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PRESS RELEASE

NOVEN ANNOUNCES POSITIVE PHASE 3 DATA RESULTS FOR INVESTIGATIONAL LOW-DOSE NONHORMONAL THERAPY FOR THE TREATMENT OF VASOMOTOR SYMPTOMS ASSOCIATED WITH MENOPAUSE

Data from 12- and 24-Week Pivotal Studies Selected to Be Presented at The North American Menopause Society Annual Meeting

October 3, 2012/Miami, FL, New York, NY, and Orlando, FL: Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., today announced positive results from two multicenter, double-blind, randomized, placebo-controlled Phase 3 clinical studies evaluating low-dose mesylate salt of paroxetine (LDMP; 7.5 mg/day) for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause. Menopausal VMS, which comprise hot flashes and night sweats, affect up to 80 percent of women experiencing menopause, and many women report them as the most bothersome symptoms related to the condition. The co-primary endpoints of the studies evaluated weekly reductions in the frequency and severity of VMS associated with menopause in patients taking LDMP versus placebo at Week 4 and Week 12. The 24-week study achieved statistical significance in all co-primary endpoints. The 12-week study also achieved statistical significance for all co-primary endpoints, except for severity of VMS symptoms at Week 12.

"If a patient is unable or unwilling to take hormone therapy, which is currently the only FDA-approved treatment option for menopausal hot flashes and night sweats, these symptoms often go untreated," said James A. Simon, MD, CCD, NCMP, FACOG, clinical professor of obstetrics and gynecology at the George Washington University School of Medicine, Washington, D.C. and study investigator. "The approval of a nonhormonal therapy would be an important milestone to expand available options for women seeking treatment for VMS associated with menopause."

Phase 3 data from 12-week and 24-week studies are being presented at the 23rd Annual Meeting of The North American Menopause Society on October 4 and 5, respectively. The 24-week study was one of four abstracts selected for oral presentation at the meeting's Top Scoring Scientific Abstract Session.

"Women often report hot flashes as the most common symptom associated with menopause, yet, there has been a decline in the use of hormone therapy among women seeking treatment for menopausal VMS," said Andrew M. Kaunitz, MD, professor and associate chair, department of obstetrics and gynecology, University of Florida College of Medicine, Jacksonville and study investigator. "LDMP was specifically developed for the treatment of menopausal VMS. It appears to be effective and well tolerated, and, if approved by the FDA, it could be the first nonhormonal option available for women."

In August 2012, Noven Pharmaceuticals, Inc., submitted a New Drug Application to the Food and Drug Administration (FDA) for LDMP for the treatment of moderate to severe VMS associated with menopause.

Safety and Efficacy of Low-dose Mesylate Salt of Paroxetine for the Treatment of Vasomotor Symptoms Associated with Menopause: A 24-Week, Randomized, Placebo-controlled Phase 3 Study: (Oral Presentation at the 23rd Annual Meeting of The North American Menopause Society – 11:30-11:45 a.m. ET – October 5, 2012 – Top Scoring Abstracts Session)

This 24-week, multicenter, double-blind, randomized, placebo-controlled study of LDMP evaluated weekly reductions in the frequency and severity of moderate to severe VMS in 568 women age 40 and older with an average of more than 7 to 8 moderate to severe hot flashes daily or 50-60 moderate to severe hot flashes per week for at least 30 days prior to the study.

Women who met eligibility criteria were randomized to receive either 7.5 mg of LDMP or placebo once daily at bedtime for 24 weeks. Participants recorded the number and severity of hot flashes in electronic daily diaries. Co-primary endpoints were mean weekly changes in the frequency of moderate to severe VMS from baseline to Weeks 4 and 12 and mean weekly changes in severity of moderate to severe VMS from baseline to Weeks 4 and 12. A responder analysis was conducted to evaluate persistence of treatment benefit at Week 24, where a responder was defined as a subject with greater than or equal to a 50 percent reduction in VMS frequency from baseline to Week 24.

Results showed, at Week 4, that women taking LDMP had a mean weekly reduction from baseline of 28.9 fewer hot flashes, compared to a mean weekly reduction from baseline of 19.0 fewer hot flashes for placebo-treated patients ($p<0.0001$). At Week 12, results showed that women taking LDMP had a mean weekly reduction from baseline of 37.2 fewer hot flashes, compared to a mean weekly reduction from baseline of 27.6 fewer hot flashes for placebo-treated patients ($p=0.0001$).

