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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported): February 10, 2014**

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**GALECTIN THERAPEUTICS INC.**

(Exact name of registrant as specified in its charter)

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**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)

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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))
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**SECTION 7 – REGULATION FD**

**Item 7.01 Regulation FD Disclosure.**

On February 10, 2014, Galectin Therapeutics Inc. (the “Company”) posted a corporate presentation on its website that contains a summary of the Company’s business. The presentation, which is being furnished and not filed, and 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.**

(a) Financial Statements of Businesses Acquired.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Shell Company Transactions.

Not applicable.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
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: February 10, 2014

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



# Corporate Presentation

February 10, 2014

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Therapeutics  
NASDAQ:GALT

**NASDAQ: GALT**

**[www.galectintherapeutics.com](http://www.galectintherapeutics.com)**

# Forward Looking Statements

This presentation contains, in addition to historical information, statements that look forward in time or that express management's beliefs, expectations or hopes. Such statements are 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 risks and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include our plans, expectations and goals regarding drugs in development, clinical trials and regulatory approval for any of our drugs or treatments, the anticipated timeline for clinical trials and results, related market opportunities for our drugs, potential benefits of our drugs, efforts related to partnering opportunities with other companies, estimates regarding cash and spending, liquidity and funding requirements for clinical trials, and estimates regarding those impacted by NASH, liver fibrosis and cirrhosis. The risks and uncertainties impacting these statements include that our plans, expectations and goals regarding drugs in development, clinical trials and regulatory approval are subject to factors beyond our control. Our clinical trials may not begin or produce positive results in a timely fashion, if at all, and any necessary changes during the course of such trials could prove time consuming and costly. We may have difficulty in enrolling candidates for testing and we may not be able to achieve the desired results. Upon receipt of regulatory approval for any drug or treatment, we may face competition with other drugs and treatments that are currently approved or those that are currently in development, which could have an adverse impact on our ability to achieve revenues from the approved indication. 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. Estimates regarding the potential benefits of our drugs and the potential market for any of our drugs may be inaccurate and, to the extent the estimates are correct, we may not be successful in achieving revenues from any such drugs, as the successful marketing of any approved drugs will be subject to strong competition within the health care industry and patient and physician acceptance of our drugs as safe, affordable and effective. Our ongoing discussions with other companies may not lead to partnering opportunities, and if we are unable to partner with other companies and/or raise additional capital, we will likely be unable to complete future stages of clinical trials and ultimately produce revenue from our drugs in development. Funding from potential sources of capital, including the potential exercise of warrants, may not materialize. To date, we have incurred operating losses since our inception, and our ability to successfully develop and market drugs 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 most recent Annual Report on Form 10-K 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.

# Agenda

- **The Company and Key Team Members**
- Galectin Inhibitors
- Fibrosis Program – our primary focus
- Cancer Immunotherapy
- Summary

## What We Do

- Clinical stage biopharmaceutical company targeting fibrotic diseases and cancer with novel compounds that inhibit galectin proteins (galectin-3)
  - Galectin proteins are important in the development and promotion of many inflammatory, fibrotic and neoplastic diseases
- Currently in clinical trials in liver fibrosis and cancer
  - Liver fibrosis indication: NASH (Fatty Liver Disease) with advanced liver fibrosis
  - Cancer immunotherapy indication: Metastatic melanoma

## Key Facts – As of February 7, 2014

Trading Symbol	Nasdaq: GALT
Corporate Headquarters	Norcross, GA (suburb of Atlanta)
Stock Price; 52 Week Range	\$13.91    \$2.61 - \$17.88
Shares Outstanding	21.5 million
Daily Volume (50 day average)	555,231 shares
Market Capitalization	\$299 million
Debt	\$0
Cash & Equivalents	\$35 million
Estimated Spending in 2014	\$14.5 million
Fiscal Year Ends	December 31
Accounting Firm	McGladrey LLP






# Experienced Leadership Team

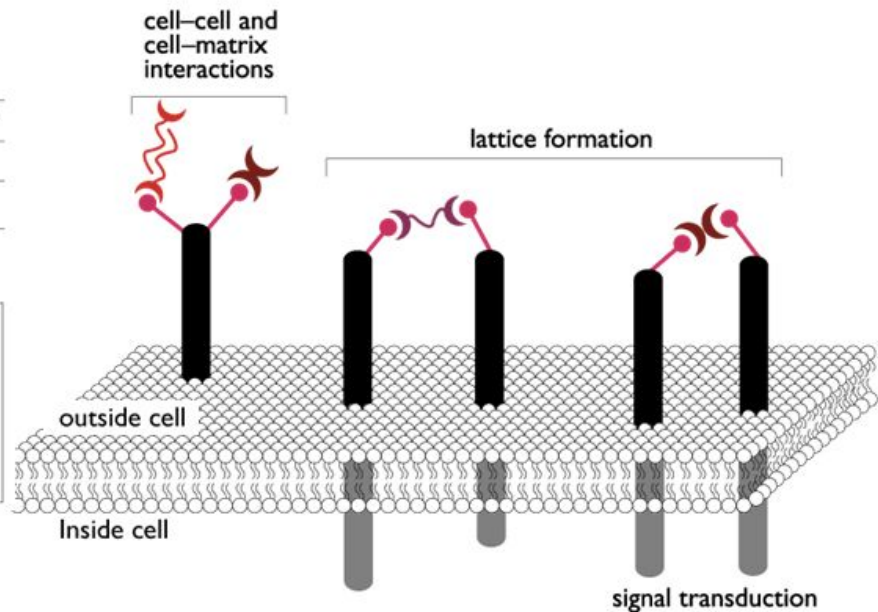
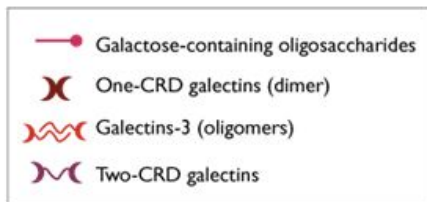
James Czirr, Executive Chairman	<ul style="list-style-type: none"> <li>• <b>Manager and general partner of 10X Fund, L.P., Co-Founder, Pro-Pharmaceuticals, CEO, Minerva Biotechnologies Corporation</b></li> </ul>
Peter G. Traber, MD President, CEO, CMO	<ul style="list-style-type: none"> <li>• <b>Over 28 years experience in biomedicine and pharmaceutical industries in research and development, clinical medicine and business development.</b></li> <li>• <b>GlaxoSmithKline (CMO), Un of Pennsylvania (CEO, Chief of GI, Chairman of Medicine), Baylor College of Medicine (CEO)</b></li> </ul>
Harold H. Shlevin, PhD COO & Corporate Secretary	<ul style="list-style-type: none"> <li>• <b>Over 32 years of senior experience in the development and commercialization of pharmaceuticals and business development including mergers and acquisitions.</b></li> <li>• <b>Solvay Pharmaceuticals (CEO), CIBA Vision Ophthalmics (nka Novartis Vision) (SVP &amp; co-founder), Tikvah Therapeutics (Founder, CEO), Board of Directors, Cardiome Pharma Corp. (NASDAQ: CRME)</b></li> </ul>
Jack W. Callicutt CFO	<ul style="list-style-type: none"> <li>• <b>Over 24 years in accounting and finance with life science and technology companies with significant experience in negotiating and closing financing transactions.</b></li> <li>• <b>CFO Reach Health, CFO of Vystar Corporation, CFO Corautus Genetics, Deloitte</b></li> </ul>
Eliezer Zomer, PhD Pharmaceutical Development	<ul style="list-style-type: none"> <li>• <b>Over 30 years experience in biotechnology engineering and regulatory in pharmaceuticals and diagnostics.</b></li> <li>• <b>Koor Biotechnologies, Charm Sciences, Glycogenesis , HU Medical School (Jerusalem), Harvard University</b></li> </ul>
J. Rex Horton Executive Director, Regulatory Affairs and Quality Assurance	<ul style="list-style-type: none"> <li>• <b>Over 24 years of experience working in the biotech and life sciences industries, regulatory affairs and manufacturing.</b></li> <li>• <b>Director Regulatory Affairs at Solvay Pharmaceuticals and Chelsea Therapeutics, Georgia Institute of Technology.</b></li> </ul>

