Enrollment Completed in Randomized Clinical Trial of Habeo™ Cell Therapy for Scleroderma and Impaired Hand Function

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SAN DIEGO, Jan. 22, 2018 (GLOBE NEWSWIRE) -- Cytori Therapeutics, Inc. (NASDAQ:CYTX) announces completion of patient enrollment in SCLERADEC II (NCT02558543), a randomized, double-blind, placebo-controlled, parallel group, multi-center clinical trial intended to study the safety and efficacy of Habeo™ Cell Therapy in up to 40 subjects with impaired hand function due to scleroderma (systemic sclerosis).

In this investigator-initiated clinical trial supported by Cytori, a total of 40 patients were enrolled among 5 French centers: Marseille, Montpelier, Rouen, Lyon, and Paris. The primary endpoint is improvement over baseline in the Cochin Hand Function Scale at 3 months. Full analysis of the unblinded data set, including results for secondary endpoints such as pain, quality of life, mobility, strength, tactile sensitivity, Raynaud's Phenomenon, and vascular suppression, will be performed upon completion of the final patient's 6 month follow-up visit. Data will be available in the second half of 2018 and may support potential future regulatory submissions in Europe and selected regions.

"Cytori would like to thank the investigators and patients participating in the SCLERADEC II trial." Said Dr. Marc Hedrick, Cytori's President and Chief Executive Officer. "We believe that the combination of the findings from SCLERADEC II, the results from Cytori's U.S. STAR clinical trial, and anticipated feedback from our FDA pre-submission meeting later this quarter will provide us with a clearer picture of the optimal path forward with this therapy in the U.S., Europe and other important markets."

In SCLERADEC II, all patients had Habeo Cell Therapy prepared from their adipose tissue. Patients randomized to the treatment arm had cells administered to their fingers via injections on the same day while patients randomized to receive placebo, had their cells cryopreserved for future use. The open-label crossover arm in the trial allows patients randomized to placebo to receive their cryopreserved cells after 6 month data have been analyzed and reviewed by an independent monitoring committee. Eligible patients electing to receive treatment with cryopreserved cells will be followed for both safety and efficacy for 6 months.

About SCLERADEC II Investigators

The SCLERADEC II trial is being led in Marseilles, France by Prof. Brigitte Granel of the Department of Internal Medicine of the Assistance Publique Hôpitaux de Marseille (APHM) with support from Prof. Florence Sabatier of the Cell Therapy Department and Prof. Dominique Casanova from the Department of Plastic Surgery, Conception Hospital, APHM. The other French centers include: Prof. I. Auquit (Plastic Surgery), Dr. Ygal Benhamou (Internal Medicine), and Dr. O Boyer (Cell and Gene Therapy Unit) of the University Hospital Center of Rouen (CHU Rouen); Prof. D. Farge (Internal Medicine), Prof. M. Chaouat (Plastic Surgery) and Prof. J Larghero (Cell and Gene Therapy Unit) of Saint Louis Hospital of Paris; Prof. A Hot (Internal Medicine) of Edouard Herriot Hospital of Lyons and Prof. C Jorgensen of University Hospital Center of Montpellier.

About Scleroderma

Scleroderma is a rare, debilitating, and sometimes fatal, chronic autoimmune disease. The word "scleroderma" is derived from two Greek words: "sclera," which means hard, and "derma," meaning skin, as hardening of the skin is one of the most visible manifestations of the disease. Systemic Sclerosis (SSc) is the most serious form of scleroderma with an estimated 125,000 active cases in the U.S. and 2.5 million globally. SSc is further sub-classified as diffuse cutaneous and limited cutaneous SSc. Patients with diffuse cutaneous SSc have more severe disease with significant hand dysfunction and internal organ involvement. Diffuse scleroderma accounts for between one-third and one-half of all cases of SSc.1,2

SSc contributes to hand impairment through inflammatory arthritis or inflammation of the joints, joint contractures, Raynaud's Phenomenon (RP, skin discoloration resulting from narrowing of the blood vessels in response to cold, emotional upset, or stress), digital ulcers, puffy hands and skin fibrosis over the fingers and hands, and calcinosis (calcium deposits in the soft tissues of the hand). These manifestations, which often coexist, can contribute to difficulty with occupational activities and activities of daily living, which can impair quality of life. Whereas current treatment recommendations focus on management of internal organ involvement, there is little treatment available for hand impairment.

About Habeo Cell Therapy

Cytori is developing cell therapies that harness the unique attributes of adipose-derived regenerative cells (ADRCs), which are living cells that are present in an adult human's own adipose tissue.

Habeo Cell Therapy is a suspension of ADRCs that are manufactured from a single lipoaspirate (material removed via liposuction, a procedure in which fat is removed from under the skin by suction). The process concentrates ADRCs intended for autologous re-implantation subcutaneously into the digits. The resultant cell suspension contains critical cells naturally occurring in the patient's own tissue. Preparation of autologous ADRCs for subcutaneous delivery involves no cell culture and can be prepared and re-implanted into the same patient within 4 hours.

About Cytori

Cytori is a therapeutics company developing regenerative and oncologic therapies from its proprietary cell therapy and nanoparticle platforms for a variety of medical conditions. Data from preclinical studies and clinical trials suggest that Cytori Cell Therapy™ acts principally by improving blood flow, modulating the immune system, and facilitating wound repair. As a result, Cytori Cell Therapy™ may provide benefits across multiple disease states and can be made available to the physician and patient at the point-of-care through Cytori's proprietary technologies and products. Cytori Nanomedicine™ is developing liposome encapsulated therapies for regenerative medicine and oncologic indications. For more information, visit www.cytori.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release includes forward-looking statements regarding events, trends and business prospects, which may affect Cytori's future operating results and financial position. Such statements, include, but are not limited to, statements regarding, Cytori's plans to evaluate the SCLERADEC II data; Cytori's anticipated feedback from our FDA pre-submission meeting, and possible future clinical trials of Habeo Cell Therapy. These statements are subject to risks and uncertainties that could cause Cytori's actual results and financial position to differ materially. Some of these risks and uncertainties include: risks in the conduct of Cytori's clinical trials and future clinical trials (including risks in the collection and results of clinical data); risks associated with the conduct of investigator-initiated trials using our cellular therapeutics, including the French, investigator-initiated SCLERADEC II trial; risks associated with potential benefits of Cytori's products (including any potential benefits of Habeo Cell Therapy); risks associated with development of Cytori's clinical pipeline, including the possibility that Cytori may determine that there may not be a viable continued development path for Habeo Cell Therapy; final clinical outcomes; regulatory risks and uncertainties, including the risk that FDA and other regulatory authorities may not approve Habeo Cell Therapy, or that any marketing approvals, if granted, may have significant limitations on their use; risks related to reimbursement (including failure to achieve desired pricing for Habeo Cell Therapy); risks related to dependence on third party performance; the risk that Habeo Cell Therapy may never be successfully commercialized, or receive anticipated levels of commercial acceptance; Cytori's ability to raise additional funding that it may need to continue to pursue its commercial and business development plans; and other risks and uncertainties described under the "Risk Factors" section in Cytori's Securities and Exchange Commission filings on Form 10-K and Form 10-Q. 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 communication.

1http://www.scleroderma.org/site/PageNavigator/patients_whatis.html#.WWZdOYjyvGh

2 Arthritis Rheumatism Vol 48, (8), August 2003, pp 2246–2255 DOI 10.1002/art.11073

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