FDA Advisory Committee Unanimously Recommends Approval of HRA Pharma’s Ulipristal Acetate for Emergency Contraception

Paris, France – June 17, 2010 - www.hra-pharma.com - HRA Pharma announced today that the U.S. Food and Drug Administration’s (FDA) Advisory Committee for Reproductive Health Drugs voted 11 to 0 that the company’s application provided sufficient information to conclude that ulipristal acetate is effective and safe for use as an emergency contraceptive.

The committee’s vote followed a review of data from the ulipristal acetate preclinical and clinical development program. Involving more than 4000 women from the U.S. and Europe, it is the largest development program ever conducted in the emergency contraceptive field.

“HRA Pharma is pleased with the outcome of the Advisory Committee’s votes on the safety and effectiveness of ulipristal acetate,” said Erin Gainer, CEO of HRA Pharma. “We look forward to working with the FDA to obtain approval for this new drug and offering a next-generation emergency contraceptive to women in the U.S.”

The FDA is currently reviewing HRA Pharma’s New Drug Application (NDA) for ulipristal acetate. While today’s vote may be considered, the Agency is not bound by the recommendations of its advisory committees.

Ulipristal acetate was approved in May 2009 by the European Commission for marketing as an emergency contraceptive within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. The product was launched in October 2009 and is marketed today in 22 European countries under the brand name ellaOne®.

As serving needs in reproductive health is a priority for HRA Pharma, the company plans to seek marketing approvals in countries worldwide. In the U.S., HRA Pharma submitted an NDA with the FDA in late 2009, and has entered into a licensing agreement with Watson Pharmaceuticals to commercialize this novel next-generation emergency contraceptive.

Note

ella® is the proposed registered trademark to be used in the United States.

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 ellaOne® can be taken for up to five days after unprotected sexual intercourse and is the only product licensed in the European Union 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 http://www.hra-pharma.com for more information.
About Watson Pharmaceuticals, Inc.

Watson Pharmaceuticals, Inc., is a leading global specialty pharmaceutical company. The Company is engaged in the development and distribution of generic pharmaceuticals and specialized branded pharmaceutical products focused on Urology and Women's Health. Watson has operations in many of the world's established and growing international markets.

In the U.S., the Watson brand portfolio includes RAPAFLO®, GELNIQUE®, TRELSTAR® and INFeD®. In addition, Watson markets the following brands under co-promotion agreements: AndroGel®, with Solvay Pharmaceuticals, Inc., and Femring®, with Warner Chilcott Limited. The Watson brand pipeline portfolio includes a number of products, including URACYST®, under development for cystitis, and four novel new contraceptives.


Contacts

For HRA Pharma:
Media and analyst/investor enquiries:
On-site
Sherry Smith
(917) 545-6493
sherry@fortexgroup.com
Office
Christina Aplington
+33 (0)1 42 22 24 10
christina@balloupr.com

For Watson
Media enquiries:
On-site
Charlie Mayr
Watson Pharmaceuticals, Inc.
(973) 355-8483
Charlie.mayr@watson.com

For Watson
Investors enquiries:
Onsite
Patty Eisenhaur
Watson Pharmaceuticals, Inc.
(973) 355-8141
Patty.eisenhaur@watson.com