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HIV drug maraviroc effective for drug-resistant patients

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As many as one quarter of HIV patients have drug resistance, limiting their treatment options and raising their risk for AIDS and death. Now, maraviroc, the first of a new class of HIV drugs called CCR5 receptor antagonists, has been shown to be effective over 48 weeks for drug-resistant patients with R5 HIV-1, a variation of the virus found in more than half of HIV-infected patients.

Results of the two Phase 3 multicenter MOTIVATE (Maraviroc Plus Optimized Therapy in Viremic Antiretroviral Treatment Experienced Patients) studies led by NewYork-Presbyterian Hospital/Weill Cornell Medical Center's Dr. Roy Gulick and published in the October 2 issue of the New England Journal of Medicine (NEJM) find that the drug, taken with an optimized standard HIV drug regimen, resulted in significantly greater suppression of the virus at 48 weeks, with concurrent increases in immune system T-cell counts, when compared with placebo. Rates of side effects were not different between the maraviroc and placebo groups.

Preliminary results of these studies led to FDA approval of maraviroc in August 2007.

Because it is from a new class of HIV medications known as HIV entry inhibitors, people living with HIV generally will not have resistance to maraviroc because they have not been exposed to any drugs from the class previously. Unlike earlier HIV drugs that target the virus, maraviroc acts on the human T-cell, binding to it in such a way that

prevents HIV from binding and subsequently infecting the T-cell.

"It is now possible to expect that a majority of treatment-experienced patients who experience failure on their current HIV drugs will regain control of their HIV infection with maraviroc combined with other newer antiretroviral drugs. This is an important step forward," says study principal investigator Dr. Roy Gulick, who is professor of medicine and director of the Cornell HIV Clinical Trials Unit of the Division of International Medicine and Infectious Diseases at Weill Cornell Medical College, and a practicing physician at NewYork-Presbyterian Hospital in New York City. "Suppressing virus levels and increasing immune system T-cells with HIV treatment regimens helps HIV-infected people live longer, healthier lives."

The double-blind study followed 1,049 of patients with advanced HIV and resistance to three antiretroviral drug classes. Patients were randomized to receive maraviroc once-daily, twice-daily or placebo. Safety and efficacy were assessed at 48 weeks. The MOTIVATE studies comprised two identical arms: MOTIVATE1 was conducted in Canada and the U.S., while MOTIVATE2 was conducted in Australia, Europe and the U.S.

More patients receiving maraviroc once- or twice-daily versus placebo achieved HIV-1 RNA