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): November 10, 2014

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))

SECTION 8 – OTHER ITEMS

Item 8.01 Other Items.

On November 10, 2014, Galectin Therapeutics Inc. posted a corporate presentation regarding its Phase 1 clinical trial on its website that contains a summary of development of GR-MD-02 for Non-Alcoholic Steatohepatitis (NASH) With Advanced Fibrosis, which is attached as Exhibit 99.1.

SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate presentation

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: November 10, 2014

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

AASLD Abstract No. 57

Phase 1 Clinical Trial Results Of GR-MD-02, A Galectin-3 Inhibitor, In Patients Having Non-Alcoholic Steatohepatitis (NASH) With Advanced Fibrosis

Stephen A. Harrison[1], Naga P. Chalasani[2], Eric Lawitz[3], Smitha Marri[2], Mazen Noureddin[4], Arun J. Sanyal[5], Thomas D. Schiano[6], Mohammad S. Siddiqui[5], Brent A. Neuschwander-Tetri[7], Peter G. Traber[8,9]

[1]Brooke Army Medical Center, Fort Sam Houston, TX; [2]Indiana University School of Medicine, Indianapolis, IN; [3]The Texas Liver Institute, University of Texas Health Science Center, San Antonio, TX; [4]University of Southern California, Los Angeles, CA; [5]VCU Medical Center, Richmond, VA; [6]Icahn School of Medicine at Mount Sinai, New York, NY; [7]St. Louis University, St. Louis, MO; [8]Galectin Therapeutics, Norcross, GA; [9]Emory University School of Medicine, Atlanta, GA

Author Disclosures

- Stephen A. Harrison – Advisory Committees or Review Panels; Merck, Nimbus Discovery, NGM Bio, Fibrogen. Grant/Research Support: Merck, Genentech; Speaking and Teaching: Merck, Gilead, Janssen, AbbVie.
- Naga P. Chalasani – Consulting: Salix, AbbVie, Lilly, Boerhinger-Ingelham, Aegerion; Grant/Research Support: Intercept, Lily, Gilead, Cumberland, Galectin
- Eric Lawitz – Advisory Committees or Review Panels: AbbVie, Achillion Pharmaceuticals, BioCryst, Biotica, Enanta, Idenix Pharmaceuticals, Janssen, Merck & Co, Novartis, Santaris Pharmaceuticals, Theravance, Vertex Pharmaceuticals; Grant/Research Support: AbbVie, Achillion Pharmaceuticals, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Idenix Pharmaceuticals, Intercept Pharmaceuticals, Janssen, Merck & Co, Novartis, Presidio, Roche, Santaris Pharmaceuticals, Vertex Pharmaceuticals; Speaking and Teaching: Gilead, Kadmon, Merck, Vertex
- Arun J. Sanyal – Advisory Committees or Review Panels: Bristol-Myers, Gilead, Abbott, Ikaria; Consulting: Salix, Immuron, Exhalenz, Nimbus, Genentech, Echosens, Takeda; Grant /Research Support: Salix, Genentech, Genfit, Intercept, Ikaria, Takeda, GalMed, Novartis, Gilead; Independent Contractor; UpToDate, Elsevier
- Brent A. Neuschwander-Tetri – Advisory Committees or Review Panels: Boehringer-Ingerheim
- Peter G. Traber – Management Position: Galectin Therapeutics
- The following people have nothing to disclose: Smitha Marri, Mazen Noureddin, Thomas D. Schiano, Mohammad S. Siddiqui

