Galectin Therapeutics

# Corporate Update

**April 9, 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

**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

**Jack W. Callicut,** CFO

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

**Eli Zomer, PhD,** Pharm Development

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

**Adam Allgood,** Pharm D., Clinical Development

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

**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 in NASH Cirrhosis**

- Positive efficacy in compensated NASH cirrhosis without varices

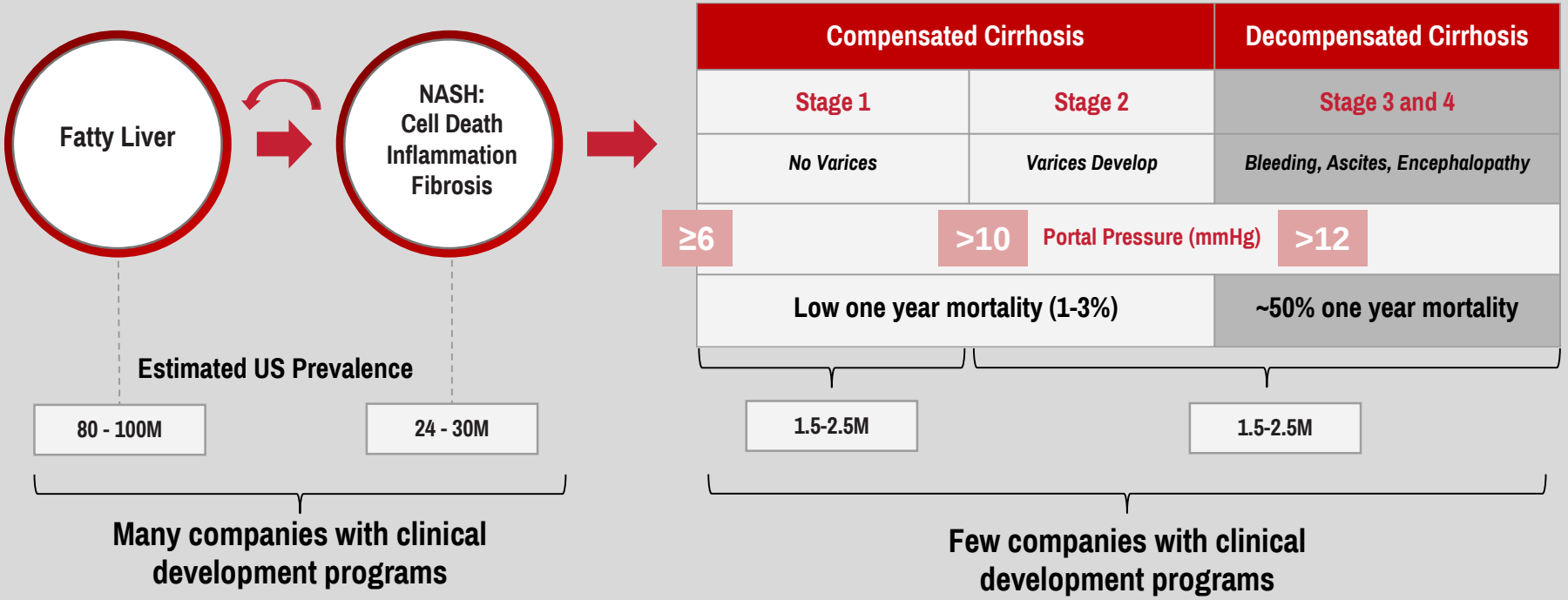
◦ Combination Cancer Immunotherapy

- 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

◦ Psoriasis and Atopic Dermatitis

- Clinically significant effect in small open label studies

# There is no Treatment for NASH Cirrhosis

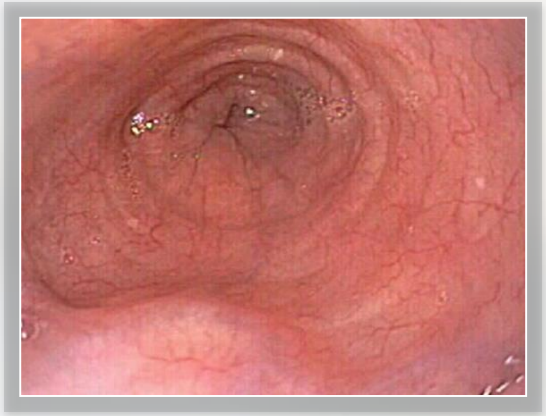



[1] *Garcia-Tsao, G., Friedman, S., Iredale, J., Prinzani, M. Hepatology. 2010;51:14451449*

