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Testo del comunicato

Vedi allegato.



CTI BIOPHARMA FILES FORM 8-K

SEATTLE, Wash., June 10, 2015—CTI BioPharma Corp. (MTA: CTIC) today announced that it has filed a Form 8-K with the U.S. Securities and Exchange Commission (SEC). Summary information in the Form 8-K is as follows:

On June 5, 2015, CTI BioPharma Corp. (the “Corporation”) entered into the First Amendment to the License Agreement (the “Amendment”), which became effective on June 8, 2015 (the “Effective Date”) amending the Development, Commercialization and License Agreement (the “License Agreement”), dated as of November 14, 2013, by and among the Corporation, Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, “Baxter”). Pursuant to the License Agreement, among other things, the Corporation granted to Baxter a license with respect to pacritinib, Baxter and the Corporation agreed to collaborate as to the development and commercialization of pacritinib, and the Corporation obtained the contingent right to receive certain milestone and royalty payments. Baxalta Incorporated, a wholly-owned subsidiary of Baxter International Inc., and certain of its affiliates (collectively, “Baxalta,” and, together with the Corporation, the “Parties”) have been assigned Baxter’s rights and obligations under the License Agreement.

Pursuant to the Amendment, two milestone payments from Baxalta to the Corporation were accelerated from the schedule contemplated by the License Agreement. The Corporation will, within three days of the Effective Date, receive a total advance of \$32 million from Baxalta relating to the following two milestone payments under the License Agreement: (i) the \$12 million development milestone payment payable in connection with the regulatory submission to the European Medicines Agency with respect to pacritinib (the “EMA Milestone”) and (ii) a \$20 million development milestone payment payable for the first treatment dosing of the last patient enrolled in PERSIST-2 (the “PERSIST-2 Milestone”), the ongoing randomized Phase 3 trial evaluating pacritinib for patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter.

Under the Amendment, each of the two milestone advances will bear interest at an annual rate of 9% percent until the earlier of (i) the date of first occurrence of the respective milestone and (ii) the date that the respective advance plus accrued interest is repaid in full. In the event that pacritinib development is terminated either because of a regulatory determination that the benefit/risk profile of the drug candidate is unacceptable or due to safety concerns or certain other reasons, including the failure of pacritinib to meet certain criteria or certain endpoints (each, a “Milestone Failure”), the Corporation would be required to repay the respective advance to Baxalta in eight quarterly installments beginning thirty days after the end of the calendar quarter of the first occurrence of a Milestone Failure and a final payment equal to the remainder of the unpaid balance (the “Repayment Terms”). Further, if (i) the EMA Milestone is not achieved prior to March 31, 2017 or (ii) the PERSIST-2 Milestone is not achieved prior to December 31, 2016, then the Corporation would also be required to repay the respective advance pursuant to the Repayment Terms. Repayment of the advances will be accelerated in the event of the commencement of insolvency proceedings, and certain other events of default. If a milestone is achieved, however, then the Corporation would remain entitled to the respective advance. In the event that the Corporation does not spend a specified amount on the development of pacritinib from the Effective Date through February 29, 2016, payments to Baxalta in an amount equal to such deficiency may be required or credited against amounts owed to the Corporation in certain circumstances.

In the Amendment, in lieu of entering into a manufacturing and supply agreement as contemplated by the License Agreement, the Parties have also agreed to changes in the provisions of the License Agreement regarding manufacturing and supply, including that the Parties will each be allocated up to 50% of the manufacturing (subject to certain conditions), with certain pricing adjustments based on comparative costs of supply.

The Current Report on Form 8-K that has been filed with the SEC is available on the SEC website at www.sec.gov as well as CTI BioPharma's website at www.ctibiopharma.com.

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 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 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. Risks that contribute to the uncertain nature of the forward-looking statements include, among others, risks associated with the biopharmaceutical industry in general and with CTI BioPharma and its product and product candidate portfolio in particular including, among others, risks associated with the following: that CTI BioPharma cannot predict or guarantee the pace or geography of enrollment of its clinical trials, that CTI BioPharma cannot predict or guarantee the outcome of preclinical and clinical studies, that top-line results observed to date may differ from future results or that different conclusions or considerations may qualify such results once existing data has been more fully evaluated, clinical trial results, that CTI BioPharma may not obtain favorable determinations by other regulatory, patent and administrative governmental authorities, that CTI BioPharma may experience delays in the commencement of preclinical and clinical studies, risks related to the costs of developing pacritinib and CTI BioPharma's other product candidates, and other risks, including, without limitation, competitive factors, technological developments, that CTI BioPharma may not be able to sustain its current cost controls or further reduce its operating expenses, that CTI BioPharma may not achieve previously announced goals, contractual milestones and objectives as or when projected, that CTI BioPharma's average net operating burn rate may increase, that CTI BioPharma will continue to need to raise capital to fund its operating expenses, but may not be able to raise sufficient amounts to fund its continued operation as well as other risks listed or described from time to time in CTI BioPharma's most recent filings with the SEC on Forms 10-K, 10-Q and 8-K. Except as required by law, CTI BioPharma does not intend to update any of the statements in this press release upon further developments.

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