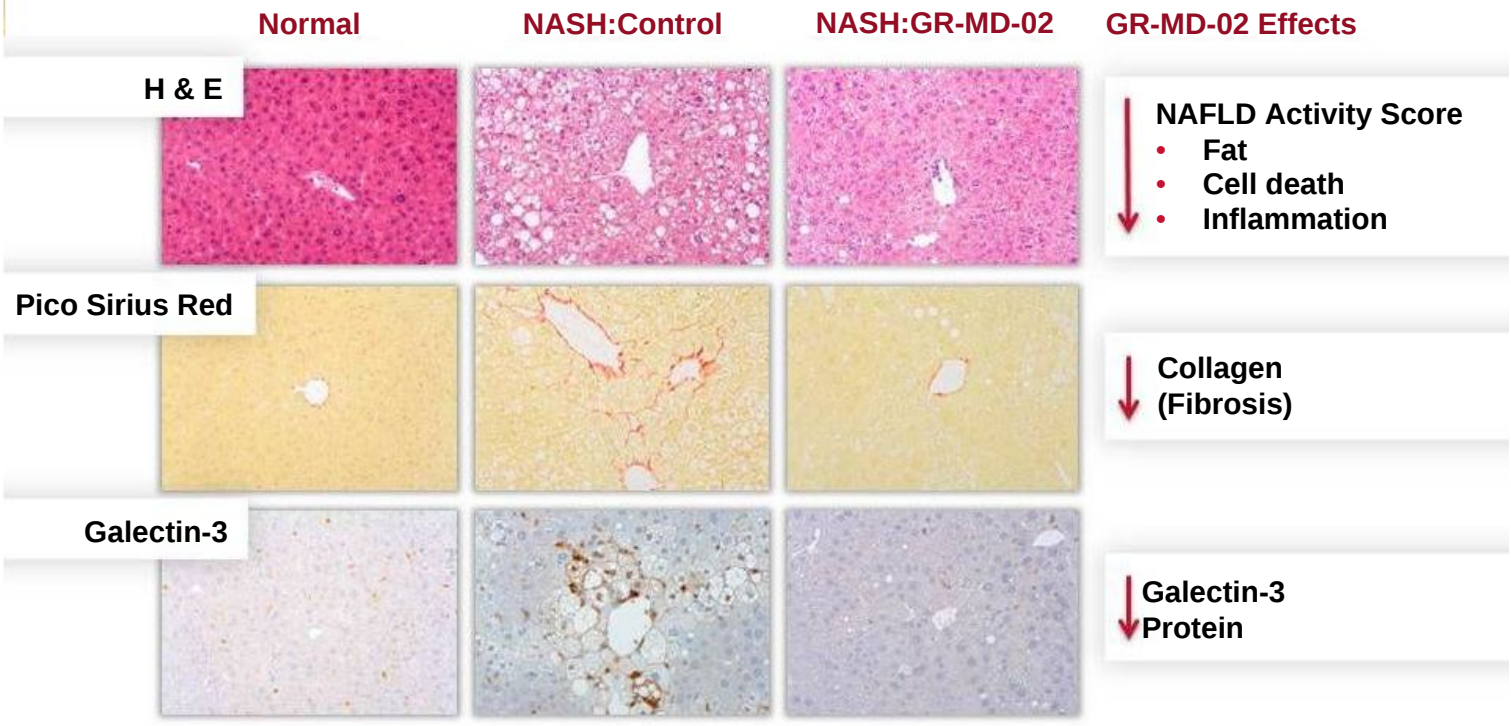
Presenter Disclosure Slide

“The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, Department of Defense or the U.S. Government.”

Background

- Advanced liver fibrosis and cirrhosis are unmet medical needs
- NASH is the most common liver disease in the US and a growing cause of cirrhosis requiring liver transplantation
- Galectin-3 is a protein that binds to terminal galactose residues on glycoproteins and is highly expressed in macrophages
- Knockout mouse experiments have shown that galectin-3 is a critical protein in fibrogenesis in multiple organs, including liver fibrosis due to toxins and NASH
- GR-MD-02 is a complex carbohydrate drug containing terminal galactose residues that binds to galectin-3 and inhibits its function

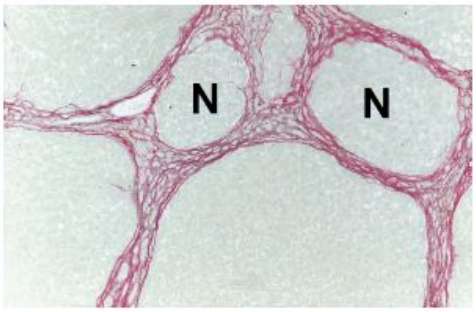
Pre-Clinical: GR-MD-02 Has Therapeutic Effect On NASH With Fibrosis In Mouse Model*