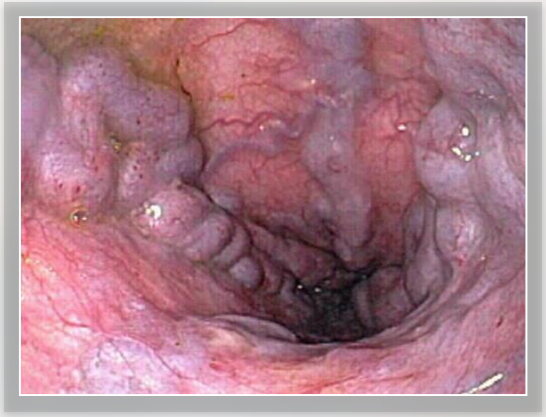
# Critical Importance of Esophageal Varices in NASH Cirrhosis

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

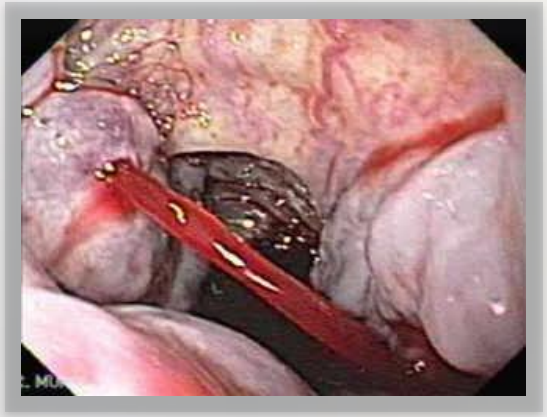
## Esophagus: No Varices



## Esophageal Varices



## Bleeding Esophageal Varices



# NASH-CX Clinical Trial Design [1]

## *Major Inclusion Criteria*

- NASH cirrhosis (biopsy)
- HVPG[2] ≥ 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 |

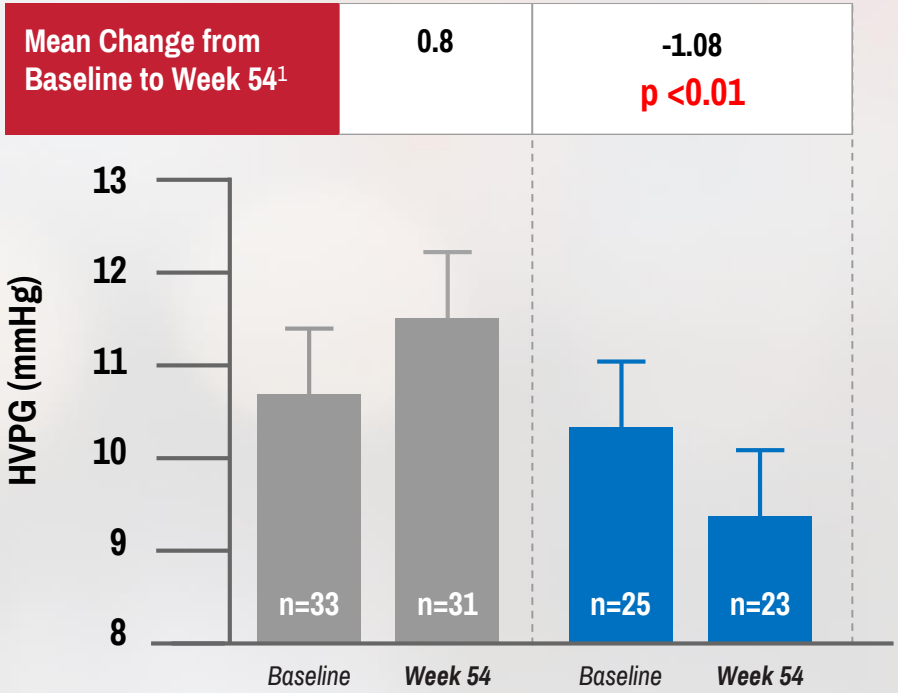
| | | Baseline | Week 54 |
|---|---|---|---|
| Primary Endpoint | Portal Pressure: HVPG[2] | X | X |
| Secondary Endpoints | Liver Biopsy[3] | X | X |
| | Endoscopy (varices) | X | X |
| | Complications[4] | X | X |

