

Cytori Provides Update in 510(k) Appeal Decision

The Associated Press

SAN DIEGO--(BUSINESS WIRE)--Mar 22, 2013--Cytori Therapeutics (NASDAQ: CYTX) today announced that the United States Court of Appeals for the District of Columbia Circuit has ruled on the Company's conjoined appeals (case no. 11-1268).

The court upheld the FDA's (Food and Drug Administration) previous determination that Cytori's cell processing devices were not substantially equivalent to the cited predicate devices. Cytori will continue to pursue its intended pathway to regulatory approval via the PMA (Premarket Approval) route, such as the active ATHENA clinical trial for refractory heart failure. Cytori received IDE (Investigational Device Exemption) in January 2012 required to initiate the ATHENA clinical trial.

"This decision reaffirms our primary regulatory pathway in the U.S.," said Christopher J. Calhoun, Chief Executive Officer of Cytori. "Our priority remains unchanged, which is completion of clinical development of our Celution® System in refractory heart failure under the FDA's PMA clinical trial-based pathway for class 3 medical devices. Such a pathway provides the necessary data for approval, adoption, and reimbursement and will raise an additional barrier-to-entry for potential competitors who would be required to pursue the same PMA pathway. As a result, this decision further clarifies the standard-of-evidence required for the field." Cytori has been pursuing parallel pathways to market. One pathway has been to obtain therapeutic indications, such as those being pursued in our cardiac development. The other pathway has been to obtain clearance for laboratory equipment that would provide technology access to researchers, for which Cytori has achieved approval in Europe and Japan. Cytori appealed the decision based on a series of prior 510(k) clearances and a 2009 determination by the FDA, through a formal request for designation by the office of FDA's combination products, that Cytori's cell processing technology would be regulated as a medical device and not a biologic. The appeal was related to the subsequent 2011 decision by the FDA to deny the 510(k) clearance for laboratory versions of our cell processing technology.

Regulatory Overview The FDA regulates medical devices as class 1, 2, or 3. Typically, class 2 devices require a demonstration of substantial equivalence to a pre-existing device with limited or no clinical data. Class 3 devices are considered novel and more complex, thus require clinical data and/or clinical testing under the PMA pathway.

Cytori and the FDA agree that marketing approval for the Company's Celution® System for use in cardiovascular disease and other therapeutic indications requires a PMA. The appeals rulings announced today relate to the Company's separate actions to seek approval for tissue processing systems for use in banking and research as class 2 medical devices.

About Cytori Therapeutics Cytori Therapeutics, Inc. is developing cell therapies

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based on autologous adipose-derived regenerative cells (ADRCs) to treat cardiovascular disease and repair soft tissue defects. Our scientific data suggest ADRCs improve blood flow, moderate the inflammatory response and keep tissue at risk of dying alive. As a result, we believe these cells can be applied across multiple “ischemic” conditions. These therapies are made available to the physician and patient at the point-of-care by Cytori’s proprietary technologies and products, including the Celution® system product family. 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 including those regarding our expected enrollment completion date of our Athena trial, are subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks include clinical and regulatory uncertainties, risks in the collection and results of clinical data, clinical outcomes, dependence on third party performance, and other risks and uncertainties described under the “Risk Factors” in Cytori’s Securities and Exchange Commission Filings. We assume no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made.

The Celution® System is available in the United States for investigational use only.

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