Galmed Pharmaceuticals

Galmed Announces Initiation of a Clinical Development Program to Evaluate Aramchol meglumine for the Treatment of Primary Sclerosing Cholangitis (PSC)

The clinical research and development program will be conducted in collaboration with the Stravitz–Sanyal Institute for Liver Disease and Metabolic Health Virginia Commonwealth University.

TEL AVIV, Israel, May 9, 2023 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and fibrotic diseases, today announced the initiation of a new clinical program to evaluate its lead compound, Aramchol meglumine for the Treatment of Primary Sclerosing Cholangitis (PSC).

PSC is a chronic cholestatic liver disease, characterized by progressive and multifocal fibrosis of the biliary system, which typically results in cirrhosis and fibrotic liver disease. It is a rare disease with no approved treatment that qualifies for the status of an orphan disease in the United States and EU; it is estimated that ~70% of the PSC patients have underlying IBD, most frequently ulcerative colitis (UC).

Galmed plans to initiate a Phase 2 study in the last quarter of 2023. The single-arm, open label, proof-of-concept clinical trial will evaluate the effects of 24 weeks of treatment with Aramchol meglumine in approximately 15 patients with PSC. The study's endpoints will include the conventional relevant laboratory parameters (alkaline phosphatase and bilirubin), sophisticated imaging including liver stiffness using MR Elastography (MRE), imaging of the biliary tract using MR cholangiopancreatography (MRCP) and hepatocyte-specific contrast agents, histological fibrosis and molecular assessment as well as a range of biomarkers of disease activity and fibrosis. These endpoints are expected to provide a robust assessment of the underlying disease and the effects of Aramchol.

Notably most patients in the study are expected to suffer also from UC. Building on the strong rationale and pre-clinical data supporting the use of Aramchol in IBD, the study will also assess the status of UC, inflammatory markers and patients related outcomes (PROs).

The study will be conducted at the Stravitz–Sanyal Institute for Liver Disease and Metabolic Health Virginia Commonwealth University with Dr. Sayed Obaidullah Aseem as Principal Investigator.

Prof. Arun Sanyal, Director, Stravitz-Sanyal Institute for Liver Disease and Metabolic Health at VCU commented "there is a great unmet need for development of effective therapeutics for primary sclerosing cholangitis. This proof-of-concept study should provide insights into the

translatability of the strong preclinical data on the utility of Aramchol on cholestasis-related fibrosis in humans with PSC and we are excited to test this new metabolically driven therapeutic approach for PSC."

Dr. Sayed Obaidullah Aseem commented "Aramchol has sound scientific rationale for use in fibrotic liver diseases. We are finding additional supportive data in pre-clinical models of PSC and cholestasis. Our initial clinical study will use state of the art modalities in addition to commonly used disease markers to develop the foundation for larger trials in PSC. This is an exciting opportunity in figuring out a treatment for PSC patients who currently do not have any effective options. "

Allen Baharaff, CEO and President of Galmed Pharmaceuticals commented "Looking at the significant anti fibrotic effects of Aramchol in the liver and the robust scientific rationale to use this compound for other fibrotic liver indications, we believe Aramchol has a promising clinical potential in patients with primary sclerosing cholangitis as well as for IBD. We look forward to the first clinical data during 2024 to further guide future development of Aramchol"

About Primary Sclerosing Cholangitis (PSC)

PSC is a rare chronic cholestatic liver disease characterized by fibroinflammatory destruction of the intrahepatic and/or extrahepatic bile ducts, leading to bile stasis, fibrosis, and ultimately to cirrhosis, and often requires liver transplantation.

PSC occurs more commonly in men and is typically diagnosed between the ages of 30 and 40. Most cases occur in association with inflammatory bowel disease (IBD).

The etiology of PSC is poorly understood, but an increasing body of evidence supports the concept of cholangiocyte injury as a result of environmental exposure and an abnormal immune response in genetically susceptible individuals.

Growing body of evidence suggests several treatment modalities mainly focusing on the inflammation aspect of this disorder, yet no effective therapy is available for halting disease progression.

Learn more about PSC at **https://www.niddk.nih.gov/health-information/liver-disease/primary-sclerosing-cholangitis/definition-facts**

About 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, 2022 filed with the SEC on March 29, 2023 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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