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Testo del comunicato

Vedi allegato.

CTI BIOPHARMA PROVIDES UPDATE ON CLINICAL HOLD OF INVESTIGATIONAL AGENT PACRITINIB AND NEW DRUG APPLICATION IN U.S.

SEATTLE, February 9, 2016 – CTI BioPharma Corp. (CTI BioPharma) (NASDAQ and MTA:CTIC) today provided an update regarding the clinical studies being conducted under the Company's Investigational New Drug ("IND") application for pacritinib. Following the issuance of the Company's February 8, 2016, press release describing the partial clinical hold issued by the U.S. Food and Drug Administration (FDA) regarding those clinical studies, the Company received an oral communication from the FDA followed by a letter notifying the Company that the Company's IND for pacritinib has been placed on full clinical hold. The Company has withdrawn its New Drug Application (NDA) until the Company has had a chance to review the safety and efficacy data from the PERSIST-2 Phase 3 clinical trial and decide next steps.

The FDA's February 8, 2016, letter notes the interim overall survival results from PERSIST-2 show a detrimental effect on survival consistent with the results from PERSIST-1. The deaths in PERSIST-2 in pacritinib-treated patients include intracranial hemorrhage, cardiac failure and cardiac arrest. The FDA made recommendations that supersede the recommendations made by the FDA in connection with the partial clinical hold imposed by the FDA on February 4, 2016. The current recommendations include conducting dose exploration studies for pacritinib in patients with myelofibrosis, submitting final study reports and datasets for PERSIST-1 and PERSIST-2, providing certain notifications, revising relevant statements in the related Investigator's Brochure and informed consent documents and making certain modifications to protocols. In addition, the FDA recommended that the Company request a meeting prior to submitting a response to full clinical hold.

Under the full clinical hold, all patients currently on pacritinib must discontinue pacritinib immediately and no patients can be enrolled or start pacritinib as initial or crossover treatment.

All clinical investigators worldwide have been delivered a notice of the full clinical hold.

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 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 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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Fine Comunicato n.0696-16	Numero di Pagine: 4