



11960 Southwest 144th Street  
Miami, Florida 33186  
305-253-1916 ▼ Toll-Free: 888-253-5099  
www.noven.com

## PRESS RELEASE

### NOVEN ACQUIRES COMMERCIAL RIGHTS TO MINIVELLE™ (ESTRADIOL TRANSDERMAL SYSTEM)

**Miami, FL and New York, NY, December 3, 2012** – Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., today announced that it has acquired commercial rights to Minivelle™ (estradiol transdermal system) in the U.S. and Canada.

Noven acquired the rights from Novogyne Pharmaceuticals, a women’s health joint venture between Noven and Novartis Pharmaceuticals Corporation. Financial terms of the transaction were not disclosed.

The U.S. Food and Drug Administration approved Minivelle™ for the treatment of moderate to severe vasomotor symptoms due to menopause on October 29, 2012. Noven expects that Minivelle™ will be available in U.S. pharmacies in the first quarter of 2013.

Noven will market and sell Minivelle™ through the Women’s Health unit of its subsidiary, Noven Therapeutics, LLC. Noven developed the Minivelle™ patch using its proprietary DOT Matrix™ transdermal delivery technology, and the product will be manufactured at Noven’s facility in Miami, Florida.

#### INDICATION

MINIVELLE™ (estradiol transdermal system) is indicated for treatment of moderate to severe vasomotor symptoms due to menopause.

#### IMPORTANT SAFETY INFORMATION

**WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER AND PROBABLE DEMENTIA**

*See full prescribing information for complete boxed warning.*

**Estrogen-Alone Therapy**

- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens
- Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia
- The Women’s Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT)
- The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

### **Estrogen Plus Progestin Therapy**

- **Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia**
- **The WHI estrogen plus progestin substudy reported increased risks of stroke, DVT, pulmonary embolism (PE), and myocardial infarction (MI)**
- **The WHI estrogen plus progestin substudy reported increased risks of invasive breast cancer**
- **The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older**

Estrogens should not be used in women with undiagnosed abnormal genital bleeding; known, suspected, or history of breast cancer; known or suspected estrogen-dependent neoplasia; active deep vein thrombosis, pulmonary embolism, or history of these conditions; active or history of arterial thromboembolic disease (e.g., stroke or MI); known anaphylactic reaction or angioedema with MINIVELLE™, liver dysfunction or disease; known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders; or known or suspected pregnancy.

Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman. Postmenopausal women should be re-evaluated periodically as clinically appropriate to determine if treatment is still necessary.

Estrogens increase the risk of gallbladder disease. Discontinue estrogen if severe hypercalcemia, loss of vision, severe hypertriglyceridemia or cholestatic jaundice occurs. Monitor thyroid function in women on thyroid replacement therapy.

In clinical trials with Vivelle® (estradiol transdermal system), the most common side effects (≥5%) were headache, breast tenderness, back pain, pain in limb, nasopharyngitis, dyspepsia, nausea, sinusitis, and intermenstrual bleeding.

### **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](http://www.noven.com). For information about Hisamitsu, visit [www.hisamitsu.co.jp/english](http://www.hisamitsu.co.jp/english).

### **Contacts**

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

Samantha Schwarz  
Executive Director  
GolinHarris  
312-729-4370