Galmed Pharmaceuticals

Galmed announces positive results of Phase 1 study of Amilo-5MER

Single and multiple escalating dose results with excellent safety profile and tolerability

Submission of an IND for mild to moderate ulcerative colitis is planned in 2022

TEL AVIV, Israel, Jan. 10, 2022 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and inflammatory diseases announced today results of a Phase 1 clinical trial of Amilo-5MER in healthy volunteers that demonstrated an excellent safety profile and tolerability.

Amilo-5MER is a synthetic peptide consisting of 5 amino acids that significantly reduces symptoms and histopathological hallmarks of IBD in animal models (TNBS, DSS). TNBS and DSS are well-established and widely recognized models of acute colitis. Amilo-5MER also showed anti-inflammatory effects in animal models of multiple sclerosis and rheumatoid arthritis. Amilo-5MER exerts its anti-inflammatory effects by binding with high affinity to pro-inflammatory amyloid proteins, preventing polymerization of Serum Amyloid A (SAA) monomers and thereby interfering with SAA-induced immune cell activation.

The safety, tolerability, and pharmacokinetics of single and multiple doses of Amilo-5MER were assessed in a first-in-human study in healthy subjects. The Phase I study was conducted in a single-center, using a double-blind, randomized, placebo-controlled design. Overall, 64 healthy male and female subjects were enrolled in the study. Cohorts of 8 subjects were randomized to receive Amilo-5MER or placebo by subcutaneous injection in a ratio of 6:2. In Part 1, cohorts of young male adults received single ascending doses of 10, 30, 90, 180 and 360 mg; in Part 2, a single cohort received doses of 180 mg BID for 5 consecutive days and in Part 3 a single cohort of healthy elderly male and female subjects received a single dose of 180 mg.

All doses of Amilo-5MER were well tolerated with no clinically significant adverse events and none considered related to the investigational product. All subjects completed the study as per protocol. Plasma concentrations of Amilo-5MER increased in proportion to dose.

Prof John Posner Visiting Professor, School of Life Sciences & Medicine, King's College London who served as medical monitor commented, "Serum Amyloid A is an important inducer of inflammation and Amilo-5MER has real potential to serve as a first in class, specific anti-inflammatory agent with multiple disease indications. It also has the potential to inhibit cytokine release syndrome."

"We are excited to bring Amilo-5MER into the clinical phase and look forward to advancing our product pipeline to address additional important indications for the benefit of patients around the world," noted Allen Baharaff, President and CEO of Galmed. Galmed is developing Amilo-5MER for multiple routes of administration and multiple indications. The Company plans to submit an IND for mild to moderate

ulcerative colitis in 2022.

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 collaborating with the Hebrew University in the development of Amilo-5MER, a 5 amino acid synthetic peptide.

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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For further information: For further information: Investor Contact: Guy Nehemya, Chief Operating Officer, Galmed Pharmaceuticals Ltd., investor.relations@galmedpharma.com, +972-3-693-8448

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