



**TOBIRA THERAPEUTICS REPORTS ENCOURAGING PHARMACOKINETIC, BIOAVAILABILITY AND SAFETY RESULTS
FROM STUDIES OF CENICRIVIROC**

***Data from Multiple Animal Models and Human Volunteers Presented Today at
Conference on Retroviruses and Opportunistic Infections (CROI)***

Manalapan, NJ and Boston, MA – February 28, 2011 – Tobira Therapeutics reported today that single-dose oral administration of cenicriviroc showed predictable pharmacokinetics, good oral bioavailability and no dose-limiting toxicity in both healthy human volunteers and animal models. Cenicriviroc (TBR-652) is a potent antagonist of both CCR5, a co-receptor required for HIV infection, and CCR2, a co-receptor that is prominently involved in a number of metabolic and cardiovascular diseases. Cenicriviroc is currently in Phase 2 clinical development for the treatment of individuals with HIV infection.

“These data confirm the pharmacokinetic and safety findings from previous cenicriviroc studies and support the planned initiation of our Phase 2b study in the second quarter of 2011,” stated [David E. Martin](#), PharmD, Senior Vice President, Drug Development/Regulatory Affairs at Tobira. “In this upcoming study, we plan to further explore cenicriviroc’s antiviral and potential cardiovascular/metabolic benefits in patients infected with HIV, as well as its effects on immunologic and inflammatory biomarkers.”

Data presented today at CROI were generated from a Phase 1 clinical study in healthy volunteers, as well as from three preclinical studies in rats, dogs and monkeys. In the human clinical study, healthy volunteers were randomly assigned to receive single oral doses of either cenicriviroc at doses ranging from 10 mg to 800 mg or placebo under fasted conditions. Ten individuals were assigned to each active dose group. Cenicriviroc was readily absorbed, well-tolerated and generated no dose-limiting toxicities. The drug was eliminated from plasma with a mean half-life of approximately 32 to 39 hours across the wide range of doses studied, suggesting nearly linear elimination kinetics.

In all three animal studies, cenicriviroc demonstrated good bioavailability. Distribution to mesenteric lymph nodes was assessed in the preclinical rat study, and cenicriviroc was found to be distributed efficiently. Mesenteric lymph nodes have been identified as a reservoir for the HIV virus, and therefore are a key target of HIV therapy. It was further determined that cenicriviroc is extensively metabolized by the liver but does not inhibit the cytochrome P450 (CYP) family of enzymes, which are responsible for drug metabolism. Cenicriviroc’s lack of CYP inhibition suggests a low potential for drug interactions.

Last year, Tobira announced its Phase 2a results, demonstrating potent antiviral and anti-inflammatory activity in treatment-experienced HIV patients. Potential for once-daily dosing, co-formulation with other antiretrovirals, such as nucleoside-sparing or ritonavir-sparing combinations, as well as inflammation-mediating properties distinguish cenicriviroc from first-generation CCR5 antagonists. The company is currently finalizing its Phase 2b protocol and successfully engaging clinical trial sites for the investigation in treatment-naïve HIV patients.

Poster details:

Title: Cenicriviroc (formerly TBR-652) *Absorption, Distribution, Metabolism, and Excretion (ADME) Profile in Rats, Dogs, Monkeys, and Humans*

Poster Board Number: 627 (Abstract N-101)

About Tobira Therapeutics, Inc.

Tobira Therapeutics is a private biopharmaceutical company focused on developing and commercializing innovative antiviral compounds to treat HIV disease. Founded in 2006 by Eckard Weber, MD, a partner at the venture capital firm Domain Associates, to develop novel treatments for HIV disease, Tobira has assembled a highly experienced management team with decades of clinical and commercial development experience specifically in HIV/AIDS drug development. For more information, visit www.tobiratherapeutics.com.

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