
**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): February 6, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 February 6, 2018, Galectin Therapeutics Inc. (the “Company”) posted to its website three presentations which are attached hereto as Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3.

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, February 6, 2018
99.2	GR-MD-02 for Indication of NASH Cirrhosis: NASH-CX Clinical Trial Results, February 6, 2018
99.3	The Galectin-3 Inhibitor GR-MD-02 for Combination Cancer Immunotherapy, February 6, 2018

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 6, 2018

By: /s/ Peter G. Traber
Peter G. Traber, M.D.
Chief Executive Officer



CORPORATE PRESENTATION

February 6, 2018

NASDAQ: GALT
www.galectintherapeutics.com



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 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 2018 and beyond. 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 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, 2016, 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.

Galectin is a Development Stage Biotech Company with an Experienced Team



Peter G. Traber, M.D., President, CEO, CMO

- Recognized leader in gastroenterology and hepatology
- University of Pennsylvania 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



Eli Zomer, PhD, Pharm Development

- Over 34 years of relevant experience: Koor Biotechnologies, Charm Sciences, Glycogenesis, HU Medical School (Jerusalem), and Harvard University



Harold H. Shlevin, Ph.D., COO & Corporate Secretary

- Over 34 years of relevant experience
- Solvay Pharmaceuticals, CEO
- CIBA Vision Ophthalmics (n/k/a Novartis Vision), SVP & co-founder
- Tikvah Therapeutics, Founder and CEO
- CIBA-Geigy Pharmaceuticals



Adam Allgood, Pharm D., Clinical Development

- Over 28 years experience in regulatory affairs, clinical development and medical affairs
- UCB Inc., Abbott Laboratories, Solvay Pharmaceuticals



Jack W. Callicut, CFO

- Over 27 years of relevant experience
- Reach Health, CFO,
- Vystar Corporation, CFO,
- Corautus Genetics, Deloitte



Rex Horton, Regulatory

- Over 26 years of experience; Director Regulatory Affairs at Solvay Pharmaceuticals and Chelsea Therapeutics; Georgia Institute of Technology



Addressing Important Unmet Medical Needs

❖ Advanced Fatty Liver Disease (NASH Cirrhosis)

- NASH global annual market could be \$35-40 Billion by 2025
- Competitively well positioned as one of the few companies focused on the most advanced form of NASH
- Our target indication of NASH cirrhosis may have 2.5M patients in US
- First and only positive phase 2 clinical data in target indication to date

❖ Combination Cancer Immunotherapy

- Large opportunity to improve results of immunotherapy of cancer
- Encouraging early clinical data with our drug in combination with KEYTRUDA with 5 of 8 objective responses (2 complete responses and 3 partial responses) in advanced melanoma



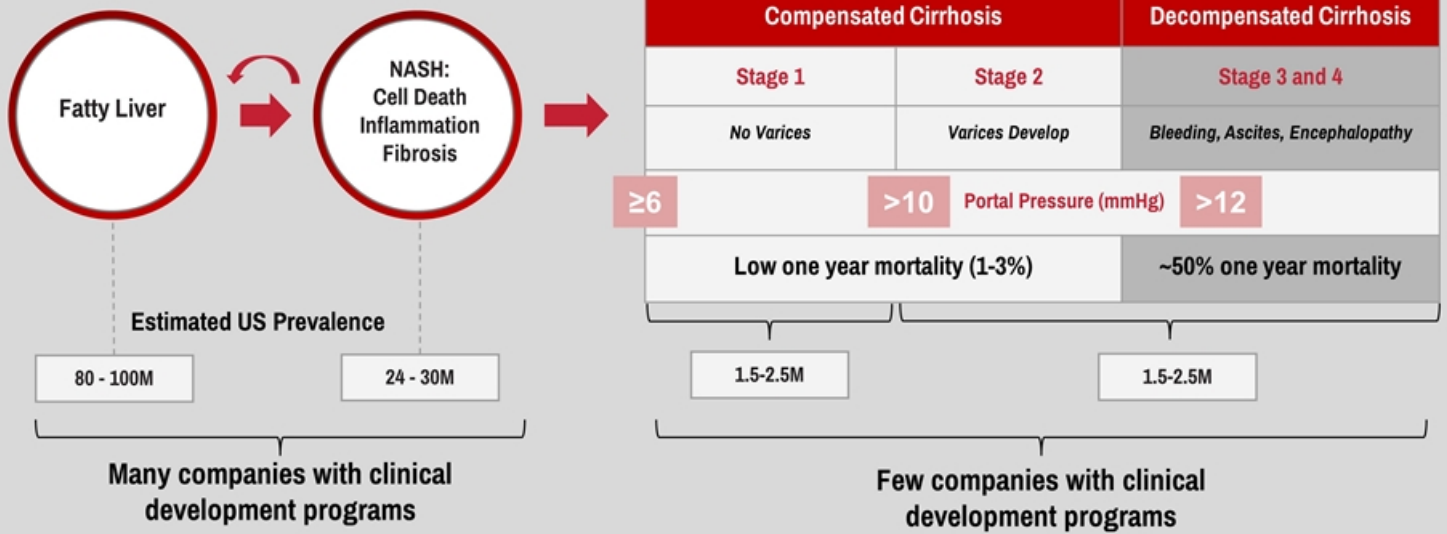
Developing Treatments Where Galectin-3 Protein is Implicated in Disease

Clinical Phase Studies with Galectin-3 Inhibitor GR-MD-02

→ Primary Program is in NASH Cirrhosis

- Positive efficacy in compensated NASH cirrhosis without varices
- o Combination Cancer Immunotherapy
 - Encouraging early clinical data in combination with KEYTRUDA with 5 of 8 objective responses (2 complete responses (CR) and 3 partial responses (PR)) in advanced melanoma
- o Psoriasis and Atopic Dermatitis
 - Clinically significant effect in small open label studies

There is no Treatment for NASH Cirrhosis



¹ Garcia-Tsao, G., Friedman, S., Iredale, J., Prinzani, M. *Hepatology*. 2010;51:1445-1449

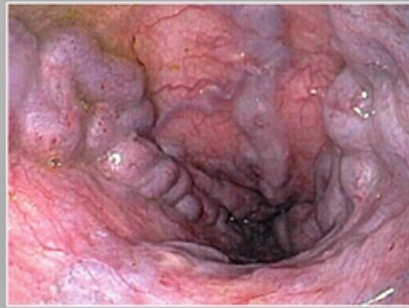
Critical Importance of Esophageal Varices in NASH Cirrhosis

An important goal of treatment of patients with Stage 1, compensated cirrhosis without esophageal varices is to prevent progression to varices and complications

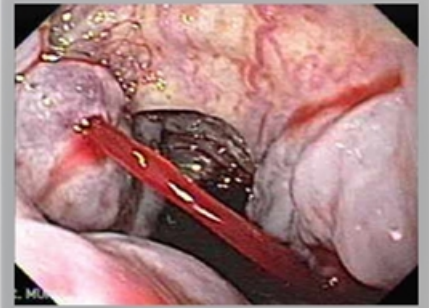
Esophagus: No Varices



Esophageal Varices



Bleeding Esophageal Varices



NASH-CX Clinical Trial Design ¹

Major Inclusion Criteria

- NASH cirrhosis (biopsy)
- HVPG² ≥ 6 mmHg
- No cirrhosis complications
- No or small varices (50:50)

Every other week infusion x 26

Treatment	#Patients
Placebo	54
GR-MD-02 2 mg/kg	54
GR-MD-02 8 mg/kg	54

		Baseline	Week 54
Primary Endpoint	Portal Pressure: HVPG ²	X	X
Secondary Endpoints	Liver Biopsy ³	X	X
	Endoscopy (varices)	X	X
	Complications ⁴	X	X

Additional trial data on website

¹ All subjects were enrolled across 36 sites in the US

² HVPG = Hepatic Venous Pressure Gradient

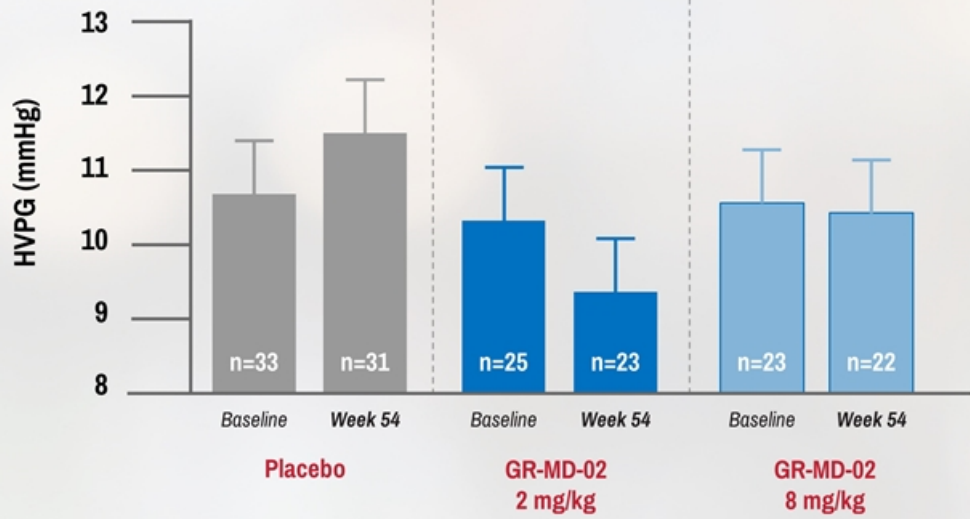
³ Histologic staging & quantitative morphometry for collagen

⁴ Liver-related complications (varices/bleeding, ascites, hepatic encephalopathy, liver-related death, or transplant)

NASH Cirrhosis Without Esophageal Varices at Baseline

Mean Change from Baseline to Week 54 ¹	0.8	-1.08 p < 0.01	0.15 ns
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Statistically significant effect of 2 mg/kg dose on change in HVPG at baseline



