

Sanofi, Regeneron cancer drug Zaltrap gets EU nod

05 February 2013 | News | By BioSpectrum Bureau



Singapore: European Commission has granted marketing authorization for Sanofi and Regeneron Pharmaceuticals (EC)'s Zaltrap 25mg/ml concentrate in the European Union. Zaltrap 25mg/ml solution is for infusion in combination with irinotecan/5-fluorouracil/folinic acid (Folfiri) chemotherapy in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen. This decision was based on the efficacy and safety results of the Velour phase III trial.

"Zaltrap is an important addition to the metastatic colorectal cancer treatment landscape and helps to fill a critical treatment gap," said Dr Eric Van Cutsem, University Hospitals Leuven, Belgium, and lead investigator of the Velour study. "Zaltrap is the first and only agent to demonstrate a survival improvement in a phase III trial in patients previously treated with an oxaliplatin-based regimen who are being treated with Folfiri for their metastatic disease."

"I would like to thank the physicians, patients, and their families for their support in moving Zaltrap through the clinical trial process leading to approval in Europe," said Dr Debasish Roychowdhury, SVP and head, Sanofi Oncology. "We are thrilled to provide a new therapy that further extends the lives of patients with metastatic colorectal cancer and look forward to working with European health authorities to ensure patients have access to Zaltrap."

In Europe, colorectal cancer is the most common cancer in both men and women and is the second leading cause of cancer death. In 2008, there were 436,000 new cases diagnosed and 212,000 deaths from colorectal cancer.

Commenting on the marketing authorization, Dr George D Yancopoulos, CSO of Regeneron and president of Regeneron Laboratories, added, "The European approval of Zaltrap provides a new option to address the unmet medical need in this patient population. There continues to be a need to develop new cancer therapies and Regeneron and Sanofi are committed to finding novel investigational treatments and combinations."