Galmed Pharmaceuticals

Galmed Announces ARRIVE Study Data

TEL AVIV, Israel, Feb. 14, 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, or NASH and other liver diseases, announced today top-line results from the ARRIVE Trial, which did not meet its primary endpoint.

ARRIVE, a Phase IIa, investigator initiated clinical trial conducted at theUniversity of California San Diego by Professor Rohit Loomba was a randomized, double-blinded, placebo-controlled, 12 weeks, proof-of-concept study that evaluated the safety and efficacy of Aramchol™ at 600mg/day versus placebo in 50 patients with HIV-associated lipodystrophy and non-alcoholic fatty liver disease, or NAFLD. The primary endpoint of the study was improvement of liver fat at 12 weeks, as measured by MRI-PDFF. Liver biopsies were not included as part of the evaluation in this pilot trial.

The trial showed no difference between HIV patients receiving Aramchol™ for 12 weeks when compared with HIV patients in the placebo arm. Aramchol™ showed a favorable safety and tolerability profile. Further analysis of the data is ongoing.

Topline data from Galmed's Phase IIb ARREST study with 248 NASH patients assessing Aramchol™ 400 and 600mg/day following 52 weeks treatment, with endpoints measured by MRS and liver biopsies, is expected in Q2 2018.

Prof. Rohit Loomba, Principal Investigator of the ARRIVE study commented: "While further analysis is required, the results may mean that the pathogenesis of HIV-related NAFLD is likely different and potentially due to a complex mix of triggers that are both unique to HIV-associated NAFLD and may also have some shared pathways with primary NAFLD. The fatty liver disease in HIV lipodystrophy patients also has underlying fat destruction which may be different from the features that are seen in "garden variety NASH."

Allen Baharaff, Chief Executive Officer of Galmed, stated, "Aramchol, with its unique mechanism of action, favorable safety and tolerability profile, is being evaluated in a variety of liver diseases. Treating fatty liver disease, in the presence of the lipodystrophy associated with HIV and/or HIV therapy, may be more complex than treating fatty liver disease (NASH) in the non-HIV infected population. Prof. Loomba is a pioneer in this research for a well-deserved patient population. It will be important for researchers and companies to evaluate other therapeutic agents, alone or in combination, in the spectrum of fatty liver disease and lipodystrophy in the HIV infected population."

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 Fast Track designation status by the FDA 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 transplantation 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, liver cancer and end-stage liver disease 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, as well as other liver associated disorders. Galmed is currently conducting 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. More information about the ARREST Study may be found on ClinicalTrials.gov identifier: NCT02279524.

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. For example, forward-looking statements are used in this press release in statements by persons quoted in this press release with respect to their views concerning the ARRIVE study or otherwise. 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 ongoing Phase IIa ARRIVE Study, 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 of these Phase IIa ARRIVE Study, Phase IIb ARREST Study and 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 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 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 23, 2017, 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.

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