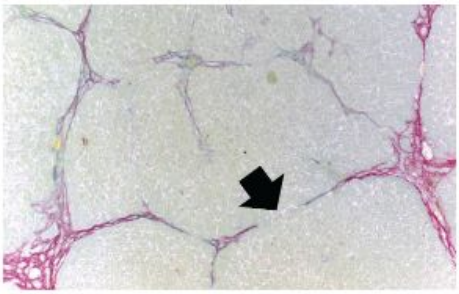
*Traber PG and Zomer E. Therapy of Experimental NASH and Fibrosis with Galectin Inhibitors. PLOS ONE 2013;8:e83481

Pre-Clinical: GR-MD-02 Reversed Cirrhosis And Improved Portal Hypertension In Thioacetamide-Treated Rat Model*

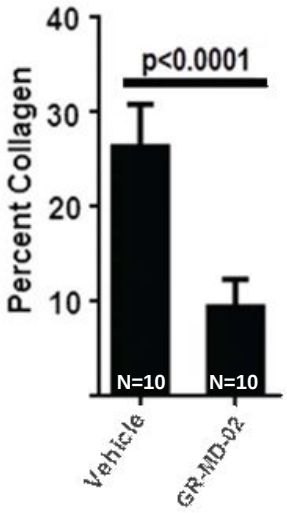
Vehicle-Treated



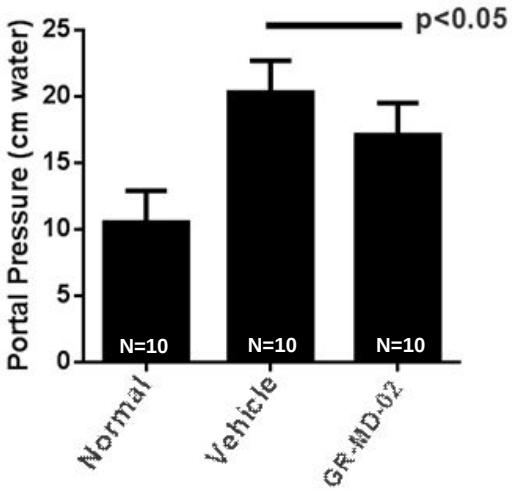
GR-MD-02-Treated (90 mg/kg, 1/W x 4)



Collagen



Portal Pressure



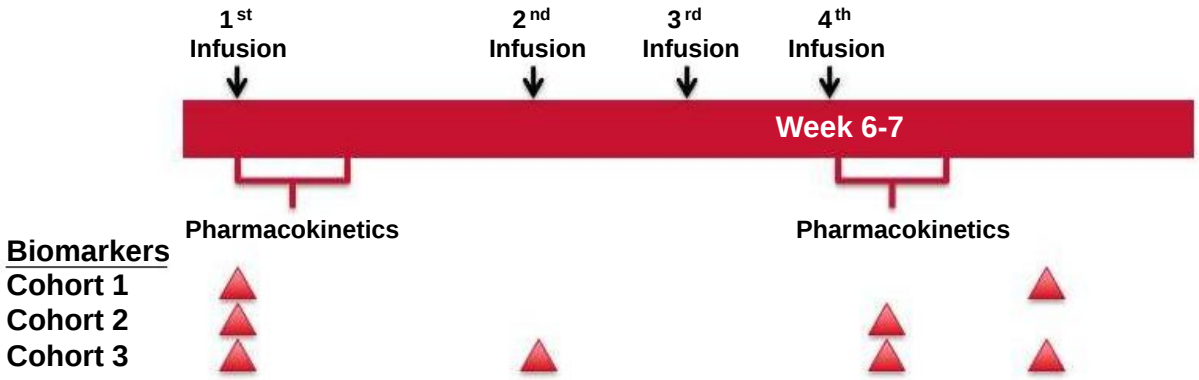
*Traber PG, Chou H, Zomer E, Hong F, Klyosov A Fiel M-I, Friedman, SL. Therapy of Regression of fibrosis and reversal of cirrhosis in rats by galectin inhibitors in thioacetamide-induced liver disease. PLOS ONE 2013;8:e75361.

