Galmed Pharmaceuticals

Galmed Continues to Drive Innovation with Three New US Patents Granted for Aramchol and its Meglumine Salt

TEL AVIV, Israel, Jan. 11, 2022 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (NASDAQ-CM: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and inflammatory diseases announced today that the United States Patent and Trademark Office (USPTO) granted Galmed new patents related to the use of Aramchol for the treatment of fibrosis and for the treatment for modulating gut microbiota. An additional patent grant protects the low dose composition of Aramchol salt until June 8, 2036. With these latest patents, Galmed is strengthening and extending the IP protection of its lead compound, Aramchol, until December 2038.

The three new patents relate to:

- The grant of a US patent (US 11,197,870 B2, expiring October 20, 2037) claims the use of Aramchol or salts thereof (e.g. Aramchol Meglumine) for the treatment of hepatic fibrosis. The patent supports the direct anti fibrotic effect of Aramchol in liver, where the hepatic fibrosis is not associated with NAFLD or NASH.
- The grant of a US patent (US 11,166,964 B2), directed to the use of Aramchol or salts thereof (e.g. Aramchol Meglumine) for the treatment of dysbiosis of the gastrointestinal (GI) tract opens potential new treatment modalities for Aramchol in GI pathology and extends Galmed's proprietary Aramchol Meglumine patent protection until December 1, 2038.
- The grant of a US patent (US 10,849,911 B2) for low dose composition of Aramchol salt extends Aramchol intellectual property protection until June 8, 2036, claiming a salt of Aramchol, including the Meglumine Salt, as a composition of matter and for the treatment of NAFLD and NASH.

"The past 12 months have been an exciting time for Galmed as we reported positive, interim data from the Open Label part of our Phase 3 ARMOR clinical trial for the treatment of NASH and fibrosis. As such, we are delighted that these newly granted patents help secure broad IP rights underpinning Aramchol and its salts. We believe the granting of these patents provides us the necessary protection to expand our clinical development program," noted Allen Baharaff, President and CEO of Galmed.

Galmed Pharmaceuticals Ltd.

Galmed Pharmaceuticals Ltd. is a clinical stage drug development biopharmaceutical company for liver, metabolic and inflammatory diseases. Their lead compound, Aramchol™, a backbone drug candidate for the treatment of NASH and fibrosis is currently in a Phase 3 registrational study. Galmed is 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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