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FDA approves ZALTRAP for colorectal cancer

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FDA approves ZALTRAP for metastatic colorectal cancer

Singapore: Sanofi and Regeneron Pharmaceuticals have received US Food and Drug Administration (FDA) approval for ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion, in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), for patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

"There are limited treatment options for metastatic colorectal cancer patients who are resistant to or whose disease has progressed after an oxaliplatin-containing regimen," said Dr Edith Mitchell, clinical professor of medicine and medical oncology at Jefferson Medical College, Thomas Jefferson University and an investigator of the VELOUR pivotal study. "The approval of ZALTRAP in combination with a FOLFIRI chemotherapy regimen offers another treatment option and is welcome news for metastatic colorectal patients and their physicians," he said.

ZALTRAP was approved following a Priority Review by the FDA. A priority review is a designation given to therapies that offer major advances in treatment or provide a treatment where no adequate therapy exists. Marketing authorization applications for ZALTRAP are also under review by the European Medicines Agency (EMA) and other regulatory agencies worldwide.

"Colorectal cancer is one of the deadliest cancers and is responsible for more than half a million deaths globally each year," said Dr Debasish Roychowdhury, senior VP and head, Sanofi Oncology. "Sanofi looks forward to making ZALTRAP available as soon as possible to patients with metastatic colorectal cancer previously treated with an oxaliplatin-containing regimen," he said.

The ZALTRAP approval was based on data from the pivotal phase III VELOUR trial, a multinational, randomized, double-blind trial comparing FOLFIRI in combination with either ZALTRAP or placebo in the treatment of patients with mCRC. The study randomized 1,226 patients with mCRC who previously had been treated with an oxaliplatin-containing regimen. Twenty-

eight percent of patients in the study received prior bevacizumab therapy. The primary endpoint was overall survival. Secondary endpoints included progression-free survival, overall response rate, and safety.

"The approval of the novel angiogenesis inhibitor ZALTRAP provides a new option to address the unmet medical need in this patient population," said Dr George D Yancopoulos, CSO, Regeneron, and president, Regeneron Research Laboratories. "However, there continues to be a need to develop new cancer therapies. Regeneron and Sanofi continue to devote resources to finding novel investigational treatments and combinations," he added.