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**FOR IMMEDIATE RELEASE**

**FDA Approves Divigel<sup>®</sup> (estradiol gel) 0.1 Percent for Treatment of Moderate to Severe Hot Flashes Associated with Menopause -Gel Provides Women with Lowest Approved Estradiol Dose-**

**MAPLE GROVE, MN, June 5, 2007** – Upsher-Smith Laboratories, Inc. announced today that it received approval from the United States Food and Drug Administration (FDA) for the marketing of Divigel<sup>®</sup> (estradiol gel) 0.1 percent. Divigel<sup>®</sup> offers the lowest approved dose of estradiol available for the treatment of moderate to severe hot flashes associated with menopause.

“Divigel<sup>®</sup> provides a valuable choice for women that are suffering from hot flashes,” said Dr. Richard Hedrick, Jr., key investigator, Hawthorne OB/GYN Associates. “Women experienced a low incidence of side effects and a decrease in the frequency and severity of hot flashes was observed as early as two weeks with Divigel<sup>®</sup> in clinical trials.”

Guidelines from the North American Menopause Society (NAMS) indicate that estrogen hormone therapy should be used at the lowest effective dose for the shortest amount of time.

“The availability of Divigel<sup>®</sup> supports the NAMS guidelines given that this product provides the lowest approved dose of estradiol therapy on the market to treat hot flashes,” said Dr. Hedrick. “Hot flashes are one of the most common symptoms of menopause, so safe, low-dose therapy is critical to help women cope with them.”

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The estrogen in Divigel<sup>®</sup> 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<sup>®</sup> 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 where it absorbs directly into the bloodstream without having to pass through the liver. Divigel<sup>®</sup> 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 and the smallest application area compared to all other available gel or lotion estrogen products.

“We are pleased that the FDA recognizes the value that this convenient, low-dose therapy brings to women that are experiencing uncomfortable hot flashes associated with menopause,” said Mark Evenstad, President, Upsher-Smith Laboratories, Inc. “Our organization has worked closely with the FDA on the approval of this therapy, and we look forward to making the product commercially available in July 2007.”

### **Important Safety Information for Patients**

**The following are not all the possible risks for Divigel<sup>®</sup>. Please read the full Patient Information leaflet and talk to your healthcare provider.**

Estrogens increase the chance of getting cancer of the uterus. 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 (womb). 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.

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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<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>.

For more information, call 1-800-654-2299 or visit [www.divigelus.com](http://www.divigelus.com).

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Orion Corporation (OMX: ORNAV, ORNBV) has a licensing agreement with Upsher-Smith Laboratories for the development of Divigel<sup>®</sup> 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](http://www.upsher-smith.com).

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