Alchemia Announces Phase III Trial Results for HA-Irinotecan in Metastatic Colorectal Cancer

Summary:

- *Phase III trial does not reach primary endpoint of statistically significant improvement in progression-free survival*
- *Alchemia to undertake further analysis of the data and review the next steps for the HA-Irinotecan program*
- *Investor conference call scheduled for 11.00am AEDST, Monday, October 27, 2014*

Brisbane, Australia – October 27, 2014: Drug discovery and development company Alchemia Limited (ASX:ACL), today announced that its pivotal Phase III trial of HA-Irinotecan in the treatment of patients with metastatic colorectal cancer (mCRC) did not meet its primary endpoint of statistically significant improvement in progression-free survival (PFS).

The Phase III trial enrolled 415 patients across 76 clinical centers worldwide. It was a randomised, double-blinded, active controlled study of Alchemia's proprietary HyACT technology formulated with the well-known chemotherapeutic drug, irinotecan. HA-Irinotecan or irinotecan were administered as part of the conventional FOLFIRI chemotherapy regimen (combination of folinic acid, fluorouracil and irinotecan) in patients with mCRC who were candidates for second- or third-line chemotherapy. The primary objective of this trial was to demonstrate superiority in progression-free survival (PFS) of Alchemia's HA-Irinotecan over irinotecan.

The trial demonstrated a median PFS of 5.5 months for patients treated with HA-Irinotecan as part of the FOLFIRI chemotherapy regimen. Patients treated with the FOLFIRI regimen containing standard irinotecan also achieved a median PFS of 5.5 months. A planned interim analysis of overall survival was performed and the FOLFIRI and HA-Irinotecan arms demonstrated an equivalent overall survival of approximately 14 months. The safety profile was equivalent between both arms of the study.

"We are extremely disappointed in the outcome of this trial and extend our appreciation to trial investigators, the clinical sites and the hundreds of patients who participated in this study," said Thomas Liquard, Alchemia's Chief Executive Officer. "We will undertake further analysis of this trial. We expect to report back to the scientific community and the market with further details on our data reviews and corporate strategy early in 2015."

Alchemia's Chief Scientific Officer Dr Tracey Brown added: "We will be conducting an in-depth review of the data to identify the possible reasons for an unexpectedly high median PFS outcome in the irinotecan control group. We will also investigate the impact of other variables, including potential regional and country-specific differences, in outcomes of our Phase III study. With these additional analyses in hand, we will be in a better position to formulate the next steps for the HA-Irinotecan development programs."

Alchemia's oncology pipeline includes ongoing investigator-sponsored Phase II trials with HA-Irinotecan in mCRC and in small cell lung cancer (SCLC), an orphan disease with high unmet need. The SCLC trial is being conducted to obtain safety and efficacy data for HA-Irinotecan in advanced SCLC and to demonstrate that HA-Irinotecan can safely be combined with the chemotherapeutic drug, carboplatin. In addition, the CHIME study, a collaboration with Merck Serono, is investigating the clinical safety and efficacy of HA-Irinotecan as a component of the FOLFIRI regimen when used in conjunction with the biological therapy Erbitux (cetuximab) in patients with mCRC.

The Company has two Focal Adhesion Kinase (FAK) inhibitor pre-clinical candidates in its pipeline. FAK is a non-receptor tyrosine kinase which plays an important role in the development and spread of numerous malignancies and has therefore emerged as a promising target in cancer therapy. Alchemia is also evaluating additional small molecule drug discovery targets via the VAST internal discovery platform, which is based on the Company's deep chemistry expertise. The VAST technology is being developed in collaboration with leading academic institutions and is partnered with AstraZeneca AB.

Alchemia will be assessing all of its ongoing programs as part of an overall review of its corporate strategy to deliver the best outcomes for shareholders.

Alchemia's financial position includes $8.9 million in cash, and a$6.5 million R&D Tax Incentive refund expected to be received by November 2014. Fondaparinux, the Company's U.S. Food and Drug Administration (FDA)-approved anti-coagulant drug, is expected to continue to provide an important revenue stream generated by the profit share agreement with its partner, Dr Reddy's Laboratories. Fondaparinux is approved in the U.S., Canada and India and is under review for approval in other key markets.

Investor Conference Call Monday October 27, 2014 at 11:00am (AEDST)

Alchemia Limited will host a conference call on Monday, October 27, 2014 at 11:00am (AEDST), 5:00pm PDT / 8.00pm EDT (U.S.) to discuss the results of the Phase III trial. The dial-in details are provided below:

Call Participant ID	**27049418** (required to access the call)
Dial in numbers	
Australia	1800 123296 / 02 80385221
Canada	1855 5616766
Hong Kong	800 908865
India	0008 001005876
New Zealand	0800 452782
Singapore	800 6162288
United Kingdom	0808 2340757
United States	1855 2931544

An archive of the call will be available on the Company's website: www.alchemia.com.au.

About Alchemia Limited

Alchemia is a drug discovery and development company marketing fondaparinux, an FDA approved injectable antithrombotic, in the US as well as in other markets via partner Dr. Reddy's Laboratories. The Company has an oncology pipeline with several ongoing preclinical and development programs through its proprietary HyACT drug delivery platform, which targets anti-cancer drugs to solid tumours. HA-Irinotecan is in two Phase II investigator-sponsored trials, one of which is in collaboration with Merck Serono combining HA-Irinotecan with Erbitux® (cetuximab). In March 2014, Alchemia also announced the in-licensing of two new pre-clinical oncology compounds targeting the FAK pathway.

Erbitux® is a trademark of Merck KGaA.

Contacts

www.alchemia.com.au

Alchemia Limited
Thomas Liquard
Chief Executive Officer
Alchemia Limited
Tel: +61 7 3340 0200
investorrelations@alchemia.com.au

Investor Relations (Australia)
Rebecca Wilson
Buchan Consulting
Tel: +61 417 382 391
rwilson@buchanwe.com.au

Investor Relations (USA)
Candice Knoll
Blueprint Life Science Group
Tel: +1 415 375 3340 Ext. 105
cknoll@bplifescience.com

Media Enquiries
Gabriella Hold
Buchan Consulting
Tel: +61 411 364 382
ghold@buchanwe.com.au