

Issued: 22 July 2011, India

GlaxoSmithKline Pharmaceuticals Limited announces launch of two drugs

- Revolade™ (Eltrombopag olamine tablets,) oral platelet generator for chronic ITP -
- Votrient™ (Pazopanib Hydrochloride Tablets) for advance renal cell carcinoma-

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Mumbai: GlaxoSmithKline Pharmaceuticals Limited today announced the launch of two drugs Revolade™ and Votrient™ at a press conference held in Mumbai. Both the drugs are targeted towards specific patient categories.

Revolade™ (Eltrombopag) is approved for the oral treatment of thrombocytopenia (reduced platelet count) in adults with the blood disorder chronic immune (idiopathic) thrombocytopenic purpura (ITP) ¹. It is indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. (It should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts).¹

Currently, there is no data available on the occurrence of ITP in the Indian population. In the European Union (EU), Revolade™ has orphan drug designation. Orphan Drug designation is given to medicines used to treat life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the European Union.²

Announcing the launch of Revolade™, Dr. Hasit Joshipura, Vice President South Asia & Managing Director, India, said, "Revolade™ is the first and only oral platelet generator. It is an innovative step forward in helping patients and their physicians meet the challenges of managing chronic ITP. Clinical trials have shown that eltrombopag is able to stimulate the production of platelets and reduce the risk of bleeding in this difficult to treat disease."

Votrient™ (Pazopanib Hydrochloride Tablets) is indicated for advanced renal cell carcinoma (RCC) ³, the most common type of kidney cancer⁴. As per estimates, in India, there were 8900 new cases and 5733 deaths due to kidney cancer in 2008⁵.The worldwide and European incidence of renal cell carcinoma (RCC) is rising by 2% annually⁴.

PRESS RELEASE



Speaking about Votrient™, Dr. Joshipura added, “Votrient™ approval in India is based on the results from a pivotal Phase III study of patients with advanced kidney cancer who had either received no prior drug treatment, or had failed a cytokine-based treatment⁶. Votrient™ has been proven to significantly delay the progression of advanced renal cell carcinoma while maintaining patients’ quality of life, when compared with placebo.”

Both the drugs will be marketed by the Oncology division of GlaxoSmithKline Pharmaceuticals Limited.

Votrient® is authorized for use in 27 member states of the European Union, Switzerland, Australia, New Zealand, Canada, Turkey, Korea, Argentina and Russia. In addition, Votrient® is approved by the US Food and Drug Administration (FDA) for patients with advanced RCC.

Eltrombopag is authorized for use in all 27 member states of the European Union. It is approved by USFDA and is available in the USA under the trade name Promacta®. It is also approved in Australia, Ireland, Japan, Taiwan, Turkey, Singapore, Kuwait, Chile, Russia and Bahrain under the trade name Revolade®.

About GlaxoSmithKline

GlaxoSmithKline – one of the world’s leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better, and live longer. For company information, visit GlaxoSmithKline PLC at www.gsk.com OR GlaxoSmithKline Pharmaceuticals Limited at www.gsk-india.com.

For More Details Contact:

Via Media & Communications

Mehak Chawla: 09310087613, mchawla@viamediahealth.net

Sonika Zalpuri: 09766904398, sonika@viamediahealth.net

Pooja Raut: 09820752565, poojaraut@viamediahealth.net

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