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): December 4, 2019

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))

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 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. ☐

SECTION 7 – REGULATION FD

Item 7.01 Regulation FD Disclosure.

On December 4, 2019, Galectin Therapeutics Inc. (the "Company) posted to its website a presentation which is attached hereto as Exhibit 99.1.

The information in this report is being furnished pursuant to this Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933 or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this report.

SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate Update Presentation, December 4, 2019

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: December 4, 2019

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

Exhibit 99.1

Galectin Therapeutics

Corporate Update – focused on NASH Cirrhosis

Annual Stockholders Meeting

December 4, 2019

Forward Looking Statements

This presentation contains 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 management’s 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 the hope that Galectin’s development program for belapectin will lead to the first therapy for the treatment of fatty liver disease with cirrhosis and those regarding the hope that our lead compounds will be successful in cancer immunotherapy and in other therapeutic indications. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that trial endpoints required by the FDA may not be achieved; Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of belapectin or any of its other drugs in development; the Company may not be successful in scaling up manufacturing and meeting requirements related to chemistry, manufacturing and control matters; the Company’s currently planned clinical trial and any future clinical studies as modified to meet the requirements of the FDA may not produce positive results in a timely fashion, if at all, and could require larger and longer trials, which would be time consuming and costly; plans regarding development, approval and marketing of any of Galectin’s drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies; regardless of the results of any of its development programs, Galectin may be unsuccessful in developing partnerships with other companies or raising additional capital that would allow it to further develop and/or fund any studies or trials. Galectin has incurred operating losses since inception, and its ability to successfully develop and market drugs may be impacted by its ability to manage costs and finance continuing operations. For a discussion of additional factors impacting Galectin’s business, see the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, and subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

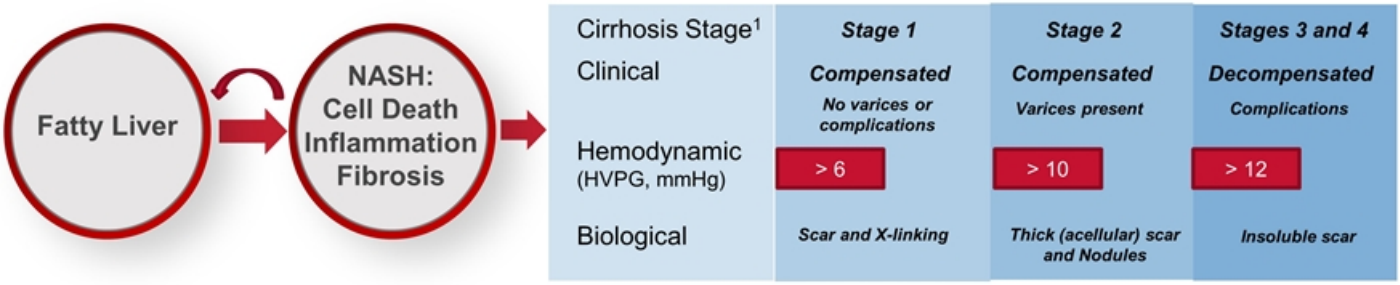
Outline of Today's Presentation
Belapectin (GR-MD-02) and NASH CIRRHOSIS

- Highlights of NASH-CX Phase 2 study
- The road to Adaptively-Designed (Phase 2b/Phase 3) NASH-RX trial start
  - Regulatory input and recent FDA interactions
  - Revised study design
    - Benefits and risks
  - Sites & study status
  - Next steps
- Summary

Targeting NASH Cirrhosis – Cirrhosis Stage

Progression to Cirrhosis (5%)

