September 12, 2016

Tobira Therapeutics Announces Initiation of Phase 1 Combination Study of Cenicriviroc and Evogliptin

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 the initiation of a Phase 1 study of cenicriviroc (CVC) in combination with evogliptin (EVO).

"NASH is a complex, multifactorial liver disease resulting from obesity and characterized by metabolic abnormalities, inflammation and fibrosis. We believe that patients will benefit the most from combination therapies that address multiple mechanisms of this disease. Thus, we are initiating a Phase 1 study of CVC and EVO, laying the foundation for rapidly advancing our combination program. This approach will enable us to provide comprehensive therapies for patients with liver fibrosis and NASH, who are at risk of progression to liver cirrhosis and currently have no approved treatment options," said Laurent Fischer, M.D., chief executive officer at Tobira. "The data generated in the CENTAUR Phase 2b study demonstrated that CVC has potent anti-fibrotic activity and was well tolerated. We believe that the anti-fibrotic mechanism of CVC provides a solid backbone to which metabolically-targeted agents such as evogliptin can be added, giving the combination of CVC and EVO the potential to address multiple drivers of NASH."

About the Phase 1 Combination Trial

The Phase 1 study is a single-center, open-label study in healthy adult subjects. The study's primary objective is to evaluate the safety, tolerability and steady-state pharmacokinetic parameters of EVO when administered with and without CVC.

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.

About Evogliptin

Evogliptin (Suganon®, evogliptin 5mg) is an oral, selective dipeptidyl peptidase-4 (DPP-4; CD26 antigen) inhibitor. DPP-4 inhibitors control glucose levels by preventing the breakdown of the incretin hormones glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1), which stimulate insulin secretion in response to the increased levels of glucose in the period following meals. In October 2015, evogliptin received its first global approval in the Republic of Korea for blood glucose control in patients with type 2 diabetes mellitus. Evogliptin is not currently approved by the FDA.

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 Dong-A ST

Dong-A ST Co., Ltd. specializes in the discovery, development, manufacture and sales of ethical drugs. It is listed on the

Korean stock exchange. For more information, visit http://www.donga-st.com.

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.

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; 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20160912005162/en/

Tobira Investor & Media Contact:
Ian Clements, Ph.D., +1 650-351-5013
ir@tobiratherapeutics.com
or
BrewLife Media Contact:
Kelly Boothe, Ph.D., +1 425-946-1076
kboothe@brewlife.com

Source: Tobira Therapeutics, Inc.