Incyte Submits New Drug Application for Ruxolitinib in Myelofibrosis to the US Food and Drug Administration

June 6, 2011
WILMINGTON, Del., Jun 06, 2011 (BUSINESS WIRE) --

Incyte Corporation (Nasdaq:INCY) announced today that it has submitted a New Drug Application (NDA) for its lead investigational compound, ruxolitinib (INCB18424), to the US Food and Drug Administration (FDA). Incyte is seeking US marketing approval of ruxolitinib for the treatment of myelofibrosis (MF), a potentially life-threatening blood cancer for which there are currently no approved therapies in the US. The Company has requested a Priority Review of the application.

Incyte obtained a Special Protocol Assessment agreement from the FDA for the pivotal Phase III registration trial, COMFORT-I. The NDA includes results from both COMFORT-I and COMFORT-II, a second Phase III trial conducted by Novartis in Europe under the Incyte-Novartis worldwide collaboration and license agreement for ruxolitinib. Data from both studies are being presented today at the 2011 American Society of Clinical Oncology (ASCO) annual meeting.

Ruxolitinib was granted Fast Track designation by the FDA in October 2009. The Fast Track program is intended to facilitate the development and expedite the review of drug candidates that demonstrate the potential to address unmet medical needs for serious, life-threatening conditions.

Ruxolitinib, the lead JAK1 and JAK2 inhibitor discovered by Incyte, entered Phase I clinical testing in May 2007 and is being investigated in a number of hematology conditions. Ruxolitinib is the first JAK inhibitor to be submitted to the FDA for the treatment of MF.

About the Regulatory Process

Upon the submission of the NDA, the FDA determines if the application is considered filed after reviewing the submission for completeness and accepting it for review. This filing decision is typically made within 60 days of receiving an application. Assuming the NDA is considered complete and accepted for review, it will then go through a detailed FDA review process through one of two systems of review times: PriorityReviewand Standard Review.

A Priority Reviewdesignation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA has a goal to complete the Priority Review in six months. In addition, most drugs that are eligible for Fast Track designation are likely to be considered appropriate to receive a Priority Review.

Standard Review is applied to all other drugs. The FDA has a goal to complete the Standard Review within a ten-monthtime frame.

About Myelofibrosis (MF)

Myelofibrosis is a potentially life-threatening blood cancer characterized by bone marrow failure, enlarged spleen (splenomegaly) and debilitating symptoms, such as fatigue, pruritus, night sweats, bone pain and early satiety. MF is one of the Philadelphia chromosome-negative myeloproliferative neoplasms (MPNs), which also include polycythemia vera and essential thrombocythemia. Aberrant activation of the Janus kinase (JAK) pathway, which regulates blood cell production, has been associated with the development of the MPNs, including MF.[1]

About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, visit the Company's web site at www.incyte.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding assuming the NDA is considered complete and accepted for review, it will then go through a detailed FDA review process through one of two systems of review times: PriorityReviewand Standard Review and that most drugs that are eligible for Fast Track designation are likely to be considered appropriate to receive a Priority Review are, all forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995.

These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in the efficacy or safety of or unanticipated additional clinical trial results for ruxolitinib, the possibility that regulatory authorities may require additional clinical trials in order to support registration of ruxolitinib in any particular indication, the possibility that there may be other interpretations of the data produced in one or more of the clinical trials for ruxolitinib, the risk that regulatory authorities will require more extensive data for the ruxolitinib NDA filing or take longer to review the ruxolitinib NDA filing than currently expected, the results of further research and development, and other risks detailed from time to time in Incyte's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2011. Incyte disclaims any intent or obligation to update these forward-looking statements.

[1]Vannucchi AM, Guglielmelli P, Tefferi A. Advances in understanding and management of myeloproliferative neoplasms.

CA Cancer J Clin. 2009;59:171-191.

SOURCE: Incyte Corporation

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