PRESS RELEASE

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FDA approves GlaxoSmithKline's VOTRIENT™ for advanced renal cell cancer

GlaxoSmithKline [NYSE: GSK] announced today that the U.S. Food and Drug Administration (FDA) has approved VOTRIENT™ (pazopanib) to treat patients with advanced renal cell carcinoma (RCC), a form of kidney cancer. Approximately 57,700 people in the U.S. will be diagnosed with kidney cancer this year, and 13,000 people will die from this disease.

"RCC is the most common malignancy of the kidney and is highly resistant to chemotherapy," said Paolo Paoletti, MD, Senior Vice President, GlaxoSmithKline Oncology R&D Unit. "While treatment has improved in the past few years with the introduction of targeted therapies, advanced RCC remains a challenging disease. VOTRIENT will join existing targeted therapies to provide physicians with a new oral treatment option to their patients with advanced renal cell cancer."

VOTRIENT, a once-daily, oral medication, is an angiogenesis inhibitor which may help prevent the growth of new blood vessels, thereby blocking the growth of kidney cancer tumors that need blood vessels to survive.

The approval of VOTRIENT was supported by a unanimous decision by the FDA's Oncology Drugs Advisory Committee (ODAC) that the benefit-to-risk profile for VOTRIENT is acceptable for patients with advanced kidney cancer. The ODAC reviewed data from a Phase III clinical trial showing that VOTRIENT reduced the risk of tumor progression or death by 54 percent compared to placebo, regardless of prior treatment.

In this Phase III trial, the overall median PFS was 9.2 months with pazopanib and 4.2 months with placebo. Treatment-naïve patients who received VOTRIENT experienced 11.1 months of median progression-free survival (PFS) versus 2.8 months with placebo. Additionally, patients who had previously received cytokine-based treatment achieved 7.4 months of median PFS with VOTRIENT versus 4.2 months with placebo.

The most common adverse events occurring in ≥20% of subjects treated with VOTRIENT included diarrhea, hypertension, hair color changes, nausea, anorexia, and vomiting. Grade 3/4 adverse events among these toxicities that differed by ≥2% included abnormal liver function, hypertension, diarrhea, asthenia, and abdominal pain. Laboratory abnormalities occurring in >10% of patients and more commonly (≥5%) in the pazopanib arm included increased transaminases, hyperglycemia, leukopenia, hyperbilirubinemia, neutropenia, hypophosphatemia, thrombocytopenia, lymphocytopenia, hyponatremia, hypomagnesemia, and hypoglycemia. Drug-related deaths were observed in 1.4% of 290 patients and included hepatic failure (n=2), stroke (n=1), and perforation (n=1). Hepatic dysfunction is included as a boxed warning in the product label. Other Warnings and Precautions in the label relate to QT prolongation and torsade de pointes, hemorrhagic events, arterial thrombotic events, gastrointestinal perforation and fistula, hypertension, impaired wound healing, hypothyroidism, proteinuria, and pregnancy.

VOTRIENT has a broad clinical program across multiple tumor types, with study details available at www.clinicaltrials.gov. More than 2,000 patients have been treated to date in clinical trials. VOTRIENT is not yet approved in any country other than the U.S.

About GSK Oncology

GSK Oncology is dedicated to producing innovations in cancer that will make profound differences in the lives of patients. Through GSK's revolutionary 'bench to bedside' approach, we are transforming the way treatments are discovered and developed, resulting in one of the most robust pipelines in the oncology sector. Our worldwide research in oncology includes collaborations with more than 160 cancer centers. GSK is closing in on cancer from all sides with a new generation of patient focused cancer treatments in prevention, supportive care, chemotherapy and targeted therapies.

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 further information please visit www.gsk.com

Note to Editors:

VOTRIENT™ is the proposed registered trademark to be used in the United States and Europe.

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Cautionary statement regarding forward-looking statements
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK' s operations are described under 'Risk Factors' in the 'Business Review' in the company' s Annual Report on Form 20-F for 2008.

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