

**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 10, 2015

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))

SECTION 7 – REGULATION FD

Item 7.01 Regulation FD Disclosure.

On September 10, 2015, Galectin Therapeutics Inc. made a corporate presentation Rodman & Renshaw 17th Annual Global Investment Conference that contains, among other information, a summary of development of GR-MD-02 for Non-Alcoholic Steatohepatitis (NASH) With Advanced Fibrosis and Cirrhosis, which presentation is attached 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.

<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: September 10, 2015

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



Rodman & Renshaw 17th Annual Global Investment Conference

September 10, 2015

NASDAQ: GALT
www.galectintherapeutics.com

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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 which 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, potential partnering opportunities and estimated spending for 2015. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, our trials may not lead to positive outcomes or regulatory approval. 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 further develop and/or fund any studies or trials. We are currently the subject of litigation, which may impact our human and capital resources. 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, 2014, 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.

Experienced Executive Leadership Team

James Czirr, Executive Chairman	<p>Over 20 years experience as biotech entrepreneur</p> <ul style="list-style-type: none">• 10X Fund, L.P., general partner• Pro-Pharmaceuticals, co-founder• Minerva Biotechnologies Corporation, CEO
Peter G. Traber, M.D. President, CEO, CMO	<p>Over 28 years relevant experience</p> <ul style="list-style-type: none">• Recognized leader in gastroenterology and hepatology• University of Pennsylvania<ul style="list-style-type: none">• Chief of Gastroenterology• Chairman of Internal Medicine• CEO of Health System, Dean of Medicine• Baylor College of Medicine, President and CEO• GlaxoSmithKline, Senior Vice President and Chief Medical Officer
Harold H. Shlevin, Ph.D. COO & Corporate Secretary	<p>Over 32 years of relevant experience</p> <ul style="list-style-type: none">• Solvay Pharmaceuticals, CEO• CIBA Vision Ophthalmics (n/k/a Novartis Vision), SVP & co-founder• Tikvah Therapeutics, Founder and CEO
Jack W. Callicutt CFO	<p>Over 25 years of relevant experience</p> <ul style="list-style-type: none">• Reach Health, CFO• Vystar Corporation, CFO• Corautus Genetics• Deloitte

Organ Fibrosis

- **45% of U.S. deaths estimated to be associated with fibrotic disease ¹**
- **Lead indication is liver fibrosis/cirrhosis due to fatty liver disease (75% of all liver disease in U.S.²)**
- **Potentially applicable to other fibrotic diseases based on pre-clinical studies**

Cancer

- **Focus on combination immunotherapy, one of the most promising approaches to cancer therapy**
- **Lead indication is advanced melanoma, but technology applicable to other cancers**

¹Wynn, TA. Nat Rev Immunol. 2004;4:583–594. doi:10.1038/nri1412

²Younossi, et al. Clin. Gastro. Hepatol. 2011;9:524–530

Galectin-3 Protein

- Binds to galactose residues (sugars) in glycoproteins and promotes interactions between these proteins
- High expression in immune cells (macrophages)
- Modulates cell signaling and immune cell function

Role in Disease

- Gal-3 is increased in inflammation and fibrogenesis
- Genetic modification in mice that eliminates gal-3 prevents fibrosis in liver, lung, kidney and heart
- The majority of cancers express high levels of gal-3, which promotes tumor growth and inhibits immune response

Lead Drug Candidate GR-MD-02

- A complex carbohydrate that disrupts gal-3 function, particularly affecting immune/repair function in macrophages
- Extensive analytical analysis using state-of-the-art methods to support human use
- Existing patent coverage through 2031 with 2 composition and 5 method patents issued
- Efficacy in preclinical models with encouraging human results

Clinical Focus		Stage of Development				
Drug	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
Fibrosis						
GR-MD-02	NASH cirrhosis					
	NASH advanced fibrosis					
	Lung, Kidney, Cardiovascular fibrosis					
Cancer Immunotherapy (combination therapy)						
GR-MD-02 + Yervoy	Melanoma					
GR-MD-02 + Keytruda	Melanoma	2H 2015				
Plaque Psoriasis (exploratory)						
GR-MD-02	Moderate-severe				Sept 2015	
New Galectin-3 Inhibitors						
Discovery program to identify subcutaneous and oral forms of carbohydrates and oral small molecules						

