

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
May 17, 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 AND CURETECH ANNOUNCE POSITIVE PHASE II DATA FROM CT-011, AN INVESTIGATIONAL ANTIBODY IN DIFFUSE LARGE B CELL LYMPHOMA**

*-- CT-011 Meets Primary Endpoint of Progression-Free Survival --*

*-- Achieved Statistically Significant Results in Secondary Endpoint of Overall Survival --*

**Jerusalem, Israel, May 17, 2011** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and CureTech, a portfolio company of Teva and Clal Biotechnology Industries announced today preliminary topline results for CT-011, an investigational anti-PD-1 monoclonal antibody. CT-011 met the primary endpoint of improved progression-free survival (PFS), in a Phase II clinical trial in patients with Diffuse Large B Cell Lymphoma (DLBCL) following autologous stem cell transplantation. Statistically significant results have also been achieved in the secondary endpoint of Overall Survival (OS).

Preliminary analyses indicate that 70% of the patients treated with CT-011 were progression-free at the end of the follow-up period, as compared to only 47% in the historical control. Furthermore, 84% of the patients treated with CT-011 were alive by the end of the follow-up period, compared to only 62% in the historical control.

"We are very pleased to have achieved this major milestone in the clinical development of CT-011", said Dr. Michael Schickler, CEO of CureTech. "Following the final results, CureTech will be ready to commence Phase III regulatory studies for the high unmet need in this severe indication."

"DLBCL is an aggressive type of non-Hodgkin's Lymphoma (NHL) affecting about 40% of all NHL patients," said Jacob M Rowe MD, Director, Department of Hematology, Shaare Zedek Medical Center in Jerusalem, Israel. "I am very encouraged by the results of this trial and am certain that if these results will be confirmed in future controlled Phase III studies, CT-011, a truly novel anti cancer therapy will improve the lives of many DLBCL patients."

"The results of this early study are exciting," said Arnon Nagler, MD, Director of the Division of Hematology, BMT and CBB at the Chaim Sheba Medical Center, Israel and co-International Principal Investigator in the study. "There is a significant unmet medical need for therapies that could benefit these patients and I am pleased that such a promising

treatment came out of Israeli science."

Following the successful completion of CureTech's first Phase I study in 2006, Teva took an equity position in the Company, and upon subsequent investments, Teva now holds approximately 33% of CureTech and has an option to further invest in the Company. This opportunity is one of many initiatives in which Teva has invested in recent years. The success of this significant Phase II study encourages Teva to continue leveraging Israeli science.

"When we expanded our collaboration with CureTech in 2008, we did so with the intention of building on CT-011's success up to that point, and we are incredibly pleased with the Phase II data announced today," said Dr. Aharon Schwartz, Head of Teva's Innovative Ventures. "Our collaboration with CureTech is just one of many oncology investments and alliances that we have made over the last several years in an effort to build out our portfolio of specialty products within niche therapeutic areas like oncology."

Final Phase II results for CT-011 in DLBCL are expected to be available during the third quarter of this year. These data will be presented at future international scientific meetings.

## **ABOUT THE PHASE II STUDY**

Seventy two patients in 30 centers in the US, Asia, South America and Israel, entered the study 1-3 months after ASCT. Patients received up to 3 injections of CT-011 every 6 weeks and were then followed for 13 months without further treatment. The historical comparator for this study was a cohort of 198 patients who had participated in the DHAP arm of the CORAL (ASCO, 2009) study (the historical control). In addition to the clinical endpoints, about 100 biomarkers were also monitored at different time points. The results indicate an increase in the number of specific T cells responsible to the maintenance of long-term immunologic memory. This may explain the long term effect of the treatment shown in the study.

## **ABOUT CT-011**

CT-011 was generated by Drs. Brita Hardy and the late Abraham Novogrodsky at the Tel Aviv University and it belongs to a new class of anticancer therapies attempting to harness the body's immune system against the disease. Cancer cells avoid the body's immune system through a mechanism involving the interaction of PD-1, a "programmed death" receptor with its cognate antigen, PD-L1. PD-1 appears on tumor-reactive lymphocytes and induces apoptosis of these cells. CT-011 blocks PD-1 and revitalizes the body's own immune system. Until recently immunotherapy was an unfulfilled dream shared by many cancer researchers. However, during the last two years the validity of this approach was rekindled by the regulatory approval of two immunotherapeutic agents which showed success in clinical trials for cancer patients. In 2007, the National Cancer Institute (NCI) rated PD-1 as the second most promising potential target among approximately 140 pathways and molecules for cancer immunotherapy.

To date more than 400 patients participate in 7 phase II and Phase I/II studies with CT-011 in different cancer indications such as colon cancer, multiple myeloma, acute leukemia, and pancreatic cancer, in cooperation with leading global researchers. CureTech has also recently announced the submission of a protocol to the US FDA for the conduct of a phase II trial in metastatic melanoma, a severe solid tumor indication with very few treatment options. These trials demonstrate the broad potential of the CT-011 antibody.

### **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® 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.

### **About CureTech**

CureTech is a privately held biotechnology company operating out of Israel and focuses on the research, development and commercialization of novel, broad-spectrum, immune modulating products for the treatment and control of cancer. CureTech products offer an alternative approach to current biological cancer treatment by directly affecting specific functions of the immune system thus providing the safety inherent to antibody-based therapy and the ability to target a wide spectrum of malignancies. CureTech's lead drug, CT-011, a humanized monoclonal antibody directed against PD-1, a B7 family-associated protein, has completed Phase I clinical testing.

### **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® (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®, Lotrel® and Protonix®, 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), 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").

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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 17, 2011

1