



4th February 2013

Alchemia Recruits Full Patient Quota to Pivotal Phase III HA-Irinotecan Trial in Metastatic Colorectal Cancer

Follows successful Phase II HA-Irinotecan study showing progression free survival times more than doubled

Highlights:

- **390th patient recruited by 31st January 2013, on time and on budget;**
- **Patients on the trial receiving treatment for longer than expected - encouraging early sign;**
- **Revised modelling using trial data suggests trial likely to report early in 2014; and**
- **Some centres being held open to recruit additional 20 patients to improve statistical power and further bolster FDA requested substudy.**

Brisbane, Australia 4th Feb 2013: Brisbane-based drug discovery and development company Alchemia Limited (ASX: ACL) has recruited the 390th patient to its pivotal Phase III clinical trial of the Company's lead cancer drug, HA-Irinotecan, as per its study protocol.

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 patients. The double blind trial is being conducted in second and third line patients (mCRC) when administered as part of the FOLFIRI regimen.

As of 31st January 2013 European time, 390 patients had been recruited at 76 sites in Australia, Eastern and Western Europe, since the study began in January 2012.

The primary endpoint will be reached when 350 patients have experienced disease progression. The Company's initial expectations, based on historic data, anticipated 350 patients would have experienced disease progression in the second half of 2013. However, statistical review and modelling on the available blinded data suggests that on average, patients on this trial are continuing treatment for longer than anticipated, before their disease progresses. While the Company is encouraged by this observation, this means that the primary the endpoint is now likely to be met early in 2014.

The study's primary objective is to demonstrate that HA-Irinotecan is superior, as indicated by an increase in Progression-Free Survival (PFS) of 6 weeks or more.

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Alchemia's CSO, Tracey Brown, said: "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 AG who are our lead contract research organisation and Practical Clinical Inc., our Canadian-based clinical consultants, investigators, site staff and patients whose combined efforts resulted in the rapid recruitment of this study."

Royal Melbourne Hospital medical oncologist and principal trial investigator Associate Professor Peter Gibbs said: "The recruitment to this clinical trial is a significant achievement. I am eagerly anticipating the first reviews of the unblinded trial data because if this trial achieves the primary endpoint of significantly increasing Progression Free Survival (PFS), then HA-Irinotecan could provide a major therapeutic benefit to many colorectal cancer patients".

Associate Professor Gibbs also leads a colorectal cancer research program at the Walter and Eliza Hall Institute.

Alchemia Executive Chairman, Dr Mel Bridges said "The recruitment update to the Phase III trial was an important milestone for the company – completed on time and within budget. We are quite confident about funding this trial through to reporting the results next year. The success of this trial will further validate the value shareholders can expect from the HA oncology assets", he added.

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.

Key vendors assisting the Alchemia team with the trial include CNF Pharma (USA), Practical Clinical Inc. (Canada) and lead Clinical Research Organisation, PSI CRO AG (Switzerland). Australian trial sites are managed by Novotech (Australia) Pty Ltd.

About Alchemia: Alchemia is a drug discovery and development Company founded on its chemistry expertise. The Company's lead drug, fondaparinux (a generic version of GlaxoSmithKline's Arixtra®, a synthetic anticoagulant mainly used for the prevention of deep vein thrombosis), was approved by the FDA and launched in July 2011 in the USA by Alchemia's marketing partner Dr Reddy's Laboratories. Alchemia's pipeline of assets is built on two platform technologies: HyACT® (targeted cancer delivery) and VAST® (drug discovery). The primary objective of the HyACT® technology is to enhance existing drugs used for cancer chemotherapy to develop a new generation of anti-cancer drugs which demonstrates better efficacy than existing drugs. The lead product candidate from the HyACT® platform is HA-Irinotecan for which a Phase III clinical trial has been initiated in metastatic colorectal cancer. Patient randomisation commenced in 2012.

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