**NuPathe's Zecuity Approved by the FDA for the Acute Treatment of Migraine**

**First FDA-Approved Migraine Patch**

**Conference Call Scheduled January 18 at 8:30 a.m. EST**

CONSHOHOCKEN, PA--(Marketwire - Jan 17, 2013) - [**NuPathe Inc.**](http://ctt.marketwire.com/?release=975802&id=2496085&type=1&url=http%3a%2f%2fwww.nupathe.com%2f) (NASDAQ: PATH) today announced that the U.S. Food and Drug Administration (FDA) has approved [**Zecuity**](http://ctt.marketwire.com/?release=975802&id=2496088&type=1&url=http%3a%2f%2fwww.zecuity.com%2f)™ (sumatriptan iontophoretic transdermal system) for the acute treatment of migraine with or without aura in adults. Zecuity is a single-use, battery-powered patch that actively delivers sumatriptan, the most widely prescribed migraine medication, through the skin. Zecuity provides relief of both migraine headache pain and migraine-related nausea (MRN).

"The approval of Zecuity represents a major milestone for NuPathe and migraine sufferers," said [**Armando Anido**](http://ctt.marketwire.com/?release=975802&id=2496091&type=1&url=http%3a%2f%2fwww.nupathe.com%2four-company%2fmanagement), CEO of NuPathe. "As the first and only FDA-approved migraine patch, we believe Zecuity will be a game-changing treatment option for millions of migraine patients, especially those with migraine-related nausea. We thank the patients and physicians who participated in our clinical trials as well as our employees for their support throughout the development of Zecuity. We now intensify our focus to securing commercial partners and preparing for the launch of Zecuity expected in the fourth quarter of this year."

"In addition to severe headache pain, migraine patients present with other significant symptoms, which commonly includes migraine-related nausea," said Lawrence C. Newman, MD, FAHS, FAAN, Director of the Headache Institute at St. Luke's-Roosevelt Hospital in New York. "For these patients, physicians need to assess and offer treatments tailored to each individual patient's array of migraine symptoms. In fact, the American Academy of Neurology guidelines recommend a non-oral route of administration for migraineurs who experience nausea or vomiting as significant symptoms."

"Migraine-related nausea can be as debilitating as migraine headache pain itself," said study investigator Stephen D. Silberstein, MD, FACP, FAHS, FAAN, Professor of Neurology and Director of the Jefferson Headache Center in Philadelphia. "Treatments bypassing the GI tract may be the best way to treat these patients."

Zecuity was approved based upon an extensive development program with phase 3 trials that included 800 patients using more than 10,000 Zecuity patches. In these trials, Zecuity was proven safe and effective at treating migraine and relieving its cardinal symptoms (headache pain, migraine-related nausea and sensitivity to light and sound) two hours after patch activation.

In the phase 3 pivotal study, twice as many patients treated with Zecuity achieved freedom from headache pain at two hours compared with placebo (18% and 9%, respectively). Additionally, 53% of patients treated with Zecuity achieved relief from headache pain and 84% were nausea free at two hours (29% and 63%, respectively, with placebo). The incidence of triptan-associated adverse events known as "atypical sensations" and "pain and other pressure sensations" was 2% each in Zecuity-treated patients. The most common (greater than 5%) side effects of Zecuity were application site pain, tingling, itching, warmth and discomfort.

**About Zecuity**[**ZECUITY**](http://ctt.marketwire.com/?release=975802&id=2496094&type=1&url=http%3a%2f%2fwww.zecuity.com%2f)™ (sumatriptan iontophoretic transdermal system) is indicated for the acute treatment of migraine with or without aura in adults. Zecuity is a single-use, battery-powered patch applied to the upper arm or thigh during a migraine. Following application and with a press of a button, Zecuity initiates transdermal delivery (through the skin), bypassing the gastrointestinal tract. Throughout the four-hour dosing period, the microprocessor within Zecuity continuously monitors skin resistance and adjusts drug delivery accordingly to ensure delivery of 6.5 mg of sumatriptan, the most widely prescribed migraine medication, with minimal patient-to-patient variability.

