

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
February 05, 2009

**FORM 6-K**

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**Report of Foreign Private Issuer**

**Pursuant to Rule 13a-16 or 15d-16  
under the Securities Exchange Act of 1934**

For the month of February 2009

Commission File Number 0-16174



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**Teva Pharmaceutical Industries Limited**

(Translation of registrant's name into English)

**5 Basel Street, P.O. Box 3190**

**Petach Tikva 49131 Israel**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F   X  

Form 40-F \_\_\_\_\_

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_\_\_\_\_

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes \_\_\_\_\_

No   X  

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b):  
82-\_\_\_\_\_



Website: [www.tevapharm.com](http://www.tevapharm.com)

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**For Immediate Release**

**COPAXONE<sup>&reg</sup> is approved for treatment of patients with A first clinical Event Suggestive of Multiple sclerosis**

*- Updated label offers early treatment with COPAXONE<sup>&reg</sup> -*

**Jerusalem, Israel, February 4, 2009** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) has approved an expanded label for COPAXONE<sup>&reg</sup> (glatiramer acetate injection) to include the treatment of patients with clinical isolated syndrome (CIS) suggestive of multiple sclerosis (MS). This approval includes 24 EU member countries that take part in the MHRA "mutual recognition procedure". *A similar application for the expanded COPAXONE<sup>&reg</sup> label is currently under review by the U.S. Food and Drug Administration (FDA).*

The *PreCISe study, conducted in patients with CIS demonstrated that COPAXONE<sup>&reg</sup> significantly reduced the risk of developing clinically definite MS (CDMS) by 45 percent versus placebo and prolonged the quartile time to conversion to CDMS to 722 days, versus 336 days in those patients receiving placebo.*

*COPAXONE<sup>&reg</sup> now has evidence-based data for early treatment and, in addition, is the only relapsing-remitting MS (RRMS) treatment with prospective long-term data demonstrating that 8 out of 10 patients adhering to COPAXONE<sup>&reg</sup> therapy are still able to walk unassisted after a mean of 15 years of therapy and 22 years of disease duration.*

*"COPAXONE<sup>&reg</sup> provides clear benefits from early phase of the disease to patients presenting with a first clinical event suggestive of MS", said Moshe Manor, Teva's Group Vice President, Global Innovative Resources, "This significant effect that adds on to the robust efficacy and safety data demonstrated over the last 15 years position COPAXONE<sup>&reg</sup> as a cornerstone in MS therapy".*

Approval of an expanded label for COPAXONE<sup>&reg</sup> to include the treatment of CIS patients was also provided by the Australian Health Authority (Therapeutic Goods Administration, TGA).

## About the PreCISe Study

The multinational, multi-center, prospective, double-blind, randomized, Phase III PreCISe study was conducted globally at 80 centers. It included a total of 481 patients presenting with a single clinical episode and magnetic resonance imaging (MRI) scans suggestive of MS. Patients included were those who had a unifocal disease manifestation (i.e., clinical evidence of a single lesion). Patients received either COPAXONE<sup>®</sup> 20mg/day or placebo as a subcutaneous injection and continued treatment for up to three years, unless a second attack was experienced and they were diagnosed with CDMS. Patients who converted to CDMS continued the trial on active treatment for an additional two years. The primary efficacy outcome was time to CDMS, based on a second clinical attack.

COPAXONE<sup>®</sup> (glatiramer acetate injection) was also shown to be very well tolerated in the PreCISe study, with 84 percent of patients completing the three-year study period; a rate similar to that observed in RRMS patients treated with COPAXONE<sup>®</sup>. All patients in the study participated in a follow-up study with COPAXONE<sup>®</sup> to prospectively assess the impact of early versus delayed treatment with COPAXONE<sup>®</sup> on the long-term course of the disease for a total observation time of up to five years.

A pre-planned interim analysis was performed on data accumulated from 81 percent of the three-year placebo-controlled study exposure. Results of the interim analysis, announced in December 2007, demonstrated the proportion of patients developing CDMS was reduced from 43 percent in the placebo group to only 25 percent in the COPAXONE<sup>®</sup> group ( $p < 0.0001$ ). The PreCISe study also demonstrated that the 25<sup>th</sup> percentile of number of days to conversion to CDMS more than doubled by COPAXONE<sup>®</sup> from 336 days to 722 days (hazard ratio 0.55,  $p = 0.0005$ ) compared with placebo.

Moreover, there was a significant reduction in the number of new T2 lesions and in the number of T1-enhancing lesions in the COPAXONE<sup>®</sup> arm compared to the placebo arm, both at year one and year two magnetic resonance imaging (MRI) scans.

*In September 2008, additional MRI data from the PreCISe study was presented at the World Congress on Treatment and Research in MS (WCTRIMS), in Montreal, Canada. The data demonstrated COPAXONE<sup>®</sup> significantly reduced MRI-disease activity and improved neuro-axonal integrity in patients presenting with a first clinical event suggestive of MS, versus patients who received placebo. These results provided the first evidence of neuro-axonal protection by a disease-modifying therapy in patients presenting with a first clinical event suggestive of MS.*

## About COPAXONE<sup>®</sup>

COPAXONE<sup>®</sup> is indicated for the reduction of the frequency of relapses in RRMS. The most common side effects of COPAXONE<sup>®</sup> are redness, pain, swelling, itching, a lump or an indentation at the site of injection, weakness, infection, pain, nausea, joint pain, anxiety, and muscle stiffness.

COPAXONE<sup>®</sup> is now approved in 51 countries worldwide, including the United States, Canada, Mexico, Australia, Israel, and all European countries. In North America, COPAXONE<sup>®</sup> is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA). In Europe, COPAXONE<sup>®</sup> is marketed

by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. COPAXONE<sup>®</sup> is a registered trademark of Teva Pharmaceutical Industries Ltd.

See additional important information at <http://www.copaxone.com/pi/index.html> or call 1-800-887-8100 for electronic releases. For hardcopy releases, please see enclosed full prescribing information.

## About Teva

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the world's leading generic pharmaceutical company. The Company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 80 percent of Teva's sales are in North America and Europe.

## 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 successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products and regulatory changes that may prevent us from utilizing exclusivity periods, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the impact of consolidation of our distributors and customers, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Neurontin<sup>®</sup>, Lotrel<sup>®</sup> and Protonix<sup>®</sup>, the effects of competition on our innovative products, especially Copaxone<sup>®</sup> sales, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, our ability to achieve expected results through our innovative R&D efforts, our ability to successfully identify, consummate and integrate acquisitions, including the integration of Barr Pharmaceuticals Inc., potential exposure to product liability claims to the extent not covered by insurance, dependence on the effectiveness of our patents and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, environmental risks, fluctuations in currency, exchange and interest rates, and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").*







Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://www.tevapharm.com)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Registrant)

By: /s/ Eyal Desheh

Name: Eyal Desheh  
Title: Chief Financial Officer

Date: February 4, 2009

