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Novartis liver cancer trial with Afinitor flops

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Singapore: Novartis highlighted that the results of a global phase III study showed that Afinitor (everolimus) did not extend overall survival as compared to placebo in patients with locally advanced or metastatic hepatocellular carcinoma (HCC) after progression on or intolerance to sorafenib. Novartis will thus not proceed with regulatory filings of Afinitor in this indication.

Dr Alessandro Riva, global head, oncology development and medical affairs, Novartis Oncology, said that, "While we are disappointed with these results, Novartis remains committed to studying everolimus through a robust research and development program to address unmet needs in different types of cancer. To date, Afinitor has proven efficacy in a number of tumor types, including hormone receptor positive advanced breast cancer, advanced pancreatic neuroendocrine tumors and advanced renal cell carcinoma."

The results of the HCC trial do not impact the worldwide approvals of Afinitor for these other indications. Everolimus is also in phase III development in other diseases, including gastrointestinal and lung neuroendocrine tumors (NET), HER2 positive breast cancer, lymphoma and tuberous sclerosis complex (TSC). Results of these trials are expected during 2014 and 2015.

The phase III study, Evolve-1 (Everolimus for liver cancer evaluation-1), is a randomized, double-blind, placebo-controlled trial examining the efficacy and safety of everolimus versus placebo, plus best supportive care (BSC), in adult patients with advanced HCC whose disease progressed after treatment with or who were intolerant to sorafenib, a targeted therapy. The study results continue to be evaluated and will be presented at an upcoming medical conference.

Evolve-1 involved 546 patients and was conducted at 156 sites worldwide. Patients in the trial were randomized (2:1) to receive therapy with everolimus 7.5 mg/day orally plus BSC or placebo plus BSC. The primary endpoint was overall survival. Secondary endpoints included time to tumor progression, disease control rate, time to deterioration of performance status, safety and quality of life.