



News Release

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FOR IMMEDIATE RELEASE

New Data: Efficacy and Responder Analyses of Divigel[®] (estradiol gel) 0.1 percent for the Treatment of Menopause

Data shows a very high percentage of women responded favorably to a bioidentical and FDA approved hormone therapy for hot flashes

MAPLE GROVE, Minnesota (June 30, 2009) Upsher-Smith Laboratories, Inc. presented the results of a secondary analysis to determine the response rates to three doses of transdermal Divigel[®] (estradiol gel) 0.1 percent at the recent 57th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists (ACOG) in Chicago. The objectives of this secondary analysis of a phase III efficacy trial were to determine the percent of postmenopausal women who achieved a greater than 50 percent reduction in the frequency of moderate to severe vasomotor symptoms (MSVMS), or hot flashes, and to assess the change from baseline in a quality of life (Kupperman) index score that evaluated various menopausal symptoms. Divigel[®] doses studied included 1.0 mg, 0.5 mg and 0.25 mg of estradiol/day - the lowest effective approved dose of estradiol available for the treatment of MSVMS. The analysis showed a significantly greater percentage of women in all treatment groups versus placebo experienced \geq 50 percent reduction in the frequency of MSVMS at week 12. In the Divigel[®] 1.0 mg

estradiol/day dosing group, 90 percent of women reported at least a 50 percent reduction in the frequency of MSVMS. Additionally, at 12 weeks, each of the doses of Divigel[®] significantly reduced the severity of menopausal symptoms identified by a quality of life index score compared to placebo.

“These data further support the safety, efficacy and tolerability of Divigel[®] as a bioidentical and FDA-approved hormone therapy for the treatment of the symptoms of menopause,” said Dr. William Koltun, a clinical investigator from the Medical Center for Clinical Research in San Diego, Calif. who presented the data at ACOG. “Divigel[®] is an important addition to the options for women and their physicians in the treatment of hot flashes associated with menopause.”

About the Study

The responder analysis presented at ACOG was a secondary analysis of the Divigel[®] phase III efficacy and safety study published earlier this year in the journal *Menopause*. A total of 488 postmenopausal women were evaluated in this 12-week efficacy and safety study, comparing placebo to the low-dose transdermal Divigel[®] at doses of 1.0 mg/day, 0.5 mg/day and 0.25 mg/day estradiol. Endpoints included the change from baseline in daily frequency and severity of moderate to severe hot flashes. The study also evaluated common adverse events and tolerability at the application site. Divigel[®] showed statistically significant improvements compared with placebo as early as week two that were maintained throughout treatment. Divigel[®] significantly decreased the frequency and severity of MSVMS at all doses evaluated in this trial. The most common treatment-related adverse events were breast tenderness and postmenopausal bleeding.

“Divigel[®] offers women the lowest effective FDA-approved dose of estrogen therapy for MSVMS in post-menopausal women and dosing flexibility with availability of three different strengths (0.25 mg estradiol/day, 0.5 mg estradiol/day and 1.0 mg estradiol/day) giving physicians greater ability to individualize treatment for each woman,” added Dr. Koltun.

About Divigel[®]

Divigel[®] is indicated for the treatment of MSVMS associated with menopause. The estrogen in Divigel[®] is derived from plant sources and is identical to the primary estrogen produced by a woman’s ovaries before menopause. Certain older oral estrogen therapies contain conjugated estrogens derived from the urine of pregnant mares. Divigel[®] is applied to the skin and takes a more direct route to the systemic blood stream, bypassing the liver. It 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.¹⁻⁴

Divigel[®] was approved by the U.S. Food and Drug Administration (FDA) in June 2007.

Important Safety Information for Patients

The following are not all the possible risks for Divigel[®]. Please see the full Prescribing Information and talk to your healthcare provider.

Estrogens increase the chance of getting cancer of the uterus (womb). Report any unusual vaginal bleeding right away while you are taking estrogens. Vaginal bleeding after menopause

may be a warning sign of cancer of the uterus. Your healthcare provider should check any unusual vaginal bleeding to find out the cause. In general, the addition of a progestin is recommended for women with a uterus to reduce the chance of getting cancer of the uterus.

Do not use estrogens, with or without progestins, to prevent heart disease, heart attacks or strokes. Using estrogens, with or without progestins, may increase your chance of getting heart attacks, strokes, breast cancer and blood clots.

Do not use estrogens, with or without progestins, to prevent dementia. Using estrogens, with or without progestins, may increase your risk of dementia.

Do not use estrogen products, including Divigel[®], if you have unusual vaginal bleeding, currently have or have had certain cancers, had a stroke or heart attack in the past year, currently have or have had blood clots, currently have or have had liver problems, are allergic to any Divigel[®] ingredients or think you may be pregnant.

The most common side effects for all estrogen products are headache, breast pain, irregular vaginal bleeding or spotting, stomach/abdominal cramps and bloating, nausea and vomiting, and hair loss. Less common but serious side effects include breast cancer, cancer of the uterus, stroke, heart attack, blood clots, dementia, gallbladder disease and ovarian cancer.

In Divigel[®] clinical trials, the most common side effects were inflammation of the nasal passages and pharynx, upper respiratory tract infection, vaginal yeast infection, breast tenderness and

vaginal bleeding. Call your healthcare provider right away if you have any symptoms that concern you.

Estrogen products should be used at the lowest dose possible for your treatment and only as long as needed. You and your healthcare provider should talk regularly about whether you still need treatment with Divigel[®].

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

Orion Corporation (OMX: ORNAV, ORNBV) has a licensing agreement with Upsher-Smith Laboratories, Inc. 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.

References: 1. Divigel[®] [package insert]. Minneapolis, MN: Upsher-Smith Laboratories, Inc.; 2007. 2. Estrasorb[®] [package insert]. Bristol, TN: Graceway Pharmaceuticals, LLC; 2008. 3. EstroGel[®] [package insert]. Herndon, VA: Ascend Therapeutics, Inc.; 2007. 4. Elestrin[™] [package insert]. Lincolnshire, IL: BioSante Pharmaceuticals, Inc.; 2007.

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