

**PRESS RELEASE**

**Noven Pharmaceuticals Announces Issuance of New U.S. Patent, an Important Addition to its Intellectual Property Portfolio for Brisdelle® (Paroxetine) Capsules, 7.5 mg**

**MIAMI and NEW YORK, March 25, 2014** – Noven Pharmaceuticals, Inc. today announced the U.S. Patent and Trademark Office has issued U.S. Patent No. 8,658,663, entitled “Method Of Treating Thermoregulatory Dysfunction With Paroxetine.” This method of use patent covers the company’s Brisdelle® (paroxetine) capsules, 7.5 mg, for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause, commonly referred to as hot flashes.

The patent, listed recently in the U.S. Food and Drug Administration (FDA)’s Orange Book, provides additional protection until April 2029, six years beyond the last to expire of the other listed Brisdelle patents.

Brisdelle is the first and only non-hormonal treatment specifically studied and FDA-approved for moderate to severe VMS associated with menopause. Although it has the same ingredient as the antidepressant paroxetine, Brisdelle is a lower dose (7.5 mg) that is not approved to treat depression or any other psychiatric condition. The method of use patent covers the use of paroxetine at this lower dose in treating moderate to severe VMS associated with menopause as a novel approach.

**About Brisdelle®**

Brisdelle® (paroxetine) capsules, 7.5 mg, was approved by the FDA in June 2013 for the treatment of moderate to severe VMS associated with menopause, commonly referred to as hot flashes. 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.

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 was clinically proven to reduce frequency and severity of these symptoms. Brisdelle has similar warnings and precautions to the higher doses of paroxetine used to treat a number of psychiatric disorders, including a Boxed Warning about Suicidal Thoughts or Behaviors. 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).

Visit [www.Brisdelle.com](http://www.Brisdelle.com) to learn more about Brisdelle, hot flashes, and savings and support, and for the full [Prescribing Information](#), including the Medication Guide.

**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.

**Call your healthcare provider right away or go to the nearest emergency room if you have any of the following symptoms, especially if they are new, worse, or worry you:**

- Attempts to commit suicide; acting on dangerous impulses; acting aggressive or violent; thoughts about suicide or dying; new or worse depression; new or worse anxiety or panic attacks; feeling agitated, restless, angry, or irritable; trouble sleeping; an increase in activity or talking more than what is normal for you or other unusual changes in behavior or mood.

**Serotonin Syndrome. This condition can be life-threatening and may include:** 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).** Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
  - Do not take an MAOI within 14 days of stopping BRISDELLE unless directed to do so by your healthcare provider.
  - Do not start BRISDELLE if you stopped taking an MAOI in the last 14 days unless directed to do so by your healthcare provider.
  - **People who take BRISDELLE close in time to an MAOI may have serious or life-threatening side effects. Get medical help right away if you have any of these symptoms:**
    - High fever, uncontrolled muscle spasms, stiff muscles, rapid changes in heart rate or blood pressure, confusion, loss of consciousness (pass out).
- **Take thioridazine or pimozide.** Do not take thioridazine or pimozide together with BRISDELLE because this can cause serious heart problems or sudden death.
- **Are allergic to paroxetine or any of the ingredients in BRISDELLE.**
- **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, including Paxil<sup>®</sup>, Paxil CR<sup>®</sup>, and Pexeva<sup>®</sup>.

### **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 are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 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 are the most common symptom 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](http://www.noven.com). For information about Hisamitsu, visit [www.hisamitsu.co.jp/english](http://www.hisamitsu.co.jp/english).

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