

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
August 26, 2008

**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 August 2008

Commission File Number 0-16174



1

**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-\_\_\_\_\_



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**For Immediate Release**

**ADAGIO TRIAL RESULTS SHOW TEVA'S AZILECT<sup>®</sup> 1 MG TABLETS SLOW PROGRESSION OF PARKINSON'S DISEASE**

*Results Presented at 12<sup>th</sup> Congress of European Federation of Neurological Societies*

**Jerusalem, Israel, August 26, 2008** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announces that results of the phase III ADAGIO trial were presented today during the 12<sup>th</sup> Congress of European Federation of Neurological Societies (EFNS) in Madrid, Spain as part of a "Late Breaking News" session. The ADAGIO study showed that Parkinson's disease (PD) patients who took AZILECT<sup>®</sup> (rasagiline) 1mg tablets once-daily upon entry into the trial, demonstrated a significant improvement compared to those who initiated the drug 9 months later. The 1mg dose met all three primary endpoints, as well as the secondary endpoint, with statistical significance.

The primary analysis included three hierarchical endpoints based on Total-UPDRS (Unified Parkinson's Disease Rating Scale) scores: A) superiority of slopes in weeks 12-36 (-0.05; p=0.013, 95%CI -0.08,-0.01), B) change from baseline to week 72 (-1.7 units; p=0.025, 95%CI -3.15,-0.21), and C) non-inferiority of slopes (0.15 margin) in weeks 48-72 (0.0; 90%CI -0.04,0.04). The safety profile of AZILECT<sup>®</sup> seen in the ADAGIO study was similar to previous experience with AZILECT<sup>®</sup>.

Main results were presented at the congress by Professor Olivier Rascol, M.D., Ph.D., Department of Clinical Pharmacology, University Hospital, Toulouse, France, one of two principal investigators of the trial.

"The rigorous trial design and the fact that all three primary endpoints were met with statistical significance reinforce the quality of the data, supporting the potential for AZILECT<sup>®</sup> to have an effect on disease progression," said Prof. Rascol. "The successful outcome of the study provides further rationale for the early use of AZILECT<sup>®</sup> among Parkinson's disease patients," he added.

"Delaying disease progression is the most important unmet need in the management of Parkinson's disease," stated Prof. C. Warren Olanow, professor and chairman of the Department of Neurology at the Mount Sinai School of Medicine, New York, NY, and ADAGIO co-principal investigator. "The ADAGIO study, the first of its kind, was prospectively designed to demonstrate if AZILECT<sup>®</sup> can slow down the progression of Parkinson's disease. Results of the study show that early treatment with once-daily rasagiline 1mg tablets provided significant clinical benefits that were not obtained by those patients where initiation of AZILECT<sup>®</sup> therapy was delayed by nine months."

The ADAGIO study, one of the largest conducted in PD, included 1,176 patients with very early Parkinson's disease in 14 countries and 129 medical centers who were randomized to receive rasagiline 1 or 2 mg/day for 72 weeks (early

start) or placebo for 36 weeks followed by rasagiline 1 or 2 mg/day for 36 weeks (delayed start).

Description of trial results can be found online (<http://www.abstracts2view.com/ana>) in the abstract submitted by Prof. Olanow and Prof. Rascol to the 133<sup>rd</sup> Annual Meeting of the American Neurological Association, Salt Lake City, UT, September 21-24, 2008.

Prof. Olanow will be presenting these results during the Works in Progress poster session on Tuesday, September 23, 2008. The abstract was also chosen to be presented orally by Prof. Olanow on Tuesday from 11:45am-noon.

Teva intends to submit these results to the regulatory authorities in the U.S. and Europe. Based on these results, Teva will work with the regulatory authorities to incorporate the results into the label for AZILECT<sup>&reg</sup>.

For more information on AZILECT<sup>&reg</sup>, please visit [www.azilect.com](http://www.azilect.com).

### **About the Study**

ADAGIO is 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 were randomized to early-start treatment (72 weeks rasagiline 1 or 2 mg once daily) or delayed-start treatment (36 weeks placebo followed by 36 weeks rasagiline 1 or 2 mg once daily [active treatment phase]). The primary analyses of the trial were based on change in total UPDRS (Unified Parkinson's Disease Rating Scale) and included slope superiority of rasagiline over placebo in the placebo-controlled phase, change from baseline to week 72, and non-inferiority of early-start vs. delayed-start slopes during weeks 48-72 of the active phase. UPDRS is the most commonly used rating scale to assess disease status.

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

AZILECT<sup>&reg</sup> 1mg tablets (rasagiline 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>&reg</sup> 1mg tablets are currently available in 30 countries, including the US, Canada, Israel, Mexico, and most of the EU countries.

### **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., 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.

**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 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 AZILECT<sup>®</sup> will be approved for marketing in a timely manner, if at all, by regulatory authorities in the EU 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.



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: August 26, 2008