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FDA Advisory Committee Recommends Approval of Teva's Asthma Biologic Reslizumab

Jerusalem, Dec. 10, 2015 – Teva Pharmaceutical Industries Ltd., (NYSE: TEVA) announced today that the U.S. Food and Drug Administration's (FDA) Pulmonary-Allergy Drugs Advisory Committee recommended approval of reslizumab, a humanized anti-interleukin-5 (IL-5) IgG4_k monoclonal antibody (mAb), in adult patients aged 18 years and older. Reslizumab is a targeted biologic therapy for the treatment of inadequately controlled asthma in patients with elevated blood eosinophils, despite an inhaled corticosteroid (ICS)-based treatment regimen.

"Patient stratification based on eosinophil levels has been an important advancement in the treatment of asthma," said Michael Hayden, M.D., Ph.D., President of Global R&D and Chief Scientific Officer at Teva Pharmaceutical Industries Ltd. "We are very encouraged by the outcome of today's FDA Advisory Committee meeting, which brings us one step closer to potentially providing a new, targeted treatment option for a specific group of patients with inadequately controlled asthma and evidence of ongoing eosinophilic inflammation. This group of patients often experiences persistent symptoms despite standard-of-care treatment, demonstrating a need for more targeted treatment options based on patient phenotype."

The Advisory Committee's recommendation will be considered by the FDA in its review of the Biologics License Application (BLA) for reslizumab. The FDA is not bound by the Committee's recommendation, but takes its advice into consideration when reviewing investigational medicines. The reslizumab BLA was accepted for standard review by the FDA and Regulatory Action is expected in March 2016. Additional regulatory filings for reslizumab have been completed in the EU and Canada.

About Reslizumab

Reslizumab is an investigational humanized interleukin-5 (IL-5) antagonist IgG4_k monoclonal antibody (mAb), for the treatment of inadequately controlled asthma in adult and adolescent patients with elevated blood eosinophils, despite an inhaled corticosteroid (ICS)-based regimen. IL-5 is the most selective eosinophil cytokine known and plays a major role in the maturation, activation and survival of eosinophils, which are the predominant type of white blood cell underlying chronic airway inflammation in the eosinophilic phenotype of asthma. In asthma patients, elevated blood eosinophils ≥ 400 cells/mcL are associated with compromised lung function, persistent symptoms, and increased risk of exacerbations. Reslizumab is thought to act by binding to and neutralizing human IL-5 to reduce eosinophilic inflammation. Reslizumab has been submitted for and is currently under review by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Health Canada.

About Teva Respiratory

Teva Respiratory develops and delivers high-quality treatment options for respiratory conditions, including asthma, COPD and allergic rhinitis. The Teva Respiratory portfolio is centered on optimizing respiratory treatment for patients and healthcare providers through the development of novel delivery systems and therapies that help address unmet needs. The company's respiratory pipeline and clinical trial program are based on drug molecules delivered in proprietary dry powder formulations and breath-actuated device

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technologies, as well as a targeted biologic treatment for inadequately controlled asthma. Through research and clinical development, Teva Respiratory continually works to expand, strengthen and build upon its treatment portfolio to positively impact the lives of the millions of patients living with respiratory disease.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions to millions of patients every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,000 molecules to produce a wide range of generic products in nearly every therapeutic area. In specialty medicines, Teva has a world-leading position in innovative treatments for disorders of the central nervous system, including pain, as well as a strong portfolio of respiratory products. Teva integrates its generics and specialty capabilities in its global research and development division to create new ways of addressing unmet patient needs by combining drug development capabilities with devices, services and technologies. Teva's net revenues in 2014 amounted to \$20.3 billion. For more information, visit www.tevapharm.com.

