Galectin Therapeutics

Media Fact Sheet

Galectin Therapeutics, Inc. (NASDAQ: GALT) is a clinical-stage biopharmaceutical company dedicated to developing novel therapies to improve the lives of patients with chronic liver disease and cancer. Galectin's lead drug candidate belapectin (formerly known as GR-MD-02) is a carbohydrate-based drug that inhibits galectin-3, a protein directly involved in multiple inflammatory, fibrotic, and malignant diseases processes. Belapectin's lead clinical development program in cirrhosis due to non-alcoholic steatohepatitis (NASH) has received a Fast Track designation by the U.S. Food and Drug Administration.

> **Galectin Therapeutics launched NAVIGATE, its international, seamless, adaptively designed Phase 2b/3 clinical trial of belapectin in NASH cirrhosis patients who have clinical signs of portal hypertension and are at risk of developing esophageal varices.**

Additional belapectin clinical development programs target advanced melanoma and other malignancies in combination with checkpoint inhibitors (e.g. Keytruda®).

Liver Fibrosis, Cirrhosis, and NASH

Liver fibrosis, caused by fatty liver disease, is a hidden epidemic across the world, largely driven by increases in obesity and diabetes. As many as one in four people globally suffer from fatty liver disease, which can progress to NASH and NASH cirrhosis as fibrosis increases. NASH is the most common liver disease and one of the largest drug development opportunities available today.

A key indicator for the prognosis for NASH cirrhosis patients is the development of esophageal varices, a widening of the veins in the esophagus caused by impeded blood flow. These varices can rupture and are then immediately life threatening. Approximately 50% of patients with NASH cirrhosis have no varices upon diagnosis and preventing the development of varices would be a major medical treatment benefit. Currently, the only treatment for patients with NASH cirrhosis is a liver transplant.

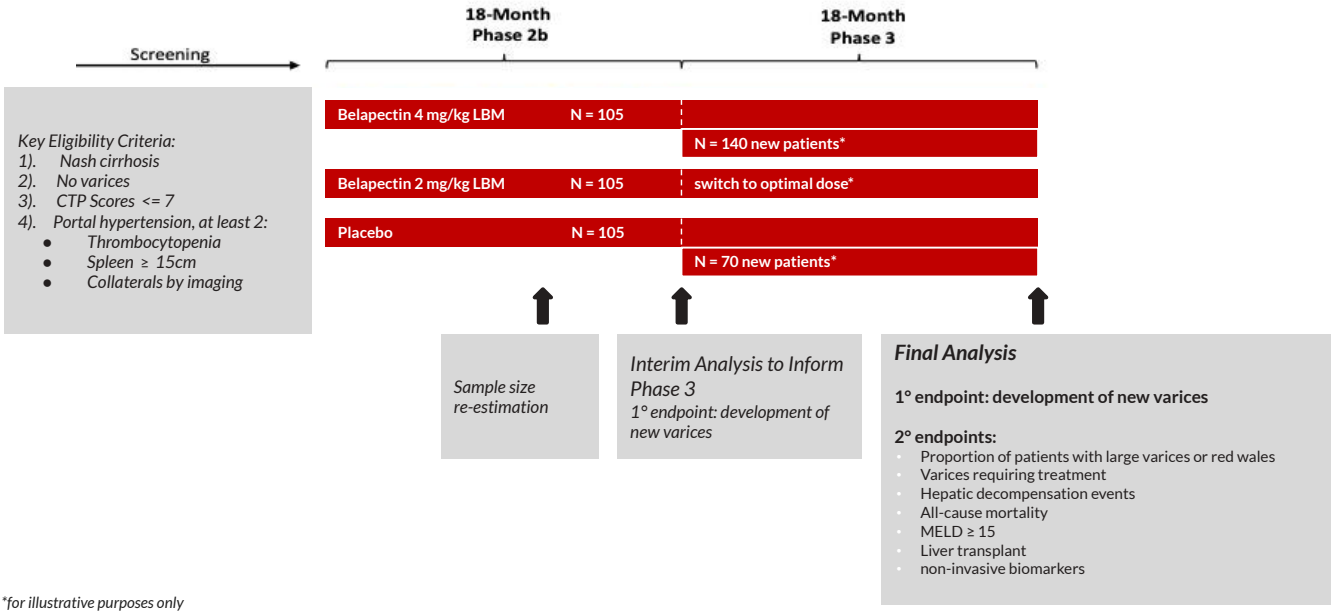
Galectin Therapeutics' previous Phase 2 NASH-CX trial showed belapectin could prevent the development of new varices in patients with compensated NASH cirrhosis who have not yet developed esophageal varices.[1]

