



## UPDATE – Galectin Therapeutics to Present Six Scientific Abstracts at The Liver Meeting™ 2021, Hosted by the AASLD

10/27/21

- **New data regarding the mechanism of action of belapectin to inhibit galectin-3**
- **Unique pharmacokinetic profile of belapectin in patients with hepatic insufficiency**
- **Innovating in Liver Cirrhosis: Belapectin's NAVIGATE phase 2b/3 study design**
- **New data regarding correlation between routine liver tests and portal hypertension**
- **Impact of NASH cirrhosis on patients' Quality of Life**
- **Use of Artificial Intelligence to further understand the histology of Liver Cirrhosis**

NORCROSS, Ga., Nov. 05, 2021 (GLOBE NEWSWIRE) -- [Galectin Therapeutics Inc.](#) (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, today announced that it will present six scientific abstracts at The Liver Meeting™ 2021, hosted by the American Association for the Study of Liver Diseases (AASLD), to be held virtually from November 12 to 15, 2021.

"Much of the focus on non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) has been on preventing the progression to liver cirrhosis, but there has been little focus on treating those affected with actual NASH cirrhosis. We are dedicated to change this situation, and our objective is to bring new solutions to cirrhotic patients, as they are in greatest need of therapeutic options," said Pol Boudes, M.D., Chief Medical Officer for Galectin Therapeutics. "Our work in developing belapectin, our galectin-3 inhibitor, focuses on the prevention of esophageal varices in NASH cirrhosis patients. We have generated a wealth of new data on NASH cirrhosis and portal hypertension and we are pleased to share this research at The Liver Meeting. Also, NAVIGATE, our phase 2b/3 global study, represents a new way to undertake clinical research in cirrhotic patients, and we hope this will trigger the interest of the hepatic community and drug developers around the world in addressing this devastating disease."

These abstracts will be available for viewing by attendees on the AASLD website and are also featured in the October supplement to the AASLD journal, *Hepatology*.

### Presentation Details

#### **Title: Mechanism of galectin-3 binding by belapectin, a galectin-3 inhibitor developed for NASH cirrhosis**

Galectin-3, a glycan binding protein, plays a central role to foster liver inflammation and fibrosis in NASH cirrhosis. Belapectin is a galectin-3 inhibitor in development for NASH cirrhosis. We use heteronuclear Nuclear Magnetic Resonance (NMR) spectroscopy to evaluate the intimate, and unique, binding of belapectin to galectin-3.

Publication Number: 2177

Authors: Pol Boudes, M.D.; Eliezer Zomer, Ph.D.; Harold Shlevin, Ph.D.

Session title: NAFLD and NASH: Therapeutics – Pharmacologic and Other

Date: Friday, November 12, 2021

Time: 6:00 am - 11:55 am ET

#### **Title: Pharmacokinetic exposure and safety of belapectin, a candidate treatment for NASH-cirrhosis, in patients with hepatic insufficiency**

We share interim results of an open-label Phase I study assessing the pharmacokinetic and safety profiles of belapectin, a galectin-3 inhibitor, in patients with different degrees of hepatic insufficiency.

Publication Number: 2177

Authors: Pol Boudes, M.D., Barbara Lomeli, M.D.; Eliezer Zomer, Ph.D.; Stephen A. Harrison, M.D.; Juan Rondon, M.D., J.D.; Eric Lawitz, M.D.

Session title: NAFLD and NASH: Therapeutics – Pharmacologic and Other

Date: Friday, November 12, 2021

Time: 6:00 am - 11:55 am ET

#### **Title: Innovating in cirrhosis: NAVIGATE, a seamless, adaptive, phase 2b/3 of belapectin, a galectin-3 inhibitor, for the prevention of esophageal varices in NASH cirrhosis**

Drug development in NASH cirrhosis is a challenge. The safety profile of candidate drugs is difficult to establish, particularly for liver-related side effects, there is no overall measure of liver function available, and there is no sensitive method to measure cirrhosis improvement on histology. These challenges led to the proposal of an innovative study design for the NAVIGATE Study. The study evaluates the risk/benefit of belapectin to prevent esophageal varices in NASH cirrhosis.

Publication Number: 2304

Authors: Pol Boudes, M.D.; Stephen A. Harrison, M.D.; Naga Chalasani, M.D.

Session title: NAFLD and NASH: Experimental: Clinical

Date: Friday, November 12, 2021

Time: 6:00 am - 11:55 am ET

#### **Title: Distribution of the AST/ALT (de Ritis) ratio in a cohort of patients with NASH cirrhosis and portal hypertension and correlation with portal pressure**

In patients with Non-Alcoholic Fatty Liver Disease (NAFLD), an increased AST/ALT ratio may indicate the progression to liver cirrhosis. This poster

uses data from Galectin Therapeutics' large Phase 2 clinical study in patients with well-documented liver cirrhosis due to NASH and hemodynamically measured portal hypertension. We explore whether the AST/ALT (de Ritis) ratio could be used as a simple, non-invasive way to estimate the degree of portal hypertension.

