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FDA end-of-phase II for head lice product

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Successful FDA end-of-phase II for Hatchtech head lice product DeOVO

Singapore: Specialty pharmaceutical company Hatchtech successfully completed end-of-phase II (EOP2) consultations with the US FDA for its lead product DeOvo, a single application topical treatment for head lice.

The completion of EOP2 follows the recent successful completion of the phase IIb clinical trial demonstrating superior efficacy in 142 subjects with head lice infestation in patients aged two years and older, at study centers in the US.
The FDA reviewed Hatchtech's current data package, phase III protocols and the readiness for phase III in all disciplines and provided assessments of the company's detailed plans for the phase III development program. An EOP2 interaction with the FDA is a key part of seeking US marketing approval for prescription drug products.

The Australia-based specialty pharmaceutical company had recently been granted a patent by the US Patent and Trademark Office for its novel head lice treatment product, DeOvo.

Dr Lewis Schulz, COO, Hatchtech, said that, "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 III 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 III program later this year."

Dr Ross Macdonald, CEO, Hatchtech, commented that, "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."