

Expanding HIV Therapy: Will Devices Pick Up Where Drugs Leave Off?

The realization that combination drug therapy for HIV can lose its clout over time has prompted device makers to focus efforts on projects that may represent new hope to patients otherwise out of options.

The emergence of drug "cocktails" constituting "highly active antiretroviral therapy" (HAART) transformed HIV in the late 90s from a virtual death sentence to a chronic, but manageable, disease in Western countries.

But it is just a matter of time, in many cases, before drug resistance takes hold and the treatment options begin to diminish. Meanwhile, development of an HIV vaccine has been slow-going.

"Devices able to assist or extend antiviral treatments did not previously evolve because expectations of drug and vaccine effectiveness indicated that such auxiliary therapies would not be required," Aethlon Medical CEO Jim Joyce said.

"However, today we understand [not only] the greatly diminished hope for a vaccine, [but the] crisis of first-generation patients, originally responsive to HAART, evolving viral strains that will cause them to fail drug therapy in the absence of new methods to clear these mutant strains." The San Diego-based firm's development-stage *Hemopurifier* could fill that void, the CEO concluded.

The product, designed to work in conjunction with portable pumps or dialysis machines already in the hospital or clinic, is still in early stages of development; but Aethlon says it could be the first medical device designed to treat infectious disease.

The Hemopurifier employs an "affinity treatment cartridge" that rapidly separates and captures infectious viruses and toxins from blood circulated outside of the body. According to Joyce, it works in a manner similar to the natural immune response of clearing viruses and toxins before cell and organ infection.

In this fashion, the system is designed to lower viral load so that drugs and the body's immune system can function more effectively.

Aethlon has so far initiated only one five-patient safety study in India for hepatitis C-infected individuals. The firm says preclinical studies have shown the Hemopurifier to be effective in capturing HIV, hepatitis C, and a virus similar to smallpox.

Potential bioterrorism agents, which could include smallpox, and pandemic influenza viruses are among the company's first targets. It expects to meet with FDA next month to discuss an investigational device exemption for these indications and aims to have its first PMA approved by 2010.

Aethlon hopes those approvals could open up longer term goals, particularly an HIV indication. Joyce says the Hemopurifier could serve either when HAART therapy fizzles or between drug regimens when the viral load can rebound to formidable levels.

Taking The Lipid Out Of HIV

Pleasanton, Calif.-based Lipid Sciences also sees long-term potential for devices to impact the drug-dominated infectious disease market. The firm's technology platform is based on delipidation – the removal of lipids from proteins circulating in blood plasma without disruption of protein function – which it says could complement existing drug therapies.

The company is initially focusing on cardiovascular disease, where the technology can have an impact by removing lipids from cholesterol molecules to enhance the “good” to “bad” cholesterol ratio. In this area, they have already entered initial clinical trials.

In the viral arena, where HIV has top priority, Lipid Sciences is expecting results from animal studies next year and, following that, plans to initiate human trials.

Although not all viruses are coated by lipids, many, including HIV, are. By removing the virus' protective lipid coating, the company's technology can expose viral proteins and increase their vulnerability to the body's immune system. Further, because lipids aid HIV in infecting host cells, delipidation can reduce the ability of the virus to disperse throughout the body.

Aethlon or Lipid Sciences clearly see device entry into the HIV market as a long term objective and, even then, a tool to assist, not supplant, drug treatment.

Nonetheless, they are cautiously optimistic about the potential impact their products could have. “Inevitably the majority of all HIV-infected patients become resistant to their drug regimen,” Aethlon's Joyce said. “We're just looking to see if we can extend the performance of drug therapy.”