

News

PREGLEM PROVIDES AN UPDATE ON ULIPRISTAL ACETATE FOR THE TREATMENT OF UTERINE FIBROIDS *Screening in PEARL II completed - No Safety Issues*

Geneva, Switzerland – 19 August 2009: PregLem, the Swiss biopharmaceutical company specializing in women's reproductive medicine, today provided an update on its two ongoing pivotal Phase III studies (PEARL I and PEARL II) of PGL4001 (ulipristal acetate) for the treatment of uterine fibroids.

The screening of patients for the PEARL II study has been successfully completed. PregLem expects the treatment phase to end in January 2010.

The PEARL I study is progressing according to plan with 72% of patients enrolled and the completion of screening is expected in October 2009.

To date, 465 patients have been treated and 197 have completed a three month treatment course. No clinical or biological safety signals (including in liver parameters) have been detected (blinded data). At its recent meeting, the independent Drug Safety Monitoring Board (DSMB) unanimously recommended continuation of the studies as per current protocols.

Ernest Loumaye, Chief Executive Officer of PregLem, commented:

“We are pleased to announce that our Phase III programme is progressing according to plan and we are well on track to report results by Q2 2010. Additionally, and in line with the Phase II data, we have no safety signals. ”

The Phase III programme consists of two separate, parallel, randomised, double-blind studies identified as PEARL I and PEARL II. Together the Phase III trial involves 540 patients in 14 countries. Final results from both studies will be available in Q2 2010 with the filing of a Marketing Authorization Application (MAA) with the European Health Authorities shortly after.

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

End

For further information please contact:

Media Contact:

Mary Clark / Joanna Whineray
Capital MS&L
Tel: +44 (0) 207 307 5330
joanna.whineray@capitalmsl.com

PregLem

Solveig Hole
CEO Office
Tel: +41 (0) 22 884 03 40
solveig.hole@preglem.com

Notes to Editors:

About PregLem

PregLem is a Swiss speciality biopharmaceutical company, dedicated to the development and commercialization of a new class of drugs for women's reproductive health conditions. The company currently has four products in clinical and pre-clinical development.

PregLem has an experienced senior management team, with a proven track record in developing, registering and commercializing reproductive health products. The Company is backed by a blue chip investor base.

PregLem in-licensed ulipristal acetate from HRA Pharma to develop and commercialize it for the treatment of uterine myoma (fibroids) in doses of 5 and 10 mg. HRA recently obtained a positive CHMP recommendation for approval of ulipristal acetate in emergency contraception, a significant step towards de-risking the registration of PregLem's PGL4001.

Visit www.preglem.com for more information.

Uterine Myoma

Current treatment options for uterine myoma remain sub-optimal. The market is dominated by invasive surgeries and there are no well tolerated medical treatments available. Surgical treatments can result in the re-growth of tumours or lost fertility. Hormone therapy - GnRH agonists – are limited to 3-6 months treatment cycles and have major side effects such as bone density loss and menopausal symptoms. NSAIDs do not control the disease progression.



Information about PregLem-Sponsored Clinical Trials:

PregLem is committed to providing information about clinical trials sponsored by the Company. We have registered our company-sponsored ongoing Phase III clinical trials on the National Institutes of Health's (NIH) web site (www.clinicaltrials.gov).