

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
March 04, 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 March, 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):  
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**Kevin Mannix** Teva North America (215) 591-8912

**For Immediate Release**

**COPAXONE<sup>®</sup> approved BY THE fda for patients with a first clinical event suggestive of Multiple sclerosis**

**Jerusalem, Israel, March 3, 2009** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA), today announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for COPAXONE<sup>®</sup> (glatiramer acetate injection) to include the treatment of patients who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis (MS).

The FDA's approval follows a similar decision by the Medicines and Healthcare Products Regulatory Agency (MHRA) in February 2009 under which 24 EU member states have mutually recognized an expanded label for COPAXONE<sup>®</sup> to include the treatment of patients with clinically isolated syndrome (CIS) suggestive of MS.

Up to 85% of MS patients initially experience a single neurological event suggestive of MS, known as CIS, and it has been demonstrated that early treatment initiation delays conversion from CIS to clinically definite MS (CDMS). This expanded indication in the U.S. and Europe allows patients to begin treatment with COPAXONE<sup>®</sup> from the very early stages of the disease.

"COPAXONE<sup>®</sup>, the world's leading MS disease modifying therapy, has demonstrated the ability to provide treatment benefits very early on, when patients present with a first clinical episode and have MRI features consistent with MS," said Moshe Manor, Teva's Vice President, Global Branded Products, "This milestone, along with the existing long-term safety and efficacy data, further position COPAXONE<sup>®</sup> as a cornerstone in MS treatment."

The FDA granted approval after reviewing the results of the PreCISe study, which indicated time to development of a second exacerbation was significantly delayed in patients treated with COPAXONE<sup>®</sup> compared to placebo (Hazard Ratio = 0.55; 95% Confidence Interval 0.40 to 0.77; p=0.0005). The cumulative probability of developing the second attack during the three year study period was significantly lower in the COPAXONE<sup>®</sup> group versus the placebo group (24.7% vs. 42.9%).

COPAXONE<sup>®</sup> is the only RRMS treatment with prospective long-term data demonstrating 8 out of 10 patients adhering to therapy are still able to walk unassisted after 15 years of therapy and 22 years of disease duration.

An approval for an expanded label for COPAXONE<sup>®</sup> was also granted by the Australian Health Authority (Therapeutic Goods Administration, TGA) in December 2008.

### **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 MRI scans suggestive of MS over a period of up to three years. 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 exacerbation was experienced. Patients who experienced a second exacerbation continued the trial on active treatment for an additional two years. The primary efficacy outcome was time to development of second exacerbation.

COPAXONE<sup>®</sup> (glatiramer acetate injection) was also shown to be well tolerated in the PreCISe study, with 84 percent of patients completing the three-year study period; this supports the safety and tolerability seen in RRMS patients treated with COPAXONE<sup>®</sup>.

A pre-planned interim analysis was performed on data accumulated from 81 percent of the three-year placebo-controlled study exposure. The PreCISe study demonstrated that the 25<sup>th</sup> percentile of number of days to second exacerbation more than doubled by COPAXONE<sup>®</sup> from 336 days to 722 days (Hazard Ratio = 0.55; 95% Confidence Interval 0.40 to 0.77) 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.

### **About COPAXONE<sup>®</sup>**

COPAXONE<sup>®</sup> is indicated for the reduction of the frequency of relapses in RRMS, including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. 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® and Lotrel® and Protonix®, the effects of competition on our innovative products, especially Copaxone® 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: March 3, 2009

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