



# Safe Harbor and Disclaimer Statement

Galmed Pharmaceuticals Ltd. (the “Company”) has filed a shelf registration statement on Form F-3 (including a preliminary prospectus supplement and the accompanying prospectus ) with the Securities and Exchange commission (“SEC”) for the offering to which this presentation relates, which was declared by the SEC effective on April 2, 2018. Before you invest, you should read the preliminary prospectus supplement and the accompanying prospectus included in the registration statement and the other documents the Company has filed with the SEC for more complete information about the Company and the offering. You may get these documents for free by visiting EDGAR on the SEC website on [www.sec.gov](http://www.sec.gov). Alternatively the Company, or any underwriter or dealer participating in this offering will arrange to send you the prospectus if you request it from Stifel, Nicolaus & Company, Incorporated, Attention: Prospectus Department, One Montgomery Street, suite 3700, San Francisco, CA 94104, or by telephone (415) 364-2720, or by e-mail [syndprospectus@stifel.com](mailto:syndprospectus@stifel.com); SunTrust Robinson Humphrey, Inc. Attention: Prospectus Department, 3333 Peachtree Road NE, 9<sup>th</sup> Floor, Atlanta, GA 30326, or by telephone (404) 926-5744, or by e-mail [strh.prospectus@suntrust.com](mailto:strh.prospectus@suntrust.com); or Cantor Fitzgerald & Co. Attention: Capital Markets, 499 Park Ave. 6<sup>th</sup> Floor, New York, New York 10022, or by e-mail [prospectus@cantor.com](mailto:prospectus@cantor.com).

This presentation contains forward-looking statements about our expectations, beliefs or intentions regarding, among other things, our product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, we or our representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as “believe,” “expect,” “intend,” “plan,” “may,” “should” or “anticipate” or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, this presentation, various filings made by us with the SEC, press releases or oral statements made by or with the approval of one of our authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the factors summarized below.

These factors include, but are not limited to, the following: the timing and cost of Galmed's phase IIb ARREST study and planned Phase III trials for Aramchol™, or whether Phase III trials will be conducted at all; completion and receiving favorable results the phase IIb ARREST study and potential Phase III trials for Aramchol™; regulatory action with respect to Aramchol™ by the FDA or the EMA; the commercial launch and future sales of Aramchol™ or any future product candidates; Galmed's ability to comply with all applicable post-market regulatory requirements for Aramchol™ in the countries in which it seeks to market the product; Galmed's ability to achieve favorable pricing for Aramchol™; Galmed's expectations regarding the commercial market for NASH in patients who are overweight or obese and have pre diabetes or type II diabetes mellitus; third-party payor reimbursement for Aramchol™; Galmed's estimates regarding anticipated capital requirements and Galmed's needs for additional financing; market adoption of Aramchol™ by physicians and patients; the timing, cost or other aspects of the commercial launch of Aramchol™; the development and approval of the use of Aramchol™ for additional indications or in combination therapy; and Galmed's expectations regarding licensing, acquisitions and strategic operations. More detailed information about the risks and uncertainties affecting Galmed is contained under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with the SEC on March 13, 2018, and in other filings that Galmed has made and may make with the SEC in the future.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. Given these uncertainties, you should not rely upon forward-looking statements as predictions of future events.

All forward-looking statements attributable to us or persons acting on our behalf included in, but not limited to, this presentation speak only as of the date hereof and are expressly qualified in their entirety by the foregoing. We undertake no obligations to update or revise forward-looking statements to reflect events or circumstances that arise after the date made or to reflect the occurrence of unanticipated events. In evaluating forward-looking statements, you should consider these risks and uncertainties.

# Galmed Snapshot

1 Galmed is advancing its lead compound, Aramchol™ towards registration with a focus on NASH, a market opportunity estimated to reach \$35-40B/yr by 2025\*

2 Effects in animals translated to NAFLD patients in Phase 2a study and in a one-year global Phase 2b study in 247 biopsy-proven NASH patients

3 We believe that data supports continued development of Aramchol™ 600mg to Phase 3

4 Expected Short Term Catalyst: 

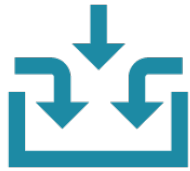
- Pre-Phase 3 meeting with the FDA Q4 2018

5 Experienced pharma leadership team

# Aramchol™ – NASH Disease Modification Potential



First-in-class,  
**orally** active,  
**liver targeted**  
SCD-1 modulator



Potent  
mechanism  
with **multiple**  
**intervention**  
**points** along  
the pathogenic  
pathway



Effects in  
animal models  
**translated** into  
**human** clinical  
data



**High safety**  
margin and  
**B/R ratio**



~400 subjects  
exposed across  
**7 clinical trials**



**Fast Track**  
**Designation** for  
development of  
Aramchol™ for  
NASH granted  
by FDA

# Leadership

## Management

### **Allen Baharaff, President and CEO**

Co-founder of Galmed

### **Dr. Liat Hayardeny, Ph.D., MBA, CSO**

+16 years of experience in drug development,  
Teva Pharmaceuticals

### **Dr. Tali Gorfine, M.D., CMO**

+10 years of experience, Senior Clinical Program Leader at  
Teva Pharmaceuticals

### **Dr. Yossi Caspi, Ph.D., Senior Director Drug Development**

+34 years of CMC experience, former Chief Scientific Officer at  
Chemagis (Perrigo API)

### **Yohai Stenzler, CPA, MBA, CFO**

+6 years of financial management experience at  
Ernst & Young LLP

### **Yael Hollander, Adv., MBA, VP, Legal Affairs & Strategy**

+6 years of experience at Gross, Kleinhendler, Hodak, Halevy,  
Greenberg & Co.

### **Guy Nehemya, Adv., MBA, VP Operations**

+4 years of experience as the Company's Director of Operations.

## BOARD OF DIRECTORS

### **Chaim Hurvitz**

CEO of CH Health; Previously, member of Teva's senior management  
team and Board of directors.

### **Carol L. Brosgart, M.D.**

Consultant to biotechnology companies in the areas of liver disease;  
Former director of Tobira Therapeutics.

### **William S. Marth**

President & CEO of Albany Molecular Research Inc. (AMRI); former  
President & CEO of Teva in the Americas.

### **David Sidransky, M.D.**

Professor of Oncology Pathology at John Hopkins University.

### **Ran Oren, M.D.**

Head of the Institute of Gastroenterology and Liver Disease at  
Hadassah Ein Kerem Hospital.

### **Tali Yaron-Eldar**

Formerly Israeli Tax Commissioner; Chief Legal Advisor of the Finance  
Ministry of the State of Israel.

### **Shmuel Nir**

President & CEO of Tushia Consulting Engineers Ltd.; Chairman of the  
Board of Directors of Matan Digital Printers Ltd.