Progression to Varices



Estimated US Prevalence

80-100M	24-30M	3-5M	1.5-2.5M	1.5-2.5M

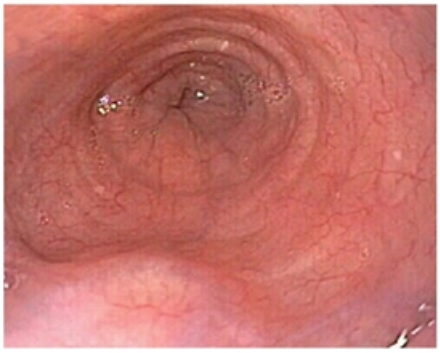
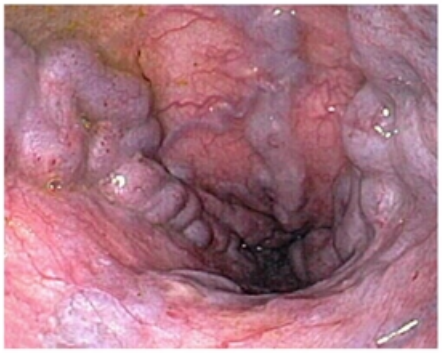
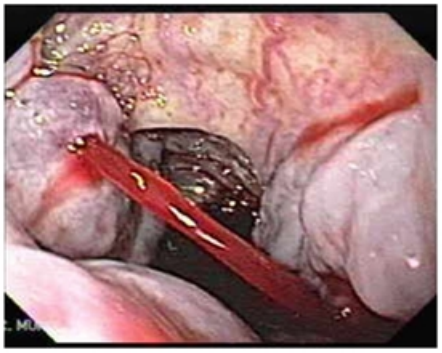
NASH-CX Trial Showed Positive Efficacy in Stage 1 NASH Cirrhosis

[1] *Garcia-Tsao, G., Friedman, S., Iredale, J., Prinzani, M. Hepatology. 2010;51:14451449*

Critical Importance of Esophageal Varices in NASH Cirrhosis

An important goal of treatment of patients with Stage 1, compensated cirrhosis without esophageal varices is to prevent progression to varices and complications
"*No varices means no potential for bleeding varices*"

Esophagus: No Varices **Esophageal Varices** **Bleeding Esophageal Varices**

Highlights of results

THE NASH-CX TRIAL

Belapectin (GR-MD-02) Development Program: Summary

- **Gal-3 null mice are resistant to development of NASH [1] and liver fibrosis [1, 2]**
- **GR-MD-02 is a glycopolymer (polysaccharide), considered a Nonbiological Complex Drug (NBCD) that binds to galectin-3 protein, has strong global patent protection, and is administered intravenously**
- **GR-MD-02 has robust efficacy in pre-clinical models of NASH and toxic cirrhosis, with action at a nexus of multiple pathophysiological processes [3, 4]**
- **Well tolerated and safe in preclinical toxicology and clinical trials (2 P1, P2a and P2b)**
- ***NASH-CX phase 2b clinical trial showed clinically meaningful positive results of GR-MD-02 in patients with NASH cirrhosis without esophageal varices (Stage 1 Cirrhosis)***
- **NASH-CX trial identified endpoints and patient population that can form the basis of phase 3 trials in NASH cirrhosis without esophageal varices**

[1] Journal of Hepatology 2011;54:975-983

[2] PNAS 2006;103:5060-5065

[3] Traber PG and Zomer E.PLOS ONE 2013;8:e83481

[4] Traber PG, Chou H, Zomer E, Hong F, Klyosov A Fiel M-I, Friedman, SL. PLOS ONE 2013;8:e75361.

NASH-CX Clinical Trial Design[1]

Major Inclusion Criteria

NASH cirrhosis (biopsy)
HVPG ≥ 6 mmHg
No cirrhosis complications
No or small varices

