Galmed Pharmaceuticals

Galmed publishes Results from Aramchol Phase 3 Open Label part in Hepatology

- The paper re-iterates the significant anti-fibrotic effect of Aramchol 300mg BID in patients with metabolic dysfunction associated steatohepatitis (MASH)
- Data is confirmed using 3 objective measurements; NASH CRN, paired ranked reading, and Artificial Intelligence (AI) quantitative digital analysis
- Continuous histological fibrosis scores generated in antifibrotic trials by digital pathology images analysis (DIA) quantify antifibrotic effects with greater sensitivity and larger dynamic range than Conventional Pathology

TEL AVIV, Israel, Sept. 25, 2024 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and fibro-inflammatory diseases announced today that the one-year results of the Open-Label part (ARCON) of its global Phase 3 trial of Aramchol in 150 patients with NASH and fibrosis (ARMOR) have been published in Hepatology.

Previously, Galmed reported results from the Open-Label part of its Phase 3 NASH study, which demonstrated that treatment with Aramchol 300mg BID resulted in a high rate of subjects with histological fibrosis improvement.

Aramchol is the most advanced down regulator of SCD-1 (Stearoyl – CoA desaturase) in clinical development. Inhibition of SCD-1 has been recently investigated in multiple indications, re-emphasizing its metabolic master switch potential and importance in multiple organs and activities. Aramchol, by targeting this single receptor, induces a cascade of events that leads to two main changes; in hepatocytes, Aramchol elevates the fatty acids oxidation (or in other words – fat burn) and influences AMPK, which results also in reducing glycemic parameters; and in hepatic stellate cells, Aramchol has been shown to down-regulate the expression and activity of stearoyl-CoA desaturase-1 (SCD-1), resulting in a direct effect on fibrogenesis.

Galmed has long believed that the optimum treatment for MASH will be combination therapy. The company further believes that Aramchol' s unique mechanism of action differentiates itself from others in the competitive landscape, potentially positioning it to work as a potent anti-fibrotic compound

alongside effective treatments in both approved and pre-approval stages.

Prof. Vlad Ratziu, Professor of Hepatology, Sorbonne Université, the paper's lead author and the ARMOR study co-principal investigator commented: "The publication of the results of the ARCON cohort in a prestigious medical journal such as Hepatology speaks to the interest of the scientific community towards this molecule with an innovative mode of action and its potential for treating fibrotic MASH. The rigorous multimodality histology assessment, using both conventional and FibroNest™ AI digital pathology (PharmaNest Inc, Princeton, USA), allowed us to see that the drug was working and identify changes of regression as well as affirming and extending findings of the AI Digital Pathology analysis that is relevant to all MASH studies."

"The publication in Hepatology highlights the significant potential of Aramchol as a therapeutic option for patients diagnosed with MASH and Fibrosis. We are grateful to all the patients and clinical sites that participated in the study around the world. Our sincere thanks to Prof. Vlad Ratziu, Prof. Arun Sanyal the study co-PIs, and Prof. Scott Friedman for their fruitful scientific and clinical guidance. We also extend our gratitude to Prof. Carolin Lackner, Prof. Cynthia Behling and Prof. William Cummings, the study pathologists for their meticulous reading and interest in exploring the benefits of Digital Pathology and Artificial intelligence in the context of MASH clinical trials", said Allen Baharaff, President and Chief Executive Officer of Galmed.

About Galmed Pharmaceuticals Ltd.

We are a biopharmaceutical company focused on the development of Aramchol. We have focused almost exclusively 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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