

Abametapir lotion, 0.74% demonstrates high elimination rates of head lice with a single application in Phase 3 trials

Lydie Hazan, MD¹; Robert S Haber, MD²; Michael Husseman, MD³; Katie Shepherd⁴; Sharon Hanegraaf⁵; Tiina Ahveninen⁶; Lisa Jenkins⁶; Hugh Alsop⁵; Vernon M Bowles, PhD⁷

¹Axis Clinical Trials, Los Angeles, CA; ²Case Western University School of Medicine, Cleveland, OH; ³Wee Care Pediatrics, University of Utah School of Medicine, Salt Lake City, UT;

⁴The Shepherd Institute for Lice Solutions, West Palm Beach, FL; ⁵Hatchtech Pty Ltd, Melbourne, Australia; ⁶Virtual Regulatory Solutions, Audubon, PA; ⁷University of Melbourne, Melbourne, Australia

Introduction

- Successful treatment of head lice infestations may be hampered by limited ovicidal efficacy of current treatments¹, increasing resistance to commonly used treatments², and poor adherence to 2-application treatment regimens.
- Abametapir lotion, 0.74%, contains the active ingredient abametapir, a compound with a new mode of action³ being developed for the single-application treatment of head lice infestation.

Objective

The objective of the current studies was to evaluate the efficacy of a single 10 minute application of abametapir lotion, 0.74% for the treatment of head lice infestation in subjects 6 months of age and older.

Methods

- Two randomized, double-blind, vehicle-controlled, parallel-group, multi-center studies were conducted in subjects aged ≥ 6 months with active head lice infestations along with household members with ≥ 1 live louse.
- Households were equally randomized to receive abametapir lotion, 0.74% or vehicle.
- Product was applied to dry hair for 10 minutes and rinsed with water. No nit combing was performed. Following treatment, subjects were inspected for live lice on days 1, 7, and 14.
- Treatment success was defined as being louse-free at all post-baseline visits through day 14.

Table 1. Overall Treatment Outcome by Study & Treatment Group

Study 1 % (N)	Abametapir Lotion, 0.74% (N=187)	Vehicle Lotion (N=192)
Treatment Success	88.2% (165)*	62.0% (119)
Treatment Failure	11.8% (22)	38.0% (73)
Study 2 % (N)	Abametapir Lotion, 0.74% (N=163)	Vehicle Lotion (N=162)
Treatment Success	81.0% (132)*	60.5% (98)
Treatment Failure	19.0% (31)	39.5% (64)

*Overall Treatment Success defined as being louse-free at all post-baseline visits through day 14

Table 2. Adverse Events Occurring in ≥ 1% of the Abametapir Lotion, 0.74% Group and at a Greater Frequency than in the Vehicle Group (Studies 1 & 2)

Adverse Reactions	Abametapir Lotion, 0.74% N=349	Vehicle Lotion N=350
Erythema	14 (4.0%)	6 (1.7%)
Rash	11 (3.2%)	8 (2.3%)
Skin Burning Sensation	9 (2.6%)	0 (0.0%)
Contact Dermatitis	6 (1.7%)	4 (1.1%)
Vomiting	6 (1.7%)	2 (0.6%)
Eye Irritation	4 (1.2%)	2 (0.6%)
Hair Color Changes	3 (1.0%)	0 (0.0%)

Results

- Enrollment included a total of 704 subjects with comparable demographics in each study.
- For all subjects treatment success was 88.2% (165/187) and 81.0% (132/163) with abametapir lotion, 0.74% for the two studies, respectively, compared with 62.0% (119/192) and 60.5% (98/162) for the vehicle groups (both P<.001) (Table1).
- The most common treatment emergent adverse events were erythema, rash, and skin burning sensation (Table 2).

Conclusions

- A single, 10-minute application of abametapir lotion, 0.74% was effective in treating active head lice infestation within 14 days in subjects 6 months or older.
- In this study, the most common adverse events were erythema, rash, and skin burning (range 2.6% to 4.0%) and there were no serious adverse events.

References

1. Mumcuoglu KY, Effective treatment of head louse with pediculicides. *J Drugs Dermatol.* 2006;5:451-452.
2. Durand RS, Bouvresse s, Berdjane Z, et al. Insecticide resistance in head lice: Clinical parasitological and genetic aspects. *Clin Microbiol Infect.* 2012;18:338-344.
3. Van Hiel MB, Breugelmanns B, Pagel CM, et al. The ovicidal, larvacidal and adulticidal properties of 5,5'-dimethyl-2,2'-bipyridyl against drosophila melanogaster. *PLOS One.* 2012;7:e49961.