Hatchtech

Media Release **4 September, 2012**

SUCCESSFUL FDA END-OF-PHASE 2 FOR HATCHTECH HEAD LICE PRODUCT DeOVO™

- **Formal end-of-phase 2 data review well received by US FDA**
- **FDA affirms proposed pivotal phase 3 program for DeOvo, Hatchtech's novel head lice treatment**
- **Company on schedule for 2014 NDA filing**

MELBOURNE, AUSTRALIA: Specialty pharmaceutical company Hatchtech Pty Ltd announced today that it had successfully completed end-of-phase 2 (EOP2) consultations with the US Food & Drug Administration (FDA) for its lead product DeOvo™, a single application topical treatment for head lice.

This follows the recent successful completion of the phase 2b clinical trial demonstrating superior efficacy in 142 subjects with head lice infestation, 2 years of age and older at study centres in the United States.

The FDA reviewed Hatchtech's current data package, phase 3 protocols and the readiness for phase 3 in all disciplines and provided assessments of the company's detailed plans for the phase 3 development program. An EOP2 interaction with the FDA is a key part of seeking US marketing approval for prescription drug products.

Dr Lewis Schulz, Hatchtech's chief operating officer said, "We appreciated the clear guidance from the FDA including the valuable, constructive feedback on several details of our pivotal study protocols. This reaffirms our proposed phase 3 program. Significantly there were no surprises and we were very encouraged by the responses to our questions. The Company remains on track to initiate the phase 3 program later this year."

Hatchtech CEO Dr Ross Macdonald, commented: "This milestone is another important achievement for Hatchtech. With the FDA we have established a clear path to product registration and the market for DeOvo, our next-generation head lice treatment product that will provide compelling advantages over currently available treatments."

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About Hatchtech

Hatchtech Pty Ltd is a venture-backed specialty pharmaceutical product company that is developing technology for the control of invertebrate pests. The Company's investors include, GBS Venture Partners, Queensland Biotechnology Fund, Uniseed, University of Melbourne Endowment Trust, AustralianSuper, and OneVentures Innovation Fund. The OneVentures Innovation Fund is supported by the Australian Government through the IIF program.

The company's lead product is DeOvo™, a class-leading head lice control agent that aims to overcome the frustrating, costly and inconvenient cycles of re-treatment experienced currently by children and their parents.

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About DeOvo™

Despite its prevalence and high cost to the community, there have been few major advances in controlling head lice infestation in recent years. Most pediculicide products have little ovicidal activity and require two treatments (approximately 7 days apart), with the second application designed to treat those lice which have hatched from eggs that survived the first treatment. Non-compliance with this regimen and the difficulty in choosing the optimal time for the second application, are major difficulties in using these products. Hatchtech's DeOvo™, a topical formulation of an inhibitor of metalloproteases, has shown both ovicidal and lousicidal activity and offers the potential for a more effective treatment following a single application.

About Pediculosis

It is estimated that 6-12 million people in the United States, mainly children aged 3-12, are infested each year with head lice (*Pediculus humanus capitis*). The direct cost of treatment is estimated at several hundreds of millions of dollars. Added to this direct economic burden are the indirect costs including missed days from school, lost work productivity by parents who stay home to treat their children and costs borne by the school itself in trying to control or prevent this problem. The total costs have been estimated to be 1billion USD in the US alone.