



FDA Approves New Drug Application (NDA) for Teva's Quartette™ (levonorgestrel/ethinyl estradiol and ethinyl estradiol) Tablets for the Prevention of Pregnancy

-- Quartette™ Represents the Next Generation of Extended Regimen Oral Contraceptives --

Jerusalem, March 29, 2013 – Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) today announced that the U.S. Food and Drug Administration (FDA) has approved Quartette™ (levonorgestrel/ethinyl estradiol and ethinyl estradiol) tablets for the prevention of pregnancy. Quartette™ represents the next generation of extended regimen oral contraceptives to be approved by the FDA, and was designed to minimize breakthrough bleeding (BTB) between scheduled periods. The approval of Quartette™ demonstrates Teva's continued commitment to the development and production of an innovative range of pharmaceutical products that support the health of women around the world.

"Breakthrough bleeding can be experienced with any birth control pill, especially during the first few months, and is one of the reasons a large number of women discontinue extended regimens," said Dr. James A. Simon, clinical professor of Obstetrics and Gynecology at the George Washington University School of Medicine. "The estrogen in Quartette™ increases at specific points and provides four short light periods a year. Breakthrough bleeding decreases over time, which might help encourage patient adherence."

The approval was based on a development program that included results from Phase I, Phase II and Phase III clinical trials designed to evaluate the safety and efficacy of Quartette™. The Phase III clinical trial, which involved more than 3,000 women, found that Quartette™ was 97 percent effective at preventing pregnancy. Data further demonstrated that the most common adverse reactions (≥2%) in the Phase III clinical trial were headaches, heavy/irregular vaginal bleeding, nausea/vomiting, acne, dysmenorrhea, weight increased, mood changes, anxiety/panic attack, breast pain and migraines. The primary clinical trial that evaluated the efficacy of Quartette™ also assessed BTB. BTB and unscheduled spotting decreased over successive 91 day cycles.ⁱ

Quartette™ features a unique 91-day oral regimen, whereby the dose of estrogen increases at three distinct points over the first 84 days and the amount of progestin remains consistent; this is followed by seven days of 10 mcg of ethinyl estradiol.

"Teva is the leader in the pharmaceutical industry in the marketing and development of extended regimen oral contraceptives, and Quartette™ represents the next generation of these contraceptives. It is a uniquely differentiated product and is based on Teva's research into when breakthrough bleeding is most likely to occur with these regimens," said Jill DeSimone, senior vice president & general manager, Global Teva Women's Health. "Quartette™ is the newest

IR Contacts:	Kevin C. Mannix	United States	(215) 591-8912
	Kristen Frank	United States	(215) 591-8908
	Tomer Amitai	Israel	972 (3) 926-7656
PR Contacts:	Hadar Vismunski-Weinberg	Israel	972 (3) 926-7687
	Denise Bradley	United States	(215) 591-8974



product in our global women's health franchise and is an example of our dedication to providing a variety of contraceptive and family planning options that fit women's lifestyles."

Important Safety Information for Quartette™

Quartette™ (levonorgestrel/ethinyl estradiol and ethinyl estradiol) tablets are indicated for use by women to prevent pregnancy.

IMPORTANT SAFETY INFORMATION

WARNING TO WOMEN WHO SMOKE

Do not use Quartette™ if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects from birth control pills, including death from heart attack, blood clots, or stroke. The risk increases with age and the number of cigarettes you smoke.

- The use of hormonal birth control is associated with increased risks of several serious side effects, including blood clots, stroke, and heart attack.
- You should not take the pill if you have blood clots, certain cancers, a history of heart attack or stroke, undiagnosed abnormal bleeding, or may be pregnant.
- The most common side effects of Quartette™ are headaches, heavy/irregular vaginal bleeding, nausea/vomiting, acne, pain with bleeding, weight gain, mood changes, anxiety/panic attack, breast pain, and migraines.
- **The pill does not protect against HIV infection (AIDS) and other sexually transmitted infections.**
- The occurrence of fewer periods (4 per year instead of 13 per year) should be weighed against the occurrence of increased bleeding and/or spotting between periods. Unscheduled bleeding and unscheduled spotting should decrease over subsequent 91-day cycles.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please [click here](#) to see the full prescribing information, including Boxed Warning.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's leading generic drug maker, with a global product portfolio of more than 1,000 molecules and a direct presence in about 60 countries. Teva's branded businesses focus on CNS, oncology, pain, respiratory and women's health therapeutic areas as well as biologics. Teva currently employs

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approximately 46,000 people around the world and reached \$20.3 billion in net revenues in 2012.

Teva's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:

This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialize additional pharmaceutical products, competition for our innovative products, especially Copaxone[®] (including competition from innovative orally-administered alternatives, as well as from potential purported generic equivalents), competition for our generic products (including from other pharmaceutical companies and as a result of increased governmental pricing pressures), competition for our specialty pharmaceutical businesses, our ability to achieve expected results through our innovative R&D efforts, the effectiveness of our patents and other protections for innovative products, decreasing opportunities to obtain U.S. market exclusivity for significant new generic products, our ability to identify, consummate and successfully integrate acquisitions, the effects of increased leverage as a result of recent acquisitions, the extent to which any manufacturing or quality control problems damage our reputation for high quality production and require costly remediation, our potential exposure to product liability claims to the extent not covered by insurance, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic version of Protonix[®], our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement, any failures to comply with complex Medicare and Medicaid reporting and payment obligations, governmental investigations into sales and marketing practices (particularly for our specialty pharmaceutical products), uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology-based products, adverse effects of political or economical instability, corruption, major hostilities or acts of terrorism on our significant worldwide operations, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, any failure to retain key personnel or to attract additional executive and managerial talent, the impact of continuing consolidation of our distributors and customers, variations in patent laws that may adversely

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Press Release

for
immediate
release

affect our ability to manufacture our products in the most efficient manner, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities, the termination or expiration of governmental programs or tax benefits, environmental risks and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2012 and in our other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

ⁱ Quartette PI

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