

Runner-up Technology
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Novel Methods for Treating Drug-Resistant Human Immunodeficiency Virus Infection

Drug-resistance is a critical factor contributing to the gradual loss of clinical benefit of currently available human immunodeficiency virus-1 (HIV-1) therapies. The available technology provides methods for treating HIV-1 in patients, who are infected with drug-resistant viral strains and are non-responsive to current therapies. The antiviral activity of the described compositions has been established against multi-protease inhibitor-resistant HIV-1 variants and demonstrated effective in patients with widespread resistance to currently available protease inhibitors. In addition, commercial development of this composition has resulted in the production of a novel drug, PrezistaTM (duranivir) which received accelerated approval by the U.S. Food and Drug Administration (FDA) on June 23, 2006. Prezista is the first FDA approved drug for the treatment of HIV-1 in experienced patients, who do not benefit from existing antiretroviral therapies.

The described composition retains the unique ability to inhibit drug-resistant mutants due to its distinctive points of interaction with the HIV-1 protease enzyme: the agent binds inside the protease substrate-binding site, a region of limited variability due to the highly specific nature of the protease-substrate interaction. Other protease inhibitors extend outside of the substrate binding site to a location of high mutation rate, which renders these drugs ineffective after repeated use. Therefore, the current innovation represents a highly effective method of targeting drug-resistant HIV-1 strains.

Data from both experimental studies and clinical trials have demonstrated the effectiveness of the current technology. Additionally, PresistaTM, a prototype drug resulting from commercial development the present technology has recently received accelerated approval from the FDA.

This technology embodies a breakthrough against multi-drug resistant HIV-1 strains and offers considerable hope for individuals who have developed or were initially infected with protease inhibitor-resistant HIV-1. Accordingly, the current invention has the potential to draw revenues at the high end of the estimated range of HIV therapeutics (\$250 million- \$1.0 billion).

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