¹ ITT with LOCF, ANCOVA with LSD

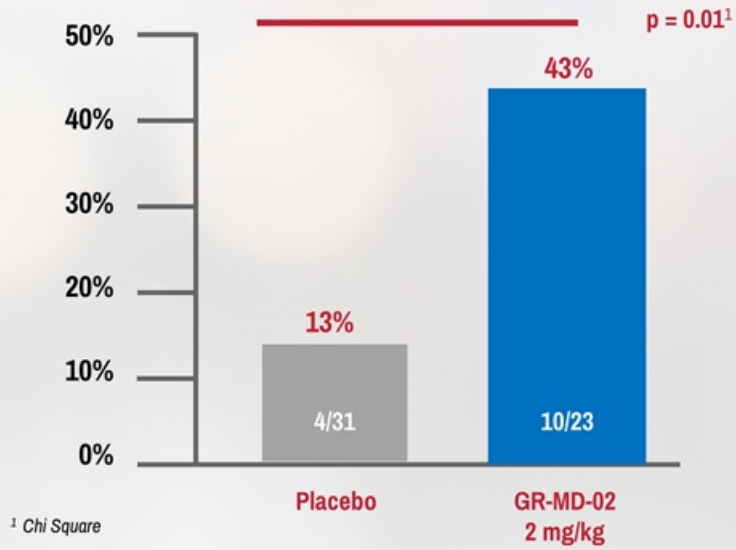
Mean ± SEM

Responder Analysis in Patients Without Varices at Baseline

Percentage of Patients Who Had a Clinically Relevant Reduction in HVPG With:

- ≥ 2 mmHg Decrease From Baseline AND
- $\geq 20\%$ Decrease From Baseline

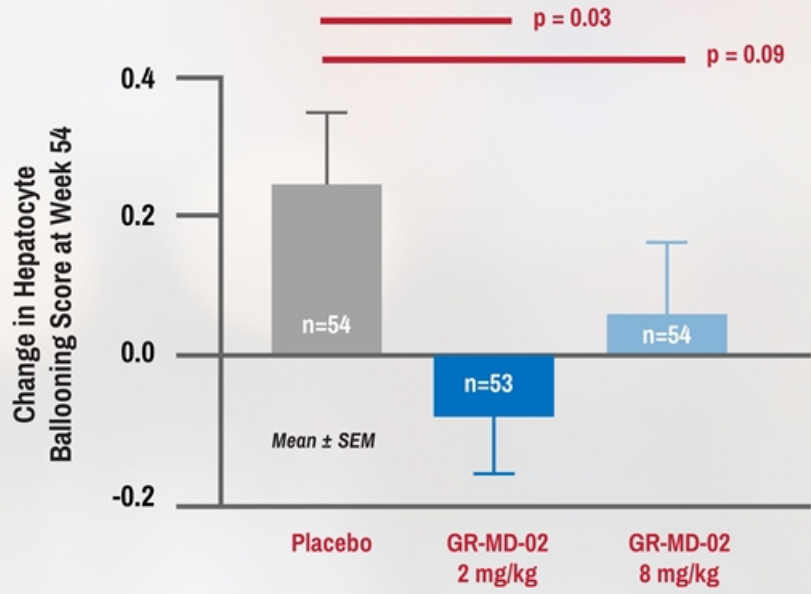
Rigorous definition of efficacy because it requires a clinically important *reduction* in HVPG from baseline



¹ Chi Square

Statistically Significant Improvement of Liver Cell Death on Liver Biopsy¹

In the total population there was improvement in cell death, a critical feature of NASH

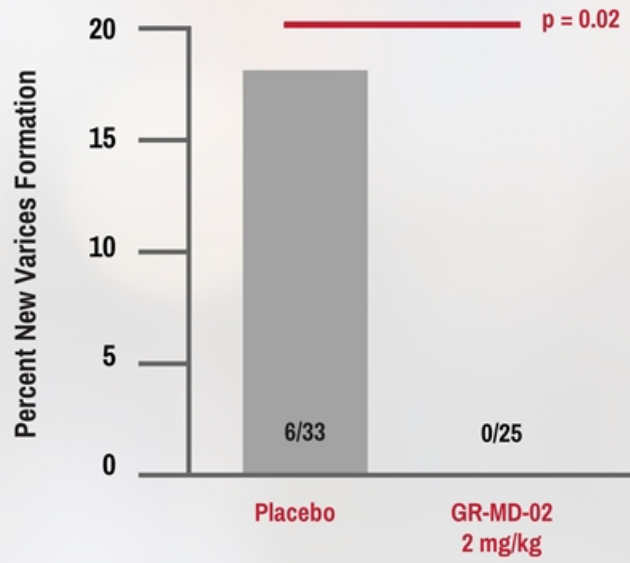


¹ITT population

Ordinal Logistic Regression Analysis

Significantly Fewer New Varices Developed in Treatment Groups Versus Placebo

Trial hit a clinically relevant endpoint related to patient outcomes



¹ Chi Square



GR-MD-02 Was Safe and Well Tolerated

- **No differences between treatment groups in the number of patients with treatment emergent adverse events (AEs), grade 3/4 AEs, serious adverse events (SAE), or grade 3/4 laboratory abnormalities**
- **All but 2 SAEs were unrelated to study drug; 2 patients in 8 mg/kg group had SAEs that were possibly related to study drug**
- **There was one death due to complications of a surgical procedure that was unrelated to study drug**
- **There was a low patient dropout rate of 6% which suggests the drug was well tolerated. Only one patient was removed from study for an AE possibly related to study drug**



Summary of GR-MD-02 in NASH Cirrhosis

NASH-CX is the first clinical trial to show positive results in compensated NASH cirrhosis without esophageal varices

- Clinically meaningful effect in reducing portal pressure
- Improvement in liver cell death, a key component of NASH
- Reduction in the development of new esophageal varices
- Drug was safe and well-tolerated

These results will propel development program to next stage

- Ongoing data analysis (pharmacokinetics of drug levels, serum biomarkers) and preparation of clinical study report
- Phase 3 clinical trial being designed to seek approval from FDA
- We believe program will be eligible for FDA “Breakthrough” designation; will be submitted when clinical study report completed
- Ongoing discussions with Pharma for potential partnerships



Developing Treatments Where Galectin-3 Protein is Implicated in Disease

Clinical Phase Studies with Galectin-3 Inhibitor GR-MD-02

- Primary Program is in NASH Cirrhosis

→ **Combination Cancer Immunotherapy**

- Encouraging early clinical data in combination with KEYTRUDA with 5 of 8 objective responses (2 complete responses and 3 partial responses) in advanced melanoma
- Psoriasis and Atopic Dermatitis
 - Small open label studies show clinically significant effect, demonstrating activity of drug in human disease

Cancer Immunotherapy

FOCUS ON IMMUNOTHERAPY

Galectin-3 secreted by cancer cells into the tumor microenvironment reduces the ability of immune system to fight cancer



MARKET OPPORTUNITY

Even with newly approved drugs, a substantial unmet medical need remains in melanoma and multiple other cancers



CRITICAL COLLABORATION ESTABLISHED

- Providence Cancer Center in Portland, Oregon
- Performed preclinical studies showing efficacy of GR-MD-02 with checkpoint inhibitors
- Conducting and funding P1b clinical trial



[Additional information on website](#)



Phase 1B Trial of GR-MD-02 Plus Pembrolizumab (KEYTRUDA) in Patients with Metastatic Melanoma and Other Cancers

GR-MD-02 used in combination with a flat dose (200 mg) of pembrolizumab in the following patients:

Metastatic melanoma with progression after other treatment including pembrolizumab alone

Recurrent or metastatic HNSCC with progression after other treatment

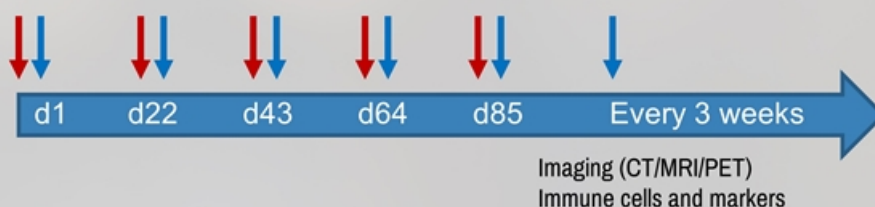
GR-MD-02

2 mg/kg (5 patients; completed)

4 mg/kg (3 patients; completed)

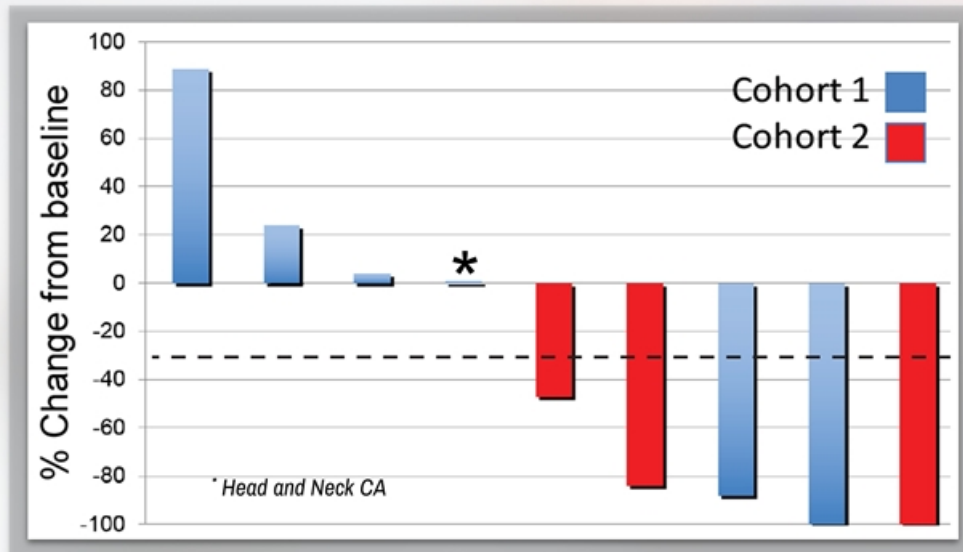
8 mg/kg (10 patients; underway)

Pembrolizumab



Clinical Results of GR-MD-02 plus Pembrolizumab (KEYTRUDA)

