TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
May 18, 2006

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 May 2006

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-_____

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

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tEVA ANNOUNCES FDA grants APPROVAL of AzILECT&reg (rasagiline) for Parkinson`s disease

Jerusalem, Israel, May 17, 2006 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) today announced that it has received approval from the U.S. Food and Drug Administration (FDA) for once-daily AZILECT&reg (rasagiline tablets) as a treatment for Parkinson`s disease both as initial monotherapy in early Parkinson`s disease patients and as adjunct therapy to levodopa in moderate-to-advanced stages of the disease. AZILECT&reg will become available in the U.S. within 8 to 10 weeks.

Israel Makov, President and CEO of Teva commented, "We are extremely pleased to receive FDA approval for AZILECT&reg, the only once-daily product and one of the few treatment options in the U.S. indicated for all stages of Parkinson`s disease including as monotherapy in the early stages and as adjunct to levodopa in the more advanced stages. AZILECT&reg fills an important unmet need, offering a new treatment which uniquely combines efficacy, convenient once-daily dosing and good tolerability. The upcoming launch of AZILECT&reg represents a key milestone

in our commitment to develop and bring to market novel therapies for neurological diseases."

Mr. Makov went on to say: "We have recently embarked on a large clinical study (ADAGIO), to investigate the impact of AZILECT&reg on slowing the progression of Parkinson`s disease. If it is demonstrated that AZILECT&reg does indeed slow the progression of PD, this will undoubtedly represent a major breakthrough for Parkinson`s disease patients."

Teva`s U.S. innovative product marketing subsidiary, Teva Neuroscience, Inc., will promote AZILECT&reg in the U.S. Eisai Co., Ltd., which has been involved in the development of rasagiline since May 2003, will continue to collaborate with Teva on the global co-development of rasagiline for potential use in the treatment of Alzheimer`s disease. However, Teva understands that Eisai, due to its own business considerations and priorities, is still considering whether or not to elect to co-promote AZILECT&reg for Parkinson`s disease in United States.

During the past few years, Teva Neuroscience has doubled its field force and has demonstrated its capabilities in its neurological franchise through its sales efforts and significant success with Copaxone&reg. Mr. Makov commented: "Teva Neuroscience has taken Copaxone&reg to the leadership position it holds in the U.S. today, and we are confident they will repeat this success with AZILECT&reg."

AZILECT&reg is the second product to come out of Teva`s substantial pipeline of innovative products, which is derived largely from a close cooperation with Israeli universities and research institutes. It was approved in Europe and Israel in 2005, where it has been successfully launched. In the EU, it is now marketed in 13 countries in collaboration with Lundbeck A/S as part of a long-term strategic alliance between the two companies.

Approval for AZILECT&reg was based on data from three large, multicenter, multinational, double-blind, randomized, placebo-controlled clinical studies. These studies in over 1,600 patients demonstrated that AZILECT&reg given once daily was effective, and well-tolerated, given as initial monotherapy in the early stages of Parkinson`s disease or when added to levodopa and other therapies in more advanced stages of the disease.

About Azilect&reg

AZILECT&reg (rasagiline tablets) is indicated for the treatment of the signs and symptoms of idiopathic Parkinson`s disease as initial monotherapy and as adjunct therapy to levodopa.

AZILECT&reg is contraindicated for concomitant use with: meperidine, other MAO inhibitors, tramadol, methadone, propoxyphene, dextromethorphan, St. John`s wort, mirtazapine, cyclobenzaprine, sympathomimetic amines including

over-the-counter cold preparations, and local anesthetics containing sympathomimetic vasoconstrictors. Patients taking AZILECT&reg should avoid tyramine-rich foods, beverages, and dietary supplements. It seems prudent, in general, to avoid the combination of AZILECT&reg with antidepressants. Caution should be used when AZILECT&reg is used concurrently with CYP1A2 inhibitors such as ciprofloxacin. AZILECT&reg should not be taken by patients with moderate to severe hepatic impairment or pheochromocytoma.

Side effects of AZILECT&reg as monotherapy include arthralgia and dyspepsia; and as adjunct to levodopa therapy include dyskinesia, accidental injury, weight loss, postural hypotension, vomiting, arthralgia, nausea, constipation, dry mouth, rash, and somnolence.

AZILECT&reg was developed by Teva based on research originating from the Technion Israel Institute of Technology.

About Parkinson`s disease

Parkinson`s disease is a chronic, progressive, neurodegenerative disorder. The exact cause of Parkinson`s disease is unknown, and is believed to be multifactorial, involving genes, environmental factors and aging.

Symptoms include tremors, slowness of movement, stiffness, gait and posture problems. As the disease progresses, symptoms worsen, and the patient will most likely experience motor complications. Ultimately, the disease impairs the patient's ability to function.

The disease, which usually affects people over the age of 50, is estimated to affect some 4 million people worldwide, of which approximately one million in the U.S. In 2005, global sales of drugs to treat Parkinson`s disease reached about USD 3 billion.

AZILECT&reg (rasagiline tablets) is a registered trademark of Teva Pharmaceutical Industries, Ltd.

About Teva

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Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world. The company develops, manufactures, and markets branded and generic human pharmaceuticals and active pharmaceutical ingredients. Close to 90 percent of Teva`s sales are in North America and Europe. Teva`s innovative R&D focuses on developing novel drugs for diseases of the central nervous system.

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 Teva`s 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 Teva`s ability to rapidly integrate Ivax Corporation`s operations and achieve expected synergies, Teva`s ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic products, the impact of competition from brand-name companies that sell or license their own brand products under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic product, the impact of consolidation of our distributors and customers, regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding litigation, including that relating to the generic versions of Allegra&reg, Neurontin&reg, Oxycontin&reg and Zithromax&reg, the effects of competition on Copaxone&reg sales, including as a result of the expected reintroduction of Tysabri&reg into the market, 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, Teva`s ability to successfully identify, consummate and integrate acquisitions, potential exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism or major hostilities, environmental risks, fluctuations in currency, exchange and interest rates, operating results and other factors that 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 publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

Teva Pharmaceutical Industries Ltd. Web Site: 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/ Dan Suesskind

Name: Dan Suesskind
Title: Chief Financial Officer

Date: May 17, 2006