- The Company and Key Team Members
- **Galectin Inhibitors**
- Fibrosis Program – our key focus
- Cancer Immunotherapy
- Summary

# Galectin Proteins: Bind galactose residues on glycoproteins

TYPE	STRUCTURE	GALECTIN
One-CRD		1,2,5,7,10,11,13,14,15
		3
Two-CRD		4,6,8,9,12

Carbohydrate Recognition Domain



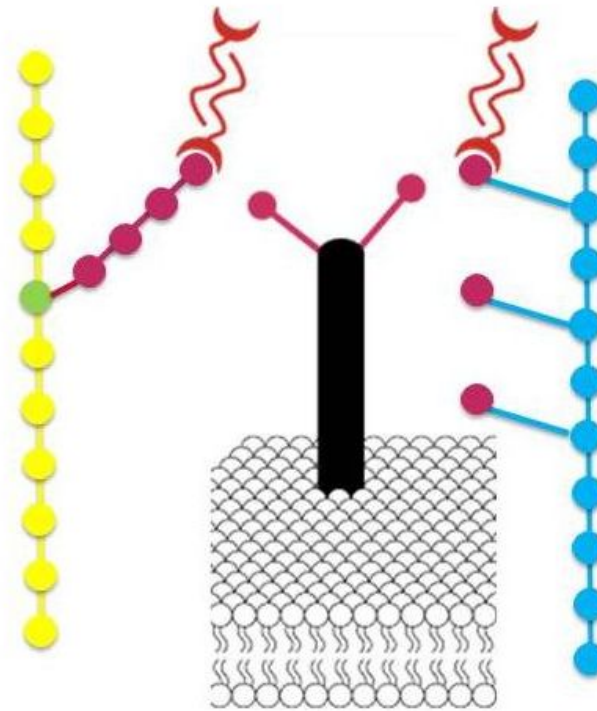
- Galectin-3 is most important in pathological situations, is widely expressed, but highest in immune cells (macrophages)
- Under normal physiological situations, galectin-3 is expressed at low levels
- In areas of acute or chronic inflammation and fibrogenesis, the gal-3 expression is markedly increased. The majority of cancers express high levels of galectin-3

# Our drugs are natural complex carbohydrates that bind to galectin-3 and block interactions with natural ligands

## GR-MD-02

(simplified schematic)

- Produced from apple pectin
- Method of use patents in liver fibrosis, fatty liver disease, and diabetic kidney disease (others pending)
- Composition of matter pending



## GM-CT-01

(simplified schematic)

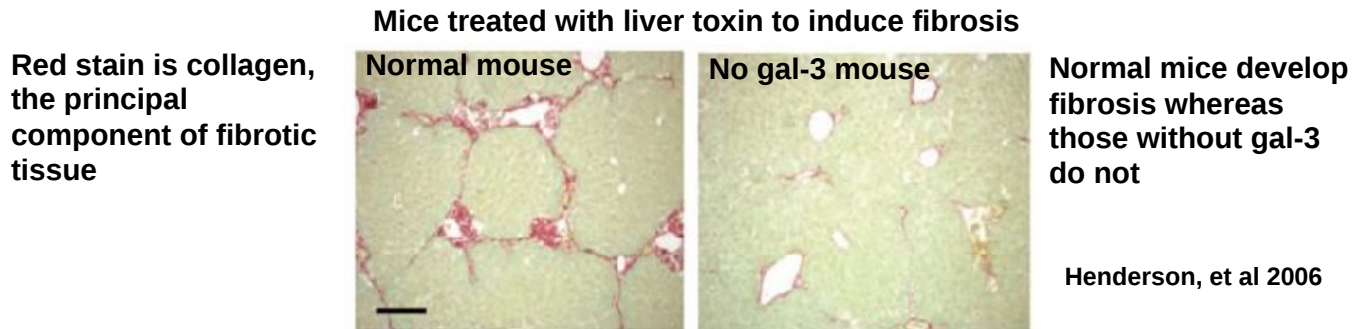
- Produced from guar gum
- Method of use patents in liver fibrosis and cancer (others pending)
- Composition of matter patent

