## Media Release



Pleasanton, Calif., December 16, 2011

### New Roche screening test for abacavir hypersensitivity available in Europe

# *The test confidently detects HLA-B\*5701 to help decrease risk of abacavir hypersensitivity reaction*

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that its HLA-B\*5701 screening test<sup>1</sup> is now commercially available in Europe. HLA-B\*5701 screening provides physicians with a means to avoid prescribing drugs to patients at high risk of allergic reactions to a drug called abacavir for the treatment of HIV and AIDS.

"We are pleased to provide physicians with a means to personalize treatment and prevent patients from experiencing adverse events," said Paul Brown, Ph.D., Head of Roche Molecular Diagnostics. "This new test may help improve HIV patient treatment and provide safer disease management."

As recommended by the US Department of Health and Human Services (DHHS), the European AIDS Clinical Society, and the International AIDS Society-USA Panel (IAS)<sup>2,3,4</sup>, all patients should be screened for the HLA-B\*5701 allele before starting or restarting treatment with abacavir or abacavir-containing medications. Avoidance of abacavir therapy in HLA-B\*5701 positive patients will significantly decrease the risk of developing clinically-suspected abacavir hypersensitivity reactions (HSR).

#### About HLA-B\*5701

Abacavir is a prescription medication that is used as a treatment for HIV and AIDS. Serious and sometimes fatal HSR caused by abacavir therapy are significantly more common in patients with a particular human leukocyte antigen (HLA) allele, HLA-B\*5701, <sup>5,6</sup>. The US Department of Health and Human Services (DHHS) and the International AIDS Society-USA

<sup>1</sup> The Roche HLA-B\*5701 Screening Test runs on the COBAS® AmpliPrep/COBAS® TaqMan® System. The COBAS® AmpliPrep/COBAS® TaqMan® HLA-B\*5701 Screening Test is not approved or available for use in the US.

<sup>2</sup> Department of Health and Human Services. Panel on Antiretroviral Guidelines for Adult and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. December 1, 2009; 1-146. Available at http://www.aidsinfo.nih.gov/Accessed December 1, 2009.

<sup>3</sup> Hammer SM, Eron JJ, Jr., Reiss P, Schooley RT, Thompson MA, Walmsley S, et al. Antiretroviral treatment of adult HIV infection: 2008 recommendations of the International AIDS Society-USA panel. JAMA 2008, 300:555-570.

<sup>4</sup> European AIDS Clinical Society (EACS), Guidelines for the clinical management and treatment of HIV infected adults in Europe, 2007. 5 Mallal, SA, et al. 2008. HLA-B\*5701 Screening for Hypersensitivity to Abacavir. NEJM 358;6:568-579.

<sup>6</sup> Hughes, AR, et al. 2008. Pharmacogenetics of hypersensitivity to abacavir: from PGx hypothesis to confirmation to clinical utility. The Pharmacogenomics Journal 8:365-374.

Panel (IAS) have recommended that all patients are screened prior to initiating abacavir containing regimens.

#### About COBAS®AmpliPrep / COBAS®TaqMan®System

The Roche HLA-B\*5701 Screening Test runs on the fully automated COBAS<sup>®</sup> AmpliPrep/COBAS<sup>®</sup> TaqMan<sup>®</sup> System.<sup>1</sup> The platform combines the COBAS<sup>®</sup> AmpliPrep Instrument for automated sample preparation and the COBAS<sup>®</sup> TaqMan<sup>®</sup> Analyzer or the smaller COBAS<sup>®</sup> TaqMan<sup>®</sup> 48 Analyzer for automated real-time PCR amplification and detection. The COBAS AmpliPrep/COBAS TaqMan System has parallel processing with other key molecular diagnostics assays targeting medically relevant diseases (Hepatitis B virus, Hepatitis C virus, and Human Immunodeficiency Virus). Roche's AmpErase enzyme is also included in each test and is designed to prevent cross reactivity and minimize testing errors in labs.

#### **About HIV-1**

Accordingly to UNAIDS, there were 33.3 million people living with HIV around the world in 2009. In that same year, 2.6 million people became newly infected with HIV— almost 20 percent fewer than in the late 1990s.<sup>7</sup> Highly active antiretroviral treatment (HAART) and viral load tests, a test to determine the amount of circulating HIV, have contributed to a steady increase in life expectancy for HIV infected people by 13 years.<sup>8</sup>

#### **About Roche**

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2010, Roche had over 80'000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

For inquiries, please call Corporate Communications at 01 925-730-8346 All trademarks used or mentioned in this release are protected by law.

<sup>&</sup>lt;sup>7</sup> The UNAIDS Report on the Global AIDS Epidemic 2010.

<sup>&</sup>lt;sup>8</sup> Lancet. Volume 372, Issue 9635, 26 July 2008-1 August 2008, Pages 293-299