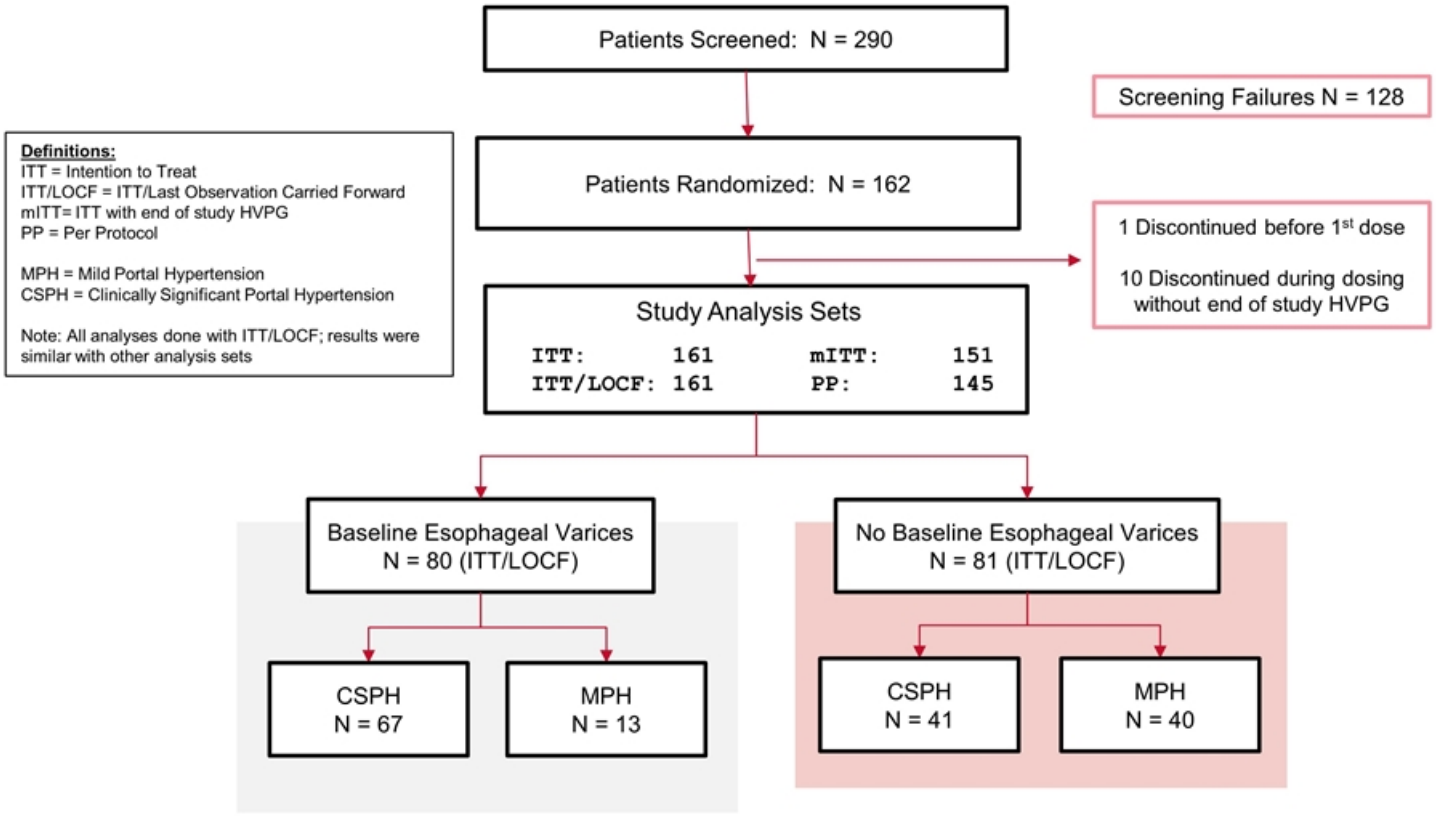
Every other week infusion X 26

Placebo (54)
GR-MD-02 2 mg/kg (54)
GR-MD-02 8 mg/kg (54)

		Baseline	*Week 26*	*Week 54*
Primary endpoint	HVPG[2]	X		X
Secondary endpoints	Liver Biopsy[3]	X		X
	FibroScan	X	X	X
	MBT[4]	X	X	X
	Complications[5]	X		X
	Endoscopy	X		X

[1] All subjects were enrolled across 36 sites in the US
[2] HVPG = Hepatic Venous Pressure Gradient
[3] Histologic staging & quantitative morphometry for collagen
[4] MBT = ^{13}C Methacetin Breath Test
[5] Liver-related complications (varices/bleeding, ascites, hepatic encephalopathy, liver-related death, or transplant)

Patient Populations – NASH-CX

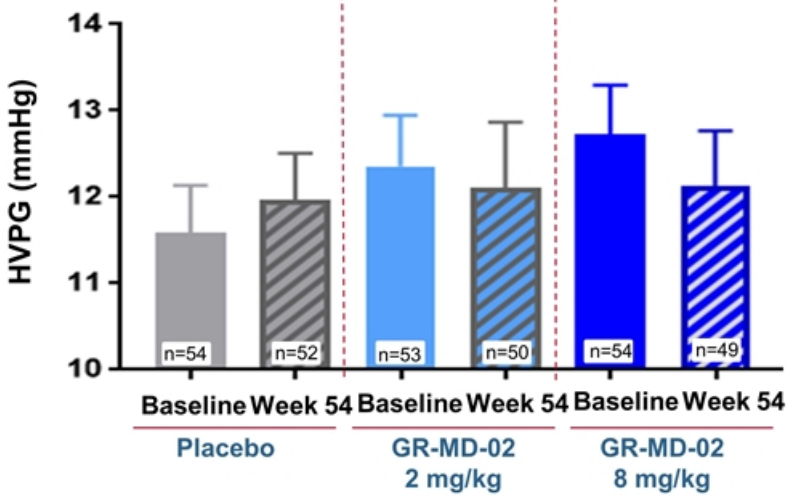


Demographic characteristics (age, gender, BMI, nationality, diabetes) and baseline HVPG measurements were balanced across the three treatment groups in study analysis sets

