



**CCR5 Antagonist Working Group
Roundtable Discussion 1
Forum for Collaborative HIV Research**

May 23, 2005

Veronica Miller

www.hivforum.org

**Forum for Collaborative
HIV Research**

**School of Public Health &
Health Services**

**The George Washington
University**



The Forum for Collaborative HIV Research is a public/private partnership including government agencies, foundations, industry, HIV researchers and clinicians, and the HIV patient/advocacy community.

Our mission is to facilitate and enhance HIV research.

**Forum for Collaborative
HIV Research**

**School of Public Health &
Health Services**

**The George Washington
University**

The Forum Executive Committee



- Government Agencies
 - US DHHS (NIH, CDC, FDA, HRSA, CMS), State Department (OGAC)
 - European Regulatory: EMEA
- Industries
 - Abbott, Bayer Diagnostic, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Roche Laboratories, Roche Molecular Systems, Pfizer-Agouron, Tibotec, Virologic
- Academia
 - US and Europe
- Providers
- Patient Advocacy
 - US and Europe
- Foundations & Organizations (Gates, IAS)

Steering Committee



Ben Cheng – FCHR

Lynda Dee- AIDS Action Baltimore

Bill Freimuth – HGS

Wayne Greaves - Schering-Plough

Trip Gulick – Cornell University

Dan Kuritzkes – Brigham & Women’s Hospital

Louise Martin-Carpenter - GSK

Howard Mayer - Pfizer

Veronica Miller – FCHR

Jeff Murray – FDA

Neil Parkin – Virologic

SPECIAL THANKS: Ipsita Das - FCHR

Working Group Goals



- Develop a platform for discussion of issues in the development of CCR5 antagonists for treatment of HIV infection
 - Effect of CCR5 antagonist treatment on viral tropism, escape and viral susceptibility
 - Long term safety issues in adults and children
 - Viral heterogeneity, host receptor heterogeneity
 - Placement of CCR5 antagonists in treatment strategies
 - Potential use of CCR5 antagonists in prevention

Meeting Objectives for May 23, 2005



- To review and discuss regulatory requirements in the US and Europe for the development of CCR5 antagonists in naïve and treatment experienced patients
- To identify unanswered questions and discuss approaches to filling the gaps in knowledge related to the safety and efficacy of CCR5 antagonists in the context of development and expanded access programs
- To discuss issues related to the diagnosis of viral tropism before and after treatment, pre- and post development phase
- To discuss and identify mechanisms for long-term follow-up of patients enrolled in CCR5 antagonist clinical studies