

Press Releases

Press Release



Watson Launches ella(R) (ulipristal acetate) Emergency Contraceptive

Only Emergency Contraceptive FDA Approved for Use Up to 5 Days after Unprotected Intercourse or a Known Contraceptive Failure

Extensive Educational Website for Consumers, Health Care Providers

MORRISTOWN, N.J., Dec. 1, 2010 /PRNewswire via COMTEX/ --

Watson Pharmaceuticals, Inc. (NYSE: WPI), announced today that ella(R) (ulipristal acetate) 30 mg, a novel oral emergency contraceptive, is now available for patients by prescription in the U.S. ella(R) was approved by the U.S. Food and Drug Administration (FDA) as safe and effective in helping to prevent unintended pregnancy for up to five days after unprotected intercourse (UPI) or a known contraceptive failure. ella(R) delays ovulation for up to five days, which is also the length of time that sperm can live in the female genital tract, and can be taken at any time during the menstrual cycle.

"ella(R) is the first truly new emergency contraceptive option for U.S. women since 1999. It has a unique sustained efficacy profile and offers women an additional therapeutic option for preventing unintended pregnancy," said Fred Wilkinson, Executive Vice President, Watson Global Brands. "We are committed to making this innovative prescription-only emergency contraceptive option available to women as soon as possible and supporting the availability of ella(R) in ways that emphasize education and access."

"We recognize that women who may seek emergency contraception rely on a number of channels for information, including the internet," Wilkinson continued. "We have built an informative website, ella-rx.com, that provides information on emergency contraception, discusses the appropriate use of ella(R), and offers insight into the prevention of unintended pregnancy," Wilkinson added.

The Company noted that the ella(R) launch will be phased over the next several months and will include physician educational initiatives, advocacy outreach and educational websites for consumers. Due to the urgent nature of emergency contraception, timely access to ella(R) will be imperative. As such, stocking efforts have ensured the product will be available immediately by prescription at most retail pharmacies, clinics, as well as online via http://www.kwikmed.com/, a licensed online pharmacy. Women can complete an extensive, physician-approved online diagnostic assessment and consultation, after which ella(R) may be prescribed by fully licensed physicians in real time and delivered overnight to an address of the woman's choice.

About ella(R)

ella(R) is a progesterone agonist/antagonist emergency contraceptive and is proven effective in helping prevent pregnancies at certain stages of the menstrual cycle, including just before ovulation - the very time in a woman's cycle when the probability of pregnancy is highest. ella(R) is effective in delaying ovulation for up to five days, which is also the length of time that sperm can live in the female genital tract. Currently available over-the-counter levonorgestrel-based emergency contraceptives are indicated for use within 72 hours of unprotected intercourse or

contraceptive failure and their effectiveness in preventing pregnancy decreases over time.

Throughout its extensive clinical investigation, ella(R) consistently demonstrated safe and effective pregnancy prevention. Among women who were administered ella(R) within 72 hours of UPI, the observed pregnancy rate was 1.9%, significantly lower than the expected pregnancy rate (5.6%). Among women who were administered ella(R) 48-120 hours post-UPI, the observed pregnancy rate was 2.2% -- again, significantly lower than the expected pregnancy rate (5.5%).

Among the more than 2,600 women who have received ella(R) in clinical trials, the most commonly reported adverse events were headache (18%), abdominal pain (12%), nausea (12%), dysmenorrhea (9%), fatigue (6%) and dizziness (5%) - a profile similar to that of other available oral emergency contraceptives.

ella(R) should not be used during an existing or suspected pregnancy, and should not replace a regular method of contraception. ella(R) may reduce the contraceptive action of regular hormonal contraceptive methods. Therefore, after use of ella(R), a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur in that same menstrual cycle. Repeated use of ella(R) within the same menstrual cycle is not recommended. ella(R) is not indicated for termination of an existing pregnancy. ella(R) does not protect against HIV (AIDS) or other sexually transmitted infections. and women who become pregnant or complain of lower abdominal pain after taking ella(R) should be examined for the possibility of an ectopic pregnancy.

Ulipristal acetate has been available in Europe as an emergency contraceptive since October 2009, where it is marketed by its developer, HRA Pharma as ellaOne(R). Watson is the exclusive marketer of ella(R) in the U.S. under terms of a distribution agreement announced earlier this year.

For additional information, including full prescribing information, please visit http://www.ella-rx.com/ or call 1-855-ella-now.

Emergency Contraception - the Unmet Need

The technology of prophylactic contraception is imperfect. Condoms break. Oral contraceptives can and do fail. Even female sterilization, assumed by many women to be 100 percent effective, is associated with a failure rate of 0.5% during the first year. Of the 6.4 million pregnancies carried to term in the US in 2001, almost half (49%) were unintended. Nearly half (48%) of these unintended pregnancies are among women using regular methods of birth control where a failure occurred.

According to the Centers for Disease Control and Prevention (CDC), unintended pregnancy can be associated with an increased risk of morbidity for women - as well as with health behaviors during pregnancy that are associated with adverse events, including a delay in prenatal care.

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(R), GELNIQUE(R), Oxytrol(R), TRELSTAR(R), Crinone(R) and INFeD(R). In addition, Watson markets the following brands under co-promotion agreements: AndroGel(R), with Solvay Pharmaceuticals, Inc., and Femring(R), with Warner Chilcott Limited. The Watson brand pipeline portfolio includes a number of products, including Prochieve(R), under development with Columbia Laboratories for prevention of pre-term birth in women with a short cervix, recombinant follicle stimulating hormone (rFSH) in development with Itero Biopharmaceuticals for female infertility, and three novel new contraceptives. All other trademarks are the property of their respective owners. For press release and other company information, visit Watson Pharmaceuticals' Web site at www.Watson.com/

Forward-Looking Statement

Statements contained in this press release that refer to non-historical facts are forward-looking statements that reflect Watson's current perspective of existing information as of the date of this release. It is important to note that Watson's goals and expectations are not predictions of actual performance. Actual results may differ materially from Watson's current expectations depending upon a number of factors affecting Watson's business. These factors include, among others, the impact of competitive products and pricing; the timing and success of product launches; difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials; successful compliance with FDA and other governmental regulations applicable to Watson, its subsidiaries, and its third party manufacturers' facilities, products and/or businesses; changes in the laws and regulations, including Medicare and Medicaid, affecting among other things, pricing and reimbursement of pharmaceutical products; and such other risks and uncertainties detailed in Watson's periodic public filings with the Securities and Exchange Commission, including but not limited to Watson's annual report on Form 10-K for the year ended December 31, 2009 and Watson's quarterly report on Form 10-Q for the period ended September 30, 2010. Except as expressly required by law, Watson disclaims any intent or obligation to update these forward-looking statements.

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