

**PRESS RELEASE**

**Noven Receives FDA Approval of a New Indication with a New Dose for Minivelle®  
(Estradiol Transdermal System)**

*Minivelle now approved for prevention of postmenopausal osteoporosis at all doses*

*New 0.025 mg/day Minivelle, for osteoporosis only, is the smallest estrogen patch ever*

**Miami, FL and New York, NY, September 24, 2014** -- Noven Pharmaceuticals, Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved a new indication with a new dose of Minivelle (estradiol transdermal system) for the prevention of postmenopausal osteoporosis. The FDA initially approved Minivelle in October 2012 to treat moderate to severe vasomotor symptoms (VMS) due to menopause, commonly known as hot flashes. With this new approval, women who are using Minivelle to treat their VMS symptoms have the benefit of also helping to prevent osteoporosis.

The new 0.025 mg/day patch is 33% smaller than Minivelle 0.0375 mg/day that is already only about the size of a dime, the planet's smallest estrogen therapy patch ever. Minivelle is now approved with five dosing options – 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day, with the newly approved, lower dose of 0.025 mg/day indicated for the prevention of postmenopausal osteoporosis only. If a patient uses Minivelle only to prevent osteoporosis from menopause, they should talk with their healthcare provider about whether a different treatment or medicine without estrogens might be better for them.

“Noven is deeply committed to offering therapies that address women’s menopausal health,” said Joel Lippman, M.D., FACOG, Noven’s Executive Vice President – Product Development and Chief Medical Officer. “We’re pleased that we now have an additional indication and the new dosage strength available for Minivelle to allow women and their doctors to individualize their treatment to best fit their needs.”

The new lower dose of 0.025 mg/day is expected to be available in pharmacies in January 2015. Noven offers a savings program to help reduce the Minivelle co-pay for eligible patients. Eligible patients pay no more than \$15 each month for up to 12 uses on their Minivelle prescriptions. Restrictions may apply. For more information, including full terms and conditions, visit [www.MINIVELLE.com](http://www.MINIVELLE.com).

**About Minivelle®**

Minivelle is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause, commonly known as hot flashes, and the prevention of postmenopausal osteoporosis. If a patient uses Minivelle only to prevent osteoporosis from menopause, they

should talk with their healthcare provider about whether a different treatment or medicine without estrogens might be better for them.

Minivelle is bioequivalent to Vivelle® (estradiol transdermal system), which demonstrated safety and efficacy for the treatment of moderate to severe vasomotor symptoms due to menopause, commonly known as hot flashes. Efficacy and safety of Vivelle in the prevention of postmenopausal osteoporosis have been demonstrated in a 2-year double-blind, randomized, placebo-controlled, parallel group study. No clinical trials were conducted with Minivelle. The most commonly reported adverse events for Vivelle (≥5 percent) were headache, breast tenderness, back and limb pain, common cold, upset stomach, nausea, inflammation of the sinuses, and irregular vaginal bleeding or spotting.

Minivelle contains bioidentical estradiol, a plant-based estrogen that is chemically identical to the estrogen produced naturally by a woman's body. Minivelle is designed to release estradiol continuously upon application, increasing estradiol levels above baseline within four hours, and, with Noven's transdermal drug delivery technology, allows for efficient delivery of estradiol through the skin, bypassing first pass metabolism. This does not mean that Minivelle is safer or more effective than other hormone therapies.

Minivelle is round with smooth, curved edges that may help prevent lifting or snagging associated with everyday wear and stays in place during showering and exercising. It leaves almost no sticky residue and causes almost no skin irritation. During clinical pharmacology studies with Minivelle, 35 percent or less of subjects experienced barely perceptible erythema.

At 1.65 cm<sup>2</sup>, the new 0.025 mg/day patch is 33% smaller than Minivelle 0.0375 mg/day that is already only about the size of a dime. Minivelle is now approved with five dosing options – 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day with the newly approved, lower dose of 0.025 mg/day indicated for the prevention of postmenopausal osteoporosis only.

Please read the Important Safety Information below and for more information, including the full Prescribing Information, visit [www.MINIVELLE.com](http://www.MINIVELLE.com).

## **INDICATION**

MINIVELLE® (estradiol transdermal system) is a prescription medicine patch that contains estradiol (an estrogen hormone). MINIVELLE is used to treat moderate to severe hot flashes due to menopause and for the prevention of postmenopausal osteoporosis.

If you use MINIVELLE only to prevent osteoporosis from menopause, talk with your healthcare provider about whether a different treatment or medicine without estrogens might be better for you.

## **IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about MINIVELLE (an estrogen hormone)?**

- **Using estrogen-alone may increase your chance of getting cancer of the uterus (womb). Report any unusual vaginal bleeding right away while you are using MINIVELLE. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause**
- **Do not use estrogen-alone to prevent heart disease, heart attacks, strokes, or dementia (decline in brain function)**
- **Using estrogen-alone may increase your chances of getting strokes or blood clots**
- **Using estrogen-alone may increase your chance of getting dementia, based on a study of women 65 years of age or older**
- **Do not use estrogens with progestins to prevent heart disease, heart attacks, strokes, or dementia**
- **Using estrogens with progestins may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots**
- **Using estrogens with progestins may increase your chance of getting dementia, based on a study of women 65 years of age or older**
- **You and your healthcare provider should talk regularly about whether you still need treatment with MINIVELLE**

MINIVELLE should not be used if you have unusual vaginal bleeding, currently have or have had certain cancers, had a stroke or heart attack, currently have or have had blood clots, currently have or have had liver problems, have been diagnosed with a bleeding disorder, are allergic to MINIVELLE or any of its ingredients, or think you may be pregnant.

The most common side effects that may occur with MINIVELLE are headache, breast tenderness, back and limb pain, common cold, upset stomach, nausea, inflammation of the sinuses and irregular vaginal bleeding or spotting.

MINIVELLE should be used at the lowest effective dose and for the shortest duration consistent with your treatment goals and risks.

### **About Noven**

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products, with a therapeutic focus in women's health, and substantial expertise in transdermal drug delivery. 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](http://www.noven.com). For information about Hisamitsu, visit [www.hisamitsu.co.jp/english](http://www.hisamitsu.co.jp/english).

Vivelle® is a registered trademark of Novartis AG.

###

**Contacts**

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

Ashley Buford  
Director  
Golin  
212-373-6045