Informazione Regolamentata n. 0696-14-2016	Data/Ora Ricezione 08 Febbraio 2016 07:05:26	MTA

Societa'	:	CTI BIOPHARMA
Identificativo Informazione Regolamentata	:	69117
Nome utilizzatore	:	CELLN02 - Bell
Tipologia	:	IROS 15
Data/Ora Ricezione	:	08 Febbraio 2016 07:05:26
Data/Ora Inizio Diffusione presunta	:	08 Febbraio 2016 07:45:18
Oggetto	:	CTI BIOPHARMA PROVIDES UPDATE ON INVESTIGATIONAL AGENT PACRITINIB

Testo del comunicato

Vedi allegato.

CTI BIOPHARMA PROVIDES UPDATE ON INVESTIGATIONAL AGENT PACRITINIB

FDA Places Partial Clinical Hold on Pacritinib IND; Currently Enrolled Patients Benefiting from Pacritinib Can Continue Receiving Pacritinib

Phase 3 Clinical Trial (PERSIST-2) Evaluating Pacritinib for Patients with Myelofibrosis and Platelet Counts of ≤100,000/µL has Completed Enrollment

SEATTLE, February 8, 2016 – CTI BioPharma Corp. (CTI BioPharma) (NASDAQ and MTA:CTIC) today announced that the Company received written communication from the U.S. Food and Drug Administration (FDA) on February 4, 2016, that the FDA has placed a partial clinical hold on the clinical studies being conducted under the Company's Investigational New Drug ("IND") application for pacritinib. This clinical hold impacts part of the clinical work currently being conducted under the IND and will also affect planned clinical trials.

Under the partial clinical hold, clinical investigators may not enroll new patients or start pacritinib as initial or crossover treatment, and patients not deriving benefit after 30 weeks of pacritinib treatment should stop using pacritinib. In addition, the FDA has recommended that the Company make certain modifications of protocols, including modifying all protocols for randomized trials to disallow crossover to pacritinib, provide certain notifications, revise relevant statements in the related investigator's brochure and informed consent documents, and take certain other actions. The Company intends to implement the FDA's recommendations. All clinical investigators worldwide have been delivered a notice of the partial clinical hold.

The Company intends to work together with the FDA and expects to submit modifications and revisions that address the recommendations noted above. In its written notification, the FDA cited the reasons for the partial clinical hold were that there was excess mortality and other adverse events in pacritinib-treated patients compared to the control arm in the PERSIST-1 trial. The excess mortality was most evident during the non-randomized crossover period following the initial 24 weeks of randomized treatment, during which patients in the control arm could switch to pacritinib treatment. In prior correspondence, the FDA acknowledged the difficulty addressing non-significant results, and that crossover designs can confound the interpretation of safety as well as the evaluation of survival.

After submission of the required information, the FDA has indicated that it would notify the Company whether it can continue the clinical studies under the IND.

Completion of PERSIST-2 Phase 3 Trial

Additionally, CTI BioPharma announced that as of February 3, 2016, it has completed patient enrollment in the PERSIST-2 Phase 3 clinical trial of pacritinib for the treatment of patients with myelofibrosis. PERSIST-2 is evaluating pacritinib for patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter (≤100,000/µL). Under the FDA partial clinical hold referenced above, patients currently receiving pacritinib may continue to do so unless they are not deriving benefit after 30

weeks of pacritinib treatment, and crossover of patients from the control arm to the pacritinib arm will not be allowed.

About CTI BioPharma Corp.
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 in Europe with respect to PIXUVRI® 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 contains "forward-looking" statements that are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning our anticipated product development and submission of data to the FDA. Such statements are subject to risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results and the trading price of the Company's securities. Specifically, the risks and uncertainties that could affect our ability to address FDA requests or the development of pacritinib more generally include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general and with pacritinib in particular including, without limitation, the potential failure of pacritinib to prove safe and effective as determined by the FDA and/or the European Medicines Agency; determinations by regulatory, patent, and administrative governmental authorities; competitive factors; technological developments; costs of developing and producing pacritinib; the risk that the FDA may expand its information request or initiate a complete clinical hold or take other actions; changes to study protocol or design or sample size to address any patient safety, efficacy or other issues raised by the FDA or otherwise; and the risk factors listed or described from time to time in the Company's filings with the Securities and Exchange Commission, including, without limitation, the Company's most recent filings on Forms 10-K, 10-Q and 8-K. The Company can give no assurances that any results or events projected or contemplated by its forward-looking statements will in fact occur and the Company cautions you not to place undue reliance on these statements. The Company undertakes no duty to update these forward-looking statements to reflect any future events, developments or otherwise.

Source: CTI BioPharma Corp.

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