NASH-CX: HVPG Primary Endpoint
Total Patient Population

1. Trend toward benefit with drug, but not statistically significant
2. Drug effect was significantly dependent on dose*varices in total group (p<0.02)
3. GR8 dose group, based on pK, was above upper limit of the therapeutic window

Mean Change From Baseline to Week 54[1]	**0.3**	**-0.37** **p=0.45** **p=0.10**	**-0.42** **p=0.49** **p=0.10**	**(Absolute Change)** **(Percent Change)**



Overall mean baseline HVPG=12.22 mmHg (No significant difference between groups at baseline-ANOVA)

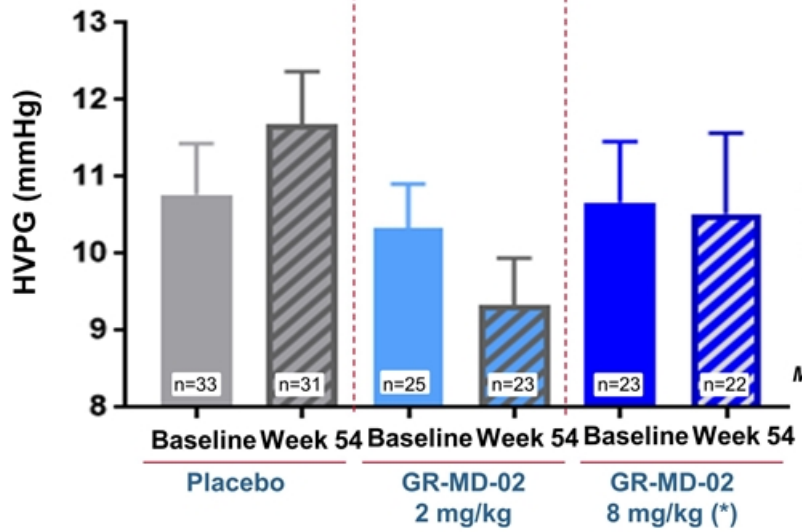
Mean ± SEM

[1]ITT with LOCF, ANCOVA with LSD

NASH-CX Patients Without Varices at Baseline
(50% of total population)

Statistically significant effect of 2 mg/kg dose on absolute change in HVPG

Mean Change From Baseline to Week 54[1]	**0.8**	**-1.08**	**0.15**	
		p < 0.01	**p = 0.36**	**(Absolute Change)**
		p = 0.01	**p = 0.17**	**(Percent Change)**



Overall mean baseline HVPG=10.6 mmHg (No significant difference between groups at baseline-ANOVA)

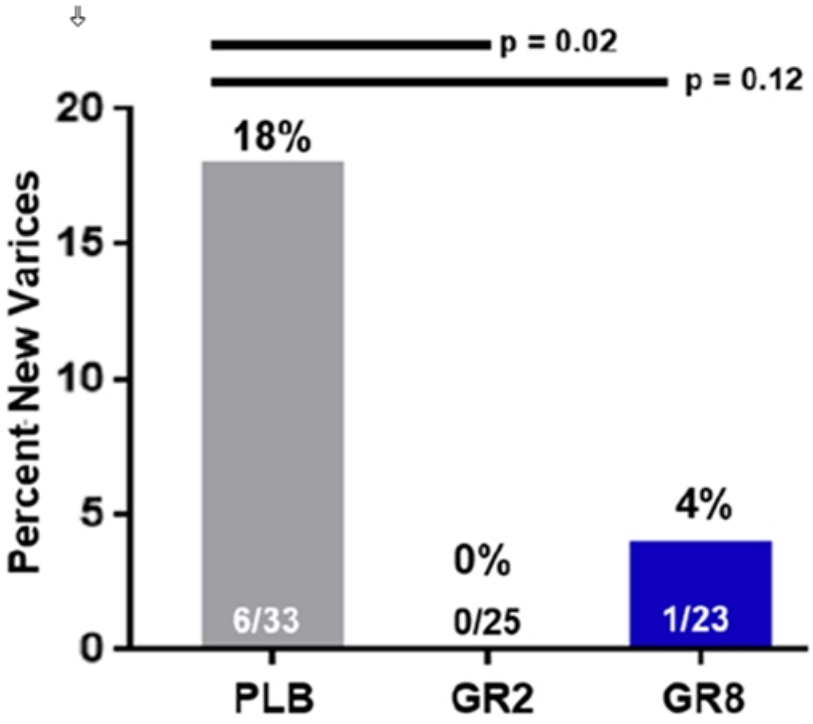
Mean ± SEM

[1]ITT with LOCF, ANCOVA with LSD

* Results at 8 mg/Kg dose, based on pK, may reflect doses outside the therapeutic window as observed in preclinical studies

