



## ParaPRO Announces FDA Approval of Natroba™ for Treatment of Head Lice

- ***Natroba™ does not require painstaking nit combing and for most patients is effective in one 10-minute application.***
- ***Product demonstrated superior efficacy in Phase III trials vs. permethrin***
- ***Availability beginning in the first half of 2011***

CARMEL, Ind., Jan. 18, 2011 (Business Wire) – ParaPRO, LLC announced today that the U.S. Food and Drug Administration (FDA) has approved Natroba™ (spinosad) Topical Suspension, 0.9% to eliminate head lice (pediculosis capitis). Natroba™ received approval as a prescription medication and is indicated for the topical treatment of head lice infestations in patients four (4) years of age and older. Natroba™ is an effective, easy-to-use product, resolving most head lice problems in about 10 minutes with just one application and no nit combing. The company expects to launch the product in the first half of 2011.

"We believe Natroba™ gives physicians and parents a game-changing solution to the problem of head lice," said Bill Culpepper III, president of ParaPRO, LLC. "Natroba™ is the only head lice treatment whose approval is supported by superiority studies versus permethrin 1%. FDA approval of Natroba™ is a significant step forward in the longstanding struggle to treat head lice infestations and we look forward to making the product available in pharmacies nationwide as soon as possible. Unlike many other currently available treatments, most children will only require one application and do not need to sit through extensive, time-consuming nit combing sessions when Natroba™ is used. This means that parents trying to rid their children of head lice will soon have an important new treatment option given the ease of use and effectiveness of Natroba™."

Natroba™ (pronounced na-<sup>1</sup>trōb-ə) treats head lice using spinosad, a compound derived from a soil microbe. Until Natroba™ was approved, the most common pediatrician-recommended head lice treatments available either over-the-counter or by prescription required nit combing, which can be painstaking and time consuming. Further, in the clinical studies, patients treated with permethrin 1%, (marketed under the brand name Nix<sup>®1</sup>) more often required an additional round of treatment than patients who were treated with Natroba™.

Head lice are the second most communicable disease among schoolchildren, after the common cold.<sup>2</sup> The U.S. Centers for Disease Control and Prevention estimate that there are between 6 to 12 million cases of head lice infestations each year, mostly in children 3 to 12 years old. Head lice are tiny, wingless

<sup>1</sup> Nix is a registered trademark and the property of its owner.

<sup>2</sup> Mayo Clinic website, available at <http://www.mayoclinic.com/health/head-lice/DS00953>. Accessed Dec. 13.2010

insects that live on the human scalp and spread between people by head-to-head contact or the sharing of hats, combs, brushes or towels.<sup>3</sup>

Costs associated with head lice infestations are estimated to be as high as \$1 billion per year in the United States alone.<sup>4</sup> Direct costs include treatments and clinic visits, while indirect costs range from school nurse time to school absenteeism to lost wages.

“Head lice are a common problem that can affect anyone regardless of where they live. Historically, it’s been a time-consuming, frustrating problem for families. Multiple treatments may be required and due to a variety of factors, the initial treatment is often ineffective,” said Dow Stough, M.D., Burke Pharmaceutical Research and an investigator in the Natroba™ Phase III clinical studies. “When available, Natroba™ will offer a safe and effective option. The Phase III studies showed that a single treatment of Natroba™ worked for most patients and with Natroba™ combing is not required. This product will represent a real advance in the treatment of head lice.”

Natroba™ is the only head lice treatment whose approval is supported by superiority studies versus permethrin 1%, the most commonly prescribed head lice treatment to date.<sup>5</sup> In two Phase III clinical studies, Natroba™ was significantly more effective in eliminating head lice than permethrin 1% (marketed under the brand name Nix®) – the head lice treatment recommended by the American Academy of Pediatrics at the time the study protocol was approved by the FDA.<sup>6</sup> The studies, published online in the journal *Pediatrics* (*Pediatrics* 2009; 124:e389-e395), also confirmed the safety and effectiveness of Natroba™. The 1,038 participants with active head lice infestations were provided either Natroba™ or Nix® to be used at home. A total of 84.6% (study 1) and 86.7% (study 2) of Natroba™-treated participants were assessed to be lice-free 14 days after the last treatment, compared with 44.9% and 42.9% treated with permethrin ( $P < 0.001$  for both studies). Most participants in the Natroba™ groups (63.8% and 86.2%) needed only one application, whereas most participants in the permethrin groups (60.3% and 64.5%) required two applications.

There were few adverse events reported in the Phase III clinical studies. The most commonly occurring adverse events included application-site erythema (redness of the skin) which occurred in 3% of the Natroba™ patients (vs. 7% of permethrin), ocular hyperemia (redness and irritation of the eyes) which occurred in 2% of the Natroba™ patients (vs. 3% of permethrin) and application-site irritation which occurred in 1% of Natroba™ patients (vs. 2% permethrin). Although adverse event rates were low for

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<sup>3</sup> Centers for Disease Control and Prevention, available at <http://www.cdc.gov/lice/head/factsheet.html>. Accessed Sept. 28, 2010.

<sup>4</sup> Lebowitz M, Clark L, Levitt J. Therapy for head lice based on life cycle, resistance and safety considerations. *Pediatrics* 2007; 119(5): 965-974

<sup>5</sup> Wolters Kluwer Health, Source® Pharmaceutical Audit Suite prescription pediculicide/head lice market audit current 12 months, November 2010.

<sup>6</sup> Frankowski BL, Weiner LB; American Academy of Pediatrics, Committee on School Health, Committee on Infectious Diseases, Head Lice, *Pediatrics* 2002; 110(3):648-643.

both products, application site redness occurred significantly less frequently in patients treated with Natroba™ than in patients treated with permethrin (P = 0.007).

### **Indication**

Natroba™ Topical Suspension is a pediculicide indicated for the topical treatment of head lice infestations in patients four (4) years of age and older.

### **Important Safety Information**

Natroba™ contains benzyl alcohol and is not recommended for use in neonates and infants below the age of 6 months. Systemic exposure to benzyl alcohol has been associated with serious adverse reactions and death in neonates and low birth-weight infants.

The most common adverse events were: application site redness (3%), redness and irritation of the eyes (2%) and application site irritation (1%).

For additional safety information, see the patient and full prescribing information at [www.Natroba.com](http://www.Natroba.com) .

### **About ParaPRO**

**ParaPRO, LLC** ([www.parapro.com](http://www.parapro.com)), based in the Indianapolis, Indiana metropolitan area, is a specialty pharmaceutical company focused on commercializing proprietary products for the pediatric market. ParaPRO is a wholly owned subsidiary of SePRO Corporation ([www.sepro.com](http://www.sepro.com)).

Natroba™ is a trademark of ParaPRO, LLC. Other trademarks are the property of their respective owners.

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