



## **PENNSAID® PHASE 3 STUDY RESULTS TO BE PUBLISHED IN LEADING INTERNATIONAL PAIN JOURNAL**

**Mississauga, Ontario, Canada – April 23, 2009 - Nuvo Research Inc. (TSX: NRI)**, a Canadian drug development company focused on the research and development of drug products delivered to and through the skin using its topical and transdermal drug delivery technologies, today announced that study results demonstrating that the Company's lead product, Pennsaid, a topical non-steroidal anti-inflammatory drug (NSAID), is an efficacious treatment for the symptoms of osteoarthritis of the knee will be published in the June 2009 edition of PAIN.

PAIN is the world's leading publication on pain research and treatments and the official journal of the International Association for the Study of Pain (IASP®). The IASP, founded in 1973, is the leading professional forum for science, practice, and education in the field of pain and has more than 6,500 members in 118 countries who are professionals involved in the research, diagnosis and treatment of pain.

The scientific article details Nuvo's previously announced study results, which demonstrated that Pennsaid is efficacious for the relief of symptoms in patients with knee osteoarthritis. In addition, the study demonstrated that Pennsaid is as effective as oral diclofenac at relieving knee osteoarthritis symptoms but with less NSAID-related systemic toxicity. The article, titled, "Efficacy and safety of topical diclofenac containing dimethyl sulfoxide (DMSO) compared with those of topical placebo, DMSO vehicle and oral diclofenac for knee osteoarthritis", was written by Dr. Lee Simon as lead author, and Dr. Lisa Grierson, Zahid Naseer, Dr. Arthur A.M. Bookman, M.D., and Dr. J. Zev Shainhouse as co-authors. It is currently available on the PAIN website.

"The publication of this article in the premier international pain journal further confirms Pennsaid's unique and compelling efficacy and safety profile among all other topical NSAIDs," said Dr. Brad Galer, Vice President and General Manager of Nuvo's Pain Group. "This published data provides further support to our conclusion that Pennsaid, when approved by the U.S. Food and Drug Administration (FDA), will be the best-in-class product available in the United States."

Nuvo resubmitted its application for Pennsaid approval to the FDA in February 2009. The FDA has indicated that it intends to advise Nuvo of its decision regarding the approval of Pennsaid by August 5, 2009 (the "PDUFA Date") under the Prescription Drug User Fee Act.

The subject of the PAIN article is Nuvo's Phase 3 trial, Study 112, which enrolled 775 patients in the U.S. and Canada with symptoms of primary osteoarthritis of the knee. Patients in this five-arm, double-blind, 12-week trial applied a topical solution and took an oral pill. The five arms were: 1) Pennsaid plus oral placebo, 2) topical placebo containing a small amount of DMSO for blinding purposes (DMSO facilitates delivery of diclofenac to the knee) plus oral placebo, 3) topical vehicle-control (containing the same concentration of DMSO as in Pennsaid) plus oral placebo, 4) topical placebo plus oral diclofenac and 5) Pennsaid plus oral diclofenac.

Pennsaid (arm 1) was superior to placebo (arm 2) with statistically significant improvement in all three primary clinical endpoints required by the FDA: pain relief ( $p=0.019$ ), improvement in physical function ( $p=0.046$ ) and improved patient overall health assessment (POHA) ( $p<0.0001$ ).

Additional results from the trial show that Pennsaid (arm 1) was superior to vehicle control (arm 3) (pain,  $p=0.009$ ; physical function,  $p=0.026$ ; POHA,  $p=0.016$ ). There was no difference between vehicle control (arm 3) and placebo (arm 2) indicating that DMSO alone is ineffective against the symptoms of knee osteoarthritis ( $p>0.05$ ). There was no difference between Pennsaid (arm 1) and oral diclofenac (arm 4) for all three efficacy endpoints ( $p>0.05$ ). Arm 5 was included in the trial at the FDA's request to review the side effect profile of Pennsaid if combined with an oral NSAID. This combination showed no increased incidence of the usual systemic side effects, just the expected additive profiles of Pennsaid alone plus oral diclofenac alone.

Dry skin was the most common adverse event with Pennsaid use. Fewer digestive system adverse events and laboratory abnormalities (decreased hemoglobin and increased AST, ALT and creatinine) were observed with Pennsaid as compared to oral diclofenac.

#### **About Nuvo Research Inc.**

Nuvo is focused on the research and development of drug products delivered to and through the skin using its topical and transdermal drug delivery technologies. Nuvo's lead product is Pennsaid<sup>®</sup>, a topical non-steroidal anti-inflammatory drug (NSAID) used for the treatment of osteoarthritis. Nuvo intends to leverage its skin-penetrating technologies to create a portfolio of topical and transdermal products targeting a variety of indications.

Nuvo Research Inc. is a publicly traded, Canadian pharmaceutical company headquartered in Mississauga, Ontario, with manufacturing facilities in Varennes, Québec and Wanzleben, Germany and a research and development Center in San Diego California. For more information, please visit [www.nuvoresearch.com](http://www.nuvoresearch.com)

*These forward-looking statements, by their nature, necessarily involve risks and uncertainties that could cause actual results to differ materially from those contemplated by the forward-looking statements. The Company considers the assumptions on which these forward-looking statements are based to be reasonable at the time they were prepared, but caution that these assumptions regarding future events, many of which are beyond the control of the Company, may ultimately prove to be incorrect. Factors and risks, which could cause actual results to differ materially from current expectations, are discussed in the annual report, as well as in the Company's Annual Information Form for the year ended December 31, 2008. The Company disclaims any intention or obligation to update or revise any forward-looking statements whether a result of new information or future events, except as required by law. For additional information on risks and uncertainties relating to these forward-looking statements, investors should consult the Company's ongoing quarterly filings, annual report and Annual Information Form and other filings found on SEDAR at [www.sedar.com](http://www.sedar.com)*

#### **For more information about Nuvo, please contact:**

Media and Investor Relations

Adam Peeler

#### **Equicom Group Inc.**

Tel: (416) 815-0700 x225

email: [apeeler@equicomgroup.com](mailto:apeeler@equicomgroup.com)