Galmed Pharmaceuticals

Galmed Pharmaceuticals Announces Successful Completion of End of Phase 2 Meeting With FDA and Plan for Start of Phase 3

TEL AVIV, Israel, April 9, 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 that the company has completed its End-of-Phase 2 meeting with the Food and Drug Administration (FDA) and reached general agreement on key aspects of the Phase 3/4 development and registration plan for Aramchol and on the pivotal registration study ARMOR. ARMOR is a Phase 3/4 multinational, multicenter, double-blind, placebo-controlled clinical study to evaluate the efficacy, safety and tolerability of Aramchol in subjects with NASH and fibrosis.

Galmed previously announced results from its Phase 2b study which were subsequently presented at AASLD 2018. Efficacy and safety data from this study included notable effects on key registrational endpoints of NASH resolution and fibrosis improvement and favorable safety supporting initiation of the Phase 3/4 study. More recently, Galmed reported results from a study comparing once daily Aramchol 600 mg to twice daily 300 mg with a significant increase in exposure in the twice daily treatment arm and potential for additional efficacy with twice daily dosing. General agreement has been reached with FDA on key aspects of the ARMOR study including patient population, study endpoints, study dose and treatment duration. Galmed plans on submitting its study protocol and other design elements of its ARMOR trial to the FDA in the coming weeks with study commencement expected in the third quarter of 2019.

Galmed plans on presenting an overview of its development plan of Aramchol at the NASH Summit in Boston on April 24, 2019.

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 downregulation of the three key pathologies of NASH: steatosis, inflammation and fibrosis. The effect of Aramchol on fibrosis is mediated by downregulation 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 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 to initiate a Phase 3/4 clinical study in the third quarter of 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. Applicable risks and uncertainties include risks and uncertainties associated with the initiation, timing, progress and results of the Company's research, preclinical studies and clinical trials as well as risks and uncertainties identified under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with the Securities and Exchange Commission, or 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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Completion-of-End-of-Phase-2-Meeting-With-FDA-and-Plan-for-Start-of-Phase-3