Incyte Sponsors First Observational Study Designed to Understand the Impact of Polycythemia Vera – a Rare, Progressive Blood Cancer

Results expected to provide better strategies for both patients and physicians to manage the burden of this disease

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 26, 2015-- Incyte Corporation (Nasdaq: INCY) today announced that it is sponsoring the first major observational study of patients living with polycythemia vera (PV) in the U.S. PV is a rare and progressive blood cancer that can lead to debilitating symptoms, serious cardiovascular complications, and death. The REVEAL (PROSPECTIVE OBSERVATIONAL STUDY OF PATIENTS WITH POLYCYTHEMIA VERA IN US CLINICAL PRACTICES) study will seek to describe the real-world clinical burden of PV and how healthcare services are utilized in the management of this disease.

"Despite increased clinical knowledge of PV in recent years, we have more to learn about the impact of PV on patients’ quality of life, work productivity, and activity impairment. We also have more to learn about treatment patterns in real-world clinical practice settings," said Brady Lee Stein, MD, MHS, Assistant Professor, Medicine, Hematology Oncology Division; Feinberg School of Medicine, and co-chair of the Scientific Advisory Committee for the REVEAL study. "Results from REVEAL should provide relevant information on contemporary disease management strategies and clinical outcomes to the scientific community and practicing oncologists and hematologists in the interest of improving the lives of patients with PV in the future."

Incyte is partnering with approximately 200 community and academic medical centers to conduct the study in the U.S. REVEAL, which recently began enrolling patients, is expected to include 2,000 patients under the supervision of a physician for the active management of PV for a period of three years.

PV is a form of blood cancer leading to the overproduction of red blood cells, white blood cells and platelets. Patients with PV often suffer from an enlarged spleen and a significant symptom burden caused by thickening of the blood and lack of oxygen to parts of the body. These symptoms commonly include fatigue, itching, night sweats, bone pain, fever, and weight loss.

"Insights gathered from REVEAL may help us better understand PV and lead to better ways to treat and manage the disease in the future," said Nicholas Sarlis, M.D., Ph.D., Vice President, Medical Affairs, Incyte. "We encourage patients and physicians to consider participating in this study."

About the REVEAL Study

The REVEAL study is a multicenter, non-interventional, non-randomized, prospective, observational study designed to provide an understanding of the natural history of PV and information on the management of this disease in the U.S., including response to PV therapies. All patients in the study will be 18 years or older, have been diagnosed with clinically overt PV and followed in either community or academic medical centers in the U.S. Patients are being enrolled over a 12-month period and observed for 36 months. Secondary objectives are to:

- Characterize the evolution of the clinical manifestations of and complications from PV
- Describe practice patterns and therapy strategies in patients treated for PV
- Describe patterns of sequencing in the introduction of various therapies and how they relate to clinical outcomes
- Assess the impact of PV on Patient Reported Outcomes (PROs), including Health Related Quality of Life (HRQoL), symptoms, work productivity and activity impairment

Characteristics such as age, medical history, health-system resource utilization (ER and doctor visits, hospitalizations, phlebotomy, paid/unpaid caregiver services, etc.), and therapeutic regimens will be observed. Researchers will also explore possible association of various clinical parameters with survival and other objectives such as determining the risk profile for disease progression.

REVEAL is the first study of its kind in the U.S. Visit www.revealpvstudy.com for more information.

About Polycythemia Vera

Polycythemia vera (PV) is a myeloproliferative neoplasm (MPN) characterized by an overproduction of red blood cells, white blood cells and platelets that leads to an increased risk of thrombosis. Erythrocytosis (elevated red blood cell mass) is the most prominent clinical manifestation of PV, distinguishing it from other MPNs. PV may occur at any age but often presents later in life, with a median age at diagnosis of 60 years. Approximately 25,000 patients in the United States living with PV are considered uncontrolled because they develop resistance to or intolerance of hydroxyurea.

Although patients may be asymptomatic for many years, PV is associated with significant symptom burden, and the most common signs and symptoms of PV are fatigue, pruritus, night sweats, bone pain, fever and weight loss. Splenomegaly is present in 30 percent to 40 percent of patients with PV. In patients who experience severe and burdensome symptoms, data show that the disease causes a significant and clinically meaningful erosion of quality of life.
About Incyte
Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics, primarily for oncology. 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 statements regarding the Company’s plans and expectations regarding the REVEAL study, contain predictions, estimates and other forward-looking statements. These forward-looking statements are based on the Company’s current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including the results of and risks associated with research and development, the ability to enroll sufficient numbers of patients in research studies, and other risks detailed from time to time in the Company’s reports filed with the Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2014. Incyte disclaims any intent or obligation to update these forward-looking statements.

References
11 Data on file. Incyte Corporation

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