CELL THERAPEUTICS INC
Form 425
December 09, 2003

Filed by Cell Therapeutics, Inc.

Pursuant to Rule 425 under the Securities Act of 1933

Subject Company: Cell Therapeutics, Inc.

Commission File No.: 001-12465

The following press release was issued by Cell Therapeutics, Inc. (CTI) on December 9, 2003. The referenced Novuspharma S.p.A. press release is filed herewith and immediately follows the CTI press release.

Pixantrone Induces Impressive 77% Major Tumor Response Rate in Patients with Relapsed Aggressive Lymphoma when Substituted for Doxorubicin in CHOP Regimen

Dec. 9, 2003 Seattle Novuspharma S.p.A. (Novuspharma) (Nuovo Mercato: NOV.MI) announced results from a phase I study where Pixantrone was administered instead of doxorubicin as part of the CHOP regimen (the new CPOP combination), in patients with relapsed aggressive non-Hodgkin s lymphoma (NHL). These initial results indicate that Pixantrone may be safely administered to relapsed patients who have previously received their maximum permitted dose of standard anthracyclines, while resulting in impressive response rates. Among the 22 patients evaluable for a response, 13 patients (59 percent) had a complete response (total disappearance of tumor), with 4 patients experiencing a 50 percent or greater shrinkage in their tumor. This corresponds to a major objective response rate of 77 percent. At the highest Pixantrone dose (150mg/m²), all 7 patients (100 percent) responded, with 6 patients (85 percent) experiencing a complete response. In the light of these highly promising results a phase II extension trial has been initiated, recruiting up to 25 patients in Europe. Results were presented on Sunday, December 7, at the 45th Meeting of the American Society of Hematology (ASH), in San Diego, California. In June, Cell Therapeutics, Inc. (CTI) (Nasdaq: CTIC) and Novuspharma announced they had entered into a merger agreement.

For more information on the study, refer to the Novuspharma website at:

http://www.novuspharma.com/nov/investorinfo/releases/

About Cell Therapeutics, Inc.

Based 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.cticseattle.com.

For further information please contact:

Investors **Media**

Cell Therapeutics, Inc.

Leah Grant

T: 206.282.7100 F: 206.272.4010

E: invest@ctiseattle.com

www.cticseattle.com/investors.htm

Cell Therapeutics, Inc.

Candice Douglass

T: 206.272.4472 F: 206.272.4010

E: media@ctiseattle.com

www.cticseattle.com/media.htm

Pixantrone Induces Impressive 77% Major Tumor Response Rate in Patients with Relapsed Aggressive Lymphoma when Substituted for Doxorubicin in CHOP Regimen

More than 50% of patients experience complete disappearance of tumors

Milan, Italy, 9 December 2003 Novuspharma SpA (Nuovo Mercato: NOV.MI and NOV IM), a biopharmaceutical company focused on developing new cancer therapeutics, today announces results from a phase I study where Pixantrone was administered instead of doxorubicin as part of the CHOP regimen (the new CPOP combination), in patients with relapsed aggressive non-Hodgkin s lymphoma (NHL). These initial results indicate that Pixantrone may be safely administered to relapsed patients who have previously received their maximum permitted dose of standard anthracyclines, while resulting in impressive response rates. Among the 22 patients evaluable for a response, 13 patients (59 percent) had a complete response (total disappearance of tumor), with 4 patients experiencing a 50 percent or greater shrinkage in their tumor. This corresponds to a major objective response rate of 77 percent. At the highest Pixantrone dose (150mg/m²), all 7 patients (100 percent) responded, with 6 patients (85 percent) experiencing a complete response. In the light of these highly promising results a phase II extension trial has been initiated, recruiting up to 25 patients in Europe. Results were presented on Sunday, December 7, at the 45th Meeting of the American Society of Hematology (ASH), in San Diego, California.