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

This release contains forward-looking statements, which 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 for our specialty products, especially Copaxone® (including competition from orally-administered alternatives, as well as from generic equivalents such as the recently launched Sandoz product) and our ability to continue to migrate users to our 40 mg/mL version and maintain patients on that version; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities (such as our pending acquisitions of Allergan's generic business and Rimsa), or to consummate and integrate acquisitions; the possibility of material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing FCPA investigations and related matters; our ability to achieve expected results from the research and development efforts invested in our pipeline of specialty and other products; our ability to reduce operating expenses to the extent and during the timeframe intended by our cost reduction program; the extent to which any manufacturing or quality control problems damage our reputation for quality production and require costly remediation; increased government scrutiny in both the U.S. and Europe of our patent settlement agreements; our exposure to currency fluctuations and restrictions as well as credit risks; the effectiveness of our patents, confidentiality agreements and other measures to protect the intellectual property rights of our specialty medicines; the effects of reforms in healthcare regulation and pharmaceutical pricing, reimbursement and coverage; governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; adverse effects of political or economic instability, major hostilities or acts of terrorism on our significant worldwide operations; interruptions in our supply chain or problems with internal or third-party information technology systems that adversely affect our complex manufacturing processes; significant disruptions of our information technology systems or breaches of our data security; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures;

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competition for our specialty pharmaceutical businesses from companies with greater resources and capabilities; the impact of continuing consolidation of our distributors and customers; decreased opportunities to obtain U.S. market exclusivity for significant new generic products; potential liability in the U.S., Europe and other markets for sales of generic products prior to a final resolution of outstanding patent litigation; our potential exposure to product liability claims that are not covered by insurance; any failure to recruit or retain key personnel, or to attract additional executive and managerial talent; any failures to comply with complex Medicare and Medicaid reporting and payment obligations; significant impairment charges relating to intangible assets, goodwill and property, plant and equipment; the effects of increased leverage and our resulting reliance on access to the capital markets; potentially significant increases in tax liabilities; the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner; environmental risks; and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2014 and in our other filings with the U.S. Securities and Exchange Commission.

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הוועדה המייעצת ל-FDA ממליצה לאשר את התרופה הביולוגית Reslizumab של טבע לטיפול באסטמה

ירושלים, 10 בדצמבר 2015 – טבע תעשיות פרמצבטיות בע"מ (NYSE & TASE: TEVA) הודיעה היום כי הוועדה המייעצת למנהל המזון והתרופות האמריקאי (FDA) בנושא תרופות לטיפול במחלות ריאה ואלרגיות המליצה לאשר את התרופה reslizumab, נוגדן חד שבטי IgG4K (mAb) נגד אינטרלוקין 5 (IL-5) עבור בוגרים מגיל 18 ומעלה. reslizumab היא טיפול ביולוגי ממוקד לטיפול באסטמה בקרב חולים עם רמות גבוהות של אאזינופילים בדם, שמחלתם אינה בשליטה מספקת חרף קבלת טיפול בקורטיקוסטרואידים במשך.

"ריבוד (סיווג) חולים על בסיס רמות אאזינופילים מייצג התקדמות משמעותית בטיפול באסטמה", אמר ד"ר מייקל היידן, נשיא ומנכ"ל המו"פ הגלובלי והמדען הראשי של טבע. "אנו מרוצים מאוד מתוצאת הפגישה של הוועדה המייעצת ל-FDA שנערכה היום. ההמלצה מקרבת אותנו צעד נוסף ליצירת אפשרות טיפול חדשה וממוקדת לקבוצה ספציפית של חולים עם אסטמה שאינה בשליטה מספקת, עם רקע של דלקת אאזינופילית מתמשכת. קבוצת חולים זו סובלת לעיתים קרובות מסימפטומים של המחלה שאינם חולפים חרף קבלת הטיפול המקובל. דבר זה מדגיש את הצורך באפשרויות טיפול ממוקדות יותר, המבוססות על הפנוטיפים של החולים".

ה-FDA ישקול את המלצת הוועדה המייעצת כחלק מבדיקת הבקשה לאישור תרופה ביולוגית חדשה (BLA) עבור reslizumab. ה-FDA אינו מחויב לפעול על פי המלצת הוועדה, אך מתחשב בהמלצתה במסגרת הבדיקה של תרופות ניסיוניות. בקשת ה-BLA עבור reslizumab התקבלה לבדיקה רגילה של ה-FDA והפעולה הרגולטורית צפויה להתבצע במרץ 2016. בקשות רגולטוריות נוספות ל-reslizumab הוגשו באירופה ובקנדה.