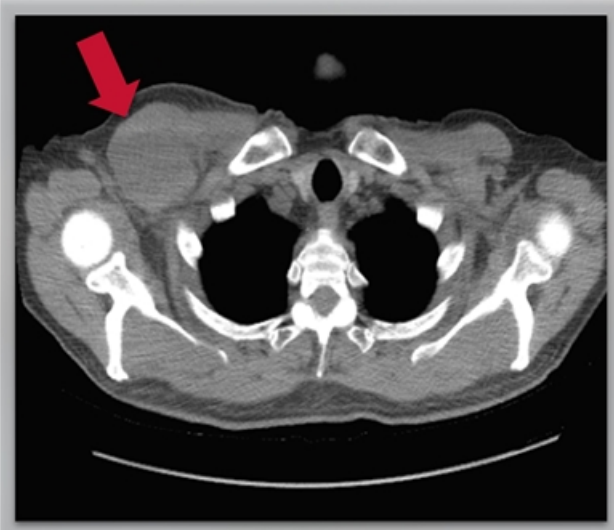
Waterfall plot of best objective clinical response post treatment (RECIST 1.1)



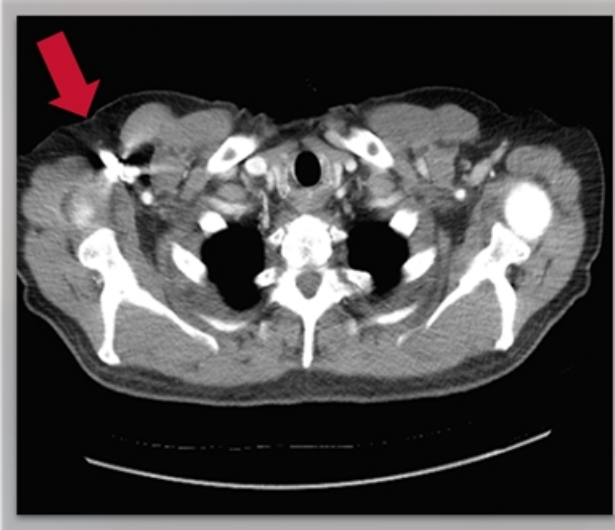
Response rate of 62.5% in melanoma compares favorably to best response of KEYTRUDA alone of 33%

CT Scan Showing Resolution of a Large Intramuscular Melanoma Deposit

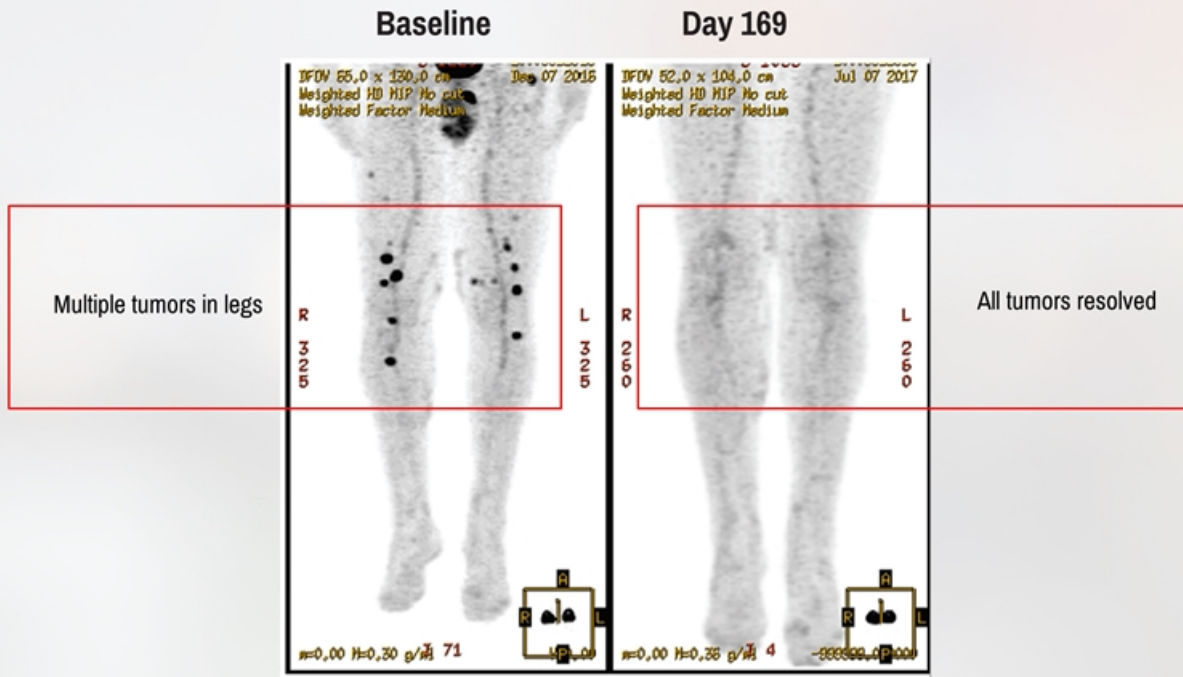
Baseline



Day 85



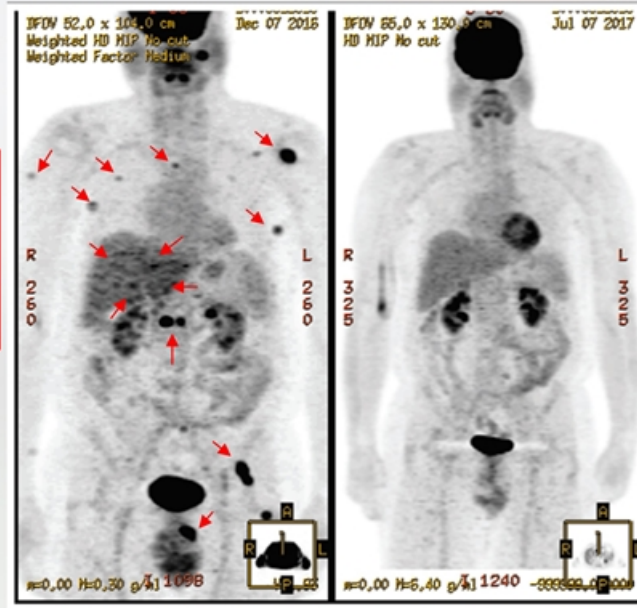
Multiple PET Scan Detected Melanoma Deposits Resolved



Multiple PET Scan Detected Melanoma Deposits Resolved

Baseline

Day 169



Multiple tumors throughout body (red arrows)

All tumors resolved: normal contrast seen in heart, kidneys and bladder



GR-MD-02 in Combination Cancer Immunotherapy

- Many combination approaches are under investigation using marketed and experimental cancer immunotherapy drugs
- As a galectin-3 inhibitor, GR-MD-02 represents a novel mechanism of action, differentiated from the many other drugs that being tested
- Potentially important advantages in combination immunotherapy
 - Enhancement of activity with multiple agents and tumors (pre-clinical)
 - Potential novel and unique markers of anti-tumor activity
 - Encouraging enhancement of tumor response in phase 1 study
 - No increase adverse events when used in combination immunotherapy
 - Cost of manufacture is relatively inexpensive compared to biologics
- Third patient cohort treated with GR-MD-02 8 mg/kg, which will enroll at least 10 additional patients, is well underway with results anticipated in mid-2018

[Additional information on website](#)

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Developing Treatments Where Galectin-3 Protein is Implicated in Disease

Clinical Phase Studies with Galectin-3 Inhibitor GR-MD-02

- Primary Program is in NASH Cirrhosis
- Combination Cancer Immunotherapy

→ Psoriasis and Atopic Dermatitis

- Small open label studies show clinically significant effect, demonstrating activity of drug in human disease

Activity of GR-MD-02: Moderate-to-Severe Plaque Psoriasis

- Psoriasis is immune-mediated chronic skin inflammation associated with NASH
- All 5 patients treated in Phase 2a open label trial showed improvement in disease activity by an average of 50% (one improved by 82%)
- Additional evidence that drug is effective in a human disease with increased galectin-3





Summary of Drug Development Program

- **GR-MD-02 is a novel antigalectin-3 drug that can modulate the immune system and may improve multiple diseases**
- **NASH Cirrhosis is a major unmet medical need with a large potential market**
 - Galectin-3 is important in development of NASH cirrhosis
 - NASH-CX trial is first and only positive phase 2 clinical data in target indication to date
 - GR-0MD-02 was safe and well-tolerated and improved portal pressure, liver biopsy, and reduced development of varices
 - GALT is competitively well positioned in the industry
- **Combination cancer immunotherapy**
 - Galectin-3 important in cancer immunity with encouraging early clinical results
 - Large opportunity to improve results of cancer immunotherapy
- **Sufficient funding for operations into early 2019**

Thank you!





GR-MD-02 for Indication of NASH Cirrhosis:

NASH-CX Clinical Trial Results

Supplemental Information to Corporate Presentation

February 6, 2018

NASDAQ: GALT

www.galectintherapeutics.com

For more information, see galectintherapeutics.com



Forward Looking Statements

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Clinical Phase Studies With Galectin-3 Inhibitor GR-MD-02

- **Primary Program is in NASH Cirrhosis (topic of this presentation)**
- **Combination Cancer Immunotherapy**
 - Investigator initiated phase 1b clinical trial of GR-MD-02 in combination with KEYTRUDA in advanced melanoma and other malignancies
 - Encouraging early data with 5 of 8 responders (2 CR and 3 PR) in advanced melanoma
- **Psoriasis and Atopic Dermatitis**
 - Small open label studies show clinically significant effect, demonstrating activity of drug in human disease

NASH Cirrhosis Development Program: Summary

- Gal-3 null mice are resistant to development of NASH¹ 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 patent protection, and is administered intravenously
- GR-MD-02 has robust efficacy in pre-clinical models of NASH and toxic cirrhosis, with action at 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*
- 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.

