NOVEN PHARMACEUTICALS, INC.
350 Fifth Avenue, 37th Floor
New York, NY 10118
Toll-Free: 888-253-5099
www.noven.com

PRESS RELEASE

Menopause Publishes Pivotal Trial Results for Brisdelle™ (Paroxetine) Capsules, an FDA-Approved Non-Hormonal Therapy for Vasomotor Symptoms Associated with Menopause

Miami, FL and New York, NY, September 18, 2013 – Noven Pharmaceuticals, Inc., today announced the publication of results from its two Phase 3 clinical studies in *Menopause*, the peer-reviewed, scientific journal of The North American Menopause Society. Brisdelle™, paroxetine capsules, 7.5 mg/day, was approved by the United States Food and Drug Administration in June 2013, for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause, commonly referred to as hot flashes and night sweats. Brisdelle™ was specifically developed for and studied in women who experience moderate to severe VMS and is the first and only FDA-approved non-hormonal therapy clinically proven to treat moderate to severe VMS. Brisdelle™ will be available in pharmacies beginning November 2013.

"The publication of these data are timely and important because approximately 24 million women in the U.S. are affected by moderate to severe hot flashes and night sweats, yet two-thirds are not currently being treated," said Joel Lippman, M.D., FACOG, Noven's Executive Vice President – Product Development and Chief Medical Officer. "Prior to the approval of Brisdelle, physicians did not have a clinically proven and FDA-approved, non-hormonal treatment option to offer women."

Menopause published the 12-week and the 24-week multicenter, double-blind, randomized, placebo-controlled Phase 3 clinical studies evaluating Brisdelle™ for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause. The co-primary endpoints of the studies evaluated weekly reductions in the frequency and severity of VMS associated with menopause in patients taking Brisdelle™ versus placebo at Week 4 and Week 12. Persistence of treatment benefit was also evaluated at 24 weeks in the 24-week study.

Brisdelle™ was studied in one Phase 2 and two Phase 3 randomized, placebo-controlled trials in 1,276 women with moderate to severe VMS associated with menopause and clinically proven to reduce the frequency and severity of hot flashes and night sweats. The most common adverse reactions, defined as those experienced by at least 2 percent of patients taking Brisdelle™ compared to placebo were headache (6.3 vs. 4.8 percent), fatigue/malaise/lethargy (4.9 vs. 2.8 percent) and nausea/vomiting (4.3 vs. 2.3 percent). Brisdelle™ shares paroxetine warnings and precautions, including the Boxed Warning about Suicidal Thoughts or Behaviors, as it contains a lower dose of paroxetine, a medicine also used to treat a number of psychiatric disorders. The lower dose of paroxetine in Brisdelle™ has not been studied in any psychiatric conditions and Brisdelle™ is not approved for any psychiatric uses.

About the Studies

Effect of Treatment on VMS Frequency and Severity

In the 12-week study, mean weekly reductions in VMS frequency were significantly greater for Brisdelle™ than for placebo at Week 4 (–33.0 and –23.5, respectively; $p < 0.0001$) and at Week 12 (–

43.5 and –37.3, respectively; p = 0.0090). In the 24-week study, mean weekly reductions in VMS frequency were significantly greater for Brisdelle™ than for placebo at Week 4 (–28.9 and –19.0, respectively; $p < 0.0001$) and at Week 12 (–37.2 and –27.6, respectively; p = 0.0001).
In the 12-week study, mean weekly reductions in VMS severity from baseline were significantly greater for Brisdelle™ than for 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). In the 24-week study, mean weekly reductions in VMS severity were significantly greater for Brisdelle™ than for placebo at Week 4 (–0.09 and –0.06, respectively; p = 0.0452) and at Week 12 (–0.12 and –0.07, respectively; p = 0.0114).

To view the full study published online in *Menopause*, the peer-reviewed, scientific journal of The North American Menopause Society please click here.

About Brisdelle™
Brisdelle™ (paroxetine capsules, 7.5 mg/day) was approved by the FDA in June 2013 for the treatment of moderate to severe VMS associated with menopause. In clinical development, Brisdelle™ was referred to as low-dose mesylate salt of paroxetine (LDMP). Prior to the approval of Brisdelle™, hormone therapy was the only FDA-approved treatment for VMS. Many women are unable or unwilling to take hormone therapy to treat their VMS associated with menopause, often leaving symptoms untreated.

To learn more about Brisdelle™, to register for updates, and for the full Prescribing Information, including the Medication Guide, visit www.Brisdelle.com and read the Important Safety Information below.

INDICATION
BRISDELLE™ (Paroxetine) Capsules is a prescription medicine used to reduce moderate to severe hot flashes associated with menopause.

