

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
May 31, 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 May 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 Data on Granulocyte Colony Stimulating Factor Compounds for the Prevention of Chemotherapy-Induced Neutropenia in Breast Cancer Patients**

*CG-10639 (formerly Neugranin) Phase II/III data demonstrated non-inferiority to pegfilgrastim*

*Dosing study of XM22 supported future Phase III trial of 6mg dose versus pegfilgrastim*

*Both compounds studied in breast cancer patients receiving myelosuppressive chemotherapy*

*Data presented at American Society of Clinical Oncology Annual Meeting*

*Teva to release Phase III study results in the near future*

Jerusalem, Israel, **May 31, 2011** - Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) announced today that data from studies of two investigational Granulocyte Colony Stimulating Factor (G-CSF) compounds in breast cancer patients receiving myelosuppressive chemotherapy will be presented at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, June 3-7, 2011.

A Phase II/III study of CG-10639, a long-acting recombinant human albumin-human G-CSF to prevent chemotherapy-induced neutropenia, demonstrated similar outcomes to pegfilgrastim (PEGF), for both efficacy and safety measures in breast cancer patients. The primary endpoint was duration of severe neutropenia (DSN) in days during cycle one of treatment. These data showed the non-inferiority of CG-10639 (40mg and 50mg) to PEGF; a confirmatory Phase III study comparing CG-10639 40mg and PEGF 6mg is currently underway. No clinically relevant immunogenicity with CG-10639 was observed.

Phase II data from a dose-finding study of another Teva investigational compound for G-CSF, XM22, will also be presented at ASCO. These data confirmed greater efficacy based on DSN with higher doses of XM22. While all formulations of XM22 studied (3mg, 4.5mg and 6mg) impacted DSN similarly in the first treatment cycle, a trend for shorter DSN was associated with the higher doses. Treatment-related adverse events were similar between treatment groups. The results supported the use of XM22 6mg in the ongoing Phase III clinical trial program.

Phase III study results will be released in the near future.

**The full abstracts can be found online at the links below:**

*A randomized, non-inferiority study of recombinant human G-CSF/human serum albumin fusion (CG-10639) and pegfilgrastim in breast cancer patients receiving myelosuppressive therapy.* (Patient & Survivor Care, June 4, Abstract: 9083)

*A randomized, double-blind, active control, multicenter, dose-finding study of XM22, glycopegfilgrastim, in patients with breast cancer receiving myelosuppressive therapy.* (Patient & Survivor Care, June 4, Abstract: 9080)

### **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 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 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 Neurontin<sup>®</sup>, 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 acquisition 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 this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").*

Website: [www.tevapharm.com](http://www.tevapharm.com)

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: May 31, 2011

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