

Once-A-Day HIV Meds Improve Quality Of Life And Hold Promise For Developing Countries

Emory University



Not so long ago, HIV sufferers took 10 to 15 pills a day and still the outcome was often bleak. Today, more than 80 percent of HIV patients take at least one of the drugs developed by Emory scientists in a single tablet, once a day. Although it's not a cure, the treatment restores life as it lowers the daily drug regimen burden, diminishes side effects, relieves disease symptoms, and adds longevity.

“They are what we call DNA chain terminators,” explains Liotta. “Think of viral DNA as a line of rail boxcars, the drugs destroy the hitch so no more cars are added. The virus accepts the compounds and mistakes them for normal nucleotides, but they lack a function group necessary to copy the RNA to DNA.”

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“Typically, HIV sufferers take a three-drug combination, with Emtriva being one of the three. “Special credit goes to the scientists at Gilead,” says Liotta. “They are the unsung heroes that developed a compression technique to fit a full day’s dosage of all three drugs in a single tablet, and it’s not a ‘horse’ pill.”

“That’s the thing, thousands of people make contributions to the ultimate success of this drug,” says Liotta. Indeed, many people have persevered at getting the drugs to patients around the globe. Gilead and Bristol-Myers Squibb gained FDA approval in 2006 for the first once-a-day, single tablet regimen for adults with HIV called Atripla®. Atripla contains three drugs—efavirenz (Sustiva®), emtricitabine (Emtriva®), and tenofovir disoproxil fumarate (Viread®), combined in one tablet and hence can be used as a stand-alone therapy in patients. Atripla reduces pill burden and simplifies dosing schedules, which not only makes things easier and more tolerable for patients, but also greatly eases storage, transport and distribution of the drug to places with less than ideal conditions.

“Gilead did a tremendous amount of work in stability studies to increase the shelf stability of the drugs in hot, humid climates and poor storage conditions typical in third world countries,” says Liotta.

Atripla is marketed jointly by Gilead and Bristol-Myers Squibb in United States, Canada and Europe, but in much of the developing world, marketing and distribution is handled by Merck & Co., Inc. In addition, Gilead established partnerships with 10 Indian companies to produce and distribute quality, low-cost generic versions of Gilead’s HIV medications in 95 developing countries.

Other industry collaborations include local manufacturing and distribution by South Africa’s Aspen Pharmacare and a manufacturing collaboration in the Bahamas with PharmaChem Technologies and the Grand Bahama Port Authority.

Meanwhile, Gilead is hard at work clearing the political and regulatory paths in developing world countries.

“If you work with import waivers you might get products into a country one month, but not the next,” explains Clifford Samuel, senior director of International Access Operations at Gilead. “We prefer to take the high road and pursue full regulatory approval in each country so that patients have sustainable access to the antivirals they need on an uninterrupted schedule.”

This is no easy task as the regulatory process varies greatly by country and not all governments are motivated by humanitarian concerns. Nonetheless, Samuel and his team continue to push their way through the various regulatory challenges in Africa, Eastern Europe, China, Southeast Asia, Latin America and the Caribbean.

While these highly coordinated efforts seem brilliant in their simplicity, the history of FTC, like other new discoveries, is a bit more convoluted. FTC was licensed by Emory in 1996 to Triangle Pharmaceuticals, a biotech company founded by Schinazi and others in 1995. In 2003, Gilead acquired Triangle for \$482 million and in the same year, Emtriva was approved by the FDA. In 2002, Shire and GlaxoSmithKline jointly licensed Emory’s patents related to 3TC, now used in at least 5 products. In 2005, Gilead Sciences and Royalty Pharma signed a deal with Emory to buy its royalty interest for FTC for \$525 million. Gilead obtained approval for Truvada®, a fixed-dose combination of Emtriva and Viread in 2004. Today’s combined efforts of Emory, Gilead, Merck and Bristol-Myers have saved millions of lives worldwide.

Although these results are very gratifying, this is far from the end of the story. Emory researchers are expanding their search for more lifesaving drugs.

The new Emory Institute for Drug Discovery will open either late fall or early winter of 2009. Within its walls, scientists will attack several diseases with an unflinching determination to stop their trek across human lives.

“We may not make a fortune, but we will make a difference,” said Liotta.

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