

## **Galmed to employ OnKai's disruptive Artificial Intelligence (AI) in its Planned Phase 2a Clinical Trial in PSC**

### **OnKai's AI models redefine the methodologies and economics of clinical trials**

TEL AVIV, Israel, July 10, 2023 /[PRNewswire](#)/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and fibrotic diseases, is delighted to announce the first step in its strategic partnership with OnKai, where OnKai will apply its artificial intelligence (AI), models for enrollment and execution of clinical trials in underserved communities, starting with Galmed's innovative Primary Sclerosing Cholangitis (PSC) clinical development program.

PSC is a rare, severe, chronic disease where progression is predominantly determined by biliary fibrosis. There are currently no approved drugs for the treatment of the disease, which gradually progresses to cirrhosis, often requiring liver transplantation. Aramchol has been shown to have anti-fibrotic effects in pre-clinical models in NASH idiopathic pulmonary fibrosis (IPF) and clinical studies in patients with NASH. The clinical development for PSC is expected to start with a Phase 2a study to be conducted at Virginia Commonwealth University beginning in the fourth quarter of 2023, followed by a Phase 2/3 confirmatory adaptive design trial.

OnKai's innovative planning tool is anticipated to generate a comprehensive enrollment plan for each trial phase utilizing five new participation models that OnKai designed for integrating underserved communities in clinical studies. OnKai's Smart-Grid AI Platform will continuously support the trial in the selected local clinics. Local clinics will receive the tools and fair compensation to accompany their patients throughout the process, ensuring individual needs are not disregarded.

The first of the five models to be applied by OnKai is TrialBridge. TrialBridge serves as a conduit, seamlessly linking free and available clinics with their patients to specialist centers, leveraging the role of the community in a patient's journey. This model enables patients equal access to quality care and, where possible, to clinical trials while maintaining continuity with their local clinic.

This collaboration presents a promising opportunity to foster mutual benefits between Galmed, its principal sites, and the relevant clinics in underserved communities.

Noam Smetana, OnKai CEO, commented, "I am thrilled about the potential of this innovative partnership to positively impact underserved communities across the US in the coming years. We believe that our project with Galmed, along with others at various stages in our pipeline, will significantly advance health equity within the network of clinics we collaborate with."

Allen Baharaff, CEO and President of Galmed Pharmaceuticals commented, "We are enthusiastic about employing OnKai's groundbreaking AI technology in our trial. The application of OnKai's AI platform is still emerging but potentially disruptive for the conduct of clinical trials. Not only does this partnership allow us to include a diverse population in our trials, but it is also expected that it will result in the faster approval and better site performance."

#### 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 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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Additional assets available online: [Photos \(1\)](#)

<https://galmedpharma.investorroom.com/2023-07-10-Galmed-to-employ-OnKais-disruptive-Artificial-Intelligence-AI-in-its-Planned-Phase-2a-Clinical-Trial-in-PSC>