NASH-CX: Development of New Varices

Among patients without varices at baseline, there were more new varices in the placebo group than in the GR2 group



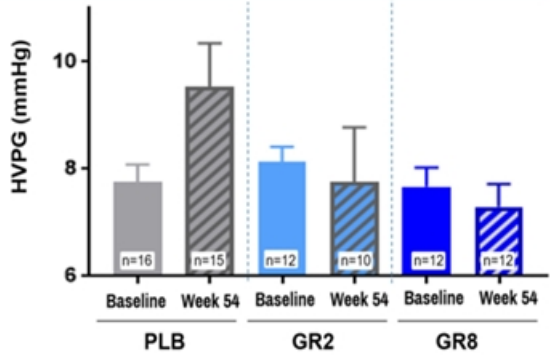
Chi-Square analysis used for comparisons

NASH-CX: HVPG in Patients Without Varices at Baseline and Mild Portal Hypertension

Both the GR2 and GR8 treatment groups had a statistically significant effect on the percent change in HVPG in patients without varices and MPH

A.

Percent Δ (%)	+25	-0.4	-0.3
SIG vs PLB		p = 0.04	p = 0.04
Absolute Δ (mmHg)	1.8	-0.3	-0.4
SIG vs PLB		p = 0.07	p = 0.04



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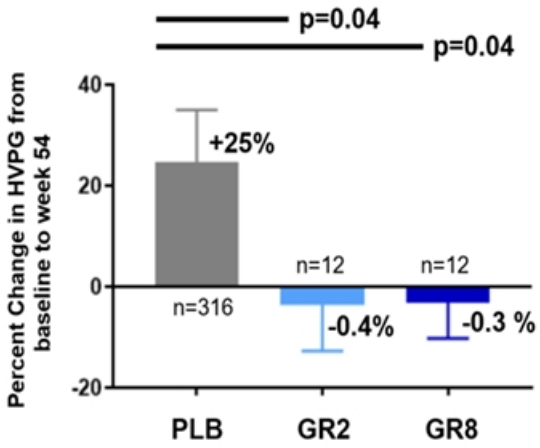
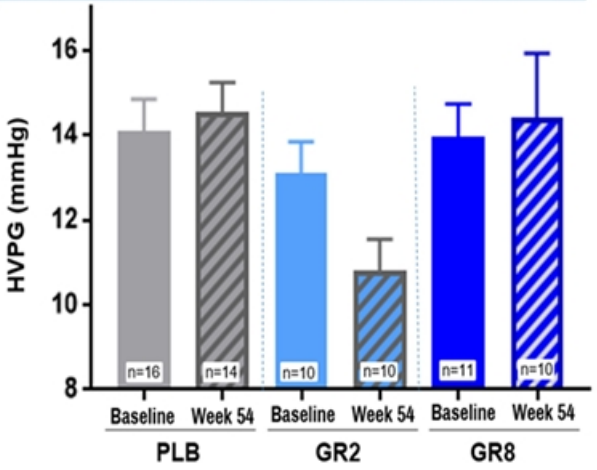


NASH-CX: HVPG in Patients Without Varices at Baseline and Clinically Significant Portal Hypertension (HVPG >10 mmHg)

Like the MPH group shown earlier, in patients with CSPH, the GR2 group showed a statistically significant reduction in HVPG when compared to placebo

A.

Percent Δ (%)	2.5	-15.8	4.6
SIG vs PLB		p = 0.04	p = ns
Absolute Δ (mmHg)	0.2	-2.3	0.7
SIG vs PLB		p = 0.02	p = ns



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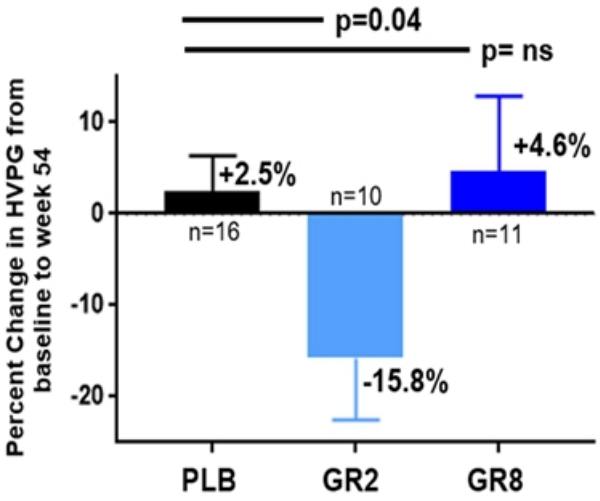


