

## **PREGLEM ANNOUNCES POSITIVE PHASE III RESULTS FOR ESMYA™**

### ***PEARL I trial meets primary efficacy and safety endpoints PregLem preparing for submission to the European Medicines Agency in 2010***

**Geneva, Switzerland, 3 June 2010:** PregLem, the European specialty biopharmaceutical company focused on women's reproductive medicine, announces positive Phase III data from its second pivotal study (PEARL I) for its lead product Esmya (ulipristal acetate), as an effective treatment for uterine fibroids (myoma) – a condition that affects millions of women worldwide.

The final set of positive Phase III results, combined with the positive PEARL II results announced in May 2010, will enable PregLem to submit a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) by the end of 2010. Upon approval, PregLem expects to launch the product in major European markets.

#### **Ernest Loumaye, CEO & Co-Founder of PregLem, said:**

"These results are another important milestone in PregLem's growth strategy. With positive results from two independent Phase III studies on our lead candidate, we now have the opportunity to move the company forward from its current focus on drug development towards our ambition of becoming a self-sustaining specialty biopharmaceutical company. Our immediate focus is on preparing the MAA dossier. However, we are simultaneously leveraging our unique research and market insight to start preparing for the launch of Esmya, our first product in Europe."

#### **Key Phase III results**

PEARL I was designed to demonstrate superior efficacy of Esmya versus placebo for the treatment of symptomatic uterine fibroids in women with heavy bleeding leading to anaemia. It was a randomised, parallel group, double-blind, placebo-controlled, multi-centre study with a total of 242 patients. It compared 5mg and 10mg doses of Esmya and placebo once daily for three months with concomitant iron administration in all three arms.

The study met its two co-primary efficacy endpoints. Esmya demonstrated statistically significant superior efficacy to placebo in reducing excessive uterine bleeding measured as a percentage of patients with a reduction of PBAC (Pictorial Blood Assessment Chart) score lower than 75 and in reduction of total fibroids volume assessed by centralised MRI reading.

Esmya also showed superior efficacy to placebo in correcting anaemia caused by uterine fibroids and suppressing fibroids-related pain using the McGill Short Form questionnaire (SF-MPQ). Both the PBAC and SF-MPQ are validated self-reporting tools.

#### **Ernest Loumaye added:**

"The combined PEARL I and II data shows that Esmya has the potential to be the first effective medical treatment for this condition, with no serious side effects, for millions of women around the world."

**Professor Tetyana Tatarchuk, the Principal investigator from the Institute of Obstetrics and Gynaecology in City Clinical Hospital (Ukraine), said:**

“These data are very convincing. A medical treatment for alleviating the symptoms related to fibroids and reducing the fibroids volume would be very useful in our day-to-day management of this significant and distressing condition. These results clearly illustrate the potential for Esmya to offer an effective and well tolerated treatment for this condition.”

Uterine fibroids affect approximately 40% of women between the ages of 35 and 55, including 24 million women in Europe and over 20 million women in North America. The condition is characterised by excessive uterine bleeding, anaemia, pain and infertility. It significantly impairs the quality of life for many women, leading in many cases to a hysterectomy. There are no effective, well tolerated medical treatments available. GnRH agonists are the only approved treatment of symptomatic uterine fibroids but their use has been relatively limited due to their side effect profile which causes suppression of oestrogen to castration levels, resulting in hot flushes, depression, mood swings, loss of libido, vaginitis and loss of bone mineral density.

**Ends**

**For further information, please contact:**

**PregLem:**

Désirée Andrey  
CEO Office  
PregLem SA  
Tel: +41 (0)22 884 03 40  
[desiree.andrey@preglem.com](mailto:desiree.andrey@preglem.com)

**Capital MS&L:**

Mary Clark, Anna Davies  
Tel: +44 (0)20 7307 5330  
[anna.davies@capitalmsl.com](mailto:anna.davies@capitalmsl.com)

**About PregLem**

PregLem is a European speciality biopharmaceutical company dedicated to the development and commercialization of a new class of drugs for women's reproductive health conditions. PregLem has an experienced senior management team, with a proven track record in developing, registering and commercialising reproductive health products. The company is backed by a blue chip investor base.

Visit [www.preglem.com](http://www.preglem.com) for more information.

**About Esmya™**

Ulipristal acetate is a first-in-class, orally active selective progesterone receptor modulator which reversibly blocks the progesterone receptors in target tissues.



PregLem's Phase III programme for Esmya consists of two separate, parallel, randomised, double-blind studies identified as PEARL I and PEARL II. Together the Phase III trials involved 540 patients in 14 countries at 5mg and 10mg doses.