



FDA Grants 510(k) Marketing Clearance for Cytori's PureGraft(TM) System; First & Only Device on Market for Aesthetic Body Contouring using Autologous Fat Grafts

SAN DIEGO, Jan 08, 2010 (BUSINESS WIRE) -- The FDA has granted Cytori Therapeutics (NASDAQ: CYTX) 510(k) marketing clearance for its PureGraft(TM) System. Cytori will now launch the first and only device in the United States cleared for aesthetic body contouring using autologous fat. PureGraft(TM) allows a patient's own fat tissue to rapidly be prepared in approximately 15 minutes for re-injection back into the same patient for aesthetic contouring.

PureGraft(TM) is able to prepare both small and large volumes of fat grafting tissue ranging from 50 mL to 250 mL. Puregraft (TM) maintains sterility while optimizing the yield of tissue to be grafted, which provides significant utility to physicians. In contrast to traditional methods of graft preparation, PureGraft(TM) washes the graft and drains the tumescent fluid, free lipid and debris in a closed sterile system, allowing for a cleaner graft in less time than it would take to prepare a comparable volume of graft tissue traditionally.

"FDA clearance provides us with a strategically important product in addition to the CelBrush(TM) to help establish our brand and build relationships with U.S. plastic and reconstructive surgeons," said Marc H. Hedrick, M.D., President of Cytori Therapeutics. "There are several advantages this product offers physicians performing autologous fat grafts, which can improve efficiencies in the operating room, decrease surgery time and, by being able to process greater volumes, to include large defects."

PureGraft(TM) will be sold in the United States directly by Cytori as well as through select distribution partners on a non-exclusive basis. The product will be available in the first quarter of 2010 and will be formally launched at the American Society of Aesthetic Plastic Surgeons in May 2010.

Cytori is also seeking marketing approval (CE Mark certification) for PureGraft(TM) in Europe, which is expected in the first half of 2010. In Europe, PureGraft(TM), in addition to being sold as a standalone product, will be used to complement Cytori's currently available autologous tissue processing system as a means to expand the potential number of clinical applications.

According to the American Society of Plastic Surgeons' most recent report of plastic surgery statistics, over 46,000 fat grafting procedures were performed in the United States in 2008. Currently, over 5,000 plastic surgeons are registered with the American Society of Plastic Surgeons.

About Cytori

Cytori is an emerging leader in providing patients and physicians around the world with medical technologies, which harness the potential of adult regenerative cells from adipose tissue. The Celution^(R) System family of medical devices and instruments is being sold into the European and Asian cosmetic and reconstructive surgery markets but is not yet available in the United States. Our StemSource^(R) product line is sold globally for cell banking and research applications. www.cytori.com

Cautionary Statement Regarding Forward-Looking Statements

This communication includes forward-looking statements regarding events, trends and business prospects, which may affect our future operating results and financial position. Such statements are subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks and uncertainties include our history of operating losses, regulatory uncertainties, dependence on third party performance, and other risks and uncertainties described under the "Risk Factors" in Cytori's Securities and Exchange Filings, including its annual report on Form 10-K for the year ended December 31, 2008. Cytori assumes no responsibility to update or revise any forward-looking statements contained in this press release to reflect events, trends or circumstances after the date of this press release.

SOURCE: Cytori Therapeutics

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