● Galactose   
 ● Galacturonic Acid   
 ● Rhamnose   
 ● Mannose

- The Company and Key Team Members
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## Fundamental Science on Target is Strong: Galectin-3 is critically important in the development of organ fibrosis

- Galectin-3 null mice (no galectin-3) are resistant to fibrosis due to toxin-induced liver toxicity

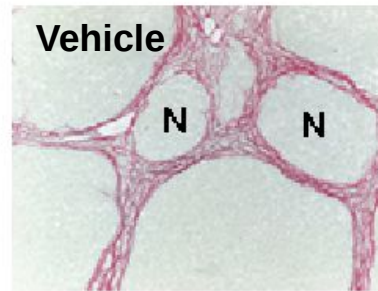
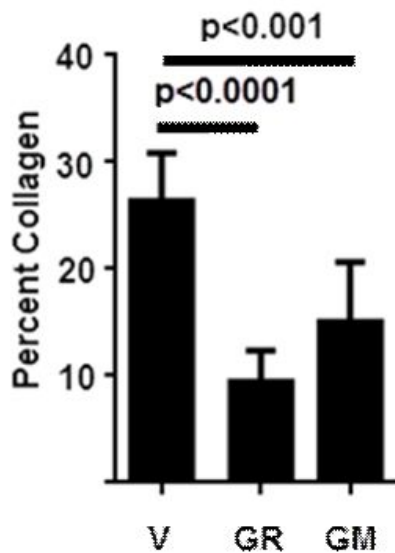


- Galectin-3 null mice are also resistant to fibrosis in:
  - Fatty liver disease
  - Lung fibrotic disease
  - Kidney fibrotic disease

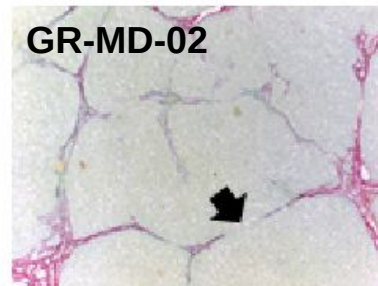


# Company's Galectin Inhibitors Reverse Cirrhosis in Rat Model

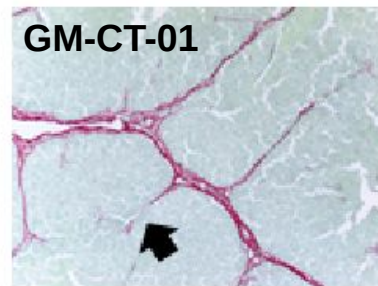
- Animal model presented a **very high hurdle** for drug treatment: Cirrhosis induced with high dose toxin and continued throughout drug treatment
- Treatment with four weekly doses



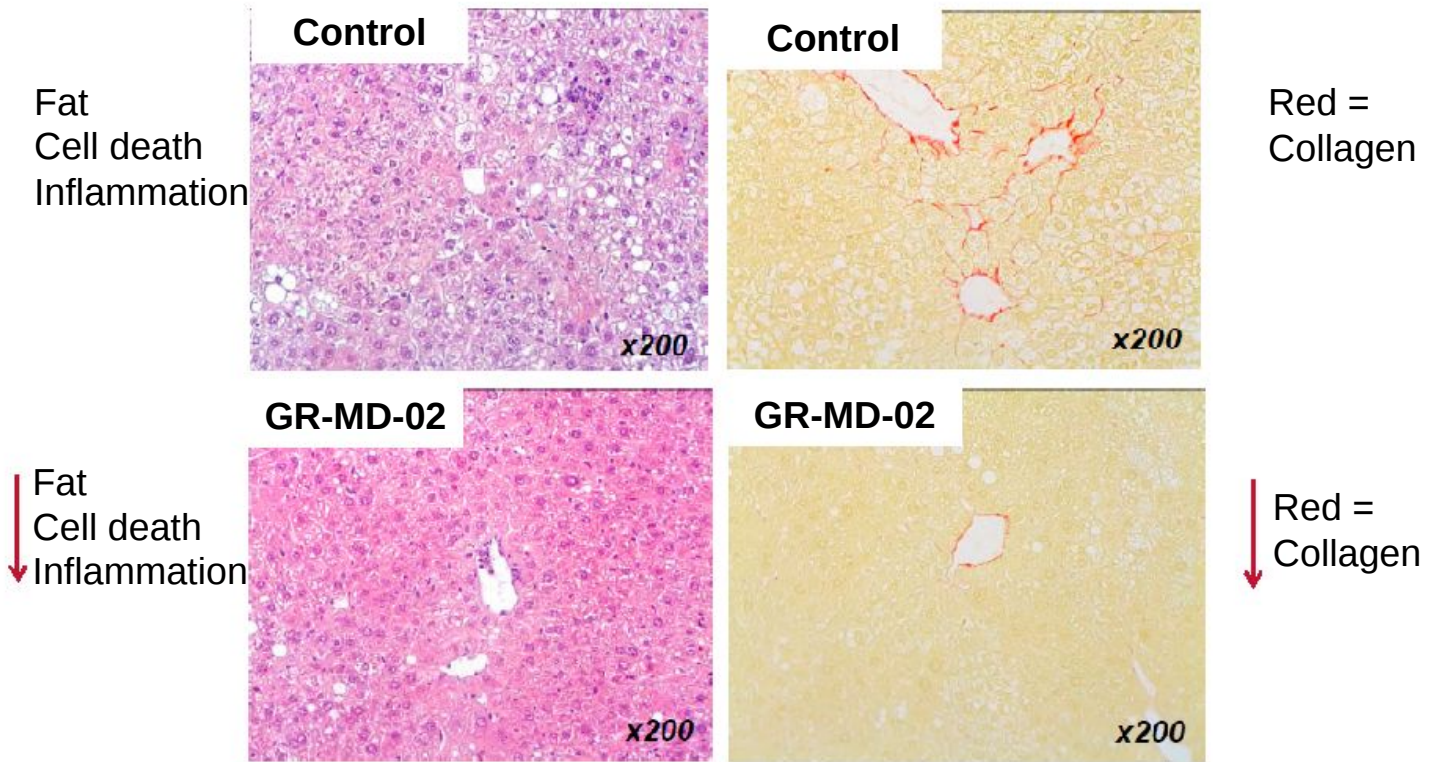
Broad bands of collagen with nodule formation (N) indicates advanced fibrosis and cirrhosis



