



October 3, 2016

## **Tobira Therapeutics Announces Presentations Related to Cenicriviroc's Development Program in NASH at the American Academy for the Study of Liver Diseases Annual Meeting**

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- Tobira Therapeutics, Inc. (NASDAQ:TBRA), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for non-alcoholic steatohepatitis (NASH) and other liver diseases, today announced upcoming data presentations at the American Academy for the Study of Liver Diseases (AASLD) Annual Meeting (the Liver Meeting®), being held in Boston, MA from November 11-15, 2016.

### **Poster Presentation Details**

Presentation Date/Time: Saturday, November 12, 2016; 5:30 p.m. - 7:00 p.m. ET

Title: Effect of Cenicriviroc on the Pharmacokinetics and Safety of HMG-CoA Reductase Inhibitors (Atorvastatin, Simvastatin and Rosuvastatin) in Healthy Subjects

Authors: E. Lefebvre, S.I. Harris, M.S. Willett, S. Seyedkazemi, W. Chang, P. Smith, M.D. Gottwald

Presentation Date/Time: Sunday, November 13, 2016; 12:30 p.m. - 2:00 p.m. ET

Title: Cenicriviroc (CVC), a dual inhibitor of chemokine receptors (CCR)2 and 5, decreases hepatic inflammation by altering inflammatory macrophage populations in a mouse model of NASH

Authors: A.J. Kruger, B.C. Fuchs, E. Lefebvre, P. Vig, L. Wei, R. Masia, J.A. Holmes, N. Alatrakchi, S. Salloum, C. Brisac, R.T. Chung

Presentation Date/Time: Saturday, November 12, 2016; 5:30 p.m. - 7:00 p.m. ET

Title: Cenicriviroc, a dual-CCR2/5 antagonist, prevents and reverses liver damage, steatosis and inflammation in alcoholic liver disease in mice

Authors: A. Ambade, K. Kodys, P. Lowe, D. Catalano, B. Gyongyosi, E. Lefebvre, P. Vig, G. Szabo

Presentation Date/Time: Friday, November 11, 2016; 12:00 p.m. - 1:30 p.m. ET

Title: Cenicriviroc (CVC) in combination with all-trans retinoic acid (atRA) has superior therapeutic effects in bile duct ligated (BDL) rats

Authors: D. Yu, S. Cai, A. Mennone, P. Vig, J.L. Boyer

### **About Cenicriviroc (CVC)**

CVC is an oral, once-daily, potent immunomodulator that blocks two chemokine receptors, CCR2 and CCR5, which are intricately involved in the inflammatory and fibrogenic pathways in NASH that cause liver damage and often lead to cirrhosis, liver cancer, or liver failure. Because of this unique mechanism of action, targeting two of the main engines driving NASH, CVC has the potential to play a differentiated role in the management of NASH and may form the cornerstone of NASH combination treatment strategies, both as a single agent and in combination with other agents targeting metabolic pathways. CVC has been granted Fast Track status in patients with NASH and liver fibrosis, the patient population at highest risk of progression to cirrhosis.

The safety and efficacy of CVC for NASH with liver fibrosis is being investigated in the CENTAUR study ([NCT02217475](#)). CENTAUR is a Phase 2b multinational, randomized, double-blind study comparing CVC to placebo in 289 adults with NASH and liver fibrosis. In July 2016, Tobira announced that CENTAUR met the key secondary endpoint of improvement in liver fibrosis by at least one stage with no worsening of steatohepatitis after one year of treatment, which was recommended by regulators as an endpoint for Phase 3 studies to support a marketing application. The CENTAUR study continues for a second year analysis of endpoints, which is expected in the third quarter of 2017. The company plans to initiate a Phase 3 program in 2017.

In addition to CENTAUR, CVC is also being evaluated in the PERSEUS study (identifier [NCT02653625](#)), a Phase 2 proof-of-concept study of CVC in patients with primary sclerosing cholangitis, a rare inflammatory liver disease.

### **About Non-Alcoholic Steatohepatitis (NASH)**

NASH is a severe type of non-alcoholic fatty liver disease (NAFLD), which is characterized by the accumulation of fat in the liver with no other apparent causes. NASH occurs when the accumulation of liver fat is accompanied by inflammation and cellular damage. The inflammation can lead to fibrosis (scarring) of the liver and eventually progress to cirrhosis, portal hypertension, liver cancer, and eventual liver failure.

NASH is an emerging health crisis impacting 3% to 5% of the U.S. population and 2% to 4% globally, and is the fastest growing cause of liver cancer and liver transplant in the U.S. The increasing prevalence of NASH is attributed to the growing obesity epidemic and the disease is often diagnosed in patients who have diabetes, high cholesterol or high triglycerides. There is currently no approved treatment for NASH.

## About Tobira Therapeutics

Tobira is a clinical-stage biopharmaceutical company focused on the development and commercialization of therapies for non-alcoholic steatohepatitis (NASH) and other liver diseases. The company's lead product candidate, cenicriviroc (CVC), is a first-in-class immunomodulator and dual inhibitor of CCR2 and CCR5 in late-stage development for the treatment of NASH, a serious liver disease that can progress to cirrhosis, liver cancer and liver failure. CVC is also being investigated to address primary sclerosing cholangitis (PSC), a disease which causes inflammation and scarring of the bile ducts, eventually leading to serious liver damage. Tobira's pipeline also includes evogliptin, a selective DPP-4 inhibitor, which it plans to develop for NASH in combination with CVC. Learn more about Tobira at [www.tobiratx.com](http://www.tobiratx.com).

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## Forward Looking Statements

*This release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the company's clinical development of cenicriviroc (CVC) and evogliptin (EVO); the potential timing and outcomes of clinical studies of Tobira's product candidates undertaken now or in the future; the ability of the company to timely source adequate supply of its development products from third party manufacturers on whom the company depends; risks and uncertainties relating the pending acquisition of Tobira by a subsidiary of Allergan plc, which remains subject to satisfaction of various closing conditions; the company's limited cash reserves and its ability to obtain additional capital on acceptable terms, or at all; the company's ability to successfully progress, partner or complete further development of its programs; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; the company's ability to protect its intellectual property; competition; changes in the regulatory landscape or the imposition of regulations that affect the company's products; and other factors listed under "Risk Factors" in the company's other filings with the Securities and Exchange Commission.*

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