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PRESS RELEASE

**Noven Announces FDA Advisory Committee Vote on Investigational Low-Dose Mesylate Salt of Paroxetine (LDMP) for Vasomotor Symptoms Associated with Menopause**

**Miami, FL and New York, NY, March 4, 2013 --** Noven Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) Reproductive Health Drugs Advisory Committee voted 10 to 4 that the overall risk/benefit profile of low-dose mesylate salt of paroxetine (LDMP; 7.5 mg/day) is not acceptable to support approval. LDMP is an investigational nonhormonal treatment specifically developed for moderate to severe vasomotor symptoms (VMS) associated with menopause.

Additionally, the committee voted:

- 7 to 7 that, based on pre-specified analyses, there is sufficient evidence to conclude that LDMP is effective in treating moderate to severe VMS associated with menopause; and
- 10 to 4 that, based on pre-specified analyses, there is not sufficient evidence to conclude that the change from baseline in VMS frequency is clinically meaningful to women.

The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the ongoing review of the New Drug Application (NDA) that was submitted for LDMP in August 2012. The scheduled Prescription Drug User Fee Act (PDUFA) action date for LDMP is June 28, 2013.

"As conveyed during Noven's presentation, we believe our clinical trial data support LDMP as a safe, effective nonhormonal treatment option offering clinical benefit to menopausal women," said Joel S. Lippman, M.D., Noven's Executive Vice President – Product Development and Chief Medical Officer. "While we are disappointed in today's outcome, we appreciate the discussion and will work closely with the FDA as it completes its ongoing evaluation."

Moderate to severe VMS affect approximately 24 million menopausal women in the United States and approximately two-thirds are not currently treating their VMS with either prescription medication or over-the-counter supplements. There are currently no FDA-approved nonhormonal options for the treatment of VMS.

**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, with a focus on treatment options for women experiencing menopausal vasomotor symptoms. 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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