



4 August 2011

Alchemia's drug launched in US market

- *Sales imminent*
- *European launch expected in 2012*

Alchemia, Brisbane, Australia (ASX: ACL) is delighted to announce the launch of generic fondaparinux sodium for injection, in the United States by its marketing partner Dr Reddy's Laboratories. (Dr Reddy's). The launch follows the approval by the US Food and Drug Administration of the Abbreviated New Drug Application (ANDA) received on 11 July 2011. The launch covers 2.5mg/0.5 ml, 5.0mg/0.4 ml, 7.5mg/0.6 ml and 10.0mg-/0.8 ml doses of the drug in prefilled colour coded, single-dose syringes with an automatic needle safety device.

US sales of the branded version of the drug, Arixtra, marketed by GlaxoSmithKline, were \$340M (+16%) in the 12 months to May 2011 (source: IMS National Sales Perspectives: Retail and Non-Retail MAT MAY 2011).

"The approval and launch of fondaparinux is a major achievement for Alchemia and its partner Dr Reddy's," said Dr Pete Smith, CEO of Alchemia. "Alchemia is fortunate in now having a launched product as well as an advanced pipeline of potential cancer therapeutics. We strongly believe this pipeline will be the source of significant shareholder value in the future," Dr Smith added.

Fondaparinux is extremely difficult to manufacture at scale. Alchemia's improved process for the manufacture of fondaparinux, licensed to Dr Reddy's, is covered by two issued, and two pending patents in the US.

Dr Reddy's is a major global generics company with revenues in FY2011 of \$1.7Bn. Dr Reddy's has a substantial and rapidly growing generics business in the US and will be responsible for the marketing of generic fondaparinux. Given the significant scale of barriers to entry for other competitors, it is likely that Alchemia's generic fondaparinux will face limited competition in the foreseeable future.

Filing for approval in the EU will take place after the expiry of a ten year period of data exclusivity in 2012. Filing cannot take place until that time as a chemically identical product needs to reference the original preclinical and clinical data of the branded product in order to gain approval as a generic.

About Alchemia Limited – www.alchemia.com.au

Alchemia is a drug discovery and development company founded on its chemistry expertise. The Company's lead program is fondaparinux (a generic version of GlaxoSmithKline's Arixtra®). The ANDA for generic fondaparinux was filed for approval with the US FDA in March 2009 and

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approval was received in July 2011. It is partnered with Dr Reddy's Laboratories, Inc for the US market.

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 develop a new generation of anti-cancer drugs which have improved clinical benefits for patients. The lead product from the HyACT® platform is HA-Irinotecan for which a Phase III clinical trial in metastatic colorectal cancer will commence recruitment shortly.. In addition to HA-Irinotecan, Alchemia has successfully taken two other anti-cancer products HA-Doxorubicin (doxorubicin and hyaluronic acid) and HA-Fluorouracil (5-fluorouracil and hyaluronic acid) into successful Phase I clinical testing and development continues on five other HyACT® drugs.

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