FDA Grants Full Approval for PROMACTAÃ,® (eltrombopag) for Treatment of Rare Blood Disorder

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PHILADELPHIA, Feb. 25, 2011 /PRNewswire/ -- GlaxoSmithKline (NYSE: GSK [1]) today announced that the United States Food and Drug Administration (FDA) granted full approval for PROMACTA® (eltrombopag), an oral tablet that can raise platelet counts in patients with the rare blood disorder chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.

PROMACTA initially received FDA orphan drug designation in May 2008 and accelerated approval in November 2008 for chronic ITP. The FDA Accelerated Approval program offers a pathway to gain provisional marketing approval for therapies that address unmet patient needs. Full approval of the therapy requires completion of post-marketing clinical trials and commitments that verify clinical benefit.

"Full approval of PROMACTA was based on clinical studies that provide physicians and patients with a broader understanding of its treatment effect and safety profile," said Steven Stein, MD, V.P. of Medicines Development, GlaxoSmithKline. "PROMACTA is a testament to how the FDA Accelerated Approval Program supports development of therapies that meet unmet patient needs. Patients with limited treatment options gained access to PROMACTA while GSK conducted clinical studies that yielded additional efficacy and safety data."

About Chronic ITP

Chronic ITP is a disorder marked by increased platelet destruction and/or inadequate platelet production in the blood, which causes an increased risk of bruising and bleeding. There are estimated to be approximately 60,000 individuals diagnosed with chronic ITP in the U.S. People with chronic ITP often bleed from small blood vessels causing bruises or nosebleeds.

Updated Prescribing Information (PI)

The major changes in the Prescribing Inform
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[1] http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=GSK
[2] http://www.bio-medicine.org/medicine-technology-1/FDA-Grants-Full-Approval-for-PROMACTA-AE--28eltrombopag-29-for-Treatment-of-Rare-Blood-Disorder-15022-1/