Reduction in collagen with thin and broken bands (arrow) indicates resolving fibrosis and cirrhosis



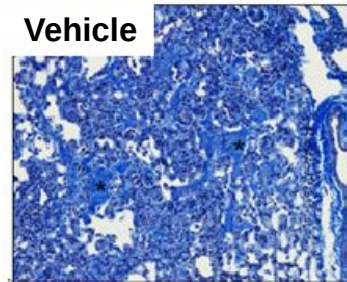
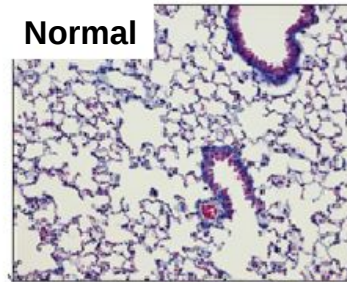
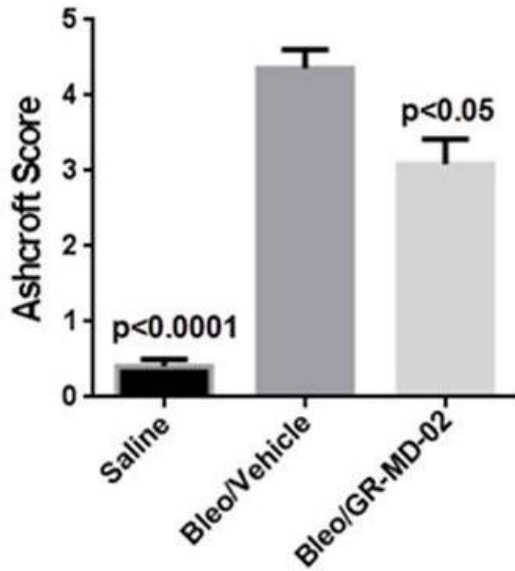
# Galectin Inhibitor GR-MD-02 Improved Fat, Liver Cell Death, Inflammation, and Fibrosis in Mouse Model of Fatty Liver Disease (NASH) with Fibrosis



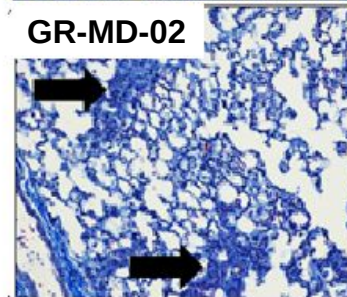


# Potential Use in Lung Fibrosis: GR-MD-02 Reduces Fibrosis in Mouse Model

Lung fibrosis induced by tracheal instillation of bleomycin followed by four infusions of either vehicle or GR-MD-02

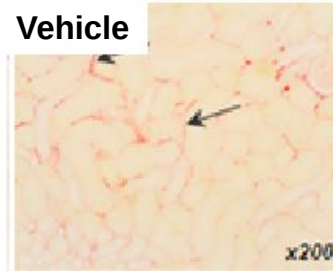
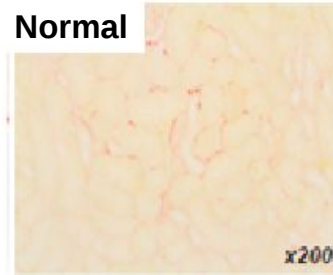
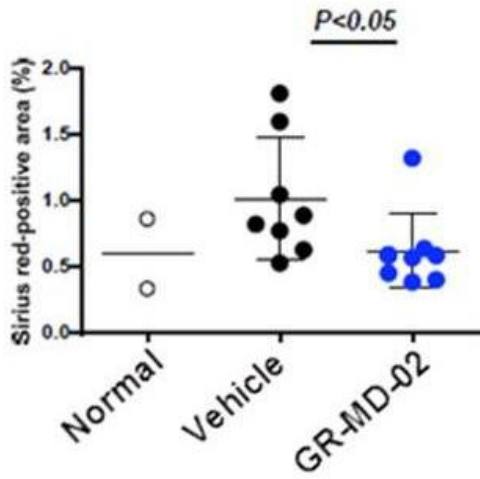


Large areas of confluent fibrosis.

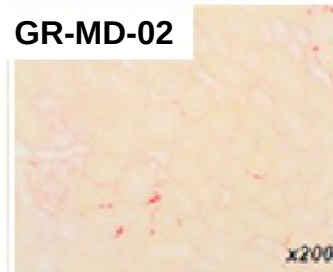


Marked reduction in area and severity of fibrosis without aggregation into larger formations

