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Taiho terminates oranitib Ph III trial

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Singapore: Faced with disappointing results, Japan's large drugmaker, Taiho Pharmaceutical has said that it is terminating a Phase III clinical trial of the angiogenesis inhibitor TSU-68 (orantinib) in patients with hepatocellular carcinoma due to disappointing results.

The company said that the trial that was conducted in Japan, South Korea and Taiwan had enrolled a total of 889 patients. Held between December 2010 and November 2013, the trial was a randomized, double-blind trial of hepatocellular carcinoma patients who were treated by transcatheter arterial chemoembolization (TACE), comparing two arms, TSU-68 arm (TACE plus TSU-68) and placebo arm (TACE plus placebo). The purpose of the study was to demonstrate superiority of TSU-68 arm in overall survival.

A news report specified that the independent data monitoring committee conducted an interim analysis, the results of which indicated that the pre-determined standard related to the primary endpoint of overall survival was not met, and they therefore recommended that the trial be terminated.

Based on this recommendation, Taiho Pharmaceutical made the decision to terminate the trial and communicated to the relevant regulatory authorities as well as all the principal investigators that the trial had been terminated.