

## Alchemia provides update on its core projects

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**Singapore:** Australia-based Alchemia has provided commercial update on four of its key projects, including its marketed drug fondaparinux; a new collaboration with Merck Serono; and its current HA-Irinotecan phase III clinical trial.

### **Fondaparinux profit share**

Alchemia's international marketing partner Dr. Reddy's Laboratories (DRL) reported net sales for the quarter ending March 31, 2013, to be \$8.8 million, resulting in a profit share of \$2.35 million that was given to Alchemia. Alchemia will also receive \$1.85 million following its contribution of \$0.5 million to the agreed activities to improve yields and cost of goods. The reduced level of profit for the quarter is primarily a result of seasonal buying patterns which have meant that volumes in the first two months of the quarter (January and February 2013) have been significantly lower than prior months. The sales volumes for March showed a return to high levels albeit at slightly weaker prices than the previous quarter.

### **Alchemia and Merck Serono collaboration**

Alchemia and Merck Serono have agreed to collaborate by supporting the initiation of a new clinical trial of HA-Irinotecan, which will be conducted by principal investigator associate professor Peter Gibbs. The collaboration between Alchemia and Merck Serono begins with an investigator-led phase II clinical trial of Alchemia's HA-Irinotecan in combination with Merck Serono's leading therapeutic antibody, Erbitux (cetuximab), for patients with metastatic colorectal cancer (mCRC). Initial patient enrolment is expected by Q3 2013. Approximately 45 patients, who are candidates for second-line treatment of mCRC, are to be enrolled at six to ten sites around Australia with the trial scheduled to run for approximately 24 months.

If Alchemia's current HA-Irinotecan phase III clinical trial (NCT01290783) is successful, and the drug obtains health authority approval for use in irinotecan-containing chemotherapy regimens, there is the possibility that HA-Irinotecan will progressively replace the current form of irinotecan used by oncologists. According to current treatment guidelines around 50-to-60 percent of mCRC patients should be considered for treatment with chemotherapeutic drugs, such as Irinotecan, in combination with the therapeutic antibody, Erbitux. The phase II study led by Dr Gibbs is intended to generate data supporting the clinical use of HA-Irinotecan with Erbitux in the treatment of mCRC. Specifically, this study will primarily evaluate the safety of Alchemia's lead HyACT drug, HA-Irinotecan, as part of the Folfiri treatment regimen, in combination with Merck Serono's Erbitux.

### **Third review of data safety and monitoring board (DSMB) for HA-Irinotecan pivotal phase III trial**

The Data Safety Monitoring Board (DSMB), which comprises an independent group of experts who review, evaluate and make recommendations on accumulated study data with a focus on participant safety, study conduct and progress in a trial, has met for the third time and provided feedback on the pivotal HA-Irinotecan phase III trial currently underway. The DSMB

considers study-specific data as well as relevant background knowledge about the disease, test agent and the patient population under study. When reviewing a clinical trial, a DSMB has the power to recommend continuation, modification or termination of the clinical trial.