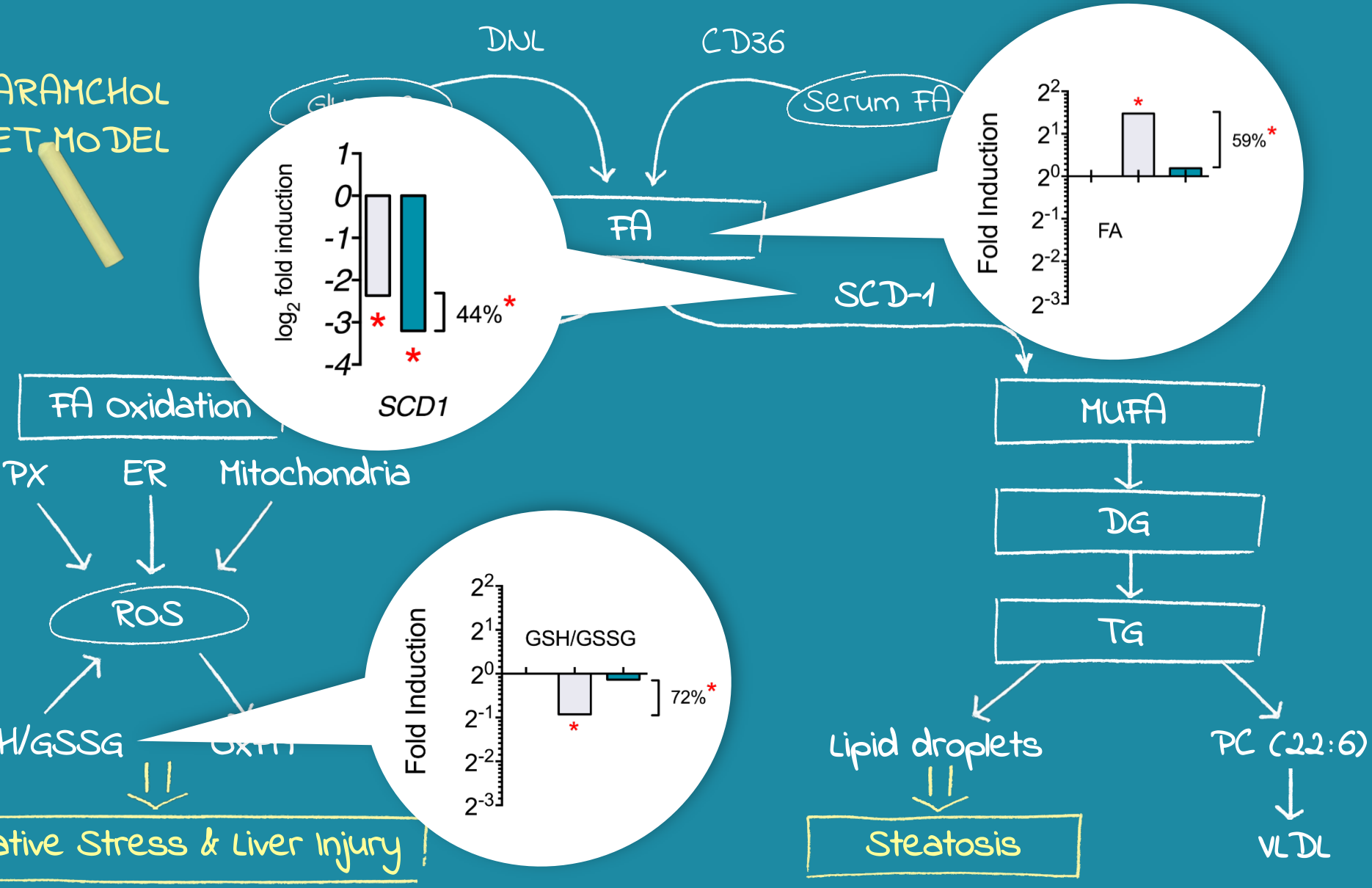
### **Allen Baharaff**

President, CEO and Co-Founder of Galmed

# Aramchol™ from Scientific Rationale to Clinical Results

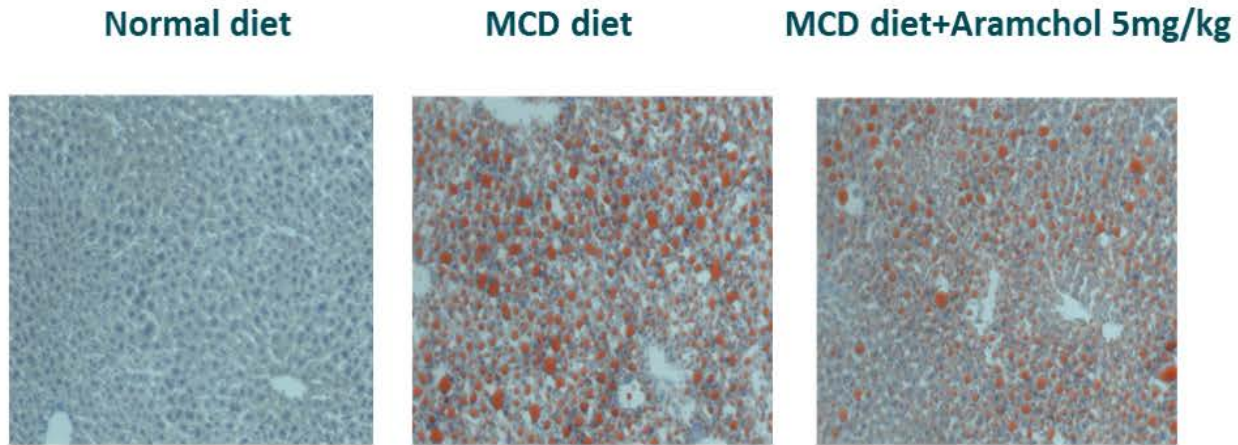
SCD 1 Modulator - One Mechanism, Multiple Activities,  
Translated to Reduction in Liver Fat and Fibrosis

# Effect of ARAMCHOL IN MCD DIET MODEL

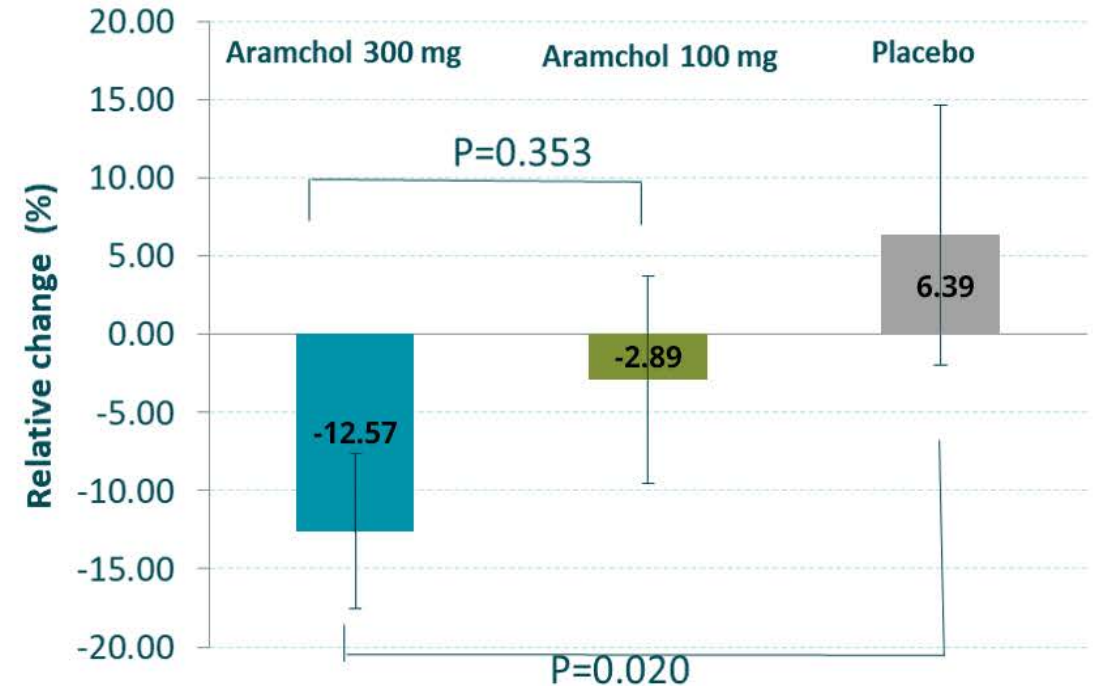


# Aramchol™ - Antisteatogenic Effect - Translation from Animal Models to Human (phase 2a and 2b)

Effect of ARAMCHOL on Liver Steatosis in mice with MCD Diet (Sudan III)



