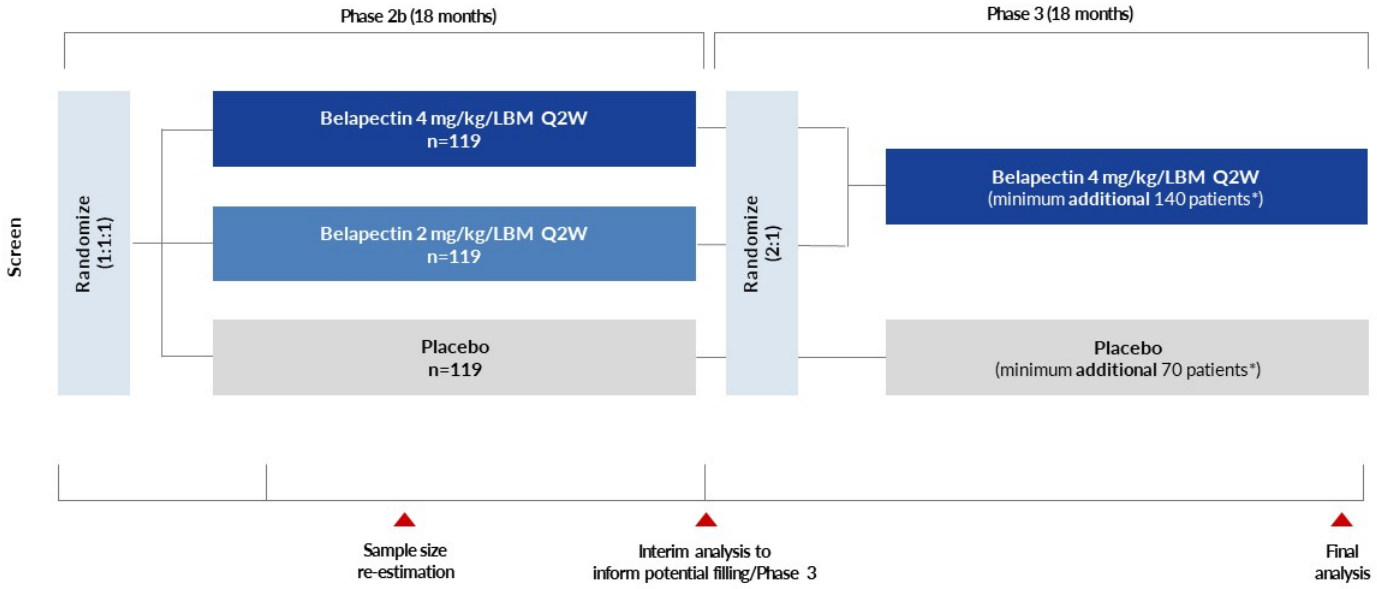
Significantly fewer new varices on belapectin vs placebo

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. *Gastroentrol.* 2020;158:1334-45.

Next Step: NAVIGATE Belapectin's Seamless, Adaptive Study



*Minimum number of additional patients in Phase 3, sample size adjusted based on Interim Analysis results.

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

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; EGD=Esophagogastroduodenoscopy; MELD=model for end-stage liver disease.

NAVIGATE Update

Recruitment complete

Approximately

130+ sites

15 countries

5 continents

No systematic liver biopsies required

Pre-screening on portal hypertension clinical criteria

Central review of esophago-gastro-endoscopies

Interim analysis phase 2b expected December 2024

Cancer Immunotherapy Program (Belapectin + checkpoint inhibitor)

Galectin Therapeutics

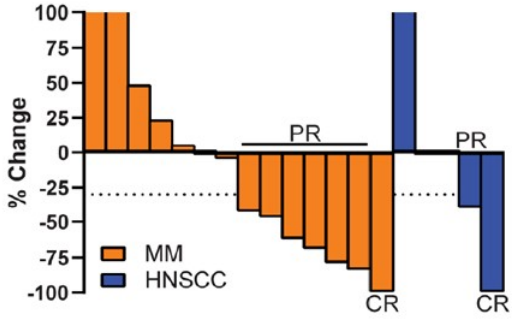
Belapectin in Combination with Pembrolizumab Showed Clinical Efficacy and Safety in Phase 1[1]

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)

Objective response to belapectin+pembrolizumab therapy at Day 85



HNSCC=head and neck squamous cell carcinoma; MM=metastatic melanoma.

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

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Thank you!