Lead Indication in Organ Fibrosis

ADVANCED FIBROSIS AND CIRRHOSIS DUE TO FATTY LIVER DISEASE

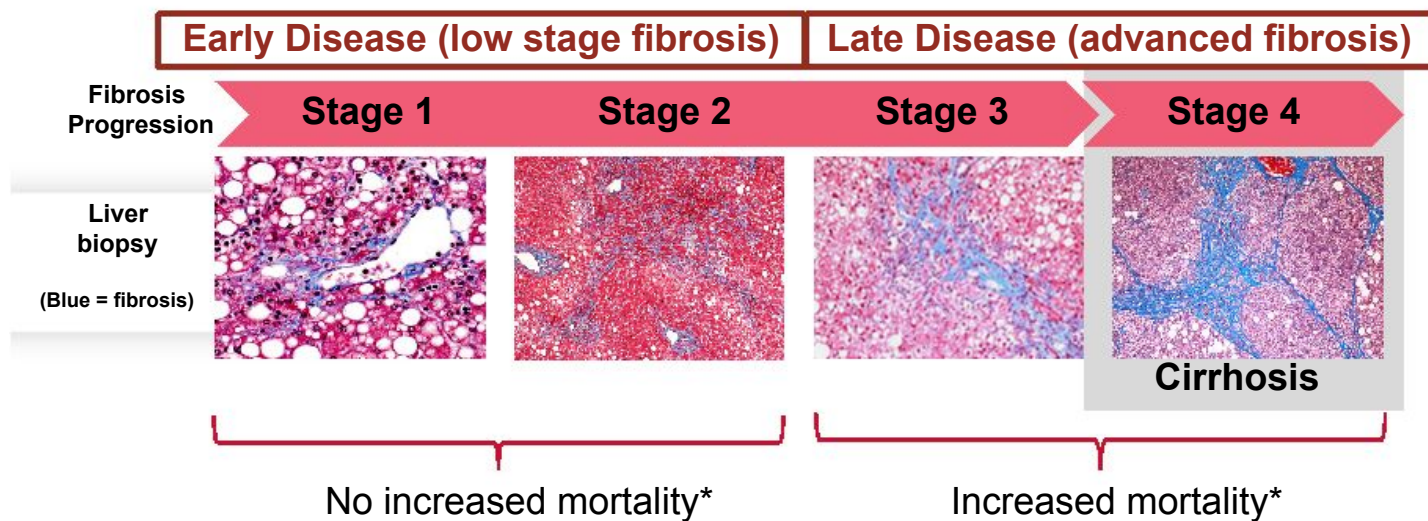
NASH: (NON-ALCOHOLIC STEATOHEPATITIS)

Extracted from Deutsche Bank Markets Research ¹

- Estimates for number of people with NASH is 18-30M in the US
- 5-9M people in U.S. may have NASH AND advanced fibrosis (Stage 2/3). 1-2M people may have cirrhosis (stage 4), the most advanced disease.
- Major global problem driven by increasing obesity & diabetes.
- NASH causes need for liver transplants and affects survival. Patients with NASH on transplant list increasing nearly 15% per year, while number of patients with hepatitis C and B are decreasing.
- U.S. NASH market could be \$25 Billion by 2025
 - Based on 1 million patients with advanced NASH being treated in the U.S.
- Global market (U.S., E.U., and Japan) could be \$35-40 Billion by 2025

¹ Who will be the kings of NASH-ville? Key players and an overview. May 21, 2015, Alethia Young, Deutsche Bank Markets Research

Scarring (Fibrosis) Of The Liver In Advanced NASH Leads To Patient Morbidity and Mortality



***All cause mortality as compared to reference group with prospective follow-up of up to 33 years (Ekstedt, et al. Hepatology 2015;61:1547-1554)**

Galectin Therapeutics Is Targeting Late-Stage NASH

Companies in Phase 2; multiple other companies in discovery and Phase 1



Early Disease (low stage fibrosis)

Late Disease (advanced fibrosis)

Stage 1

Stage 2

Stage 3

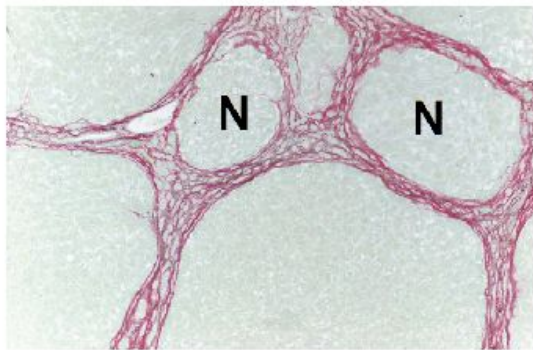
Stage 4 (Cirrhosis)

