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ASIA EDITION

Alchemia recruits patients for rectal cancer trial

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Singapore: Brisbane-based R&D company Alchemia has recruited the 390th patient for the pivotal phase III clinical trial of its lead cancer drug, HA-Irinotecan, as per its study protocol. As of January 31, 2013, 390 patients had been recruited at 76 sites in Australia, Eastern and Western Europe, since the study began in January 2012. Key vendors assisting the Alchemia team with the trial, include CNF Pharma, US; Practical Clinical, Canada; and PSI CRO, Switzerland. Australian trial sites are managed by Novotech.

The final stage study compares the safety and efficacy of Alchemia's proprietary HyACT technology in combination with standard chemotherapy drug irinotecan (HA-Irinotecan) against irinotecan alone in metastatic colorectal cancer (mCRC) patients.

The double blind trial is being conducted in second and third line mCRC patients when administered as part of the Folfiri regimen. The study's primary objective is to demonstrate that HA-Irinotecan is superior, as indicated by an increase in progression-free survival (PFS) of six weeks or more.

Alchemia's CSO, Ms Tracey Brown, said that, "Successful completion of patient recruitment to Alchemia's pivotal phase III clinical trial in just over 12 months is a credit to Alchemia's clinical team, which has worked tirelessly to execute this trial within the tight timeline and budget. I would like to specially thank PSI CRO who are our lead contract research organisation and Practical Clinical, our Canadian-based clinical consultants, and our site staff and patients, whose combined efforts resulted in the rapid recruitment of this study."

The phase III protocol includes an 80-patient substudy being performed at selected study sites, to investigate the pharmacokinetic and cardiotoxicity of HA-Irinotecan. This substudy is optional and currently has 53 patients enrolled. To improve recruitment to this substudy, as well as to increase the power of the overall study, the company has determined that it will hold recruitment open to a further 20 patients, bringing the total number of patients on the trial to 410. The addition of these patients does not affect the timing of the clinical trial endpoint where the PFS will still be reported in the first half of 2014.