



## **Tobira Therapeutics Presents Pharmacokinetics and Safety Data that Support Coadministration of Cenicriviroc with Tenofovir DF in Healthy Adults**

### ***Data from Phase I Study Announced at the International AIDS Society (IAS) Conference***

**Manalapan, NJ** – July 19, 2011 – Tobira Therapeutics, a biopharmaceutical company focused on the development and commercialization of innovative therapies for HIV infection, announced the results of a Phase I, open-label, cross-over study that explored the pharmacokinetics (PK), safety and tolerability of cenicriviroc (CVC) and tenofovir disoproxil fumarate (TDF) when coadministered in healthy adults. The study findings were presented today at the 6<sup>th</sup> International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention in Rome, Italy.

“These data show that the coadministration of CVC with TDF in healthy adult volunteers did not substantially affect the bioavailability of either drug, thus supporting coadministration as part of HIV treatment regimens in future controlled clinical trials,” said David E. Martin, PharmD, Senior Vice President, Drug Development/Regulatory Affairs and lead author of the poster. “We are encouraged by these data as part of our broader CVC clinical development program and are pleased to have recently initiated a Phase IIb study in combination with tenofovir disoproxil fumarate and emtricitabine (TDF/FTC), evaluating CVC in treatment-naïve, HIV-infected individuals.”

The study presented today at IAS – A Phase I, Open-Label, Single-Dose, Randomized, Cross-Over Study of Cenicriviroc (CVC) and Tenofovir (TDF) in Healthy Volunteers (Poster # TUPE236; Abstract # 710) – assessed the PK, safety and tolerability of CVC administered with and without TDF. Volunteers each received a single dose of CVC, TDF and the coadministration of CVC with TDF with a washout period of 14 days between doses. The potential for a drug-drug interaction was determined by measuring the impact of CVC on TDF’s bioavailability and safety profile when coadministered; and conversely measuring the impact of TDF on these same CVC parameters. It was determined that TDF did not significantly impact the rate (C<sub>max</sub>) or extent (AUC 0-t or AUC 0-inf) of plasma exposure of CVC. Conversely, CVC did not impact the extent of absorption of TDF, but it was shown to increase the rate of absorption. There was no effect of CVC on TDF clearance since the TDF half-life was unchanged.

“This study represents a milestone in our clinical development program by demonstrating CVC’s ability to be combined with TDF, a key component of most current HIV treatment regimens. As part of Tobira’s development strategy, it is essential to demonstrate that CVC can be combined with a range of antiviral agents,” said Andrew Hindman, President and Chief Executive Officer. “The full potential of CVC’s clinical utility will be determined as its antiviral activity, long-term safety and anti-inflammatory activity (measured via effects on various biomarkers via CVC’s effect on CCR2 receptor inhibition) are further investigated in our on-going clinical studies.”

#### **About Cenicriviroc**

Cenicriviroc (CVC, formerly TBR-652) 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. Cenicriviroc is well-differentiated from available and emerging HIV medicines, and 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 the 2010 International AIDS Conference and the 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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