

Galmed Pharmaceuticals

## **Galmed Announces a delay in the initiation of its Primary Sclerosing Cholangitis (PSC) Phase 2a Study**

TEL AVIV, Israel, Nov. 20, 2023 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and fibrotic diseases, announced today a delay of at least 6 months in the initiation of its Primary Sclerosing Cholangitis (PSC) Ph 2a Study.

In May 2023, Galmed announced the pivoting of its clinical program to evaluate the safety and efficacy of its lead compound, Aramchol meglumine, for the treatment PSC. All work was designed to ensure the initiation of a proof-of-concept Phase 2a study in the last quarter of 2023. Prior to the initiation of the Ph 2a study, Galmed had planned to complete a Ph1 pharmacokinetic (PK) study to determine the bioavailability of the newly improved Aramchol meglumine formulation and then submit a new IND application for Aramchol meglumine for PSC to the US FDA.

Due to the unexpected events of October 7th, Galmed no longer will be able to meet the original planned timelines of its Ph1 study. As new time estimates depend on timelines established by our US and European partners and vendors, Galmed currently estimates a delay of 6-9 months in the initiation of the Ph2a PSC Study.

Allen Baharaff, CEO and President of Galmed Pharmaceuticals commented " The brutal attack of Hamas on October 7<sup>th</sup> resulted in a disruption of our work. Notwithstanding the Israel's declaration of "being at war", over the past few weeks we have been returning to full activity together with our local vendors and consultants. The unfortunate events result in delays which would prohibit us from meeting our original timelines. We are diligently working together with our local and international partners to mitigate the delays and will continue to update as soon as practical".

About Galmed Pharmaceuticals Ltd.

We are a clinical stage biopharmaceutical company focused on the development of Aramchol for liver and fibro-inflammatory diseases. We have focused almost exclusively on developing Aramchol for the treatment of NASH and are currently developing Aramchol for PSC and exploring the feasibility of developing Aramchol for other fibro-inflammatory indications outside 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 steatohepatitis, 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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Additional assets available online: [Photos \(1\)](#)

<https://galmedpharma.investorroom.com/2023-11-20-Galmed-Announces-a-delay-in-the-initiation-of-its-Primary-Sclerosing-Cholangitis-PSC-Phase-2a-Study>