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Testo del comunicato

Vedi allegato.

CTI BIOPHARMA AND BAXALTA COMPLETE SUBMISSION OF NEW DRUG APPLICATION FOR PACRITINIB FOR UNMET MEDICAL NEED IN MYELOFIBROSIS

SEATTLE, Wash. and BANNOCKBURN, Ill., January 5, 2016 – CTI BioPharma Corp. (CTI BioPharma) (NASDAQ and MTA: CTIC) and Baxalta Incorporated (Baxalta) (NYSE: BXLT) today announced the completion of the rolling submission of the 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 are requesting 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) – a specific patient population for which there is an existing unmet medical need. The Companies are seeking accelerated approval and have requested a Priority Review of the application.

Pacritinib is an investigational treatment being developed for patients with myelofibrosis regardless of their platelet counts. If approved, pacritinib would be the first JAK2 inhibitor indicated for the treatment of patients with myelofibrosis and baseline platelet counts of less <50,000/µL.

"We are pleased to have completed the rolling submission and look forward to working with the FDA during the review process with the goal of bringing this important treatment to people living with myelofibrosis, including those with low platelet counts," said James Bianco, M.D., president and chief executive officer of CTI BioPharma.

Myelofibrosis is a rare, but serious and life-threatening chronic leukemia that disrupts the normal production of blood cells and results in scarring of the bone marrow, limiting the ability to produce new blood cells and prompting the spleen and other organs to take over this function. The disease often leads to an enlarged spleen and lower than normal counts of blood cells – including red blood cells and platelets, which are essential for blood clotting.

"Pacritinib has the potential to change the treatment paradigm for people with intermediate and high-risk myelofibrosis, particularly those patients with cytopenias," said David Meek, executive vice president, president of Oncology at Baxalta. "Together with CTI BioPharma, we are continuing to develop this potential new treatment for more people in need around the world."

About the Pacritinib NDA

The NDA includes data from the PERSIST-1 Phase 3 trial – as well as data from Phase 1 and 2 studies of pacritinib. Submission of an NDA after a single Phase 3 trial under accelerated approval, instead of waiting to complete two Phase 3 trials, could potentially reduce time to market by up to 14 months. 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 (low platelet counts); patients experiencing treatment emergent thrombocytopenia on another JAK2 therapy; or patients who are intolerant to or whose symptoms are not well controlled (or sub-optimally managed) on another JAK2 therapy.

CTI BioPharma and Baxalta 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 Myelofibrosis and Myeloproliferative Neoplasms
Myelofibrosis is one of three main types of myeloproliferative neoplasms (MPN), which are a closely related group of hematological blood cancers. The three main types of MPNs are myelofibrosis, polycethemia vera and essential thrombocythemia.[1]

Myelofibrosis is a serious and life-threatening chronic bone marrow disorder caused by the accumulation of malignant bone marrow cells that triggers an inflammatory response and scars the bone marrow. The replacement of bone marrow with scar tissue limits its ability to produce red blood cells, prompting the spleen and liver to take over this function. Symptoms that arise from this disease include enlargement of the spleen, anemia, extreme fatigue, and pain.

The estimated prevalence of MPNs suggest there are approximately 300,000 people living with the disease in the U.S., of which myelofibrosis accounts for approximately 18,000 patients.[2] In Europe, there is a wide variation of prevalence observed across data sources. Myelofibrosis has a median age of 64 at the time of diagnosis[2] and is a progressive disease with approximately 20 percent of patients eventually developing AML.[3] The median survival for high-risk myelofibrosis patients is less than one and a half years, while the median survival for patients with myelofibrosis overall is approximately six years.[4]

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.

About Baxalta
Baxalta Incorporated (NYSE: BXLT) is a $6 billion global biopharmaceutical leader developing, manufacturing and commercializing therapies for orphan diseases and underserved conditions in hematology, oncology and immunology. Driven by passion to make a meaningful impact on patients' lives, Baxalta's broad and diverse pipeline includes biologics with novel mechanisms and advanced technology platforms such as gene therapy. The Baxalta Global Innovation and R&D Center is located in Cambridge, Massachusetts. Launched in 2015 following separation from Baxter International, Baxalta's heritage in biopharmaceuticals spans decades. Baxalta's therapies are available in more than 100 countries and it has advanced biological manufacturing operations across 12 facilities, including state-of-the-art recombinant production and plasma fractionation. Headquartered in Northern Illinois, Baxalta employs 16,000 employees worldwide.

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, expectations with respect to the potential therapeutic utility of pacritinib, including pacritinib's potential to achieve treatment goals across patients with myelofibrosis, regardless of baseline characteristics, such as starting platelet count and in particular, its potential to reduce spleen volume and

symptom burden and improve HRQoL, expectations to submit regulatory submissions in the coming months; the potential reduction in time to market if accelerated approval is granted, the estimated prevalence of MPNs, myelofibrosis and myelofibrosis patients that develop AML and the survival rates for patients with myelofibrosis. 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.

1. MPN Research Foundation website, www.mpnresearchfoundation.org.
2. Based on Mesa R, ASH 2012 poster.
3. Cervantes F, et al., New prognostic scoring system for primary myelofibrosis based on a study of the International Working Group for Myelofibrosis Research and Treatment. *Blood*. 2009; 113:2895-2901.
4. Vannucchi, A. Management of Myelofibrosis. ASH Education Book. 2011; 1:222-230.

Source: CTI BioPharma Corp. and Baxalta Incorporated

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