**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

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



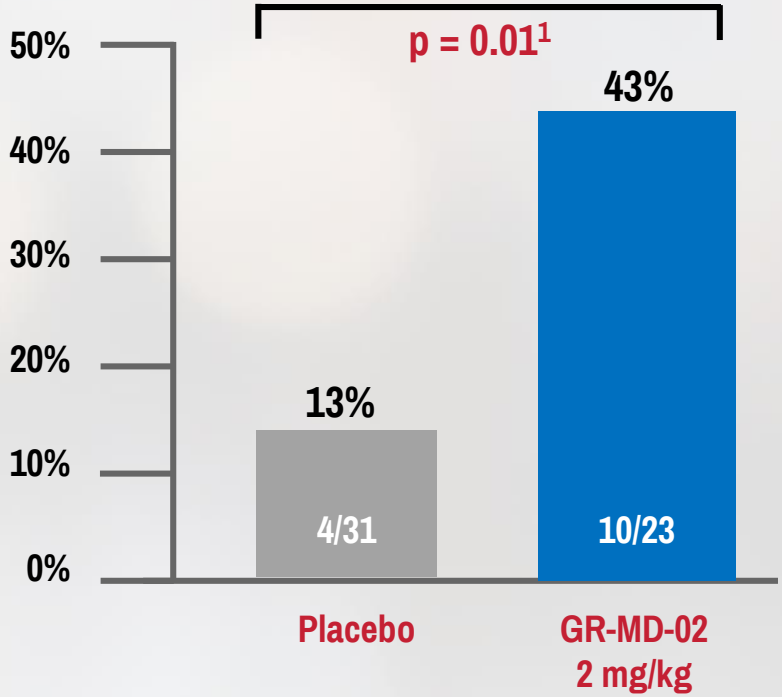

[1] ITT with LOCF, ANCOVA with LSD

***Mean ± SEM***

# Patients Without Varices had Clinically Relevant Drug Response

**Percentage of Patients Who Had a Clinically Relevant Reduction in HVPG With:**
- **≥ 2 mmHg Decrease From Baseline AND**
- **≥ 20% Decrease From Baseline**

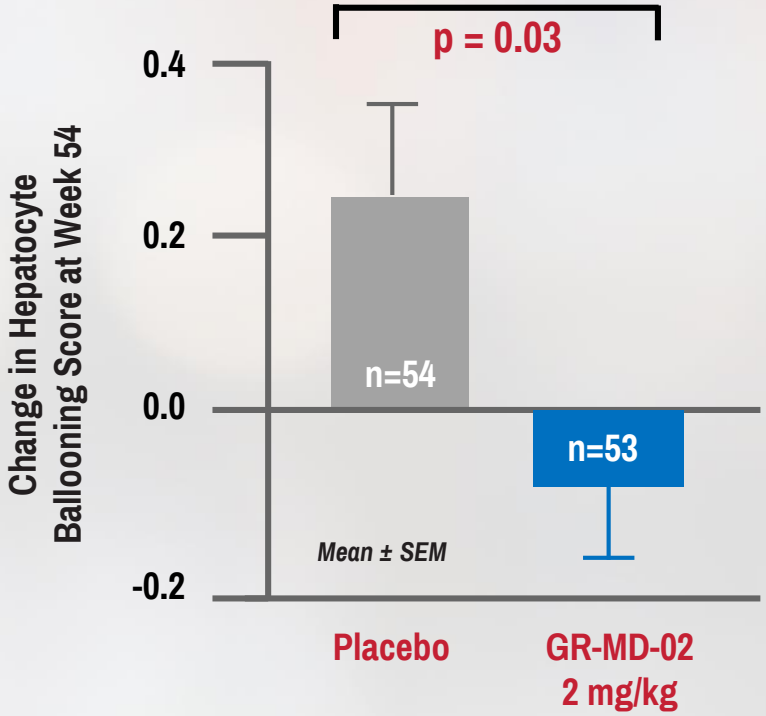
**Rigorous definition of efficacy because it requires a clinically important *reduction* in HVPG from baseline**




