Cytori rises on FDA clearance for fat graft device

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Shares of Cytori Therapeutics Inc. jumped more than 11 percent Friday after the medical device maker said it received U.S. approval for a new version of its Puregraft system, which is used in cosmetic surgery.

Plastic Surgeons use the device in fat grafting procedures that take fat from one part of the body and inject it into another. The device removes unwanted fluid, blood cells and debris from the fat and prepares it for grafting. Many procedures use fat from the thighs and abdomen and graft it into the breasts or face, to create a smoother, firmer look. Plastic surgeons performed nearly 60,000 fat grafting procedures in the U.S. in 2010, according to industry figures

Shares of San Diego, Calif.-based Cytori rose 33 cents, or 11.5 percent, to $3.16 in afternoon trading.

Cytori has attracted attention from analysts for another device, called the Celution system, which some plastic surgeons have reportedly used to create fat grafts enhanced with adult stem cells. The device supposedly separates and purifies adult stem cells, which can then be mixed with fat grafts. Plastic surgeons in Los Angeles, Miami and elsewhere claim the so-called "stem cell facelift" creates a younger, healthier-looking physique than the incisions and implants associated with traditional surgery. But there are few studies to support such claims, and the Food and Drug Administration has not approved any therapies using stem cells for cosmetic use.

Early this year the two largest professional societies for plastic surgeons issued a joint statement calling on their members to avoid stem cell procedures. A review of the medical literature found little human data to support the benefits of injecting stem cells into patients, according to the statement from the American Society of Plastic Surgeons and the American Society for Aesthetic Plastic Surgery.

"The marketing and promotion of stem cell procedures in aesthetic surgery is not adequately supported by clinical evidence at this time," reads the joint statement, published in January.

"This is modern-day snake oil," said Dr. Felmont Eaves, president of the American Society of Plastic Surgeons, in an interview last year with the Associated Press. "It is the worst form of merchandising for a procedure that doesn't have scientific evidence to back it up."

Eaves pointed out that surgeons have been using fat grafts to plump up cheeks and breasts for decades. The practice has a mixed record of success, and has never eclipsed the more popular facelift and breast implant procedures.

"There's no evidence that going the extra step to create a stem cell version of this makes any difference," Eaves said.

Adult stem cells are found in bone, fat and tissue throughout the body and are thought to be able to morph into several different types of cells. They differ from embryonic stem cells, which are more controversial because their use involves destroying human embryos.

Cytori does not market its products in the U.S. for use with stem cells. However, the company has sold its Celution system to plastic surgeons across the country.

The device is approved in Europe for several uses, including breast reconstruction in patients who have had cancerous tumors removed. That approval was based on a 70-patient study in which patients and their doctors were asked whether they were "satisfied" with the appearance and feel of the stem cell-injected breasts. The company reported one-year follow up data last year, with 85 percent of physicians and 75 percent of patients reporting satisfaction.

Such studies are not accepted by the FDA, which requires a higher standard of evidence than European regulators. Cytori recently received FDA approval to begin a small study using Celution system-derived stem cells to treat heart disease. The company has no U.S. studies of the device for cosmetic use. But Cytori is still able to sell its device to U.S. doctors as laboratory equipment, which is not regulated by the FDA.

"We have to be very careful about making sure we're strictly compliant with U.S. regulations. But you can sell laboratory equipment into hospitals and then doctors can choose to use it to practice medicine," said Cytori President Mark Hedrick, in an interview with the Associated Press last year. "I know of no instance where there's anything going on that doesn't follow U.S. law," he added.

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