# Potential Use in Kidney Fibrosis: GR-MD-02 Reduces Fibrosis in Diabetic Mouse



Arrows show areas of interstitial fibrosis



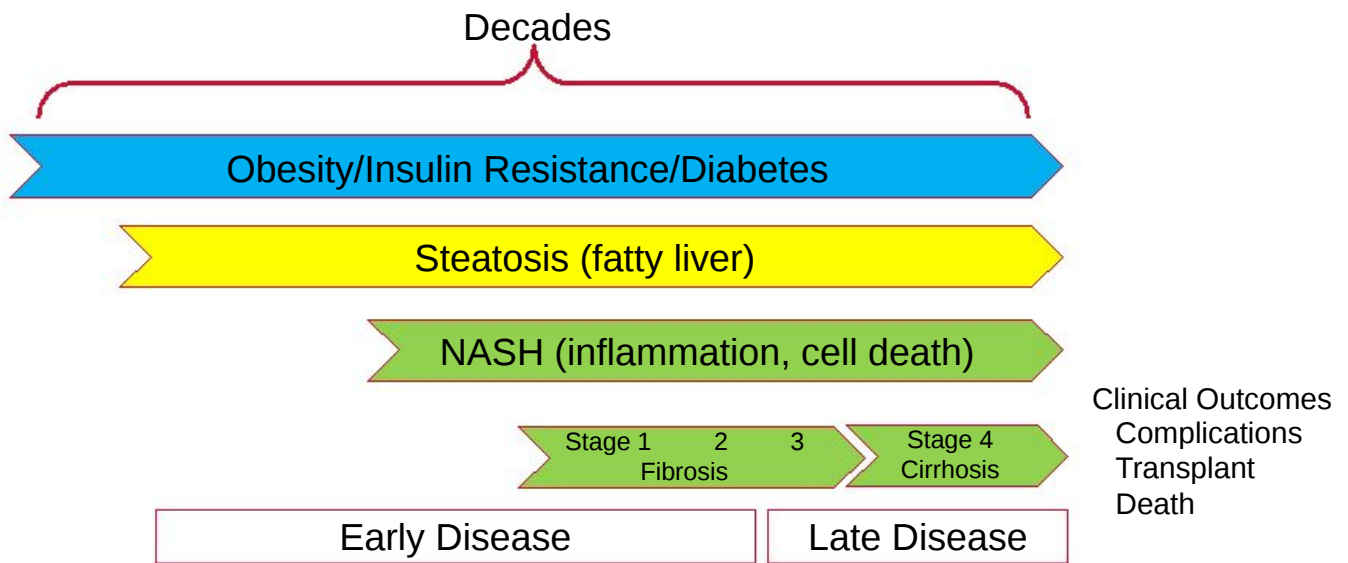
Reduction in interstitial fibrosis

# Liver Fibrosis Development Program

## NASH (Non-Alcoholic SteatoHepatitis): Very Large Unmet Medical Need

- Multiple liver diseases lead to fibrosis which leads to liver failure, medical complications, and death
- There is no approved medical therapy for liver fibrosis
  - Only current therapy is liver transplantation
- First indication is fatty liver disease with fibrosis (non-alcoholic steatohepatitis, or NASH).
  - Prevalence of NASH in U.S. is between 9-15 million people
  - Approximately 30% will develop cirrhosis; estimated prevalence of patients with advanced fibrosis is approximately 6 million.
  - NASH cirrhosis projected to be primary reason for liver transplant
- IND for GR-MD-02 with advanced fibrosis: Jan. 30, 2013
- **Fast Tract Designation received in August 2013**
- **Phase 1 trial: First cohort enrollment completed. Data to be reported around end of first quarter 2014.**

# Development Program: Targeting Therapy In The Progression of NASH



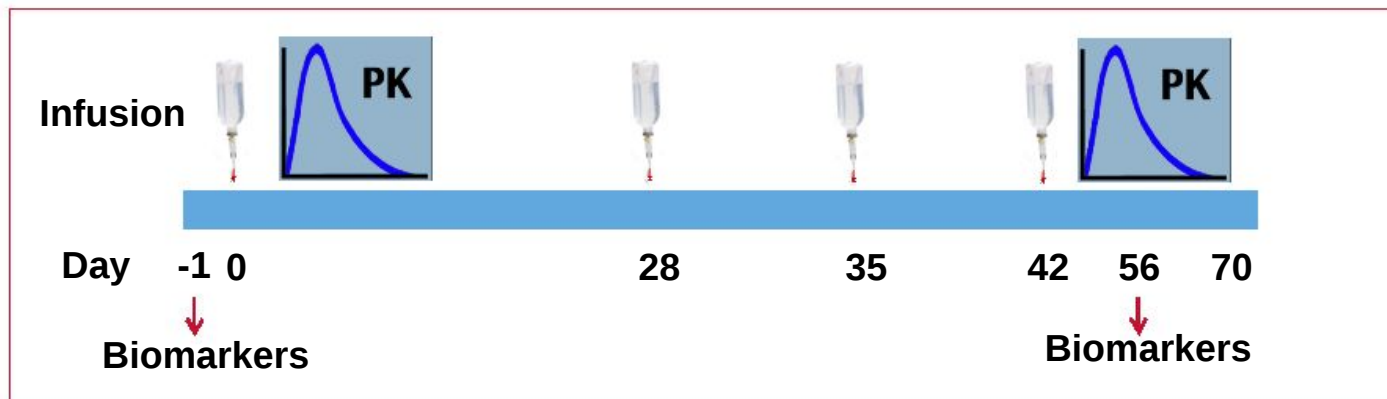
- No certainty of progression from early to late disease in an individual
- Late disease much closer to clinical outcomes
- Because of effect on inflammation in NASH and ability to reduce existing fibrosis, our clinical program **targets NASH patients with late disease**

# Phase 1 Clinical Trial of GR-MD-02 in NASH (Fatty Liver Disease) with Advanced Fibrosis

**Patient inclusion:** Biopsy proven NASH with advanced fibrosis (stage 3)

**Design:** Each cohort has 8 patients (6 active, 2 placebo, blinded)

**Dose:** Starting dose of 2 mg/kg which is within the presumptive therapeutic range; next two cohort doses 4 mg/kg and 8 mg/kg.



**Primary endpoints:** Safety; Pharmacokinetics

**Secondary endpoints:** Serum biomarkers to assess for potential treatment

**Timing of expected data from each cohort**

Cohort 1: Mar-Apr 2014

Cohort 2: Jul-Aug 2014

Cohort 3: Oct–Nov 2014

# Key Biomarkers for Assessing Potential Efficacy in Phase 1 Clinical Trial

- Most important biomarkers are clinically validated composite scores that have been shown to correlate with fibrosis
  - **ELF (Enhanced Liver Fibrosis) Score:** Includes measurement of hyaluronic acid, tissue inhibitor of metalloproteinase-1, and PIIINP (amino terminal propeptide of type III pro-collagen)
  - **Fibrotest:** age and gender, alpha-2-macroglobulin, haptoglobin, apolipoprotein A1, GGTP, total bilirubin
  - Other fibrosis markers: TGF- $\beta$ , lumican, Matrix metalloproteinase-1, -3, and -9
- Biomarkers associated with NASH—ballooning degeneration of hepatocytes
  - Cytokeratin-18 (M30 and M65 antibody tests)
- A variety of inflammatory biomarkers are also being explored

