Galmed Pharmaceuticals

Galmed updates business and clinical development strategy to better leverage Aramchol's anti-fibrotic effects

- **Recent data reinforce the anti-fibrotic activity of Aramchol previously observed in a wide range of pre-clinical models, in addition to the known effects in liver fibrosis**
- **The Open-Label Part of the ARMOR study met its objectives demonstrating consistent anti-fibrotic effects at 48 weeks in NASH patients and will be discontinued**
- **Cost reduction will allow rapid transition to anti-fibrotic indications with high unmet need and faster development pathways**
- **Company evaluating strategic alternatives to enhance shareholder value**

TEL AVIV, Israel, May 17, 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 the Company's clinical development strategy will expand into new anti-fibrotic indications to maximize the potential of its lead compound, Aramchol while at the same time discontinuing the Open Label Part of the Armor Study having reached its objectives.

Expansion of Aramchol's clinical development to additional indications provide a potentially faster development pathway for regulatory approval based on three important factors: positive results from the first part of the ARMOR study showing a consistent antifibrotic effect, the timing of the initiation of the Double-Blind Part with the improved formulation of Aramchol Meglumine, and the pre-clinical data supporting the anti-fibrotic activity of Aramchol in other fibrotic and pro-fibrotic indications. The change aims to maximize the potential of Aramchol with better use of Company resources.

The Company believes that the positive results obtained from the Open Label Part already provide sufficient data with regards to treatment duration, magnitude and consistency of effect, and taking into consideration biopsy reading challenges and potential new biopsy reading modalities, the Company concluded that the Open-Label Part has met its objective. At this stage continuing the Open Label Part as a standalone study is not expected to provide additional data to justify its continuation.

In connection with the shift in development strategy, the Company is initiating a comprehensive plan which includes a cost reduction effort which will enable Galmed to develop Aramchol for new fibrotic indications with high unmet need and faster development pathways, while preparing for the registrational part of the ARMOR study which is expected to commence in the second half of 2023. To date, only limited anti-fibrotic drugs are approved or are in development, most of which have restricting side effects. The distinctive, direct anti-fibrotic mechanism of action of Aramchol and long-term safety profile demonstrated so far in advanced clinical studies make Aramchol a promising candidate for such indications. Galmed expects to be able to leverage in part the current clinical data to rapidly progress Aramchol into Phase 2 and 3 studies in new indications for use as monotherapy and in-combination.

Allen Baharaff, Co-founder, President and CEO of Galmed commented "Over the last year we have seen

highly encouraging data of Aramchol's anti-fibrotic effects. Together with the extended patent for Aramchol meglumine to 2038, I am excited to prioritize anti fibrotic indications for Aramchol. Galmed remains optimistic that future years will see a breakthrough in the treatment of NASH and that Aramchol will be among the leading future NASH drug candidates. Simultaneously, Galmed is evaluating its strategic alternatives and its structuring to best enhance shareholder value and achieve its goals".

The Company has not stated a definitive timeline for completion of the evaluation process and there can be no assurance that the evaluation process will result in Galmed pursuing any strategic alternative, or that a strategic alternative, if any, would be completed successfully or at all. There can be no assurance that the review will result in any transaction or other strategic change or outcome. The Company does not intend to comment further until it determines that further disclosure is appropriate or necessary.

About Galmed Pharmaceuticals Ltd.

Galmed Pharmaceuticals Ltd. is a clinical stage drug development biopharmaceutical company for liver, metabolic and inflammatory diseases. Galmed's 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.

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 COVID19 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 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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