



## **Tobira Therapeutics Initiates Phase IIb Trial of Cenicriviroc, a Novel CCR5/CCR2 Antagonist for the Treatment of HIV Infection**

### **Enrollment Begins in Study to Investigate Antiviral, Immunologic and Anti-inflammatory Effects in HIV-infected Adults**

**MANALAPAN, NJ** – June 22, 2011 – Tobira Therapeutics, Inc., a biopharmaceutical company focused on the development and commercialization of innovative therapies for HIV, announced today that it has initiated a Phase IIb clinical trial for the CCR5/CCR2 inhibitor cenicriviroc (TBR-652). The multi-center, double-blind, double-dummy, 48-week comparative study is designed to evaluate the efficacy, safety and tolerability of cenicriviroc in 150 HIV-1-infected, antiretroviral treatment-naïve patients with only CCR5-tropic virus. The trial is actively enrolling patients in more than 50 sites across the United States and Puerto Rico.

Participants will receive either once-daily 100 mg or 200 mg doses of cenicriviroc in combination with emtricitabine/tenofovir disoproxil fumarate (Truvada®), or once-daily efavirenz (Sustiva®) plus Truvada. The trial's primary objective is to determine the efficacy, safety and tolerability of each cenicriviroc regimen versus the comparator regimen. The primary study analyses will be performed at Week 24; the secondary analyses at Week 48. Additionally, several sub-studies will assess changes in biomarkers associated with inflammation, cardiovascular function, metabolic indicators of glucose control and immune function.

"This study is based on the strength of the cenicriviroc Phase IIa proof of concept, pharmacokinetic and safety findings that were presented at key HIV/AIDS conferences and published in peer-reviewed journals," said Melanie Thompson, M.D., of the AIDS Research Consortium of Atlanta, and a lead investigator in Phase IIb study. "The study will further explore cenicriviroc's antiviral activity and safety as well as effects on immunologic and inflammatory biomarkers, including the effects of CCR2 receptor inhibition in HIV-1 infected patients."

"We're pleased to announce this significant development milestone for cenicriviroc," said [Andrew Hindman](#), President and Chief Executive Officer. "The quality and range of participating trial sites underscore the strong clinical interest in cenicriviroc, which shows promise to be a truly transformational HIV medicine with novel attributes. This study will establish the optimal dose, evaluate the antiviral activity, safety and tolerability and advance the understanding of the role CCR2 blockade may have in mitigating some of the co-morbidities associated with HIV infection."

For more information on the Phase IIb trial of cenicriviroc in HIV-positive adults, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).



### **About Cenicriviroc (TBR-652)**

Cenicriviroc is a potent antagonist of CCR5, a co-receptor required for HIV infection, and CCR2, a co-receptor involved in the inflammation process that may play a key role in metabolic and cardiovascular diseases. Well-differentiated from available and emerging HIV medicines, cenicriviroc shows promise as a highly potent, unboosted once-daily oral CCR5 antagonist with potentially important CCR2-mediated anti-inflammatory effects.

Clinical data have been presented at key medical meetings including last summer's International AIDS Conference and the February 2010 and 2011 Conference on Retroviruses and Opportunistic Infections (CROI). Key cenicriviroc data have been published in peer-reviewed journals including the *Journal of Acquired Immune Deficiency Syndromes* (Volume 57, Number 2, June 1, 2011) and *Antimicrobial Agents and Chemotherapy* (Volume 55, Number 6, June, 2011).

### **About Tobira Therapeutics Inc.**

Tobira Therapeutics is a private biopharmaceutical company focused on developing and commercializing innovative antiviral compounds to treat HIV infection. The Company was founded in 2006 by Eckard Weber, MD, a partner at Domain Associates, LLC, a life sciences venture capital firm. 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, please visit [www.tobiratherapeutics.com](http://www.tobiratherapeutics.com).

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