



British Columbia
Centre for Excellence
In HIV/AIDS

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Genetic Test Predicts Response to Maraviroc in Treatment-Experienced HIV Patients

Vancouver, British Columbia, Canada, July 22 2009 - A genetic approach to determining HIV tropism can be used to effectively identify patients who will respond to treatment with the CCR5 antagonist maraviroc, according to new data presented today at the 5th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention in Cape Town, South Africa.

Using screening samples from patients enrolled in the maraviroc treatment-experienced clinical trial program, results of this retrospective analysis showed that changes in HIV viral levels and the percentage of patients who achieved undetectable viral loads were comparable between those patients tested with HIV V3 Genotyping and Trofile™ (the recombinant-phenotypic assay originally used in the clinical trial program), indicating comparable accuracy of both tests at identifying treatment-experienced patients that will respond to treatment with maraviroc.

"HIV V3 Genotyping shows promise as a significantly faster and more cost-effective way to correctly identify patients who would benefit from CCR5 antagonists like maraviroc," said Richard Harrigan Ph.D., lead investigator and Director of Research Laboratories, B.C. Centre for Excellence in HIV/AIDS, Vancouver, Canada. "Since the genotypic test is based on methods that are already widely used through the same labs that provide HIV drug resistance testing, this approach could become broadly available and conducted at the same time as resistance testing to determine susceptibility to all drugs, including maraviroc."

CCR5 antagonists, such as Pfizer's maraviroc, work by preventing HIV from entering CD4 cells via the CCR5 co-receptor. HIV V3 Genotyping uses HIV-tropism-prediction algorithms based on the genetic signature of viruses that use this co-receptor.

About the Analysis:

The analysis was designed to compare the performance of genotypic assays versus the original Trofile in predicting virologic response to maraviroc.

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Population-based sequencing was performed on screening samples from patients enrolled in the maraviroc treatment-experienced clinical trials program, which included the MOTIVATE 1 and MOTIVATE 2 (patients with R5 virus) and A4001029 (patients with non-R5 virus) studies. Results from MOTIVATE were used to support the approval of maraviroc in Canada, the U.S. and the EU for treatment-experienced patients with only CCR5-tropic HIV-1 detectable.

HIV tropism was predicted using Geno2pheno (g2p), a widely available algorithm. Change in viral load at week eight was measured due to it being long enough to determine response to maraviroc and short enough to be relatively unaffected by patient drop-outs and other confounding factors.

Results show that at eight weeks a similar number of patients with CCR5 virus treated with maraviroc achieved undetectable virologic suppression (<50 copies/mL or a >2 log₁₀ copies/mL), regardless of which assay was used to identify their tropism (g2p= 71.9%, N=366; Trofile = 71.6%, N=380). A similar number of patients with CCR5 virus treated with maraviroc also achieved undetectable virologic suppression at 24 weeks (<50 copies/mL), regardless of which assay was used to identify their tropism (g2p= 46.1%, N=393; Trofile = 46.4%, N=405).

Pfizer provided researchers of the study with samples and clinical data from the MOTIVATE 1 and 2, and A4001029 trials. Pfizer also assisted with the statistical analysis.

About the B.C. Centre for Excellence in HIV/AIDS:

The B.C. Centre for Excellence in HIV/AIDS is Canada's largest HIV/AIDS research, treatment and education facility. Located in Vancouver, Canada, it is dedicated to improving the health of British Columbians with HIV through the development, monitoring and dissemination of comprehensive research and treatment programs for HIV and related diseases.

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