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PRESS RELEASE

NOVEN COMPLETES PHASE 3 CLINICAL PROGRAM FOR INVESTIGATIONAL NON-HORMONAL THERAPY FOR MENOPAUSAL VASOMOTOR SYMPTOMS

Miami, FL and New York, NY, March 20, 2012 – Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., today announced that it has completed the Phase 3 clinical development program evaluating low-dose mesylate salt of paroxetine (LDMP) for the treatment of vasomotor symptoms (VMS) associated with menopause (hot flashes). The Phase 3 clinical program was comprised of two studies involving an aggregate of 1,180 subjects from more than 130 centers across the U.S.

The first Phase 3 study was a 24 week, multi-center, double-blind, randomized, placebo-controlled efficacy and safety study 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. As announced in December 2011, all primary outcome measures in the first study were achieved with statistical significance.

The second Phase 3 study, which received a Special Protocol Assessment (SPA) by the U.S. Food & Drug Administration (FDA), was completed in February 2012. It was a 12 week, multi-center, double-blind, randomized, placebo-controlled efficacy and safety study of LDMP for 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. All primary outcome measures in the second study were achieved with statistical significance, except for severity at week twelve, which did not reach statistical significance.

In accordance with the SPA, the second study included a responder analysis necessary to demonstrate the clinical meaningfulness of subject response. The first study also included a responder analysis, and in both studies the responder analysis endpoints were achieved with statistical significance. The most frequent adverse events observed in the Phase 3 program were nasopharyngitis, upper respiratory tract infection, diarrhea, headache, nausea and fatigue.

“Our LDMP Phase 3 program has generated what we consider to be a robust clinical data set that will form the basis of our planned New Drug Application (NDA) for this developmental low-dose non-hormonal option to treat menopausal VMS,” said Joel S. Lippman, M.D., Noven’s Executive Vice President – Product Development and Chief Medical Officer. “As next steps, we are scheduling a pre-NDA meeting with the FDA, and expect to submit our NDA for LDMP in 2012.” Noven plans to publish additional details on the LDMP clinical development program at future medical/scientific forums.

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.

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