Galmed Pharmaceuticals

Galmed and MyBiotics to Collaborate in Development of Bespoke Microbiome Signature for Aramchol

Collaboration Seeks to Enhance Response Rate and Identify Biomarker for Treatment of NASH and Fibrosis

TEL AVIV and REHOVOT, Israel, Nov. 9, 2020 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (NASDAQ: GLMD) and MyBiotics Pharma Ltd. announced today they have entered into a research and development collaboration agreement to identify and optimize the selected microbiome repertoire associated with the response to Aramchol. The research will also focus on development of a standalone microbiome-based treatment for non alcoholic steatohepatitis (NASH) and fibrosis.

Under the collaboration, MyBiotics will employ its proprietary SuperDonor technology in combination with its MyLiveIn computational AI and screening platforms to identify and optimize consortia of bacteria to reconstitute a NASH patient's gut flora in order to enhance Aramchol's clinical efficacy and response rate. The collaboration also aims to identify specific microbial biomarkers for Aramchol based on macrobiome data collected from Galmed's clinical studies that could serve as a biomarker for Aramchol at early stage of treatment.

MyBiotics' microbiome therapeutic technology enables the design of bespoke microbial consortia profiles based on MyBiotics' unique culturing and fermentation capabilities. The microbiome therapeutic technology is a nature-derived culturing and fermentation technology which can be leveraged for single strains, consortia of strains and whole microbiome solutions, integrated with a computational AI platform. It increases the bacterial diversity which can be leveraged for product candidates, and at the same time produces bacteria which are more resistant to gastrointestinal conditions, increasing bioavailability and colonization. The microbiome therapeutic technology was validated in multiple in-vitro and in-vivo models. MyBiotics' lead product candidate for treatment of recurring clostridium difficile infection (CDI), MBX-SD-202, is expected to enter Phase I clinical trials in 2021.

Prof. Scott Friedman, Dean for Therapeutic Discovery, Chief Division of Liver Diseases, Icahn School of Medicine at Mount Sinai, commented, "Galmed's strategic alliance with Mybiotics is both timely and exciting. The microbiome is a major driver of NASH that is still untapped yet offers great promise as a totally new approach to treat this challenging disease. I look forward to this relationship evolving successfully as we learn more about how to harness emerging knowledge about the microbiome in pursuit of better strategies for disease management."

"The collaboration, which aims to elevate the response rate of Aramchol, is part of our overall plan to maximize Aramchol clinical efficacy. This builds on our work to date that includes dosage optimization (a PK study that demonstrated 300 BID resulted in higher exposure of Aramchol by 53%), product optimization (development of Aramchol meglumine with higher solubility and lower variability) and

treatment duration optimization," stated Allen Baharaff, co-founder and CEO of Galmed. "Furthermore, with the growing interest around the microbiome as a novel drug modality, following the recent positive topline data from the SER-109 Phase 3 study, the combining of Galmed's proven track record in the NASH space coupled with MyBiotics novel and proprietary knowhow and core competences in the microbiome field, puts this collaboration at the forefront of the microbiome NASH therapeutic development space," added Mr. Baharaff.

David Daboush, co-founder and CEO of MyBiotics, commented, "The correlation of microbiome and multiple clinical conditions has been investigated and published in the last few years, particularly the correlation with NASH and fibrosis, which is well recognized. We, at MyBiotics, established our unique SuperDonor and MyLiveIn technologies that can be used for developing a possible solution for NASH and fibrosis. SuperDonor is an innovative alternative to FMT – it is safer, and able to produce 100's treatments from a single stool sample. We are very excited to enter into this collaboration with Galmed, a leading company in the development of therapeutics for NASH, and leverage our technology and knowhow to develop products which could provide better solutions to NASH patients around the world."

About Aramchol and Non-alcoholic Steatohepatitis (NASH)

Aramchol (arachidyl amido cholanoic acid) is a novel fatty acid bile acid conjugate, inducing beneficial modulation of intra-hepatic lipid metabolism. 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 MyBiotics

MyBiotics discovers and develops microbiome-based products aimed at restoring microbiome equilibrium for the therapeutics and food markets. MyBiotics' technologies are effective for single microbes, complex microbial consortia and whole microbiome products, and are integrated with a computational AI platform which enables the design of unique microbial consortia and whole microbiome profiles. The Company's pipeline includes MBX-SD-201 and MBX-SD-202, for Clostridium difficile Infection (CDI) developed for oral delivery, that may become the first alternative for fecal microbiota transplant (FMT). MBX-SD-202 is

planned to enter Phase I clinical studies in 2021. Additional products in the pipeline focus on woman's health, gastro and oncology indications, as well as probiotics and prebiotic programs.

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 and plan to initiate a first in human study by the fourth quarter of 2020.

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 12, 2020, 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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