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ASIA EDITION

Daiichi, ArQule cancer trial fails to meet endpoint

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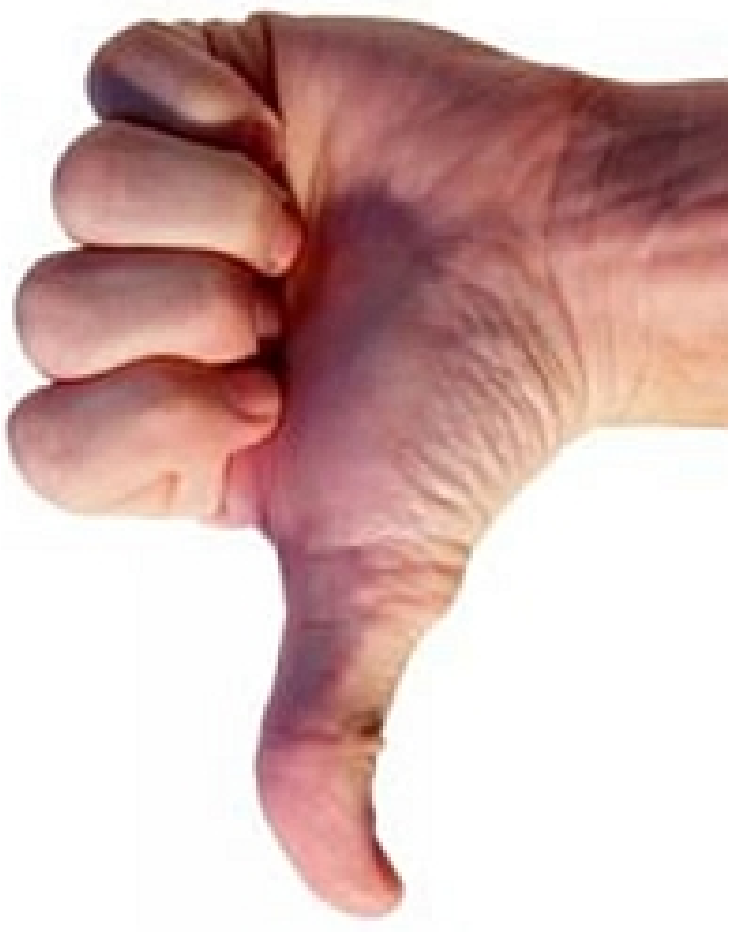

Singapore: Daiichi Sankyo Company and ArQule announced the top-line results of a randomized phase II signal generation trial of tivantinib (ARQ 197) used in combination with irinotecan and cetuximab in patients with refractory or relapsed colorectal cancer (CRC).

Although the trial did not meet its primary endpoint of Progression-Free Survival (PFS), the analysis of the patients enrolled (n=122) showed that median PFS was 8.3 months in the experimental arm (patients treated with irinotecan and cetuximab plus tivantinib), compared with 7.3 months in the control arm (patients treated with irinotecan and cetuximab plus placebo) (hazard ratio = 0.85, 95 percent CI: 0.55, 1.33).

"We are encouraged by these findings that expand the body of data for tivantinib in CRC and offer the potential for further exploration," said Mr Reinhard von Roemeling, MS, vice president, clinical development-oncology, Daiichi Sankyo. "We plan to continue discussions with key opinion leaders in the field of CRC to determine how best to proceed with further clinical development of tivantinib in this tumor type."

Adverse events were reported at similar rates in the experimental and control arms, except for increased neutropenia observed in the experimental arm, with no discontinuations of treatment for this reason. No treatment-emergent adverse events leading to death were assessed as related to study treatment. Tivantinib was generally well tolerated in combination with the doses of cetuximab and irinotecan studied in this trial.