

The logo for Upsher-Smith Pharmaceuticals, featuring the company name in white, bold, sans-serif capital letters inside a black rectangular box with a thin white border.

Pharmaceuticals Since 1919

**New Analyses Indicate that Divigel® (estradiol gel) 0.1%
is a Valuable Option for Certain Postmenopausal Women with Hot Flashes
- Transdermal Estrogen Analyses Continue
to Show Benefits of Hormone Therapy Use in Menopausal Women -**

MAPLE GROVE, MN, September 25, 2008 – Upsher-Smith Laboratories, Inc. today announced that clinical abstracts featuring Divigel® (estradiol gel) 0.1% were presented at the North American Menopause Society's 19th Annual Meeting in Orlando, Florida. Divigel® is a transdermal estrogen therapy that was approved by the FDA in June 2007. It offers the lowest approved dose of estradiol gel for the treatment of moderate to severe hot flashes associated with menopause.

“These analyses indicate that Divigel® (estradiol gel) 0.1% is a valuable alternative for certain postmenopausal women with moderate to severe hot flashes,” said Ronald Ackerman, MD, FACOG, CEO and principal investigator, Comprehensive Clinical Trials. “Analyses like these are crucial to further educate women about the benefits of hormone therapy for the management of hot flashes.”

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The first abstract presented at the meeting was a post-hoc analysis of 488 patients from a Phase III clinical trial to determine the effect of uterine status (intact, absent) plus Divigel[®] (1.0 g/day, 0.5 g/day, 0.25 g/day) compared to placebo on the change from baseline to week 12 in the frequency and severity of hot flashes. This study revealed that Divigel[®] is an effective treatment for the relief of moderate to severe hot flashes in postmenopausal women regardless of ovarian or uterine status.

The second abstract used the same patient population to evaluate the effect of age (<50 years, 50-59 years, ≥60 years) and age plus Divigel[®] (1.0 g/day, 0.5 g/day, 0.25 g/day) combined compared to placebo on the change from baseline to week 12 in frequency and severity of moderate to severe hot flashes. This study revealed that Divigel[®] is an effective treatment for relief of hot flashes in postmenopausal women of any age; however, the effects of treatment may be most appreciable in women over age 50.

The third abstract used the same patient population to investigate the effect of body mass index (≤ 30 , > 30) and BMI plus Divigel[®] (1.0 g/day, 0.5 g/day, 0.25 g/day) combined compared to placebo on the change from baseline to week 12 in the frequency and severity of hot flashes. Results indicated that body mass index had a significant interaction with treatment on both the frequency ($P = 0.036$) and severity ($P = 0.019$) of hot flashes, whereas, normal/overweight women experienced a significant reduction in both the frequency and severity of hot flashes ($P < 0.0001$).

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“Estrogen therapies, such as Divigel[®], continue to be the gold standard for the management of hot flashes and transdermal therapies, in particular, are emerging as safe and effective alternatives for women experiencing the most common physical sign of menopause,” said Dr. Ackerman.

The estrogen in Divigel[®] is derived from plant sources and is identical to the primary estrogen produced by a woman’s ovaries before menopause. Divigel[®] is a quick-drying gel that is odorless when dry, and is available in convenient, individual-use packets. One packet of gel is applied daily to an area that measures approximately 5 x 7 inches on the thigh, the smallest application area compared to all other available gel or lotion estrogen products. Divigel[®] also offers dosing flexibility with three different strengths (0.25 mg estradiol/day, 0.5 mg estradiol/day and 1.0 mg estradiol/day) to individualize treatment for each woman.

For more information, call 1-800-654-2299 or visit www.divigelus.com.

Important Safety Information

Estrogens should not be used in women with undiagnosed abnormal vaginal bleeding; known, suspected, or history of breast cancer; known or suspected estrogen-dependent neoplasia; active or history of deep vein thrombosis (DVT) or pulmonary embolism; active or recent arterial thromboembolic disease; liver dysfunction or disease; known hypersensitivity to Divigel[®] ingredients; or known or suspected pregnancy.

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Estrogens increase the risk of endometrial cancer. Close clinical surveillance of all women taking estrogens is important. Adequate diagnostic measures, including endometrial sampling when indicated, should be undertaken to rule out malignancy in all cases of abnormal vaginal bleeding. There is no evidence that the use of “natural” estrogens results in a different endometrial risk profile than synthetic estrogens at equivalent doses. Long-term continuous administration of estrogen, with or without progestin, has also shown increased risk of breast and ovarian cancers.

Cardiovascular and other risks. Estrogens with or without progestins should not be used for the prevention of cardiovascular disease or dementia.

The Women’s Health Initiative (WHI) studies reported increased risks of stroke and DVT in postmenopausal women (50 to 79) during 6.8 and 7.1 years of treatment, respectively, with daily oral conjugated estrogens (CE) 0.625 mg alone, relative to placebo, and increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and DVT in

postmenopausal women (50 to 79) during 5.6 years of treatment with daily oral CE 0.625 mg and medroxyprogesterone acetate (MPA) 2.5 mg, relative to placebo.

The WHI Memory Study (WHIMS) reported increased risk of developing probable dementia in postmenopausal women 65 or older during 5.2 years of treatment with daily oral CE 0.625 mg alone and during 4 years of treatment with daily oral CE 0.625 mg and MPA 2.5 mg, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women.

These risks should be assumed to be similar for other combinations and dosage forms of estrogens and progestins.

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Less common but serious risks reported with estrogen therapy include certain cardiovascular disorders, certain malignant neoplasms, dementia, gallbladder disease, hypercalcemia and visual abnormalities. The most frequently reported adverse events in Divigel® clinical trials were nasopharyngitis, upper respiratory tract infection, vaginal mycosis, breast tenderness and metrorrhagia.

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.

This safety information is not all-inclusive. Please see full prescribing information, including black box and other warnings. For more information, call 800-654-2299 or visit www.divigelus.com.

Orion Corporation (OMX: ORNAV, ORNBV) has a licensing agreement with Upsher-Smith Laboratories for the development of Divigel® in the United States. Orion is one of the leading pharmaceutical companies in northern Europe through its development, manufacturing and marketing of pharmaceuticals, active pharmaceutical ingredients and diagnostic tests for global markets. The core therapeutic areas in Orion's product and research strategy are central nervous system disorders, cardiology, critical care and hormonal and urological therapies.

Upsher-Smith Laboratories, Inc. is a rapidly growing pharmaceutical company that manufactures and markets both prescription and consumer products. Privately held since 1919, the company strives to recognize the unmet healthcare needs of our customers. Upsher-Smith prides itself in providing safe, effective, and economical therapies to the ever-challenged healthcare environment. For additional information about Upsher-Smith, visit www.upsher-smith.com.

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