A Multi-Center, Partially Blinded, Maximum Tolerated Multiple Dose Escalation, Phase 1 Clinical Trial to Evaluate the Safety of GR-MD-02 in Subjects with Non-Alcoholic Steatohepatitis (NASH) with Advanced Hepatic Fibrosis

- Overall Objective:
  - Evaluate safety and pharmacokinetics of GR-MD-02 to provide information and support to design a Phase 2 clinical program to assess efficacy of GR-MD-02 in patients with NASH with advanced fibrosis and cirrhosis.
- Clinical trial sites
  - Brooke Army Medical Center, Fort Sam Houston, TX
  - Indiana University School of Medicine, Indianapolis, IN
  - The Texas Liver Institute, San Antonio, TX
  - University of Southern California, Los Angeles, CA
  - VCU Medical Center, Richmond, VA
  - Icahn School of Medicine at Mount Sinai, New York, NY
  - St. Louis University, St. Louis, MO
- Study Sponsor: Galectin Therapeutics Inc

Methods: Three Cohort Design Of Phase 1 Clinical Trial

- **Subjects:** Biopsy proven NASH with Brunt Stage 3 fibrosis
- **Design:**
  - Blinded, placebo controlled, sequential dose escalation
  - Three cohorts: 2, 4, and 8 mg/kg lean body weight administered by IV infusion over one hour
- **Primary Endpoints:** Safety and Pharmacokinetics
- **Exploratory Endpoints:** Potential serum biomarkers



Results: Patient Characteristics

	Cohort 1 (2 mg/kg)	Cohort 2 (4 mg/kg)	Cohort 3* (8 mg/kg)
Enrolled	8	10	13
Completed	8	9	9
Pending Completion by end of December	--	--	4
Completed Patients			
Age Range (Mean)	40-64 (54)	34-69 (51.5)	44-69 (61)
Sex (M/F)	2/6	6/4	5/4
BMI (Mean)	39	39.6	33.2
BMI ≥ 30	8/8	9/9	5/9
Diabetes	6	4	7

*** Enrollment of cohort 3 terminated at 13 patients since sufficient information obtained for phase 2 trial design**

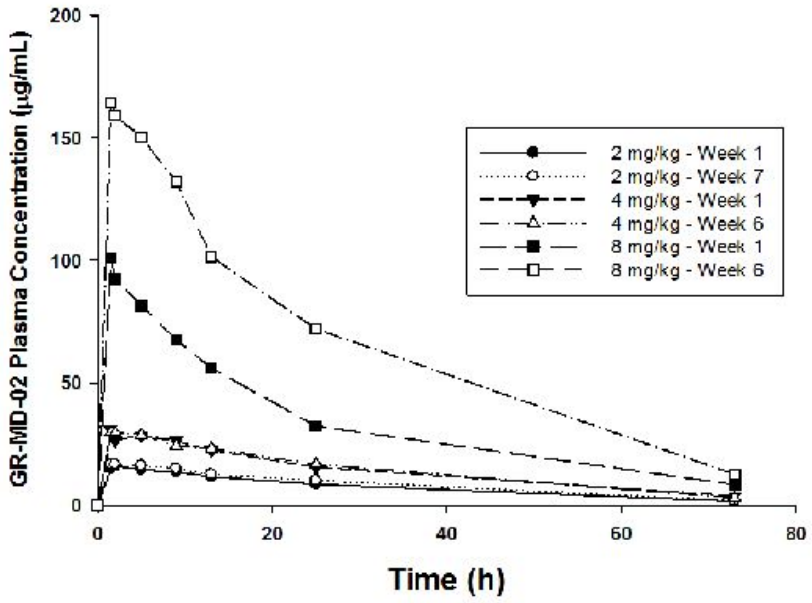
Results: Safety Data On Completed Patients

	Cohort 1 (2 mg/kg)		Cohort 2 (4 mg/kg)		Cohort 3 (8 mg/kg)	
	Active	Placebo	Active	Placebo	Active	Placebo
Completed protocol	**6**	2	**7**	2	**6**	3
Serious Adverse Events	0	0	0	0	0	0
TEAE's probably related	0	0	0	0	0	0
TEAE's possibly related	0	2	2	0	0	1

- Therapy Emergent Adverse Events, possibly related to study drug were reported in 3 subjects who received placebo and 2 subjects who received GR-MD-02. All adverse events were mild (grade 1) and transient.
- An independent Data Safety Monitoring Board (DSMB) reviewed all data after first and second cohorts.

