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Nexavar seeks marketing authorization in Japan

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Singapore: Bayer HealthCare has submitted an additional application for marketing authorization to the Ministry of Health, Labour and Welfare (MHLW) in Japan for Nexavar (Sorafenib) tablets, for the treatment of locally advanced or metastatic thyroid cancer. The MHLW granted sorafenib orphan drug status for this indication in September.

"The regulatory filing in Japan for sorafenib for the treatment of thyroid cancer brings us another step closer to addressing a significant medical need for patients whose disease has advanced and who have limited or no treatment options," said Dr Kemal Malik, member of the Bayer HealthCare Executive Committee and head of Global Development. "Nexavar is already approved for the treatment of hepatocellular carcinoma and advanced renal cell carcinoma. We are committed to fully exploring sorafenib's utility across tumor types, especially in hard-to-treat cancers where there are limited treatment options," Dr Malik added.

In June 2013, Bayer submitted Nexavar for regulatory review to the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of locally advanced or metastatic differentiated thyroid cancer refractory to radioactive iodine (RAI). Nexavar received priority review designation from the FDA in August of this year for this indication. The FDA grants priority review to medicines that, if approved, would significantly improve the efficacy or safety of treatment for serious conditions. Under the Prescription Drug User Fee Act (PDUFA), the FDA aims to complete priority review within six months, rather than the standard ten-month review cycle.

The regulatory submission is based on data from the phase III DECISION (stuDy of sorafEnib in loCally advanced or metastatIc patientS with radioactive Iodine refractory thyrOid caNcer) trial, an international, multicenter, placebo-controlled trial. The safety and tolerability profile of sorafenib in the trial were generally consistent with the known profile of sorafenib. The most common treatment-emergent adverse events in the sorafenib arm were hand-foot skin reaction, diarrhea, alopecia, rash/desquamation, fatigue, weight loss and hypertension. Results from the trial were presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2013.

Thyroid cancer has become the fastest-increasing cancer in the world in recent years and is the sixth most common cancer in women. There are more than 213,000 new cases of thyroid cancer annually and approximately 35,000 people die from thyroid cancer worldwide each year.