NASH-CX: Major Conclusions

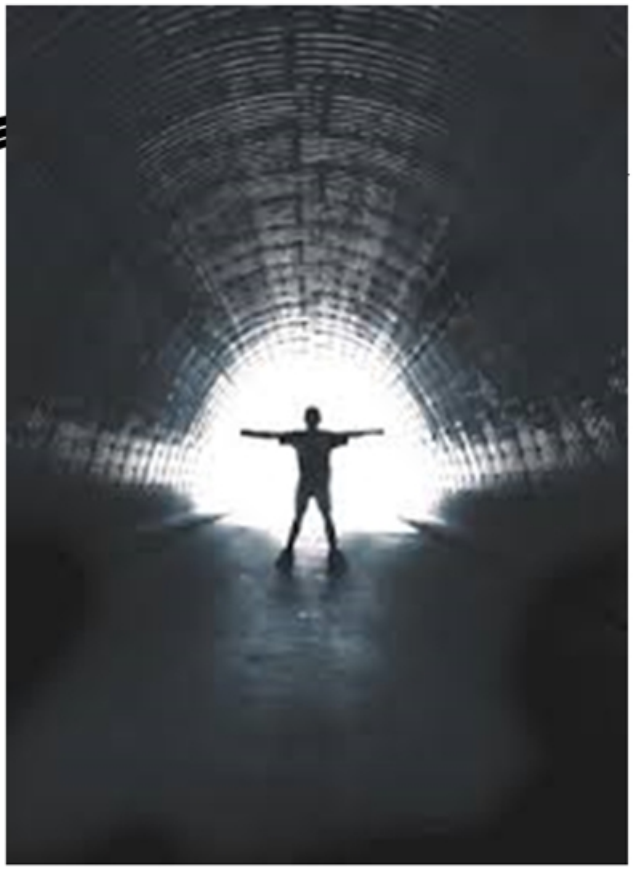
- **GR-MD-02 had a statistically significant and clinically meaningful effect in reducing HVPG in patients with NASH cirrhosis who did not have baseline esophageal varices (50% of total patient population)**
- **Important drug effect in the total study population on liver biopsy, with a statistically significant improvement in hepatocyte ballooning (cell death)**
- **Statistically significant reduction in the development of varices in drug-treated patients compared to placebo**
- **While there was a drug effect in both dosage groups on liver biopsy and in the mild portal hypertension group, there was a consistently greater and statistically significant effect of the 2 mg/kg dose**
- **GR-MD-02 appears to be safe and well tolerated in this one year, phase 2b clinical trial**
- **We believe this is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in portal hypertension or liver biopsy in patients with NASH cirrhosis without varices**
- **It is estimated that 50% of those suffering with NASH cirrhosis have not yet developed esophageal varices**
- **Full length paper accepted by Journal of *Gastroenterology***