[1] *Chi Square*

# Statistically Significant Improvement of Liver Cell Death on Liver Biopsy[1]

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

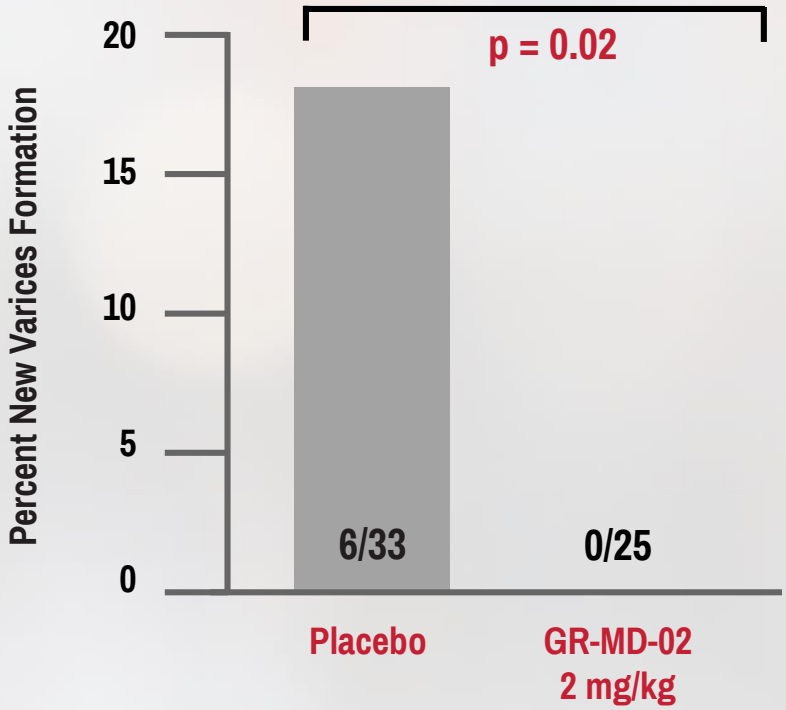



[1] ITT population

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 safety issues detected related to study drug**

**Low patient dropout rate of 6% which suggests the drug was well tolerated.**

# 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**

# Next Stages in NASH Cirrhosis Development Program

## FDA Meeting in May 2018 (materials submitted)

- Present results of NASH-CX clinical trial
- Seek agreement on phase 3 clinical trial plans

