



Media release

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## **FDA Approves Xeglyze™ for the topical treatment of head lice infestation**

### ***Xeglyze New Drug Application Approved by the US FDA***

Hatchtech, an Australian pharmaceutical company developing an innovative prescription head lice product, today announced that its commercialisation partner, Dr Reddy's Laboratories, has achieved US Food and Drug Administration approval of Xeglyze (abametapir) Lotion 0.74% for the topical treatment of head lice infestation in patients 6 months of age and older. Xeglyze was developed by Hatchtech who completed a full development program through to the submission of a new drug application by the company in September 2015. At the same time, Hatchtech sold the rights to Xeglyze to Dr Reddy's Laboratories for selected territories, including the US.

"The FDA approval of Xeglyze is the culmination of the journey to gain approval of the product originally developed by Hatchtech. This is a fantastic outcome for Dr Reddy's, Hatchtech and our shareholders. We are excited to finally see this product gain approval and we look forward to product launch in the United States, enabling availability of this novel product for the treatment of head lice infestation" stated Hatchtech's CEO, Hugh Alsop.

Whilst Xeglyze was filed by Hatchtech with the US FDA in September 2015 and subsequently transferred to Dr. Reddy's, a complete response letter for the application was received in August 2016, citing manufacturing deficiencies at the Dr Reddy's drug substance manufacturing plant in India, which had received a Warning Letter in November 2015. These deficiencies have only now been resolved, paving the way for approval of the product.

Hatchtech Chairman, and OneVentures Managing Partner, Dr Paul Kelly, said today of the approval: "We are excited that Dr Reddy's have secured approval for Xeglyze. Whilst this program has experienced a significant delay, we have never wavered in our support for the product or the team that has achieved this outcome. This is a real credit to those that have been involved in this journey over the many years, and is a testament to resilience, teamwork, and an unwavering focus on the issues that really matter."

University-backed venture capital firm Uniseed provided the initial seed funding for Hatchtech, which was founded in 2001 by Dr Vern Bowles whilst Deputy Director of the Centre for Animal Biotechnology at The University of Melbourne. "Hatchtech was one of Uniseed's first investments and is the first of our human therapeutics companies to get product approval, validating our model of facilitating early stage commercialisation of research partner IP", said Uniseed CEO, Dr Peter Devine. The approval of Xeglyze is the culmination of over a decade of Dr Bowles' work on human head lice, and the University of Melbourne continues to be a significant shareholder in the company.

Milestone payments associated with product approval signifies a welcome return for Hatchtech's venture capital investors, including OneVentures, QIC, GBS Venture Partners, Uniseed and the University of Melbourne, along with a number of sophisticated investors. A total \$33 million has been invested since the formation of the company, with OneVentures being Hatchtech's largest shareholder holding over 30% of the Company.

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## About Hatchtech

Hatchtech Pty. Ltd. is an Australian specialty pharmaceutical company developing technology for the control of invertebrate pests. The Company's lead product is Xeglyze™, a novel, next generation prescription head lice product in development that aims to overcome the frustrating, costly and inconvenient cycles of retreatment for head lice infestation currently experienced by children and their parents. The Company's investors include OneVentures, University of Melbourne Endowment Trust, Queensland Biotechnology Fund (QIC), GBS Venture Partners, and Uniseed. Hatchtech is an investment of OneVentures Innovation Fund I which is supported by the Australian Government's Innovation Investment Fund (IIF) program. The IIF is an Australian Government venture capital initiative that provides investment capital and managerial expertise through licensed venture capital fund managers to investee companies.

## About Xeglyze

Despite its prevalence and high cost to the community, there have been few major advances in controlling head lice infestation in recent years. Most head lice products have little ovicidal activity and require two treatments (approximately 7 to 10 days apart), with the second application required to treat those lice that have hatched from eggs that survived the first treatment and were not physically removed by nit combing. Non-compliance with this regimen and the difficulty in choosing the optimal time for the second application, are major drawbacks in using these products. Xeglyze, a topical formulation containing abametapir, an inhibitor of metalloproteases, has demonstrated both ovicidal<sup>1</sup> and lousicidal activity and offers the potential for a more effective treatment using only a single, 10-minute application<sup>2</sup>.

## About Dr. Reddy's

Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Major markets include – USA, India, Russia & CIS countries, and Europe. [www.drreddys.com](http://www.drreddys.com)

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<sup>1</sup> Bowles VM, HanegraafS, Ahveninen T, et al. *Effect of a New Head Lice Treatment, Abametapir Lotion, 0.74%, on Louse Eggs: A Randomized, Double-Blind Study*. Global Pediatric Health. 2019; Volume 6; <https://doi.org/10.1177/2333794X19831295>

<sup>2</sup> Bowles VM, VanLuvanee LJ, AlsopH, et al. *Clinical studies evaluating abametapir lotion, 0.74%, for the treatment of head louse infestation*. *Pediatr Dermatol*.2018; 35:616–621. <https://doi.org/10.1111/pde.13612>