



ASX / Media Release

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Alchemia Announces Filing of Abbreviated New Drug Application with U.S. FDA for Fondaparinux Approval

Brisbane, Australia, 13 March 2009: Australian drug developer, Alchemia Limited (ASX:ACL), today announced that its global manufacturing and U.S. marketing partner Dr Reddy's Laboratories (NYSE:RDY) has submitted an Abbreviated New Drug Application (ANDA) with the United States Food and Drug Administration (FDA) for Fondaparinux Sodium for Injection in 2.5mg, 5.0mg, 7.5mg and 10.0mg doses. The application has been filed with a Paragraph II certification indicating that there is no remaining patent listed for the drug.

Fondaparinux is marketed by GlaxoSmithKline under the brand name Arixtra[®]. It is an anticoagulant currently approved for a number of indications including the treatment and prevention of deep vein thrombosis (blood clots) in a number of medical settings such as post-operative knee and hip surgery. In 2008, global sales of Arixtra were \$315 million USD (+58%) and sales in the U.S. market were \$163 million USD (+50%).

"The filing of the ANDA is a major achievement for Alchemia. Of all the drugs used in modern medicine, fondaparinux is one of the most challenging molecules to synthesize, and we are proud to have accomplished this feat with Dr Reddy's, our partner for its manufacturing and commercialization," said Pete Smith, PhD, Chief Executive Officer of Alchemia. "Whilst the key patents on Arixtra expired in 2002, no company has filed for the approval of its generic until now, and we are not aware of any other generic manufacturers currently capable of making this molecule at commercial scale. Because we do not foresee the entry of other competitors in the near term, we expect pricing, market share and profitability to remain higher compared to a typical generic product."

The manufacturing process for fondaparinux used by Dr Reddy's utilizes a novel, synthetic pathway developed by Alchemia. In the U.S., one patent has been issued and another is pending that cover key steps in this pathway.

Under the terms of the 2007 Licence Agreement between Alchemia and Dr Reddy's, profits from U.S. sales of generic fondaparinux will be divided in an agreed proportion between the partners. Dr Reddy's also has a right of first refusal to market generic fondaparinux in Europe once data exclusivity expires in 2012.

Under the FDA's Generic Initiative for Value and Efficiency (the GIVE initiative), the agency has a stated objective of reviewing first generics within six months of filing. Alchemia believes that fondaparinux will be eligible for this priority review. Because fondaparinux is a fully synthetic molecule, Alchemia does not believe it will face the regulatory issues of other anticoagulant drugs, such as the low molecular weight heparins, which are complex mixtures derived from animal material.

About Abbreviated New Drug Applications (ANDA)

According to the FDA's Center for Drug Evaluation and Research (CDER), an ANDA contains data that provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product as an alternative to the branded drug. A generic drug product is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. Generic drug applications are

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termed "abbreviated" because they are generally not required to include preclinical and clinical data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is equivalent to the branded drug.

For those drugs that do not receive priority review, the average review time for ANDA submission is 15-18 months based on FDA data from 2007, although this average includes several different types of filings. The quality of the ANDA filing also influences review time with the FDA.

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 (synthetic heparin, a generic version of GlaxoSmithKline's Arixtra®) which is expected to generate near term revenues for the company and is partnered with Dr Reddy's Laboratories Inc. for the U.S. market. Alchemia's pipeline of assets is built on two platform technologies: HyACT® (targeted cancer delivery) and VAST™ (drug discovery). HA-irinotecan, for the treatment of colorectal cancer, recently achieved positive Phase II clinical trial results.

Arixtra® is a registered trademark of GlaxoSmithKline.

VAST™ and HyACT® are trademarks of Alchemia and Alchemia Oncology.

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