

## **Galmed Pharmaceuticals and SAMIL Pharm Sign a License Agreement for the Commercialization of Aramchol™ in Korea**

TEL AVIV, Israel, July 28, 2016 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of a once-daily, oral therapy for the treatment of liver diseases, and SAMIL Pharm. Co., Ltd. ("Samil") today announced the execution of a license agreement (the "Agreement") for an exclusive, royalty-bearing license for the commercialization of Aramchol™ (with an option to manufacture) for the treatment of fatty liver indications including nonalcoholic steatohepatitis, or NASH, in the Republic of Korea, along (the "License").

Upon the signing of the Agreement, Samil will pay Galmed an up-front fee of approximately \$2.0 million. Samil has also agreed to pay additional clinical- and regulatory-based milestone payments, which may aggregate to \$6.0 million, as well as tiered, double-digit royalties payable on sales (under certain limitations). The funds provided by this Agreement will provide additional financing for Galmed's development programs. Additionally, following the ARREST Study, Samil has an option to extend the License to Vietnam, which, if exercised, would increase the clinical- and regulatory-based milestone payments.

"Samil has a focused, gastrointestinal- and liver-related therapeutic strategy, which represents about one-third of their 2015 annual sales, as well as proven commercialization capabilities in these areas," stated Allen Baharaff, Galmed's President and Chief Executive Officer. Mr. Baharaff continued, "Since 2007, we have developed a deep relationship with Samil's executive management and are enthusiastic to ink our first commercial partnership with Samil, and in Asia."

According to Samil and Korean-based key opinion leaders, the prevalence of fatty liver disease in Korea is significant, growing, and of serious medical concern. The prevalence of NAFLD in subjects with diabetes, obesity and dyslipidemia is estimated to range between 25-35% of the high-risk population<sup>1</sup>. Accordingly, Samil estimates that the addressable market of possible NASH patients in South Korea is between 500,000 to 1,000,000<sup>2</sup>.

Mr. Seung Bum Huh, Samil's President and Chief Executive Officer, added "Our focus on gastrointestinal and liver-related therapeutics is already evident in Korea, and we have every intention to fortify and build our capabilities, and range of drugs in this category even larger going forward." Mr. Huh continued, "We have evaluated a host of new therapeutics within the NASH category, and believe that Aramchol™ fits well into our strategy. "Furthermore, in the NASH space, we also believe Aramchol™ is uniquely positioned, as it targets the underlying cause of the disease, addresses both the hepatic and metabolic-related issues, and has demonstrated a clean safety profile in its clinical development to date," Mr. Huh

concluded.

### **About Nonalcoholic Fatty Liver Disease and Nonalcoholic Steatohepatitis:**

Nonalcoholic fatty liver disease (NAFLD) is the most common cause of chronic liver disease in the United States and it affects almost 30% of adults in Western countries. With climbing obesity rates and more sedentary patient populations, the prevalence of NAFLD is increasing worldwide and is becoming the predominant cause of chronic liver disease in parts of the world. NAFLD represents a spectrum of diseases ranging from simple excess liver fat, or steatosis, to nonalcoholic steatohepatitis (NASH). NASH is the progressive form of fatty liver disease that can lead to cardiovascular disease, cirrhosis and liver-related mortality in persons who drink little or no alcohol. NASH represents the more severe end of this spectrum and is characterized by steatosis, ballooning degeneration and lobular inflammation with or without fibrosis. Long-term risks of NASH include cardiovascular disease, cirrhosis, hepatocellular carcinoma and end stage liver disease requiring liver transplantation.

### **About Galmed Pharmaceuticals Ltd.:**

Galmed is a clinical-stage biopharmaceutical company focused on the development of a novel, once-daily, oral therapy for the treatment of liver diseases utilizing its proprietary first-in-class family of synthetic fatty-acid/bile-acid conjugates, or FABACs. Galmed believes that its product candidate, Aramchol™, has the potential to be a disease modifying treatment for fatty liver disorders, including NASH, which is a chronic disease that Galmed believes constitutes a large unmet medical need. Galmed is currently conducting the ARREST Study, a multicenter, randomized, double blind, placebo-controlled Phase IIb clinical study designed to evaluate the efficacy and safety of Aramchol™ in subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. More information about the ARREST Study may be found on [ClinicalTrials.gov identifier: NCT02279524](https://clinicaltrials.gov/ct2/show/study/NCT02279524).

### **About SAMIL Pharm. Co., Ltd.**

Founded in 1947 and headquartered in Seoul, South Korea, Samil Pharm. Co., Ltd. produces and supplies indispensable medicines for various diseases within the categories of prescription drugs, OTC and medical devices primarily in South Korea. Samil primarily focuses on gastroenterology, hepatology, ophthalmology and CNS indications, along with the respiratory drugs, genito-urinary drugs and circulatory drugs. The Company has formed several partnerships with global pharmaceutical companies as a part of its growth strategy.

### **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. Applicable risks and uncertainties include risks and uncertainties associated with the timing, progress and results of the Company's research, preclinical studies and clinical trials as well as risks and uncertainties identified under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with the Securities and Exchange Commission, or the SEC, on March 22, 2016, 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.*

<sup>1</sup> Deepak N A, Etsuko H. et. al. How common is non-alcoholic fatty liver disease in the Asia-Pacific region and are there local differences? Journal of Gastroenterology and Hepatology 22 (2007) 788-793.

<sup>2</sup> Lee JY, Kim KM, Lee SG, Yu E, Lim YS, Lee HC, et al. Prevalence and risk factors of non-alcoholic fatty liver disease in potential living liver donors in Korea: a review of 589 consecutive liver biopsies in a single center. J Hepatol 2007;47:239-244.

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For further information: Josh Blacher, CFO, Galmed Pharmaceuticals Ltd., [josh@galmedpharma.com](mailto:josh@galmedpharma.com), +1-646-780-7605

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