Unlike most other clinical trials focused primarily on earlier stages of NASH, the NAVIGATE study involves patients with compensated liver cirrhosis. NAVIGATE is expected to enroll approximately 315 cirrhotic patients in the Phase 2b part of the trial at approximately 130 sites in 12 countries in North America, Europe, Asia and Australia. After all subjects in the Phase 2b component have completed 18 months of treatment and a gastro-esophageal endoscopic assessment, Galectin will undertake an Interim Assessment to determine what changes might be necessary during the Phase 3 component.

[1]Gastroenterology 2020;158:1334–1345

Interim Analysis between the Phase 2b arm of the NAVIGATE Study and the start of the Phase 3 component is expected in Q2 2023. The trial's adaptive design allows for patients to seamlessly transition from the Phase 2b component into the Phase 3 stage, as well as helps determine the optimal dose, confirms safety and efficacy, and re-evaluates the sample size and statistical power for the Phase 3 stage.

Belapectin Phase 2b/3 Adaptively Designed Trial



*for illustrative purposes only

Cancer Immunotherapy

Galectin-3 also plays a role in the immune response to cancer. Galectin Therapeutics is exploring belapectin in combination with immunotherapy in advanced melanoma and head and neck cancer. The company announced positive preliminary results from its Phase 1b clinical trial of belapectin with Keytruda®. Data showed an objective response rate of 50% in seven of fourteen patients in this study, compared to 33% in patients taking Keytruda® alone as reported in previous studies. Galectin Therapeutics is continuing its collaboration with Providence Cancer Institute to further expand the investigator-led trial.

About Galectin Proteins and Belapectin

Galectins are proteins that play a key role in the immune system, and the most important galectin is galectin-3. Although galectin-3 is normally expressed at low levels in many different cell types, it is overexpressed in the presence of an immune attack, particularly in macrophages. In cirrhosis, following constant immune stimulation, macrophages invade the liver and there is an increase in galectin-3 expression and production. Experiments in galectin-3 genetic knock-out animals and animal models treated with belapectin support the critical role of galectin-3 in the fibrotic process that creates liver cirrhosis.

Belapectin is a complex carbohydrate drug that binds and inhibits galectin-3. Because of its molecular structure belapectin is captured by macrophages and can inhibit galectin-3 at its site of production, notably in the cirrhotic liver. Belapectin has demonstrated low toxicity potential, as carbohydrates are generally metabolized to simple sugars with limited toxicity. This is important for cirrhotic patients, as their liver disease prevents them from metabolizing drugs, and they are potentially at increased risk of side effects.

Management Team

The management team at Galectin Therapeutics has significant drug-development, commercialization, and manufacturing experience in biotech and pharmaceutical companies.

CEO and President Joel Lewis has over 22 years of executive management experience where he has compiled an extensive track record of achieving high-impact results. Prior to joining Galectin Therapeutics, Mr. Lewis served for 13 years as the Managing Director of Shareholder Services at Uline, Inc. where he assisted Dick Uihlein and the other principals with financial strategies. Before his employment with Uline Inc., Mr. Lewis served as Tax and Accounting Manager for Century America LLC from 2001 to 2006. Mr. Lewis also worked for the accounting firm Deloitte & Touche from 1998 to 2001. Mr. Lewis has served on the Board of Directors of Galectin Therapeutics since December 2017.

Additionally, the team consists of the following: Pol F. Boudes, M.D., CMO; Jack W. Callicutt, CPA, CFO; Rex Horton, Vice President of Commercial Development, Regulatory Affairs and Quality Assurance; Eliezer Zomer, Ph.D, Vice President of Discovery Research and Product Development; and Harold H. Shlevin, Ph.D., Consultant, Director and former CEO.

Galectin Therapeutics
4960 Peachtree Industrial Blvd, Suite 240 Norcross, GA 30071 | 678-620-3186 | galectintherapeutics.com
Media contact: lexib@gregoryfca.com