- Obeticholic Acid (Intercept)
- GFT505 (Genfit)
- Liraglutide (Novo Nordisk)
- Aramchol (Galmed)
- Cysteamine (Raptor)
- Cenicriviroc (Tobira)
- Emricasan (Conatus)
- PX104 (Gilead/Phenex)
- KD025 (Kadmon)
- NGM282 (NGM (Merck))
- Pradigastat (Novartis)
- Roflumilast/Pioglitazone (Takeda)
- GR-MD-02 (Galectin)
 - Reduce inflammation*
 - Reduce fibrosis progression*
 - Reverse existing fibrosis*
- Simtuzumab (Gilead)
 - Reduce fibrosis progression*

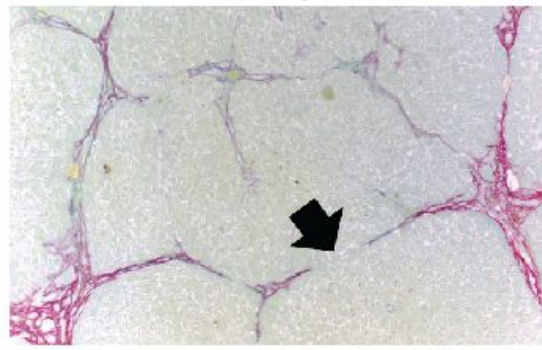
*Based on effects seen in preclinical studies and mechanisms of action

- **Mouse model of NASH**
 - Reduces inflammation, fat, and cell death
 - Prevents as well as reverses fibrosis
- **Rat model of liver cirrhosis**
 - Reduces inflammation and cell death
 - Reverses fibrosis and cirrhosis
 - Reduces portal hypertension associated with cirrhosis

Control (No treatment)



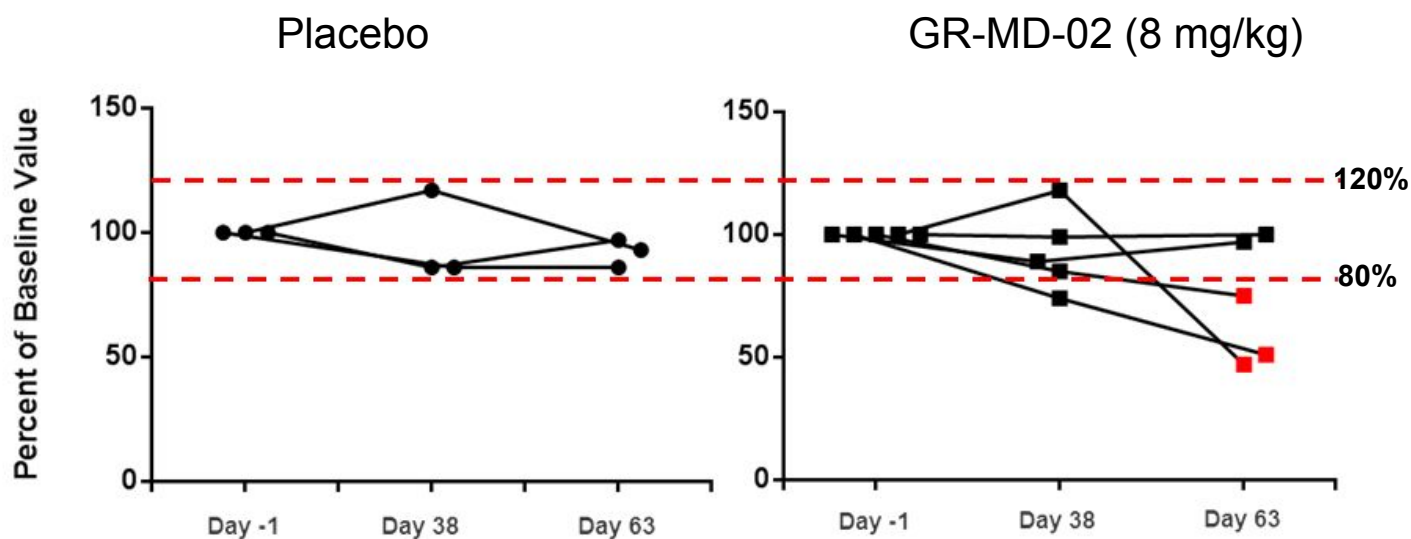
GR-MD-02 (4 weekly doses)