The NASH-RX trial

Adaptively-Designed Phase 2b/3 Trial of Belapectin in NASH Cirrhosis

The Road to Phase 3 is often a Long Path

There is light at the end of the tunnel



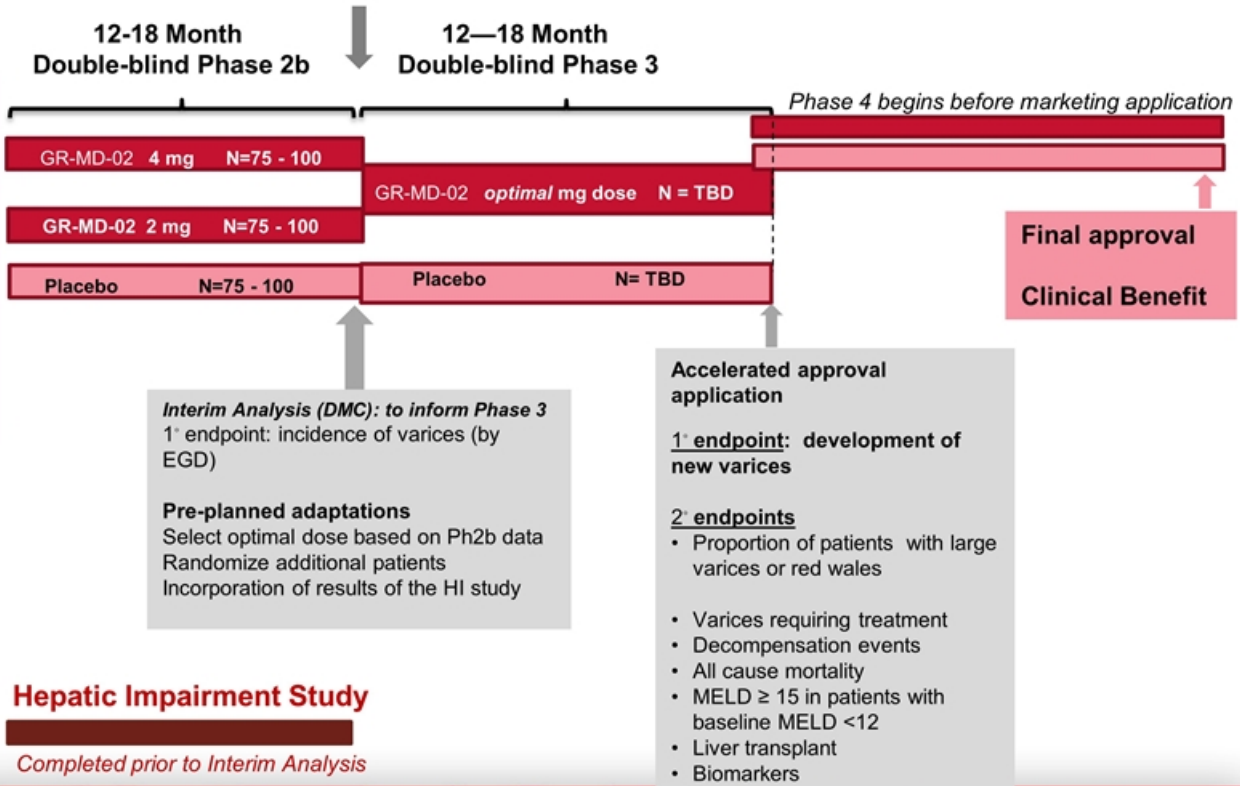
Road to Phase 3: Sequence of Events and Highlights

- Feb 2019 - FDA Meeting
  - Purpose: Discuss potential surrogate endpoint of progression to varices for Phase 3 trial
  - Indicated supportive of "***the potential use of progression to varices as a surrogate endpoint and progression to large varices (or to small varices with a weal) as a component of a composite clinical benefit endpoint*** …."
  - FDA requested follow up review of Phase 3 protocol via Type C, Written Request Only (WRO) submission
- July 2019 – Filed WRO Submission
  - Phase 3 and Phase 4 protocols
  - Addressed other FDA questions and suggestions
- October 2019 – FDA responded
  - FDA felt justifications for not doing Hepatic Impairment (HI) study and dose selections seemed reasonable
  - FDA suggested we affirm NASH-CX efficacy and dose selection
  - In conjunction with KOLs and Covance, developed a response plan – Adaptively-designed Phase 3 trial with interim analysis and accelerated review with proposed surrogate endpoint
- November 2019 - GALT filed 10-Q and Press Release describing key FDA responses
  - Conservatively described what we felt were the key FDA messages
    - Solidify dose selection and reaffirm efficacy seen in NASH-CX trial
    - Recommending a traditional approval pathway (not surrogate)
  - Highlighted a revised study approach and few month delay in study start
- **November 14, 2019 - GALT and co-PIs had informal teleconference with FDA seeking clarifications and proposed a new study design to address FDA comments**
  - **FDA indicated they felt the new design was more reasonable (subject to review of protocol)**
  - **FDA indicated they were still supportive of the surrogate end-point concepts proposed**


What's
the
plan?

NASH-RX: Adaptively-Designed Phase 3 Study in NASH Cirrhotics

Subject to Change



Key eligibility criteria

1. NASH cirrhosis
2. Without varices
3. CTP score <7
4. Clinical signals suggesting portal hypertension, with at least 2 of:
   - thrombocytopenia
   - spleen size ≥ 15 mm
   - evidence of collaterals by imaging

Interim Analysis (DMC): to inform Phase 3

1° endpoint: incidence of varices (by EGD)

Pre-planned adaptations

Select optimal dose based on Ph2b data
Randomize additional patients
Incorporation of results of the HI study

Accelerated approval application

1° endpoint: development of new varices

2° endpoints

- Proportion of patients with large varices or red wales
- Varices requiring treatment
- Decompensation events
- All cause mortality
- MELD ≥ 15 in patients with baseline MELD <12
- Liver transplant
- Biomarkers

