



## PRESS RELEASE

### **PregLem starts Phase III trials of PGL4001 in Uterine Myoma**

**Geneva, Switzerland, 19 August 2008** – PregLem SA, a Swiss biopharmaceutical company specialized in reproductive medicine, today announced the start of an international Phase III clinical trial program for PGL4001 (ulipristal) in symptomatic uterine myoma, a common benign solid tumor of the genital tract in women of reproductive age. PGL4001, an orally active, selective progesterone receptor modulator, was shown in a previous Phase II study to be well tolerated and effective both in immediately stopping uterine bleeding, a major symptom associated with the condition, and in reducing myoma volume. Results of the Phase III trials are expected in 2010.

The program is composed of two separate Phase III clinical trials involving a total of 540 patients and being carried out in parallel in a total of 14 countries. The trials are being coordinated by Professor Jacques Donnez of the Université Catholique de Louvain in Brussels.

The first trial (PEARL I) is a randomized, parallel group, double-blind, placebo-controlled, multi-center study on a total of 240 patients. This trial will assess the efficacy and safety of PGL4001 versus placebo over a 3-month period for the pre-operative treatment of pre-menopausal women suffering from excessive uterine bleeding due to uterine myoma. PGL4001 at dosages of 5 and 10 mg will be compared with placebo, with concomitant iron administration in all groups. Parameters to be evaluated include reduction in uterine bleeding, correction of anemia, change in both myoma and uterine volume, and improvement in pain and other symptoms.

The second trial (PEARL II) is a randomized, parallel group, double-blind, double-dummy, active comparator-controlled, multi-center study on a total of 300 patients. This trial will assess the efficacy and safety of PGL4001 versus the only currently approved medication, a GnRH (gonadotropin-releasing hormone) agonist, over a 3-month period for the pre-operative treatment of pre-menopausal women suffering from excessive uterine bleeding due to uterine myoma. PGL4001 at dosages of 5 and 10 mg will be compared with leuprorelin 3.75 mg. Parameters to be evaluated will be similar to those in the first trial.

Dr. Ernest Loumaye, CEO of PregLem, commented, “Uterine myoma is a highly common condition that often negatively affects women’s quality of life and can, in its severest form, lead to surgery. With this Phase III program, we expect to confirm PGL4001’s demonstrated efficacy and its potential to significantly improve the clinical treatment of this condition. This is our second clinical trial authorization in just five months, proof that our young company is now fully operational and on track to develop therapeutic innovations for female reproductive health.”

### **About Uterine Myoma**

Uterine myoma is the most common benign solid tumor of the genital tract in women of reproductive age. It affects approximately 40% of women between 35 and 55 years of age, including 24 million women in Europe and 14 million in the US. The cardinal symptoms of uterine myoma are heavy menstrual bleeding, abdominal pressure and pain, increased urinary frequency and infertility. Beyond its physical morbidity, the condition frequently causes a significant impairment of quality of life and is a leading reason for the performance of hysterectomies. The main therapy for uterine myoma is surgery, including hysterectomy as the most invasive option, myomectomy and uterine artery embolisation, and in some cases endometrial ablation. As a medical approach to treating symptomatic uterine myoma, GnRH (gonadotropin-releasing hormone) agonists have been shown to be effective, but their use is restricted due to side effects that include bone mineral density loss and a range of symptoms associated with castration. PregLem is addressing symptomatic uterine myoma with PGL4001, an orally active new chemical entity with the potential for faster efficacy than GnRH agonists without their associated side effects.

### **About PregLem**

PregLem SA is a Swiss specialty biopharmaceutical company focused on the development and commercialization of innovative compounds for the treatment of major benign gynecological conditions as well as infertility. PregLem currently has four products in clinical and pre-clinical development. Its most advanced product, PGL4001, in-licensed from French pharmaceutical company HRA Pharma, is in Phase III clinical trials for the treatment of uterine myoma. PregLem raised CHF 68 million from leading life science investors in Series A and B funding rounds in 2007. The company obtained SME status from the European Medicines Agency (EMA) in November 2007. PregLem was founded in Geneva in 2006 by Ernest Loumaye and Eric Rolin.

More information is available at [www.preglem.com](http://www.preglem.com).

For further information, please contact:

Solveig Hole, PregLem CEO office, Tel: +41 22 884 03 40, Email: [solveig.hole@preglem.com](mailto:solveig.hole@preglem.com)

Dr. Jonathan Leighton, Leighton Communications, Tel: +41 76 559 67 88, Email: [jonl@sunrise.ch](mailto:jonl@sunrise.ch)