Percent relative change in liver TG levels, baseline and end of treatment



Aramchol™ 5mg/kg in mice and 300mg in humans demonstrated statistically significant reduction of liver fat

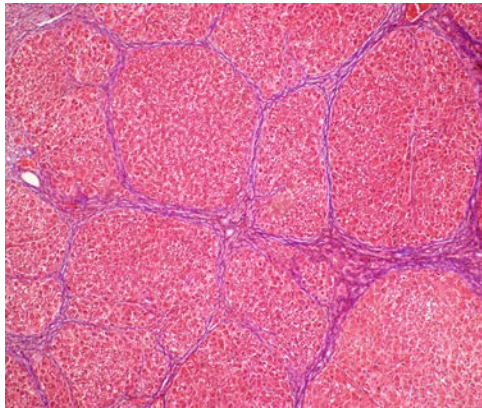
1. Iruarrizaga-Lejarreta, Marta, et al. "Role of Aramchol in steatohepatitis and fibrosis in mice"; Hepatology Communications 1.9 (2017)
2. Safadi et al. "The fatty acid–bile acid conjugate Aramchol reduces liver fat content in patients with nonalcoholic fatty liver disease." Clinical Gastroenterology and Hepatology 12.12 (2014)



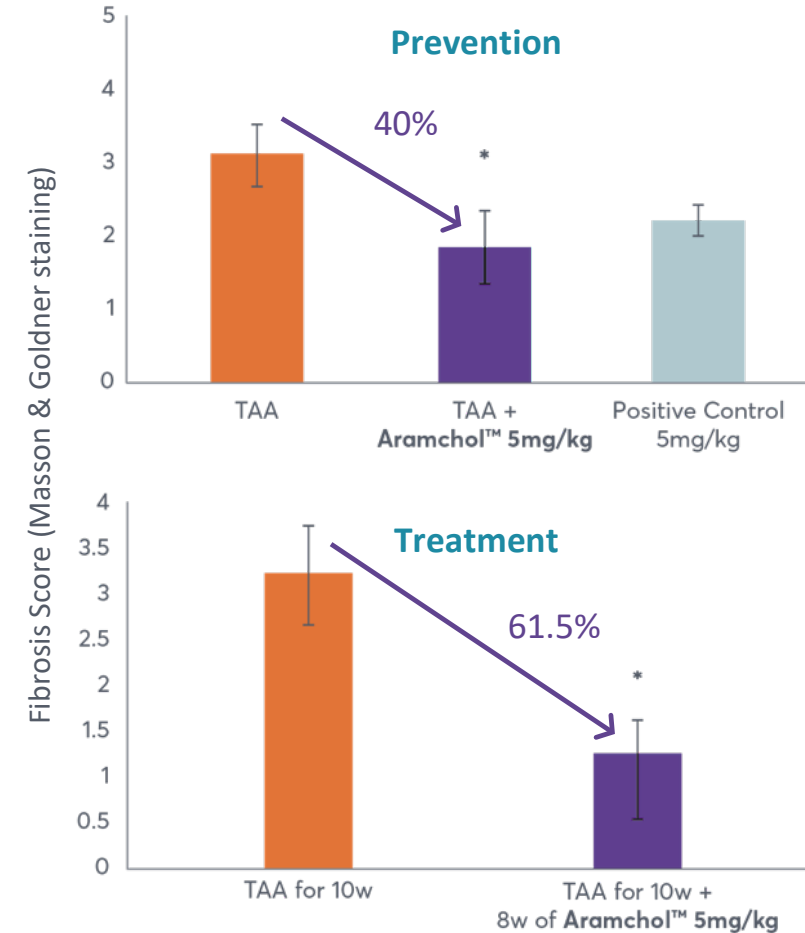
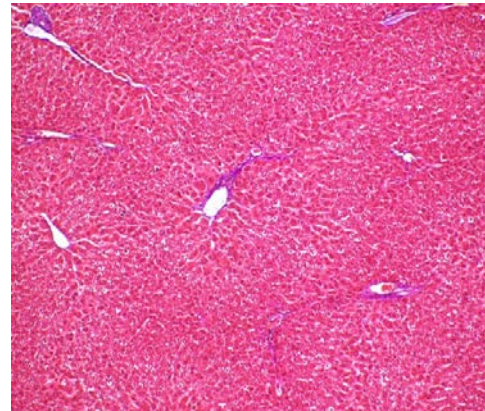
# Aramchol™ – Antifibrogenic Translation from HSC's (Collagen producing cells ) to Animal Models to Human Studies

Effect in the TAA model is considered the best predictor of efficacy in humans

TAA No Treatment



TAA + Aramchol™ 5mg/kg



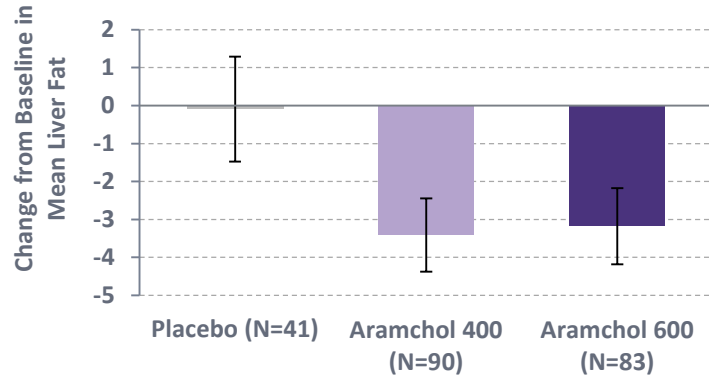


In a one year, global Phase 2b ARREST study, Galmed's Aramchol 600mg achieved NASH resolution without worsening of fibrosis, one of two endpoints that may currently constitute a primary endpoint for a Phase 3 trial to support an FDA marketing application.

