

Abametapir lotion, 0.74%, a novel therapy for the treatment of head lice, pooled safety results from 11 trials, in children as young as 6 months

Lydie Hazan, MD¹; David Cardona, MD²; Sharon Hanegraaf³; Tiina Ahveninen³; Hugh Alsop³; Vernon M Bowles, PhD⁴; ¹Axis Clinical Trials, Los Angeles, CA; ²Universal BioPharma Research Institute Inc., Dinuba, CA; ³Hatchtech, Melbourne, Australia; ⁴University of Melbourne, Melbourne, Australia;

Introduction

Abametapir lotion, 0.74% is being developed for the single application treatment of head lice infestation. The active ingredient is a novel compound, abametapir. Abametapir lotion, 0.74% has been tested in 11 clinical trials, including 6 trials with pediatric subjects.

Objectives

- To evaluate the clinical safety results in children as young as 6 months following exposure to abametapir lotion 0.74%.
- A total of 1372 subjects were evaluated in 11 clinical studies of abametapir lotion, 0.74% including 6 studies with a total of 676 pediatric subjects (aged 6 months to 17 years).

Methods

- These 6 trials included one phase 2b trial, one phase 2 ovidical efficacy trial, two open-label phase 2 PK trials of maximal use, and two phase 3 vehicle-controlled trials.
- Across all trials, subjects ranged in age from 6 months to 60 years and exposure times ranged from 10 minutes to 20 minutes.
- Of the 905 subjects exposed to study treatment for 10 minutes, 483 received abametapir lotion, 0.74% and 422 received vehicle lotion.
- Safety assessments included vital signs, physical examination, clinical laboratory tests, and adverse events (AEs).

Results

- The most frequently reported treatment-emergent AEs for pediatric subjects were in the system organ class of *Skin and Subcutaneous Tissue Disorders*, primarily erythema, rash, skin burning sensation, and contact dermatitis.
- TEAEs were similar for adult and pediatric subjects.
- The majority of AEs were mild and there was no evidence of an age-related effect.
- The two maximal-use pediatric trials had study drug exposure ranging from 3.3 g to 200.8 g, and reported 14 AEs (23.3%) (Table 1).
- In the two phase 3 trials, AEs were reported by 24.4% subjects using abametapir lotion, 0.74% and 18.6% subjects using vehicle (Table 2). One serious AE, unrelated to study treatment, was reported in the vehicle group.
- There were no deaths, no discontinuations due to AEs and no clinically meaningful changes in vital signs, physical exams or laboratory tests in any of these trials.

Conclusions

- In 11 clinical studies of abametapir lotion, 0.74% for the treatment of head lice in subjects ranging in age from 6 months to 60 years, AEs were mild, not age-related, and primarily in the system organ class of *Skin and Subcutaneous Tissue Disorders*.

Table 1. Summary of Adverse Events in the SOC of Skin and Subcutaneous Tissue Disorders in Phase 2 PK Trials

SOC Preferred Term	Study Ha02-003		Study Ha03-003	Study Ha03-004
	ABA 0.74% n = 49	Vehicle n = 47	ABA 0.74% n = 22	ABA 0.74% n = 38
Overall Incidence	13 (26.5)	27 (57.4)	6 (27.3)	8 (21.1)
Skin & Subcutaneous Tissue Disorders	7 (14.3)	19 (40.4)	4 (18.2)	5 (13.2)
Pruritus	2 (4.1)	18 (38.3)	1 (4.5)	0
Erythema	0	2 (4.3)	0	0
Dermatitis	0	0	1 (4.5)	0
Dermatitis contact	3 (6.1)	0	0	2 (5.3)
Dermatitis allergic	2 (4.1)	0	0	0
Rash	0	0	1 (4.5)	0
Exfoliative rash	1 (2.0)	0	0	0
Dry Skin	0	1 (2.1)	0	0
Rash macular	0	0	0	1 (2.6)
Rash popular	0	0	0	1 (2.6)
Skin disorder	0	0	1 (4.5)	0
Skin irritation	0	0	0	1 (2.6)

Note: ABA 0.74% = abametapir lotion, 0.74%

Table 2. Summary of AEs in the SOC of Skin and Subcutaneous Tissue Disorders Reported in Two Phase 3 Trials and One Phase 2 Ovidical Efficacy Trial

SOC Preferred Term	Ha03-001		Ha03-002		Ha03-008	
	ABA 0.74% N = 186 n (%)	Vehicle N = 188 n (%)	ABA 0.74% N = 163 n (%)	Vehicle N = 162 n (%)	ABA 0.74% N = 25 n (%)	Vehicle N = 25 n (%)
Overall Incidence	37 (19.9)	32 (17.0)	48 (29.4)	33 (20.4)	6 (24.0)	4 (16.0)
Skin & Subcutaneous Tissue Disorders	16 (8.6)	14 (7.4)	32 (19.6)	23 (14.2)	5 (20.0)	3 (12.0)
Erythema	4 (2.2)	0	10 (6.1%)	6 (3.7)	0	1 (4.0)
Skin exfoliation	1 (0.5)	0	2 (1.2)	8 (4.9)	0	0
Skin burning sensation	0	0	9 (5.5)	0	0	0
Rash	2 (1.1)	0	7 (4.3)	8 (4.9)	4 (16.0)	2 (8.0)
Pruritus	1 (0.5)	8 (4.3)	2 (1.2)	2 (1.2)	1 (4.0)	0
Dermatitis	0	0	0	3 (1.9)	0	0
Dry skin	0	0	0	3 (1.9)	0	0
Hair color changes	0	0	3 (1.8)	0	0	0
Urticaria	0	0	0	2 (1.2)	0	0
Rash pruritic	0	0	0	1 (0.6)	0	0
Skin plaque	0	1 (0.5)	0	1 (0.6)	0	0
Swelling face	0	0	0	1 (0.6)	0	0
Dermatitis contact	6 (3.2)	4 (2.1)	0	0	0	0
Rash erythematous	0	1 (0.5)	0	0	0	0
Skin disorder	2 (1.1)	0	0	0	0	0
Skin irritation	2 (1.1)	0	0	0	0	0

Note: ABA 0.74% = abametapir lotion, 0.74%