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Testo del comunicato

Vedi allegato.

CTI BioPharma Announces Presentation of Preclinical Data Demonstrating Potential Synergistic Combination of Pacritinib and an EGFR Inhibitor in Targeting Brain Tumor Initiating Cells

-- Combination Therapy Has Potential to Improve Outcomes for Patients with Glioblastoma Multiforme (GBM) –

SEATTLE, Wash., November 23, 2015—CTI BioPharma Corp. (CTI BioPharma) (NASDAQ and MTA: CTIC) today announced findings from an investigator-sponsored preclinical study showing the potential synergistic effect of combining pacritinib, an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R, with an epidermal growth factor receptor (EGFR) inhibitor in decreasing brain tumor initiating cells (BTIC) viability. BTICs have cancer stem cell characteristics and are believed to be responsible for disease initiation and recurrence. Additionally, high rates of mutations in BTICs may lead to the rapid emergence of resistance in GBM, the most common and aggressive primary brain cancer. Given that upregulation of the JAK/STAT pathway may be a common mechanism of resistance to EGFR antagonists, the current study demonstrates the potential for combination therapies with pacritinib to be a promising therapeutic avenue in GBM. The early phase findings also showed prolonged survival in an intracerebral BTIC xenograft preclinical model of human GBM when delivered in combination with temozolomide.

These findings were presented by Ms Katharine Jensen from the laboratory of Drs Artee Luchman and Samuel Weiss, at the Hotchkiss Brain Institute, University of Calgary in an oral presentation (abstract #ATPS-52) during the 20th Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology (SNO) held November 19-22, 2015 in San Antonio, Texas.

“Although activating mutations in EGFR are common in GBM, physiological challenges with drug penetration, drug pharmacokinetics and rapid emergence of resistance have resulted in EGFR inhibitors showing limited effectiveness as monotherapies,” said Dr. Weiss, Professor at the University of Calgary’s Cumming School of Medicine and Director of the Hotchkiss Brain Institute. “Our findings support the hypothesis that combination therapy, for example targeting both the JAK/STAT pathways inhibited by pacritinib and EGFR, may improve clinical outcomes for patients with GBM.”

“The tolerability profile of pacritinib observed in the clinic to date, along with the ability to achieve meaningful intracerebral levels in preclinical models, makes it a candidate to be explored for use in combination therapy for GBM,” said Jack W. Singer, M.D., Chief Scientific Officer and Global Head of Translational Medicine at CTI BioPharma. “We believe these findings further support the potential for clinical trials of pacritinib in difficult to treat, non-hematological cancers.”

The combination of pacritinib with one of three different EGFR inhibitors (afatinib, lapatinib, erlotinib) each resulted in decreased BTIC viability. Additionally, the effect of combining pacritinib with afatinib was shown to be synergistic in BTIC growth inhibition. Ongoing investigations are focusing on whether combinatorial therapy can improve survival in a preclinical model.

About Pacritinib
Pacritinib is an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. In August 2014, pacritinib was granted Fast Track designation by the FDA for the treatment of intermediate and high risk myelofibrosis, including but not limited to patients with disease-related thrombocytopenia, patients experiencing treatment-emergent thrombocytopenia on other JAK2 inhibitor therapy, or patients who are intolerant of, or whose symptoms are sub-optimally managed on other JAK2 inhibitor therapy. The FDA's Fast Track process is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Pacritinib does not have regulatory approval and is not commercially available.

CTI BioPharma and Baxalta Incorporated (NYSE:BXLT) are parties to a worldwide license agreement to develop and commercialize pacritinib. CTI BioPharma and Baxalta will jointly commercialize pacritinib in the U.S. while Baxalta has exclusive commercialization rights for all indications outside the U.S.

About Glioblastoma Multiforme
According to the National Cancer Institute, GBM is the most common and deadliest type of primary brain tumor in adults. GBM has an incidence of two to three per 100,000 adults per year, and accounts for 52 percent of all primary brain tumors.[1] The current standard of care for patients with GBM is a surgical resection, if possible, followed by radiation given with concurrent temozolomide. The prognosis for the majority of patients with GBM is poor with median survival of approximately 14.6 months with less than 30 percent of patients surviving two years using current therapies.[2]

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 related to pacritinib and a related preclinical study, which are 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 expectations with respect to the potential therapeutic utility of pacritinib in combination with an EGFR inhibitor, including the potential to decrease BTIC viability, to serve as a therapeutic avenue in GBM, to decrease STAT3 activation and to prolong survival, the possibility that high rates of mutations in BTICs may lead to the rapid emergence of resistance in GBM, the tolerability profile of pacritinib, the potential for clinical trials of pacritinib in difficult to treat, non-hematological cancers and the prevalence of GMB. 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; preclinical 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 respective issuer'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. American Association of Neurological Surgeons, Glioblastoma Multiforme. http://tinyurl.com/pclszwh. Accessed November 2015.
2. American Brain Tumor Association, Available at http://tinyurl.com/olqbp9a. Accessed November 2015.

Sources: CTI BioPharma Corp.

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