There is no Treatment for NASH Cirrhosis



Estimated US Prevalence

80 - 100M

24 - 30M

Many companies with clinical development programs

Compensated Cirrhosis		Decompensated Cirrhosis
Stage 1	Stage 2	Stage 3 and 4
No Varices	Varices Develop	Bleeding, Ascites, Encephalopathy

≥ 6 > 10 Portal Pressure (mmHg) > 12

Low one year mortality (1-3%)

~50% one year mortality

1.5-2.5M

1.5-2.5M

Few companies with clinical development programs

¹ Garcia-Tsao, G., Friedman, S., Iredale, J., Prinzani, M. Hepatology. 2010;51:1445-1449

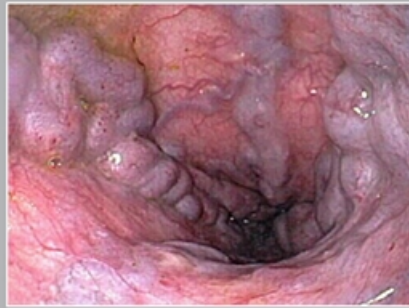
Critical Importance of Esophageal Varices in NASH Cirrhosis

An important goal of treatment of patients with Stage 1, compensated cirrhosis without esophageal varices is to prevent progression to varices and complications

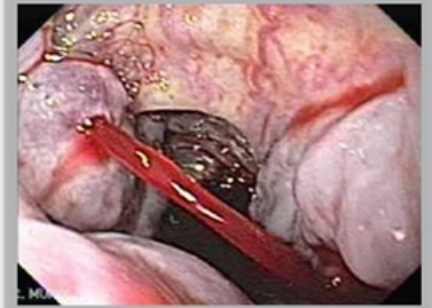
Esophagus: No Varices



Esophageal Varices



Bleeding Esophageal Varices



NASH-CX Clinical Trial Design¹

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 (Appendix 1)

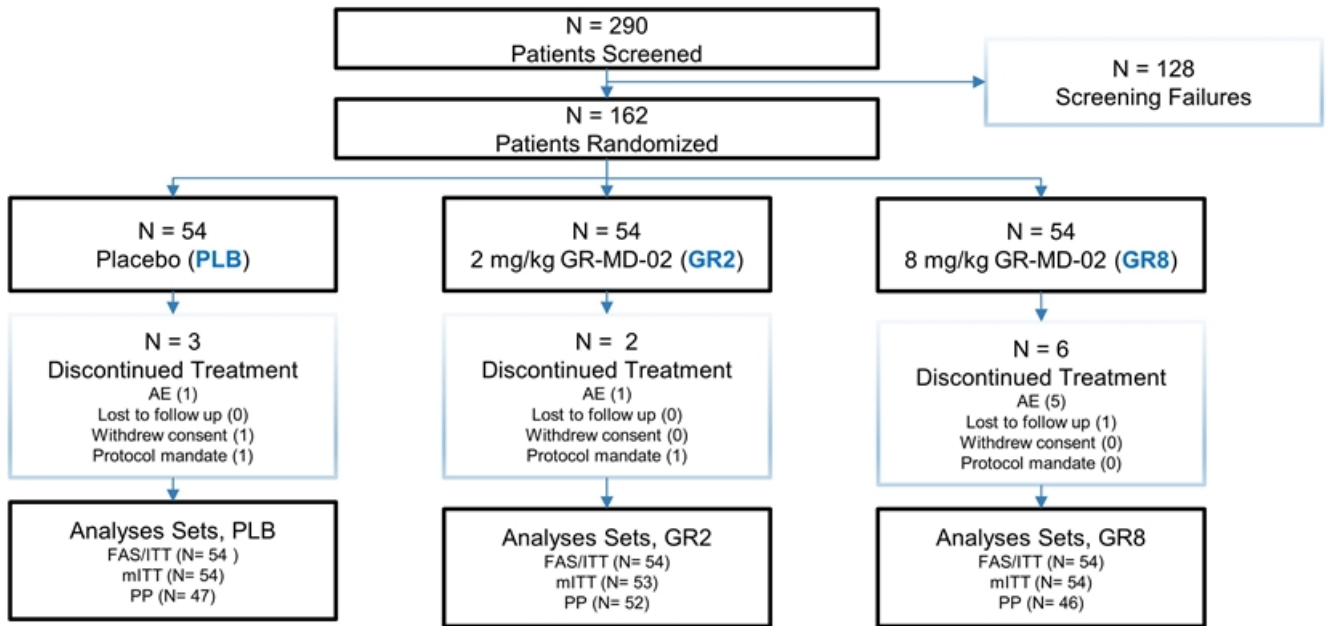
² HVPG = Hepatic Venous Pressure Gradient

³ Histologic staging & quantitative morphometry for collagen

⁴ MBT = ¹³C Methacetin Breath Test

⁵ Liver-related complications (varices/bleeding, ascites, hepatic encephalopathy, liver-related death, or transplant)

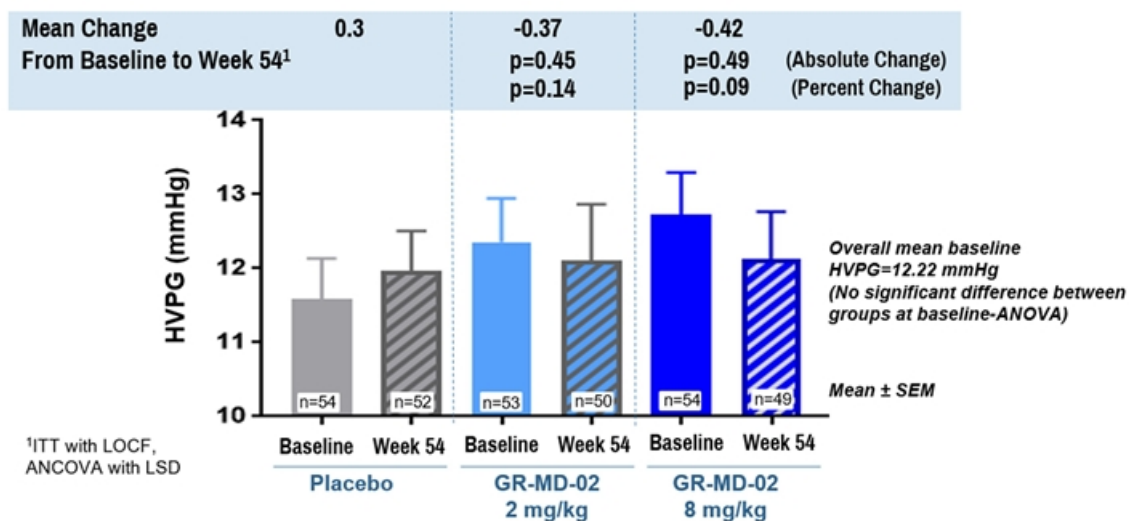
Patient Populations: Total Group



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

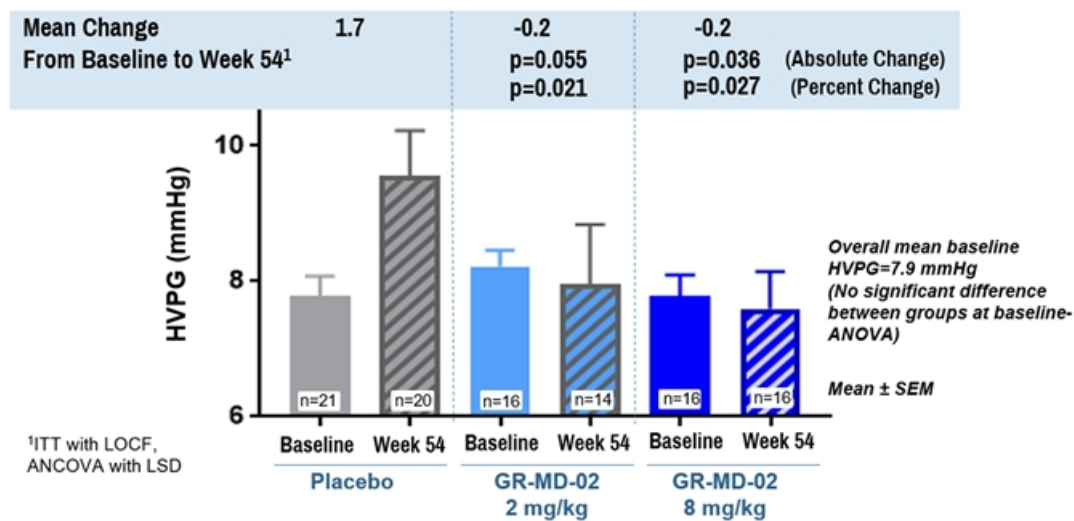
HVPG Primary Endpoint: Total Patient Population

1. HVPG increased in placebo, whereas it decreased in treatment groups by end of study
2. While there was a trend toward benefit with drug, it was not statistically significant

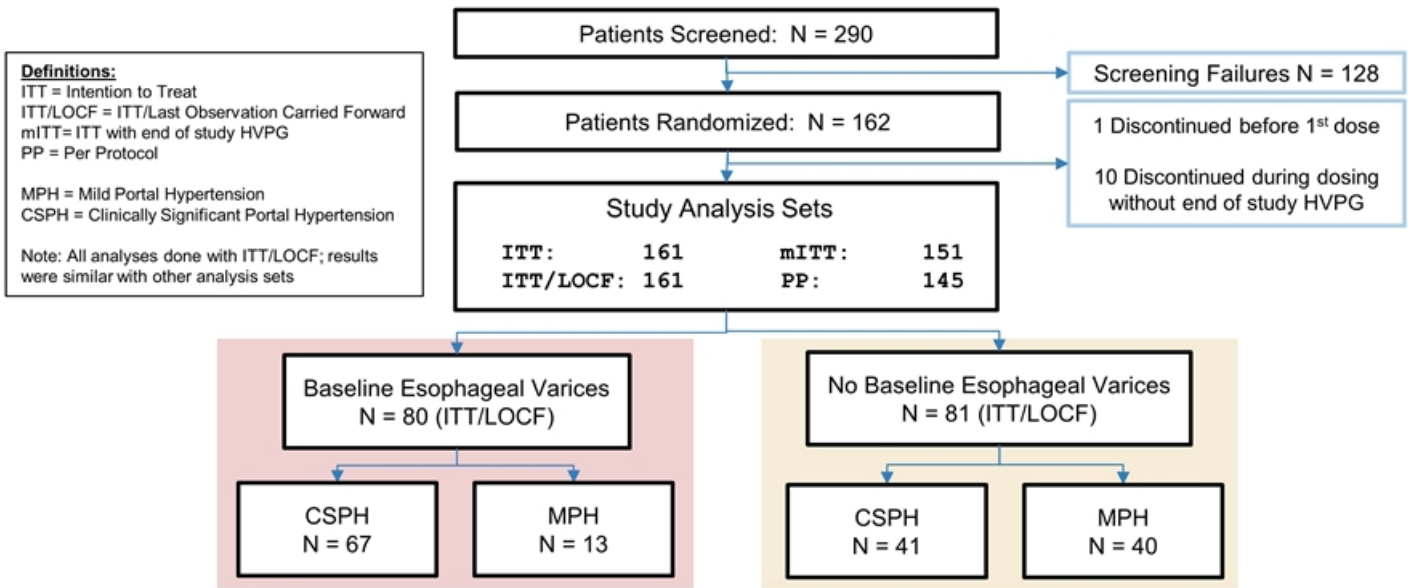


HVPG Primary Endpoint: Mild Portal Hypertension in Total Population Group

1. Evaluation of mild portal hypertension was a pre-determined statistical analysis
2. There was a statistically significant effect of both doses of GR-MD-02
3. There was no effect on those with high portal pressure (data not shown)



