

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
March 17, 2009

**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 March, 2009

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   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):                   

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   X  

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



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**Kevin Mannix** Teva North America (215) 591-8912

**For Immediate Release**

**Study Demonstrates that QVAR<sup>®</sup> IS More Likely to Achieve  
Successful Asthma Control with Less Exacerbations**

**-- Real Life Study Shows the Effectiveness of QVAR<sup>®</sup> vs.  
Beclomethasone-CFC and Fluticasone --**

**Jerusalem, Israel, March 17, 2009** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced results from a study demonstrating that Inhaled Corticosteroid (ICS) therapy with QVAR<sup>®</sup> (Beclomethasone HFA), an ICS that is able to effectively treat both large and small airway inflammation, may be particularly effective for patients who require a step-up in ICS therapy and may have advantages over ICSs such as beclomethasone dipropionate-CFC (BDP-CFC) and fluticasone propionate (FP) which target primarily the large airways in patients with asthma. This "real life" study followed more than 4,000 asthma patients in the UK for 12 months.

Previously, several short-term, randomized controlled trials (RCTs) have demonstrated that QVAR<sup>®</sup> and other ICS therapies, including beclomethasone (BDP-CFC) and fluticasone propionate (FP) metered dose inhalers (pMDI), are efficacious. The one year "real life" study being reported on today was designed to assess the effectiveness of QVAR<sup>®</sup> and other ICS therapies in patients identified from the UK General Practice Research Database (GPRD), the world's largest primary care computerized database of anonymized longitudinal medical records. This real life analysis showed that the choice of ICS may impact overall asthma control under actual living conditions, including asthma exacerbation rates.

"ICSs are considered the most effective anti-inflammatory therapy for persistent asthma and are the preferred treatment for initiating maintenance therapy. However, most currently available ICSs are unable to reach the small airways, where underlying inflammation in patients with asthma may be uncontrolled" said **David Price, GPIAG professor of primary care medicine, University of Aberdeen's Center of Academic Care and lead investigator** of the study. "Because QVAR<sup>®</sup> distributes medication throughout the entire lung while delivering more to the small airways than other ICSs; these new data may support the action site of an ICS as an important factor in real life effectiveness of ICSs in asthma."

Professor Price added, "Although randomized trials have shown the efficacy of ICS therapies, they are not designed to demonstrate treatment effectiveness in everyday practice. This real life effectiveness study has the advantage of demonstrating the impact of various ICS therapies in `real life patients,` not `study subjects.` There is no conflict between the two approaches; rather they complement each other."

Teva offers QVAR<sup>®</sup> in the U.S., UK, France, several other European countries as well as Israel. In Germany QVAR<sup>®</sup> is sold under the brand name Ventolair<sup>®</sup> and in the Scandinavian countries QVAR<sup>®</sup> is sold under the brand name Aerobec<sup>®</sup>.

These results are presented at the 2009 American Academy of Allergy Asthma & Immunology annual meeting (AAAAI) in Washington DC, on March 17, 2009.

### **About the Study**

Asthma patients, aged 5-60, without other chronic respiratory diseases, receiving QVAR<sup>®</sup>, BDP-CFC or FP MDIs who subsequently had ICS increase between January 1997 - June 2006 were identified from UK GPRD. Multiple logistic regression, adjusted for baseline severity provided odds of successful asthma control (no asthma hospital attendances, oral steroids, consultations or hospital admissions for lower respiratory tract infections requiring antibiotics) during 12 month follow-up. Poisson regression was used to compare asthma exacerbation rates (unscheduled hospital admissions/A&E attendances for asthma or use of oral steroids).

Data were available for 4,133 patients (8% QVAR<sup>®</sup>, 15% FP, 77% BDP-CFC). Odds ratio (95% CI) for successful asthma control were significantly lower with BDP-CFC, 0.65 (0.47 - 0.90) than QVAR<sup>®</sup>. Asthma exacerbation rates (95% CI) were significantly higher with FP, 1.61 (1.02 - 2.55) than QVAR<sup>®</sup>.

### **About GPRD**

The GPRD is the world's largest computerized database of anonymized longitudinal medical records from primary care. Data are being collected on over 3.6 million active patients (approx. 13 million totals) from around 450 primary care practices throughout the UK. It is the largest and most comprehensive source of data of its kind and is used worldwide for research by the pharmaceutical industry, clinical research organizations, regulators, government departments and leading academic institutions. GPRD is considered the gold standard of research databases.

### **About QVAR<sup>®</sup>**

QVAR<sup>®</sup> (beclomethasone dipropionate HFA) Inhalation Aerosol is indicated in the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age or older. QVAR<sup>®</sup> is also indicated for asthma patients who

require systemic corticosteroid administration, where adding QVAR<sup>®</sup> may reduce or eliminate the need for systemic corticosteroids.

### Important Safety Information

QVAR<sup>®</sup> is not a bronchodilator and is not indicated for relief of acute bronchospasm. Common side effects associated with the use of QVAR<sup>®</sup> and placebo in clinical trials includes, but is not limited to, headache (12% and 9%, respectively) and pharyngitis (8% and 4%, respectively). **Caution: Adrenal insufficiency may occur when transferring patients from systemic steroids (see WARNINGS, Prescribing Information).** A reduction in growth velocity in growing children and teenagers may occur as a result of inadequate control of chronic diseases such as asthma or from use of corticosteroids for treatment

### About Teva

Teva Pharmaceutical Industries Ltd., (NASDAQ: TEVA) headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Western Europe.

### *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<sup>®</sup>, Lotrel<sup>®</sup> and Protonix<sup>®</sup>, the current economic conditions, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the effects of competition on our innovative products, especially Copaxone<sup>®</sup> sales, dependence on the effectiveness of our patents and other protections for innovative products, the impact of consolidation of our distributors and customers, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, 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, the uncertainty surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, the regulatory environment and changes in the health policies and structures of various countries, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, our ability to successfully identify, consummate and integrate acquisitions, including the integration of Barr Pharmaceuticals, Inc., the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, our ability to enter into patent litigation settlements and the intensified scrutiny by the*



*U.S. government, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, 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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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/ Eyal Desheh

Name: Eyal Desheh  
Title: Chief Financial Officer

Date: March 17, 2009