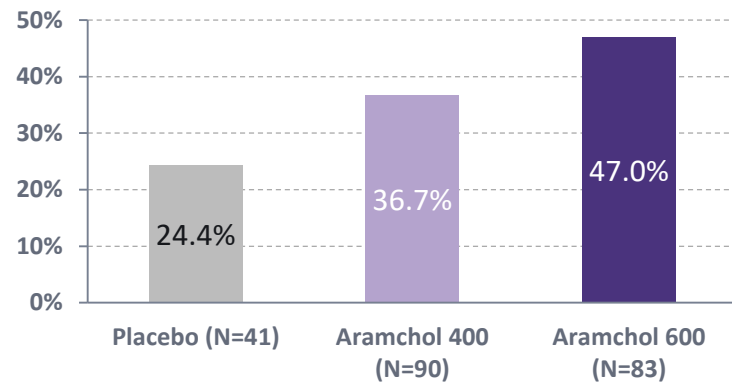
# Aramchol™ Across Modalities

## MRS

Liver fat - Mean Change from Baseline

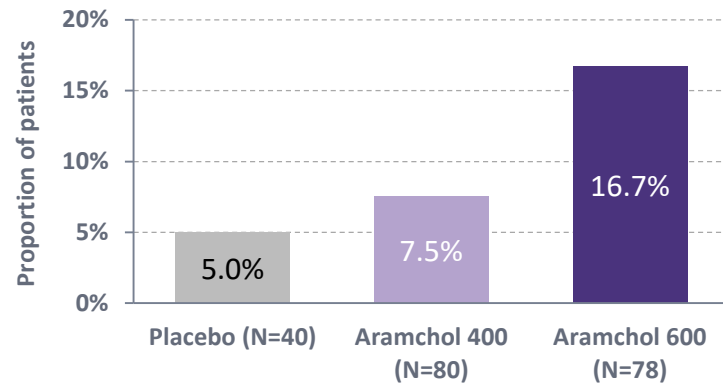


MRI Responders - Reduction  $\geq$  5% absolute change

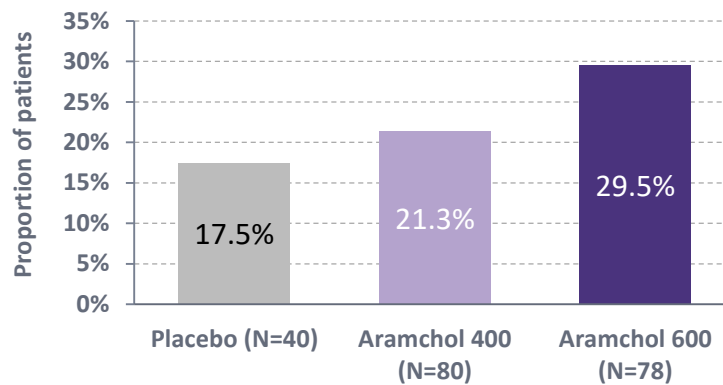


## Biopsy

NASH Resolution without Worsening of Fibrosis

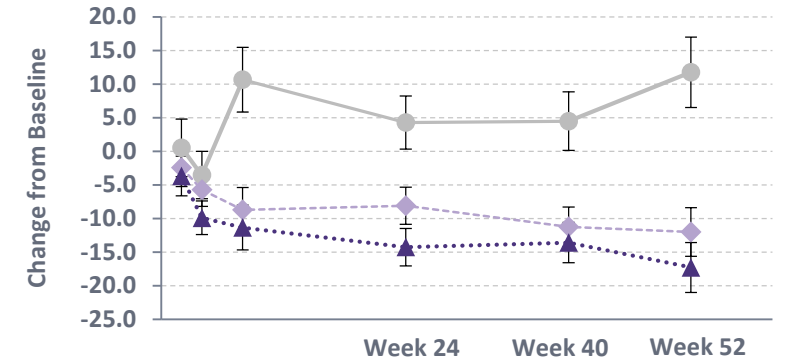


Fibrosis Improvement Without Worsening of NASH

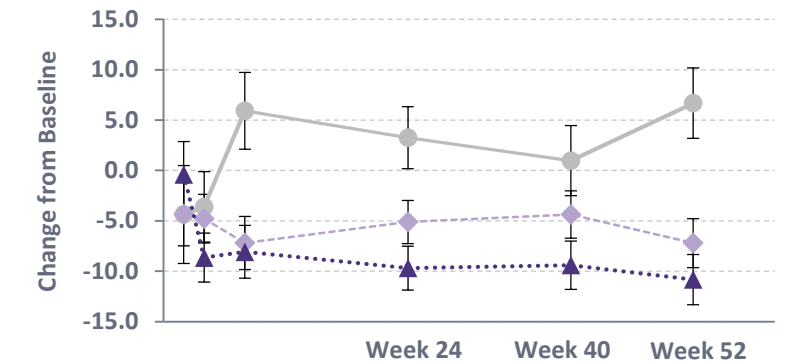


## Liver Enzymes

ALT – mean change from Baseline



AST – mean change from Baseline



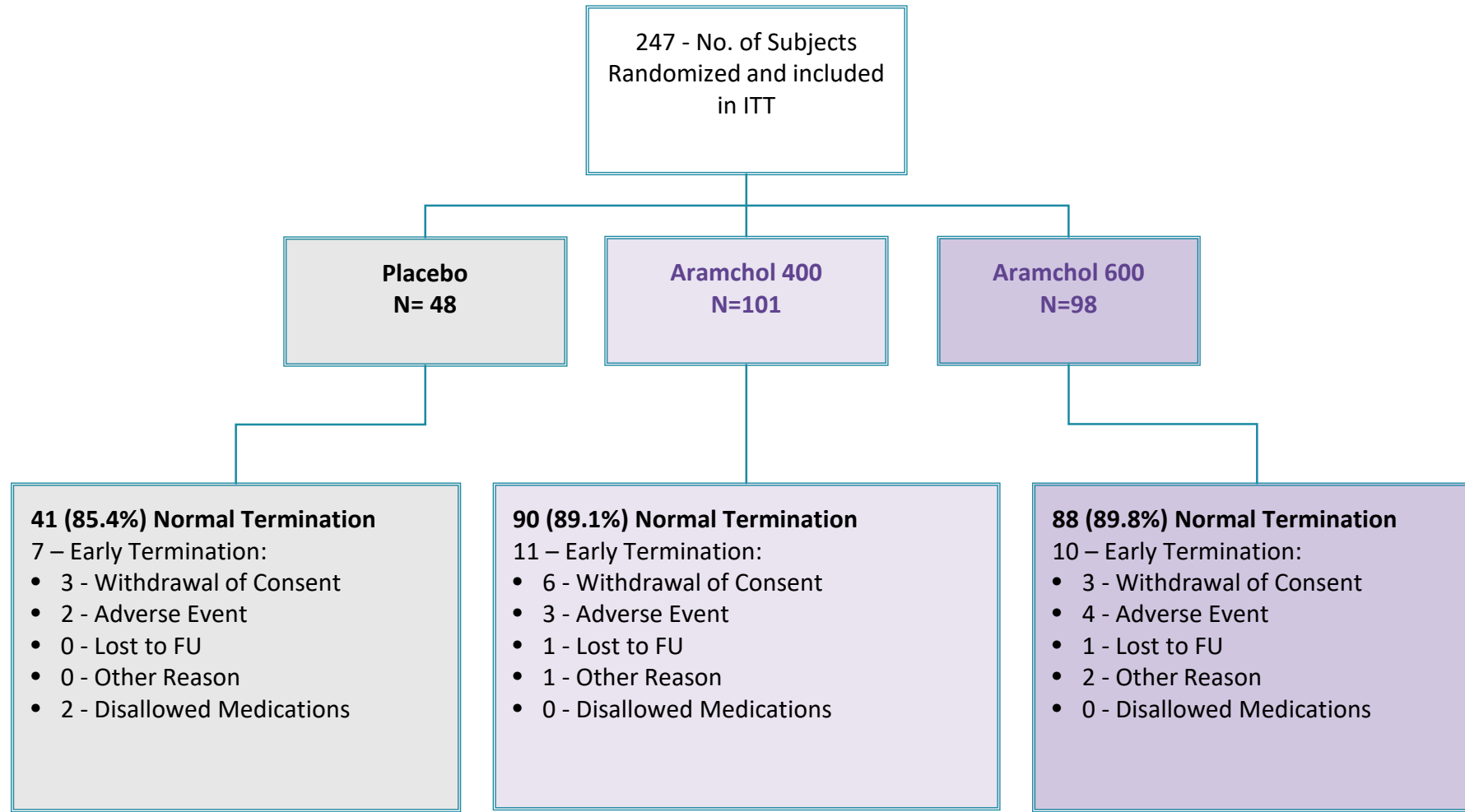
# Phase 2b Study: ARREST

## ARamachol™ for RESolution of Steatohepatitis

A Phase 2b, double blind randomized, controlled clinical trial, to evaluate the efficacy and safety of two Aramchol™ doses versus placebo in patients with Non-Alcoholic Steatohepatitis (NCT 02279524)

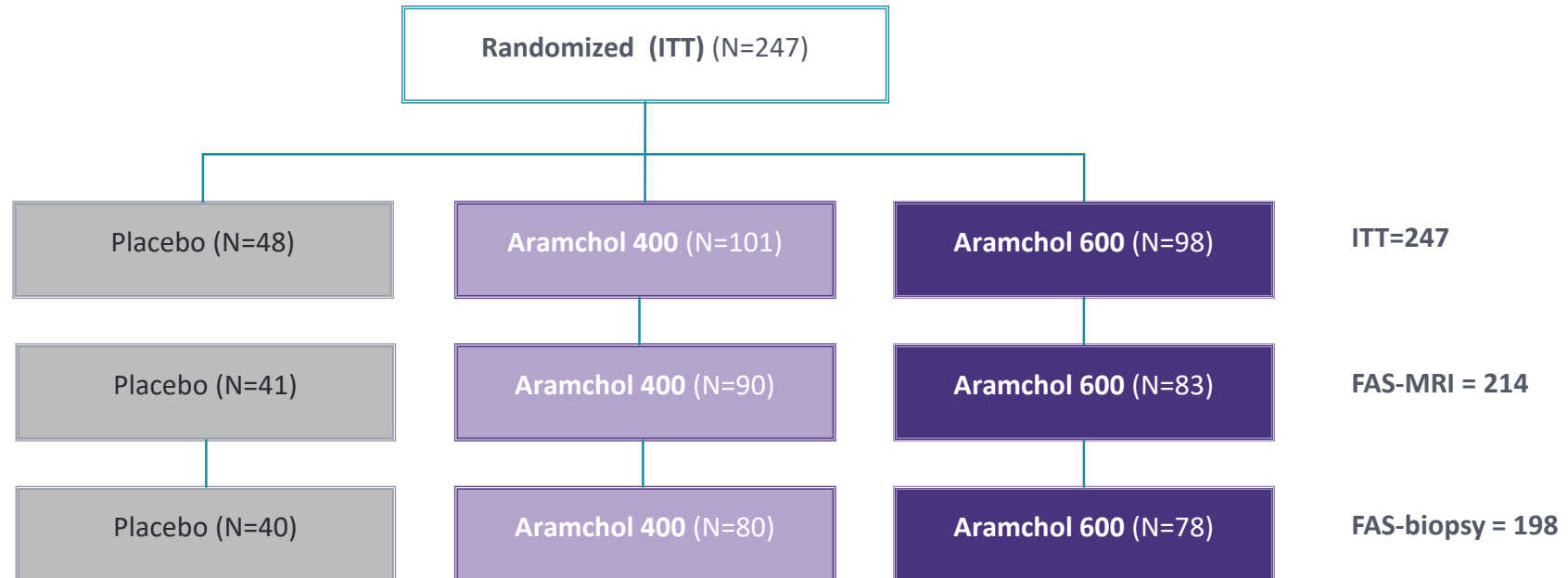
<b>Design:</b>	Multicenter, global, randomized, double-blind, placebo-controlled, dose ranging study ~ 1/3 USA, 1/3 Latin America, 1/3 Europe and Israel
<b>Participants:</b>	Biopsy-diagnosed NASH patients with overweight/obesity and pre-diabetic/ type II diabetic <b>60% having stage 2 and 3 fibrosis and 70% having NAS≥5 at baseline</b>