- **Study GT-020:** Multiple dose escalation, double-blind, placebo-controlled trial in NASH patients with advanced fibrosis
 - GR-MD-02 was safe and well tolerated
 - Doses in targeted therapeutic window for drug administration
 - Highest dose tested may have an effect on liver fibrosis
 - Reduced serum alpha-2 macroglobulin, a marker of fibrosis
 - Reduced liver stiffness assessed by FibroScan®
- **Study GT-029:** No interaction between GR-MD-02 and midazolam
 - Adds to strong safety profile
 - Allows for expansion of number of patients eligible to be included in Phase 2 clinical trials and future commercial population
- In total, 38 subjects receiving 132 doses of GR-MD-02 showed excellent safety profile
- Fast Track designation from FDA

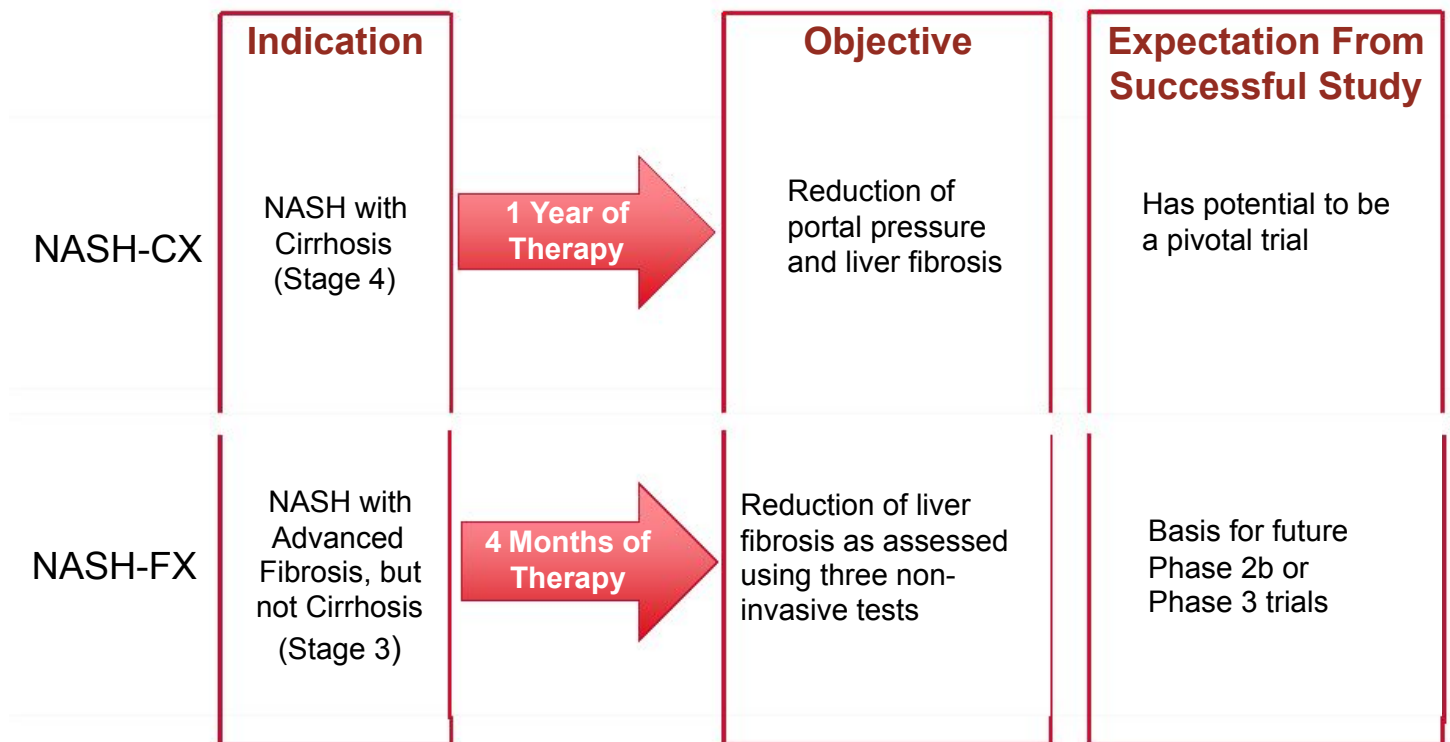
Evidence Of Reduced FibroScan® Scores In Cohort 3 Patients Treated With GR-MD-02

3 of 5 patients treated with GR-MD-02 had reduction in liver stiffness to below 80% of baseline values (red squares)*



*FS added during cohort 2, but only available at most centers for cohort 3. In cohort 3 there were technically adequate scans at baseline, Day 38 and Day 63 in 5 patients administered GR-MD-02 and 3 patients administered placebo. Five patients in cohort 3 were not available for FibroScan® analysis (3 placebo and 2 active) because of unavailability of the instrument at the site (1 placebo and 1 active), unavailability of the appropriate instrument probe (1 active), a technically inadequate baseline scan (1 placebo), and the Day 63 scan not being performed (1 placebo).

