TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
April 07, 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 April 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): _____

Website: **www.tevapharm.com**

Teva and OncoGenex Present Preclinical Data on the Activity of its Antisense Compound Custirsen (OGX-011/TV-1011) at the American Association of Cancer Research (AACR) Annual Meeting 2011

-- New Data Suggests Novel Strategies for the Treatment of Prostate Cancer --

Jerusalem, Israel, Bothell, WA and Vancouver, **British Columbia, April 6, 2011** - Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) and OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today that new preclinical data of their investigational compound custirsen (OGX-011/TV-1011) in castrate resistant prostate cancer (CRPC) were presented this week at the 102nd Annual Meeting of the AACR. These data provide additional evidence in support of the clinical potential of custirsen, a drug designed to block production of clusterin, that is currently being investigated in Phase III studies for CRPC.

Clusterin, a cell survival protein is over-produced in several cancer types and in response to many cancer treatments.

Study results show that clusterin regulates epithelial-mesenchymal transition (EMT) induced by the growth factor TGF beta and the transcription factor TWIST1 in prostate cancer cells. Both TGF beta and TWIST1 are known to be important regulators of EMT, the process in which cells undergo multiple biochemical changes that result in cancer cell migration, invasion and metastasis. These findings provide supporting evidence to the mechanism of clusterin expression and its relevance in the EMT of cancer cells.

"This study demonstrated that by inhibiting clusterin we can help reverse EMT, thereby identifying an important mechanism by which novel drugs like custirsen may inhibit cancer progression and improve patient outcomes," said Dr. Martin Gleave, Director of The Vancouver Prostate Centre at The University of British Columbia and study researcher. "These results establish clusterin inhibition as a valid therapeutic target, and underscore the importance of the ongoing Phase III trial program to demonstrate the clinical manifestation of the compound's mechanism of action."

Additionally, data were presented earlier this week that showed an inhibitory effect of custirsen on heat-shock protein 90 (HSP90) in prostate cancer cells. Inhibition of HSP90 is being investigated as a novel strategy for the treatment of prostate cancer, and the addition of custirsen may be able to enhance the activity of HSP90 inhibitors. Both abstracts can be found on the AACR website at http://www.aacr.org/.

These preclinical data further support the ongoing, Phase III custirsen development program in prostate cancer:

The Prostate Cancer SATURN trial, evaluating a durable pain palliation benefit for custirsen in combination with docetaxel retreatment as second-line chemotherapy in approximately 300 patients with CRPC.

The SYNERGY trial, evaluating a survival benefit for custirsen in combination with first-line docetaxel treatment in approximately 800 patients with CRPC.

More information on these trials can be found at:

http://www.clinicaltrials.gov/ct2/show/NCT01083615

http://www.clinicaltrials.gov/ct2/show/NCT01188187

http://www.oncogenex.com/clinicalTrials/index.html

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&reg, 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 OncoGenex Pharmaceuticals

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new cancer therapies that address treatment resistance in cancer patients. OncoGenex has a diverse oncology pipeline, with each product candidate having a distinct mechanism of action and representing a unique opportunity for cancer drug development. OncoGenex and Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) have entered a global collaboration and license agreement to develop and commercialize OncoGenex' lead drug candidate, custirsen.

Custirsen is currently in Phase 3 clinical development as a treatment in men with metastatic castrate-resistant prostate cancer. The companies plan to begin Phase 3 development of custirsen in first-line treatment of advanced, unresectable non-small cell lung cancer in 2011. OGX-427 is in Phase 2 clinical development; SN2310 has completed a Phase 1 clinical trial; and CSP-9222 and OGX-225 are currently in pre-clinical development.

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 Gemzar&reg, the extent to which any manufacturing or quality control problems damage our reputation for high quality production, the effects of competition on sales of our innovative products, especially Copaxone&reg (including potential generic and oral competition for Copaxone&reg), the impact of continuing consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of ratiopharm), interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, intense competition in our specialty pharmaceutical businesses, 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, 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, dependence on the effectiveness of our patents and other protections for innovative products, our ability to achieve expected results through our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, our potential exposure to product liability claims to the extent not covered by insurance, the termination or expiration of governmental programs or tax benefits, current economic conditions, 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").

.

OncoGenex' Forward Looking Statements:

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning our anticipated product development activities, the timing and costs of these activities and the potential benefits of our product candidates. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements. Such forward-looking statements are subject to risks and uncertainties, including, among others, the risk that we are unable to complete our product development activities as planned, if at all, the risk that our product development activities are not successful and that our product candidates do not obtain the requisite regulatory approvals for commercialization, and the risk factors set forth in the Company's

filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K for fiscal year 2010. The Company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

# # #

Website: **www.tevapharm.com**

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 April 6, 2011