SEATTLE, Oct. 15, 2013 /PRNewswire/ -- Cell Therapeutics, Inc. (CTI) (NASDAQ and MTA: CTIC) today announced that the National Institute for Health and Care Excellence (NICE), a non-departmental public body of the Department of Health in the Unite d Kingdom (UK), issued second draft guidance on PIXUVRI ® (pixantrone) as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma (aggressive B-cell NHL). NICE's independent Appraisal Committee met on September 11, 2013, to consider the cost effectiveness of pixantrone taking into consideration CTI's initial patient access scheme that was approved by the Department of Health in July 2013. The result is a second appraisal consultation document, or ACD, whereby the Committee concluded that this scheme does not overcome the uncertainties in the evidence for pixantrone's (PIXUVRI) clinical effectiveness and once again requests that consultees, including CTI, healthcare professionals and members of the public, comment on the draft guidance via the NICE website. The ACD consultation will close on November 4, 2013, and any comments received will be considered by the NICE appraisal committee to enable them to develop the next stage of guidance. It should be noted that this is not NICE's final guidance on pixantrone and that a third Appraisal Committee meeting is expected to be held on November 13, 2013, where subject to approval, CTI hopes the Committee will consider an 'enhanced' patient access scheme to demonstrate the cost effectiveness of pixantrone for use by the NHS in the UK.

In May 2012, the European Commission (EC) granted conditional marketing authorization in the European Union (E.U.) for PIXUVRI as a monotherapy for adult patients with multiply relapsed

or refractory aggressive B-cell NHL based on the results of the EXTEND, or PIX301, pivotal randomized Phase 3 clinical trial. PIXUVRI was made available to patients in eight countries in the European Union in the fourth quarter of 2012, and some patients in other countries have already started to receive the treatment. Prior to the approval of PIXUVRI in the E.U., there were no approved agents or standard of care in this stage of the disease. The PIX301 trial was designed utilizing agents in the comparator arm that have anti-tumor activity in relapsed disease and are typically employed as palliative therapy for these patients.

"We look forward to collaborating with NICE during the final stage of the process as we seek to bring this new approved therapy to patients in the UK with aggressive non-Hodgkin lymphoma in the 3rd line salvage setting," said James A. Bianco, M.D., President and CEO of CTI.

About PIXUVRI (pixantrone)

PIXUVRI is a novel aza-anthracenedione with unique structural and physiochemical properties. Unlike related compounds, PIXUVRI forms stable DNA adducts and in preclinical models has superior anti-lymphoma activity compared to related compounds. PIXUVRI was structurally designed so that it cannot bind iron and perpetuate oxygen radical production or form a long-lived hydroxyl metabolite -- both of which are the putative mechanisms for anthracycline induced acute and chronic cardiotoxicity. These novel pharmacologic properties allow PIXUVRI to be administered to patients with near maximal lifetime exposure to anthracyclines without unacceptable rates of cardiotoxicity.

In May 2012, the European Commission (EC) granted conditional marketing authorization for PIXUVRI as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive NHL. The benefit of PIXUVRI treatment has not been established in patients when used as fifth line or greater chemotherapy in patients who are refractory to last therapy. The Summary of Product Characteristics (SmPC) has the full prescribing information, including the safety and efficacy profile of PIXUVRI in the approved indication. The SmPC is available at www.pixuvri.eu . PIXUVRI does not have marketing approval in the United States.

About Non-Hodgkin Lymphoma

Non-Hodgkin lymphoma is the sixth most common cancer in the UK; in 2010, 12,180 people were diagnosed with the disease.[1] NHL is caused by the abnormal proliferation of lymphocytes, cells that are key to the functioning of the immune system. It usually originates in lymph nodes and spreads through the lymphatic system. NHL can be broadly classified into two main forms—aggressive and indolent NHL. Aggressive NHL is a rapidly growing form of the disease that moves into advanced stages much faster than indolent NHL, which progresses more slowly.