Results: Mean GR-MD-02 Plasma Concentration-Time Profiles After First And Fourth Doses In All Three Cohorts

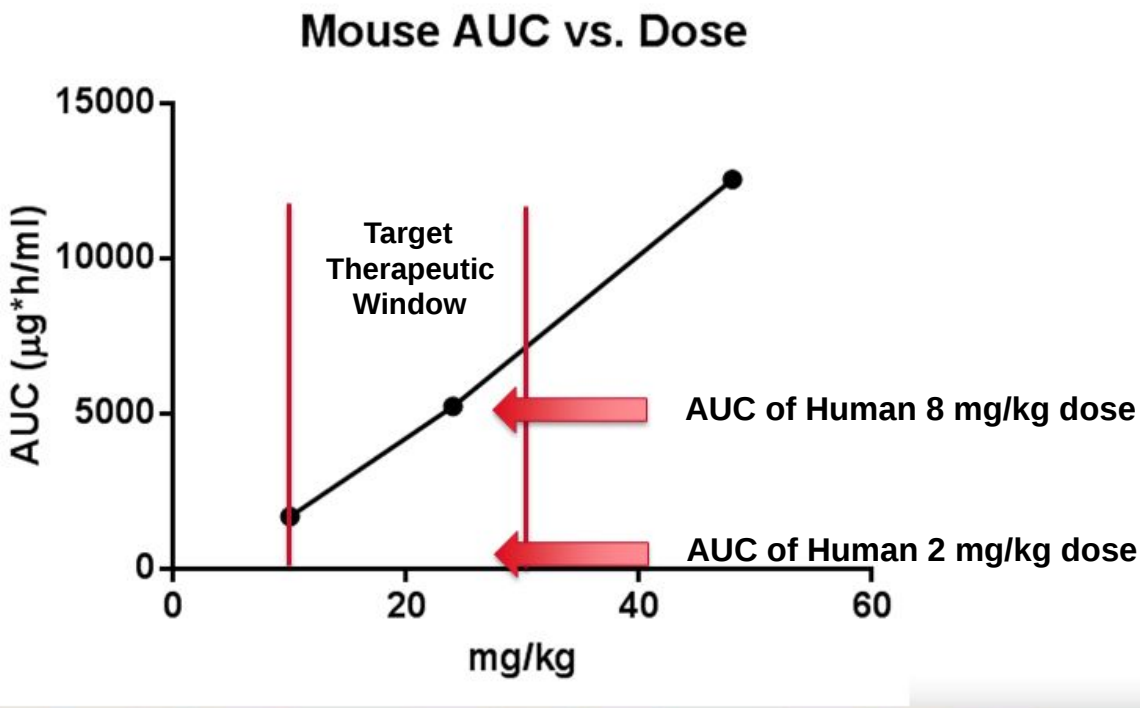
- **Proportional increase in drug coverage (AUC) for 2 mg/kg, 4 mg/kg, and first dose of 8 mg/kg**
- **Increase in AUC after four doses of 8 mg/kg indicates a saturable compartment model**



	Cmax µg/mL	T1/2 H	AUC µg*h/mL
2 mg/kg x1	**16.3**	**19.9**	**573**
2 mg/kg x4	**17.7**	**20.5**	**645**
4 mg/kg x1	**30**	**19.8**	**1039**
4 mg/kg x4	**31**	**19.5**	**1075**
8 mg/kg x1	**99.5**	**18.2**	**2449**
8 mg/kg x4	**169.9**	**18.4**	**4909**

Pharmacokinetics Indicates 8 mg/kg dose Is Within The Upper Range Of The Targeted Therapeutic Window

