TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
June 28, 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 June 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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TEVA AND ACTIVE BIOTECH ANNOUNCE THE SUBMISSION OF AN IND TO THE FDA FOR LAQUINIMOD, AN ORAL PRODUCT FOR THE TREATMENT OF RELAPSING MS

Jerusalem, Israel, and Lund**, Sweden**, **June 28, 2005** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech AB (Stockholm: ACTI.ST) announced today the submission of an investigational new drug application (IND) to the U.S. Food and Drug Administration (FDA) to initiate a clinical trial in the U.S. with laquinimod to assess drug-drug interaction. Based on the results of this study and of the ongoing phase IIb study in Europe (see below), the phase III clinical program to confirm the efficacy and safety of laquinimod in relapsing forms of MS, is planned to start in 2006.

Laquinimod is a novel orally administered immunomodulatory substance, developed by Active Biotech and recently licensed to Teva.

"I am pleased to report on this significant milestone," said Israel Makov, President and CEO of Teva. "This IND filing is an important step towards the initiation of pivotal studies with laquinimod which, along with Teva's development of an oral form of Copaxone&reg, enhance the likelihood that Teva will be the first to market an oral treatment. This further demonstrates our commitment to developing new and improved therapies for multiple sclerosis patients in order to help treat their disease and improve their quality of life".

"We are very pleased to see how Teva`s development program is diligently progressing towards starting phase III studies in the U.S. and Europe," said Sven Andréasson, President & CEO of Active Biotech. "Laquinimod has a profile that meets the need for a safe and efficacious oral MS drug suitable for long term treatment."

Laquinimod has the potential to be the first orally-administered disease modifying treatment for multiple sclerosis, both as a single agent therapy and in combination with Copaxone&reg, Teva's well-established and leading product on the market today.

A double-blind, placebo-controlled multi center phase IIb clinical study is currently on-going in several European countries, in which the effects of laquinimod, administered orally, once-daily, at dose levels of 0.3 and 0.6 mg/day, are compared to those of placebo over 9 months of treatment.

About laquinimod

Laquinimod is a novel immunomodulatory substance developed as an orally bio-available disease modifying treatment of MS. Laquinimod is the lead candidate drug identified from Active Biotech's SAIK research program, in which the safety/activity ratio has been optimized.

In a completed randomized, double-blind, placebo-controlled, multi-center phase II trial, 209 patients received either laquinimod, at dose levels of 0.1 or 0.3mg/day, or placebo, orally, once daily for 24 weeks. Laquinimod, at the dose of 0.3mg/day, reduced disease activity (as measured by MRI) by 44%. In a sub-group of patients with active MRI brain lesions prior to treatment initiation, the same dose of laquinimod reduced disease activity by 52%. In this study, laquinimod demonstrated a very favorable safety profile, suitable for long-term treatment (*Neurology 2005; vol 64, No. 6 p 987).*

About Multiple Sclerosis (MS)

Multiple sclerosis (MS) is a chronic, progressive disease of the central nervous system. It is the most common neurological disease causing disability in young adults. It has been described as an autoimmune disease because it is one of many diseases in which the immune system attacks healthy areas of the body as if they were foreign. In MS, these attacks are aimed at the central nervous system. The central nervous system is made up of nerves covered by a substance called *myelin,* which is similar to insulation protecting electrical wires because it surrounds and protects nerve fibers. When myelin or the nerve fiber is destroyed or damaged, the nerves cannot send electrical impulses to and from the brain, causing the onset of MS symptoms.

About Teva:

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 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% 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 Active Biotech

Active Biotech AB is a biotechnology company focusing on research and development of pharmaceuticals. Active Biotech has a strong R&D portfolio with pipeline products focused on autoimmune/inflammatory diseases and cancer. Its most advanced projects are **laquinimod**, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, as well as **ANYARA** for use in cancer immunotherapy with the primary indication non-small cell lung cancer. Further key projects in clinical development comprise the three orally administered compounds **TASQ** for prostate cancer **57-57** for SLE and **RhuDex&reg** for RA.

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, 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: June 28, 2005