TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
December 01, 2009

**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 December 2009

Commission File Number 0-16174

**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): _____

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**www.tevapharm.com**


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**For Immediate Release**

**TEVA ANNOUNCES THE SUBMISSION OF A BIOLOGICS LICENSE APPLICATION (BLA) FOR XM02 FOR THE TREATMENT OF CHEMOTHERAPY-INDUCED NEUTROPENIA**

Jerusalem, Israel, December 1, 2009 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA), today announced the submission of a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for XM02, a granulocyte colony-stimulating factor (G-CSF) for the reduction in the duration of severe neutropenia and the incidence of febrile neutropenia in patients treated with established myelosuppressive chemotherapy for cancer. XM02 was principally developed as a similar biological medicinal product to Neupogen&reg, the trademark for filgrastim (G-CSF). In September 2008, XM02 received marketing authorization in the European Union (EU) where a biosimilars pathway exists. XM02 was launched in several EU markets under the trade name TevaGrastim&reg and will be launched in additional EU markets over time.

Teva`s BLA submission is based on results from a clinical program consisting of five studies with more than 680 patients. The key study, conducted in breast cancer patients, was a three-arm study of XM02, Neupogen&reg or placebo in the first cycle of chemotherapy. Two additional clinical trials evaluating safety and efficacy were conducted in lung cancer and Non-Hodgkin`s Lymphoma patients, which compared XM02 and Neupogen during the first cycle of chemotherapy. These studies demonstrated the efficacy of XM02 with regard to the duration of severe neutropenia, incidence of febrile neutropenia and measure of absolute neutrophil count change over time which now needs to be reviewed by the U.S. Food and Drug Administration.

"We are pleased to complete the BLA submission for XM02, and as a result, mark a U.S. milestone for us as it is our first biologic product. Our G-CSF product was the first G-CSF biosimilar product approved in Europe and we look forward to working closely with the FDA to bring this important treatment option to the U.S.," William S. Marth, President and Chief Executive Officer of Teva North America stated. "Teva is dedicated to bringing high quality and affordable biologics to our customers, including a portfolio of additional follow on biologic drugs currently in research and development."

**About Neutropenia**

Neutropenia is a hematological disorder characterized by an abnormally low number of neutrophils, the most important type of white blood cell in the blood. Neutrophils usually make up 50-70% of circulating white blood cells and serve as the primary defense against infections by destroying bacteria in the blood. Cancer or other diseases that damage bone marrow, as well as drugs that destroy neutrophils or damage bone marrow such as chemotherapy may cause Neutropenia.

**About Teva**

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is the world's leading generic pharmaceutical company and is among the top 20 pharmaceutical companies in the world. 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.

**Teva's 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 our 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: our ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products and regulatory changes that may prevent us from utilizing exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Neurontin&reg, Lotrel&reg, Protonix&reg and Eloxatin&reg, the current economic conditions, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the effects of competition on our innovative products, especially Copaxone&reg sales, dependence on the effectiveness of our patents and other protections for innovative products, the impact of consolidation of our distributors and customers, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, our ability to achieve expected results though our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the uncertainty surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, the regulatory environment and changes in the health policies and structures of various countries, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, our ability to successfully identify, consummate and integrate acquisitions, the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, our ability to enter into patent litigation settlements and the intensified scrutiny by the U.S. government, the termination or expiration of governmental programs and tax benefits,

impairment of intangible assets and goodwill, environmental risks, and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

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

**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 December 1, 2009