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## Article



Blood Works

Mary Ellen Egan, 06.06.05

### **A novel therapy using patients' own blood may reverse a deadly component of heart disease**

For more than a decade medical researchers have been making huge strides in proving the link between inflammation and heart disease. No longer are vascular doctors focusing all their attention on levels of fatty cholesterol clogging coronary arteries. They now track the inflammation caused by an immune system gone berserk trying to remove the cholesterol. When artery walls get inflamed, they eventually cause fatty plaque to rupture and block flow to the heart.

Exotic gene-based anti-inflammatory drugs are working their way through the pipeline, but that's cold comfort to the 12 million Americans who currently suffer from chronic heart failure and peripheral arterial disease.

A more prosaic but innovative approach may be soon at hand. Vasogen, a publicly traded biotech in Mississauga, Ont., has spent \$150 million developing a novel therapy using a modified sample of a patient's own blood to trick the immune system into fighting cardiac inflammation.

Called Celacade, the treatment has already been approved for use in Europe and is currently in late-stage trials in the U.S. Vasogen expects to complete a 500-patient trial for peripheral arterial disease this summer and wrap up a trial of 2,000 chronic heart failure patients a few months later.

The human body is constantly bombarded with foreign microorganisms and antigens, a battle that triggers inflammation responses. If the body were to remain on constant high alert, tissues and organs would wear out. What saves the body over time are naturally occurring anti-inflammatory responses. Vasogen's approach is to trigger more of these responses, keeping the immune system on an even keel.

Vasogen was founded in 1991 by its chief executive, David Elsley, and Dr. Anthony Bolton, an immunologist and former head of biomedical sciences at Sheffield Hallam University in England. Bolton's earlier work on immune regulation in pregnancy convinced him that there

was a way to trigger a physiological reaction to inflammation by pushing cells to the brink of death. "Apoptosis [cell death] is inherently anti-inflammatory," says Bolton.

In Celacade therapy 10 milliliters of whole blood is drawn from a patient and placed inside a Vasogen device slightly larger than a desktop PC. Once inside, the blood is exposed to oxygen, ozone and ultraviolet light for three minutes at 108.5 degrees Fahrenheit. The stress initiates the dying process in some of the white blood cells, and then this apoptotic blood sample is injected into the patient's buttocks. Upon reintroduction to the bloodstream the dying cells get eaten up by debris-scavenging macrophages, which in turn start producing anti-inflammatory cytokines, small proteins that do a variety of jobs, including regulating inflammation. These cytokines signal certain T cells to travel to a swollen, inflamed site and scale back the inflammation.

Celacade follows other so-called immune modulation therapies such as Amgen and Wyeth's Enbrel, and Centocor's Remicade. Although the two drugs have had success treating arthritis patients, Enbrel and Remicade block only a single cytokine, tumor necrosis factor alpha, leaving dozens of other cytokines untouched. Inflammation is a result of a fiendishly complex physiological cascade. Fighting it requires inhibiting the production of some cytokines and/or promoting that of others.

Celacade appears to work well because it stimulates the production of two anti-inflammatory cytokines at once, says Dr. James Young, chairman of the department of medicine at the Cleveland Clinic Foundation, and lead investigator for Vasogen's heart failure trials.

According to Young, the early data for Celacade look very promising. In midstage trials 73 chronic heart failure patients, their bodies wasting away from the disease, were given either Celacade or saline placebo for six months, along with their regular drug regime of blood pressure reducers and diuretics. The Celacade group had one patient death compared with seven in the placebo group. Fewer Celacade patients later wound up in the hospital: 12 compared with 21 placebo patients.

"This will be a huge boon to heart failure patients," says Young. "We need novel approaches because patients are on so many medications and there can be problems with interactions."

Celacade had similarly positive results in a midstage trial with patients with peripheral arterial disease, which hardens the arteries supplying blood to the legs. This disease afflicts at least 7 million Americans and results in tens of thousands of amputations each year. In the trial 85 patients on either Celacade or a placebo were tested on how long they could walk on a treadmill before the onset of pain. Significantly more Celacade patients improved their walking distance by 50% from six months earlier. "This is very exciting and very encouraging," says Dr. Jeffrey Olin, director of vascular medicine at New York's Mount Sinai School of Medicine.