

Incyte Provides Top-Line Results from Phase II Proof-of-Concept Trial of Ruxolitinib in Patients with Refractory Metastatic Pancreatic Cancer

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- *Overall survival analysis demonstrated a hazard ratio of 0.79 and a pre-specified subgroup analysis achieved a significant benefit with a hazard ratio of 0.47*
- *Results expected to define and support a pivotal registration program in metastatic pancreatic cancer*

WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 21, 2013-- **Incyte Corporation (Nasdaq: INCY)** announced top-line results of the Phase II, randomized, double-blind, placebo-controlled RECAP trial of ruxolitinib, its oral JAK1 and JAK2 inhibitor, in combination with capecitabine in patients with recurrent or treatment refractory metastatic pancreatic cancer. The hazard ratio (HR) for overall survival (OS) in the intent to treat population was 0.79 (one-sided $p=0.12$), and in a pre-specified subgroup analysis conducted in patients identified prospectively as most likely to benefit from JAK pathway inhibition, the HR for OS was 0.47 (one-sided $p=0.005$). Within this subgroup of patients, which represented 50% of the randomized population, 6 month survival in the ruxolitinib arm was 42% vs. 11% for placebo. Durable tumor responses were only observed in patients receiving ruxolitinib, and ruxolitinib treated patients achieved a significant improvement in body weight relative to placebo.

"Results of the RECAP trial provide the first evidence that JAK inhibition is active in this disease and suggest a demonstrable survival benefit in a well-defined group of patients with refractory metastatic pancreatic cancer who can be identified without the development of a companion diagnostic test. Coupled with the overall survival benefit observed in the ongoing Phase III trials in myelofibrosis, these results solidify our belief in the therapeutic opportunity that exists for Jakafi, and provide us with an acceleration strategy to advance our JAK1 inhibitor portfolio into additional areas of unmet medical need," stated Paul A. Friedman, M.D., Incyte's President and Chief Executive Officer.

Richard S. Levy, Incyte's Executive Vice President and Chief Drug Development and Medical Officer added, "Advanced pancreatic cancer is a devastating disease, and the RECAP study has provided us with a unique opportunity to bring ruxolitinib forward into Phase III development in a population with no attractive treatment options. We look forward to working with the FDA to define the core components of the Phase III program in pancreatic cancer as rapidly as possible, and in parallel, leveraging these results to expand our ruxolitinib and JAK1 inhibitor programs into additional solid tumor populations, including those that may benefit from selective JAK1 inhibition."

Full results of the RECAP trial are expected to be presented at a future scientific meeting.

Safety

Ruxolitinib in combination with capecitabine was generally well tolerated in this study. Among patients receiving ruxolitinib plus capecitabine 12% discontinued therapy for an adverse event, compared with 20% who received capecitabine alone. The rates of new onset grade 3 anemia, thrombocytopenia or neutropenia were 16%, 2% and 0%, respectively, among patients receiving ruxolitinib plus capecitabine and were 2%, 3% and 2%, respectively, among patients receiving capecitabine alone.

About The RECAP Trial

The purpose of this initial proof-of-concept study was to determine whether ruxolitinib in combination with capecitabine could improve the overall survival of patients with refractory metastatic pancreatic cancer as compared to capecitabine alone. RECAP included pre-specified analyses to determine the base line characteristics of patients most likely to benefit from treatment with ruxolitinib. The study included a total of 136 patients and consisted of an open-label, safety run-in period involving nine patients to determine the safety of the ruxolitinib and capecitabine combination. This was followed by a double-blind study of 127 patients randomized 1 to 1 to capecitabine plus ruxolitinib or capecitabine plus placebo. Patients received treatment as long as the regimen was tolerated or the patient did not meet any of the discontinuation criteria. In the event of disease progression, capecitabine therapy was discontinued while treatment with ruxolitinib or placebo continued unless patients withdrew consent for further participation in the trial. In addition to the primary endpoint of overall survival, secondary endpoints included progression free survival, body weight and nutritional markers, tumor response rate, quality of life outcomes and pain status.

About Pancreatic Cancer

Pancreatic cancer is the fourth leading cause of cancer-related death in the US and the eighth leading cause of cancer-related death worldwide. For patients with advanced pancreatic cancer, the 5-year overall survival rate is less than 1 percent. Most patients die within the first year. Pancreatic cancer has the lowest 5-year overall survival rate of any cancer in the US. In Europe, the reported survival rate is less than 10 percent survival at five years. Unfortunately, most patients do not exhibit symptoms until their disease is advanced. Additionally, pancreatic cancer progresses and metastasizes rapidly, highlighting the need to identify high-risk candidates early.

About Ruxolitinib

Ruxolitinib is an oral, selective inhibitor of Janus kinases 1 and 2 (JAK1 and JAK2). Ruxolitinib, brand name Jakafi®, is indicated for treatment of patients with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. This life-threatening blood cancer is characterized by bone marrow failure, enlarged spleen (splenomegaly) and debilitating symptoms.

Important Safety Information

Jakafi can cause serious side effects including:

Low blood counts: Jakafi may cause your platelet, red blood cell, or white blood cell counts to be lowered. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will perform blood tests to check your blood counts before you start Jakafi and regularly during your treatment. Your healthcare provider may change your dose of Jakafi or stop your treatment based on the results of your blood tests. Tell your healthcare provider right away if you experience unusual bleeding, bruising, fatigue, shortness of breath, or a fever.

Infection: You may be at risk for developing a serious infection while taking Jakafi. Tell your healthcare provider if you develop symptoms such as chills, nausea, vomiting, aches, weakness, fever, or painful skin rash or blisters.

The most common side effects of Jakafi include dizziness and headache.

These are not all the possible side effects of Jakafi. Ask your healthcare provider or pharmacist for more information. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Before taking Jakafi, tell your healthcare provider about all the medications, vitamins, and herbal supplements you are taking and all your medical conditions, including if you have an infection, have or had liver or kidney problems, are on dialysis, or have any other medical condition. Do not drink grapefruit juice while taking Jakafi.

Women should not take Jakafi while pregnant or planning to become pregnant, or if breast-feeding.

Please see the Full Prescribing Information available at www.jakafi.com, which includes a more complete discussion of the risks associated with Jakafi.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, please visit the Company's website at www.incyte.com.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation, statements as to results of the RECAP trial being expected to define and support a pivotal registration program for ruxolitinib in metastatic pancreatic cancer, that results of the RECAP trial suggest a demonstrable survival benefit in a well-defined group of patients with refractory metastatic pancreatic cancer who can be identified without the development of a companion diagnostic test, our plans to work with the FDA to define the core components of the Phase III program in pancreatic cancer as rapidly as possible and to expand and advance our JAK1 program into additional solid tumor populations that may benefit from selective JAK1 inhibition and areas of unmet medical need, and our expectation that full results of the RECAP trial will be presented at a future scientific meeting, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to the efficacy or safety of ruxolitinib, risks related to market competition, the results of further research and development, risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, the ability to enroll sufficient numbers of subjects in clinical trials, other market or economic factors and technological advances, unanticipated delays, the ability of Incyte to compete against parties with greater financial or other resources, and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including our Form 10-Q for the quarter ended June 30, 2013.

Incyte disclaims any intent or obligation to update these forward-looking statements.



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