BRISDELLE contains a lower dose of paroxetine, a medicine also used to treat a number of psychiatric disorders. The lower dose of paroxetine in BRISDELLE has not been studied in any psychiatric conditions and BRISDELLE is not approved for any psychiatric uses.

IMPORTANT SAFETY INFORMATION
What is the most important information I should know about BRISDELLE?

Call your healthcare provider right away if you have any of the following symptoms, or go to the nearest emergency room:

Suicidal thoughts or actions:

- **BRISDELLE, and related antidepressant medicines, may increase suicidal thoughts or actions within the first few months of treatment.**
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.
- Watch for these changes and call your healthcare provider right away if you notice:

- New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.

- Pay particular attention to such changes when BRISDELLE is started.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Serotonin Syndrome: Nervousness, hallucinations, coma, or other changes in mental status; coordination problems or small movements of the muscles that you cannot control; racing heartbeat, high or low blood pressure; sweating or fever; nausea, vomiting, or diarrhea; muscle rigidity; dizziness; flushing; tremors; seizures.

Reduced effectiveness of tamoxifen: Tamoxifen (a medicine used to treat breast cancer) may not work as well if it is taken at the same time as BRISDELLE. If you are taking tamoxifen, tell your healthcare provider before starting BRISDELLE.

Abnormal bleeding: BRISDELLE may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin, or non-steroidal anti-inflammatory drugs (NSAIDs), like ibuprofen, naproxen, or aspirin.

Low salt (sodium) levels in the blood: Elderly people may be at greater risk for this. Symptoms may include: headache; weakness or feeling unsteady; confusion, problems concentrating or thinking or memory problems.

Bone Fractures: Women who take BRISDELLE may have a higher risk of bone fractures.

Manic episodes: Greatly increased energy; severe trouble sleeping; racing thoughts; reckless behavior; unusually grand ideas; excessive happiness or irritability; talking more or faster than usual.

Seizures or convulsions.

Restlessness: Women who take BRISDELLE may feel an inner restlessness, nervousness, or be unable to sit still or stand still especially when they start taking BRISDELLE.

Visual symptoms.

Who should not take BRISDELLE?
Do not take BRISDELLE if you:

- **Take a Monoamine Oxidase Inhibitor (MAOI)**, including the antibiotic linezolid. Unless directed to do so by your physician, do not take an MAOI within 14 days of stopping BRISDELLE and do not start BRISDELLE if you stopped taking an MAOI in the last 14 days. **People who take BRISDELLE close in time to an MAOI may have serious or life-threatening side effects.**
- **Take thioridazine or pimozide.** Do not take thioridazine or pimozide together with BRISDELLE because this can cause serious heart problems or sudden death.
- **Are pregnant**. BRISDELLE is not for pregnant women. Paroxetine can harm your unborn baby.

What should I tell my healthcare provider before starting BRISDELLE?

Before starting BRISDELLE, tell your healthcare provider if you:

- Have liver or kidney problems; bipolar disorder or mania; low sodium levels in your blood; glaucoma (high pressure in the eye); have or had seizures, convulsions, or bleeding problems; have any other medical conditions; **are breastfeeding or plan to breastfeed**.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines such as migraine headache medication (triptans), other antidepressants and antipsychotics, vitamins, and herbal supplements.

If you take BRISDELLE, you should not take any other medicines that contain paroxetine.

What should I avoid while taking BRISDELLE?
You should not drive, operate heavy machinery, or do other dangerous activities until you know how BRISDELLE affects you.

What are the most common side effects of BRISDELLE?
The most common possible side effects of BRISDELLE include: headache; tiredness; nausea and vomiting.

Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of BRISDELLE.

Please read the Medication Guide within the full Prescribing Information before taking BRISDELLE. **Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.**

About Menopause
During perimenopause, the transition period before a woman reaches menopause, estrogen levels gradually decline and periods may become irregular. Natural menopause is typically confirmed when a woman has missed her menstrual periods for 12 consecutive months. The average age of a woman entering natural menopause is 51 years old. Some women may undergo surgical menopause, which can take place at any age. Surgical menopause occurs when both ovaries are surgically removed (called an oophorectomy), often along with the uterus (called a hysterectomy). Because ovaries are the body's main source of estrogen production, a woman enters menopause when they are removed. The severity of symptoms associated with menopause varies from woman to woman. Hot flashes and night sweats are the most common symptoms of menopause. 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 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.

Contacts

Joseph C. Jones
Vice President – Corporate Affairs
Noven Pharmaceuticals, Inc.
305-253-1916

Ashley Buford
Director
GolinHarris
212-373-6045