Updated results from a phase I/II trial of Pixantrone in the BSHAP regimen were also presented at ASH. In this trial Pixantrone was administered in combination with steroids, platinum and ARA-C, to 21 patients who had failed one or more prior multi-chemotherapeutic regimens for relapsed aggressive NHL. Sixty-Four percent of patients had disease refractory to prior chemotherapy. Of the 18 patients evaluable for response, 61 percent had a major tumor response, with 39 percent demonstrating a complete response and 22 percent experiencing a tumor shrinkage of at least 50 percent (PR). Furthermore, the updated results reveal that 6 patients (over half of those who responded) have proceeded to bone marrow transplant. Bone marrow transplant is currently the only procedure which can cure patients with relapsed aggressive NHL. No clinically significant cardiac events or decreases in cardiac function were reported.

CHOP and the new CHOP-variant regimen containing Pixantrone

The CHOP chemotherapy regimen (a combination of cyclophosphamide, vincristine, prednisone and doxorubicin) is the standard-of-care treatment for newly diagnosed (front line) aggressive NHL, which represents an estimated population of 14,500 patients. Response rates following CHOP in front line aggressive NHL can reach 70% and the regimen is potentially curative in up to 35 to 40% of patients. The prognosis is poor for patients who have a recurrence of the disease (relapsed patients). Despite its impressive anti-tumor activity, CHOP cannot be used to retreat the 60 to 65% of patients who will relapse following CHOP, due to the cumulative cardiotoxicity associated with one of its constituent agents, doxorubicin; a chemotherapy agent which belongs to the anthracycline family. The maximum life time recommended dose of doxorubicin ranges from 450mg/m² to 550mg/m² and this level is often reached during front line treatment with CHOP. There is estimated to be more than 100,000 patients with relapsed aggressive NHL in the US.

Pixantrone is an investigational drug that is being developed by Novuspharma, which was designed to potentially increase anti-tumor activity and decrease the potential for cardiac toxicity associated with the currently marketed anthracycline drugs. This trial examined the safety and potential efficacy of Pixantrone when substituted for doxorubicin in the CHOP regimen among patients who had failed prior doxorubicin containing CHOP therapy for aggressive NHL. Pixantrone s efficacy in this context was predicted based on the synergy seen with cyclophosphamide and vincristine in preclinical studies.

Dose determination and safety results from the Pixantrone CHOP variant trial

This phase I trial was an open-label, dose ranging study, with Pixantrone administered on day 1 of a 21 day cycle, in combination with standard fixed doses of cyclophosphamide, vincristine and prednisone. The trial s primary objective was to identify the recommended dose of Pixantrone for subsequent studies, in addition to obtaining safety and preliminary efficacy data. The trial recruited 23 patients in total, across 4 dose levels: 80mg/m², 100mg/m², 120mg/m² and 150mg/m², the latter of which was identified as the maximum tolerated dose based on these study findings.

The majority of patients were elderly, with a median age of 67 (range 34-77) and had received a median of 3 prior regimens (range 1-9). Median prior anthracycline exposure was 535mg/m² doxorubicin, or equivalent (range 60 to 1002mg/m²). Toxicities were predominantly hematological (suppression of blood cell growth) and the dose limiting toxicity was neutropenia (low levels of white blood cells, which is commonly seen with chemotherapy treatment). No grade IV non-hematological toxicity was observed.

Cardiac side effects were infrequent. Two patients had an asymptomatic reduction in their cardiac ejection fraction (LVEF) to 20 percent below their baseline value. One patient with a history of coronary artery disease and diabetes developed Grade II angina pectoris. The low rate of cardiac events is very encouraging, considering the patients age and their level of pre-treatment with the traditional anthracyclines.

Efficacy results

The preliminary efficacy data indicate that Pixantrone is highly effective in the CHOP-variant regimen, with an overall response rate of 77% and disease control rate of 95%. Thirteen patients (59%) experienced a complete response (CR) or complete response unconfirmed (CRu), 4 (18%) experienced a partial response (PR) and 4 (18%) achieved stable disease (SD), out of 22 evaluable patients. Furthermore, patients responded at every Pixantrone dose level and 7 / 7 patients responded at the highest dose (150mg/m²). Patients continue to be followed for response duration.

