

Hatchtech headlice treatment to go to Phase II trial after US FDA green light

FDA accepts Hatchtech's Investigational New Drug application for product to stop lice eggs hatching

21 January 2008, Melbourne: The US Food and Drug Administration (FDA) has accepted Hatchtech's Investigational New Drug (IND) application allowing immediate commencement of Phase II clinical trials of the new ovicidal head lice treatment DeOvo™. These are multi-centre US and Australian trials and come after Hatchtech successfully completed DeOvo™ Phase I studies in Australia in 2007.

DeOvo™ is the lead product of Hatchtech Pty Limited, an Australian company developing novel technology for the control of a variety of insect, arachnid and nematode pests.

DeOvo™ is designed to give healthcare professionals and parents the ability to achieve definitive treatment of head lice infestations as a single treatment. It will potentially overcome the inability to kill affect nits that affects current products and those in development. This inability is a major cause of treatment failure for the current products. DeOvo™ should enable a cure at a single time and treatment point making the current multiple treatments at weekly intervals unnecessary. The product has already been shown to be safe in adult volunteers.

"This IND acceptance and the entry of our first paediatric subjects into clinical trials will bring us closer to a significant improvement in the treatment of head lice." said Dr Paul MacLeman, Hatchtech's chief executive officer.

"Current approaches to treatment on the market continue to become less effective because of lice resistance. Many also contain substances known to be hazardous to the patients. In addition to a high level of safety demonstrated to date, DeOvo™ utilises a novel mechanism of action that stops the louse eggs hatching."

"We remain confident that DeOvo™ will be proven safe and effective and will greatly alleviate the frustration, embarrassment and adverse effects on schooling and families associated with head lice infestations."

Approximately 12 million children are affected by head lice each year in the United States alone. In many cases, affected children are dismissed from school and not allowed to return until they are declared "lice free", impacting schooling, carers and children.

The global annual market for head lice control products is estimated to be in excess of US\$450 million.

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About Hatchtech

Hatchtech is an Australian company developing a proprietary technology platform that has enabled the creation of a new generation of low-toxicity pest control products. Specifically, the patented technology allows the complete blocking of pest species egg hatch and life cycle changes through a novel mode of action. The technology has applicability for controlling parasites and pests of humans, animals, crops and the built environment.

Hatchtech's most advanced programme is focussed on developing a new generation of low-toxicity ovicides for controlling human head lice – an area of high unmet need due to toxicity and resistance issues with current products. Hatchtech's second program is developing novel products for animal health and applications. These products are now entering development. In addition, the company has broad proof-of-principle and is developing compounds for the control of important pests in the crop protection and household/industrial sectors.

Hatchtech's current investors include Uniseed, Biocomm, GBS Venture Partners, Queensland Biocapital Fund and Westscheme and is additionally supported by Commercial Ready Grants and the Victorian State Government Vicstart Program.