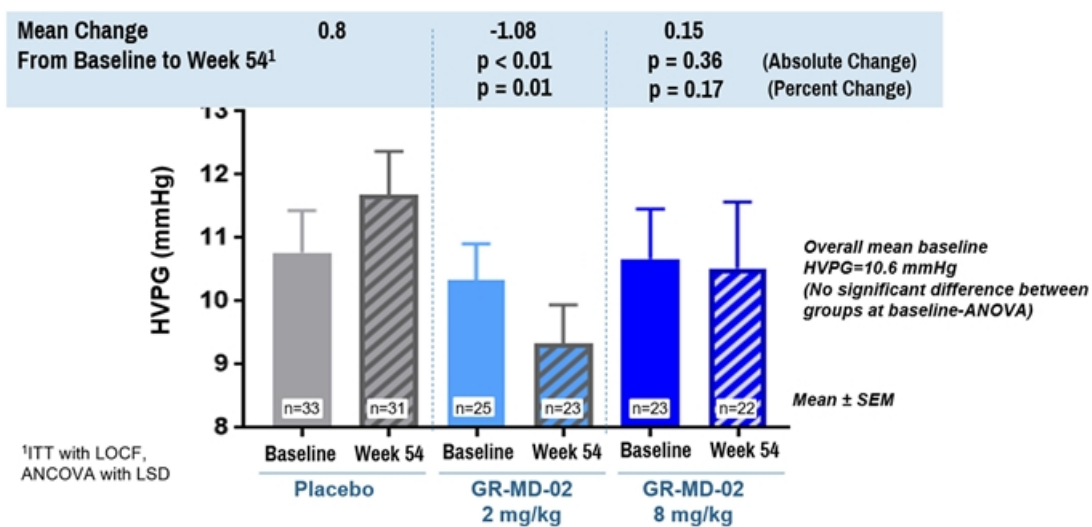
Patient Populations Based on Esophageal Varices



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

NASH Cirrhosis Without Varices at Baseline (50% of total population)

1. Drug effect was significantly dependent on dose*varices in total group ($p < 0.04$)
2. Presence or absence of esophageal varices is an important clinical finding
3. Statistically significant effect of 2 mg/kg dose on absolute and percent change in HVPG in patients without baseline esophageal varices

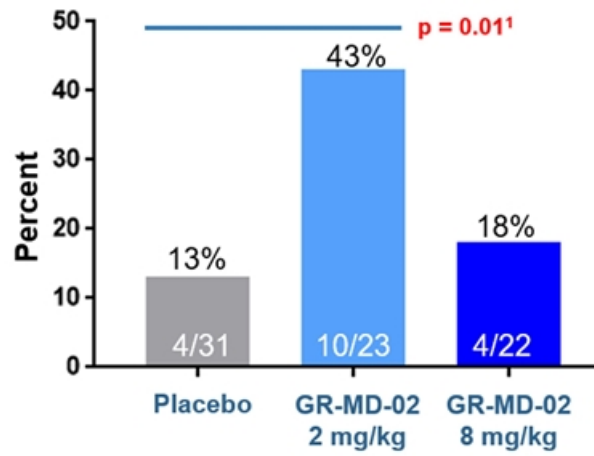


Responder Analysis in Patients Without Varices at Baseline

Percentage of Patients Who Had a Clinically Relevant Reduction in HVPG With:

- ≥ 2 mmHg Decrease From Baseline AND
- $\geq 20\%$ Decrease From Baseline

Rigorous definition of efficacy because it requires a clinically important *reduction* in HVPG from baseline

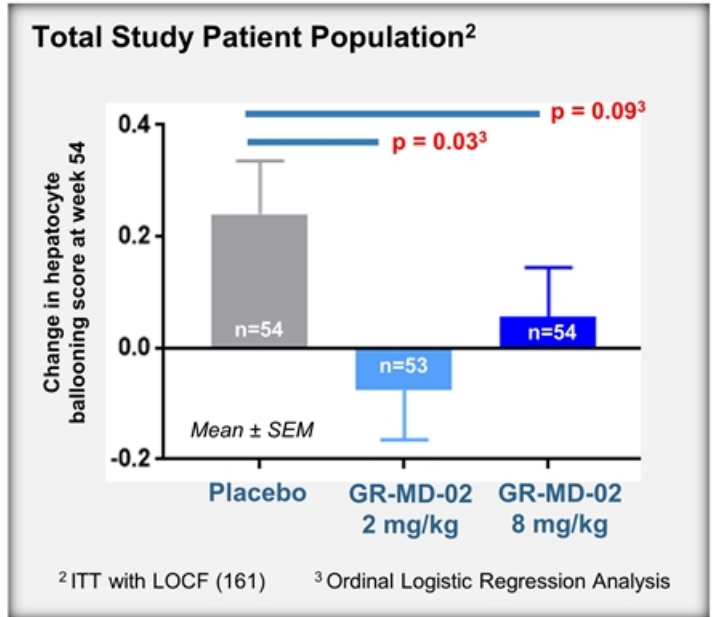


¹ Chi Square

Statistically Significant Improvement of Hepatocyte Ballooning on Liver Biopsy

- There was a statistically significant improvement in hepatocyte ballooning (liver cell death) with GR-MD-02 (2 mg/kg) and a strong trend with 8 mg/kg compared to placebo
- The reduction in ballooning hepatocytes with GR-MD-02 correlates with what was seen in NASH animal models¹
- NAFLD activity score had a trend towards improvement because of improved ballooning, but not statistically significant
- No differences in steatosis or inflammation scores
- No differences in fibrosis staging or % collagen on morphometry, but not powered for these endpoints

¹ Traber PG and Zomer E. PLOS ONE 2013;8:e83481



Cirrhosis Complications¹

In patients without varices, there were statistically significant fewer new varices that developed in treatment groups versus placebo

	Patients with at least one complication			Comments
	PLB	GR2	GR8	
Intention to Treat Group (n=161)	11 (54)	8 (53)	7 (54)	No difference between groups
No Baseline Esophageal Varices (n=81)	7 (33)	3 (25)	2 (23)	No difference between groups
New Esophageal Varices	6	0	1	p = 0.02 ² , PLB vs GR2 p = 0.12 ² , PLB vs GR8 p = 0.01 ² , PLB vs GR2 + GR8

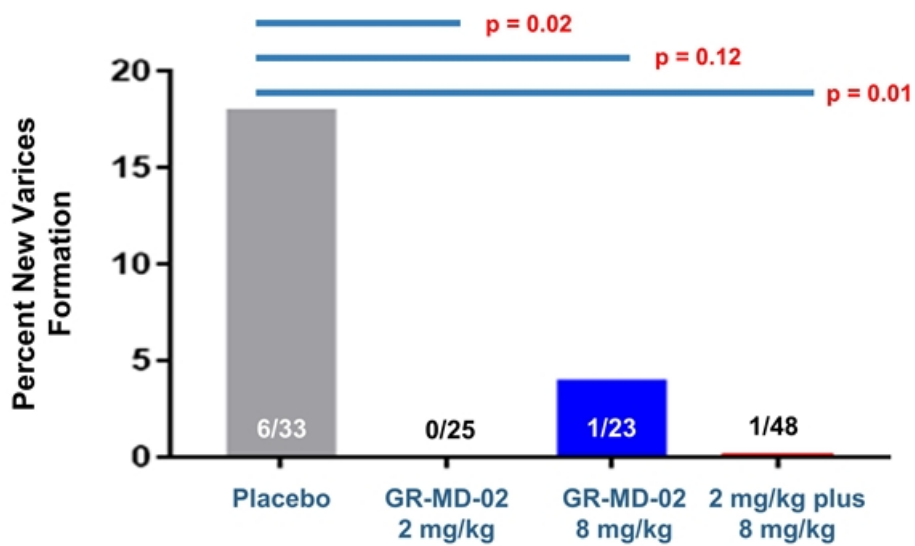
² Chi Square

¹Complications Include:

1. Development of new esophageal varices
2. Progression to medium or large varices
3. Variceal hemorrhage
4. Clinically Significant Ascites
5. Spontaneous bacterial peritonitis

6. Overt Hepatic Encephalopathy
7. Increase in CPT Score ≥ 2
8. MELT score ≥ 15
9. Liver Transplant
10. Liver related death

Significantly Fewer New Varices Developed in Treatment Groups Versus Placebo



Chi Square

Safety Results

	Total (n=162)	PLB (n=54)	GR2 (n=54)	GR8 (n=54)
All adverse events	1422	464	541	417
Grade 3-4 (patients (total events))	31 (69)	10 (19)	10 (22)	11 (28)
SAE ¹ (patients (total events))	25 (39)	9 (13)	5 (10)	11 (16)
Rx stopped due to AE	5	0	0	5 ²
Death	1	0	1 ³	0
Grade 3/4 lab (patients (total events))	8 (15)	3 (3)	2 (2)	3 (10)

¹ Two SAEs were determined by the PI to be possibly related to study drug (transient ischemic attack and worsening of hyponatremia, both GR8); All others SAEs were felt to be unrelated to study drug

² *Possibly related to drug:* spasmodic cough (1); *Unrelated to study drug:* esophageal variceal bleeding (2), sepsis (1), pancreatitis (1)

³ Pulmonary embolism following hernia repair surgery, judged to be unrelated to study drug

GR-MD-02 Was Safe and Well Tolerated

- **No differences between treatment groups in the number of patients with treatment emergent adverse events (AEs), grade 3/4 AEs, serious adverse events (SAE), or grade 3/4 laboratory abnormalities**
- **All but 2 SAEs were unrelated to study drug; 2 patients in 8 mg/kg group had SAEs that were possibly related to study drug**
- **There was one death due to complications of a surgical procedure that was unrelated to study drug**
- **There was a low patient dropout rate of 6% which suggests the drug was well tolerated. Only one patient was removed from study for an AE possibly related to study drug**

