Galmed Pharmaceuticals

# Galmed Pharmaceuticals Initiated ARMOR, a Phase 3/4 Registrational Study of Aramchol in Subjects With NASH and Fibrosis

TEL AVIV, Israel, Sept. 26, 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 the initiation of its Phase 3/4 ARMOR clinical study to evaluate the efficacy and safety of Aramchol in subjects with NASH and fibrosis. This double-blind, placebo-controlled, global study will be conducted in approximately 185 sites in the U.S., Europe, Latin America and Asia.

The ARMOR study will evaluate the efficacy and safety of Aramchol in subjects with NASH and fibrosis stages 2-3 who are overweight or obese and have prediabetes or type 2 diabetes. A total of 2000 subjects will be randomized 2:1 to receive Aramchol 300mg BID or matching placebo. The study is designed to consist of two parts. In the first part (Histology-Based) 1200 subjects will be treated with Aramchol or matching placebo for 52 weeks. The Histology-Based data will serve as the basis for the submission of a marketing authorization application under regulatory provisions of accelerated/conditional approval. In the second part (clinically-based), all subjects will continue with the same treatment assignment until study completion to confirm clinical efficacy.

The ARMOR study is designed based on the phase 2b results and FDA guidance and is powered to meet the two alternative key Histology-Based endpoints: (i) NASH resolution and no worsening of liver fibrosis, and (ii) fibrosis improvement without NASH worsening. Meeting one of these endpoints is expected to suffice for the study success of the first part. More information about the ARMOR Study may be found on ClinicalTrials.gov identifier: NCT04104321.

**Prof. Arun Sanyal,** Principal Investigator of the study commented, "Aramchol improves both the metabolic underpinning and lipotoxic stress driving NASH and fibrogenic drive by its effects on stellate cells.  These pleiotropic beneficial effects along with the excellent safety and tolerability profile plus the positive data from earlier Phase 2A and 2B trials provide a strong rationale to proceed to a Phase 3/4 trial.  The possibility of developing a safe, well tolerated and effective treatment of active NASH with this molecule is exciting and I look forward to participating in this trial."

**Prof. Vlad Ratziu**, Principal Investigator of the study commented, "I share the excitement of having a strong drug candidate, with such good benefit/risk ratio, moving into a global, multi-national, major, late-phase NASH trial. I also look forward to collaborating with colleagues around the world, in US and Europe but also in areas outside the western World where NASH is highly prevalent. ARREST, a truly global Phase 2b trial that recruited worldwide including in Central America and Asia, created much anticipation and interest with Aramchol and should help Galmed drive fast recruitment in a timely manner."

"The commencement of the ARMOR Study is a significant milestone in the development of Aramchol for NASH patients" said Allen Baharaff, Chief Executive Officer of Galmed. "Aramchol has a unique mode of action which has been translated to clinical efficacy targeting directly both steatosis and fibrosis with an excellent safety profile and a potential to become the backbone therapy for NASH. I am delighted that the study is underway on time placing it as one of the most advanced therapeutic candidates for NASH. We look forward to rapidly completing enrollment by Q2 of 2021 with the aim of reporting top-line results by the fourth quarter of 2022."

Galmed previously announced results from its Phase 2b ARREST 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 excellent 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 combined with the dose response pattern observed in prior Phase 2 studies, provides potential for additional efficacy with twice daily dosing.

**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 Pharmaceuticals Ltd. is a clinical stage drug development biopharmaceutical company for liver, metabolic and inflammatory diseases. Our lead compound, Aramchol™, a backbone drug candidate for the treatment of NASH and fibrosis is currently in a Phase 3/4 registrational study.

**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 pivotal Phase 3/4 ARMOR trial, or the ARMOR Study or whether a pivotal trial will be conducted at all; completion and receiving favorable results of the ARMOR Study 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 patients; 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, 2019, 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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