## FDA “Breakthrough Designation” application submitted

## Presentation at International Liver Meeting (Paris, April 2018)

- Oral presentation at late breaker session

## 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 eliminate cancer cells

**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**

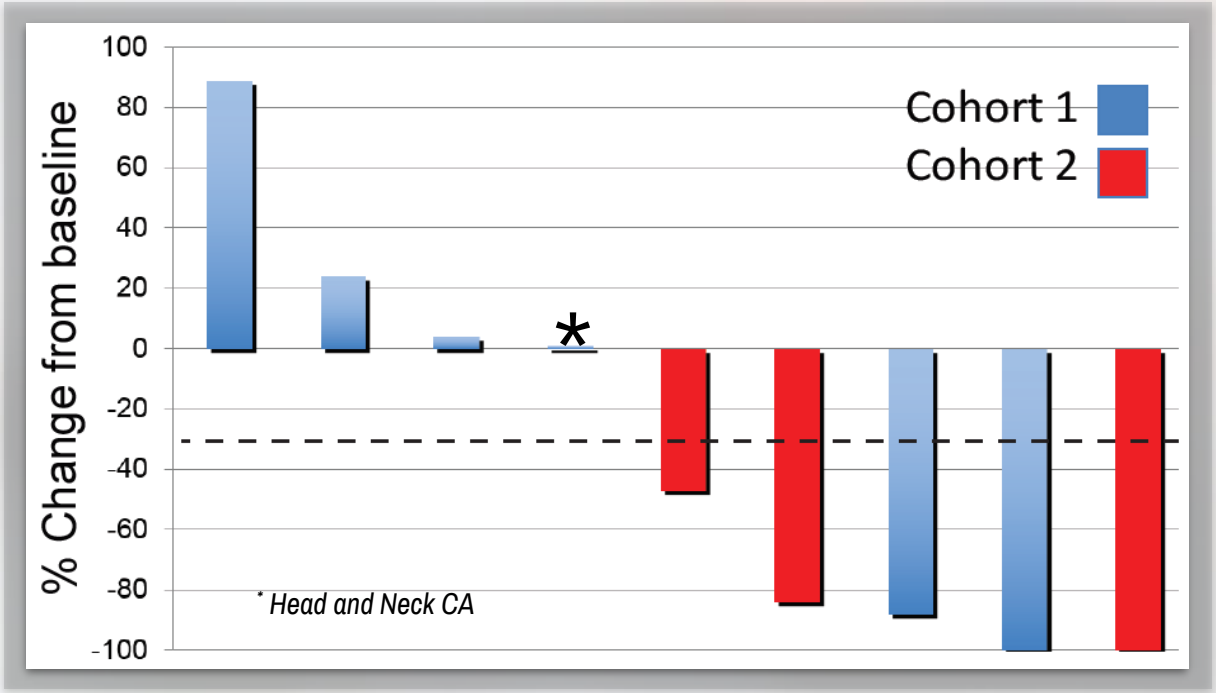
# Phase 1B Trial of GR-MD-02 Plus Pembrolizumab (KEYTRUDA) in Patients with Metastatic Melanoma and Other Cancers

**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**

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

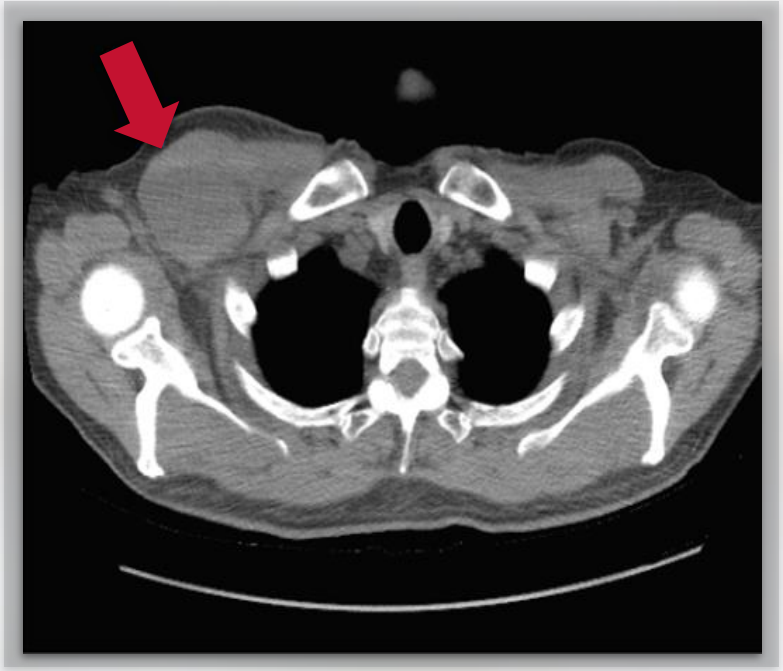
Waterfall plot of best objective clinical response post treatment (RECIST 1.1)



