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## NUPATHE REPORTS POSITIVE PHASE III RESULTS FOR ZELRIX, A NOVEL TRANSDERMAL PATCH FOR ACUTE MIGRAINE

### *Migraine Treatment Candidate Meets the Five Key Efficacy Endpoints*

**Conshohocken, PA, August 11, 2009** – [NuPathe Inc.](#), a specialty pharmaceutical company developing innovative products for the treatment of neurological and psychiatric diseases, today announced top-line results from the pivotal Phase III clinical trial of [Zelrix™](#), a novel transdermal patch in clinical development for the treatment of acute migraine. In this multi-center, randomized, parallel group, double-blind, placebo-controlled trial, the efficacy and tolerability of Zelrix were compared with placebo in a total of 530 adults.

The Zelrix patch combines NuPathe's proprietary [SmartRelief™](#) iontophoretic transdermal technology with sumatriptan, the most prescribed treatment for acute migraine in the United States. "Zelrix was designed to overcome key barriers to successful treatment of migraine: treatment-altering nausea, treatment-limiting side effects, and inconsistent drug absorption," said [Jane Hollingsworth](#), chief executive officer of NuPathe.

According to the [National Headache Foundation](#), 55 percent of migraine sufferers frequently experience nausea as part of their migraine attacks commonly resulting in patients delaying, modifying, or skipping treatment. Concerns about treatment-related side effects also lead patients to delay, modify, or skip treatment in over one-third of migraine attacks. Moreover, many patients experience inconsistent relief, which experts attribute, in part, to substantial variation in oral drug absorption.

Results of the pivotal Phase III clinical study demonstrated statistically significant improvement for patients two hours after applying the Zelrix patch compared to patients applying a placebo patch for each of the five key efficacy endpoints:

- pain free (pain symptom score = 0)
- pain relief
- nausea free
- photophobia free
- phonophobia free



Zelrix was well-tolerated in the trial. Skin tolerability was typical of other transdermal products with mild to moderate erythema present upon patch removal. The incidence of triptan-specific adverse events was very low. The most common adverse events were itching, pain, and tingling at the application site. The majority of adverse events were reported as mild and transient.

“The pivotal Phase III results confirm that Zelrix provides clear clinical benefits for patients. Zelrix demonstrated efficacy consistently across all symptoms of acute migraine combined with a very low incidence of triptan adverse events,” said [Mark Pierce](#), M.D., Ph.D., chief scientific officer at NuPathe. “Patients need a migraine treatment that can deliver effective relief in a well-tolerated manner without being undermined by the treatment-altering nausea, vomiting, or other gastric symptoms associated with migraine. This milestone brings NuPathe one step closer to bringing the first and only migraine patch to the market. We look forward to submitting an NDA for Zelrix in 2010.”

NuPathe plans to present a comprehensive summary of the data from this trial at the upcoming 14<sup>th</sup> Congress of the [International Headache Society](#) being held in Philadelphia, PA from September 10-13, 2009.

### **About Zelrix**

Zelrix is a novel migraine therapy in clinical development for the treatment of acute migraine. If approved for marketing, Zelrix would be the first and only transdermal patch for migraine patients. Zelrix utilizes a proprietary state-of-the-art transdermal delivery system, SmartRelief, to deliver sumatriptan, the most widely prescribed migraine therapy in the United States, in a rapid but controlled manner.

Zelrix was designed to address key limitations of existing therapies. Oral therapies are often difficult to take when patients are nauseated during migraine attacks and can lead to inconsistent efficacy. In addition, side effects associated with peak plasma concentrations limit patients’ ability or willingness to take certain treatments. Based upon clinical results to date, Zelrix has the potential to offer patients improved control of their migraine attacks, regardless of GI symptoms, in a well-tolerated manner. NuPathe expects to submit an NDA for Zelrix in 2010.

### **About Migraine**

Migraine is an episodic headache disorder associated with various combinations of neurologic, gastrointestinal, and autonomic symptoms that affects approximately 28 million Americans, mostly women. Common symptoms of migraine include recurrent headaches, nausea, vomiting, photophobia (sensitivity to light) and phonophobia (sensitivity to sound).

### **About NuPathe**

NuPathe Inc. is a specialty pharmaceutical company developing innovative therapeutic products for the treatment of neurological and psychiatric diseases. NuPathe’s mission is to identify and address the needs of patients that are insufficiently met by current treatments. NuPathe’s product portfolio includes Zelrix which, if approved, would be the first and only transdermal patch for the treatment of acute migraine, and NP201, a long acting injectable implant for the treatment of Parkinson’s disease. Please visit NuPathe’s web site at [www.nupathe.com](http://www.nupathe.com).