

## Media Release

31 August 2011

# HATCHTECH COMPLETES TREATMENT PHASE OF 2b CLINICAL TRIAL OF NEW-GENERATION HEAD LICE TREATMENT DeOvo™

**MELBOURNE**, **VICTORIA**: Pharmaceutical company Hatchtech Pty Ltd has completed treatment of subjects for its Phase 2b clinical study to confirm the efficacy of its novel head lice treatment DeOvo<sup>™</sup>.

This Phase 2b trial is evaluating the efficacy, safety and tolerability of two dose levels of a single application of DeOvo<sup>™</sup> compared to vehicle. The trial consists of treating 132 healthy subjects with head lice infestation, 2 years of age and older, in two study centers in the United States.

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

Hatchtech Chairman Dr Paul Kelly commented: "We continue to be encouraged by Hatchtech's progress with its next generation head lice product DeOvo™ in line with our business objectives. The recruitment and treatment of subjects in this study has been achieved and we look forward to receiving results of the study later this year as planned."

"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."

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## **About the Trial**

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

| Name of Trial                         | Ha02-003  |
|---------------------------------------|---|
| Blinding Status                       | Double-blind  |
| Placebo Controlled                    | Randomized, vehicle-controlled                        |
| Design                                | Parallel treatment group                              |
| Route                                 | Topical   |
| Frequency                             | Single application                                    |
| Dose Levels                           | 0.37% w/v or 0.74% w/v                                |
| Number of Subjects                    | 132   |
| Subject Selection Criteria            | 2 years of age or older                               |
|                                       | Good health   |
|                                       | Has an active head lice infestation as determined by  |
|                                       | an experienced evaluator                              |
|                                       | ·   |
| Primary End Points                    | Proportion of all subjects who are lice free at all   |
|                                       | follow-up visits through the Day 14 visit             |
|                                       |   |
| Secondary End Points                  | Safety and tolerability of Ha44 Gel                   |
|                                       | Proportion of index subjects who are lice free at all |
|                                       | follow-up visits through the Day 14 visit             |
|                                       | Tonon up vione un ough the Duy 1.1 vion               |
|                                       | Proportion of all subjects who are lice free at each  |
|                                       | follow-up study visit (Day 1, 7, 14)                  |
|                                       | ionon up clauf tion (2 uf 1, 1 , 1 )                  |
|                                       | To evaluate the pharmacokinetics of Ha44 Gel in a     |
|                                       | subset of children 2-12 years of age and adults ≥ 18  |
|                                       | years of age  |
|                                       | , 54 51 kg  |
| Trial Location                        | 2 sites in USA  |
| <b>Expected Duration of the Trial</b> | The trial is expected to in completed in 9 months     |
| Commercial Partners                   | None  |
| Sponsor                               | Hatchtech Pty Ltd                                     |



#### **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, 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<sup>TM</sup>, 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 1billion USD in the US alone.