

## **MHRA Agrees with Galmed's Plan to use Aramchol meglumine in the Randomized Double-blind Placebo-Controlled Part of the Phase 3 ARMOR study**

**- MHRA agreement follows similar agreement from the FDA which allows Galmed to proceed with its proposed clinical studies with Aramchol meglumine in lieu of Aramchol free acid without the need to repeat nonclinical and clinical studies**

TEL AVIV, Israel, Aug. 16, 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 Medicines and Healthcare products Regulatory Agency (MHRA), the pharmaceuticals regulator in the UK, agreed with Galmed's plan to proceed with its proposed clinical studies with Aramchol meglumine in lieu of Aramchol free acid without the need to repeat nonclinical and clinical studies other than planned limited pharmacology studies relating to Aramchol meglumine. This follows similar agreement received from the FDA that was recently announced.

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 circulates in the blood as Aramchol.

Allen Baharaff, Galmed co-founder and CEO commented: "Our shift to Aramchol meglumine is part of our overall optimization strategy for our Phase 3 ARMOR study and the MHRA's agreement, which follows on the heels of the FDA's agreement, represents important validation of the steps that we are taking." Mr. Baharaff continued "We are fully focused on the open label part of our Phase 3 ARMOR Study and look forward to presenting the results of the first one-third of patients during the fourth quarter of 2021."

### **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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Additional assets available online: [Photos \(1\)](#)

<https://galmedpharma.investorroom.com/2021-08-16-MHRA-Agrees-with-Galmeds-Plan-to-use-Aramchol-meglumine-in-the-Randomized-Double-blind-Placebo-Controlled-Part-of-the-Phase-3-ARMOR-study>