Hepatic Impairment Study

Completed prior to Interim Analysis

NASH-RX: Segment 1 - Features

- Inclusion/Eligibility Criteria
  - NASH cirrhosis
  - No varices
  - CTP score < 7 (Class A)
  - Clinical signals suggesting portal hypertension with at least 2 of:
    - Thrombocytopenia
    - Spleen size ≥ 15 mm
    - Evidence of collaterals by imaging
- Double-blind
  - Duration 12-18 months (to be refined)
  - Size: 75-100 patients/study arm
  - GR-MD-02 (belapectin) at dose of 2 mg/Kg and 4 mg/Kg LBM
    - Expected to be well within therapeutic window based on NASH-CX pK results

Key Feature of NASH-RX Design at End of Segment 1 Interim Analysis (DMC) to inform Phase 3

- Interim Analysis informs:
  - Primary EP: Incidence of varices
  - Confirms dose selection from NASH-CX results and dose adjustment
    - Informs a single dose into Phase 3
  - Event rate allows 'right-sizing' of Phase 3
    - e.g., randomization of additional patients
  - Hepatic Impairment study may allow inclusion of ≥ CTP B patients
  - Potential adjustment in randomization ratio
  - Termination of Study – e.g., due to 'futility'
- Segment 1 patients expected to roll into next study phase
  - Creates a cohort with an additional year of treatment at time of the accelerated approval application presuming positive results

NASH-RX: End of Segment 2
Accelerated approval application

- Accelerated approval
  - Primary Endpoint
    - Development of new varices
  - Secondary Endpoints
    - Proportion of patients with large varices or red wales
    - Varices requiring treatment
    - Decompensation events
    - All-cause mortality
    - MELD > 15 in patients with baseline MELD<12
    - Liver transplant
    - Biomarkers
  - Informs Phase 4 features – sizing, duration

NASH-RX: Adaptively-Designed P3 trial Feature, Benefits and Risks

- Study features potentially improving likelihood of showing Drug effects
  - Clarity and reaffirmation of NASH-CX efficacy & safety
  - Appropriate selection of dose – e.g., single dose (2 or 4 mg/kg) for P3 or both
  - Hepatic Impairment study results may allow inclusion of CTP-B / CTP-C patients which have a much higher rate of varices progression and bleeding & other decompensating events
  - Reduced frequency of EGDs and elimination of biopsy and HVPG subgroup may make it easier to enroll trial; offset by robust sizing in P2 component (e.g. 75-100+ pts/group) and a difficulty in frequently monitoring patients for varices progression
  - Potential to select a single dose for P3 component simplifying trial and to adjust randomization ratio for P3
  - Patients from P2 will roll into P3 component adding patients with another year (tot. ~2.5 to 3 yrs.) exposure to drug and increasing the likelihood of showing drug effect as patient cirrhosis progresses
  - Adaptation to size and power calculations based on more robust Phase 2b component will allow better estimates of Phase 3 cohort sizing and statistical power estimations
  - Interim Analysis – provides preplanned adaptations and interim efficacy and safety results
- Study Features increasing risk
  - Interim Analysis – affects statistics (“statistical hit”) requiring larger size P3 component
  - Interim Analysis – could result in trial being stopped for lack of at least a clear trend in efficacy
  - Preplanned Adaptations at time of Interim Analysis – we may have insufficient knowledge to pre-plan for adaptations that a more robust P2 dataset would have given insight into

NASH-RX: Current Study Status

- Sites qualified by Covance
  - ~130 sites in 12 countries
  - Revisiting sites passed over due to biopsy, EGD testing frequency and HVPG requirements of earlier study design
  - Sites being kept informed of status of study start
- Work completed for
    - NASH-specific site network and numerous vendor contracts
    - EGD and associated adjudication processes
    - Patient questionnaires – QoL and Alcohol Use Assessment
    - Databases: Study & Central Lab will require tweaking
- Foreign regulatory filings proceeding according to timeline
- Protocol being tweaked for new design elements
  - Biostatistics assessing sizing and duration
- Response to other minor FDA suggestions being addressed

NASH-RX: Additional Considerations & Next Steps

- There is a delay due to modifying the protocol and resubmitting to FDA
- Change in first patient first visit to late Q1, 2020
  - Sites have been informed to maintain their interests
- Costs being reassessed
  - Elimination of HVPG subgroup and reduced frequency of EGDs will reduce costs compared to original estimate
  - Offset by potentially increased patient numbers and perhaps sites which will be determined when the final protocol is established
- Revised protocol expected to be filed with FDA mid to late first quarter 2020

THANK YOU