

Garnet testing cell therapy to reduce abdominal scars

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MALVERN — An experimental cell therapy product being developed by Garnet BioTherapeutics Inc. to reduce scarring was used for the first time on a patient.

The new drug candidate, GBT-009, was administered to a woman at Unity Hospital in Rochester, N.Y., as part of a multicenter phase-II clinical trial. She was treated for incision wounds in the abdomen following breast reconstruction surgery.

The cell therapy works by secreting a variety of both pro-regenerative growth and anti-inflammatory factors, which help repair damaged tissue and reduce inflammation, ultimately augmenting the body's ability to heal itself.

"We decided to focus on this area because we met with groups of plastic surgeons and thought leaders and they said [breast construction surgery] is a procedure where there is often an ugly scar," said Gerri Henwood, Garnet's CEO.

Henwood said in breast reconstruction surgery, plastic surgeons will perform a procedure using an abdominal flap technique that uses skin, muscle tissue and fat tissue from the lower abdomen to create a very natural-looking breast. The surgery, called transverse rectus abdominis myocutaneous, leaves patients with a scar across their abdomen.

Patients enrolled in Garnet's phase-II clinical study will serve as their own control group, with part of the incision area treated with the company's cell therapy and the other part treated with a placebo.

GBT-009 is the lead product being developed by Garnet, a Chester County regenerative medicine company founded in 1999 as Neuronyx by the late Hubert J.P. Schoemaker, a biotech pioneer who helped start the Philadelphia region's life sciences industry when he co-founded **Centocor**.

Garnet's cell therapy is derived from adult bone marrow stem cells.

During Garnet's manufacturing process, Henwood explained, the GBT-009 cells lose the ability to morph into other cell types [a trait of embryonic stem cells]. The result is a product that is homogeneous, pure and consistent.

"We believe we are better off with cells having one fate," Henwood said. "There are no unexpected results, and I think that makes the regulatory agencies feel more comfortable."

Garnet hopes to enroll 75 patients in the phase-II study this year, and announce results in mid-2011.

"You aren't going to have a completely scarless area, but we believe [the treatment] will result in a marked reduction in scars from abdominal incisions," Henwood said. "... Our hope is to use [the cell treatment] in other areas where you want to minimize scars."

Dr. Joseph M. Serletti, chief of the division of plastic surgery at the University of Pennsylvania School of Medicine and a specialist in breast reconstruction in cancer patients, is serving as principal investigator for Garnet's cell therapy study.

Serletti said advances in reconstructive surgery give women who have breast cancer choices not widely available 10 years ago, but procedures such as abdominal flap technique can result in a large scar.

“Scarring is a very individual thing [that varies] patient to patient,” he said. “We are excited about what is really a novel cell therapy that will give us a way to modulate the scarring in a way we have never been able to do before.”

Serletti, a consultant to Garnet, said if the therapy works as intended — to improve scar formation and repair damaged tissue — on the section of the scar treated with the cell therapy, patients will have the option of having the remaining scar area redone.