<b>Doses:</b>	<ul style="list-style-type: none"><li>• 400 mg; 600 mg; Placebo</li><li>• 2:2:1</li></ul>
<b>Treatment Plan:</b>	12 months treatment (once daily tablet) and 3 months of follow-up
<b>Number of Subjects:</b>	247 patients
<b>Primary Endpoint:</b>	Change from baseline to end of study in liver triglycerides ratio as measured by MRS (Aramchol 600mg vs placebo) - centrally read
<b>Key Secondary Endpoints:</b>	Biopsy – centrally read; fibrosis improvement; ≥ 2 point NAS improvement; NASH resolution ALT

# Subjects Disposition



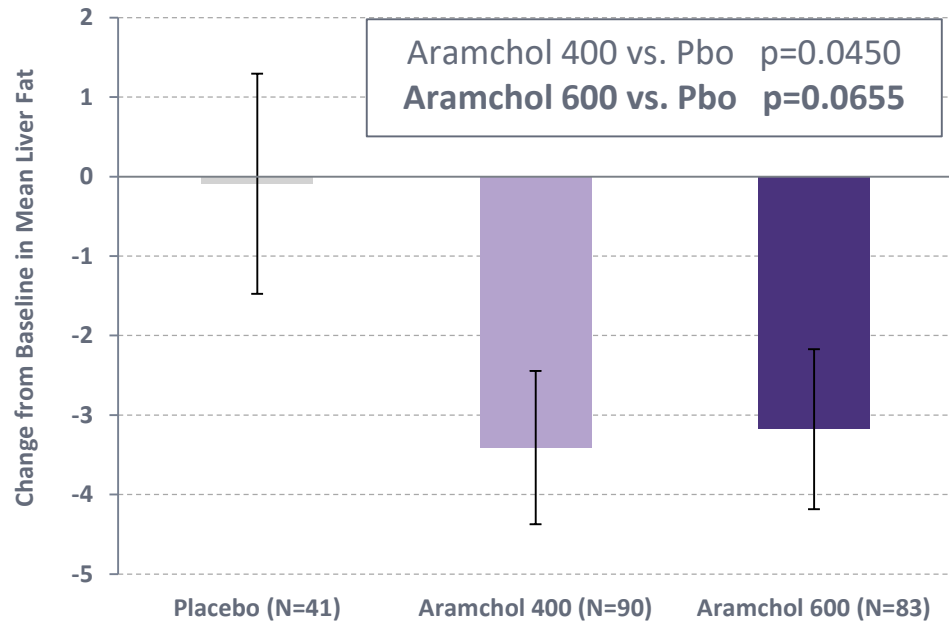
# Pre-defined Analysis Sets

- Statistical analysis plan pre-defined few analysis sets including:
  - **Full Analysis Set for MRI (FAS - MRI):** all ITT patients with baseline and at least one 2nd MRS
  - **Full Analysis Set for Liver Biopsy (FAS - biopsy):** all ITT patients with baseline and 2nd biopsy
    - Majority of missing biopsies are Israeli patients (N=24) without 2nd biopsy - regulatory limitation
    - Only 3 patients that completed 52 weeks of treatment refused the 2nd biopsy
- Good tolerability - ~ 10% early termination during treatment phase