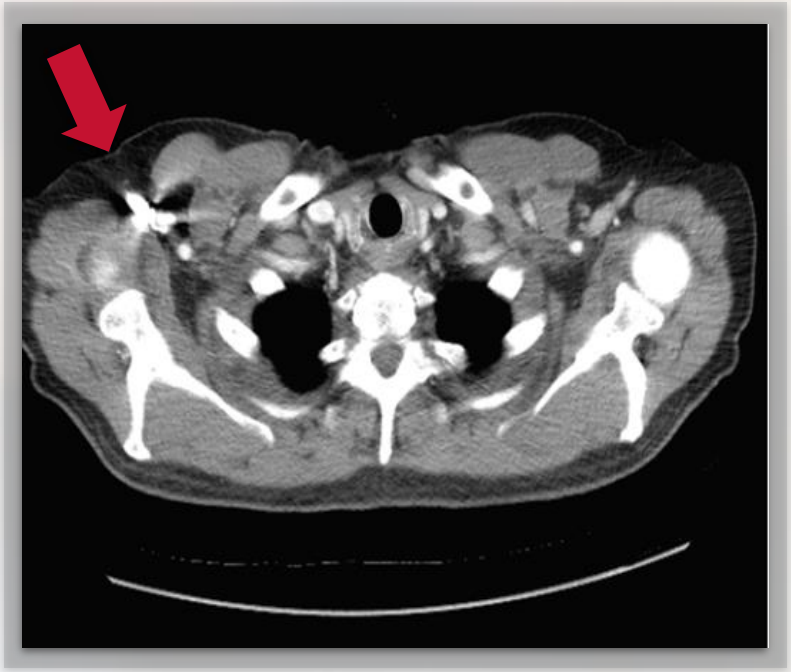

**Response rate of 62.5% in melanoma compares favorably to best response of KEYTRUDA alone of 33%**

# CT Scan Showing Resolution of a Large Intramuscular Melanoma Deposit

**Baseline**



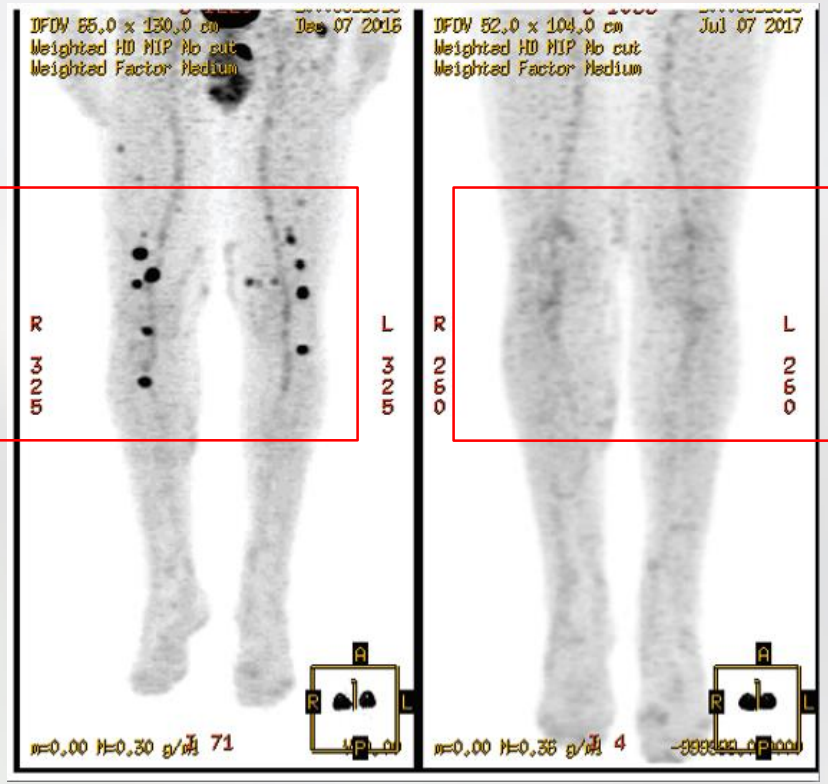
**Day 85**



# Multiple PET Scan Detected Melanoma Deposits Resolved

**Baseline** **Day 169**

Multiple tumors in legs

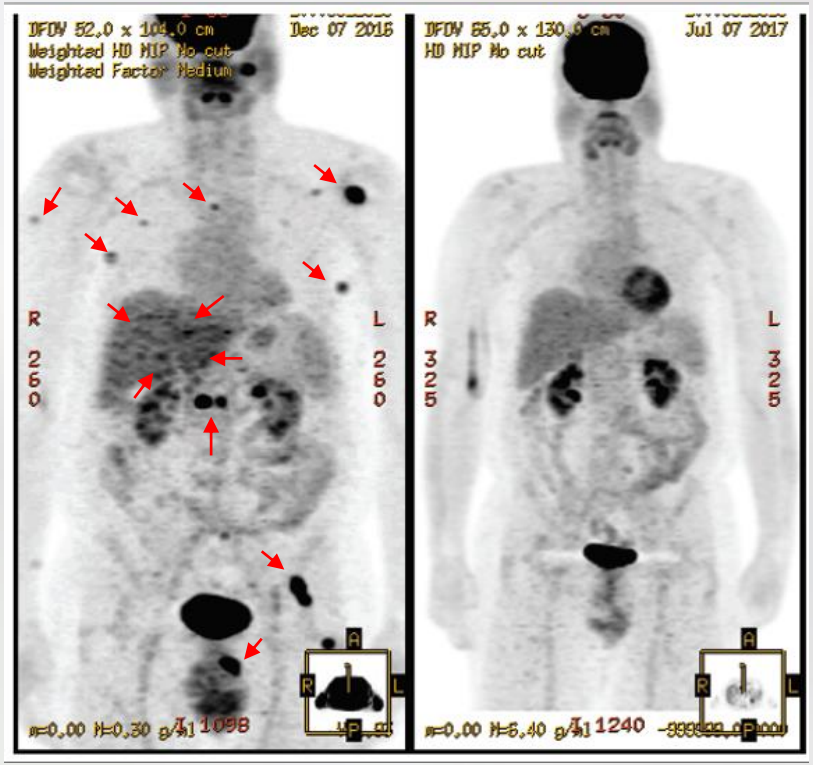



All tumors resolved

