Galmed Pharmaceuticals

Galmed Reports Positive Results From Pharmacokinetic Split Dose Study of Aramchol

TEL AVIV, Israel, March 12, 2019 /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, an oral therapy for the treatment of nonalcoholic steatohepatitis ("NASH") and fibrosis, announced today positive results from a pharmacokinetic (PK) study showing that dose splitting of Aramchol 600mg to twice daily 300mg significantly increased plasma levels.

The aim of this Phase I, open-label, two-period, randomized, crossover PK study was to assess whether dose splitting of Aramchol 600mg to twice daily 300mg will significantly increase plasma levels. 16 healthy subjects took part in two study periods. Eight subjects received each regimen in the first period and the alternate regimen in the second period. A PK profile was obtained over the dosing interval at steady state on day ten of each period.

Results of the study showed that the administration of Aramchol 300 mg twice daily resulted in 24-hour plasma concentrations significantly greater than those observed with the administration of Aramchol 600 mg once daily ($P<0.0001$). The average plasma levels (exposure) were 53% higher and exposure was greater in all 16 subjects with the twice daily dosing. The treatment in both dosing regimens was similar in terms of safety and was well tolerated.

"As previously seen in our presentations, a dose response pattern was observed in the recently completed Phase 2b ARREST study. Aramchol 600mg resulted in higher efficacy compared to 400mg, with only a 20% elevation in plasma levels. We find a further increase of 53% highly encouraging as this implies the potential for significantly higher efficacy on both NASH resolution and fibrosis improvement," stated Allen Baharaff, Chief Executive Officer of Galmed.

"The results of this study were recently obtained and submitted to the FDA. We are planning to discuss these new findings in our forthcoming end of Phase 2b meeting," added Mr. Baharaff.

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, 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 2b 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 2b meeting with the FDA to discuss the results of the ARREST Study and a Phase 3/4 study protocol, with a view to initiating a Phase 3/4 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 3/4 trial for Aramchol, or whether a Phase 3/4 trial will be conducted at all; completion and receiving favorable results of a Phase 3/4 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, Chief Operating Officer, Galmed Pharmaceuticals Ltd., guy@galmedpharma.com

---