BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Alchemia enrolls patients for cancer trial

01 March 2013 | News | By BioSpectrum Bureau

Singapore: Alchemia has completed enrollment of patients in a pivotal phase III clinical trial evaluating its lead product, HA-Irinotecan, for the treatment of metastatic colorectal cancer.

Final trial enrollment totalled 415 patients, including 71 patients who are enrolled in a trial sub-study. Although the trial was originally planned for 390 patients, enthusiasm for the clinical trial shown by both investigators and patients resulted in an additional 25 patients being recruited in four weeks. Patients were recruited across 76 sites in Australia, Eastern, and Western Europe.

The optional pharmacokinetic and cardiotoxicity sub-study conducted along with this pivotal trial is intended to provide further confirmation of HA-Irinotecan's safety profile. The additional 25 patients enrolled served to boost the size of this sub-study, increasing patient numbers to around 90 percent of the sample size targeted by Alchemia. Supplementary patient enrollment also increases the statistical power of the whole trial, and improves the predictability of when the primary endpoint of progression free survival is likely to be met.

"The rapid recruitment of these additional 25 patients will allow Alchemia to determine the success of this pivotal trial in the first half of 2014," said Dr Tracey Brown, chief scientific officer of Alchemia. "We have been encouraged by the initial statistical review and modelling of the available blinded data, as it suggests that patients as a group are continuing on treatment for longer than anticipated before their disease progresses. Additionally, we anticipate these further recruitments will provide enhanced validation of the safety and efficacy of the HyACT platform technology."

HA-Irinotecan is a new formulation of irinotecan which targets the drug to the tumour. It enables the drug to be retained at the tumour site for longer, allowing substantially more drug to be internalised by the cancer cells. This occurs through a well established receptor-based mechanism. Increased uptake of the anti-cancer drug into tumour cells has resulted in a superior efficacy profile, as shown in a phase II trial of HA-Irinotecan in metastatic colorectal cancer, where a statistically significant increase in Progression Free Survival (PFS) compared with irinotecan (5.2 months vs 2.4 months, p=0.017) with no increase in toxicity was observed.