TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
October 19, 2010

**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 October 2010

Commission File Number 0-16174

**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): _____

Website: **www.tevapharm.com**

**early initiation of treatment with COPAXONE&reg PRovides greater effects in delaying conversion to clinically definite MS**

*Early Initiation of Treatment with Copaxone&reg Reduced the Risk of Developing MS by 41 Percent*

*Copaxone&reg Delayed Time to Conversion to Clinically Definite MS by Almost 3 Years*

*Results of the PreCISe Five-Year Trial Presented at Late-Breaking News Session at the 26th ECTRIMS Congress*

**JERUSALEM, October 16, 2010** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced new data from the five-year extension of the PreCISe study demonstrating that earlier initiation of treatment with Copaxone&reg (glatiramer acetate injection) in patients presenting with first signs of multiple sclerosis (MS), provided greater effects in delaying conversion to clinically definite MS (CDMS) compared to later treatment initiation after diagnosis of CDMS or after three years on the study. Early treatment with Copaxone&reg reduced the risk of progression to CDMS by 41 percent (p=0.0005) compared with delayed treatment and delayed time to conversion to CDMS by almost three years or 972 days.

The study reached both its primary and secondary clinical and MRI endpoints, all of which were significantly positive. Earlier initiation of treatment with Copaxone&reg significantly slowed the rate of brain atrophy over the five-year study period. Additional secondary MRI results showed that the cumulative number of new T2 lesions (p<0.0001) and T2 lesion volume (p=0.0005) were lower in the early-Copaxone&reg treatment group compared with the delayed treatment group.

"The PreCISe five-year results underscore the clinical benefit of early treatment initiation with Copaxone&reg to delay the onset of this chronic disease by almost three years and reduce brain damage as shown by the deceleration of brain atrophy," said principal study investigator, Professor Giancarlo Comi, Director of the Department of Neurology and Institute of Experimental Neurology at the University Vite Salute, San Raffaele, Italy. "These long-term findings reinforce previously published PreCISe data, confirming the positive effect of Copaxone&reg, even before a definite

onset of MS, and establishing it as a core treatment for MS. Finally in MS what is lost is never regained and it particularly applies in the early phase of the disease."

The PreCISe five-year results were presented during two late-breaking news sessions at the 26th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).

**ABOUT THE ABSTRACTS**

**[P 986] Benefit of early treatment with glatiramer acetate: MRI results from the 5-year prospectively planned follow up in patients with clinically isolated syndrome enrolled in the PreCISe study.**

Poster Session: Late Breaking News, October 15, 3:30pm-5:00pm CET (*M. Filippi, M.A. Rocca, E. Perego, F. Agosta, A. Meani, O. Bajenaru, A. Carra, I. Elovaara, F. Fazekas, H.-P. Hartung, J. Hillert, J. King, S. Komoly, C. Lubetzki, X. Montalban, K.M. Myhr, M. M Ravnborg, P. Rieckmann, D. Wynn, C. Young, G. Comi for the PreCISe study group)*

# o To determine if early initiation of treatment with Copaxone&reg reduces disease activity and brain atrophy, as measured using MRI, in patients presenting with a first clinical event and neuroradiological features suggestive of MS. These results indicate that early treatment with Copaxone&reg can reduce disease activity and slow down accumulation of brain atrophy over five years.

# [135, Congress Hall] Benefit of early treatment with glatiramer acetate (Copaxone&reg): results from the 5-year prospectively planned follow up in patients with clinically isolated syndrome from the PreCISe study.

**Parallel Session: Late Breaking News, October 16, 8:45am-9:00am CET *(G. Comi, V. Martinelli, M. Rodegher, L. Moiola, O. Bajenaru, A. Carra, I. Elovaara, F. Fazekas, H.-P. Hartung, J. Hillert, J. King, S. Komoly, C. Lubetzki, X. Montalban, K.M. Myhr, M. Ravnborg, P. Rieckmann, D. Wynn, C. Young, M. Filippi)***

**o To determine whether early initiation of treatment with Copaxone&reg prevents progression to CDMS in patients presenting with a first clinical event and MRI features suggestive of MS. These results demonstrate the positive effect of early treatment with Copaxone&reg.**

**ABOUT THE PRECISE EXTENSION STUDY**

The study followed patients presenting with a first clinical event and magnetic resonance imaging (MRI) features suggestive of multiple sclerosis (MS) who were initially randomized to receive Copaxone&reg, compared to patients with delayed treatment initiation after diagnosis of CDMS or after three years in the study. PreCISe extension study results were presented during two late-breaking sessions at the 26th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).

**ABOUT COPAXONE&reg**

Copaxone**&reg** 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**&reg** are redness, pain, swelling, itching, or a lump at the site of injection, flushing, rash, shortness of breath, and chest pain.

Copaxone**&reg** (glatiramer acetate injection) is now approved in 51 countries worldwide, including the United States, Russia, Canada, Mexico, Australia, Israel, and all European countries. In North America, Copaxone**&reg** is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA). In Europe, Copaxone**&reg** is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. Copaxone&reg is a registered trademark of Teva Pharmaceutical Industries Ltd.

See additional important information at http://www.copaxone.com/pdf/PrescribingInformation.pdf or call 1-800-887-8100 for electronic releases.

**ABOUT TEVA**

Teva Pharmaceutical Industries Ltd. (NASDAQ: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 largest generic drug maker, with a global product portfolio of more than 1,250 molecules and a direct presence in approximately 60 countries. Teva's branded businesses focus on neurological, respiratory and women's health therapeutic areas as well as biologics. Teva's leading innovative product, Copaxone&reg, is the number one prescribed treatment for multiple sclerosis. Teva employs more than 40,000 people around the world and reached $13.9 billion in net sales in 2009.

**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, 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&reg, Lotrel&reg, Protonix&reg and Yaz&reg, the extent to which any manufacturing or quality control problems damage our reputation for high quality production, the effects of competition on sales of our innovative products, especially Copaxone&reg (including potential generic and oral competition for Copaxone&reg), the impact of continuing consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of ratiopharm), interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, intense competition in our specialty pharmaceutical businesses, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, dependence on the effectiveness of our patents and other protections for innovative products, our ability to achieve expected results through our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, our potential exposure to product liability claims to the extent not covered by insurance, the termination or expiration of governmental programs or tax benefits, current economic conditions, any failure to retain key personnel or to attract additional executive and managerial talent, environmental risks and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").*

*# # #*

o To determine whether early initiation of treatment with Copaxone&reg prevents progression to Created Using

o To determine whether early initiation of treatment with Copaxone&reg prevents progression to Created Using

Teva Pharmaceutical Industries Ltd. Web Site: www.tevapharm.com

**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 October 16, 2010

o To determine whether early initiation of treatment with Copaxone&reg prevents progression to Created Using

o To determine whether early initiation of treatment with Copaxone&reg prevents progression to Created Using