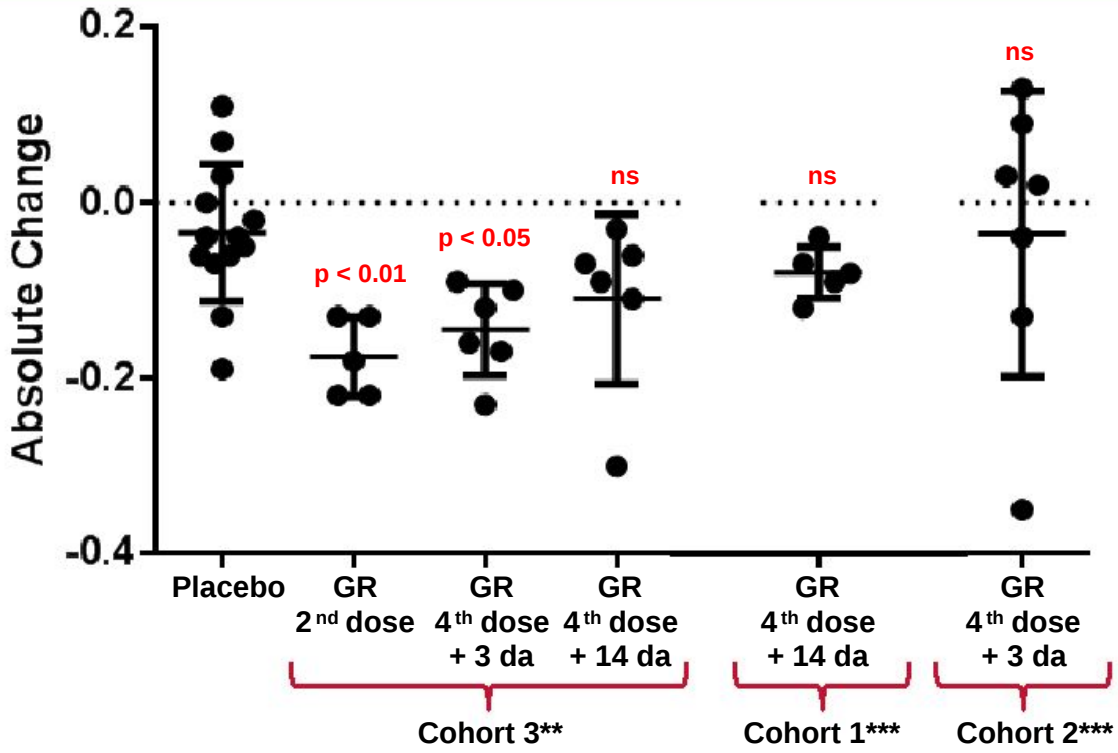
- The best therapeutic dose in mouse NASH was between 10 and 30 mg/kg
- Relationship between AUC and dose shows mouse and human equivalency



