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Sankyo halts phase III trial of cancer drug

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Sankyo halts Ph3 clinical trial of cancer drug

Singapore: The independent Data Monitoring Committee (DMC) of the phase III MARQUEE (Met inhibitor ARQ 197 plus Erlotinib vs Erlotinib plus placebo in NSCLC) trial recommended that Sankyo's study be stopped early following a planned interim analysis. This decision was taken as the study would not meet its primary endpoint of improved overall survival.

Although the interim analysis showed a statistically significant improvement in progression-free survival (PFS) in the intent-to-treat (ITT) population, the benefit did not carry over to overall survival. There were no safety concerns identified by the DMC to Daiichi Sankyo or ArQule during this interim analysis.

"We are disappointed that the MARQUEE trial did not provide statistically significant results for overall survival in a disease and treatment setting which remains a major unmet medical need," said Mr Paolo Pucci, chief executive officer, ArQule.

"Fighting cancer is a complex process in that therapies work differently in different tumor settings, so we will continue to investigate tivantinib in other tumor types," said Dr Glenn Gormley, global head, R&D and senior executive officer, Daiichi Sankyo.

Approximately 1,000 patients were recruited in MARQUEE from more than 200 clinical sites worldwide. In December 2008, ArQule and Daiichi Sankyo signed a license, co-development and co-commercialization agreement to co-develop tivantinib in the US, Europe, South America and the rest of the world, excluding Japan, China (including Hong Kong), South Korea and Taiwan.