TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
February 24, 2005

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 February 2005

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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Contact: Dan Suesskind

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Teva Pharmaceutical Industries Ltd.

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George Barrett

President and CEO

Teva North America

FOR IMMEDIATE RELEASE (215) 591-3030

Dorit Meltzer

Director, Investor Relations

Teva Pharmaceutical Industries Ltd.

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Teva and Lundbeck Announce European Approval for AZILECT&reg (rasagiline) 1mg for Parkinson's Disease

Approved for use as monotherapy in early disease and adjunct therapy in moderate to advanced stages

Jerusalem, Israel and Copenhagen, Denmark, February 22, 2005 - Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) and H. Lundbeck A/S announced today that the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product AZILECT&reg (rasagiline 1mg, once daily), for the treatment of Parkinson`s disease (PD) both as monotherapy in patients with early PD and as adjunct treatment in moderate to advanced disease. The companies intend to market the product in various countries across Europe during the second quarter 2005.

Approval for AZILECT 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 given once daily was effective, safe and well-tolerated, whether given on its own in the early stages of PD or added to existing therapy in more advanced disease. Patients with moderate-to-advanced PD experienced significant improvements in `on-off` fluctuations and motor function when AZILECT was added to levodopa and other PD medications.

About AZILECT&reg

AZILECT is a novel, potent, second generation, highly selective, irreversible inhibitor of monoamine oxidase-B (MOA-B), the enzyme that breaks down dopamine in the central nervous system. Inhibition of MOA-B reverses the depletion of dopamine, which is responsible for the characteristic symptoms of PD - tremor, slowness of movement and rigidity. AZILECT has a side effect profile that is similar to placebo, and data from studies has confirmed its very good tolerability and acceptability for PD patients.

The development of AZILECT is part of a long-term strategic alliance for co-development in Parkinson's disease and European marketing between Lundbeck and Teva.

AZILECT is a joint development of Teva and the Technion - Israel Institute of Technology.

About Parkinson's disease

Parkinson`s disease (PD) is a progressive neurodegenerative condition. Symptoms include tremor, slowness of movement, stiffness, gait and posture problems.

As the disease progresses, symptoms worsen and the patient is likely to experience motor complications, including a fluctuating response to treatment. During "on" states, medication works effectively, but during "off" states, which correspond to the medication wearing off between doses, patients experience relatively poor function and mobility.

PD affects men and women equally, and an estimated four million people worldwide suffer from the disease, which typically occurs at a late age. Approximately 1% of the population over the age of 65 suffer from PD. It is estimated that well over one million people in the EU suffer from PD. In 2003, the worldwide market for PD drugs was valued at USD 2.2 billion with approximately 40% of this in Europe.

About Teva

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 25 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. The company develops, manufactures and markets generic and innovative 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.

About Lundbeck

H. Lundbeck A/S is an international pharmaceutical company engaged in the research and development, production, marketing and sale of drugs for the treatment of psychiatric and neurological disorders. In 2003, the company`s revenue was DKK 9.9 billion. The number of employees is approx. 5,000.

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 Teva`s ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competitive generic products, the impact of competition from brand-name companies that sell or license their own generic products (so called "authorized generics") or successfully extend the exclusivity period of their branded products, the effects of competition on Copaxone&reg sales, including potential competition from the launch of Tysabri&reg Teva's ability to rapidly integrate the operations of acquired businesses, including its acquisition of Sicor Inc., regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to completion of appellate litigation, including that relating to Neurontin, 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 Association and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, Teva`s ability to successfully identify, consummate and integrate acquisitions, exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations outside the United States that may be adversely affected by terrorism or major hostilities, 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.

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TEVA ANNOUNCES APPROVAL OF METHYLPREDNISOLONE ACETATE INJECTABLE SUSPENSION

Jerusalem, Israel, February 24, 2005 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announced today that the U.S. Food and Drug Administration has granted final approval for the Company`s ANDA for Methylprednisolone Acetate Injectable Suspension, 40 mg/mL and 80 mg/mL in single dose vials.

Teva`s Methylprednisolone Acetate Injectable Suspension is the AP-rated generic equivalent of Pfizer`s Depo-Medrol&reg Injection, an anti-inflammatory glucocorticoid for intramuscular, intrasynovial, soft tissue or intralesional injection.

The brand product has annual sales of approximately $41 million.

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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: February 24, 2005