



PRESS RELEASE

PREGLEM'S PARTNER HRA REACHES MAJOR MILESTONE WITH POSITIVE CHMP OPINION FOR ULIPRISTAL ACETATE

- *HRA receives positive CHMP opinion for ulipristal acetate (EllaOne®), the company's emergency contraceptive*
- *CHMP opinion an important step for the registration of PregLem's PGL4001*

Geneva, Switzerland - 25 March 2009: PregLem, the Swiss biopharmaceutical company specializing in women's reproductive medicine, is pleased to report that their partner company, HRA Pharma, received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), recommending to grant a marketing authorization for ellaOne® (ulipristal acetate). The final European Commission approval is expected within the next three months. (www.hra-pharma.com)

HRA has developed ulipristal acetate as a 30mg single use next generation emergency contraception. PregLem in-licensed ulipristal acetate from HRA to develop it as PGL4001 for the treatment of uterine myoma (fibroids) in lower doses of 5 and 10 mg. This investigational product is currently in Ph III trials.

Ernest Loumaye, CEO of PregLem, commented, "We in-licensed ulipristal acetate to develop this new chemical entity as a treatment for uterine myoma. This condition affects approximately 40% of women between the ages of 35 and 55, including 24 million women in Europe, and significantly impairs the quality of life, leading to hysterectomy in many cases".

"This positive recommendation from CHMP for ulipristal acetate in emergency contraception is a significant milestone for the PGL4001 registration strategy. It validates common sections of the registration dossier; such as important parts of pre-clinical and manufacture (CMC) sections hence further reducing regulatory risk for PGL4001. Our pivotal Phase III programme is progressing according to the plan and we expect study results by mid 2010."



Current treatment options for uterine myoma remain sub optimal with the market dominated by invasive surgeries and an absence of well tolerated medical treatment. PGL4001 is a selective progesterone receptor modulator (SPRM) which reversibly blocks the progesterone receptors in target tissues.

A completed Phase II programme demonstrated that PGL4001 rapidly controls bleeding and significantly reduces myoma size, improving quality of life with a good safety profile. The Phase III program was initiated in August 2008 and consists of two separate parallel, randomised trials (called PEARL I&II), involving 540 patients in 14 countries. The results of the Phase III data are expected in 2010.

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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. 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. (www.preglem.com)

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).