אודות Reslizumab

reslizumab הוא נוגדן חד שבטי (mAb) נגד אינטרלוקין 5 (IL-5). IL-5 הוא ציטוקין מרכזי המעורב בהבשלה, צמיחה והפעלה של אאזינופילים, שהינם תאי דם לבנים דלקתיים המעורבים במספר מחלות כגון אסתמה. רמות גבוהות של אאזינופילים בדם נחשבות לגורם סיכון להתקפי אסתמה עתידיים. אאזינופילים הם סוג של תאי דם לבנים הנוכחים ברמות מסוימות בריאות ובדם של אסתמטיים רבים. מחקרים מראים כי אאזינופילים משחקים תפקיד פעיל בהתפתחות הפתולוגית של המחלה. הוכח כי ל-IL-5 הוכח תפקיד מהותי בהבשלה, צמיחה והפעלה של אאזינופילים. נמצא כי רמות גבוהות של אאזינופילים בדם ובלחיה קשורות עם עוצמת והישנות התקפי אסתמה. reslizumab קושר עצמו ל-IL-5 ההקפיים ועל ידי כך מונע מ-IL-5 להתחבר לקולטן שלו. Reslizumab הוגש ומצוי לבחינה על ידי ה-FDA, ה-EMA, ושירות הבריאות הקנדי.

אודות תחום הנשימה בטבע

תחום הנשימה בטבע מפתח ומספק אפשרויות טיפול איכותיות לתופעות נשימתיות ובהן אסתמה, מחלת ריאות חסימתית כרונית ונזלת אלרגית. הפורטפוליו של תחום הנשימה בטבע ממוקד בהשגת אופטימיזציה עבור טיפולי

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נשימה למטופלים וספקי שירותי בריאות באמצעות פיתוח דרכי מתן תרופה וטיפולים חדשניים בכדי לענות על צרכים ללא מענה. צבר המוצרים ותכניות הפיתוח הקליני של תחום הנשימה בטבע מתבססים על מולקולות המועברות למטופל באמצעות טכנולוגיות תכשירים קנייניות של פורמולציות אבקה יבשה ומשאפים מופעלי-נשימה, כמו גם טיפולים ביולוגיים ממוקדים לטיפול באסתמה הנשלטת באופן בלתי מספק. באמצעות מחקר ופיתוח קליני, תחום הנשימה בטבע ממשיך להרחיב, לחזק ולבנות על הפורטפוליו הטיפולי שלו בכדי להשפיע לחיוב על חייהם של מיליוני מטופלים החיים עם מחלות נשימה.

אודות טבע

טבע תעשיות פרמצבטיות בע"מ (NYSE & TASE: TEVA) היא חברת תרופות גלובלית המספקת פתרונות בריאות ממוקדי-מטופל באיכות גבוהה למיליוני מטופלים מדי יום. טבע, שבסיסה בישראל, היא יצרנית התרופות הגנריות הגדולה בעולם, הממנפת את צבר מוצריה הכולל יותר מ-1000 מולקולות לייצר מגוון רחב של מוצרים גנריים בכמעט כל התחומים הטיפוליים. בתחום התרופות הייחודיות, טבע הינה חברה מובילה בטיפולים חדשניים למחלות מערכת העצבים המרכזית, כולל כאב, ומחזיקה גם בצבר מוצרים חזק בתחום מחלות הנשימה. טבע משלבת את כישוריה בתחום התרופות הגנריות ובתחום התרופות הייחודיות בחטיבת המחקר והפיתוח הגלובלית שלה, במטרה ליצור דרכים חדשות לענות על צרכי המטופלים וזאת על ידי שילוב יכולות בתחום פיתוח תרופות יחד עם פיתוח תכשירים, שירותים וטכנולוגיות. הכנסות טבע בשנת 2014 הסתכמו ב-\$20.3 מיליארד. למידע נוסף על החברה, בקרו באתר www.tevapharm.com.

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