Major Conclusions from NASH-CX Clinical Trial Results

- **GR-MD-02 had a statistically significant and clinically meaningful effect in improving HVPG versus placebo in patients with NASH cirrhosis who did not have baseline esophageal varices**
- **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 new esophageal 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**

Summary Conclusions and Next Steps

NASH-CX is the first clinical trial to show positive results in compensated NASH cirrhosis without esophageal varices

- **Clinically meaningful effect in reducing portal pressure**
- **Improvement in liver cell death, a key component of NASH**
- **Reduction in the development of new esophageal varices**
- **Drug was safe and well-tolerated**

These results will propel development program to next stage

- **Ongoing data analysis (pharmacokinetics of drug levels, serum biomarkers) and preparation of clinical study report**
- **Phase 3 clinical trial being designed to seek approval from FDA**
- **We believe program will be eligible for FDA “Breakthrough” designation; will be submitted when clinical study report completed**
- **Ongoing discussions with Pharma for potential partnerships**



Appendix

NASDAQ: GALT
www.galectintherapeutics.com

For more information, see galectintherapeutics.com

Appendix 1: Deep Gratitude to Patient Volunteers and Clinical Study Sites

Indiana University School of Medicine-Dr. Chalasani
The Texas Liver Institute-Dr. Lawitz
Duke University Medical Center-Dr. Abdelmalek
Feinberg School of Medicine - Northwestern University-Dr. Rinella
Pinnacle Clinical Research, PLLC-Dr. Harrison
Digestive and Liver Disease Specialists-Dr. Ryan
Cedars Sinai Medical Center-Dr. Nouredin
Digestive Health Specialists, PA-Dr. Jue
Medical University of South Carolina-Dr. Rocky
Thomas Jefferson University-Dr. Haleboua-De Marzio
Texas Clinical Research Institute LLC-Dr. Ghalib
Virginia Commonwealth University-Dr. Sanyal
University of Mississippi Medical Center-Dr. Borg
Bon Secours Richmond Health System-Dr. Shiffman
University of Colorado Denver-Dr. Wieland
Columbia University Medical Center-Dr. Wattacheril
University of Michigan-Dr. Conjeevaram
Mcguire Veterans Affairs Medical Center-Dr. Fuchs
Baylor College of Medicine-Dr. Vierling
Piedmont Hospital-Dr. Rubin

Mary Immaculate Hospital-Dr. Shiffman
Saint Louis University-Dr. Tetri
Mercy Medical Center-Dr. Thuluvath
Swedish Medical Center-Dr. Kowdley
UH Cleveland Medical Center-Dr. Gholam
International Medical Investigations Center-Dr. Rodriguez
Intermountain Medical Center-Dr. Charlton
Tulane University Health Sciences Center-Dr. Balart
Vanderbilt University Medical Center-Dr. Scanga
Walter Reed National Military Medical Center-Dr. Torres
Tampa General Medical Group-Dr. Kemmer
University of California San Diego Medical Center-Dr. Loomba
Beth Israel Deaconess Medical Center-Dr. Lai
University Gastroenterology-Dr. Sepe
Minnesota Gastroenterology PA-Dr. Zogg
Brooke Army Medical Center-Dr. Paredes
HVPG
Yale University School of Medicine-Dr. Garcia-Tsao
Liver Biosy
Inova Fairfax Hospital-Dr. Goodman



**The Galectin-3 Inhibitor GR-MD-02 for
Combination Cancer Immunotherapy**
Supplemental Information to Corporate Presentation
February 6, 2018

NASDAQ: GALT
www.galectintherapeutics.com

For more information, see galectintherapeutics.com



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 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 2018 and beyond. 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 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, 2016, 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.

Clinical Phase Studies With Galectin-3 Inhibitor (GR-MD-02)

- **Combination Cancer Immunotherapy (topic of this presentation; supplemental information to January 7, 2018 Corporate Presentation)**
 - Investigator-initiated phase 1b clinical trial of GR-MD-02 in combination with KEYTRUDA in advanced melanoma and other malignancies
 - Encouraging early data with 5 of 8 responders (2 CR and 3 PR) in advanced melanoma
- **Primary Program is in NASH Cirrhosis**
 - First randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in portal hypertension or important aspects of liver biopsy in patients with compensated NASH cirrhosis
- **Psoriasis and atopic dermatitis**
 - Small open label studies show clinically significant effect demonstrating activity of drug in human disease

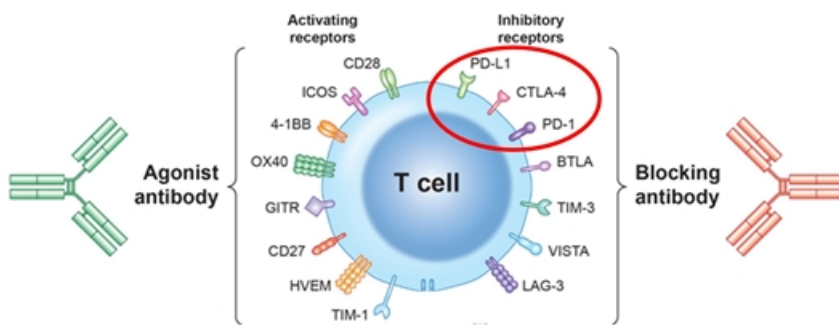
Combination Cancer Immunotherapy Development Program Summary

- The vast majority of human (& experimental animal) cancers have a large increase of galectin-3 protein
- Galectin-3 inhibits the immune system from killing cancer cells and has other effects that allows cancers to thrive and spread to other areas of the body
- GR-MD-02 is a glycopolymer (polysaccharide), considered a Nonbiological Complex Drug (NBCD) that binds to galectin-3 protein, has strong patent protection, and is administered intravenously
- GR-MD-02 has robust efficacy in pre-clinical cancer models when used with immunotherapy agents
- GR-MD-02 is well tolerated and safe in preclinical toxicology and clinical trials (2 P1, P2a and P2b), including when used in combination with the immunotherapy pembrolizumab (KEYTRUDA)
- Investigator-initiated phase 1b clinical trials of GR-MD-02 in combination with KEYTRUDA (and Yervoy) in advanced melanoma and other malignancies
- **Encouraging early data in KEYTRUDA trial with 5 of 8 responders (2 Complete responders (CR) and 3 Partial responders (PR)) in advanced melanoma**

Critical Collaboration with Providence Cancer Center

- **The Earle A. Chiles Research Institute at Providence Portland Medical Center**
 - Established 1993 by Dr. Walter Urba, MD, PhD
 - Internationally recognized team of scientists and clinicians with focus on cancer immunotherapy
- **William L. Redmond, PhD**
 - Associate Member and Director of Immune Monitoring Laboratory
 - Research focused on mechanisms regulating the efficacy of combination immunotherapy and reversing tumor-induced immune suppression
 - Conducted pre-clinical work with GR-MD-02
- **Brendan D. Curti, MD**
 - Director of Biotherapy Clinical Program
 - Principal Investigator of GR-MD-02 immunotherapy clinical trials

T Cell-Modulating Antibodies For Cancer Immunotherapy

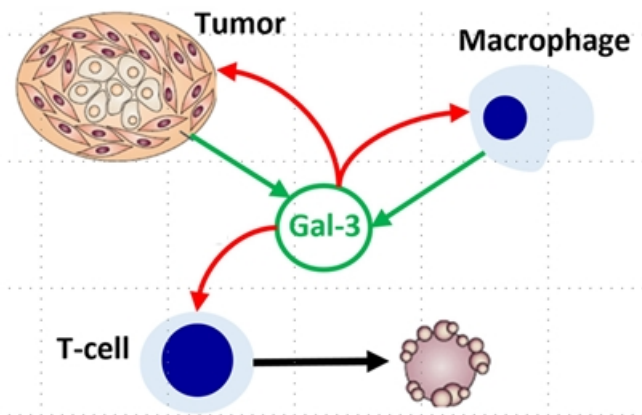


Multiple therapies have been developed, or are in development, that stimulate the immune system to treat cancer

Recent effective classes of immunotherapies are those that stimulate T cells by blocking inhibitory inputs (blocking antibodies or checkpoint inhibitors) or stimulate T cells (agonist antibodies)

Marketed drugs (red circle)

- Anti-CTLA-4 (ipilimumab; Yervoy)
- Anti-PD1 (pembrolizumab; KEYTRUDA)
- Anti-PD-L1 (nivolumab; Opdivo)

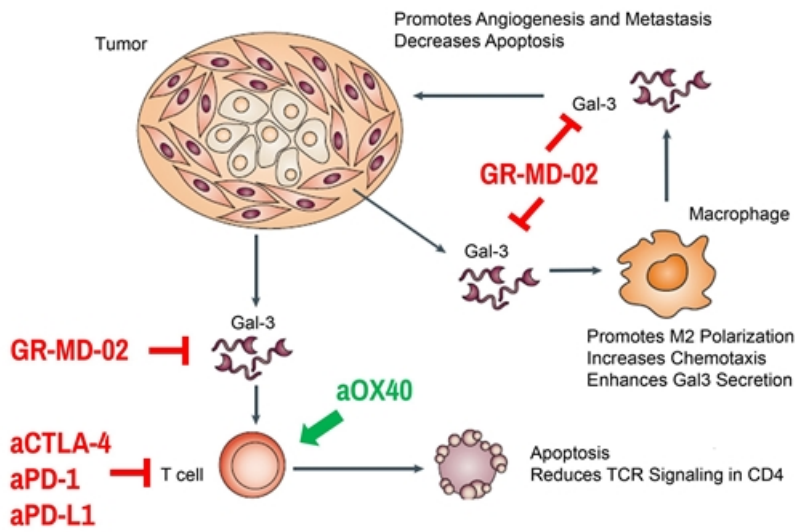


Gal-3 effects on cancer cells, macrophages and T-cells in the tumor microenvironment

- **Gal-3 is produced by both tumor cells and macrophages and has multiple effects, including**
 - Reducing T cell receptor signaling thereby blocking immune effects on tumor cells
 - Promoting T-cell apoptosis (cell death)
 - Promoting angiogenesis and metastasis of cancer cells
 - Promoting macrophage M2 polarization, increasing chemotaxis to recruit more macrophages, and enhancing gal-3 secretion