There are many subtypes of NHL, but aggressive B-cell NHL is the most common and accounts for about 50 percent of NHL cases.[2] After initial therapy for aggressive NHL with anthracycline-based combination therapy, one-third of patients typically develop progressive disease. [3] Approximately half of these patients are likely to be eligible for intensive second-line treatment and stem cell transplantation, although 50 percent are expected not to respond. [3] For those patients who fail to respond or relapse following second-line treatment, treatment options are limited, and usually palliative only.
[3]

About Conditional Marketing Authorization

Similar to accelerated approval regulations in the United States, conditional marketing authorizations are granted in the E.U. to medicinal products with a positive benefit/risk assessment that address unmet medical needs and whose availability would result in a significant public health benefit. A conditional marketing authorization is renewable annually. Under the provisions of the conditional marketing authorization for PIXUVRI, CTI will be required to complete a post-marketing study aimed at confirming the clinical benefit previously observed.

The European Medicines Agency's (the EMA) Committee for Medicinal Products for Human Use has accepted PIX306, CTI's ongoing randomized controlled Phase 3 clinical trial, which compares PIXUVRI-rituximab to gemcitabine-rituximab in patients who have relapsed after one to three prior regimens for aggressive B□ cell NHL and who are not eligible for autologous stem cell transplant. As a condition of approval, CTI has agreed to have available the PIX306 clinical trial results by June 2015.

About Cell Therapeutics, Inc.

CTI (NASDAQ and MTA: CTIC) is a biopharmaceutical company committed to the development and commercialization of an integrated portfolio of oncology products aimed at making cancer more treatable. CTI is headquartered in Seattle, WA. For additional information and to sign up for email alerts and get RSS feeds, please visit
www.CellTherapeutics.com
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Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements are subject to a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results and the trading price of CTI's securities. Such statements include, but are not limited to, statements regarding expectations with respect to the development of the Company and its product and product candidate portfolio, NICE's processes, the expected timing thereof and whether NICE will consider an 'enhanced' patient access scheme to demonstrate the cost effectiveness of pixantrone for use by the NHS in the UK, pricing arrangements and the cost-effectiveness and availability of PIXUVRI to patients in the UK. Risks that contribute to the uncertain nature of the forward-looking statements include, among others, risks that NICE does not consider PIXUVRI to be cost-effective or clinically effective over and above current alternative treatments as a result of uncertainties relating to failure to recruit the planned number of patients, use of a primary endpoint of complete or unconfirmed response to treatment rather than a primary end point of overall survival or progression-free survival, differences between the PIX301 trial population and UK clinical practice and the absence of statistically significant differences in overall survival between treatment arms in the PIX301 trial or other reasons, risks associated with the biopharmaceutical industry in general and with CTI and its product and product candidate portfolio in particular including, among others, risks associated with the following: that CTI cannot predict or guarantee the pace or geography of enrollment of its clinical trials, that CTI cannot predict or guarantee the outcome of preclinical and clinical studies, that CTI may not obtain reimbursement for PIXUVRI in certain markets in the European Union as planned, that the conditional marketing authorization for PIXUVRI may not be renewed, that the second Phase 3 clinical trial of pacritinib will not occur as planned, that CTI may not obtain favorable determinations by other regulatory, patent and administrative governmental authorities, that CTI may experience delays in the commencement of preclinical and clinical studies, risks related to the costs of developing, producing and selling PIXUVRI, pacritinib, and CTI's other product candidates, and other risks, including, without limitation, competitive factors, technological developments, that CTI's operating expenses continue to exceed its net revenues, that CTI may not be able to sustain its current cost controls or further reduce its operating expenses, that CTI may not achieve previously announced goals and objectives as or when projected, that CTI's average net operating burn rate may increase,

that CTI will continue to need to raise capital to fund its operating expenses, but may not be able to raise sufficient amounts to fund its continued operation as well as other risks listed or described from time to time in CTI's most recent filings with the Securities and Exchange Commission on Forms 10-K, 10-Q and 8-K. Except as required by law, CTI does not intend to update any of the statements in this press release upon further developments.

PIXUVRI is a registered trademark of Cell Therapeutics, Inc.

References:1. Cancer Research UK http://www.cancerresearchuk.org/cancer-info/cancerstats/incidence/commoncancers/ Accessed April 2013.2. Harris NL, et al. Ann Oncol. 1999;10(12):1419-323. Friedberg ASH Education Book 2011;1:498-505

Contacts: Monique Greer+1 206-272-4343 mgreer@ctiseattle.com

Ed Bell+1 206.282.7100 ebell@ctiseattle.com

In EuropeCTI Life Sciences Limited, Milan BranchLaura Villa E: lvilla@cti-lifesciences.com T: +39 02 89659706
http://www.celltherapeutics.com/italiano

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