



**Media Release**

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**HATCHTECH COMMENCES 2b CLINICAL TRIAL OF NEW-  
GENERATION HEAD LICE TREATMENT DeOvo™**

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**MELBOURNE, VICTORIA. (2 May, 2011)** – Venture-backed pharmaceutical company Hatchtech Pty Ltd has enrolled the first subjects for its Phase 2b clinical study to confirm the efficacy of its novel head lice treatment DeOvo™.

This Phase 2b trial will evaluate the efficacy, safety and tolerability of two dose levels of a single application of DeOvo compared to vehicle. It will be conducted in approximately 132 healthy subjects with head lice infestation, 2 years of age and older in two study centers in the United States.

Hatchtech's proprietary agent DeOvo™ is a topical formulation of a known metalloprotease inhibitor which targets certain proteases that are key to biological processes involved in insect hatch and survival.

Hatchtech Chairman Dr Paul Kelly commented: "This is a big milestone for Hatchtech. DeOvo™ is a next generation head lice treatment therapy that targets all life cycle stages of the parasite with a single 10 minute application."

"We have previously demonstrated that this agent effectively treats eggs and crawling lice in a small number of infested adults. Now we are assessing the compound in a larger clinical trial including adult and pediatric subjects."

In the US it is estimated that 6-12 million people, mainly children aged 3-12 years, are infested each year with head lice (*Pediculus humanus capitis*). With the emergence of drug resistant lice and often poor efficacy of existing products, this under-served market represents a substantial commercial opportunity.

The trial is expected to be completed by the end of 2011.

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### About the Trial

The following information is provided in accord with the AusBiotech Code of Best Practice for Report by Life Sciences Companies.

<b>Name of Trial</b>	<b>Ha02-003</b>
<b>Blinding Status</b>	<b>Double-blind</b>
<b>Placebo Controlled</b>	<b>Randomized, vehicle-controlled</b>
<b>Design</b>	<b>Parallel treatment group</b>
<b>Route</b>	<b>Topical</b>
<b>Frequency</b>	<b>Single application</b>
<b>Dose Levels</b>	<b>0.37% w/v or 0.74% w/v</b>
<b>Number of Subjects</b>	<b>132</b>
<b>Subject Selection Criteria</b>	<ul style="list-style-type: none"><li>• 2 years of age or older</li><li>• Be in good health</li><li>• Has an active head lice infestation as determined by an experienced evaluator</li></ul>
<b>Primary End Points</b>	<ul style="list-style-type: none"><li>• Proportion of all subjects who are lice free at all follow-up visits through the Day 14 visit</li></ul>
<b>Secondary End Points</b>	<ul style="list-style-type: none"><li>• Safety and tolerability of Ha44 Gel</li><li>• Proportion of index subjects who are lice free at all follow-up visits through the Day 14 visit</li><li>• Proportion of all subjects who are lice free at each follow-up study visit (Day 1, 7, 14)</li><li>• To evaluate the pharmacokinetics of Ha44 Gel in a subset of children 2-12 years of age and adults <math>\geq 18</math> years of age</li></ul>
<b>Trial Location</b>	<b>2 sites in USA</b>
<b>Expected Duration of the Trial</b>	<b>The trial is expected to be completed in 9 months</b>
<b>Commercial Partners</b>	<b>None</b>
<b>Sponsor</b>	<b>Hatchtech Pty Ltd</b>



## **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 Biocomm, GBS Venture Partners, Queensland Biotechnology Fund, Uniseed, University of Melbourne Endowment Trust, Westscheme and OneVentures Innovation Fund. The OneVentures Innovation Fund is supported by the Australian Government through the IIF program. The IIF is an Australian Government venture capital initiative that has supported Hatchtech

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 survive 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 a known metalloprotease inhibitor, 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 1 billion USD in the US alone.