- **Patient inclusion:** Biopsy proven NASH with advanced fibrosis (stage 3 and stage 4 with no complications of cirrhosis)
- **Design:** Randomized, placebo controlled, and double blind.
- **Dose:** Likely two dosage groups
- **Treatment Duration:** TBD
- **Primary endpoint:** Liver biopsy: Collagen proportional area
  - Galectin human NASH biopsy study done to guide design
- **Timeline:** Start around end of 2014; Top line data dependent on trial design: expectation is 1H 2016.
- **Secondary endpoints:**
  - Liver Biopsy: NASH Activity Score and Fibrosis Stage
  - Liver function testing: HepQuant (bile acid clearance test)
  - Imaging methods—Fibroscan and/or MR-elastography
  - Serum biomarkers based on analysis of Phase 1 data: Fibrotest and ELF Score key biomarkers

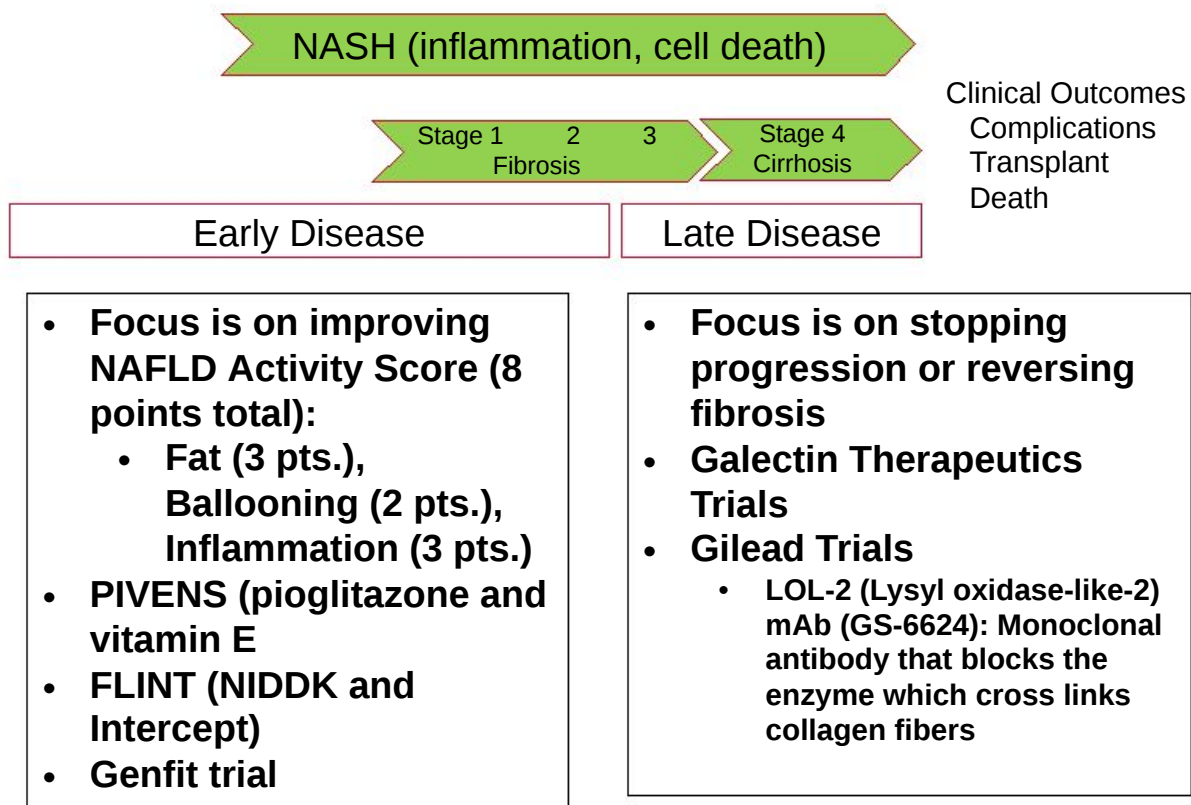
# Comparison of Galectin-3 Inhibitors

	Galectin Thera.	La Jolla Pharm.	Galecto Biotech
Drug	GR-MD-02	GCS-100	TD 139
Drug Characteristics	Mod. apple pectin: MW: 20-70K; aqueous solution*	Mod. citrus pectin; MWt >100K colloidal solution**	Modified lactose, a disaccharide
Cell culture effects	No cytotoxicity or apoptosis; inhibits cytokine production *	Kills cells through apoptosis**; no effect on cytokines*	Shown to reduce TGF- $\beta$ signaling
Human side effects	TBD; in phase 1	DLT was Grade 3 maculopapular rash (vasculitis). Animal studies.***	Unknown, pre-clinical
Clinical Development	NASH with advanced fibrosis	Kidney insufficiency	Pre-clinical; Lung fibrosis; inhalation
Dosing in clinical program	Phase 1 starting dose= 2 mg/kg	Highest dose= 0.75 mg/kg #	TBD

\*GALT patents \*\*LJPC patents \*\*\*GCS-100 published abstract #LJPC press release



