Company Profile for Galectin Therapeutics Inc.

06/22/18

Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver disease and cancer. Galectin's lead drug (GR-MD-02) is a carbohydrate drug that inhibits the galectin-3 protein that is directly involved in multiple inflammatory, fibrotic, and malignant diseases. The lead development program is in non-alcoholic steatohepatitis (NASH) with cirrhosis, a more advanced form of NASH-related fibrosis. This is one of the most common liver diseases and is believed to be amongst the largest drug development opportunities available today. As many as one in four people globally suffer from fatty liver disease, also known as NASH (non-alcoholic steatohepatitis), with a lifetime risk of approximately 20 million liver-related deaths among fatty liver disease patients currently alive. Currently, the only treatment for patients with NASH and cirrhosis is a liver transplant. The potential market opportunity for drugs targeting NASH and cirrhosis is projected by analysts to be $35 - $40B worldwide by 2025. Additional exploratory development programs are in combination immunotherapy for advanced melanoma and other malignancies. Galectin seeks to leverage extensive scientific and development expertise, as well as established relationships with external sources, to achieve cost-effective and efficient development.

GR-MD-02 is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of fatty liver disease and fibrosis. Galectin-3 plays a major role in diseases that involve scarring of organs including fibrotic disorders of the liver, lung, kidney, heart and vascular system. The drug binds to galectin-3 proteins and disrupts their function. Preclinical data in animals have shown that GR-MD-02 has robust treatment effects in reversing liver fibrosis and cirrhosis as well as experimentally induced pulmonary, renal, vascular and cardiac fibrosis.

The target population of the Phase 3 clinical program will be patients with NASH cirrhosis without esophageal varices. The basis for advancing the drug product to Phase 3 is positive effects of GR-MD-02 on hepatic venous pressure gradient (HVPG) and possible prevention or postponement of development of esophageal varices observed in the Phase 2 NASH-CX trial, which was reported on Dec. 5, 2017. The Company believes the NASH-CX trial is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in these patients. The primary endpoint will be chosen from two endpoints that the FDA agreed may be acceptable: A change in HVPG, which is a measure of liver blood pressure, or progression to esophageal varices. Both primary endpoints may be considered surrogate endpoints for clinical outcomes in the target population with NASH cirrhosis. The potential choice between two primary endpoints for Phase 3 trials provides enhanced flexibility in designing the strongest trial to replicate the efficacy demonstrated in the Phase 2 NASH-CX trial. Additionally, the clinical trial design discussed with the FDA provides for interim analysis which may provide confirmation of Phase 2 results and enhanced confidence for the ultimate results of the Phase 3 trial. Please review important additional information available at www.galectintherapeutics.com.

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