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**FOR IMMEDIATE RELEASE**

**FERRING REPORTS ON ENDOMETRIN® PRESENTATIONS AT  
PACIFIC COAST REPRODUCTIVE SOCIETY ANNUAL MEETING**

**Progesterone Vaginal Supplement Studied in Largest-Ever IVF Trial in US**

Rancho Mirage, CA – April 18, 2007 – Results of four studies evaluating Ferring Pharmaceuticals' ENDOMETRIN®, a novel progesterone vaginal insert in development for luteal phase support (supplementation to provide support for implantation and the early stages of pregnancy) in assisted reproductive technologies (ART) were presented at the 55<sup>th</sup> Annual Meeting of the Pacific Coast Reproductive Society in Rancho Mirage, CA, April 18 to 22, 2007.

ENDOMETRIN is micronized progesterone in a tablet form that is vaginally inserted with a matched applicator. Marketing applications for ENDOMETRIN for luteal phase support in ART have been filed in the United States, Hong Kong and Israel.

“ENDOMETRIN was evaluated in the largest IVF trial ever undertaken in the United States across a wide range of patient types. Results from the trial show that ENDOMETRIN provided quality luteal phase support, measured by continuing pregnancy rates, and it is administered in an easy, patient-friendly way,” said Kenneth B. Kashkin, M.D., Senior Vice President, Global Clinical Research and Development, Chief Medical Officer (U.S.), Ferring Pharmaceuticals. “Our studies also show that administering MENOPUR® and BRAVELLE® once a day in a single combined injection, another patient convenience, provided equivalent efficacy compared with twice-daily dosing, and excellent pregnancy rates.”

**Largest-Ever IVF Trial in the United States**

The activity and tolerability of ENDOMETRIN were evaluated in a multicenter, randomized, open-label, assessor-blinded trial of 1,211 women, ages 18-42, undergoing *in vitro* fertilization (IVF). MENOPUR (menotropins for injection, USP) and BRAVELLE (urofollitropin for injection, purified), human-derived FSH, were used for the stimulation phase of IVF, with a minimum of one vial of MENOPUR per day. The centers had the option of combining BRAVELLE and MENOPUR and administering it as one single daily injection, which was done for approximately one third of the patients (n=777). On the day of oocyte retrieval, patients were randomized to ENDOMETRIN 100 mg twice daily, ENDOMETRIN 100 mg three times

-more-

daily, or an active control (progesterone vaginal gel (90 mg) QD)\*. In the study, efficacy was measured by continuing pregnancy rates. An analysis was also conducted to evaluate once-daily compared with twice-daily dosing of gonadotropins during the stimulation phase.

The results showed that ENDOMETRIN was efficacious, with no significant differences in efficacy parameters between treatment arms. Continuing pregnancy rates were 42.3 percent with ENDOMETRIN TID and 38.6 percent with ENDOMETRIN BID. The groups also showed equivalent tolerability, with no significant differences in the incidence of adverse events between groups.

### **Results in Harder-to-Treat Patients**

The activity of ENDOMETRIN was also evaluated in harder-to-treat patients – women over age 35, or with elevated basal follicle stimulating hormone (FSH) or body mass index (BMI). Excellent continuing pregnancy rates were observed across a broad range of patient types with the use of BRAVELLE, MENOPUR and ENDOMETRIN.

### **Once-Daily Mixed Protocol**

The trial data also demonstrated that administration of MENOPUR and BRAVELLE once a day as a single combined injection provided equal efficacy compared with twice-daily dosing, and that twice-daily dosing offers no additional patient benefits.

Parameter	Bravelle+Menopur QD N=777	Bravelle+Menopur BID N=434	p-value
Age	32.5	34.0	<0.001
BMI	25.0	24.9	0.181
Duration	10.0	10.6	
Oocytes	14.0	13.4	0.225
Continuing Pregnancy (%)	41.3	40.6	0.808

### **Comparison With Intramuscular (IM) Progesterone**

A separate study, led by Naveed Khan, M.D. at Shady Grove Fertility Reproductive Science Center in Rockville, MD, evaluated the effectiveness of vaginal progesterone supplementation with ENDOMETRIN compared with intramuscular IM progesterone supplementation. Forty patients were randomized to one of three forms of vaginal supplementation -- ENDOMETRIN BID (n=12), ENDOMETRIN TID (n=11), and vaginal gel QD (n=17) -- for luteal support after IVF embryo transfer for 10 weeks. Pregnancy outcomes were

compared to those for patients treated with IM progesterone in the same ART center during the same time period in which patients were treated with the center's standard protocol for luteal phase support using IM progesterone. Subjects receiving IM progesterone were matched to case cycles for age, baseline FSH, endometrial thickness on the day of hCG trigger injection, stage of embryo transfer, and number of embryos transferred. Each case cycle was matched to five control cycles, for a total of 200 control cycles.

