

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
September 24, 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 September 2009

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): \_\_\_\_\_

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

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**RESULTS OF ADAGIO STUDY WITH AZILECT<sup>®</sup> IN PARKINSON'S DISEASE  
PUBLISHED IN *NEW ENGLAND JOURNAL OF MEDICINE***

*-- One of the largest Parkinson's disease studies demonstrates  
benefit of early treatment with AZILECT<sup>®</sup> 1 mg/day --*

**Jerusalem, Israel, September 23, 2009** - Results from the ADAGIO trial, published

online today in *The New England Journal of Medicine*, demonstrated that Parkinson's disease patients receiving AZILECT<sup>®</sup> (rasagiline) 1mg/day at the start of the study (early-start group) experienced superior benefit over 18 months compared with those who started the exact same treatment nine months later (delayed-start group).<sup>1</sup> This finding is consistent with a possible disease-modifying effect for AZILECT<sup>®</sup> (rasagiline) 1mg/day.

Professor C. Warren Olanow, MD, Department of Neurology, Mount Sinai School of Medicine, New York and co-principal investigator of the ADAGIO study, commented, "A therapy that slows or stops disease progression is the greatest unmet need in the treatment of patients with Parkinson's disease. Current therapies do not prevent the development of disability in such patients. The results of the ADAGIO study provide support for the possibility that early treatment with AZILECT<sup>®</sup> (rasagiline) 1mg/day may slow the development of disability."

AZILECT<sup>®</sup> is the first Parkinson's disease treatment to succeed in a prospective delayed-start study, a trial design specifically developed to test for the possibility of a disease-modifying effect.

Professor Olivier Rascol, Department of Clinical Pharmacology, University Hospital, Toulouse, France and ADAGIO co-principal investigator, stated, "The results of the ADAGIO study provide novel data to support the use of AZILECT<sup>®</sup> 1mg daily as initial treatment of patients with Parkinson's disease. The ADAGIO study, which utilized a novel trial design with three primary endpoints, suggests that the drug has a positive impact on slowing the progression of patients' disability, beyond its already known symptomatic benefit."

In the study, rasagiline 2mg/day, which is not a marketed dose for AZILECT<sup>&reg</sup>, did not meet the second primary endpoint. As discussed in *The New England Journal of Medicine* article, it is possible that a greater symptomatic effect of the 2mg/day dose may have masked a benefit associated with early-start treatment in the population of patients with very mild disease included in the ADAGIO study. A post-hoc analysis conducted on a sub-group of patients with highest baseline UPDRS (the upper quartile) showed positive results with the 2mg/day dose, supporting this hypothesis.

"Patients with Parkinson`s disease are in need of treatments that can slow or even halt the progression of their disease. After years of clinical experience and innovative scientific study with AZILECT<sup>&reg</sup>, we are proud to have contributed to the expanding body of knowledge in Parkinson`s disease," said William S. Marth, President and Chief Executive Officer of Teva North America. "Teva has been working to respond to questions raised by the FDA regarding ADAGIO and anticipates further discussions with the FDA to review and interpret the findings from this landmark study. Following those discussions, we expect to file a supplemental NDA in 2010, with the scope of any modification to the AZILECT<sup>&reg</sup> 1mg/day label remaining subject to the conclusion of those discussions."

#### **Teva to Host Conference Call with Professor C. Warren Olanow, MD**

Teva will host a conference call with Professor C. Warren Olanow, MD, co-principal investigator of the ADAGIO trial and William Marth, President and Chief Executive Officer, Teva North America to discuss the ADAGIO study results on Thursday, September 24, 2009, from 8:30 a.m. - 9:30 a.m. ET. The number to call from within the United States is (866) 700-7101 or (617) 213-8837 internationally and using the participant code 30733492. The call will also be webcast and may be accessed through the Company's website at [www.tevapharm.com](http://www.tevapharm.com). Following the conclusion of the call, a replay of the webcast will be available within 24 hours at the Company's Web site. To access the replay, go to Investor Relations and click on Conference Calls.

#### **About ADAGIO**

ADAGIO (**A**ttenuation of **D**isease progression with **A**ZILECT<sup>&reg</sup> **G**iven **O**nce-daily) was a randomized, multi-center, double-blind, placebo-controlled, parallel-group study prospectively examining rasagiline's potential disease-modifying effects in 1,176 patients with early, untreated Parkinson's disease. Patients from 129 centers in 14 countries participated and were randomized to initiate treatment for 72 weeks with rasagiline 1mg/day or 2mg/day, or to initiate treatment for 36 weeks with a placebo followed by 36 weeks with rasagiline 1mg/day or 2mg/day.

The primary analysis included three hierarchical endpoints based on total scores in the Unified Parkinson`s Disease Rating Scale (UPDRS). AZILECT<sup>&reg</sup> 1 mg/day early-start met all endpoints of the primary analysis: less deterioration in UPDRS score than placebo between weeks 12 and 36; less worsening than delayed-start in UPDRS score in comparing change between baseline and week 72 despite being on the same medication for the last 9 months; and non-inferiority to delayed-start in rate of deterioration between weeks 48 and 72. The ADAGIO study also confirmed the positive symptomatic effect and safety profile of AZILECT<sup>&reg</sup>, in line with prior studies.<sup>2</sup>

#### **About Azilect<sup>&reg</sup>**

AZILECT<sup>®</sup> (rasagiline) 1mg tablets are indicated for the treatment of the signs and symptoms of Parkinson's disease both as initial therapy alone and to be added to levodopa later in the disease. AZILECT<sup>®</sup> 1mg tablets are now available in 38 countries, including the U.S., Canada, Israel, Mexico and all of the European Union countries, where it is marketed by Teva in collaboration with Lundbeck A/S as part of a long-term strategic alliance.

### **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 four million people worldwide suffer from the disease, which usually affects people over the age of 60.

### **About Teva**

Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA), headquartered in Israel, is among the top 20 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. 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 Teva's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements, including statements relating to the results of the ADAGIO phase III trial, the timing of a submission to the FDA, if any, the possibility of any modification to the AZILECT<sup>®</sup> label and the scope of any such modification, and the potential efficacy or future market or marketability of AZILECT<sup>®</sup>. Following further analysis, Teva's interpretation of the results could differ materially depending on a number of factors, and we caution investors not to place undue reliance on the forward-looking statements contained in this press release, as there can be no guarantee that the results from the phase III trial discussed in this press release will be confirmed upon full analysis of the results of the trial, and additional information relating to the safety, efficacy or tolerability of AZILECT<sup>®</sup> may be discovered upon further analysis of data from the phase III trial. Even if the results described in this release are confirmed upon full analysis of the ADAGIO study, we cannot guarantee that any submission related to AZILECT<sup>®</sup> will be approved in a timely manner, if at all, by regulatory authorities in the European Union or in the U.S. Additional risks relating to Teva and its business are discussed in Teva's Annual Report on Form 20-F and its 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.*

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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 September 24, 2009

