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ellaOne[®] now reimbursed in France

Paris, France - September 20, 2010 - HRA Pharma announced today that its novel emergency contraceptive ellaOne[®] (ulipristal acetate) has received approval for reimbursement by France's Ministry of Health. The official decision was made public in the September 15, 2010 issue of the Official Journal of the Government of France (1). As a result of this decision, ellaOne is now available as a reimbursed drug, on prescription only.

"We are very pleased to have obtained reimbursement in France for ellaOne," said Erin Gainer, CEO of HRA Pharma. "French health authorities have a particularly rigorous review process: the inclusion of ellaOne on the list of drugs eligible for reimbursement is a testament to the robust body of clinical evidence that supports the product's efficacy and safety. It is also an important milestone for emergency contraception in France, demonstrating that France remains a country committed to progress in this sector."

ellaOne prevents pregnancy when taken orally within 120 hours (five days) of unprotected sex or contraceptive failure. Ulipristal acetate, the active ingredient that composes ellaOne, is a selective progesterone receptor modulator with antagonistic and partial agonistic effects at the progesterone receptor. Its primary mechanism of action is inhibition or delay of ovulation. This prescription-only emergency contraceptive product has been available in Europe since October 2009, and was approved by the US Food and Drug Administration in August 2010.

The safety and efficacy of ellaOne were demonstrated in two Phase III clinical trials. One study was a prospective, multi-center, open-label, single-arm trial conducted in the United States (2); the other was a randomized, multi-center, single-blind comparator-controlled trial conducted in the United States, United Kingdom and Ireland (3). Side effects most frequently observed with ellaOne in the clinical trials include: headache, nausea, abdominal pain, pain/discomfort during menstruation (dysmenorrhea), fatigue, and dizziness.

Despite having one of the highest rates of contraceptive coverage in the world, unintended pregnancies and abortion remain common in France. It is estimated that one third of all pregnancies are unintended, and some 220 000 abortions are performed every year (4, 5). Women of all ages experience unintended pregnancy: 60% of abortions performed in France are in women 25 and older (5). Emergency contraception was developed to respond to this unmet need. By reducing a woman's risk of becoming pregnant after a contraceptive accident or unprotected sexual intercourse, emergency contraception offers a woman a second chance to prevent an unintended pregnancy.

References

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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 programs, such as contraception education in developing countries, to promote healthy management of drugs and diseases. A pioneer in emergency contraception, its product ulipristal acetate can be taken for up to five days after unprotected sexual intercourse and is the only product licensed in the European Union (ellaOne®) and the U.S. (ella®) for this indication. Headquartered in Paris, France and with offices in Germany, Italy, Spain, France and the UK, 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.