Phase 2 Clinical Trials Focus On Two Indications In NASH Patients With Advanced Fibrosis



With positive results, either of these studies could be basis for FDA Breakthrough application

For more details on clinical trials, please visit clinicaltrials.gov

- **Preclinical studies show galectin-3 to be a well-validated target that is inhibited by GR-MD-02**
- **In preclinical models GR-MD-02 has multiple effects**
 - Reduces inflammation, fat and ballooning hepatocytes in NASH
 - Reduces and reverses liver fibrosis and cirrhosis
 - Reduces portal pressure, an endpoint of NASH-CX trial
- **NASH is an unmet medical need with a very large potential market**
- **GR-MD-02 is well suited to target NASH with advanced fibrosis and cirrhosis, an area with less competition than early NASH**
- **In NASH patients with advanced fibrosis, GR-MD-02 is safe and well tolerated, therapeutic doses have been defined, and there is evidence of effect on fibrogenic process in patients**
- **Phase 2 clinical trial program addresses different patient populations**
 - NASH-CX trial in cirrhosis with top line results end of 2017
 - NASH-FX trial in stage 3 fibrosis with top line results 2H 2016

Lead Indication in Cancer Immunotherapy

ADVANCED MELANOMA

Focus on Immunotherapy

- Immunotherapy is a major breakthrough in cancer
- Galectin-3 plays an important role in reducing the ability of immune system to fight cancer

Advanced Melanoma as Initial Indication

- In U.S. 76,000 new diagnoses and 9,100 deaths per year*
- Even with newly approved drugs, a substantial unmet medical need remains

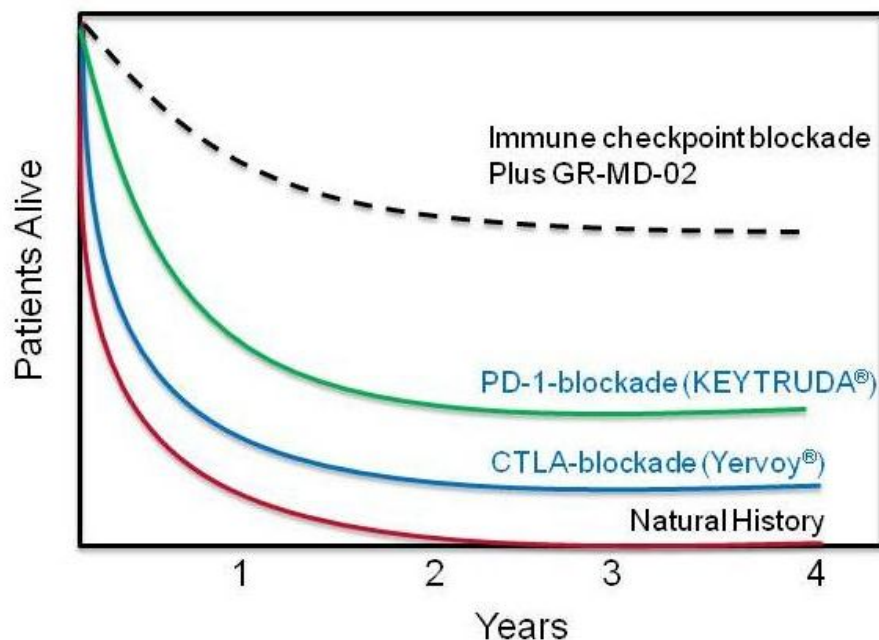
Critical Collaboration Established

- Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute Providence-Portland Medical Center (PPMC), Portland Oregon
- Demonstrated clinical trial expertise in melanoma and tumor immunology basic science research
- Ability to conduct clinical trials and assist in funding

*Siegel, et al. CA Cancer J Clin 2012;62:10

GR-MD-02 May Be Used In Combination With Other Immunotherapies To Enhance Patient Survival

PPMC preclinical studies in mice demonstrated that GR-MD-02 has a synergistic effect on multiple tumors in combination with other immunotherapies



Note: these are illustrative curves not representative of actual data; redrawn from figure of the American Association for Cancer Research, 2013

