Galmed Pharmaceuticals

Galmed Announces Issuance of New Composition of Matter Patent for Aramchol meglumine Salt

- **Expands foundational patent protection for Galmed's innovative first-in- class drug Aramchol through the end of 2034**
- **This patent provides protection for Aramchol *per se*, not limited to any therapeutic application, and protects its use in the treatment of NASH & Fibrosis**

TEL AVIV, Israel, Feb. 8, 2023 /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 United States Patent and Trademark Office (USPTO) granted Galmed United States Patent 11,571,431 B2, which is expected to provide exclusivity of Aramchol meglumine salt until December 2034. With the latest patent, Galmed is fortifying the IP protection of its lead compound, Aramchol, extending Aramchol's IP protection until end of 2038 (for its longest-term patent in US).

Similar composition of matter patents have been granted in Canada, Europe, Australia, China, Hong-Kong, Korea, Israel, Japan and other territories for Aramchol salts. Specifically, the invention provides the Aramchol amine salts and use thereof in medical treatment having advantageous physicochemical properties. In particular, the N-methylglucamine (meglumine) salt has been shown to possess advantageous properties, including increased solubility, as well as increased absorption and exposure, which correlate with higher bioavailability. These patents further confirm Galmed's innovative drug developments are covered by the same level of robust protection as traditional new chemical entities.

In total, Galmed's research and development platform has produced a patent portfolio comprising over 20 issued patents covering key pharmaceutical markets.

"*This new patent which covers critical compositions of matter enhances our already robust patent portfolio, further strengthening and extending the potential commercial horizon for Aramchol*," said Allen Baharaff, President and Chief Executive Officer of Galmed Pharmaceuticals. *"We expect that this long patent runway will assist us in maximizing the full therapeutic potential of Aramchol, which we are currently investigating across a number of potential anti-fibrotic indications."*

Galmed Pharmaceuticals Ltd.

We are a biopharmaceutical company focused on the development of Aramchol. Historically, we have focused almost exclusively on developing Aramchol for the treatment of liver disease. We are also collaborating with the Hebrew University in the development of Amilo-5MER, a 5 amino acid synthetic peptide.

Forward-Looking Statements:

Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, our ability to identify, evaluate and complete any strategic alternative that yields value for our shareholders; the timing and cost of our any pre-clinical or clinical trial, for our product candidates; completion and receiving favorable results of any pre-clinical or clinical trial; regulatory action with respect to Aramchol or any other product candidate by the U.S. Food and Drug Administration, or the FDA, or the European Medicines Authority, or EMA, including but not limited to acceptance of an application for marketing authorization, review and approval of such application, and, if approved, the scope of the approved indication and labeling; the commercial launch and future sales of Aramchol and any future product candidates; our ability to comply with all applicable post-market regulatory requirements for Aramchol or any other product candidate in the countries in which we seek to market the product; our ability to achieve favorable pricing for Aramchol or any other product candidate; our expectations regarding the commercial market for non-alcoholic steato-hepatitis, or NASH, in patients or any other targeted indication; third-party payor reimbursement for Aramchol or any other product candidate; our estimates regarding anticipated capital requirements and our 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; our ability to obtain and maintain adequate protection of our intellectual property; the possibility that we may face third-party claims of intellectual property infringement; our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; our ability to establish adequate sales, marketing and distribution channels; intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do; the development and approval of the use of Aramchol or any other product candidate for additional indications or in combination therapy; our ability to maintain the listing of our ordinary share on The Nasdaq Capital Market; and our expectations regarding licensing, acquisitions and strategic operations. We believe these forward-looking statements are reasonable; however, these statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in our Annual Report on Form 20-F for the year ended December 31, 2021 filed with the SEC on May 2, 2022 in greater detail under the heading "Risk Factors" and elsewhere in the Annual Report, in our Reports on Form 6-K filed with the SEC on August 4, 2022 and November 16, 2022 and this press release. Given these uncertainties, you should not rely upon forward-

looking statements as predictions of future events. All forward-looking statements attributable to us or persons acting on our behalf speak only as of the date hereof and are expressly qualified in their entirety by the cautionary statements included in this report. We undertake no obligations to update or revise forward-looking statements to reflect events or circumstances that arise after the date made or to reflect the occurrence of unanticipated events. In evaluating forward-looking statements, you should consider these risks and uncertainties.

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