



## **Galectin Therapeutics to Present Data on Liver Cirrhosis at the 9th Edition of the Paris NASH meeting, at Institut Pasteur, September 7th & 8th 2023**

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NORCROSS, Ga., Sept. 07, 2023 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, announced today the Company will participate in the 9<sup>th</sup> Edition of the Paris NASH meeting, where a select group of international experts gather each year at the prestigious Institut Pasteur in Paris to discuss the latest scientific and clinical research developments in non-alcoholic steatohepatitis (NASH) and its complications, including liver cirrhosis. This year, Galectin Therapeutics, in collaboration with HistoIndex of Singapore, will present a poster on the use of artificial intelligence to better explore the complex histology of liver cirrhosis resulting from NASH and highlight potential differences between lean cirrhotic patients and overweight/obese cirrhotic patients.<sup>1</sup>

Pol Boudes, MD, Chief Medical Officer of Galectin Therapeutics, commented: "Artificial Intelligence is an interesting tool that can improve the definition, description, and understanding of architectural changes in the liver tissue of cirrhotic patients. Current histology methods are not precise enough to be clinically relevant to stage the cirrhotic process and, consequently, are not generally used in clinical practice. Conventional histology is also not granular enough and not quantitative enough to evaluate the efficacy of candidate drugs. We are happy to contribute to the scientific progress in this field by sharing our data collected in our previous phase 2 cirrhosis program and by using the innovative technology that our colleagues at HistoIndex have developed."

Dr. Boudes continued: "The Paris meeting is another opportunity to discuss our innovative pivotal program regarding patients with portal hypertension that results from NASH cirrhosis. We are using an innovative clinical outcome criteria – the prevention of esophageal varices, a direct consequence of portal hypertension – to evaluate the efficacy of belapectin. We have now collected more than 500 video recordings of esophago-gastro-duodeno endoscopies in this patient population and, at the appropriate time, we will be very excited to share the unique set of data we have collected with the medical, patient, and regulatory communities."

<sup>1</sup> Akbary K, Ren Y, Tai D, Inkmann M, Boudes PF. Comparing fibrosis distribution in lean versus overweight/obese NASH-cirrhosis patients using SHG/TPE microscopy: an observational analysis. 9<sup>th</sup> Paris NASH Meeting, Sept 7-8, 2023

### **About Belapectin**

Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH when it has progressed to the liver cirrhosis stage as well as advanced cancers. Galectin-3 is produced by activated macrophages, a key inflammatory cell, and plays a major role in diseases that involve scarring of organs, including fibrotic disorders of the liver, lung, kidney, heart, as well as in the cancerous tumor microenvironment. Belapectin binds to galectin-3 and disrupts its function. Belapectin, because of its unique structure, is also captured by activated macrophages and exerts its activity directly at the source of galectin-3 production. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis associated with liver cirrhosis, a disease that is characterized by an invasion of activated macrophages into the liver parenchyma. A Phase 2 study showed belapectin may prevent the development of esophageal varices in NASH cirrhosis, and these results provide the basis for the conduct of the NAVIGATE trial. The NAVIGATE trial ([www.NAVIGATENash.com](http://www.NAVIGATENash.com)), titled "A Seamless Adaptive Phase 2b/3, Double-Blind, Randomized, Placebo-controlled Multicenter, International Study Evaluating the Efficacy and Safety of Belapectin for the Prevention of Esophageal Varices in NASH Cirrhosis," completed randomization of 357 patients in February 2023 with top-line data expected from the Phase 2b portion in the fourth quarter of 2024, and is posted on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04365868). Galectin-3 has a significant role in cancer, in making the tumor microenvironment resistant to immunological treatment, and the Company has supported a Phase 1b study in combined immunotherapy of belapectin and Keytruda in advanced melanoma and in head and neck cancers. This trial provided a strong rationale for moving forward into a Company-sponsored Phase 2 development program, which the company is exploring.

### **About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis**

Non-alcoholic steatohepatitis (NASH), a complication of fatty liver disease, has become a common disease of the liver with the rise in obesity and other metabolic diseases. NASH is estimated to affect up to 28 million people in the U.S. It is characterized by the presence of excess fat in the liver along with inflammation and hepatocyte damage in people who consume little or no alcohol. Over time, patients with NASH can develop excessive fibrosis, or scarring of the liver, and ultimately liver cirrhosis. It is estimated that as many as 1 to 2 million individuals in the U.S. will develop cirrhosis as a result of NASH, for which liver transplantation is the only curative treatment available. Approximately 9,000 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis or cirrhosis.

### **About Galectin Therapeutics**

Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver disease and cancer. Galectin's lead drug belapectin (formerly known as GR-MD-02) is a carbohydrate-based drug that inhibits the galectin-3 protein, which is directly involved in multiple inflammatory, fibrotic, and malignant diseases, for which it has Fast Track designation by the U.S. Food and Drug Administration. The lead development program is in non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH-related fibrosis. This is the most common liver disease and one of the largest drug development opportunities available today. Additional development programs are in treatment of combination immunotherapy for advanced melanoma and other malignancies. Advancement of these additional clinical programs is largely dependent on finding a suitable partner. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. Additional information is available at [www.galectintherapeutics.com](http://www.galectintherapeutics.com).

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*Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc. Belapectin is the USAN assigned name for Galectin Therapeutics' galectin-3 inhibitor GR-MD-02.*