Manhattan Pharmaceuticals Announces Positive Clinical Results for Hedrin in Treatment of Head Lice

Hedrin Demonstrates Statistically Significant Increase in Cure Rate Versus Malathion

NEW YORK, Nov 28, 2007 (PrimeNewswire via COMTEX News Network) -- Manhattan Pharmaceuticals, Inc. (AMEX:MHA) today announced the publication of positive clinical results for Hedrin(tm), the company's novel, non-insecticide product candidate for the treatment of head lice. These results appeared in the November issue of PLoS One, a leading international, peer-reviewed journal published by the Public Library of Science (PLoS).

The study findings demonstrate Hedrin's superior efficacy compared to malathion, a widely used insecticide treatment in both Europe and North America. In this randomized, controlled, assessor blinded, parallel group clinical trial, 73 adult and child subjects with active head lice infestations were treated with Hedrin or malathion liquid. Using intent-to-treat analysis, Hedrin achieved a statistically significant cure rate of 70% compared to 33% with malathion liquid. Using the per-protocol analysis Hedrin achieved a highly statistically significant cure rate of 77% compared to 35% with malathion. Additionally, Hedrin treated subjects experienced no irritant reactions, and Hedrin showed clinical equivalence to malathion in its ability to inhibit egg hatching. Overall, investigators and study subjects rated Hedrin as less odorous, easier to apply, and easier to wash out. Further, subjects treated with Hedrin stated they were significantly more inclined to use the product again (97%) versus those using malathion (31%).

"These findings are striking in that the data demonstrate such a dramatic increase in the head lice cure rate of Hedrin as compared to malathion," stated principal investigator, and head lice expert Ian Burgess, PhD, Director of Insect Research and Development Limited. "In addition to being shown to be a significantly more effective treatment alternative, Hedrin also appears to provide patients with key ease-of-use and lifestyle advantages over malathion. In their totality, these findings make a strong argument for Hedrin as a far superior head lice treatment option as compared to malathion."

To date, Hedrin has been clinically studied in 326 subjects and is currently marketed as a device in Western Europe and as a pharmaceutical in the United Kingdom (U.K.). In Europe, Hedrin has been launched in 21 countries and has achieved annual sales through its licensees of approximately $45 million at in-market public prices (which equates to a projected 21% market share), and is the market leader in the U.K. with $11 million in sales (23% market share) and France with a 21% market share. In the United States Manhattan Pharmaceuticals is planning to pursue a development pathway for Hedrin as a medical device, and will initiate that process in the fourth quarter of 2007. The company owns North American rights to Hedrin.

About Hedrin

Hedrin is a unique, proprietary combination of silicones (dimeticone and cyclomethicone) that acts as a pediculicidal (lice killing) agent by disrupting the insect's mechanism for managing fluid and breathing. Hedrin contains no traditional chemical insecticides in contrast with most currently available lice treatments. Recent studies have indicated that resistance to traditional chemical insecticides may be increasing and therefore contributing to insecticide treatment failure. Because Hedrin kills lice by preventing the louse from excreting waste fluid and by asphyxiation (smothering), rather than by acting on the central nervous system, the insects cannot build up resistance to the treatment. Both silicones in this proprietary formulation of Hedrin are used extensively in cosmetics and toiletries.

In a previous randomized, controlled equivalence, clinical study conducted in Europe and published in the British Medical Journal in 2005, Hedrin was administered to 253 adult and child subjects. These study results demonstrated Hedrin's equivalence compared to the insecticide treatment, phenothrin, another widely-used insecticide lice treatment in the U.K. According to the same study, the Hedrin-treated subjects also experienced significantly less irritation (2%) than those treated with phenothrin (9%).

About Head Lice

According to the American Academy of Pediatrics an estimated 6-12 million Americans are infested with head lice each year, with pre-school and elementary age children and their families affected most often.

Journal Reference

Burgess IF, Lee PN, Matlock G (2007) Randomised, Controlled, Assessor Blind Trial Comparing 4% Dimeticone Lotion with 0.5% Malathion Liquid for Head Louse Infestation. PLoS ONE 2(11): e1127. doi:10.1371/journal.pone.0001127

About Manhattan Pharmaceuticals, Inc.

Manhattan Pharmaceuticals, Inc. is a pharmaceutical company that acquires and develops novel, high-value drug candidates primarily for the treatment of dermatologic and immunologic disorders. With a pipeline consisting of four clinical-stage product candidates, Manhattan Pharmaceuticals is developing potential therapeutics for large, underserved patient populations seeking superior treatments for conditions including psoriasis, atopic dermatitis (eczema), head lice, and mastocytosis. (http://www.manhattanpharma.com)

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements involve risks and uncertainties that could cause Manhattan Pharmaceuticals, Inc.'s actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "anticipates," "expects," "plans," "believes," "intends," "will," and similar words or phrases. These statements are based on Manhattan Pharmaceuticals, Inc.'s current expectations, forecasts and assumptions, which are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Among other things, there can be no assurances that Manhattan Pharmaceuticals, Inc.'s development efforts relating to its PTH (1-34), Altoderm(tm), Altolyn(tm) or Hedrin(tm) product candidates, or any future product candidates, will be successful, that the clinical study referenced in this press release or any other clinical study will be completed or will return positive results, or that Manhattan Pharmaceuticals, Inc. will be able to out-license its discontinued programs to other companies on terms acceptable to Manhattan Pharmaceuticals, Inc. or at all. Other risks that may affect forward-looking information contained in this press release include the possibility of being unable to obtain regulatory approval of Manhattan Pharmaceuticals, Inc.'s product candidates, the risk that the results of clinical trials may not support the company's claims, the risk that the company's product candidates may not achieve market acceptance in North America or elsewhere, the company's reliance on third-party researchers to develop its product candidates, availability of patent protection, the risk that sufficient capital may not be available to develop and commercialize the company's product candidates, and the company's lack of experience in developing and commercializing pharmaceutical products. Additional risks are described in the company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-KSB for the year ended December 31, 2006. Manhattan Pharmaceuticals, Inc. assumes no obligation to update these statements, whether as a result of new information, future events, or otherwise, except as required by law.

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