Rabinovich G, *Nat Rev Immunol*, 2009

The Galectin-3 Inhibitor GR-MD-02 Appears to Augment Anti-Tumor Activity of Cancer Immunotherapies



A galectin-3 inhibitor such as GR-MD-02 theoretically would have synergistic effects with other immunotherapies

Pre-clinical studies have shown positive effects on multiple tumors when GR-MD-02 was combined with:

Checkpoint inhibitors:

- Anti-CTLA-4 (ipilimumab; Yervoy)
- Anti-PD1 (pembrolizumab; KEYTRUDA)
- Anti-PD-L1 (nivolumab; Opdivo)

T-cell agonists

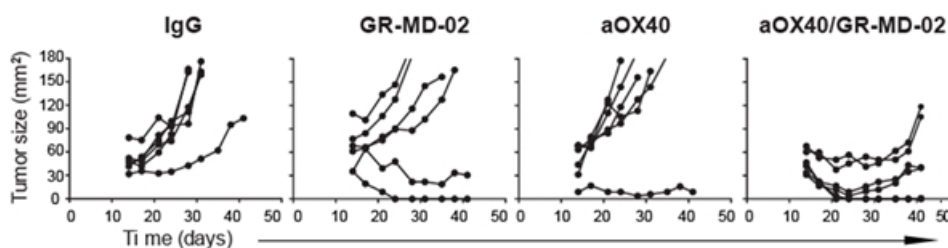
- Anti-OX40 (in development)

Pre-Clinical Summary: GR-MD-02 in combination with other immunotherapies, vaccines, and radiation therapy enhances efficacy in multiple tumor models

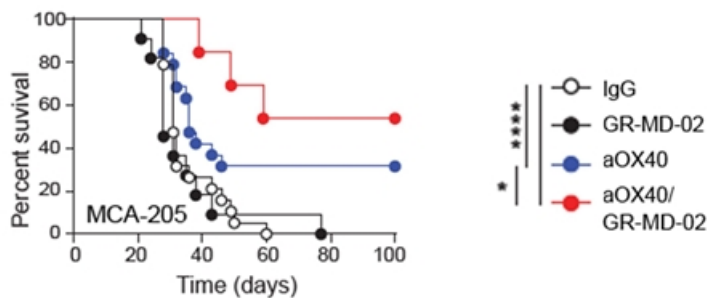
- **GR-MD-02 boosts frequency and persistence of antigen-specific T cells in non-tumor bearing mice alone and in combination with anti-CTLA-4**
- **GR-MD-02 in combination with anti-CTLA-4, anti-PD-L1, or anti-PD-1 reduces tumor size and enhances survival in multiple tumor models (melanoma, prostate, breast, sarcoma)**
- **GR-MD-02 in combination with the anti-OX40 immunotherapy agonist**
 - Improves survival and reduces lung metastases (4T1 breast cancer model)
 - Improves survival in the MCA-205 sarcoma model in a CD8 T cell-dependent manner
 - Reduces the frequency of suppressive cells (MDSC) in the tumor microenvironment
 - Reduces vascular endothelial frequency within the tumor
- **GR-MD-02 plus Lm-Her2 tumor vaccine augments expansion of tumor-specific CD8 T cells, increases tumor regression, and boosts tumor-free survival**
- **GR-MD-02 in combination with radiation therapy increases tumor regression and boosts tumor-free survival**

Preclinical Data Example: GR-MD-02 plus anti-OX40 antibody reduces tumor growth and prolongs survival in MCA-205 sarcoma in mice

The combination of GR-MD-02 with anti-OX40 markedly enhances effect on tumor growth of either agent alone



The combination of GR-MD-02 with anti-OX40 statistically significantly enhances survival over either agent alone



Phase 1b Clinical Trials Conducted by Providence Cancer Center

- **Galectin Inhibitor (GR-MD-02) plus Ipilimumab (Yervoy) in Patients With Metastatic Melanoma**

Trial initiated in 2015, enrolled 7 subjects with GR-MD-02 doses of 1 and 2 mg/kg

There were no adverse events identified due to GR-MD-02

No notable changes in the peripheral immune signature

Trial stopped due to changes in the standard of care for melanoma (Keytruda was approved and replaced the use of Yervoy in many patients)

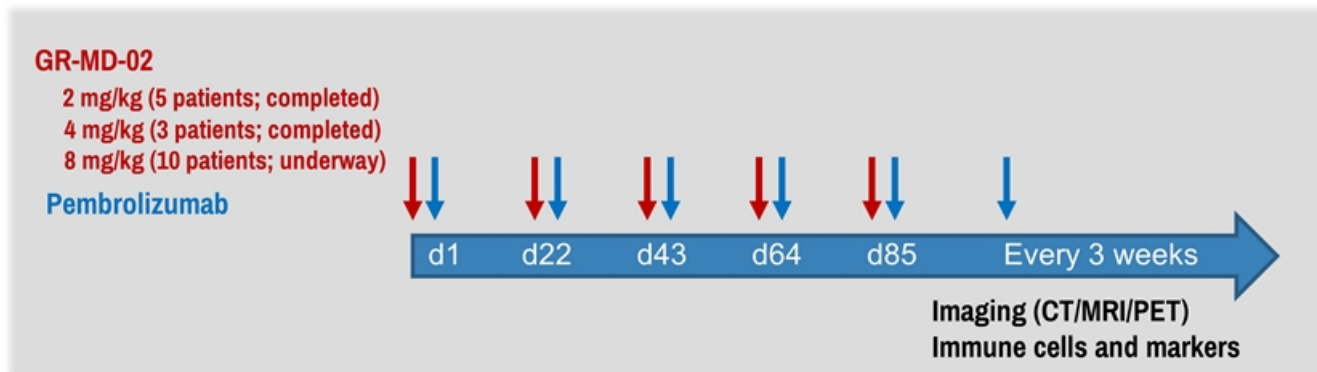
- **GR-MD-02 Plus Pembrolizumab (KEYTRUDA) in Patients with Metastatic Melanoma and Other Cancers (oral head & neck, non small cell lung cancer)--ONGOING**

GR-MD-02 Plus Pembrolizumab (KEYTRUDA)

GR-MD-02 used in combination with a flat dose (200 mg) of pembrolizumab in the following patients:

Metastatic melanoma with progression after other treatment including pembrolizumab alone

Recurrent or metastatic HNSCC with progression after other treatment



<https://clinicaltrials.gov/ct2/show/NCT02575404?term=gr-md-02&rank=2>

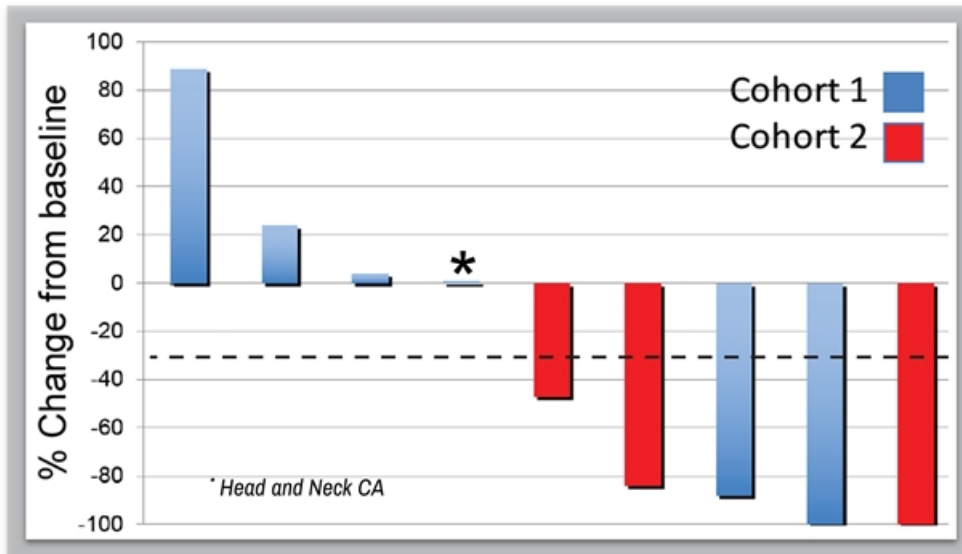
Pembrolizumab plus GR-MD-02 Patients: Cohorts 1 and 2

Cohort	Diagnosis	Gender	Age	Disease Sites	Prior Treatments	Response
1	Melanoma	Male	76	Subcutaneous (SQ), lung	Surgery/IL-2/RT/oncolytic virus/Yervoy	PR
1	Melanoma	Female	63	SQ, muscle, lymph node (LN)	Interferon/Yervoy	SD→PD
1	Melanoma	Female	82	SQ, bone, LN	Surgery, Radiation	PD
1	Melanoma	Male	62	Brain/bone/lung/SQ/LN/liver	IL-2, Yervoy, Opdivo	SD→PD
1	Melanoma	Male	65	SQ, LN, lung	Vemurafenib, Dabrafenib + Trametinib	CR
1	H & N Cancer	Male	55	LN	Surgery	SD→PD
2	Melanoma	Female	70	LN, lung	Surgery, IL-2, Radiation	PR
2	Melanoma	Male	83	Lung, pleura	Surgery	CR
2	Melanoma	Male	37	LN	Surgery	PR

SD=stable disease; PD=progressive disease; PR=partial response; CR=complete response

Clinical Results of GR-MD-02 plus Pembrolizumab (KEYTRUDA)

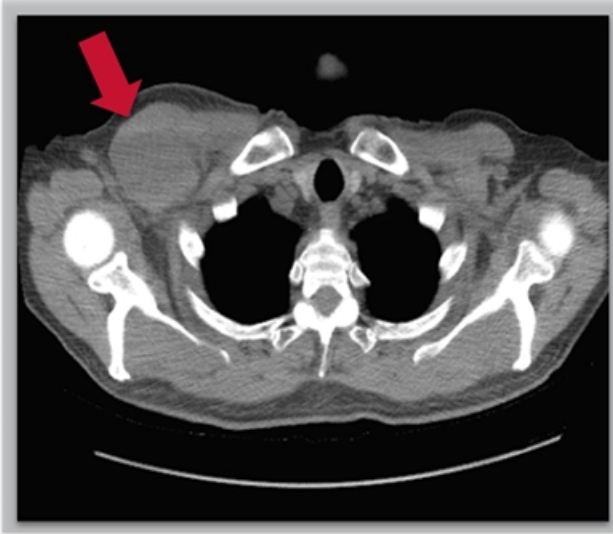
Waterfall plot of best objective clinical response post treatment (RECIST 1.1)



