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Cell Therapeutics Announces that the European Organization for Research and Treatment of Cancer Completes Enrollment in Phase II Clinical Trial of Brostallicin as First Line Therapy for Advanced or Metastatic Soft Tissue Sarcoma

Potential for data analysis early 2009

August 12, 2008 Seattle — Cell Therapeutics, Inc.'s (CTI) (NASDAQ and MTA: CTIC) subsidiary Systems Medicine (SM) announced today that planned enrollment is complete in the European Organization for Research and Treatment of Cancer (EORTC) randomized phase II clinical trial of brostallicin in patients with newly diagnosed advanced or metastatic soft tissue sarcoma who have had no prior chemotherapy. The primary endpoint of the trial is progression-free survival at six months. Patients are randomized in a 2:1 ratio either to receive brostallicin or the standard therapy, doxorubicin. The EORTC designed the study to enroll a total of 108 eligible and treated (evaluable) patients, and plans to conduct the final data analysis in early 2009.

“New therapies are needed to improve outcomes in patients with advanced non-GIST soft tissue sarcomas. This study is the second EORTC study of brostallicin in soft tissue sarcoma. The initial study used brostallicin as single agent salvage therapy in patients whose disease had progressed following initial chemotherapy. The EORTC considered the results in that trial to be of sufficient magnitude to conduct the current study, using brostallicin as first line therapy in patients with advanced or metastatic soft tissue sarcoma who have not received any prior chemotherapy,” said Jack Singer, M.D., EVP, Chief Medical Officer of Cell Therapeutics. “A standard-of-care arm (doxorubicin) is included as a reference arm, although not used to determine comparative efficacy. If the study results are encouraging, a Phase III study in soft tissue sarcoma could be initiated in 2009.”

The title of the trial is “Randomized phase II study of brostallicin (PNU-166196A) versus doxorubicin as first line chemotherapy in patients with advanced or metastatic soft tissue sarcoma.” Hans Gelderblom, M.D., Ph.D., of Leiden University Medical Center in the Netherlands, is the Principal Investigator (PI) and Jean Yves Blay, M.D., Ph.D., chair of the EORTC Soft Tissue and Bone Sarcoma Group, is overseeing it.

“Based on the results of the first EORTC study with brostallicin, we conducted the current study in patients with soft tissue sarcoma to further define the activity of this drug in this patient population,” said Blay. “In the first study, two patients treated with brostallicin had confirmed partial responses and many others had prolonged disease control. Such activity is rare in this group of patients, and we very much hope to confirm or improve on those results and to expand our knowledge of brostallicin in the treatment of these patients.”

“Brostallicin represents a promising new agent with a unique mechanism of action for patients with metastatic sarcoma where there is a clear unmet medical need,” said Gelderblom. “The current standard approach for newly diagnosed patients with sarcoma is essentially limited to doxorubicin so clearly new treatment options are needed.”

About the Study

To participate in the study, patients had to be at least 60 years of age or at least 18 years of age and non suitable for intensive chemotherapy combination treatment, with a WHO performance status 0 or 1. The EORTC's protocol called for a maximum of 6 treatment cycles, unless the patient withdrew before completion of treatment due to disease progression, drug related event, concurrent illness, or patient refusal to continue therapy. A patient's tumor will be re-evaluated every 6 weeks during treatment, and at least 4 weeks after the first observation of a complete or partial response. After discontinuation of protocol treatment, patients who have not progressed will be re-evaluated every 12 weeks, unless they have started a new anti-cancer therapy. The primary end-point is proportion of patients who are progression free at 6 months (26 weeks) after start of treatment according to RECIST. Secondary objectives are progression free survival (PFS), objective tumor response based on RECIST, duration of response, and overall survival. A total enrollment of 108 eligible and evaluable patients was required (36 in the doxorubicin arm, 72 in the brostallicin arm).