**Important Safety Information**Patients should not take ZECUITY if they have heart disease, a history of heart disease or stroke, peripheral vascular disease (narrowing of blood vessels to your legs, arms, stomach or kidney), transient ischemic attack (TIA) or problems with blood circulation, uncontrolled blood pressure, migraines that cause temporary paralysis on one side of the body or basilar migraine, Wolff-Parkinson-White syndrome or other disturbances of heart rhythm. Very rarely, certain people, even some without heart disease, have had serious heart-related problems after taking triptans like ZECUITY.

Patients should not use ZECUITY if they have taken other migraine medications such as ergotamine medications or other triptans in the last 24 hours or if they have taken monoamine oxidase-A (MAO-A) inhibitors within the last 2 weeks.

Patients should not use ZECUITY during magnetic resonance imaging (MRI).

Patients should not use ZECUITY if they have an allergy to sumatriptan or components of ZECUITY or if they have had allergic contact dermatitis (ACD) following use of ZECUITY. If patients develop ACD, they should talk to their healthcare provider before using sumatriptan in another form.

ZECUITY, like other triptans, may be associated with a potentially life-threatening condition called serotonin syndrome, mainly when used together with certain types of antidepressants including serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs).

Patients should tell their healthcare provider before using ZECUITY if they have heart disease or a family history of heart disease, stroke, high cholesterol or diabetes; have gone through menopause; are a smoker; have had epilepsy or seizures or if they are pregnant, nursing or thinking about becoming pregnant.

The most common side effects of ZECUITY are application site pain, tingling, itching, warmth and discomfort. Most patients experience some skin redness after removing ZECUITY. This redness typically goes away in 24 hours.

Please see full [**Prescribing Information**](http://ctt.marketwire.com/?release=975802&id=2496097&type=1&url=http%3a%2f%2fwww.zecuity.com%2fprescribing-info.html) for ZECUITY.

Patients are encouraged to report negative side effects of prescription drugs to the FDA. Visit [**www.FDA.gov/medwatch**](http://ctt.marketwire.com/?release=975802&id=2496100&type=1&url=http%3a%2f%2fwww.fda.gov%2fmedwatch) or call 1-800-FDA-1088.

Patients and healthcare providers interested in more information on Zecuity should visit [**www.zecuity.com**](http://ctt.marketwire.com/?release=975802&id=2496103&type=1&url=http%3a%2f%2fwww.zecuity.com%2f).

**Company to Host Investor Conference Call**NuPathe will host a conference call tomorrow, January 18, 2013, at 8:30 a.m. EST to discuss the FDA approval of Zecuity. A question and answer session will follow NuPathe's remarks. To participate on the live call, please dial 888-329-8862 (domestic) or +1-719-325-2420 (international), and provide the participant passcode 9170164 five to ten minutes before the start of the call. A live audio webcast of the call will be available via the Investor Relations page of the NuPathe website, [**www.nupathe.com**](http://ctt.marketwire.com/?release=975802&id=2496106&type=1&url=http%3a%2f%2fwww.nupathe.com%2f). Please log on through NuPathe's website approximately 10 minutes prior to the scheduled start time.

A replay of the webcast will also be archived on the Company's website for 90 days following the call. A replay of the call will be available for 90 days within a few hours after the call ends. Investors may listen to the replay of the call by dialing 888-203-1112 (domestic) or +1-719-457-0820 (international), with the passcode 9170164.

**About Migraine and Migraine-Related Nausea (MRN)**Migraine is a debilitating neurological disease afflicting a large underserved patient population. Migraine is characterized by headache pain accompanied by associated neurological and GI symptoms including nausea, vomiting, photophobia, and phonophobia.1,2 In the U.S., 31 million adults, with approximately three times as many women as men,3 suffer from migraine.3,4,5 Of the 16 million migraine patients who are diagnosed and treated, approximately eight million experience migraine-related nausea (MRN) in at least half of their migraine attacks.6 These frequent-MRN patients report significantly more migraine symptom burden and experience significantly more interference with work, social and family life.6 Many migraine patients who experience MRN delay or avoid taking orally administered medications due to nausea or vomiting.7

