



News: PREGLEM'S PARTNER HRA PHARMA IS GRANTED EUROPEAN MARKETING AUTHORIZATION FOR ULIPRISTAL ACETATE

HRA Pharma is granted European Marketing Authorization for ellaOne® (ulipristal acetate): an important step for the registration of PregLem's PGL4001.

Geneva, Switzerland – 05 June 2009: PregLem, the Swiss biopharmaceutical company specializing in women's reproductive medicine, is pleased to report that its partner company, HRA Pharma, has been granted European Marketing Authorization for ellaOne® (ulipristal acetate) by the European Commission. HRA Pharma has developed ellaOne® as a 30mg single use, next generation emergency contraception.

The marketing authorization follows the positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in March 2009.

PregLem in-licensed ulipristal acetate from HRA Pharma and is currently proceeding with a Phase III clinical trial program of PGL4001 at lower doses (5 and 10 mg) for the treatment of uterine myoma (fibroids).

While being a significant achievement for HRA Pharma, the marketing authorization provides an important element to PregLem's development and registration of PGL4001. It validates common sections of the registration dossier, such as important parts of the pre-clinical and manufacture (CMC) sections, therefore further reducing the regulatory risk for PGL4001.

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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).

HRAPharma <http://www.hra-pharma.com/>