ALTANA AKTIENGESELLSCHAFT
Form 6-K
May 25, 2004

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Form 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer
Pursuant to Rules 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

Dated: May 25 th , 2004

ALTANA Aktiengesellschaft

(Translation of Registrant s name into English)

Am Pilgerrain 15
D-61352 Bad Homburg v. d. Höhe
Federal Republic of Germany
(Address of principal executive offices)

Indicate by check mark whether the Registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F þ Form 40-Fo

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):o

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):o

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

Yes o No þ

If Yes is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

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This Report on Form 6-K is hereby incorporated by reference into the Registrant s Registration Statements on Form S-8, dated September 13, 2002 (File No. 333-99485) and dated September 24, 2003 (File No. 333-109074)

This Report on Form 6-K contains:

Press Release of May 24th , 2004

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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.

ALTANA Aktiengesellschaft

By: /s/ Hermann Küllmer

Name: Dr. Hermann Küllmer
Title: Chief Financial Officer and Member of the Management Board

By: /s/Rudolf Pietzke

Name: Dr. Rudolf Pietzke
Title: General Counsel

Dated: May 25 th , 2004

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Press release

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Data Suggest Once-Daily Alvesco (ciclesonide) Has Minimal Potential for Systemic and Local Adverse Effects

Studies Show No Effect on Normal Adrenal Function in Asthma Patients

Bad Homburg, Orlando, May 24, 2004 New data presented at the American Thoracic Society s 2004 International Conference show that once-daily treatment with the investigational therapy Alvesco ® (ciclesonide) in mild-to-moderate asthma patients has no effect on normal adrenal function, as demonstrated by measurements of the hypothalamic-pituitary-adrenal (HPA)-axis.

The HPA-axis is a major part of the neuroendocrine system, involving the interactions of the hypothalamus, the pituitary gland and the adrenal glands. The HPA-axis is believed to be a focus of the body s reactions to stress and is recognized as a surrogate marker for common adverse effects associated with the body s reaction to extra cortisol production, as seen with steroid treatment. [1]

Alvesco ® is an inhaled corticosteroid with novel release and distribution properties resulting in lung-targeted anti-inflammatory effects. Inhaled corticosteroids, considered to be the foundation of asthma treatment, work by reducing inflammation the underlying disease process in the lungs and airways.

In this study, ciclesonide has shown no identifiable effects on the normal cortisol system. This indicates that the drug may have no detectable effects on the adrenal glands , said Edward M. Kerwin, MD, medical director, Clinical Research Institute of Southern Oregon and lead investigator of the study.

Trial Design and Results

Effects of ciclesonide on the HPA-axis were investigated in two identical Phase III, multicenter, double-blind, randomized, placebo-controlled, parallel-group trials. Mild-to-moderate persistent asthma patients (n=1,015) twelve years and older received 80, 160 or 320µg of ciclesonide, or placebo, once-daily in the morning for 12 weeks. HPA-axis function was assessed at baseline and at week 12 by determining peak serum cortisol levels stimulated by 1 µg cosyntropin. Additionally, 24-hour urinary cortisol levels corrected for creatinine were assessed.

Results of the two studies showed that no significant differences were observed from baseline to week 12 in cosyntropin-stimulated peak serum cortisol (µg /dL) levels (PBO: +0.49; CIC80: +0.22; CIC160: +1.51; CIC 320:

+0.38), or 24-hour urinary cortisol levels corrected for creatinine (µg /mg) for ciclesonide versus placebo (PBO: +0.0009; CIC80: -0.0013; CIC160: +0.0033; CIC 320: +0.0001).

Pooled Analysis Shows Comparable Incidence of Local Side Effects to Placebo

In another analysis presented at the Conference, adverse events affecting the throat (oropharynx) were pooled from 4,260 patients who received ciclesonide in clinical trials, and compared with 1,652 patients who received other inhaled asthma medications (budesonide, beclomethasone dipropionate or fluticasone proprionate), and 934 patients who received placebo.

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The ciclesonide patients experienced a lower incidence of oral candidiasis (fungal infection) than the placebo control group, and potential local adverse events rates were dose-independent and comparable to placebo.

These findings underscore the benefits of ciclesonide s novel release and distribution properties and suggest that ciclesonide exerts its effects in the airways, while minimizing risk elsewhere in the body, noted Professor Heinz-Werner Radtke, Head of research and development at ALTANA Pharma. The low incidence of local side effects we see with ciclesonide is promising news for patients and their physicians.

About Asthma

Asthma is a chronic lung disease caused by airway inflammation and results in airway constriction in response to certain stimuli. It is characterized by a variety of symptoms including wheezing, coughing and a tightening of the airways, which causes shortness of breath and can be life-threatening. According to the Global Initiative for Asthma (GINA), more than 300 million people worldwide suffer from asthma. The prevalence of asthma is increasing by approximately 50 percent every decade and worldwide deaths from asthma total more than 180,000 annually.

About Alvesco ®

In clinical trials, Alvesco ® was shown to improve lung function, asthma symptoms, and reduce the need for medications necessary to treat acute asthma attacks. The most frequently reported adverse events seen in Alvesco ® clinical trials were nasopharyngitis, headache and upper respiratory tract infection. Alvesco ® was approved in Australia and the United Kingdom this year, and has been submitted for approval in other countries around the world. Additionally, ALTANA s U.S. partner, Aventis, applied to the FDA for approval of the asthma drug Alvesco® at the end of 2003. Teijin, ALTANA s partner in Japan, submitted an application for approval for Alvesco® in January 2004.

[1] Webster s Online Dictionary, The Rosetta Edition. Available at: http://www.websters-online-dictionary.org/definition/english/st/stress.html. Accessed April 26, 2004.

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This press release contains forward-looking statements, i.e., current estimates or expectations of future events or future results. The forward-looking statements appearing in this press release include information on the presentation of study results. These statements are based on beliefs of ALTANA s management and information currently available to ALTANA. Many factors that ALTANA is unable to predict with accuracy could cause ALTANA s actual performance to be materially different from the one that may be expressed or implied by such forward-looking statements. Forward-looking statements speak only as of the date they are made. ALTANA does not intend, and does not assume any obligation, to update forward-looking statements to reflect facts, circumstances or events that have occurred or changed after such statements have been made.

This press release is also available on the Internet at **www.altana.com**p

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