

Rutgers laboratory helped to create new HIV drug

June 23 2011

Two decades after a Rutgers team began working with legendary drug developer Paul Janssen, founder of a Belgian subsidiary of pharmaceutical giant Johnson & Johnson in an effort to create new and potent drugs to fight AIDS, the U.S. Food and Drug Administration has approved the second anti-HIV drug that came from this collaboration.

"For a drug to successfully make it to the finish line, countless obstacles must be overcome," said Eddy Arnold, Board of Governors Professor of Chemistry and Chemical Biology, and a resident faculty member of the Center for Advanced Biotechnology and Medicine who led the Rutgers team. "As a researcher in biomedical sciences I can tell you that helping to create new medicines is something you always dream about."

The newest AIDS drug, (rilpivirine) Edurant – the first to be approved by the FDA in the last three years and manufactured by Tibotec Therapeutics, a subsidiary of J&J – was developed in 2001 and took a decade to make its way through the regulatory process and clinical trials.

"From the beginning, we knew this would be a long-term project," said Arnold whose research group team received \$20 million mostly from the National Institutes of Health as well as two prestigious MERIT (Method to Extend Research in Time) NIH awards, an honor bestowed on less than 5 percent of NIH grant recipients. "Many challenges have been faced and overall it has been more like a marathon than anything else."

Resistant strains of [HIV](#) are a growing medical problem because the

virus is constantly mutating, and the changes can cause existing AIDS drugs from being able to work. Arnold's team developed innovative models that explain not only why Edurant, approved by the FDA last month, and Intelence, approved in 2008, are particularly effective against drug-resistant viruses but can also be used in the development of treatments for a wide variety of other diseases. The gist of the model is that flexibility of a drug can allow it to adapt to changes in HIV.

Clinical trials for Edurant, which included more than 1,300 adults with HIV, indicated that 83 percent of those who were given this anti-AIDS drug for a 48-week period had undetected levels of HIV in their blood at the conclusion of the clinical trial. The new drug can be prescribed as a once-a-day pill to HIV-positive adults who have not received any prior treatment or therapy. Besides being available in the United States, a generic form of the drug will be made available to millions of people in Saharan Africa, India and other developing nations.

"Development of this newest AIDS drug represents a wonderful example of the biomedical power that can be harnessed by scientific collaborations and partnerships between university, government, and private sector research enterprises," said Kenneth J. Breslauer, dean of Life and Health Sciences. "No more satisfying and important outcome can result from university research."

This scientific collaboration began in 1987 when the Rutgers team entered into a partnership with Stephen Hughes, an AIDS researcher at the National Cancer Institute. Both were interested in understanding the molecular structure and function of reverse transcriptase, an essential part of the [AIDS virus](#), not only for its fundamental significance, but also because they believed it would provide guidance for the design of more effective drugs.

Three years later, Arnold reached out to Janssen at the J&J subsidiary,

Janssen Pharmaceutica, which had developed promising compounds to prevent reverse transcriptase from being able to create a genetic copy of the AIDS virus. The Rutgers team suggested that crystal structures of the compound created by Janssen, bound to the reverse transcriptase enzyme, could help the company understand and improve its chemical structures and be used to develop more effective AIDS drugs.

They worked together for the next 13 years, during which time Janssen provided \$2 million to help fund the Rutgers team's research efforts to develop drugs that would be effective against drug-resistant mutants of the AIDS virus. A pivotal breakthrough happened in 1998 when dapavirine -- which works by preventing HIV from replicating its genetic material after the virus enters a healthy cell – was developed. Further refinements of the drug led to creation of two anti-AIDS drugs: Intelence approved by the FDA in 2008, and Edurant, which came on the market in May and has shown exceptional potency against [drug resistant HIV](#).

Provided by Rutgers University

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