Media Contact
Julian Barlow
Barlow Frith Communications Ltd for HRA Pharma
Phone D - +44 –(0)1296 468540
M +44 – (0)7747 - 852070
Email julian@barlowcomms.co.uk

NEJM Features Two Positive Pivotal Trials of HRA Pharma Compound Ulipristal Acetate for the Treatment of Uterine Fibroids

Paris, February 2, 2012 - The New England Journal of Medicine (NEJM) today published results of two phase III clinical trials introducing ulipristal acetate, HRA Pharma proprietary compound, as an effective pre-operative treatment of symptoms of uterine fibroids.

According to data published in NEJM from two pivotal clinical trials, PEARL I and PEARL II, treatment with ulipristal acetate was associated with a reduction of excessive uterine bleeding and reduction of total fibroids volume. Ulipristal acetate also showed superior safety and tolerance with statistical significance versus leuprolide acetate (the injectable GnRH agonist, used as comparator for PEARL II study) regarding castration-related symptoms and their consequences. The published study findings also showed that ulipristal acetate treatment was associated with a clinically relevant rapidity in controlling excessive bleeding in patients receiving ulipristal acetate versus in those receiving leuprolide acetate and a sustained efficacy in fibroids volume reduction, which was maintained for at least 6 months after treatment is discontinued.

Both studies were conducted by Preglem, HRA Pharma's development and marketing partner that licensed ulipristal acetate for benign gynaecological disorders (including uterine fibroids) for Europe and the U.S. HRA Pharma retains the rights to license the compound in other countries worldwide.

The Committee for Medicinal Products for Human Use (CHMP), part of the European Medicines Agency (EMA), has recently issued a positive opinion recommending a marketing authorisation for Esmya® (ulipristal acetate) for the pre-operative treatment (3months) of moderate to severe symptoms in patients with uterine fibroids. Subject to approval by the European Commission, PregLem, a wholly owned subsidiary of Gedeon Richter, is expected to receive a marketing authorization for Esmya® valid for all European Union Member States in the first part of 2012.

"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. "Guided by our commitment to deliver innovative and original medicines worldwide, we initiated in collaboration with the U.S. National Institutes of Health the original studies and undertook proof of concept activity as the originators of this uterine fibroids treatment. Results obtained today are 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."

About uterine fibroids

Uterine fibroids are the most common benign, solid tumours of the female genital tract, affecting between 20 and 25 percent of women of reproductive age. It is estimated that about 300,000 surgical procedures are performed annually in the EU for uterine fibroids, including approximately 230,000 hysterectomies. The condition is characterized by excessive uterine bleeding, anemia, pain, frequent urination or incontinence, and infertility. GnRH agonists are the only approved pre-operative treatment for uterine fibroids but their use has been relatively limited due to side effects resulting from the suppression of estrogen to castration levels (hot flashes, depression, mood swings, loss of libido, vaginitis and loss of bone mineral density).

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. Founded by Dr. Andre Ulmann, 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.