

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
June 30, 2008

**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 2008

Commission File Number 0-16174



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**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

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):

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes

No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b):  
82-



Web Site: [www.antisense.com.au](http://www.antisense.com.au)

Teva Pharmaceutical Industries Ltd. Web Site: [www.tevapharm.com](http://www.tevapharm.com)

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Contact:	<b>Elana Holzman</b>	Teva Pharmaceutical Industries Ltd.	972 (3) 926-7554
	<b>Kevin Mannix</b>	Teva North America	(215) 591-8912
Contact:	<b>Mark Diamond</b>	Antisense Therapeutics Ltd	61 (3) 9827 8999

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**For Immediate Release**

**TEVA & ANP ANNOUNCE THAT ATL/TV1102, A NOVEL DRUG FOR THE TREATMENT OF RELAPSING REMITTING MULTIPLE SCLEROSIS (RRMS), DEMONSTRATED SIGNIFICANT REDUCTION IN DISEASE ACTIVITY**

*-- Results Demonstrate Impressive Reduction of Disease Activity as Early as 8 Weeks -*

***-- Teva Intends to Conduct Additional Pre-Clinical and Clinical Research Before Continuing to a Phase III Study with this Unique and Promising Molecule --***

**Jerusalem, Israel & Melbourne, Australia, June 30, 2008** - Teva Pharmaceutical Industries Ltd. (NASDAQ: Teva) and Antisense Therapeutics Ltd. (ASX: ANP) announced today that ATL/TV1102, a novel, anti-sense drug, significantly reduced disease activity in patients with relapsing-remitting multiple sclerosis (RRMS). A randomized, double-blind, placebo-controlled Phase IIa study met its primary endpoint showing a significant reduction by 54.4% ( $p=0.01$ ) in cumulative number of new active lesions in patients taking ATL/TV1102 for 8 weeks, compared to placebo, as measured by magnetic resonance images (MRI).

Based on these encouraging results, Teva intends to conduct additional pre-clinical and clinical research before continuing to a Phase III study with this unique and promising molecule.

The Principal Investigator for the trial, Volker Limmroth MD PhD, Chairman of the Department of Neurology, Cologne City Hospitals, Germany, said, "The results of this international multi-center clinical study are very encouraging and demonstrate a highly significant effect for ATL/TV1102 on disease activity in MS patients."

"Following these results, we are planning to continue the development of this new and exciting molecule designed to confirm the efficacy of ATL/TV1102," said Moshe Manor, Teva's Group Vice President, Global Innovative Resources. "Together with COPAXONE<sup>®</sup>, a market-leading MS therapy and Laquinimod, an oral MS treatment currently in Phase III studies, Teva continues with its commitment to help MS patients and improve their quality of life."

"We are very pleased with the results of this study. Achieving the primary endpoint to such a significant degree vindicates our efforts in developing this unique drug, the first to use antisense technology in the treatment of MS. We now look forward to continuing the development of ATL/TV1102 for MS with one of the leading pharmaceutical companies in the world", said Mark Diamond, Chief Executive Officer of Antisense Therapeutics Ltd.

Teva is responsible for funding and performing future development activities as outlined above for ATL/TV1102. This decision by Teva to move forward with the development of ATL/TV1102 triggers a US\$4 million milestone payment in accordance with the license agreement between Teva and ANP.

## **Study Design and Results**

ATL/TV1102 Phase IIa trial was a randomized, double-blind, placebo-controlled clinical trial of ATL/TV1102. Patients received either ATL/TV1102 or placebo injections subcutaneously at a dose of 200 mg three times a week for the first week and twice weekly over additional 7 weeks after which they were monitored for additional 8 weeks. Assessment was done using monthly MRI brain scans. 77 patients were enrolled in the trial, which was conducted at multiple trial sites across six European countries. The goal of the trial was to obtain preliminary evidence of ATL/TV1102's effectiveness in reducing MS-related MRI brain lesions and assess its safety profile.

In the primary endpoint of the study, ATL/TV1102 showed a significant 54.4% reduction in cumulative number of new active MRI lesions on weeks 4, 8 and 12 ( $p=0.01$ ).

