

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
April 22, 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 April 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](http://www.tevapharm.com)

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## **ADAGIO analysis Demonstrates THAT THE NATURAL PROGRESSION OF CLINICAL SYMPTOMS in Parkinson`s disease MAY BE slower IN EARLIER STAGES**

*Additional subgroup analyses may explain increased ability to detect disease-modifying effects in patients with higher baseline UPDRS scores*

*New findings provide further insights into the ADAGIO results which support early treatment initiation with Azilect<sup>®</sup>*

**Jerusalem, Israel, April 19, 2010** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced results from the placebo group analyses of the ADAGIO study (Attenuation of Disease progression with AZILECT<sup>®</sup> Given Once-daily) that were presented at the 62nd Annual Meeting of the American Academy of Neurology (AAN). The ADAGIO study stands out from other Parkinson`s disease (PD) trials as it is the largest clinical study conducted in patients who were still in the very early stages of their disease course (average time from PD diagnosis of 4.5 months).

The placebo analyses demonstrated that the natural progression of clinical symptoms in PD may be slower in the earlier stages of disease development than was expected from previous findings. These results may have implications for the overall interpretation of the ADAGIO results. Specifically, the clinical significance of the 1.7 UPDRS (Unified Parkinson's Disease Rating Scale) units seen between the AZILECT<sup>®</sup> (rasagiline tablets) 1 mg/day early and delayed-start groups during the nine month time period represents, on average, a 40 percent reduction from baseline in the early group when compared to the delayed group.

The results of the subgroup analysis showed faster progression in placebo patients with the highest baseline UPDRS scores (upper quartile), which may provide an explanation for the reported ability to detect a larger magnitude of disease-modifying effect with AZILECT<sup>®</sup> in ADAGIO patients in this subgroup.

"One interpretation about what was found in the subgroup analyses of placebo patients with the highest UPDRS scores is that the faster progression of these patients may explain the previously reported ability to detect a larger magnitude of disease modifying effect in this population, as well as a significant effect for the 2 mg dose," said Olivier Rascol, MD, University UPS, Toulouse, France, the co-principal investigator of the ADAGIO study.

## About the Study

*The Natural Progression of Clinical Symptoms in Parkinson's Disease may Not Be Faster in the Earlier Stages: Results From the ADAGIO Delayed-Start Study*

The ADAGIO study was an 18-month, placebo-controlled, double-blind, multicenter trial using a delayed-start design, involving patients with early, previously untreated Parkinson's disease (PD) (n=1176). Subsequent analyses were performed on placebo subjects (n=588), including a subgroup analysis of those with high (>25.5) and low (<14) baseline total UPDRS scores. Overall, the rate of progression for subjects on placebo was slower than anticipated (~6 UPDRS units/year), despite the fact that subjects were recruited at an earlier stage of disease progression than other trials as well as the belief that dopaminergic cell loss is thought to progress faster in the earlier stages of the disease.

Patients on placebo with more advanced PD (higher UPDRS baseline scores; n=145) showed faster disease progression (change from baseline extrapolated to 9 units/year as measured by Total-UPDRS). In contrast, patients with less advanced disease (lower UPDRS baseline scores; n=160) deteriorated at a slower pace (by 4 units/year as measured by Total-UPDRS).

## About Azilect<sup>®</sup>

Azilect<sup>®</sup> 1mg tablets are indicated for the treatment of the signs and symptoms of Parkinson's disease both as initial monotherapy and as adjunct to levodopa later in the disease. Azilect<sup>®</sup> 1mg tablets are currently available in 39 countries, including the US, Canada, Israel, Mexico, and all EU countries.

Teva has a long-term agreement for the joint development and marketing of Azilect<sup>®</sup> in Europe and some additional markets with H. Lundbeck A/S. In North America, Azilect<sup>®</sup> is marketed by Teva's wholly-owned subsidiary Teva Neuroscience ([www.tevaneuro.com](http://www.tevaneuro.com)).

See additional important information at <http://www.azilect.com/PrescribingInformation.pdf.ashx>. For hardcopy releases, please see enclosed full prescribing information.

### **About Parkinson's disease**

Parkinson's disease is an age-related degenerative disorder of the brain. Symptoms can include: tremor, stiffness, slowness of movement, and impaired balance. An estimated five million people worldwide suffer from the disease, with an average age of onset of about 60 years.

### **About Teva**

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 15 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Western 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, 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 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®<sup>®</sup> (including potential generic and oral competition for Copaxone®<sup>®</sup>), the impact of continuing consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions, 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").

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Teva Pharmaceutical Industries Ltd. Web Site: [www.tevapharm.com](http://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 April 19, 2010