**About NuPathe**NuPathe Inc. is a specialty pharmaceutical company focused on innovative neuroscience solutions for diseases of the central nervous system including neurological and psychiatric disorders. NuPathe's lead product, [**Zecuity**](http://ctt.marketwire.com/?release=975802&id=2496109&type=1&url=http%3a%2f%2fwww.zecuity.com%2f) (sumatriptan iontophoretic transdermal system), has been approved by the FDA for the acute treatment of migraine with or without aura in adults. Zecuity is expected to be available by prescription in the fourth quarter of 2013. In addition to Zecuity, NuPathe has two proprietary product candidates based on its LAD™, or Long-Acting Delivery, biodegradable implant technology that allows delivery of therapeutic levels of medication over a period of months with a single dose. NP201, for the continuous symptomatic treatment of Parkinson's disease, utilizes a leading FDA-approved dopamine agonist, ropinirole, and is being developed to provide up to two months of continuous delivery. NP202, for the long-term treatment of schizophrenia and bipolar disorder, is being developed to address the long-standing problem of patient noncompliance by providing three months of continuous delivery of risperidone, an atypical antipsychotic. NuPathe is actively seeking partnerships to maximize the commercial potential for Zecuity and its other product candidates in the U.S. and territories throughout the world.

For more information about NuPathe, please visit our website and our blog at [**www.nupathe.com**](http://ctt.marketwire.com/?release=958370&id=2323537&type=1&url=http%3a%2f%2fwww.nupathe.com%2f). You can also follow us on StockTwits ([**stocktwits.nupathe.com**](http://ctt.marketwire.com/?release=975802&id=2496112&type=1&url=http%3a%2f%2fstocktwits.nupathe.com%2f)), Twitter ([**twitter.nupathe.com**](http://ctt.marketwire.com/?release=975802&id=2496115&type=1&url=http%3a%2f%2ftwitter.nupathe.com%2f)), SlideShare ([**slideshare.nupathe.com**](http://ctt.marketwire.com/?release=975802&id=2496118&type=1&url=http%3a%2f%2fslideshare.nupathe.com%2f)) and LinkedIn ([**linkedin.nupathe.com**](http://ctt.marketwire.com/?release=975802&id=2496121&type=1&url=http%3a%2f%2flinkedin.nupathe.com%2f)).

**Cautionary Note Regarding Forward-Looking Statements**This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to: the potential benefits of, and commercial opportunity for, Zecuity and NuPathe's other product candidates; partnering plans for Zecuity and NuPathe's other product candidates; the timing of the expected launch and availability of Zecuity; and other statements relating to NuPathe's plans, objectives, expectations and beliefs regarding its future operations, performance, financial condition and other future events. Forward-looking statements are based upon management's current expectations and beliefs and are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results and events to differ materially from those indicated herein including, among others: NuPathe's ability to obtain sufficient capital to launch Zecuity; NuPathe's ability to obtain commercial and development partners for Zecuity and its other product candidates; NuPathe's reliance on third parties to manufacture Zecuity; NuPathe's ability to establish and effectively manage its supply chain; NuPathe's ability to establish effective marketing and sales capabilities; market acceptance among physicians and patients and the availability of adequate reimbursement from third party payors for Zecuity; and the risks, uncertainties and other factors discussed in NuPathe's Annual Report on Form 10-K for the year ended December 31, 2010 and Quarterly Report on Form on Form 10-Q for the quarter ended September 30, 2012 under the caption "Risk Factors" and elsewhere in such reports, which are available on NuPathe's website at [**www.nupathe.com**](http://ctt.marketwire.com/?release=763099&id=377803&type=1&url=http%3a%2f%2fwww.nupathe.com) in the "Investor Relations -- SEC Filings" section. While NuPathe may update certain forward-looking statements from time to time, it specifically disclaims any obligation to do so, whether as a result of new information, future developments or otherwise. You are cautioned not to place undue reliance on any forward-looking statements.

**References**

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