In addition, patients taking ATL/TV1102 experienced a 65% reduced cumulative number of Gadolinium (Gd)-enhancing lesions on weeks 4, 8, and 12 ( $p=0.0053$ ). ATL/TV1102 was also effective in significantly reducing T1-enhancing lesion volume by 84% at week 12.

ATL/TV1102 demonstrated an increasing effect with time on the reduction of new active lesions over 12 weeks - one month after the completion of dosing. This extended duration of activity post dosing was anticipated based on the drug's long (>3 week) half-life, and would support the proposition of less frequent dosing than the twice weekly dosing employed in the current trial though this would need to be confirmed in future clinical studies.

Data from this study demonstrated that in general, ATL/TV1102 was well-tolerated. Potentially attributable adverse events included injection site reactions which were mild to moderate and thrombocytopenia. Thrombocytopenia was reversible after treatment interruption returning to within normal ranges and was not accompanied with any clinical consequences.

The companies plan to present the results of this study at future scientific meetings.

### **About Multiple Sclerosis**

Multiple Sclerosis (MS) is the leading cause of neurological disability in young adults. It is estimated that 400,000 people in the United States are affected by this disease, and that over two million people are affected worldwide. MS is a progressive, demyelinating disease of the central nervous system affecting the brain, spinal cord and optic nerves.

Patients with MS may experience physical symptoms and/or cognitive impairments, including weakness, fatigue, ataxia, physical dysfunction, bladder and bowel problems, sensory effects, and visual impairment. MS also has a significant impact on the sufferers' social functioning and overall quality of life.

### **About ATL/TV1102**

ATL/TV1102 is a 2<sup>nd</sup> generation antisense drug discovered by Isis Pharmaceuticals Inc. (NASDAQ: ISIS) and licensed to ANP. Antisense drugs block specifically disease-causing proteins from being produced by interacting with their intended target based on information in the genetic code. ATL/TV1102 is a second generation anti-sense inhibitor of CD49d, a subunit of VLA-4 (Very Late Antigen-4), and is currently in Phase IIa clinical trials as a treatment for MS. In inflammation, white blood cells (leukocytes) move out of the bloodstream into the inflamed tissue, for example, the CNS in MS, and the lung airways in asthma. The inhibition of VLA-4 may prevent white blood cells from entering sites of inflammation, thereby halting progression of the disease. VLA-4 is a clinically validated target in the treatment of MS. Antisense inhibition of VLA-4 has demonstrated positive effects in a number of animal models of inflammatory disease including MS (Myers et al. J Neuroimmunol 160, p12-24, 2005).



### **About Teva Pharmaceutical Industries**

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the world's leading generic pharmaceutical company. The Company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 80 percent of Teva's sales are in North America and Europe.

### **About Antisense Therapeutics**

Antisense Therapeutics Limited (ASX: ANP) is an Australian publicly listed biopharmaceutical drug discovery and development company. Its mission is to create, develop and commercialize antisense pharmaceuticals for large unmet markets. ANP has two drugs in development and two drugs in pre-clinical research. ATL/TV1102 (injection) is in the advanced stages of a Phase IIa trial as a potential treatment of multiple sclerosis. ATL1103 is a second-generation antisense drug designed to lower blood IGF-I levels and is entering pre-clinical development as a potential treatment for acromegaly and vision disorders. ATL/TV1102 (inhaled) is at the pre-clinical research stage as a potential treatment for asthma. ATL1101 is a second-generation antisense drug at the pre-clinical research stage being investigated as a potential treatment for prostate cancer. ATL/TV1102 has been licensed to Teva Pharmaceutical Industries Ltd.

Copaxone<sup>®</sup> (glatiramer acetate injection) is indicated for the reduction of the frequency of relapses in patients with RRMS.

### **Teva Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:**

This release contains forward-looking statements. 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 Teva's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements, including statements relating to the results of the ATL/TV1102 Phase IIa study and the potential efficacy, tolerability and marketability of ATL/TV1102. Additional risks relating to Teva and its business are discussed in Teva's Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://www.tevapharm.com)

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**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/ Dan Suesskind

Name: Dan Suesskind  
Title: Chief Financial Officer

Date: June 30, 2008