Galmed Pharmaceuticals

Galmed Reports Significant Anti-Fibrotic Effects of Aramchol in a Lung Fibrosis Model

- **Statistically significant clinical and histology improvements were also demonstrated in a model of inflammatory bowel disease (IBD)**
- **Data reinforcing the expansion of Aramchol's Clinical Development to Additional Indications**

TEL AVIV, Israel, July 7, 2022 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic, fibrosis and inflammatory diseases, announced today results showing significant effects of Aramchol in pre-clinical model of both lung and gastrointestinal (GI) fibrosis.

Fibrosis is a common complication of chronic inflammation and can affect all organs and tissues. To date, only limited anti-fibrotic drugs are approved or are in development, most of which have restricting side effects. Aramchol is a partial inhibitor of SCD1 with distinctive, direct, anti-fibrotic activity demonstrated in several pre-clinical models.

Treatment with Aramchol resulted in statistically significant fibrosis improvement in a validated bleomycin model of lung fibrosis (IPF), comparable to Pirfenidone which is the gold standard treatment. Findings were seen across all important indicators for the severity of fibrosis including hydroxyproline (a marker for collagen deposition in the fibrotic tissue) $P< 0.05$, Ashcroft score $P < 0.005$, % CPA (Percentage Collagen Proportionate Area of the lung) $P < 0.001$, and immunohistochemistry (type I collagen and a SMA) $P < 0.005$ for both staining.

Statistically significant improvements were also demonstrated in a validated DSS model of inflammatory bowel disease (IBD). Dextran sulfate sodium (DSS) induced colitis model is widely used because of its similarities with human ulcerative colitis. Clinical improvements were statistically significant at least by p value < 0.05 while in histological score (based on inflammation and colon structural changes) significance was as low as $p<0.01$. Aramchol was found to be the most effective compound tested. Control groups included 5-ASA and local steroids which are the gold standards for current treatment.

Galmed continues to assess Aramchol's anti-fibrotic effects also in kidney and skin.

"I am excited with today's news showing that established data about the role of SCD1 in lipid metabolism and fibrosis in the liver, is being replicated in other organs. Today we show that Aramchol's effect is evident in other organs, such as lung and gastrointestinal tract and may be as substantial as the one observed in the liver. The new findings, together with the robust anti-fibrotic effects demonstrated in clinical studies of patients with NASH and advanced fibrosis could potentially enable Galmed to quickly transition to Phase 2/3 clinical studies with Aramchol in indications with unmet need and faster

development pathways." stated Allen Baharaff co-founder, President and CEO of Galmed."

About Idiopathic pulmonary fibrosis (IPF)

Idiopathic pulmonary fibrosis (IPF) is a severe, chronic, progressive, fibrotic interstitial disease of unknown etiology, which remains an unmet need despite approved treatments which are limited by side effects. Bleomycin, an anti-neoplastic agent that causes lung fibrosis in human patients, has been used extensively in rodent models to mimic IPF and serves as the standard agent for induction of experimental pulmonary fibrosis in animals. Bleomycin reproduces typical features of the human disease.

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 registrational study. Galmed is also collaborating with the Hebrew University in the development of Amilo-5MER, a 5 amino acid synthetic peptide.

About Aramchol

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.

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; Galmed's expectations regarding licensing, acquisitions and strategic operations; and the outcome of any evaluation of Galmed's strategic alternatives. 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 May 2, 2022, 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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