Galmed Pharmaceuticals

Galmed Announces Allowance of New Patent for Aramchol for the Treatment of Pulmonary and Dermal Fibrosis

TEL AVIV, Israel, Sept. 26, 2023 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and fibrotic diseases announced today the allowance of a Japanese patent related to treatment of pulmonary and dermal fibrosis. A similar patent was already granted in Mexico. The approval of the patent in the US and the rest of the world is pending. With this latest patent, Galmed is strengthening and extending the patent protection of its lead compound, Aramchol, until November 2037.

Previously, Galmed reported results showing significant anti-fibrotic effects of Aramchol in a pre-clinical model of lung fibrosis. Treatment with Aramchol resulted in statistically significant fibrosis improvement in a validated bleomycin model of lung fibrosis (IPF), comparable to Pirfenidone which is the gold standard treatment. Findings were seen across all important indicators for the severity of fibrosis including hydroxyproline (a marker for collagen deposition in the fibrotic tissue) $P< 0.05$, Ashcroft score $P < 0.005$, % CPA (Percentage Collagen Proportionate Area of the lung) $P < 0.001$, and immunohistochemistry (type I collagen and a SMA) $P < 0.005$ for both staining.

Allen Baharaff, CEO and President of Galmed Pharmaceuticals, commented: "Fibrosis is a common complication of chronic inflammation and can affect all organs and tissues. To date, only limited anti-fibrotic drugs are approved or are in development, most of which have restricting side effects. These patents reinforce the value of Aramchol Meglumine as a potential treatment for a wide range of unaddressed fibrotic indications beyond our initial focus of the liver and bile duct."

About Idiopathic pulmonary fibrosis (IPF)

Idiopathic pulmonary fibrosis (IPF) is a severe, chronic, progressive, fibrotic interstitial disease of unknown etiology, which remains an unmet need despite approved treatments which are limited by side effects. Bleomycin, an anti-neoplastic agent that causes lung fibrosis in human patients, has been used extensively in rodent models to mimic IPF and serves as the standard agent for induction of experimental pulmonary fibrosis in animals. Bleomycin reproduces typical features of the human disease.

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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