Results also showed that mean weekly reductions in VMS severity were also significantly greater for LDMP than for placebo at Week 4 (–0.089 and –0.056, respectively; $p=0.0452$) and at Week 12 (–0.123 and –0.067, respectively; $p=0.0114$).

In addition, significantly more women treated with LDMP than placebo were responders at Week 24 (47.5 percent compared to 36.3 percent, respectively; $p=0.0066$), demonstrating persistence of treatment benefit.

Hot flash composite scores were also used to evaluate hot flash severity of moderate and severe menopausal VMS. Mean weekly reductions in VMS hot flash composite scores (moderate and severe) from baseline were significantly greater for LDMP than placebo at Week 4 (–76.08 and –49.50 respectively; $p<0.0001$) and at Week 12 (–97.73 and –70.20 respectively; $p=0.0001$).

The most commonly reported adverse events in the LDMP treatment group were nausea and bronchitis.

Safety and Efficacy of Low-dose Mesylate Salt of Paroxetine for the Treatment of Vasomotor Symptoms Associated with Menopause: A 12-Week, Randomized, Placebo-controlled Phase 3 Study (Poster Presentation at the 23rd Annual Meeting of The North American Menopause Society – 6-7 p.m. ET – October 4, 2012)

This 12-week, multicenter, double-blind, randomized, placebo-controlled study of LDMP evaluated weekly reductions in the frequency and severity of moderate to severe VMS in 606 women age 40 and older with an average of more than 7 to 8 moderate to severe hot flashes daily or 50-60 moderate to severe hot flashes per week for at least 30 days prior to the study.

Women who met eligibility criteria were randomized to receive either 7.5 mg of LDMP or placebo once daily at bedtime for 12 weeks. Participants recorded the number and severity of hot flashes in electronic daily diaries. Co-primary endpoints were mean weekly changes in the frequency of moderate to severe VMS from baseline to Weeks 4 and 12 and mean weekly changes in severity of moderate to severe VMS from baseline to Weeks 4 and 12.

Results showed, at Week 4, that women taking LDMP had a mean weekly reduction from baseline of 33.0 fewer hot flashes, compared to a mean weekly reduction from baseline of 23.5 fewer hot flashes for placebo-treated patients ($p<0.0001$). At Week 12, results showed that women taking LDMP had a mean weekly reduction from baseline of 43.5 fewer hot flashes, compared to a mean weekly reduction from baseline of 37.3 fewer hot flashes for placebo-treated patients ($p=0.0090$).

Results also showed that mean weekly reductions in VMS severity from baseline were significantly greater for LDMP than placebo at Week 4 (–0.09 and –0.05, respectively; $p=0.0048$) but not at Week 12 (–0.10 and –0.09, respectively; $p=0.2893$).

Hot flash composite scores were also used to evaluate hot flash severity of moderate and severe menopausal VMS. Mean weekly reductions in VMS hot flash composite scores (moderate and severe) from baseline were significantly greater for LDMP than placebo at Week 4 (–85.51 and –60.83 respectively; $p<0.0001$) and at Week 12 (–111.9 and –96.85 respectively; $p=0.0063$).

The most frequently reported adverse events in the LDMP group were dizziness and fatigue.

About Menopause

Menopause is a natural part of every woman's life and is better understood and more openly discussed than it was years ago. The average age of a woman entering menopause is 51 years old. Menopause is typically confirmed when a woman has missed her menstrual periods for 12 consecutive months. During perimenopause, the transition period before a woman reaches menopause, estrogen levels gradually decline and periods may become irregular. The severity of symptoms associated with going through menopause varies from woman to woman. Symptoms associated with menopause include hot flashes, night sweats and vaginal dryness and atrophy, with hot flashes being the most common symptoms. Because the journey is unique for each

woman, it is important for women going through menopause to have a thorough discussion about the transition with their doctors and determine if treatment is appropriate.

About LDMP
LDMP, formerly referred to as *Mesafem*, is an oral low-dose nonhormonal therapy (7.5 mg once daily taken at bedtime) specifically developed by Noven for the treatment of moderate to severe VMS associated with menopause. More information about clinical trials involving LDMP can be found at www.clinicaltrials.gov. If approved by the FDA, LDMP may be a potential nonhormonal therapy option for women seeking treatment for VMS associated with menopause. Hormone replacement therapy is currently the only FDA-approved treatment for VMS. If patients are not appropriate for or not interested in initiating or continuing hormone therapy, these symptoms often go untreated.

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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