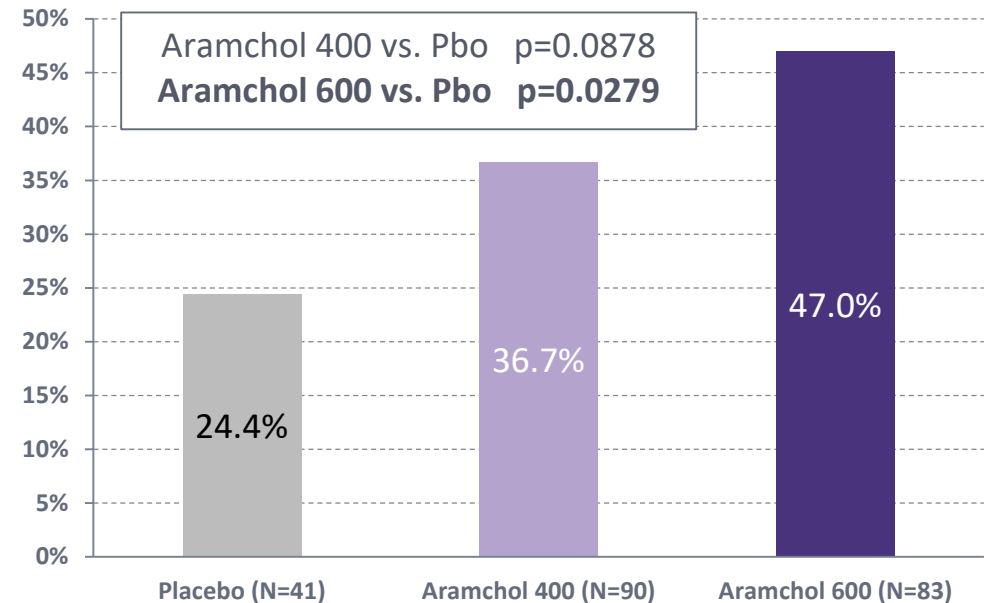


# Change from Baseline in Liver Fat (MRS)

Mean change from Baseline in Liver fat



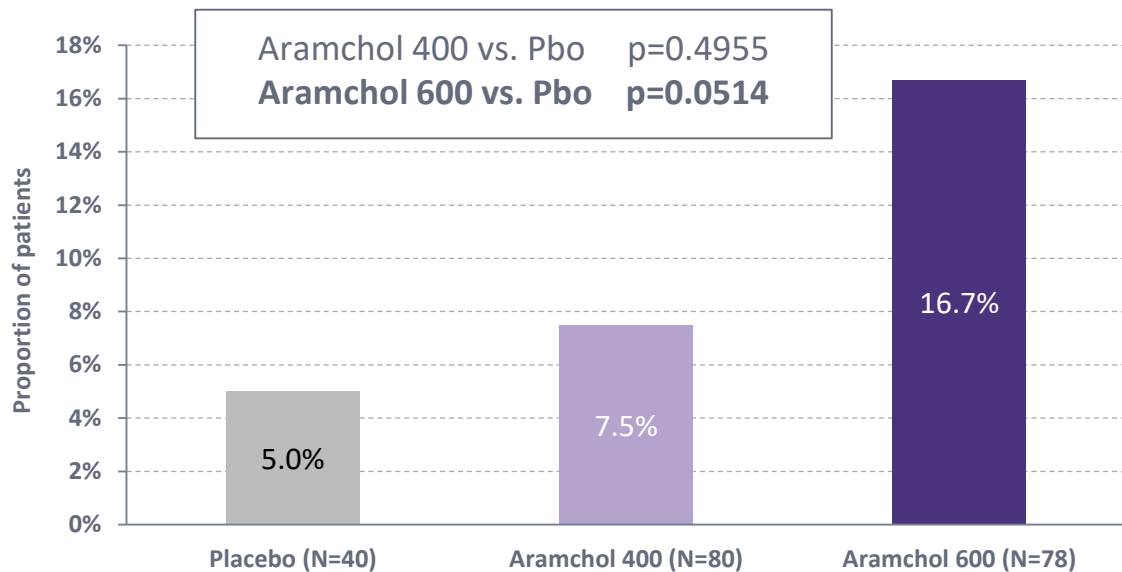
MRI Responders Analysis: Reduction  $\geq 5\%$  absolute change from baseline  
Post-hoc analysis



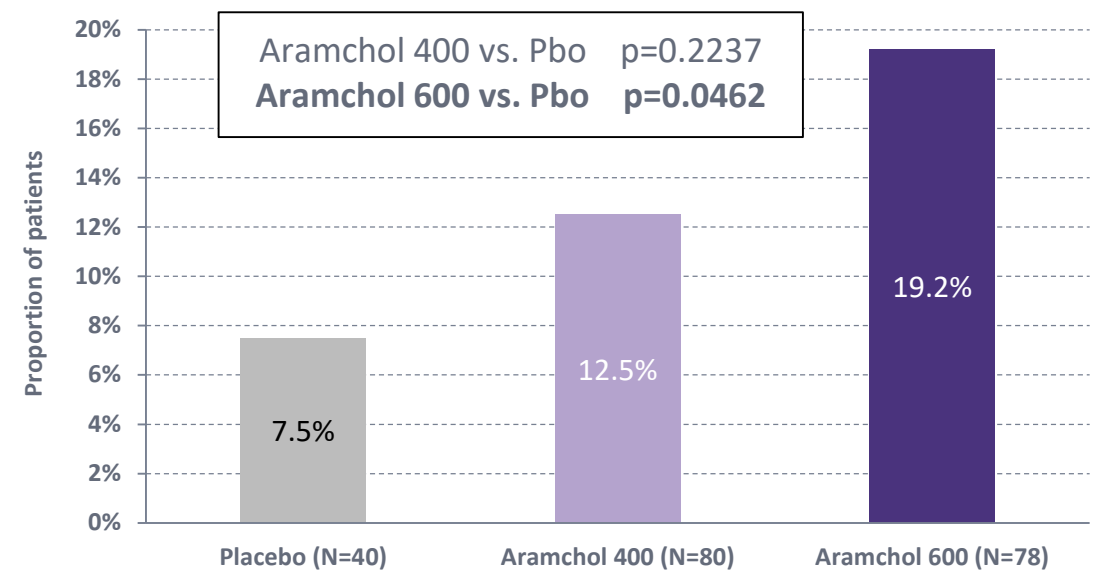
The primary endpoint based on mean change in liver fat for the 600mg dose vs placebo was not met. Statistical significant effect noted with Aramchol™ 600mg using the acceptable cut-off  $> 5\%$  absolute change