- **Phase 1b Clinical Trial In Patients With Advanced Melanoma Using GR-MD-02 In Combination With Yervoy®**
 - Advanced melanoma with indication for Yervoy® treatment
 - Dose escalation with GR-MD-02 plus standard Yervoy®
 - Measure tumor and immune system response
 - Two dosing groups complete showing no dose-limiting toxicity
 - Study details on clinicaltrials.gov
- **Phase 1b Clinical Trial In Patients With Advanced Melanoma Using GR-MD-02 In Combination With KEYTRUDA®**
 - Melanoma progression after Yervoy® and/or BRAF targeted therapy
 - Melanoma progression after KEYTRUDA® monotherapy
 - Remainder of design mirrors first study
 - Plan to initiate in 2H 2015

- **Collaboration with investigative group at PPMC who have significant expertise in basic tumor immunology and translational clinical trials**
- **Preclinical studies demonstrate in multiple cancers that GR-MD-02 augments the anti-tumor effects of monoclonal antibody checkpoint inhibitors**
- **Initial target is advanced melanoma, but also applicable to other cancer types**
- **Two Phase 1b clinical trials funded by PPMC**
- **May get early evidence of effect since advanced immune response markers being used to evaluate drug effect in addition to tumor response**

- **Moderate-to-severe plaque psoriasis**
- **Patient in Phase 1 trial had apparent remission of severe psoriasis while receiving 4 mg/kg of GR-MD-02**
- **Galectin-3 plays important role in skin and there is increase in skin vessels of patients with psoriasis^{1,2}**
- **Open-label, single-site, 10-patient study to evaluate the effect of 3 months of GR-MD-02 on the number of patients who have at least 75% improvement in Psoriasis Activity Severity Index (PASI-75)**
- **Details on clinicaltrials.gov**
 - <https://clinicaltrials.gov/ct2/show/NCT02407041?term=GR-MD-02&rank=5>

¹ Larsen L, et al. J. Derm Sci. 2011;64:85-91

² Lacina L, et al. Folia Biologica. 2006;52:10-15

Advanced Liver Fibrosis/Cirrhosis

Study	Indication	Endpoints	Start	Data Reporting
GT-026 "NASH-CX"	NASH with cirrhosis	Portal pressure (HVPG); liver biopsy	Underway	End 2017
GT-028 "NASH-FX"	NASH with advanced fibrosis	Multi-parametric MRI Comparisons include MRE and FibroScan®	Sept. 2015	2H 2016

Advanced Melanoma

Study	Indication	Endpoints	Start	Data Reporting
Phase 1b: Yervoy®	Advanced melanoma	Safety ir-RECIST Immune markers	Underway	Dose Group 1: complete Dose Group 2: complete Dose Group 3: initiated
Phase 1b: KEYTRUDA®	Advanced melanoma	Safety ir-RECIST Immune markers	2h 2015	TBD

Psoriasis

Study	Indication	Endpoints	Start	Data Reporting
Phase 2a: GT-030	Moderate-to-severe plaque psoriasis	Psoriasis Activity Severity Index (PASI 75)	Sept. 2015	Q3 2016

- **NASH (non alcoholic steatohepatitis) is an unmet medical need with a very large potential global market**
- **Late-stage NASH, with advanced fibrosis/cirrhosis is desirable from regulatory and commercial perspectives**
- **Preclinical studies with GR-MD-02 indicated positive effects on multiple aspects of NASH, including *fibrosis reversal***
- **Completed Phase 1 studies demonstrated drug was safe and well tolerated and provided proof-of-concept on anti-fibrotic activity**
- **Currently engaged in two Phase 2 NASH clinical trials in cirrhosis and advanced fibrosis without fibrosis**
- **Investigator-initiated studies in cancer immunotherapy and psoriasis enhance the GR-MD-02 opportunity**
- **Strong executive leadership team with extensive experience**

- New communication feature to provide in depth information on clinical development programs and other news



- <http://perspectives.galectintherapeutics.com/>
- Most recent posts
 - **The Potential for Treatment of Liver Fibrosis With Galectin's Drug Candidate GR-MD-02**
 - **Clinical Development Program in Liver Fibrosis**
 - **Successful Phase 1 Clinical Trial Supports Phase 2 Clinical Development Program**
 - **Clinical Trial to Establish Efficacy of GR-MD-02 in NASH Cirrhosis**
- Please sign up on web site to receive notification of blog articles



Thank You

NASDAQ: GALT

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