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Uliprisrtal Acetate Granted European Marketing Authorisation for the Treatment of Symptoms Of Uterine Fibroids

Paris, France – February 27, 2012: HRA Pharma announces today that the European Commission has issued marketing authorisation for Esmya® (ulipristal acetate) for the pre-operative treatment (3 months) of moderate to severe symptoms in patients with uterine fibroids. The authorisation, granted to HRA Pharma's licensee PregLem, extends to all European Union Member States and follows a positive recommendation from the Committee for Medicinal Products for Human Use (CHMP) last year.

In European studies, ulipristal acetate has been shown to be an effective and safe treatment of symptoms of uterine fibroids, a condition that affects millions of women worldwide. The condition is the most common type of non-cancerous hormone-dependent tumour of the female reproductive system.

The European Commission's decision to grant a community marketing authorisation comes following a review of the positive recommendation originally made by the CHMP in December 2011 which was based on a comprehensive quality, preclinical and clinical package including data from two Phase III pivotal studies (1-3).

HRA Pharma has licensed the development rights of the ulipristal acetate molecule for benign gynaecological disorders to PregLem, a wholly owned subsidiary of Gedeon Richter Plc. Richter is itself an expanding multinational pharmaceutical company which acquired PregLem in October 2010 as part of its growth strategy and as a result, procured the marketing and distribution rights for Esmya® in the European Union and North America in addition to China, Russia and other CIS countries. HRA Pharma retained the worldwide rights to the compound in other countries worldwide

"HRA Pharma was the first to investigate the potential of harnessing ulipristal acetate successfully to help with a great variety of women's debilitating health issues," said Erin Gainer, CEO of HRA Pharma. "We are delighted to be working with PregLem to bring this product to women throughout Europe and the recent European marketing authorisation is further testimony of HRA Pharma's ability to shape the appropriate product, source the correct partner and build the best team in order to realise the full potential of a promising compound."

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About uterine fibroids

Uterine fibroids are the most common type of non-cancerous hormone-dependent tumor of the female reproductive system. The condition affects between 20-50% of women, and is most common in women between the ages of 35 and 50. Symptomatic uterine fibroids are characterized by excessive uterine bleeding, pain, anemia or infertility. There are no effective, well tolerated medications available. Treatment most frequently consists of surgery and interventional radiology.

About HRA Pharma

HRA Pharma is a privately-held European pharmaceutical company that designs products, devices and supporting services in niche areas of health and makes them available to doctors and patients worldwide. The company targets therapeutic gaps in the areas of reproductive health and endocrinology, and uses innovative marketing solutions and socially-conscious programmes, such as contraception education in developing countries, to promote healthy management of drugs and diseases. Headquartered in Paris, France and with offices throughout Europe, HRA Pharma has built a strong network of R&D, manufacturing, distribution and NGO partners which enables it to satisfy critical patient needs and improve patient health in over 50 countries across the globe. Visit www.hra-pharma.com for more information.

References

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