# NASH Resolution

## NASH Resolution without Worsening of Fibrosis



## NASH Resolution

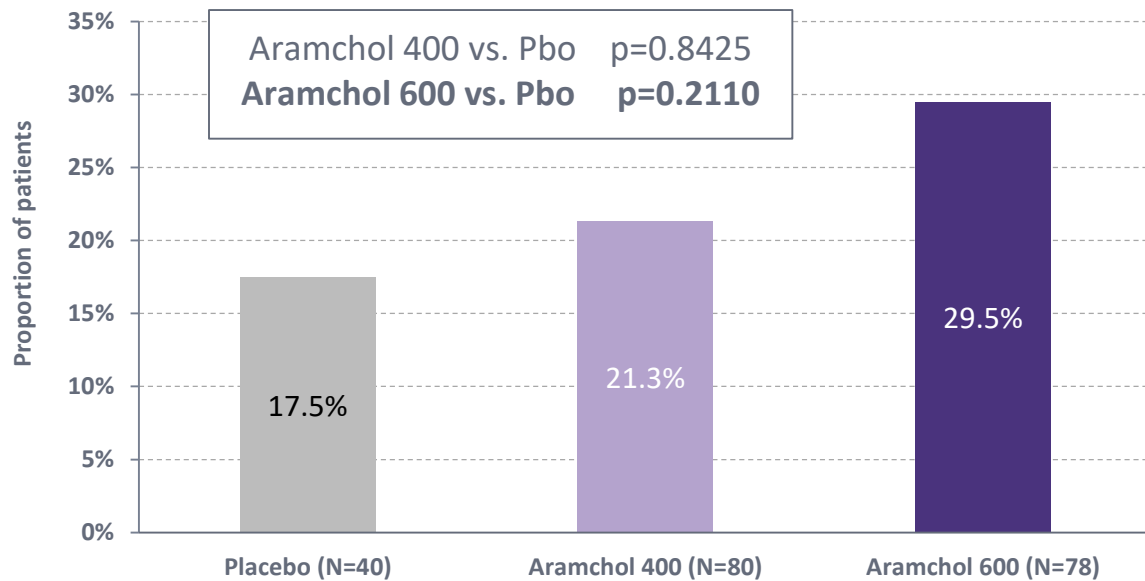


Significantly more patients treated with Aramchol™ 600mg showed NASH resolution without worsening of fibrosis, one of two endpoints that may currently constitute a primary endpoint for a Phase 3 trial to support an FDA marketing application

