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 the galectin-3 protein. Galectin-3 is directly involved in multiple inflammatory, fibrotic, and malignant diseases. Belapectin has received a Fast Track designation from the U.S. Food and Drug Administration.

Galectin's lead development program is in non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH-related fibrosis. Currently, these patients' only hope is to receive a liver transplantation.

> **In June 2020, Galectin Therapeutics launched its international, seamless, adaptively-designed NASH-RX 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 (ClinicalTrials.gov Identifier: NCT04365868).**

Additional belapectin development programs are in combination with immunotherapy for advanced melanoma and other malignancies. Preliminary results indicated that belapectin, when combined with pembrolizumab (KEYTRUDA®), a widely used check point inhibitor, could improve its efficacy and tolerance. Consequently, this study has been expanded to confirm these promising results (ClinicalTrials.gov identifier: NCT02575404).

NASH, Liver Fibrosis and Cirrhosis

NASH, caused by fatty liver disease, has reached epidemic proportions 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, as liver fibrosis increases, to NASH cirrhosis. NASH is the most common liver disease and one of the largest drug development opportunities available today. It is also anticipated that NASH cirrhosis will soon become the most frequent reason for liver transplantations.

A key indicator of prognosis for NASH cirrhosis patients is the development of esophageal varices, a widening of the veins in the esophagus caused by impeded blood flow called "portal hypertension." It is estimated that 50% of patients with NASH cirrhosis have no varices upon diagnosis.[1]

Galectin Therapeutics' previous Phase 2 NASH-CX trial showed belapectin could prevent the development of new varices in patients with compensated NASH cirrhosis without esophageal varices.[1]

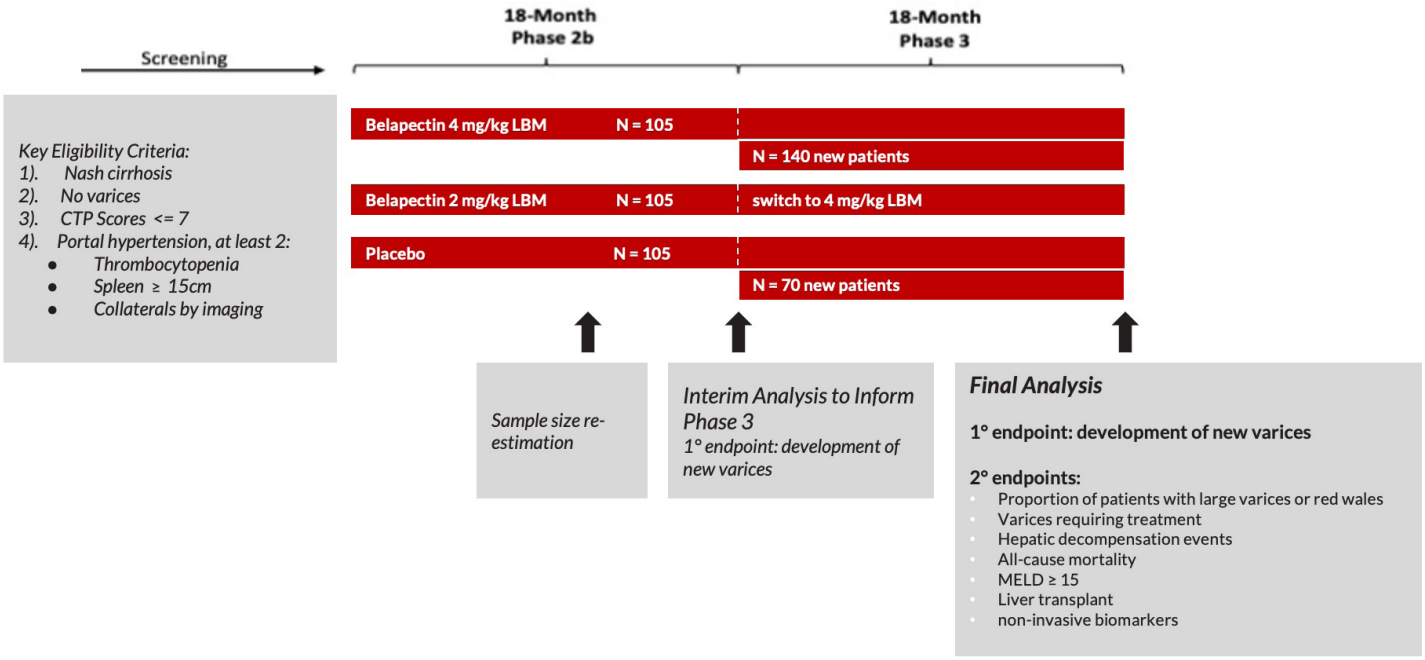
Unlike most other clinical trials focused primarily on earlier stages of NASH, the NASH-RX study involves patients with compensated liver cirrhosis, who have an urgent need for new therapies. NASH-RX is expected to enroll approximately 315 NASH patients in the Phase 2b part of the study at approximately 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

[1]Gastrointest Endosc. 2007 Jan;65(1):82-8

assessment, Galectin will perform an Interim Assessment to evaluate the results and determine what changes might be necessary during the Phase 3 component. At this time also, the study might be stopped for futility or overwhelming efficacy and a positive risk benefit profile.

Interim Analysis for the Phase 2b part is expected in Q2 2023. The trial's adaptive design provides for two paths to success. Patients will seamlessly transition from the Phase 2b into the Phase 3 stage, and the Interim Analysis provides for a determination of the optimal belapectin dose and re-evaluation of sample size to assure the statistical power for the Phase 3 stage.

Belapectin Phase 2b/3 Adaptively Designed Trial



Cancer Immunotherapy

Galectin-3 also plays a role in dampening the immune response in 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. The data showed a 50% objective response rate in advanced melanoma and a significant decrease in the frequency of suppressive myeloid-derived suppressor cells (MDSC) following treatment in the responding patients (on day 85 post-treatment). The combination was also well tolerated and appeared safe. The published data on KEYTRUDA alone have shown an objective response rate of 33% in this patient population.

We further expanded this study, in collaboration with Providence Cancer Institute, to confirm these encouraging preliminary results.

About Belapectin

Belapectin is a complex carbohydrate drug, that binds and inhibits galectin-3, a protein that plays a central role in inflammation, fibrogenesis, and tumor formation. Belapectin demonstrated activity to improve NASH fibrosis in animal models. Belapectin improved portal hypertension while reducing the

incidence of esophageal varices in selected patients. Belapectin has demonstrated low toxicity potential, as carbohydrates are generally metabolized to simple sugars with limited toxicity. Belapectin also appeared safe and well-tolerated in clinical trials conducted so far. These characteristics are essential to address the need of patients affected with liver cirrhosis, who have diminished capacity to metabolize drugs.

Management Team

The management team at Galectin Therapeutics has significant drug-development, manufacturing, and commercialization experience both in biotech companies and large 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 its co-founder, 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 management team consists of the following: Adam E. Allgood, Pharm.D., R.Ph., VP of Clinical Development and Clinical Operations; Pol F Boudes, M.D., CMO; Jack W. Callicutt, CPA, CFO; Rex Horton, Vice President of Commercial Development, Regulatory Affairs and Quality Assurance; Dr. Harold H. Shlevin, Ph.D., Consultant, Director and former CEO; and Eliezer Zomer, Ph.D, Vice President of Discovery Research and Product Development.

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