Informazione Regolamentata n. 0696-150-2015	Data/Ora Ricezione 24 Novembre 2015 07:21:45	MTA

Societa'	:	CTI BIOPHARMA
Identificativo Informazione Regolamentata	:	66191
Nome utilizzatore	:	CELLN02 - Bell
Tipologia	:	IRAG 10
Data/Ora Ricezione	:	24 Novembre 2015 07:21:45
Data/Ora Inizio Diffusione presunta	:	24 Novembre 2015 07:45:08
Oggetto	:	CTI BioPharma Announces United Kingdom National Cancer Research Institute AML Cooperative Group Advances Tosedostat to Next Stage of “Pick-a-Winner” L

Testo del comunicato

Vedi allegato.

CTI BioPharma Announces United Kingdom National Cancer Research Institute AML Cooperative Group Advances Tosedostat to Next Stage of "Pick-a-Winner" LI-1 Trial for Older Patients with AML or High-Risk MDS

SEATTLE, Wash., November 24, 2015–CTI BioPharma Corp. (CTI BioPharma or the Company) (NASDAQ and MTA: CTIC) today announced that the United Kingdom's National Cancer Research Institute (NCRI) Haematological Oncology Clinical Studies Group has chosen to advance tosedostat, the Company's investigative oral aminopeptidase inhibitor, to the second stage of a randomized clinical trial of low-dose cytarabine plus or minus tosedostat in older patients with Acute Myeloid Leukemia (AML) or high risk Myelodysplastic Syndrome (MDS). The AML Less Intensive (LI-1) trial is designed as a "Pick-a-Winner" trial to be able to simultaneously test a number of promising agents added to standard therapy with low-dose cytarabine in older patients with AML or MDS who are unfit for standard aggressive induction therapy. Nine regimens have been tested in the Pick-a-Winner program, of which only 4, including tosedostat, have passed the initial hurdle for progression (which requires evidence of an improvement in remission rate with acceptable safety). The ultimate aim of the trial is to identify treatments that can double the 2-year survival of patients in this group. Based on the randomized Phase 2 interim analysis, the trial management group determined that tosedostat should proceed to the next stage of the study. It is anticipated that an additional 110 patients will be required in such phase. A further evaluation will take place before the intended expansion to a 400 patient Phase 3 trial.

Tosedostat is a potential first-in-class selective inhibitor of aminopeptidases, which are enzymes required by some tumor cells, but not normal cells, to provide a source of amino acids necessary for growth and tumor cell survival.

"A large portion of older patients and patients with comorbid conditions are poorly suited for conventional intensive chemotherapy due to a high rate of treatment-related mortality. For these patients, there is a significant unmet need for effective and well tolerated alternative therapies," said Jack Singer, M.D., Chief Scientific Officer of CTI BioPharma. "We are pleased that tosedostat has been selected to continue in this trial and is moving forward to the next stage. Tosedostat has demonstrated encouraging clinical activity in three prior Phase 2 studies in both first-line AML in older patients and in patients who relapsed following standard therapies. Tosedostat is an oral agent given once daily on an outpatient basis that has not been associated with drug-related blood count suppression."

About the LI-1 Trial

In this Phase 2/3 trial, referred to as the AML Less Intensive (LI-1) trial, patients are randomized to standard treatment with low dose cytarabine, versus several investigational treatments - each usually in combination with low dose cytarabine. This is called a "Pick-a-Winner" trial design. Under this design, the Phase 2 portion of the trial initially randomized 50 patients per arm, and, if the complete response rate of cytarabine plus novel therapy appeared satisfactory, the randomization continues to the next stage usually with an additional 50 patients per arm. There is

then a further assessment by the data monitoring committee to allow the trial to continue to the final stage in which case up to a total of approximately 200 patients per arm would be enrolled. Overall survival will serve as the primary endpoint of the trial. The NCRI Haematological Oncology Clinical Studies Group under the sponsorship of Cardiff University is conducting the trial.

About Tosedostat
Tosedostat is an oral aminopeptidase inhibitor that has demonstrated anti-tumor responses in blood-related cancers and solid tumors in Phase 1-2 clinical trials. Tosedostat is currently being evaluated in multiple Phase 2 clinical trials for the treatment of patients with AML or high-risk MDS. Tosedostat is not approved or commercially available.

About Acute Myeloid Leukemia and Myelodysplastic Syndrome
AML is the most common acute leukemia affecting adults, and its incidence increases with age. In older patients, AML may occur de novo or secondary to prior anti-cancer therapy, or from progression of other diseases, such as myelodysplasia. AML is a cancer characterized by the rapid growth of abnormal white blood cells that accumulate in the bone marrow and interfere with the production of normal blood cells. AML is the most common acute leukemia affecting adults, and its incidence increases with age.[1] The symptoms of AML are caused by the replacement of normal bone marrow with leukemic cells, which causes a drop in red blood cells, platelets, and normal white blood cells, leading to infections and bleeding. AML progresses rapidly and is typically fatal within weeks or months if left untreated. In 2015, approximately 20,830 new cases of AML are expected to be diagnosed in the United States and an estimated 10,460 are expected to die from the disease.[2] While AML may occur at any age, adults at least 60 years of age are more likely than younger people to develop the disease.[2] Although a substantial proportion of younger individuals who develop AML can be cured, AML in the elderly typically responds poorly to standard therapy with few complete remissions.

AML may develop from the progression of other diseases, such as MDS. MDS are a group of diverse bone marrow disorders in which the bone marrow does not produce enough healthy blood cells. MDS is often referred to as a "bone marrow failure disorder."

About CTI BioPharma
CTI BioPharma Corp. (NASDAQ and MTA: CTIC) is a biopharmaceutical company focused on the acquisition, development, and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and healthcare providers. CTI BioPharma has a commercial presence with respect to PIXUVRI® in Europe and a late-stage development pipeline, including pacritinib, CTI BioPharma's lead product candidate, which is currently being studied in a Phase 3 program for the treatment of patients with myelofibrosis. CTI BioPharma is headquartered in Seattle, Washington, with offices in London and Milan under the name CTI Life Sciences Limited. For additional information and to sign up for email alerts and get RSS feeds, please visit www.ctibiopharma.com.

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 BioPharma's securities. Such statements include, but are not limited to, statements regarding CTI BioPharma's expectations with respect to the development of CTI BioPharma and its product and product candidate portfolio, the therapeutic potential of tosedostat, including to meet a current unmet medical need in the

treatment of patients with AML (and in particular, with respect to older patients and patients who relapse following standard therapies), potentially starting a Phase 3 registrational trial in 2016, prevalence of AML and mortality rates associated with AML. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. A number of results and uncertainties could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; pre-clinical and clinical trial results; changes in laws and regulations; product quality, product efficacy, study protocol, data integrity or patient safety issues; product development risks; and other risks identified in the CTI BioPharma's most recent filings on Form 10-K and other Securities and Exchange Commission filings. CTI BioPharma does not undertake to update its forward-looking statements.

[1] The Leukemia and Lymphoma Society, Acute Myeloid Leukemia, Rev. 2011.http://tinyurl.com/d72ycja. Accessed June 2015
[2] American Cancer Society, Cancer Facts & Figures 2015. Available at http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2015/. Accessed June 2015

PIXUVRI® is a registered trademark of CTI BioPharma Corp.
Source: CTI BioPharma Corp.

###

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

Ed Bell
+1 206-272-4345
ebell@ctibiopharma.com

Fine Comunicato n.0696-150	Numero di Pagine: 5