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## PRESS RELEASE

### NOVEN ANNOUNCES PHASE 3 RESULTS FOR INVESTIGATIONAL NON-HORMONAL THERAPY FOR VASOMOTOR SYMPTOMS

**Miami, FL and New York, NY, December 22, 2011** – Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., today announced top-line results from the first of two planned Phase 3 clinical studies evaluating low-dose mesylate salt of paroxetine (LDMP, formerly referred to as *Mesafem*) for the treatment of vasomotor symptoms (VMS) associated with menopause (hot flashes).

This first study, sponsored by Noven, was a 24 week, multi-center, double-blind, randomized, placebo-controlled Phase 3 efficacy and safety study of LDMP for the treatment of VMS associated with menopause. The primary objective of the study was to assess the safety and efficacy of LDMP for the treatment of menopausal VMS. The primary outcome measures were mean changes in frequency and severity of moderate-to-severe hot flashes from baseline to the fourth and twelfth weeks of the study, as well as maintenance of therapeutic effect at week 24.

All primary outcome measures in the study were achieved with statistical significance. The most frequent adverse events observed in the study were nasopharyngitis, upper respiratory tract infection, headache, nausea and fatigue.

A second, 12 week study of LDMP is underway. If that study meets its primary endpoints, Noven expects to submit a New Drug Application for LDMP to the U.S. Food & Drug Administration in 2012.

#### **About Noven**

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven's business and operations are focused in three principal areas – transdermal drug delivery and related manufacturing, the Novogyne joint venture in women's health, and Noven Therapeutics, Noven's specialty pharmaceutical unit. 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](http://www.noven.com). For information about Hisamitsu, visit [www.hisamitsu.co.jp/english](http://www.hisamitsu.co.jp/english).

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