About Brostallicin

Brostallicin, a novel synthetic second-generation DNA minor groove binder, has potent cancer killing activity and has demonstrated synergism in combination with standard cytotoxic agents as well as with newer targeted therapies in preclinical experimental tumor models. Brostallicin binds covalently to DNA within the DNA minor groove, interfering with DNA division and leading to tumor cell death. More than 230 patients have been treated with brostallicin in single-agent and combination studies. Brostallicin had predictable and predominantly hematologic toxicities. Activity was demonstrated in a number of solid tumor types. A phase II study of brostallicin in relapsed/refractory soft tissue sarcoma had sufficient activity based on 3 and 6 month progression free survival and safety profile, which resulted in the first-line phase II study that is currently being conducted by the EORTC.

Context of Vulnerability

CTI and SM are employing a new method of drug development, the "context of vulnerability" approach. Using cutting-edge genomic profiling tools, the Company creates a profile of which cells react to certain drugs in an effort to discover cells' vulnerabilities (weak spots) and where the drugs are the strongest. With these data, investigators can target those patients with the highest probability of benefiting from a particular drug. By treating only the patients with the genetic characteristics known to react well to the drug, scientists may be able to decrease the time and money necessary to develop a drug and bring it to market. This approach also has the potential to improve the rate of treatment success and increase the number of approved drug products across the drug development industry.

About the EORTC

Created in 1962, the European Organization for Research and Treatment of Cancer (EORTC) is a not-for-profit international cancer research organization under the Belgian law. The EORTC has the mission to develop, conduct, coordinate and stimulate translational and clinical research in Europe to improve the management of cancer and related problems by increasing survival but also patients' quality of life. The ultimate goal of the EORTC is to improve the standard of cancer treatment in Europe, through the evaluation of new drugs and other innovative approaches, and to test more effective therapeutic strategies, using drugs which are already commercially available, or surgery or radiotherapy. The EORTC has the aim to facilitate the passage of experimental discoveries into state-of-the-art treatment by keeping to a minimum the time lapse between the discovery of new anticancer agents and the implementation of their therapeutic benefit for patients with cancer.

The EORTC promotes multidisciplinary cancer research in Europe and is linked to other leading biomedical research organizations around the world. EORTC research takes place in over 300 hospitals, universities and cancer centers in 32 countries, and the unique network of investigators of the EORTC comprises more than 2000 clinicians collaborating on a voluntary basis in 19 multidisciplinary groups. <http://www.eortc.be>

About Systems Medicine (SM)

In July 2007, CTI acquired Systems Medicine (SM), a privately held oncology company, in a stock-for-stock merger. SM applies a systems biology approach to drug development, combining pharmacogenomics and bioinformatics with experienced preclinical, clinical and regulatory expertise to find and exploit a specific cancer's 'context of vulnerability.' Specifically, SM defines the molecular and genetic alterations (context) that cause cancer cells to be particularly sensitive (vulnerable) to a drug or combination of drugs—the 'context of vulnerability'.

About Cell Therapeutics, Inc.

Headquartered in Seattle, CTI is a biopharmaceutical company committed to developing an integrated portfolio of oncology products aimed at making cancer more treatable. For additional information, please visit www.celltherapeutics.com.

This press release includes forward-looking statements that involve a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results. Specifically, the risks and uncertainties that could affect the development of brostallicin include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general and with brostallicin in particular including, without limitation, the potential failure of brostallicin to prove safe and effective for treatment of solid tumors, determinations by regulatory, patent and administrative governmental authorities, competitive factors, technological developments, costs of developing, producing and selling brostallicin, and the risk factors listed or described from time to time in the Company's filings with the Securities and Exchange Commission including, without limitation, the Company's most recent filings on Forms 10-K, 8-K, and 10-Q. In addition, there can be no guarantee that the "Context of Vulnerability" development method will prove to be cost-effective or that it will decrease the time and cost of bringing new drugs to market, or that it will be successful in improving treatment success or increase the number of drugs that can be brought to market. Except as may be required by law, CTI does not intend to update or alter its forward-looking statements whether as a result of new information, future events, or otherwise.

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