# 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**

# Developing Treatments Where Galectin-3 Protein is Implicated in Disease

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

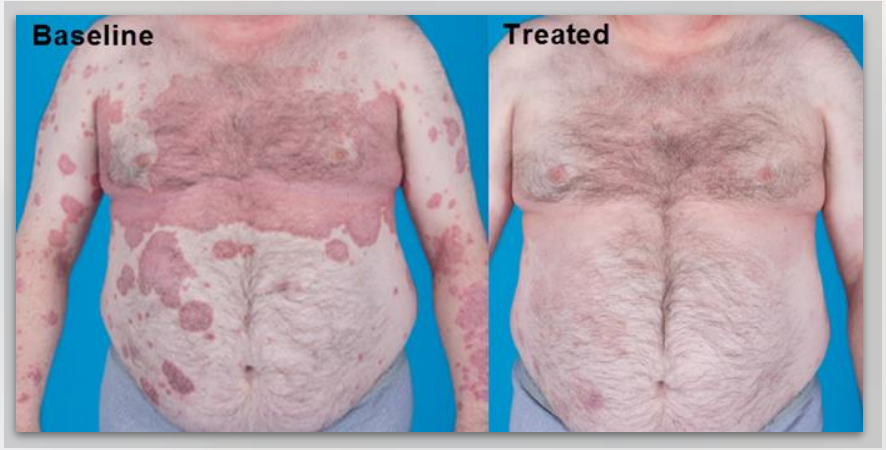
- Primary Program is in NASH Cirrhosis
- Combination Cancer Immunotherapy

➔ **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 may treat multiple diseases**
- **NASH Cirrhosis is a major unmet medical need with a large potential market**
  - NASH-CX trial is first and only positive phase 2 clinical in target indication
  - Drug 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!