# Competition in NASH



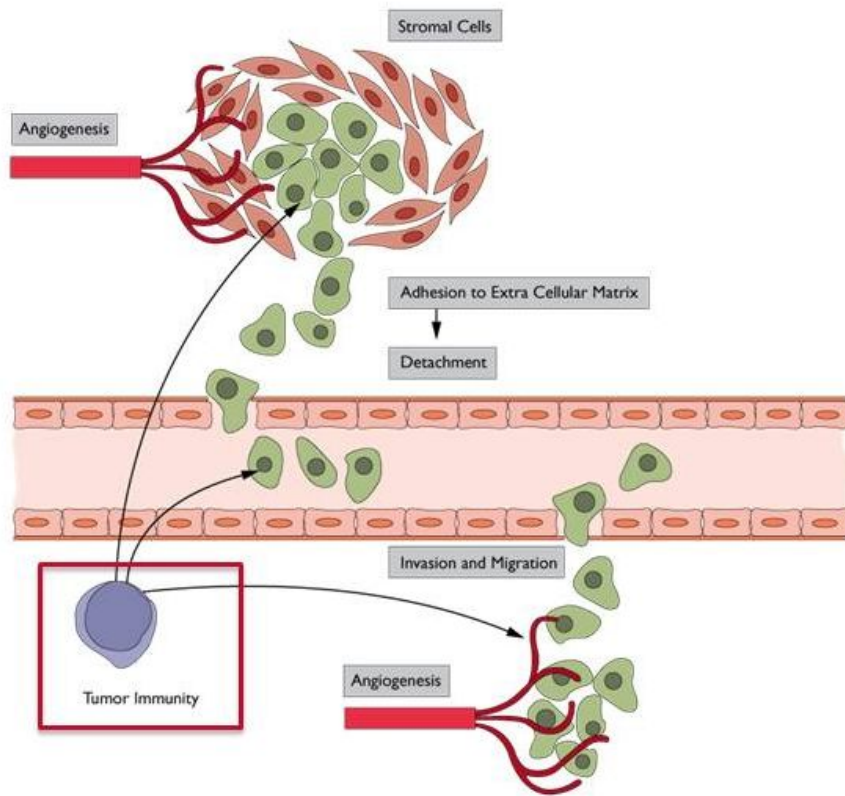
## Fibrosis Strategy Summary

- NASH with Advanced Fibrosis: Evidence of efficacy of GR-MD-02 from well controlled phase 2 clinical trial
- Other Organ Fibrosis: Potential for partnering opportunities
  - Lung fibrosis – pre-clinical results suggest possible use in Idiopathic Pulmonary Fibrosis
  - Kidney fibrosis
- Ongoing discussions with large pharmaceutical companies
  - Discussions will provide foundation for partnering opportunities at the most opportune time

# Agenda

- The Company and Key Team Members
- Galectin Inhibitors
- Fibrosis Program – our key focus
- **Cancer Immunotherapy**
- Summary

# The Vast Majority of Cancers Secrete Large Amounts of Galectins Which Have Multiple Roles in Tumor Pathogenesis



- Tumor cell invasion: extracellular matrix adhesion & detachment
- Metastasis: cell invasion and migration
- Angiogenesis
- **Tumor immunity** has recently been shown to be critically affected by galectins

# Cancer immunotherapy drugs will soon be a \$35 bn global industry

May 22, 2013

"We believe this market will generate sales of up to \$35 billion (a year) over the next 10 years and be used in some way in the management of up to 60 percent of all cancers," Citi analyst Andrew Baum said on Wednesday.

## Checkpoint Inhibitor Blockade

- **Marketed:**
  - CTLA4 receptor mAb: Yervoy® (Ipilimumab, BMS)
- **In Development:**
  - Anti-PD-1 (nivolumab BMS; lambrolizumab Merck)
  - Anti PD-L1 (MPDL3280A , Roche)

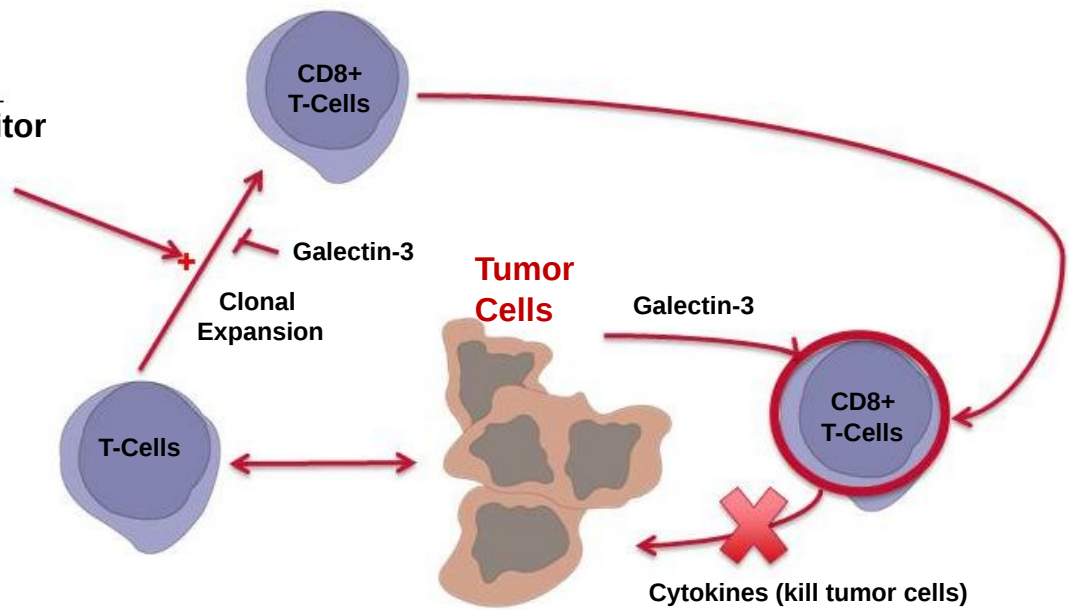
**Cancer Immunotherapy Named Top Scientific Breakthrough of 2013 by Science Magazine**

## Cancer Therapy Strategy

- Focus on cancer immunotherapy based on the hypothesis that galectin inhibitors will enhance efficacy of immunotherapies
- Metastatic melanoma is initial cancer indication
  - In US 76,000 new diagnoses and 9,100 deaths annually
  - 5% five year survival for metastatic disease
  - Even with newly approved drugs, still a substantial unmet medical need
- We have sought collaborations with institutions that have:
  - Demonstrated clinical trial expertise in melanoma
  - Tumor immunology basic science research
  - Ability to conduct clinical trials and assist in funding
- Two collaborations have been established
  - Ludwig Cancer Institute, Brussels Belgium
  - Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute (EACRI) Providence-Portland Medical Center, Portland Oregon

