TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
November 18, 2004

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 November 2004

Commission File Number 0-16174

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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. H. Lundbeck A/S.

Web Site: www.tevapharm.com Web Site: www.lundbeck.com

FOR IMMEDIATE RELEASE

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Teva and Lundbeck announce that Azilect&reg (rasagiline) for Parkinson's disease is recommended for approval in the EU

Jerusalem, Israel, Copenhagen, Denmark, November 18, 2004 - Teva Pharmaceutical Industries Ltd. and H. Lundbeck A/S announced today that the Committee for Medicinal Products in Human use (CHMP) of the European Medicines Agency (EMEA) has issued a positive opinion recommending approval of Azilect&reg (rasagiline) for the treatment of Parkinson's disease both as initial monotherapy in patients with early PD and as adjunct treatment in moderate-to-advanced disease.

Following this recommendation, final Marketing Authorization covering European Union (EU) countries, is expected to be granted by the European Commission in the first quarter of 2005.

Upon approval, Teva and Lundbeck will launch rasagiline in the EU under the brandname Azilect&reg.

"We are extremely pleased to have received the Committee`s positive recommendation, which is a significant step towards Azilect&reg becoming an important new treatment option in the EU for patients suffering from Parkinson's disease," said Israel Makov, President and CEO of Teva. "This achievement reflects the strength of the collaboration between Teva and Lundbeck and we look forward to continued success in the launch and co-promotion of Azilect&reg in the first half of next year."

The CHMP, comprised of regulators from the EU countries, based its positive opinion on the review of a comprehensive data package supporting the efficacy and safety of rasagiline, collected from studies that enrolled over 1,600 patients in all stages of the disease. In early PD, Azilect&reg monotherapy showed significant improvement in motor symptoms and quality of life. In advanced PD, Azilect&reg significantly reduces daily `off` time thereby improving the disabling motor fluctuations associated with advanced stages of the disease.

"Azilect&reg provides a new opportunity for people suffering from PD by offering a treatment that significantly improves PD symptoms throughout the course of the disease," said Claus Bræstrup, President & CEO of Lundbeck. "Azilect&reg is of strategic importance to Lundbeck as it constitutes the Company`s first launch of a treatment for Parkinson's disease thereby expanding its presence within the neurology area".

About Azilect&reg

Azilect&reg is a novel, potent, second-generation, selective, irreversible monoamine oxidase type-B (MAO-B) inhibitor that blocks the breakdown of dopamine, a substance in the brain needed to facilitate movement.

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

Azilect&reg is a joint development of Teva and the Technion - Israel institute of Technology.

About Parkinson`s disease

Parkinson`s disease is a chronic, progressive neurodegenerative condition. The exact cause of PD is not known and is believed to be multifactorial involving genes, environmental factors and aging.

Symptoms include tremor, slowness of movement, stiffness, gait and posture problems. As the disease progresses, symptoms worsen, the patient is likely to experience motor complications. Eventually, the disease impairs the patient`s ability to function.

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

About Teva

Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA), 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.

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 expected launch of Antegren&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.

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: November 18, 2004