



COMPREHENSIVE CLINICAL TRIALS, LLC

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FOR IMMEDIATE RELEASE

**New Data Reveal Topical Divigel[®] (estradiol gel) 0.1% Significantly
Reduces Frequency and Severity of Hot Flashes
- *Lowest Dose of Estradiol Shown to Be Safe and Effective for Menopausal Women* -**

WEST PALM BEACH, FL, October 3, 2007 – A study presented today at the 2007 Annual Meeting of the North American Menopause Society (NAMS) revealed that Divigel[®] (estradiol gel) 0.1% significantly reduced the frequency and severity of moderate to severe hot flashes associated with menopause. Additional data presented at the meeting found that Divigel[®] is a safe and well-tolerated therapy offering the lowest approved dose of estradiol available for the treatment of hot flashes, the most common symptom of menopause.

“These data demonstrate that Divigel[®] is a safe and highly effective low dose therapy that quickly manages the uncomfortable side effects of menopause,” said Dr. Ronald Ackerman, FACOG, CEO and principal investigator, Comprehensive Clinical Trials. “Women that have been reluctant to take older hormone therapies with higher doses of estrogen now have the choice of taking Divigel[®], the lowest dose of estradiol available.”

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.

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“Divigel[®] is applied to the skin where it absorbs directly into the bloodstream without having to pass through the liver. This provides treatment continuity allowing women to use less estrogen than is needed in a pill because of the way the therapy is delivered,” said Dr. Ackerman. “Transdermal therapies have been used in Europe for years, and they are becoming increasingly common in the United States. The availability of this lowest dose estrogen gel combined with its convenience makes Divigel[®] a valuable option for physicians and patients.”

This 12-week study evaluated 488 postmenopausal women presenting with moderate to severe vasomotor symptoms. The study compared placebo to Divigel[®] at doses of 1.0 g gel/day, 0.5 g gel/day and 0.25 g gel/day. Approximately 120 patients were randomized to each treatment group. Study endpoints included mean change from baseline in daily frequency and severity of moderate to severe hot flashes.

Consistent with FDA requirements, both the Divigel[®] 0.5 g and 1.0 g treatment groups demonstrated a statistically significant reduction in the frequency and severity of vasomotor symptoms by week four. The Divigel[®] 0.25 g group demonstrated a statistically significant reduction in the frequency and severity of vasomotor symptoms by week seven. Statistically significant differences were maintained through the duration of treatment (12 weeks). Divigel[®] also had an excellent tolerability profile and less than one percent of patients experienced skin irritation reactions at the treatment application site.

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

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