Galmed Pharmaceuticals

FDA Agrees with Galmed's Plan to use Aramchol Meglumine in the Randomized Double-Blind Placebo-Controlled Part of the Phase 3 ARMOR study

- FDA agreed that Galmed can proceed with its proposed clinical studies with Aramchol meglumine in lieu of Aramchol free acid without the need to repeat nonclinical and clinical studies.

- FDA supported Galmed's limited clinical pharmacology study plan with respect to Aramchol meglumine.

- Based on the clinical data generated from the ongoing open-label part of the Phase 3 ARMOR study, initiation of the randomized, double-blind, placebo-controlled part of the Phase 3 study will be conducted with the Aramchol meglumine once daily regimen.

TEL AVIV, Israel, Aug. 2, 2021 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and inflammatory diseases announced today that the FDA agreed with its plan to use Aramchol meglumine (in lieu of Aramchol free acid) in its Phase 3 ARMOR study without the need to conduct additional nonclinical and clinical studies other than planned limited pharmacology studies relating to Aramchol meglumine.

Aramchol meglumine is an improved compound using a salt form of Aramchol that has significantly greater water solubility than the free acid and an NCE patent protection valid until December 2034. Aramchol meglumine contains the same active pharmaceutical ingredient (API) called Aramchol.

Prof. John Posner of the Centre for Pharmaceutical Medicine Research, King's College,London and Galmed Senior Advisor commented: "Clinical pharmacology studies in healthy volunteers demonstrated that administration of Aramchol meglumine doubled the systemic exposure of Aramchol compared with that after dosing Aramchol free acid. Exposure with once daily (QD) 383mg Aramchol meglumine oral dosage corresponds to that obtained with the existing twice daily (BID) 300mg Aramchol free acid form which is currently being evaluated in the Phase 3 ARMOR study. This allows future development of the QD regimen with a potential improvement in convenience and adherence".

Allen Baharaff, Galmed co-founder and CEO commented: "In addition to its longer IP protection until December 2034, the transition to Aramchol meglumine will benefit our patients in two meaningful ways: achieving the required exposure with 50% less API as well as significantly reducing our target marketing price once Aramchol is approved via the potential saving of ~50% of COGs." Mr. Baharaff continued " We consider the FDA's agreement a significant validation of Galmed's consistent efforts to maximize the potential of Aramchol in developing a NASH treatment. The transition to Aramchol meglumine is the final step in our drug product optimization which started with the move to the BID Aramchol free acid regimen (with it higher exposure than the once daily regimen used in our Phase IIb study). The data on the optimization of treatment duration and potential Non-Invasive Tests (NITs) associated with NASH and fibrosis, which will be revealed from the ongoing open label part of the ARMOR study, is aimed at de-

risking our clinical development plan while increasing the probability of success of Aramchol's ARMOR registrational Study."

About Aramchol and Non-alcoholic Steatohepatitis (NASH)

Aramchol (arachidyl amido cholanoic acid) is a novel fatty acid bile acid conjugate, liver targeted SCD1 modulator, developed as an oral therapy for the treatment of nonalcoholic steatohepatitis ("NASH") and fibrosis. 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.

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 registrational study. We are also developing Amilo-5MER, a 5 amino acid synthetic peptide and recently initiated a first in human 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 pivotal Phase 3 ARMOR trial, or the ARMOR Study or any other pre-clinical or clinical trials; completion and receiving favorable results of the ARMOR Study for Aramchol or any other pre-clinical or clinical trial; the impact of the COVID-19 pandemic; regulatory action with respect to Aramchol or any other product candidate 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 or any other product candidate in the countries in which it seeks to market the product; Galmed's ability to achieve favorable pricing for Aramchol or any other product candidate; Galmed's expectations regarding the commercial market for NASH patients or any other indication; third-party payor reimbursement for Aramchol or any other product candidate; Galmed's estimates regarding anticipated capital requirements and Galmed's needs for additional financing; market adoption of Aramchol or any other product candidate by physicians and patients; the timing, cost or other aspects of the commercial launch of Aramchol or any other product candidate; the development and approval of the use of Aramchol or any other product candidate 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 18, 2021, 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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