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## PRESS RELEASE

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Contact: Public Affairs Office, Tioga Research, Inc.

[info@tiogaresearch.com](mailto:info@tiogaresearch.com)

[www.tiogaresearch.com](http://www.tiogaresearch.com)

### **FDA Approves PENNSAID® 2%**

-- Inventions of Tioga Research Team Members Poised for Major Commercial Success --

**San Diego, CA, January 18<sup>th</sup> 2014** – The U.S. Food and Drug Administration (“FDA”) has approved the New Drug Application (“NDA”) for PENNSAID® (diclofenac sodium topical solution) 2% w/w (“PENNSAID® 2%”), a formulation invented by senior members of the Tioga Research team.

PENNSAID 2% is a follow-on product to the original PENNSAID® (diclofenac sodium topical solution) which has been marketed since 2010 in the U.S. by Mallinckrodt under license from Nuvo Research (“Nuvo”). Mallinckrodt also acquired from Nuvo U.S. rights to PENNSAID 2% and had been responsible for its clinical development. PENNSAID 2% will be the first topical non-steroidal anti-inflammatory drug (“NSAID”) available in the U.S. with twice per day dosing for the treatment of knee osteoarthritis pain.

PENNSAID 2% is protected under two issued US Patents, numbered 8,252,838 (issued August 28, 2012) and 8,563,613 (issued Oct 22, 2013). The two inventors in both cases are Dr. Edward T. Kisak and Dr. Jagat Singh, now respectively the Chief Scientific Officer, and Director of Chemistry, Manufacturing and Controls (“CMC”) of Tioga Research.

“With this FDA approval we are pleased that the millions of patients who suffer from the pain of knee osteoarthritis will now be able to benefit from the PENNSAID 2% product” commented Dr. John M Newsam, Chief Executive Officer of Tioga Research, “And we wish our colleagues at Nuvo and their U.S. sales and marketing partner, Mallinckrodt, substantial commercial success. When our team was tasked with devising a novel diclofenac sodium topical formulation, that would be a substantial improvement over PENNSAID® (for example in allowing twice a day dosing rather than PENNSAID®’s four times a day regimen) yet comprise only a minor compositional change, it was clearly a challenge. It is, I think, a testament both to the creativity of our formulation scientists and to the effectiveness of our technologies and capabilities that PENNSAID 2%, already protected under robust composition of matter patents, has now been progressed successfully through to regulatory approval”.

***About Tioga Research, Inc.***

Tioga Research supports the research and early development of skin-applied products (for superficial, topical, regional or transdermal delivery), offering especially formulation innovation and skin permeation screening CRO services. Tioga Research has pioneered high throughput experimentation (“HTE”) technologies for screening skin delivery. Tioga Research is based in San Diego, CA.

***Contact for additional information on Tioga Research:***

Public Affairs Office, Tioga Research, Inc., 6330 Nancy Ridge Drive Suite 102, San Diego CA 92121

E-mail: [info@tiogaresearch.com](mailto:info@tiogaresearch.com) web: [www.tiogaresearch.com](http://www.tiogaresearch.com)

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