



## **NUVO ANNOUNCES FURTHER UPDATE ON DISCUSSIONS WITH THE FDA RELATED TO REVIEW OF PENNSAID**

**Mississauga, Ontario, Canada – March 7, 2007 - Nuvo Research Inc. (TSX: NRI)** today provided an update on discussions with the U.S. Food and Drug Administration ("FDA") to clarify matters raised by the FDA in its approvable letter (the "Approvable Letter") for Pennsaid issued on December 28, 2006.

In the Approvable Letter, the FDA confirmed that Pennsaid could be approved for sale in the U.S. once certain conditions were satisfied. None of the conditions relate to clinical efficacy or clinical safety of Pennsaid, which were evidenced in Nuvo's Phase III trials. The FDA has not requested that Nuvo conduct any additional Phase III clinical trials.

Based on recent discussions with the FDA, the Company plans to begin studies that it expects to conclude in time to file a response to the FDA in the fourth quarter of 2007.

The Company is also continuing discussions with the FDA to resolve other matters raised in the Approvable Letter including the FDA's apparent change in its conclusion regarding the adequacy of data provided to evidence the dermal safety of Pennsaid and its constituent components. The Company believes that these issues were adequately addressed in its submissions for approval and that any FDA concerns should be dealt with via appropriate post approval animal studies and/or labeling warnings. However, it is possible that the FDA may require the Company to conduct additional animal studies before approval to address these matters which could result in a further significant delay to submission of the Company's response and approval. The Company will provide further updates as the steps toward Pennsaid approval are clarified.

"Our top priority remains the final approval of Pennsaid," said Henrich Guntermann, President and CEO. "We are utilizing every avenue possible to secure the approval of Pennsaid in the U.S. in a timely manner."

Nuvo continues to be in discussions with potential partners for the licensing of Pennsaid in the U.S.

To meet the FDA's clinical efficacy and clinical safety requirements as outlined in the Non-Approvable Letter, Nuvo conducted study 112, a 12-week Phase III, 5-arm, double-blind trial of 775 patients. This trial enrolled patients in the U.S. and Canada with symptoms of primary osteoarthritis of the knee. The trial met all of its primary endpoints with respect to pain, physical function and patient overall health assessment. The trial also demonstrated comparable efficacy of Pennsaid to oral diclofenac. To address the long-term safety requirements as outlined in the Non-Approvable Letter letter, Nuvo conducted study 112E, a long-term multi-centre, single-arm safety study of Pennsaid applied by patients with symptoms of osteoarthritis of the knee. In total, 793 patients were treated, including 448 patients for at least six months and 116 patients for at least one year. The key observation was that long-term use did not cause any new, unexpected adverse events.

In total, more than 2,500 patients have been treated with Pennsaid in clinical studies. Pennsaid has been approved in Canada and several European countries and more than 1.5 million prescriptions for Pennsaid have been written to date in those countries.

### **About Pennsaid®**

Pennsaid® is a topical non-steroidal anti-inflammatory drug (NSAID) for the treatment of osteoarthritis and is currently approved for sale in Canada and several European countries. Pennsaid® allows the diclofenac solution to be delivered to a specific site via the surface of the skin. The systemic exposure of Pennsaid is approximately 1/200<sup>th</sup> of that from the oral dosage form of diclofenac, greatly decreasing the potential for complications associated with the oral route of delivery. According to published clinical trials, Pennsaid® is as effective as the maximum daily dose of comparable oral medication at relieving pain and stiffness associated with osteoarthritis of the knee, as well as improving overall well-being. There is currently no topical NSAID product approved in the approximately \$4 billion U.S. osteoarthritis pain relief market. In December 2006, the U.S. Food and Drug Administration issued an Approvable Letter that indicated Pennsaid® is approvable subject to Nuvo satisfying certain conditions.

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

Nuvo is focused on developing innovative site-specific therapeutics that are delivered topically using the Company's skin-penetrating technologies. Nuvo's lead product is Pennsaid®, 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 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 facility in San Diego, California. For more information, please visit [www.nuvoresearch.com](http://www.nuvoresearch.com).

*This release may contain forward-looking statements, subject to risks and uncertainties beyond management's control. Actual results could differ materially from those expressed here. Risk factors are discussed in the Company's annual information form filed with the securities commissions in each of the provinces of Canada. The Company undertakes no obligation to revise forward-looking statements in light of future events.*

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