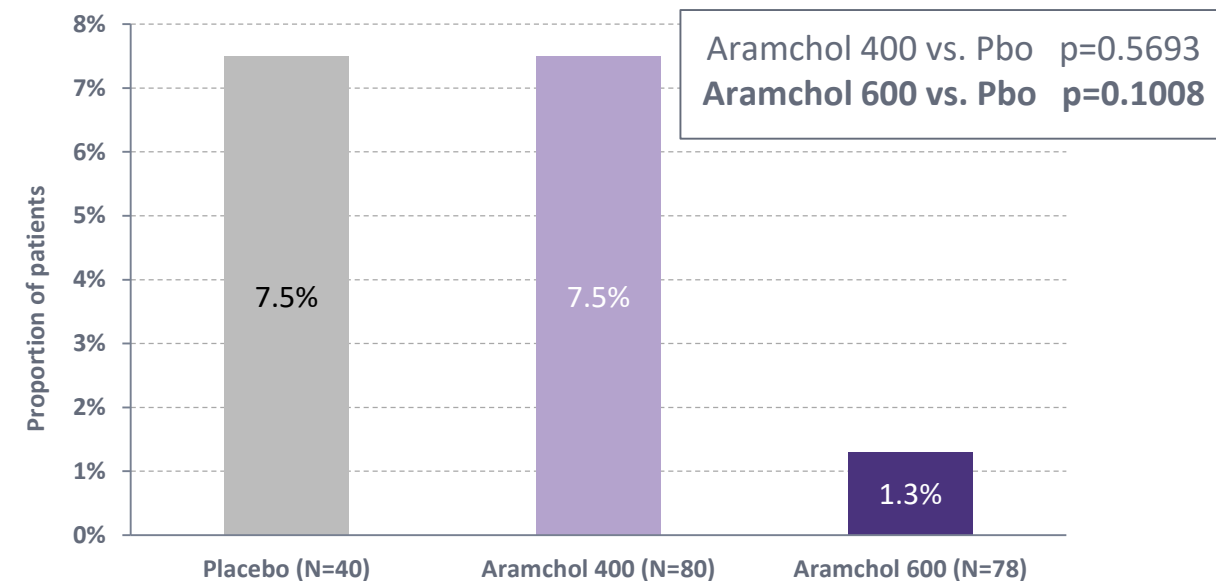


# Fibrosis Improvement

## Fibrosis Improvement ( $\geq 1$ stage) Without Worsening of NASH

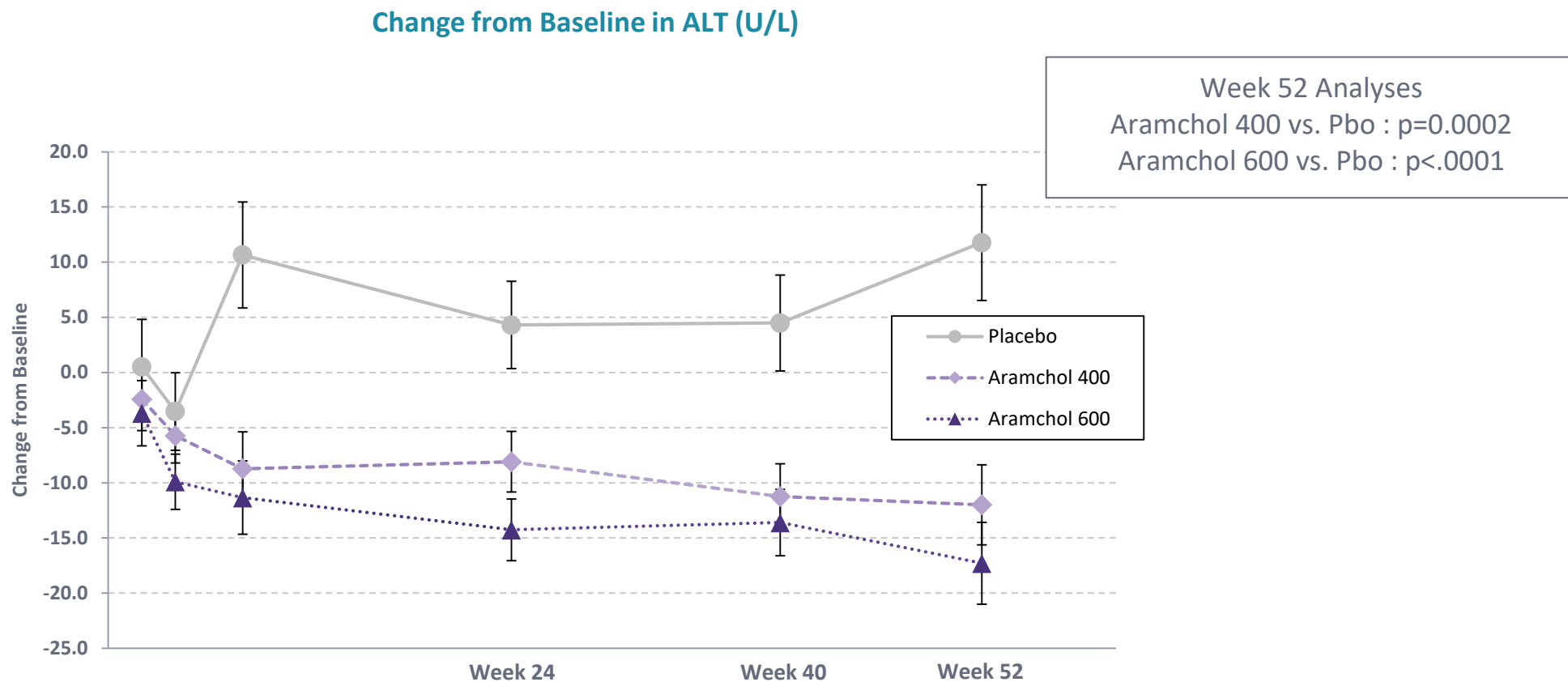


## Post-Hoc Analysis - Progression to Cirrhosis



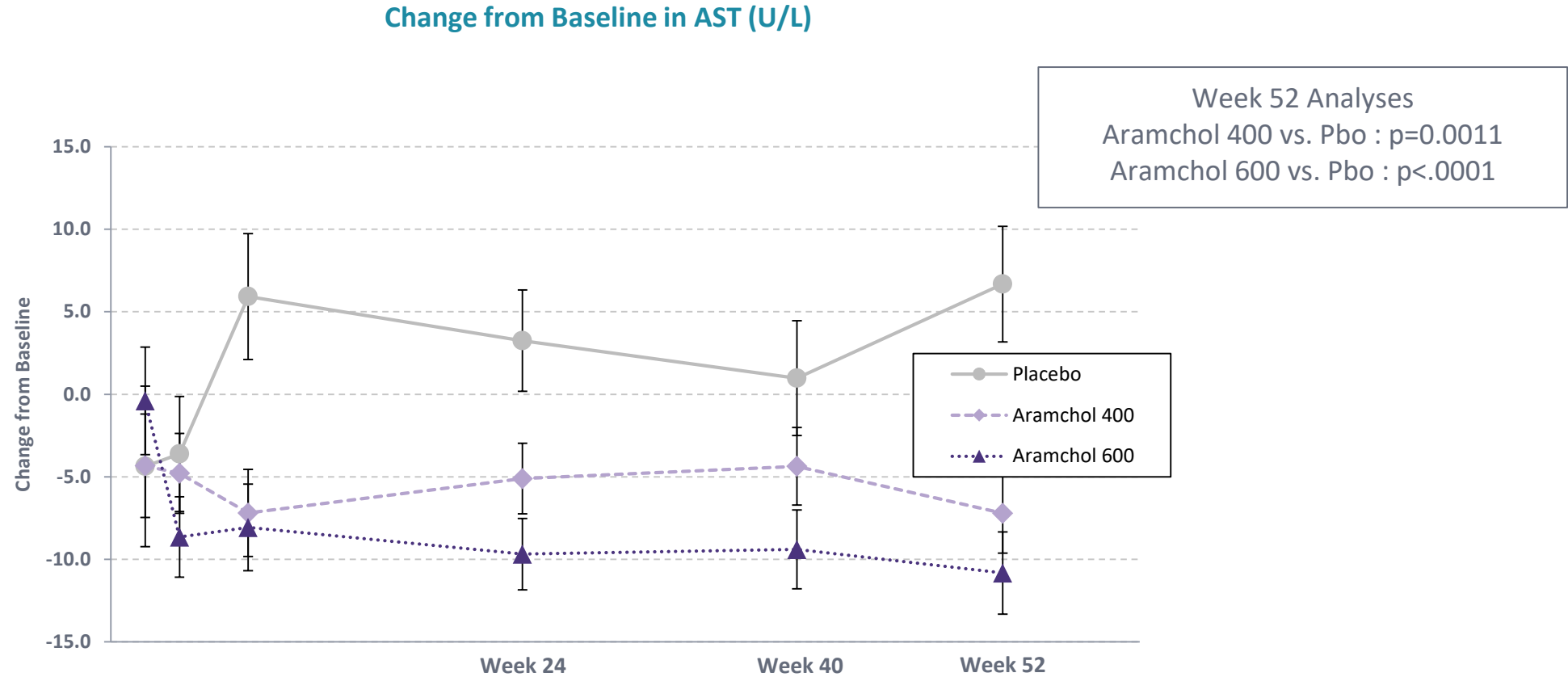
More patients with fibrosis improvement and less patients progressing to cirrhosis with Aramchol™ 600mg

# Change from Baseline to week 52 in ALT (U/L)



A statistically significant reduction in ALT with Aramchol™ 400mg and 600mg

# Change from Baseline to week 52 in AST (U/L)



A statistically significant reduction in AST with Aramchol™ 400mg and 600mg

# Aramchol's safety and tolerability

- Good tolerability
  - Early terminations due to AEs occurred in 4.2%, 3.0% and 4.1% in placebo, Aramchol 400mg and 600mg arms respectively
- SAEs reported in 12.5%, 8.9% and 9.2% of patients in placebo, Aramchol 400mg and 600mg arms respectively
  - No clustering of events were reported in either Aramchol arms
  - No atypical events for the studied population
- Severe AEs reported in 10.4%, 6.9% and 6.1% of patients in placebo, 400mg and 600mg arms respectively

Aramchol™ continues to show a favorable safety and tolerability profile

# Conclusions

- ARREST was a placebo-controlled, one year global phase 2b study in 247 biopsy-proven NASH patients with risk factors
- Study results are compelling for Aramchol™ 600mg demonstrating:
  - A significant effect on NASH resolution without worsening of fibrosis, one of two endpoints that may currently constitute a primary endpoint for a Phase 3 trial to support an FDA marketing application
  - An increase in the number of patients that show fibrosis improvement by at  $\geq 1$  stage without worsening of NASH, one of two endpoints that may currently constitute a primary endpoint for a Phase 3 trial to support an FDA marketing application
  - High proportion of patients benefit from treatment with Aramchol 600mg
  - Good safety profile and tolerability

Data Supports Continued Development of Aramchol™ 600mg to Phase 3

We presented here a set of data that speaks to the potential effect of Aramchol™ on multiple pathologies in NASH as measured by different modalities, MRS, biopsy and liver enzymes

The totality of the data together with the good safety profile and tolerability gives us confidence in advancing Aramchol™ to a pivotal study

# Corporate Overview



## Financials\*

- Market Cap ~\$295M
- 52W Low-High: \$3.61-\$27.06
- 3M Average Volume: ~495K
- Outstanding Shares: ~20.9M
- Cash: ~\$92.0M \*\*
- Long-Term Liabilities: \$0\*\*\*

\* As of June 22, 2018

\*\* Unaudited

\*\*\* Consisting of cash, cash equivalents and marketable securities



## Intellectual Property

- 10 Patent Families
- Areas of Focus: NASH, Combinations, Chemistry of Aramchol™, New Indications
- Patent family (WO 2002/2083147) for use of Aramchol™ for the treatment of fatty liver granted worldwide.
- 2 patent families (2017) for the use of Aramchol™ for treating fibrosis.

Thank You!

NASDAQ: GLMD