First patient recruited in a phase II trial using the CHOP-variant regimen

Novuspharma also announces today that the first patient has been recruited in a phase II extension to this trial. This phase II is expected to recruit around 25 patients in Europe, who will receive CHOP-variant with Pixantrone at 150 mg/m². The trial s primary objective is to obtain additional efficacy data in terms of objective response rate (CR + PR).

Professor Andreas Engert, Principal Investigator on the study commented: The CHOP chemotherapy regimen has become standard-of-care in the treatment of front-line aggressive NHL, where it is associated with a high rate of complete remission and cure. The safety and preliminary efficacy data from this phase I/II trial suggest that substituting Pixantrone, in the place of doxorubicin in CHOP, produces a regimen that may be safely used in relapsed aggressive NHL patients. This could potentially allow relapsed patients to benefit from the high efficacy of CHOP a second time, providing them with a much needed treatment option. I look forwards to further studying Pixantrone in the CHOP-variant regimen.

Enquiries:

Novuspharma SpA

Karl Hanks Tel: +39 335 7882247
Candice R. Douglass of CTI Tel: +1 206 850 6084

Financial Dynamics
Sarah Macleod Tel: +44 (0)20 7831 3113
Francetta Carr

Notes to Editors

Novuspharma SpA and its merger agreement with Cell Therapeutics (CTI)

Novuspharma, based in Bresso, Milan, is an emerging biopharmaceutical company leveraging its expertise in the field of oncology to discover and develop innovative new treatments for cancer. It has three products in clinical development and a dynamic research program. Novuspharma was established in 1998 following the merger of Boehringer Mannheim and Hoffmann-La Roche, to exploit the R&D team s proven track record in product development. On June 17th, 2003, Novuspharma announced it had signed a merger agreement with Cell Therapeutics (CTI) (NASDAQ CTIC) of Seattle. CTI is a public biopharmaceutical company, which markets TRISENOX® in the US and Europe and is developing XYOTAX (CT-2103), which is in pivotal phase III trials for lung cancer. For further information, please visit the Company s website at www.novuspharma.com. For an explanation of technical terms please see www.novuspharma.com/nov/glossary/

***

CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on management s current expectations and beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The forward-looking statements contained in this press release include statements about future financial and operating results, the proposed CTI/Novuspharma merger, and risks and uncertainties that could affect CTI s product and products under development. These statements are not guarantees of future performance, involve certain risks, uncertainties and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed herein. For example, if either of the companies fail to satisfy conditions to closing, the transaction will not be consummated. In any forward-looking statement in which CTI expresses an expectation or belief as to future results, such expectation or belief is expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will result or be achieved or accomplished. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: risks associated with preclinical, clinical and sales and marketing developments in the biopharmaceutical industry in general and in particular including, without limitation, the potential failure to meet TRISENOX® revenue goals, the potential failure of XYOTAX to prove safe and effective for treatment of non-small cell lung and ovarian cancers, the potential failure of TRISENOX® to continue to be safe and effective for cancer patients, determinations by regulatory, patent and administrative governmental authorities, competitive factors, technological developments, costs of developing, producing and selling TRISENOX® and CTI s products under development in addition to the risk that the CTI and Novuspharma businesses will not be integrated successfully; costs related to the proposed merger; and other economic, business, competitive, and/or regulatory factors affecting CTI s and Novuspharma s businesses generally, including those set forth in CTI s filings with the SEC, including its Annual Report on Form 10-K for its most recent fiscal year and its most recent Quarterly Report on Form 10-Q, especially in the Factors Affecting Our Operating Results and Management s Discussion and Analysis of Financial Condition and Results of Operations sections, its Current Reports on Form 8-K and its filings on Forms S-3 and S-4. CTI is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements whether as a result of new information, future events, or otherwise.