TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
May 19, 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): _____

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Teva and OncoGenex to Present Data on Custirsen in Prostate Cancer

at the 2011 ASCO Annual Meeting

Pre-Clinical Data Show Potential Combinability and Enhanced Anti-Tumor Activity

With Two Different Agents

Jerusalem, Israel, Bothell, WA and Vancouver, **British Columbia, May 19, 2011** - Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) and OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today that data from three studies of their investigational compound custirsen (OGX-011/TV-1011) in castrate resistant prostate cancer (CRPC) will be presented at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, June 3-7, 2011.

Custirsen is the only compound in development designed to inhibit the production of clusterin, a protein commonly over-produced in cancer cells and a potential cause of treatment resistance. Previous clinical data from the Phase II trials demonstrated that custirsen combined with docetaxel improved overall survival rates as well as durable pain palliation.

Findings from the two pre-clinical studies that will be presented demonstrate the clinical potential of custirsen combinability with anti-cancer agents in the treatment of prostate cancer. Additionally, an overview of the ongoing Phase III SYNERGY trial in metastatic castration resistant prostate cancer (mCRPC) patients will be presented. The SYNERGY trial is one of three Phase III trials initiated under a global collaboration and license agreement between Teva and OncoGenex to develop and commercialize custirsen.

"Despite the advances made in the treatment of prostate cancer, overcoming treatment resistance remains a large unmet need," said Professor Yitzhak Peterburg, Teva's Group Vice President, Global Branded Products. "Teva and OncoGenex are encouraged by the new custirsen findings presented at ASCO this year, which are consistent with the benefits demonstrated by custirsen to date. We hope to further confirm these benefits in our ongoing Phase III

program."

Custirsen Data to be Presented:

1) A pre-clinical evaluation of custirsen in combination with MDV3100 in a castrate resistant prostate cancer model will be presented (Translational Science Advancing AR Targeting in Prostate Cancer, Abstract #4502, June 4)

The study showed a synergistic effect in combining custirsen and MDV3100, down-regulating androgen receptor levels and suppressing androgen-sensitive prostate cancer cell growth *in vitro* and *in vivo*

At this time both custirsen and MDV3100 are being evaluated separately in Phase III trials for the treatment of mCRPC

2) Another pre-clinical evaluation explored the potential for custirsen as an adjunct therapy to heat-shock protein 90 (Hsp90) inhibitors (Genitourinary Cancer poster session, Abstract #4573, June 5)

Hsp90 inhibitors trigger the elevation of compensatory survival mechanisms that result in production of clusterin, leading to cancer cell survival and treatment resistance

Results of this study showed that when an Hsp90 inhibitor was combined with custirsen, both agents work synergistically to inhibit tumor growth and prolong survival in mice

3) Also being presented is an overview of the Phase III SYNERGY trial, an ongoing randomized, open-label, global multi-center study evaluating a survival benefit for custirsen in combination with first-line docetaxel treatment in approximately 800 men with mCRPC. SYNERGY is one of the two Phase III trials underway evaluating custirsen in the treatment of mCPRC. (Trials in Progress poster session, Abstract #TPS180, June 6).

About Custirsen

Custirsen is the only compound currently in development designed to inhibit the production of clusterin, a protein commonly over-produced in cancer cells, and one cause of treatment resistance. In Phase II trials of patients with metastatic castration resistant prostate cancer (mCRPC), custirsen combined with docetaxel showed a 6.9 month improvement in overall survival over docetaxel alone. Additionally, 50 percent of patients experienced durable pain

palliation for a duration of 12 weeks or longer. Unlike opioids or agents that target the androgen receptor, custirsen is mechanistically unique in its ability to impact pain responses via the regulation of NF-kB (nuclear factor kappa-light-chain-enhancer of activated B cells) activity. This is a potential attribute that could contribute to custirsen`s clinical benefit in combination with numerous anti-cancer treatments.

Custirsen has received Fast Track designation from the U.S. Food and Drug Administration (FDA).

More information is available at www.OncoGenex.com and

www.tevapharm.com/research.

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 relapsing-remitting 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. 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; 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 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&reg (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&reg, Lotrel&reg and Protonix&reg, 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").

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 the potential benefits of our product candidates and statements regarding our anticipated product development activities. 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2011. 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.

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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: May 19, 2011

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