Galmed Pharmaceuticals

Phase 2 Data for Galmed Pharmaceutical's Aramchol™ in Non-Alcoholic Steatohepatitis (NASH) Presented During Late-Breaking Abstract Oral Session of The Liver Meeting® 2018

The Phase 2b data has identified Aramchol 600mg as potentially effective to resolve NASH and improve fibrosis

Aramchol improved liver enzymes and glycemic control

Results favor further testing in a Phase 3 trial

Data was selected for "The Best of The Liver Meeting 2018"

TEL AVIV, Israel, Nov. 13, 2018 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of the liver targeted SCD1 modulator Aramchol, a once-daily, oral therapy for the treatment of nonalcoholic steatohepatitis ("NASH") and fibrosis, announced today the oral abstract presentation of one-year results of the Company's global Phase 2b ARREST study of Aramchol in patients with non-alcoholic steatohepatitis (NASH). These results were presented during a Late Breaking Abstract Oral Session at The Liver Meeting® 2018 during the American Association for the Study of Liver Diseases 2018 Annual Meeting being held in San Francisco.

Additionally, the Company's oral abstract of the Phase 2 ARREST study has been selected by the American Association for the Study of Liver Diseases for inclusion in *The Best of The Liver Meeting 2018.*

The ARREST study enrolled 247 NASH patients who were overweight/obese and had prediabetes/diabetes with HbA1C at baseline of 6.6%. More than 50% were hypertensive and had dyslipidemia. Baseline histology demonstrated a population with advanced disease, with 60% having stage 2 and 3 fibrosis and 70% having NAS≥5.

In this one-year study, Aramchol showed liver fat reduction, biochemical improvement, NASH resolution and fibrosis reduction. Results favored the 600mg dose with a dose response pattern. In particular, compared to placebo, the Aramchol 600mg arm achieved the following endpoints:

- NASH resolution without worsening of fibrosis – a regulatory approval endpoint in NASH Phase 3 trials
- Fibrosis stage reduction without worsening of NASH - a regulatory approval endpoint in NASH Phase 3 trials
- Decrease in ALT and AST
- Better glycemic control (HbA1C)

Aramchol showed excellent safety and tolerability profiles with a low discontinuation rate, no weight loss

and no change in lipid parameters.

To view the slide presentation of the ARREST study data presented at the Late Breaking Oral Session go to: http://galmedpharma.investorroom.com/download/Aramchol_Late-Breaking_liver_meeting+AASLD_2018.pdf

"The results favor Aramchol 600 mg therapeutic potential for testing in a Phase 3 trial," said Prof. Vlad Ratziu, France, principal investigator of the ARREST trial. "The higher proportion of resolution of steatohepatitis together with the potential for direct fibrosis improvement and excellent safety and tolerability place Aramchol among the most promising candidates in development for NASH patients."

"Aramchol is a once daily, liver target, oral medication with an excellent safety profile that has now clearly demonstrated in a large Phase 2b study, in patients with advanced NASH, results on the two important biopsy-based endpoints key for further assessment in a NASH pivotal study," said Allen Baharaff, President and Chief Executive Officer of Galmed Pharmaceuticals. "We are advancing Aramchol into a Phase 3 registration trial with the planned initiation of the ARMOR pivotal study at the end of the second quarter or early in the third quarter of 2019."

ARREST is a multicenter, Phase 2b, randomized, double blind, placebo-controlled study designed to evaluate the efficacy and safety of two Aramchol doses (400 and 600 mg tablets) in patients with NASH confirmed by liver biopsy who were overweight or obese and who were pre- diabetic or type II diabetic. Top line results from the study were released by Galmed on June 12, 2018.

About Aramchol™ and Non-alcoholic Steatohepatitis (NASH)

Aramchol™ (arachidyl amido cholanoic acid) is a novel fatty acid bile acid conjugate, inducing beneficial modulation of intra-hepatic lipid metabolism. Aramchol™'s ability to modulate hepatic lipid metabolism was discovered and validated in animal models, demonstrating down regulation of the three key pathologies of NASH; steatosis, inflammation and fibrosis. The effect of Aramchol™ on fibrosis is mediated by down regulation of steatosis and directly on human collagen producing cells. Aramchol™ has been granted by the FDA Fast Track designation status for the treatment of NASH.

NASH is an emerging world crisis impacting an estimated 3% to 5% of the U.S. population and an estimated 2% to 4% globally. It is the fastest growing cause of liver cancer and liver transplant in the U.S. due to the rise in obesity. NASH is the progressive form of non-alcoholic fatty liver disease that can lead to cardiovascular disease, cirrhosis and liver-related mortality.

About Galmed Pharmaceuticals Ltd.

Galmed is a clinical-stage biopharmaceutical company focused on the development of Aramchol, a first in class, novel, once-daily, oral therapy for the treatment of NASH for variable populations. Galmed recently announced top-line results of the ARREST Study, a multicenter, randomized, double blind, placebo-controlled Phase IIb clinical study designed to evaluate the efficacy and safety of Aramchol in subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. Galmed is currently preparing for an end of Phase IIb meeting with the FDA to discuss the results of the ARREST Study and a Phase III study protocol, with a view to initiating a Phase III clinical study of Aramchol in 2019.

Forward-Looking Statements:

This press release may include forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to Galmed's objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that Galmed intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Many factors could cause Galmed's actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: the timing and cost of Galmed's planned Phase III trial for Aramchol, or whether a Phase III trial will be conducted at all; completion and receiving favorable results of a Phase III trial for Aramchol or any other pre-clinical or clinical trial; regulatory action with respect to Aramchol by the FDA or the EMA; the commercial launch and future sales of Aramchol or any other future products or 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; 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. The forward-looking statements contained in this press release are made as of the date of this press release and reflect Galmed's current views with respect to future events, and Galmed does not undertake and specifically disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events

or otherwise.

SOURCE Galmed Pharmaceuticals Ltd.

For further information: Timothy McCarthy, LifeSci Advisors, LLC, +1-212-915-2564, tim@lifesciadvisors.com. Guy Nehemya, Vice President, Operations, Galmed Pharmaceuticals Ltd., guy@galmedpharma.com

---

Additional assets available online: Photos (1)

https://galmedpharma.investorroom.com/2018-11-13-Phase-2-Data-for-Galmed-Pharmaceuticals-Aramchol-TM-in-Non-Alcoholic-Steatohepatitis-NASH-Presented-During-Late-Breaking-Abstract-Oral-Session-of-The-Liver-Meeting-R-2018