Galmed Pharmaceuticals

Galmed Announces Approval of IND Application in China for Aramchol for the Treatment of NASH & Fibrosis in the Global Phase 3 ARMOR Registrational Study

China to Join Galmed's Phase 3 ARMOR Registrational Study for the Treatment of NASH & Fibrosis

TEL AVIV, Israel, May 3, 2021 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and inflammatory diseases announced today that the National Medical Products Administration (NMPA) has granted approval for the Investigational New Drug (IND) application for Galmed's Phase 3 ARMOR registrational study of Aramchol for the treatment of NASH & Fibrosis.

"With the increasing globalization of drug development, it has become essential that data from multi-regional clinical trials (MRCTs) is accepted by regulatory authorities across regions and countries as the primary source of evidence, to support and facilitate efficient marketing approval of drugs," said Allen Baharaff, Chief Executive Officer of Galmed. "In line with these considerations, the ARMOR study was designed as an MRCT in approximately 215 centers located in U.S., Europe, Latin America, Australia, and now China. Being granted the trial approval by the NMPA is of great significance as it brings us a step closer to offering an optimized new oral therapy to patients with NASH and fibrosis who now have very limited treatment options."

The ARMOR study is evaluating the efficacy and safety of Aramchol in subjects with NASH and fibrosis stages 2-3 who are overweight or obese and have prediabetes or type 2 diabetes. The study consists of two parts. The first part is an open-label study that is designed to evaluate the treatment response, pharmacokinetics and safety of twice daily administration (BID) of Aramchol 300mg and explore the kinetics of histological outcome measures as well as several non-invasive tests (including ProC3, ELF and Fibroscan) associated with NASH and fibrosis for the treatment duration of 24, 48 and 72 weeks. The second part is a randomized, double-blind, placebo-controlled study with a histology-based surrogate endpoint that is intended to serve as the basis for the submission of a marketing authorization application under regulatory provisions of accelerated/conditional approval. All subjects will continue with the same treatment assignment until study completion to confirm clinical efficacy. More information about the ARMOR Study may be found on ClinicalTrials.gov identifier: NCT04104321.

Nonalcoholic fatty liver disease (NAFLD), a precursor of NASH, has an estimated prevalence rate inChina

that is expected to increase from 15%-20% in 2018 to 25%-30% in 2033, driven by increasing prevalence of obesity and type 2 diabetes.

"The approval of the IND application of the ARMOR Study inChina is a significant milestone in the development of Aramchol for NASH patients," said Prof. Junqi Niu, Chief Physician, The First Hospital of Jilin University and ARMOR China Principal Investigator. "Drug development is globalizing with worldwide interaction, licensing, and cross-licensing as regional studies are recognized unfeasible and China has the size and resources to become a leader in pharmaceutical innovation. I am delighted that China will be taking part in the ARMOR regulatory Phase 3 study of Aramchol which is one of the most advanced therapeutic candidates for NASH and Fibrosis. We look forward to rapidly initiating enrollment in China later in H2 2021."

About Aramchol and Non-alcoholic Steatohepatitis (NASH)

Aramchol (arachidyl amido cholanoic acid) is a novel fatty acid bile acid conjugate, liver targeted SCD1 modulator, developed as an oral therapy for the treatment of nonalcoholic steatohepatitis ("NASH") and fibrosis. Aramchol's ability to modulate hepatic lipid metabolism was discovered and validated in animal models, demonstrating downregulation of the three key pathologies of NASH: steatosis, inflammation and fibrosis. The effect of Aramchol on fibrosis is mediated by downregulation of steatosis and directly on human collagen producing cells. Aramchol has been granted Fast Track Designation status by the FDA for the treatment of NASH.

NASH is an emerging world crisis impacting an estimated 3% to 5% of the U.S. population and an estimated 2% to 4% globally. It is the fastest growing cause of liver cancer and liver transplant in the U.S. due to the rise in obesity. NASH is the progressive form of non-alcoholic fatty liver disease that can lead to cardiovascular disease, cirrhosis and liver-related mortality.

About Galmed Pharmaceuticals Ltd.

Galmed Pharmaceuticals Ltd. is a clinical stage drug development biopharmaceutical company for liver, metabolic and inflammatory diseases. Our lead compound, Aramchol™, a backbone drug candidate for the treatment of NASH and fibrosis is currently in a Phase 3 registrational study. We are also collaborating with the Hebrew University in the development of Amilo-5MER, a 5 amino acid synthetic peptide.

Forward-Looking Statements:

This press release may include forward-looking statements. Forward-looking statements may include, but

are not limited to, statements relating to Galmed's objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that Galmed intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Many factors could cause Galmed's actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: the timing and cost of Galmed's pivotal Phase 3 ARMOR trial, or the ARMOR Study or any other pre-clinical or clinical trials; completion and receiving favorable results of the ARMOR Study for Aramchol or any other pre-clinical or clinical trial; the impact of the COVID-19 pandemic; regulatory action with respect to Aramchol or any other product candidate by the FDA or the EMA; the commercial launch and future sales of Aramchol or any other future products or product candidates; Galmed's ability to comply with all applicable post-market regulatory requirements for Aramchol or any other product candidate in the countries in which it seeks to market the product; Galmed's ability to achieve favorable pricing for Aramchol or any other product candidate; Galmed's expectations regarding the commercial market for NASH patients or any other indication; third-party payor reimbursement for Aramchol or any other product candidate; Galmed's estimates regarding anticipated capital requirements and Galmed's 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; the development and approval of the use of Aramchol or any other product candidate for additional indications or in combination therapy; and Galmed's expectations regarding licensing, acquisitions and strategic operations. More detailed information about the risks and uncertainties affecting Galmed is contained under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with the SEC on March 18, 2021, and in other filings that Galmed has made and may make with the SEC in the future. The forward-looking statements contained in this press release are made as of the date of this press release and reflect Galmed's current views with respect to future events, and Galmed does not undertake and specifically disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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For further information: Guy Nehemya, Chief Operating Officer, Galmed Pharmaceuticals Ltd., investor.relations@galmedpharma.com, +972-3-693-844

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