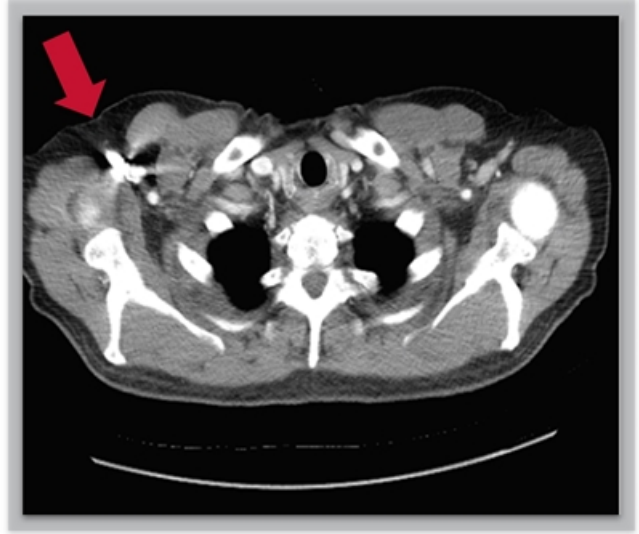
Response rate of 62.5% in melanoma compares favorably to best response of KEYTRUDA alone of 33%

CT Scan Showing Resolution of a Large Intramuscular Melanoma Deposit

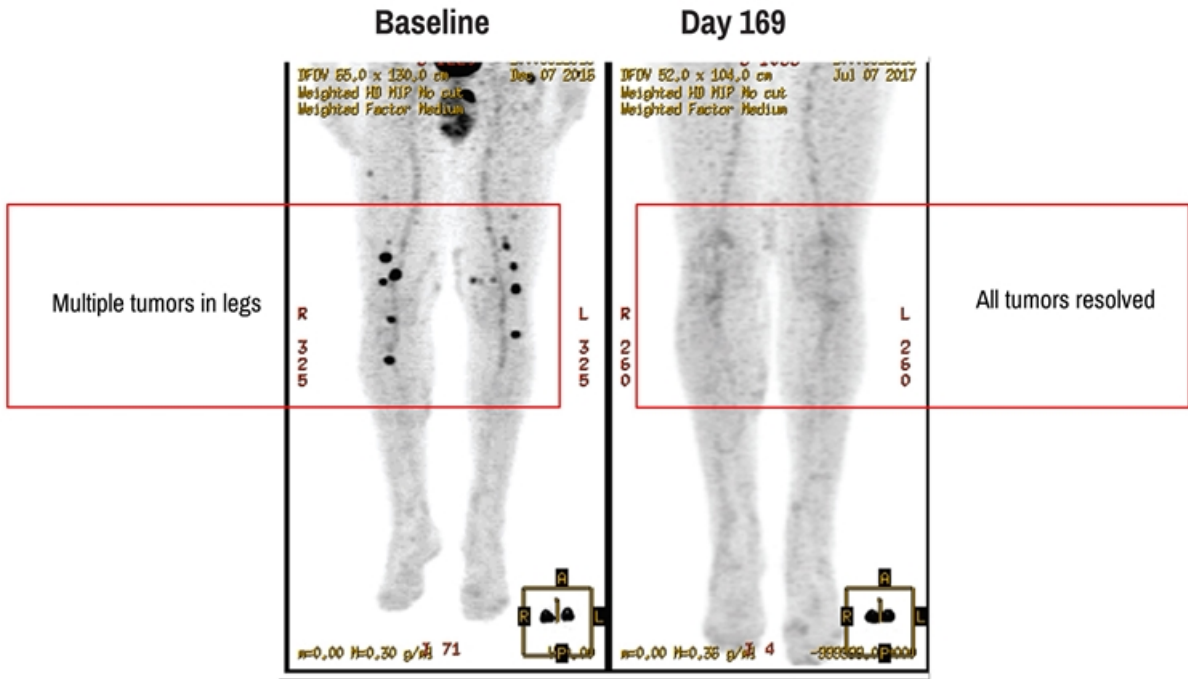
Baseline



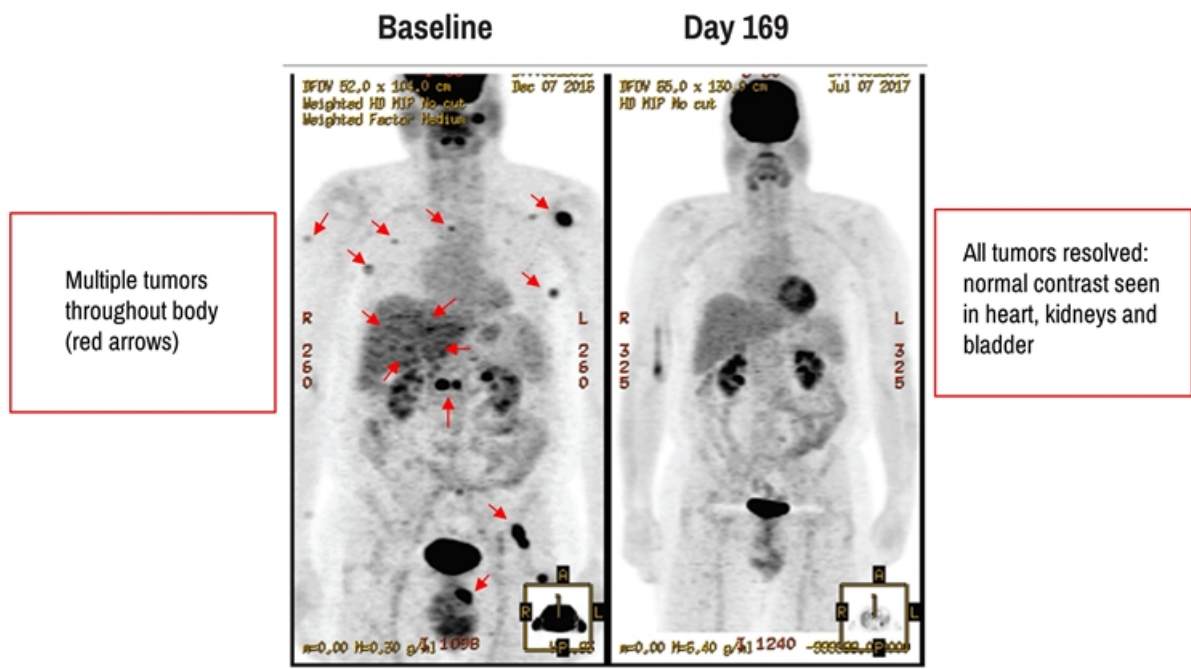
Day 85



Multiple PET Scan-Detected Melanoma Deposits Resolved



Multiple PET Scan-Detected Melanoma Deposits Resolved

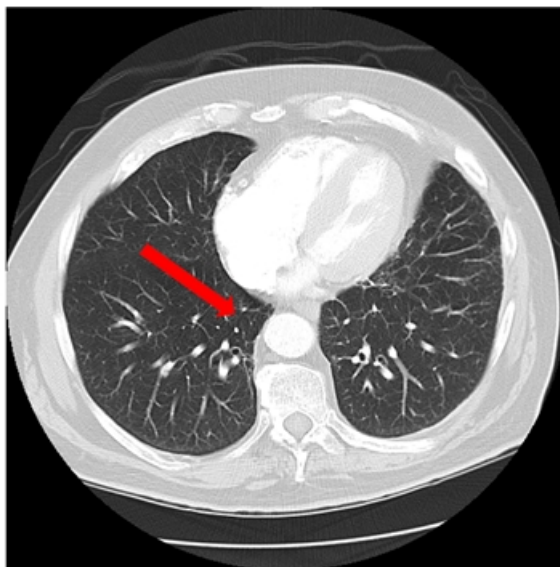


CT Scan Showing Resolution of a Lung Melanoma Deposit

Baseline



Day 85



18

Extensive Laboratory Analysis of Immune Cells and Immune Molecules

- The immune monitoring laboratory at EACRI (Earle A. Chiles Research Institute) performs analysis of multiple type of immune cells and immune molecules in the blood and tumors of patients before, during, and after therapy
- This analysis suggests that responders to therapy appear to have higher baseline levels of activated T lymphocytes which may provide better targeting of patients likely to respond
- Measurement of Monocyte Derived Suppressor Cells (MDSC) suggests that these are decreased by combination therapy in patients who respond to therapy. This is an important and novel observation since MDSC cells impair the response of the immune system to tumors.
- The extensive immune monitoring of patients in this trial will help elucidate the mechanism of action of GR-MD-02 in combination with pembrolizumab and help to identify the patients who will most benefit from combination therapy

Addition of GR-MD-02 to Pembrolizumab Appears Safe and Well Tolerated

- **Pembrolizumab has significant toxicities and adverse effects on patients**
- **In the patients treated thus far with the combination of GR-MD-02 and pembrolizumab, the Principal Investigator has documented that there have been no additional adverse events or toxicities attributed to GR-MD-02 over those that would be anticipated with pembrolizumab**
- **If this observation holds up in further patients, this would be a potential advantage of GR-MD-02 as a combination agent because most combination therapies with pembrolizumab that are currently used or being studied add significantly to the toxicity of the therapy**

Summary: GR-MD-02 for Combination Cancer Immunotherapy

- **Many combination approaches are under investigation using marketed and experimental cancer immunotherapy drugs**
- **As a galectin-3 inhibitor, GR-MD-02 represents a novel mechanism of action, differentiated from the many other drugs that are currently being tested**
- **As a combination agent, GR-MD-02 has a number of potential advantages**
 - Broad enhancement of anti tumor activity in pre-clinical studies with checkpoint inhibitors (e.g. anti PD-1/PD-L1), immuno-stimulatory agonists (e.g. aOX40), cancer vaccines, and radiation therapy
 - Potential novel and unique markers of anti-cancer activity
 - GR-MD-02 is safe and well tolerated and does not appear to increase adverse events when used in combination immunotherapy with pembrolizumab
 - Cost of manufacture is relatively inexpensive when compared to biologics
- **The third patient cohort treated with GR-MD-02 8 mg/kg, which will enroll at least 10 additional patients, is well underway with results anticipated in mid-2018**