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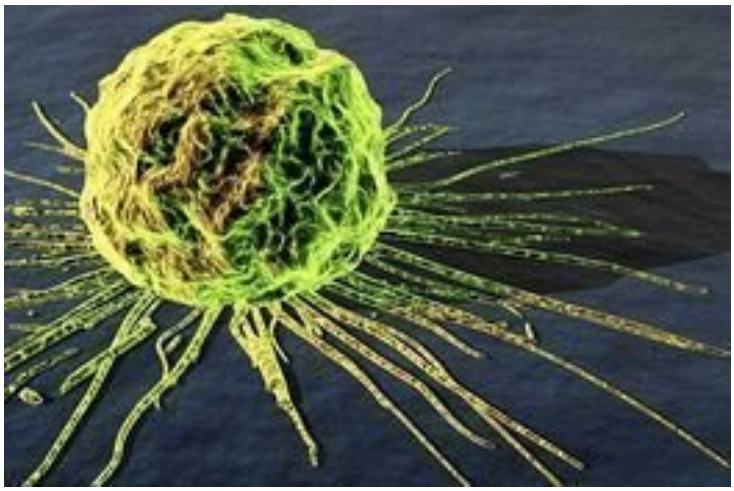

Singapore: Amgen decided to stop the ganitumab (AMG 479) phase III GAMMA (gemcitabine and AMG 479 in metastatic adenocarcinoma of the pancreas) trial following the recommendation of an independent data monitoring committee (DMC) overseeing the trial.

Based on the review of a pre-planned interim analysis, the DMC concluded that the addition of ganitumab to gemcitabine is unlikely to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to gemcitabine alone. There were no safety concerns raised in the DMC review of the study.

The GAMMA study is a randomized, multicenter, double-blind, phase III trial to determine if ganitumab plus gemcitabine improves overall survival, compared to placebo plus gemcitabine, in the first-line treatment of patients with metastatic adenocarcinoma of the pancreas.

Dr Sean E Harper, executive VP, R&D, Amgen, said that, "These disappointing results underscore the difficulty of treating pancreatic cancer, which remains a major unmet medical need," said "We would like to thank the patients, caregivers and investigators for their participation and engagement in the study."

Amgen has communicated with regulatory authorities and is in the process of notifying study investigators that treatment with ganitumab should be discontinued in the GAMMA trial, as well as a separate ongoing phase II trial in locally advanced pancreatic cancer. Ganitumab is an investigational fully human monoclonal antibody that targets type 1 insulin-like growth factor receptor (IGF1R).