

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
June 27, 2011

**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 2011

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):

**TEVA ANNOUNCES SUCCESSFUL RESULTS OF PHASE III STUDY OF ITS LONG-ACTING G-CSF PRODUCT (LIEPGFILGRASTIM) IN BREAST CANCER PATIENTS**

**Jerusalem, Israel, June 6, 2011** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announced today that lipegfilgrastim (INN; internal code - XM22) achieved its primary endpoint of reducing the duration of severe neutropenia in a Phase III study designed to evaluate the efficacy and safety of lipegfilgrastim (XM22) compared to pegfilgrastim (Amgen's Neulasta(TM)).

Lipegfilgrastim (XM22), a long acting granulocyte colony-stimulating factor (G-CSF), was added to Teva's portfolio through the acquisition of ratiopharm. It is being developed to reduce the duration of severe neutropenia in cancer patients undergoing chemotherapy. Neutropenia is a condition in which the number of white blood cells is decreased, leaving patients more susceptible to potentially life-threatening bacterial infections.

"We are pleased with the successful results of this Phase III study. Teva is committed to the development of biologics and biosimilars, which make up one of the fastest growing segments of the global pharmaceutical market and offer efficacious yet more affordable treatment to all patients," said Professor Yitzhak Peterburg, Teva's Group Vice President, Global Branded Products.

World-wide sales in 2010 of G-CSF totaled \$4.2 billion, of which Neulasta(TM) sales represented \$3.56 billion.

The Phase III, multinational, randomized, double-blind controlled study was conducted in over 200 breast cancer patients receiving four cycles of chemotherapy (doxorubicin/ docetaxel). Patients were randomized to receive treatment with either 6mg of lipegfilgrastim (XM22) or with the active comparator, pegfilgrastim 6mg (Neulasta(TM)).

Initial study results demonstrate that the duration of severe neutropenia (DSN) was similar in both treatment groups and the difference was well below the limit of 1 day, as required by the EMA, and below 0.62 days, as required by the

U.S. FDA. Additionally, no significant differences were observed in treatment-emergent adverse events between the two treatment groups.

Further analysis of the study results is ongoing.

An additional efficacy and safety study comparing lipegfilgrastim (XM22) to placebo in preventing chemotherapy-induced neutropenia in non-small cell lung cancer patients is currently ongoing, with results expected later this year.

## **ABOUT LIPEGFILGRASTIM**

Lipegfilgrastim (INN; internal code - XM22) is a glyco-PEGylated recombinant human G-CSF being developed to reduce the duration of severe neutropenia and incidence of febrile neutropenia in cancer patients undergoing chemotherapy.

Lipegfilgrastim (INN; internal code - XM22) was added to the Teva's portfolio through the acquisition of ratiopharm and is a long-acting G-CSF based on glyco-PEGylation technology, which leads to a prolonged plasma half-life. The product is designed to provide clinical efficacy and safety profiles which are fully comparable to Neulasta(TM).

## **ABOUT THE STUDY**

This multinational, multicenter, randomized, double-blind, controlled Phase III study was designed to evaluate the efficacy and safety of lipegfilgrastin 6mg compared to pegfilgrastim 6mg (Neulasta(TM)) in preventing chemotherapy-induced neutropenia in breast cancer patients receiving 4 cycles of doxorubicin and docetaxel.

Approximately 24 hours after the initiation of chemotherapy, 101 patients received a single subcutaneous injection of lipegfilgrastim on each of the 4 cycles. In parallel, 101 patients were treated accordingly with pegfilgrastim. Study results show that the primary outcome measure of reducing the duration of severe neutropenia in cycle 1 was well met. No relevant differences in safety parameters were observed. Further analysis is ongoing.

## **ABOUT TEVA**

Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's largest generic drug maker, with a global product portfolio of more than 1,450 molecules and a direct presence in about 60 countries. Teva's branded businesses focus on neurological, respiratory and women's health

therapeutic areas as well as biologics. Teva's leading innovative product, COPAXONE<sup>®</sup>, is the number one prescribed treatment for relapsing-remitting multiple sclerosis. Teva employs approximately 40,000 people around the world and reached \$16.1 billion in net sales in 2010.

**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 develop and commercialize additional pharmaceutical products, competition from the introduction of competing generic equivalents and due to increased governmental pricing pressures, the effects of competition on sales of our innovative products, especially COPAXONE<sup>®</sup> (including competition from innovative orally-administered alternatives as well as from potential generic equivalents), potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Lotrel<sup>®</sup> and Protonix<sup>®</sup>, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products, the extent to which any manufacturing or quality control problems damage our reputation for high quality production and require costly remediation, our ability to identify, consummate and successfully integrate acquisitions (including the pending acquisitions of Cephalon and Taiyo), our ability to achieve expected results through our innovative R&D efforts, dependence on the effectiveness of our patents and other protections for innovative products, intense competition in our specialty pharmaceutical businesses, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, our potential exposure to product liability claims to the extent not covered by insurance, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, the impact of continuing consolidation of our distributors and customers, the difficulty of complying with U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority requirements, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, the termination or expiration of governmental programs or tax benefits, any failure to retain key personnel or to attract additional executive and managerial talent, environmental risks and other factors that are discussed in our filings with the U.S. Securities and Exchange Commission.*

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Teva Pharmaceutical Industries Ltd. Web Site: [www.tevapharm.com](http://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: June 21, 2011