Publication Number: 2307

Authors: Pol Boudes, M.D.; Jörn M. Schattenberg, M.D.; Eric Lawitz, M.D.

Session title: Portal Hypertension and Other Complications of Cirrhosis: Varices and Bleeding

Date: Friday, November 12, 2021

Time: 6:00 am - 11:55 am ET

**Title: Features of portal hypertension predict health related quality of life over time in NASH cirrhosis**

Nonalcoholic steatohepatitis has a significant negative effect on health-related quality of life. In cirrhosis, age and features of clinically significant portal hypertension at baseline are determinants of lower quality of life.

Publication Number: 1687

Authors: Andrea Mladenovic, M.D.; Raj Vuppalanchi, M.D.; Pol Boudes, M.D.; Harold Shlevin, Ph.D.; Stephen A. Harrison, M.D.; Naga P. Chalasani, M.D.; Archita Parikh Desai, M.D.

Session title: NAFLD and NASH: Epidemiology and Natural History, Prevention and Outcomes

Date: Friday, November 12, 2021

Time: 6:00 am - 11:55 am ET

**Title: Development of machine learning histological scores that correlated with portal pressures and development of varices in NASH patients with cirrhosis**

In this study, portal pressure was accurately extrapolated from liver histology in patients with NASH cirrhosis by use of a machine learning algorithm. Clinically significant portal hypertension and the development of varices were also accurately predicted.

Publication Number: 1591

Authors: Mazen Nouruddin, M.D., MHSc; Zachary Goodman, M.D., Ph.D.; Dean Tai, Ph.D.; Yayun Ren Sr., Pol Boudes, M.D.; Elaine Lay Khim Chng, Ph.D. Harold Shlevin, Ph.D.; Stephen A. Harrison, M.D.; Naga P. Chalasani, M.D.

Session title: NAFLD and NASH: Diagnostics and Biomarkers

Date: Friday, November 12, 2021

Time: 6:00 am - 11:55 am ET

**About Belapectin**

Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH 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. Belapectin binds to galectin-3 and disrupts its function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis. 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 ([NAVIGATENash.com](http://NAVIGATENash.com)), entitled "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" began randomization of patients in August, 2020, and is posted on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04365868).

Galectin-3 also has a significant role in cancer, and the Company has supported a Phase 1b study in combined immunotherapy of belapectin and KEYTRUDA® in advanced melanoma and in head and neck cancer. This trial provided a strong rationale for moving forward into a Phase 2 development program, which the company is considering.

**About the American Association for the Study of Liver Diseases (AASLD)**

AASLD is the leading organization of scientists and health care professionals committed to preventing and curing liver disease. AASLD fosters research that leads to improved treatment options for millions of liver disease patients. It also advances the science and practice of hepatology through educational conferences, training programs, professional publications, and partnerships with government agencies and sister societies. AASLD's annual scientific conference, The Liver Meeting™, is the world's premier meeting on liver disease, bringing together clinicians, associates, and scientists from around the world to exchange information on the latest research, discuss new developments in liver treatment and transplantation, and network with leading experts in the field of hepatology.

**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 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).

**Forward Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future financial performance, and use words such as "may," "estimate," "could," "expect" and others. They are based on management's current expectations and are subject to factors and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include those regarding the hope that Galectin's development program for belapectin will lead to the first therapy for the treatment of fatty liver disease with cirrhosis and those regarding the hope that our lead compounds will be successful in cancer immunotherapy and in other therapeutic indications. Factors that could cause actual performance to differ materially from those discussed in the

forward-looking statements include, among others, that trial endpoints required by the FDA may not be achieved; Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of belapectin or any of its other drugs in development; the Company may not be successful in scaling up manufacturing and meeting requirements related to chemistry, manufacturing and control matters; the Company's current clinical trial and any future clinical studies as modified to meet the requirements of the FDA may not produce positive results in a timely fashion, if at all, and could require larger and longer trials, which would be time consuming and costly; plans regarding development, approval and marketing of any of Galectin's drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies; regardless of the results of any of its development programs, Galectin may be unsuccessful in developing partnerships with other companies or raising additional capital that would allow it to further develop and/or fund any studies or trials. Galectin has incurred operating losses since inception, and its ability to successfully develop and market drugs may be impacted by its ability to manage costs and finance continuing operations. Global factors such as coronavirus may continue to impact NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs. For a discussion of additional factors impacting Galectin's business, see the Company's Annual Report on Form 10-K for the year ended December 31, 2020, and subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

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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.*



Source: Galectin Therapeutics Inc.