SEATTLE, Oct. 7, 2013 /PRNewswire/ -- Cell Therapeutics, Inc. (CTI) (NASDAQ and MTA: CTIC) today announced that the company reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for the planned pivotal Phase 3 clinical trial, known as the PERSIST-2 trial, evaluating pacritinib compared to best available therapy, including approved JAK2 inhibitors such as ruxolitinib, in patients with myelofibrosis whose platelet counts are <100,000/uL. The SPA is a written agreement between CTI and the FDA regarding the design, endpoints and planned statistical analysis approach of the trial to be used in support of a potential New Drug Application (NDA) submission. The PERSIST-2 trial is the second of two planned Phase 3 clinical trials in patients with myelofibrosis. CTI expects to initiate the PERSIST-2 clinical trial in the fourth quarter of 2013.

"The FDA worked closely with us to achieve SPA agreement during first cycle review of the PERSIST-2 trial protocol for pacritinib," stated James A. Bianco, M.D., CTI's President and CEO. "As a result of the SPA, which established agreement on trial design to support regulatory approval, we expect that we will be able to initiate this pivotal Phase 3 clinical trial of pacritinib by the end of the year. Myelofibrosis is a chronic disease and JAK inhibitors have had a dramatic impact on the lives of people living with myelofibrosis. Data from earlier studies of pacritinib showed a clinically meaningful improvement in symptoms with minimal suppression of platelets or red blood cells. We believe patients with myelofibrosis, particularly those with low platelet counts, could benefit from new treatment options."

PERSIST-2 is a 300 patient randomized, open-label, multi-center pivotal trial in patients with myelofibrosis whose platelet counts are <100,000/uL. The trial will evaluate pacritinib as compared to best available therapy, including approved JAK2 inhibitors that are dosed according to the product label for myelofibrosis patients with thrombocytopenia. Patients will be

randomized (1:1:1) to receive 200 mg pacritinib twice daily, 400 mg pacritinib once daily or best available therapy. The agreed upon co-primary endpoints are the percentage of patients achieving a 35 percent or greater reduction in spleen volume measured by MRI or CT at 24 weeks of treatment and the percentage of patients achieving a Total Symptom Score (TSS) reduction of 50 percent or greater using six key symptoms as measured by the modified Myelofibrosis Symptom Assessment Form (MF-SAF) diary. The trial is expected to enroll patients at clinical sites in the United States, Europe and Australia.

Pacritinib Development Strategy

Based on pacritinib's efficacy and tolerability profile demonstrated to date, CTI is pursuing a broad approach to advancing this therapy for myelofibrosis patients by conducting two Phase 3 clinical trials: one in a broad set of patients without limitations on blood platelet counts, the PERSIST-1 trial, and the other in patients with low platelet counts, the PERSIST-2 trial, as described above, which is expected to begin in the fourth quarter of 2013.

In January 2013, CTI initiated PERSIST-1, which is a 270 patient randomized, open-label, multicenter Phase 3 trial comparing the efficacy and safety of pacritinib with that of best available therapy in patients with myelofibrosis. Best available therapy includes any physician-selected treatment other than JAK inhibitors and there is no exclusion by patient platelet count. The trial is currently enrolling patients at clinical sites in Europe,

Australia
,
Russia
and the United States. More details on the PERSIST-1 study can be found at
www.clinicaltrials.gov
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About Pacritinib

Pacritinib is an oral tyrosine kinase inhibitor (TKI) with dual activity against JAK2 and FLT3. The JAK family of enzymes are a central component in signal transduction pathways, which are critical to normal blood cell growth and development as well as inflammatory cytokine expression and immune responses. Mutations in these kinases have been shown to be directly related to the development of a variety of blood related cancers including myeloproliferative

neoplasms, leukemia and lymphoma. Pacritinib may offer an advantage over other JAK inhibitors through effective treatment of symptoms while having less treatment-emergent thrombocytopenia and anemia than has been seen in currently approved and in-development JAK inhibitors.

About Myelofibrosis

Myelofibrosis is classified as a myeloproliferative neoplasm and is a chronic bone marrow disorder. Myelofibrosis is caused by the accumulation of malignant bone marrow cells that triggers an inflammatory response, scarring the bone marrow and limiting its ability to produce red blood cells prompting the spleen and liver to take over this function. Symptoms that arise from this disease include enlargement of the spleen, anemia, extreme fatigue and pain.

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 CTI's expectations with respect to the development of CTI and its product and product candidate portfolio, the expected commencement of the PERSIST-2 clinical trial in the fourth quarter of 2013, the expected efficacy and potential benefits of pacritinib and the expectations concerning enrollment locations for the PERSIST-2 clinical trial. Risks that contribute to the uncertain nature of the forward-looking statements include, among others, 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.

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