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July 24, 2009

ADAP Advocacy Association Commends Gilead Sciences and Tibotec Pharmaceuticals Agreement to Develop and Commercialize a New Fixed-Dose Combination of TMC278 And Truvada®

For Immediate Release

WASHINGTON, D.C. (July 24, 2009) – The <u>ADAP Advocacy Association</u>, also known as <u>ada</u>+, today commended Gilead Sciences and Tibotec Pharmaceuticals for its agreement to develop and commercialize a new fixed-dose combination of Gilead's Truvada® (emtricitabine and tenofovir disoproxil fumarate) and Tibotec's investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) TMC278. This agreement, if approved by the U.S. Food & Drug Administration (FDA), would represent only the second complete antiretroviral treatment regimen for HIV available in a single tablet taken once daily.

"The importance of this collaborative approach to the treatment of HIV to our community by Gilead Sciences and Tibotec Pharmaceuticals cannot be under stated," said **Brandon M. Macsata**, CEO of the ADAP Advocacy Association. "If approved represents a remarkable option to people living with HIV/AIDS in that it holds the potential to improve treatment adherence, save consumers money and also avail to the HIV community yet one more treatment."

Numerous studies have demonstrated a number of factors associated with adherence to anti-retroviral treatment, among them treatment regiment including the number of pills prescribed, dosing frequency and food instructions, type of antiretroviral drugs, and the short and long-term medication side effects. The new fixed-dose combination of Truvada® and TMC278 provides a promising application to improve adherence.

Summarized Bill Arnold, Executive Director of the Community Access National Network and ada+ board cochair: "Once again, Tibotec and Gilead have demonstrated their commitment to providing high-quality treatment options to people living with HIV/AIDS in the United States and across the globe. The pending introduction of a second once-daily AVR further demonstrates how the pharmaceutical industry is cooperating on improving treatments options for HIV-positive patients, which is a very welcomed by the ADAP Advocacy Association and Community Access National Network. Only by all HIV stakeholders working in concert on prevention, diagnosis, access and treatment can we effectively combat this disease."

Truvada® combines two anti-HIV-1 medications, Emtriva[®] (emtricitabine 200 mg) and Viread[®] (tenofovir disoproxil fumarate 300 mg), into one pill that is taken once a day with or without food. Truvada® is an anti-HIV-1 drug in the nucleoside reverse transcriptase inhibitor (NRTI or "nuke") family and is always given in combination with other anti-HIV-1 drugs.¹

¹ Gilead Sciences, Truvada.com.

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TMC278 is an investigational non-nucleoside reverse transcriptase inhibitor, and the safety and efficacy of it, in combination with other antiretroviral agents, has not been established. Two major phase III trials for TMC278 are currently being conducted in the United States, Canada, Africa, Asia, Europe and South America.²

"Gilead and Tibotec share a strong focus on bringing safe and effective treatment options to people living with HIV/AIDS," said **John C. Martin**, PhD, Chairman and Chief Executive Officer, Gilead Sciences. "Fixed-dose regimens have become the standard of care as HIV treatment has evolved toward more simplified regimens for patients. We are very pleased to collaborate with Tibotec and look forward to advancing this new fixed-dose product."

"A simplified regimen may help improve patient adherence and decrease overall pill burden," said **Roger Pomerantz**, MD, President Tibotec R&D. "We are very pleased to collaborate with Gilead, one of the leading companies in the fight against HIV/AIDS, and look forward to advancing this new fixed-dose product in addition to TMC278 as a single agent."

aaa+ promotes and enhances the AIDS Drug Assistance Programs (ADAPs) and improves access to care for persons living with HIV/AIDS. aaa+ works with advocates, community, health care, government, patients, pharmaceutical companies and other stakeholders to assure that access to services recognize and afford persons living with HIV/AIDS to enjoy a healthy life. For more information about aaa+ please visit www.adapadvocacyassociation.org.

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Truvada is a registered trademark of Gilead Sciences, Inc.

² Tibotec Therapeutics, Tibotec.com.