

NuPathe Reports Positive Phase I Results for NP101, a Novel Transdermal Patch for Acute Migraine

Phase I Data Presented at the 50th Annual Scientific Meeting of the American Headache Society Demonstrate That NP101 Delivers Sumatriptan in a Rapid, Predictable, and Consistent Manner

CONSHOHOCKEN, Pa.--(BUSINESS WIRE)--NuPathe Inc., a privately held specialty pharmaceutical company developing innovative products for the treatment of neurological and psychiatric diseases, announced positive Phase I results for NP101, a novel drug-device patch for acute migraine in clinical development.

NP101 combines NuPathe's SmartRelief™ proprietary iontophoretic transdermal technology with sumatriptan, the most widely prescribed treatment for acute migraine in the United States and the active ingredient in Imitrex®.

The study was a Phase I, single center, single-dose, open label, five-way crossover study to compare the pharmacokinetics of two NP101 patch formulations with three FDA approved formulations of Imitrex® (20 mg nasal spray, 100 mg oral tablet, 6 mg subcutaneous injection) in 23 healthy volunteers. Tolerability and safety were assessed for all formulations and skin evaluations were performed for subjects after administration of NP101. Results of the study were presented June 28, 2008 at the American Headache Society meeting in Boston, MA.

The plasma concentrations for NP101 were more consistent among subjects compared to either the 20 mg nasal spray or 100 mg oral tablet formulations. "These findings support the hypothesis that parenteral administration of sumatriptan, either through subcutaneous injection or transdermal delivery, provides a more predictable method of drug delivery by bypassing absorption through the gastrointestinal system," said Mark Pierce, M.D., Ph.D., chief scientific officer at NuPathe who presented the results in Boston.

NP101 was well tolerated. Adverse events for NP101 were generally mild and most resolved without treatment. The most common reported adverse event was pruritus at the patch application site. Upon patch removal, 75% of subjects had minimal or no skin erythema and by 48 hours all subjects had minimal or no erythema. No subject withdrew from the study due to skin irritation.

No subject reported atypical sensations such as flushing or pain and pressure sensations after application of NP101. These adverse events, common with triptans, were reported for both the 6 mg subcutaneous injection and the 100 mg oral tablet at frequencies similar to previously reported data. "This absence of atypical, pain and pressure sensations with the NP101 patch may reflect the lower and more consistent peak plasma concentration levels obtained with NP101 patches when compared to the 100 mg oral tablet and 6 mg subcutaneous injection of Imitrex®," reported Dr. Pierce.

According to Jane Hollingsworth, chief executive officer of NuPathe, “Patients clearly need better options for acute migraine. Triptans, the gold standard in treatment today, can be quite efficacious, but are inadequate for many in their current forms. Many patients experience difficulty taking their medication due to nausea that accompanies their migraine and many experience troublesome side effects from current medications.”

Ms. Hollingsworth also said that “The results of this study are extremely exciting for patients and NuPathe as they demonstrate that NP101 delivers sumatriptan in a rapid, predictable, and consistent manner. Large Phase III clinical trials are being initiated now to evaluate the efficacy and safety of NP101 for the treatment of acute migraine.”

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 NP101, which, if approved, will be the first and only transdermal patch for the treatment of acute migraine, and NP201, a 2-3 month injectable implant for the treatment of Parkinson’s disease.

About NP101

NP101 is a novel drug-device patch in clinical development for acute migraine. Today, only 50% of migraine patients are satisfied with their migraine treatment due to issues such as migraine-associated nausea/vomiting, inconsistent relief, and side-effects. NP101 was designed to address these issues, providing patients with improved ability to take control over their migraine as compared to currently available oral and non-oral options.

NP101 is based on NuPathe’s proprietary SmartRelief™ technology, a breakthrough in iontophoretic patch technology that utilizes low-level electrical energy to transport drugs through the skin.

Imitrex® is a registered trademark of GlaxoSmithKline.

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