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ASIA EDITION

Daiichi, ArQule enroll patient for cancer trial

01 February 2013 | News | By BioSpectrum Bureau

Singapore: Daiichi Sankyo and ArQule announced that the first patient has been enrolled in the pivotal phase III METIV-HCC (MET-high patients with tivantinib in HCC) trial of tivantinib (ARQ 197). Tivantinib, an investigational selective inhibitor of MET, a receptor tyrosine kinase, is being evaluated for the treatment of patients diagnosed with hepatocellular carcinoma (HCC) who have received one or two prior systemic anti-cancer therapies.

The METIV-HCC trial is a randomized, double-blinded, controlled study of previously treated patients with MET-high inoperable HCC who will receive tivantinib or placebo. The primary endpoint is overall survival (OS), and the secondary endpoint is progression-free survival (PFS). Approximately 300 patients are planned to be enrolled at approximately 120 clinical centers worldwide.

"We are very pleased to begin this phase III trial to advance our understanding of the potential role of tivantinib in the treatment of HCC," said Dr Glenn Gormley, MD, global head of research and development and senior executive officer, Daiichi Sankyo. "It is our hope that this late-stage study will confirm the positive results we saw in phase II in time to progression (TTP) and overall survival (OS) observed in patients whose tumors were MET-high."

"Hepatocellular carcinoma is a devastating disease, and patients with advanced HCC are in need of new therapies that can help extend their lives," said Mr Paolo Pucci, chief executive officer of ArQule. "The METIV-HCC trial follows positive phase II results that demonstrated improvements in overall survival and time to progression observed among MET-high patients."

In October 2012, agreement was reached with the US FDA on a Special Protocol Assessment (SPA) for this pivotal phase III trial. The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a New Drug Application. Final marketing approval depends on the results of the trial.