# Potential sites of action for galectin inhibition in tumor immunology

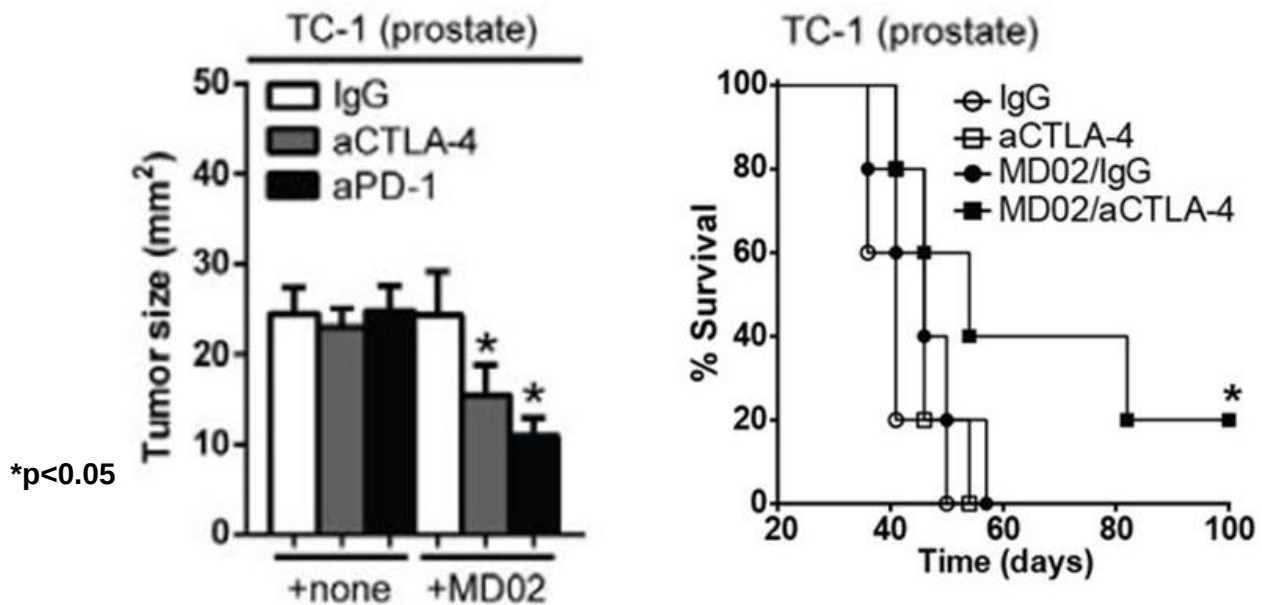
**Immunotherapies**  
Checkpoint Inhibitor  
Blockage:  
anti-CTLA4  
anti-PD1  
Tumor Vaccines



Potential for galectin inhibitors to enhance anti-tumor immune response

Potential for galectin inhibitors to enhance anti-tumor activity of T-cells by blocking "Galectin Effect"

**Checkpoint inhibitors plus GR-MD-02 boosts anti-tumor immunity, reduce tumor size and increase survival in mouse model of prostate cancer (similar results in breast cancer, melanoma and sarcoma)**



**aCTLA-4 = anti-CTLA-4 mAb [ipilimumab in humans (Yervoy, BMS)]**  
**aPD-1 = anti-PD-1 mAb [positive results in clinical trials, BMS, Merck]**

Unpublished data 2013: Stefanie N. Linch, Melissa J. Kasiewicz, Peter G. Traber, and William L. Redmond, Galectin Therapeutics and Earle A. Chiles Research Institute (EACRI), Portland Oregon



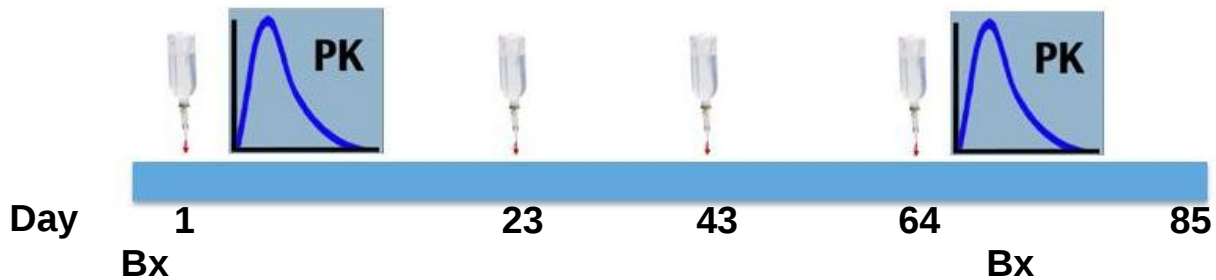
## Phase 1B Clinical Trial in patients with advanced melanoma using GR-MD-02 in combination with Yervoy® (ipilimumab): March 2014 Start

**Patient inclusion:** Advanced melanoma with indication for Yervoy Rx

**Design:** 3+3 dose escalation; 10 patients treated with MTD

**Dose:** Starting dose of 1 mg/kg

Infusion: GR-MD-02 followed by Yervoy at standard doses



Followed every 12 weeks for survival

### **Endpoints:**

- Safety; Pharmacokinetics
- Tumor response: immune response RECIST criteria
- Biological responses including memory CD4+ T-cells, memory CD8+ T-cells, melanoma specific T-cells, and composition of tumor immune infiltrate from tumor biopsies when available.

- Two immunotherapy agents have been approved for use to date, with many more vaccines and activators in development
- Our strategy is to leverage world class expertise in basic tumor immunology and in the conduct of melanoma clinical trials.
  - **Providence Portland Medical Center and Earle A. Chiles Research Institute (EACRI)** : Ongoing pre-clinical studies; IND accepted for phase 1B clinical trial in patients with advanced melanoma treated with a combination of Yervoy and GR-MD-02
  - Initial funding of clinical trial by PPMC/EACRI. Galectin is providing GR-MD-02 study drug, reference to its IND, and PK analysis
- Ongoing discussions with large pharmaceutical companies in the immunotherapy space to seek a partnering opportunity to take beyond proof of concept from initial clinical trials

# Agenda

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## Summary of Development Program

- Liver Fibrosis
  - First indication: GR-MD-02 in NASH with advanced fibrosis
  - Phase 1 clinical trial underway; interim data expected March-April 2014
- Other Organ Fibrosis: Studies to demonstrate broad application of drugs in organ fibrosis; seek partner
- Cancer Therapy: Combination immunotherapy to enhance the ability of the immune system to recognize and kill tumor cells in metastatic melanoma
  - Leverage world class expertise in basic tumor immunology and in the conduct of melanoma clinical trials.
- Ongoing discussions with large pharmaceutical companies to provide foundation for partnering opportunities at the most opportune time