

11960 Southwest 144th Street
Miami, Florida 33186
305-253-1916 Toll-Free: 888-253-5099
www.noven.com

## PRESS RELEASE

# NOVEN CONFIRMS FILING OF ABBREVIATED NEW DRUG APPLICATION FOR GENERIC VERSION OF EXELON® (RIVASTIGMINE TRANSDERMAL SYSTEM)

## Paragraph IV Litigation Initiated by Patent Holders

**Miami, FL and New York, NY, April 3, 2013** -- Noven Pharmaceuticals, Inc. today confirmed that it has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) seeking approval to market its rivastigmine transdermal system in 4.6 mg/24 hours and 9.5 mg/24 hours dosage strengths. Noven's product, if approved, would be a generic version of Novartis Pharmaceuticals Corporation's Exelon<sup>®</sup> product.

On February 18, 2013, pursuant to the Hatch-Waxman Act, Noven provided its Paragraph IV Certification Notice Letter advising Novartis and LTS Lohmann Therapie-Systeme AG (holders of certain patents asserted to cover the Exelon® product) that Noven's ANDA had been accepted for review by the FDA.

Under the Hatch-Waxman Act, the filing of an ANDA containing a Paragraph IV Certification gives the patent or NDA holder the right to commence a pre-approval patent lawsuit in the U.S. federal courts. Earlier today, Novartis (and affiliates) and LTS Lohmann filed suit against Noven (and affiliates) in the U.S. District Court for the District of Delaware seeking to prevent Noven from commercializing its rivastigmine transdermal system prior to the expiration of the relevant U.S. patents. Under the Hatch-Waxman Act, this lawsuit prevents final FDA approval of Noven's ANDA for 30 months from the date Novartis and LTS Lohmann received Noven's notice letter, or until the court declares that the asserted patents are invalid, unenforceable or not infringed, whichever occurs earlier.

Exelon<sup>®</sup> (rivastigmine transdermal system) is indicated for the treatment of mild to moderate dementia of the Alzheimer's type, and for the treatment of mild to moderate dementia associated with Parkinson's disease. Exelon<sup>®</sup> is a registered trademark of Novartis AG Corporation.

#### **About Noven**

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven is committed to developing and offering products and technologies that meaningfully benefit patients, its customers and its industry partners. Noven is a stand-alone operating subsidiary of Japan-based Hisamitsu Pharmaceutical Co., Inc., and serves as Hisamitsu's U.S. growth platform in prescription pharmaceuticals. For more information about Noven, visit www.noven.com. For information about Hisamitsu, visit www.hisamitsu.co.jp/english.

#### **Contacts**

Joseph C. Jones Vice President – Corporate Affairs Noven Pharmaceuticals, Inc. 305-253-1916