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## **HRA Pharma Receives CHMP Positive Opinion for ellaOne®**

*Leader in reproductive health now one step closer to providing greater contraceptive solutions to women in the European Union*

**Paris, France – March 20, 2009** – HRA Pharma ([www.hra-pharma.com](http://www.hra-pharma.com)), a privately-held, European pharmaceutical company that designs products, devices and supporting services in reproductive health and endocrinology, announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending a marketing authorization for ellaOne® (ulipristal acetate), the company's next generation emergency contraceptive. The positive recommendation is the critical final step in the application process before a marketing authorization is granted by the European Commission.

The positive opinion is based on HRA Pharma's comprehensive quality, preclinical and clinical data package which has been under evaluation via the EMA centralized procedure since June 25th, 2008. The European Commission will now review the CHMP final opinion in order to grant a community marketing authorization which will be valid throughout the European Union. HRA Pharma expects to obtain the European Commission's decision within the next three months.

Once formally approved, ellaOne® will be the first product to have been specifically designed and developed for use as an emergency contraceptive. Based on a new chemical entity, ellaOne® presents improved clinical characteristics over existing hormonal treatments: a good safety and tolerability profile and the advantage of sustained efficacy up to five days following unprotected intercourse or contraception failure.

"Ulipristal acetate has the potential to become the new reference in hormonal emergency contraception," said Dr. André Ulmann, founder and CEO of HRA Pharma. "HRA Pharma has a history of targeting unmet needs in therapeutic areas, and felt that emergency contraception that can be administered over a longer period of time was one of them. The positive opinion for ellaOne brings us one step closer to giving women in the European Union a greater choice in terms of contraceptive solutions."

HRA Pharma expects to file for marketing approvals in countries worldwide under the trademarks ellaOne® and ella®. The company is also developing their compound ulipristal acetate for other reproductive health indications outside of emergency contraception.

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**About HRA Pharma**

HRA Pharma is an emerging, 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 NorLevo was the first emergency contraceptive based on one type of progesterone to be approved for sale by health authorities. Headquartered in Paris, France and with offices in Bochum, Germany, 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](http://www.hra-pharma.com) for more information.