Galmed Pharmaceuticals

Galmed Announces an Expansion of its Activities to Cancer and major Cardiometabolic Diseases

- Aramchol is the most clinically advanced, first-in-class, Stearoyl-CoA desaturase1 (SCD1) oral inhibitor, demonstrating in Ph2 and Ph3 (open label part) an excellent safety profile with metabolic and anti-fibrotic effects.
- Galmed raised an aggregate of $7.5 million in warrant exercises and drawdowns on its recently adopted equity line

TEL AVIV, Israel, Sept. 19, 2024 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for fibroinflammatory indications announced today that based on the recently published results from the Open-Label part of its Phase 3 NASH study, new scientific publications on the role of SCD1 as a critical metabolic signaling hub as well as an extended cash runway, it plans to broaden its drug development activities.

The planned expansion consists of two additional programs over the next two years. One program aims to identify novel Aramchol-based drug combinations to overcome resistance to standard-of-care oncological treatments for patients with advanced colorectal and hepatic cancers. Another program aims to unravel new mechanisms of action that will allow the development of a novel Aramchol-based drug combination targeting cardiac fibrosis, or scarring of the heart, which occurs in many cardiovascular diseases that can lead to heart dysfunction and failure. The Company plans on releasing new data from in-vitro and ex-vivo studies in these programs during the fourth quarter of 2024.

Recent scientific publications reveal that:

- SCD1 inhibition emerges as a novel therapeutic strategy for clinically important cardiometabolic diseases which affect more than 60 million people in the United States alone.
- The combination of SCD1 inhibitor with standard-of-care oncology agents has the potential of the prevention of drug resistance thus ameliorating the prognosis of patients with hepatoma (hepatocellular carcinoma, HCC), colorectal cancer and glioma (GBM).
- The newly discovered link between lipid metabolism and synucleinopathies (Parkinson

disease and some forms of dementia) provides validation of SCD inhibition as a neuroprotective treatment.

Allen Baharaff, President and CEO of Galmed Pharmaceuticals commented: "The conditions Galmed plans to focus upon in the coming years are major public health problems impacting millions of people worldwide and posing huge financial burden on health providers. SCD1 is a key enzyme that critically regulates many physiological processes, thereby promoting the progression of cardiovascular, cancer and neurodegenerative diseases. We are leveraging on two decades of development of the most clinically advanced SCD1 inhibitor (Aramchol) to date as we broaden our drug development activities. Recent scientific breakthroughs identifying the role of SCD1 as a "master-switch" in lipid metabolism together with our recent infusion of cash, encourage us to expand from liver diseases to major cardiometabolic and cancer indications in dire need of new therapies. In this research, Galmed is collaborating with both leading academia and industry, employing cutting-edge drug development methodologies like AI data mining and proprietary "organ-on-a-chip" systems to accelerate our development processes."

About Galmed Pharmaceuticals Ltd.

We are a biopharmaceutical company focused on the development of Aramchol. We have focused on developing Aramchol for the treatment of liver disease and have been developing Aramchol for PSC and exploring the feasibility of developing Aramchol for other fibroinflammatory and oncological indications outside of liver disease. We are also collaborating with the Hebrew University in the development of Amilo5MER, 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. Forward-looking statements may include, but are not limited to, statements relating to our objectives plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that we intend, expect, project, believes or anticipate will or may occur in the future. 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, the timing and cost of 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, 2023 filed with the SEC on April 4, 2024 in greater detail under the heading "Risk Factors." 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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