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Testo del comunicato

Vedi allegato.

CTI BIOPHARMA ANNOUNCES POSITIVE PROGRESS OF LEAD CLINICAL PROGRAMS AND GENERAL OUTLOOK FOR TRANSFORMATIONAL 2016

SEATTLE, January 11, 2016 – CTI BioPharma Corp. (CTI BioPharma) (NASDAQ and MTA: CTIC) today announced positive progress of its lead clinical program in addition to several key business priorities for 2016.

"After a productive 2015, we have entered 2016 well capitalized and focused on preparing for the potential accelerated approval and launch of a new treatment option for people with intermediate and high-risk myelofibrosis with low platelet counts," said James A. Bianco, M.D., CTI BioPharma's President and Chief Executive Officer. "With the recently completed NDA submission for pacritinib, interim data indicating the potential therapeutic utility for tosedostat in AML and high-risk MDS, and a strong financial position, we believe the stage is set for a transformational year for our company."

Recent Progress Update

Pacritinib

In January 2016, CTI BioPharma announced the completion of the rolling New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for pacritinib, an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. CTI BioPharma and Baxalta Incorporated (Baxalta) are seeking U.S. marketing approval of pacritinib for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of less than 50,000 per microliter (<50,000/µL).

In December 2015, researchers presented results from a new analysis of the pivotal Phase 3 trial, PERSIST-1, evaluating pacritinib versus best available therapy, excluding treatment with JAK2 inhibitors (BAT), in patients with myelofibrosis. Data examining patient outcomes across baseline demographic factors that are associated with prognosis showed that treatment with pacritinib resulted in consistent rates of spleen volume reduction and control of disease-related symptoms across all intermediate or high-risk myelofibrosis subgroups.

Tosedostat

In December 2015, researchers presented an update on results from an investigator-sponsored Phase 2 trial of tosedostat – CTI BioPharma's investigational oral selective aminopeptidase inhibitor – in elderly patients with either primary (de novo) acute myeloid leukemia (AML) or secondary AML. The data showed a complete response (CR) of 48.5 percent with tosedostat in combination with low dose cytarabine/Ara-C (LDAC) – 33 percent of these patients were still responding after a median of 506 days.

In November 2015, CTI BioPharma announced that the United Kingdom's National Cancer Research Institute (NCRI) Haematological Oncology Clinical Studies Group has chosen to advance tosedostat to the second stage of a randomized clinical trial of low-dose cytarabine plus or minus tosedostat in older patients with 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 four, including tosedostat, have passed the initial hurdle for progression (which requires

evidence of an improvement in remission rate with acceptable safety). CTI BioPharma plans to discuss potential approval pathways with regulators in the U.S. and EU in 2016.

Corporate and Financial

In December 2015, the Company announced receipt of a $10 million milestone payment from Teva Pharmaceutical Industries Ltd. related to the achievement of sales milestones for TRISENOX® (arsenic trioxide).

In September 2015, the Company completed a registered direct offering and in October and December 2015, the Company completed two underwritten public offerings resulting in aggregate net proceeds of approximately $115 million. CTI BioPharma's current cash balance is anticipated to fund operations for at least the next two years based on our current budget expectations and development plans.

CTI BioPharma plans to provide 2016 financial guidance in its fourth quarter and year-end 2015 financial results announcement.

2016 Key Objectives

Seek U.S. regulatory approval and launch pacritinib. CTI BioPharma seeks U.S. marketing approval of pacritinib for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of <50,000/μL.

Complete enrollment and report PERSIST-2 topline results. CTI BioPharma expects to complete enrollment in the PERSIST-2 Phase 3 trial of pacritinib for patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter in the first quarter 2016 and unblind and report top-line data late in the fourth quarter of 2016.

Initiate trial in second indication for pacritinib. CTI BioPharma intends to advance a pacritinib development program in other hematologic malignancies in the fourth quarter of 2016.

Initiate registration-directed trial for tosedostat. CTI BioPharma plans to consult with the FDA and European Medicines Agency (EMA) regarding a registration-directed strategy for tosedostat, including the potential to utilize the results from the ongoing investigator-sponsored LI-1 trial to support registration and approval. If positive, these discussions could help enable the start of a pivotal program in 2016.

Secure ex-U.S. partner for tosedostat. CTI BioPharma intends to secure a partnership for the development and commercialization of tosedostat in certain territories outside the U.S.

Complete enrollment in PIX306. CTI BioPharma expects to complete enrollment in the ongoing PIX306 post-marketing commitment Phase 3 study of PIXUVRI in the fourth quarter of 2016.

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 includes forward-looking statements, 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 the issuers' securities. Such statements include, but are not limited to, the currently expected sufficiency of our existing cash balance to fund operations for the next two years and expectations regarding the timing of potential regulatory submissions, marketing approvals, initiation and enrollment of trials and reporting of trial results, , expectations with respect to the potential therapeutic utility of pacritinib, including pacritinib's potential to achieve treatment goals across patients with myelofibrosis, the potential therapeutic utility of tosedostat, including tosedostat's potential to achieve treatment goals across patients with AML and high-risk MDS, advancing pacritinib into new indications, the anticipated completion of enrollment in PIX306 and future regulatory, development, and commercialization plans.. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. In particular, this release addresses select clinical trial data and results, and should be evaluated together with information regarding primary and secondary endpoints, safety and additional data once such data has been more fully analyzed and is made publicly available. The statements are based on assumptions about many important factors and information currently available to us to the extent we have thus far had an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. A number of results and uncertainties could cause actual results to differ materially from those in the forward-looking statements, including: satisfaction of regulatory and other requirements; that trial results observed to date may differ from future results or that difference conclusions or considerations may qualify such results once existing data has been more fully evaluated, actions of regulatory bodies and other governmental authorities; other 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 each issuer's most recent filings on Forms 10-K and 10-Q and other Securities and Exchange Commission filings. Neither CTI BioPharma nor Baxalta undertakes to update its forward-looking statements.

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

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

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

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