The pregnancy rates (50 percent for vaginal, 51.5 percent IM) and live birth rates (47.5 percent vaginal, 47 percent IM) were similar between treatment groups, and there were no significant differences for any of the examined variables.

	Vaginal progesterone	IM progesterone
Number of cycles	40	200
Age (years)	35.5	35.4
FSH (IU/L)	7.3	7.4
Endometrium (mm)	12.1	11.0
ET stage (% blastocyst)	35.0	35.0
Embryos per ET	2.2	2.3
Clinical intrauterine pregnancy (per cycle)	20 (50.0%)	103 (51.5%)
1 <sup>st</sup> trimester pregnancy loss	0 (0.0%)	6 (5.8%)
2 <sup>nd</sup> trimester pregnancy loss	1 (5.0%)	3 (2.9%)
Live birth (per cycle)	19 (47.5%)	94 (47.0%)

### **About Luteal Support**

Successful implantation of the embryo depends on adequate preparation of the endometrium, the mucous membrane lining the uterus. The corpus luteum, formed after the oocyte is released, secretes progesterone to induce secretory transformation of the endometrium. Since natural progesterone production may be compromised by *in vitro* fertilization (IVF), progesterone supplementation is believed to be necessary to provide the proper support for implantation and the early stages of pregnancy. Studies have shown that luteal support with progesterone after an assisted reproductive technology (ART) can result in increased pregnancy rates.

Currently available progesterone supplements come in oral, intramuscular (IM) injection, vaginal gel and suppository forms.

### **About BRAVELLE and MENOPUR**

BRAVELLE<sup>®</sup> (urofollitropin for injection, purified) and MENOPUR<sup>®</sup> (menotropins for

injection, USP), like all gonadotropins, are potent substances capable of causing mild to severe adverse reactions, including OHSS (incidence of 6.0% and 3.8%, respectively), with or without pulmonary or vascular complications, in women undergoing therapy for infertility.

The treatments are marketed by Ferring Pharmaceuticals Inc., a world leader in naturally occurring protein hormones. Only physicians thoroughly familiar with infertility treatment, including the risk of multiple births and adverse reactions, should prescribe these medications. Like other products for ovarian stimulation, treatment with BRAVELLE<sup>®</sup> and/or MENOPUR<sup>®</sup> may result in multiple gestations.

### **About Ferring Pharmaceuticals**

Ferring Pharmaceuticals, part of the Ferring Group, a privately owned, international pharmaceutical company, markets BRAVELLE<sup>®</sup>, MENOPUR<sup>®</sup>, REPRONEX<sup>®</sup> and NOVAREL (chorionic gonadotropin for injection, USP) in the U.S. to infertility specialists and their patients. Ferring also offers the Q-CAP<sup>™</sup>, the first and only needle-free reconstitution device, for use with its fertility treatments.

Ferring's line of orthopaedic and urology products includes EUFLEXXA<sup>™</sup>, hyaluronic acid for pain from osteoarthritis in the knee. Other products include ACTHREL<sup>®</sup> (corticotropin ovine triflutate for injection) for the differential diagnosis of Cushing's syndrome and DESMOPRESSIN ACETATE in injectable and rhinal tube forms for the treatment of diabetes insipidus and primary nocturnal enuresis.

The Ferring Group specializes in the research, development and commercialization of compounds in general and pediatric endocrinology, urology, gastroenterology, obstetrics/gynecology and infertility. For more information, call 888-337-7464 or visit [www.ferringusa.com](http://www.ferringusa.com) or [www.ferringfertility.com](http://www.ferringfertility.com).

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\*Crinone (progesterone vaginal gel) 8% is marketed by Columbia Laboratories.

*Please contact Andrea Preston for MENOPUR and BRAVELLE full prescribing information*