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PRESS RELEASE

FDA ACCEPTS NOVEN'S NDA FOR AN INVESTIGATIONAL NONHORMONAL THERAPY FOR MENOPAUSAL VASOMOTOR SYMPTOMS

Miami, FL and New York, NY, November 12, 2012 – Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., today announced that its New Drug Application (NDA) for low-dose mesylate salt of paroxetine (7.5 mg) for the treatment of moderate to severe vasomotor symptoms (hot flashes and night sweats) due to menopause has been accepted for filing by the U.S. Food and Drug Administration (FDA).

The acceptance of the NDA reflects the FDA's determination that the application is sufficiently complete to permit a substantive review. The NDA has been assigned a Prescription Drug User Fee Act (PDUFA) action date of June 28, 2013, which represents the goal date for the FDA to complete its review of the NDA.

In addition, the FDA advised Noven that the NDA for LDMP will be discussed at a meeting of the FDA's Reproductive Health Drugs Advisory Committee tentatively scheduled for March 4, 2013.

Low dose mesylate salt of paroxetine (LDMP) is an investigational oral nonhormonal therapy using 7.5 mg of paroxetine mesylate that was specifically developed for the treatment of vasomotor symptoms due to menopause. Noven submitted the LDMP NDA in August 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 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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