Results: Exploratory Serum Biomarkers

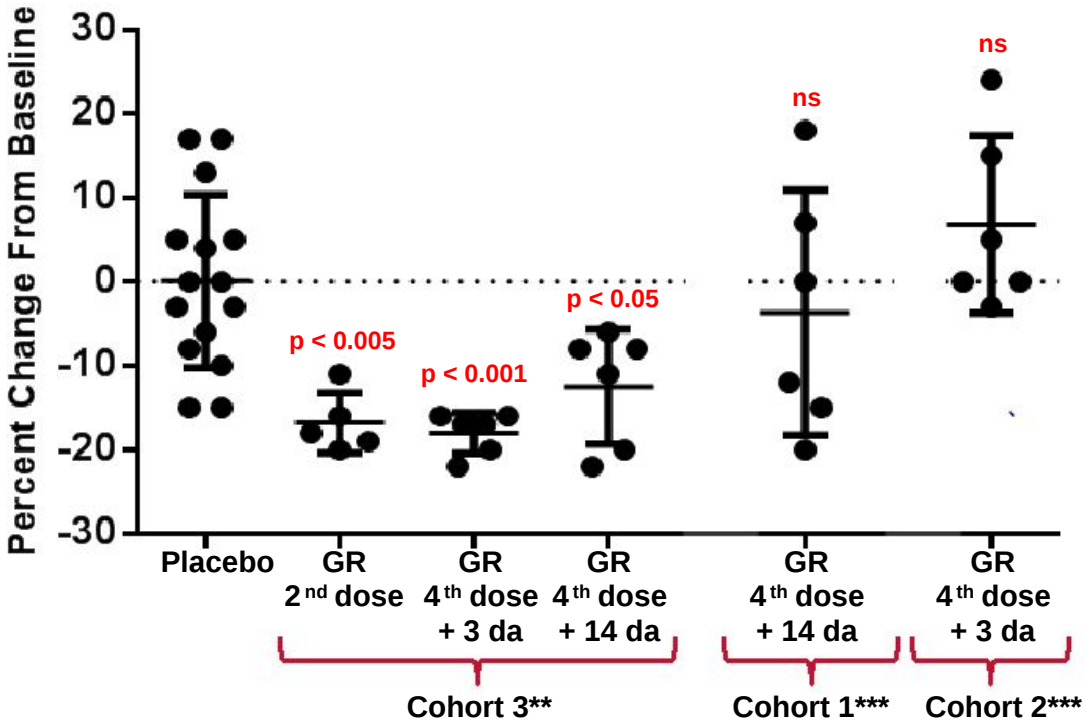
- There are no validated serum biomarkers for evaluation of potential therapeutic changes over time in NASH or fibrosis
- A panel of serum tests were evaluated to explore potential biomarkers for use in future studies
- Most of the putative biomarkers showed high variability within the same individual in placebo and GR-MD-02 patients, rendering them not useful as reliable biomarkers
  - CK-18 (M30 and M65), TGF-β, Osteopontin, VEGF, IP-10, IL-6, IL-8, TNF-α, CD-40 ligand, metalloproteinases, INF-γ, Endothelin-1
  - The ELF scores were not significantly changed relative to placebo
- Earlier results in this patient population that suggested changes in certain biomarkers were not evident with increased numbers of placebo patients for comparison
- FibroTest®, a composite score that has been correlated with the extent of liver fibrosis, was significantly reduced by GR-MD-02 treatment in cohort 3.
  - Includes following serum levels: alpha-2-macroglobulin, haptoglobin, apolipoprotein A1, gamma glutamyl transpeptidase, and total bilirubin

Results: FibroTest® (FibroSure®) Scores



* Placebo values were combined after showing that there was no difference between different time points
** Statistical test: Three groups versus placebo, ANOVA with Dunnett's test for multiple comparisons
*** Statistical test: Versus placebo, two-sided t-test

Results: Alpha-2 Macroglobulin Serum Levels



* Placebo values were combined after showing that there was no difference between different time points
** Statistical test: Three groups versus placebo, ANOVA with Dunnett's test for multiple comparisons
*** Statistical test: Versus placebo, two-sided t-test

Summary

- **Administration of 2, 4, and 8 mg/kg lean body weight of GR-MD-02 intravenously for four doses over 6 weeks was safe and well tolerated in NASH patients with advanced fibrosis**
- PK analysis demonstrated 8 mg/kg achieves targeted therapeutic dosing range derived from animal studies
- Analysis of most putative serum biomarkers showed high variability in both placebo and drug groups and are not felt to be useful in future studies
- Changes in the FibroTest were seen in the high dose cohort 3, attributable to a reduction in alpha-2 macroglobulin.

Phase 2 Clinical Trial Plans

- A Phase 2 clinical trial is planned based on:
  - Pre-clinical efficacy
  - Phase 1 safety and tolerability
  - Phase 1 PK and animal model/human dose equivalency
  - Phase 1 evidence of pharmacodynamic effect at high dose
- The company has informed the study investigators that it has met with FDA to discuss Phase 2 trial design
- Preliminary Phase 2 clinical trial design
  - Target patient population: Cirrhosis due to NASH
  - Study endpoints will include those that are closely associated with outcomes in patients with cirrhosis
    - Primary endpoint: Hepatic venous pressure gradient (HVPG)
    - Secondary endpoint: Morphometric analysis of collagen on liver biopsies
    - Other secondary endpoints will include non-invasive tests to evaluate for correlation with HVPG and liver collagen
  - Timeline: Study is planned to be initiated in second quarter of 2015 and an RFP has been responded to by 4 recognized CROs