



## Press Release

for  
**immediate**  
release

### **Teva Announces FDA Approval of ProAir RespiClick® (albuterol sulfate) Inhalation Powder for Pediatric Asthma Patients Ages 4 to 11**

*New Pediatric Indication Provides Treatment Option for Children that Eliminates Need for Spacer and Hand-Breath Coordination During Inhalation*

**Jerusalem, April 29, 2016** – Teva Pharmaceutical Industries Ltd., (NYSE and TASE: TEVA) announced today that the U.S. Food and Drug Administration (FDA) has approved ProAir RespiClick® (albuterol sulfate) Inhalation Powder for the treatment or prevention of bronchospasm in children 4 to 11 years of age with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm (EIB).

ProAir RespiClick® was approved by the FDA for use in patients 12 years of age and older in March 2015 and remains the only breath-activated, multi-dose, dry powder, short-acting beta-agonist (SABA) inhaler available in the U.S.

“The prevalence of childhood asthma in the U.S. is high, at more than six million patients, and that number continues to rise,” said Dr. Erwin Gelfand, Chairman, Department of Pediatrics at National Jewish Health. “For this young population of asthma patients, learning to use inhalers properly can be quite challenging. Thus, the pediatric indication for ProAir RespiClick® is important as it represents a new rescue inhaler option for younger patients that eliminates the need for hand-breath coordination during inhalation and was designed to be used without a spacer.”

The pediatric approval of ProAir RespiClick® comes after the FDA’s review of data from Teva’s Phase III clinical trial program that evaluated the safety and efficacy of the treatment in patients as young as four years of age, living with asthma. The data demonstrated that treatment with ProAir RespiClick® resulted in significantly greater improvement in forced expiratory volume (FEV<sub>1</sub>) compared to placebo. The most common adverse events associated with treatment with ProAir RespiClick® included upper respiratory infections, mouth and throat pain and vomiting.

“We are very pleased with the FDA’s decision to expand the indication of ProAir RespiClick® for the treatment of patients as young as four years of age,” said Tushar Shah, MD, Senior Vice President, Teva Global Respiratory Research and Development. “The availability of this treatment option for younger patients is a demonstration of Teva’s commitment to optimizing respiratory therapies through the development of new delivery systems that help address needs in the marketplace.”

#### **Approved Uses**

ProAir RespiClick® (albuterol sulfate) Inhalation Powder is indicated in patients 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.

#### **Important Safety Information**

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- Do not use ProAir RespiClick® (albuterol sulfate) Inhalation Powder if you are allergic to albuterol sulfate, lactose, or milk proteins. Call your doctor right away if you develop red, itchy bumps on your skin, swelling beneath your skin or in your throat, rash or worsening trouble breathing
- If your symptoms become significantly worse when you use ProAir RespiClick®, seek medical attention immediately. This may indicate either a worsening of your asthma or a reaction to the medication. Either of these could be life-threatening
- **Do not** increase your dose or take extra doses of ProAir RespiClick® without first talking to your healthcare professional
- Before using ProAir RespiClick®, be sure to tell your healthcare professional if you have a heart, blood, thyroid or seizure disorder, high blood pressure, diabetes, are pregnant or planning to become pregnant, or are breastfeeding or planning to breastfeed
- ProAir RespiClick® can cause significant heart-related side effects, such as an increase in pulse, blood pressure and/or related symptoms. If you have a heart condition, your healthcare professional will determine if ProAir RespiClick® is right for you
- Make sure your healthcare professional knows all the medicines you are taking – especially other inhaled medicines, other asthma medicines, heart and blood pressure medicines and drugs that treat depression – because some medicines may interfere with how well your asthma medicines work
- Common side effects in patients 12 years of age and older taking ProAir RespiClick® include back pain, body aches and pains, upset stomach, sinus headache, and urinary tract infection
- Common side effects in patients 4 to 11 years of age taking ProAir RespiClick® include upper respiratory infections, mouth and throat pain, and vomiting
- Tell your healthcare provider if you have any side effect that bothers you or that does not go away
- These are not all of the possible side effects of ProAir RespiClick®. For more information, ask your healthcare provider or pharmacist
- You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088

[Please click here for Full Prescribing Information](#)

### 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 technologies, as well as a targeted biologic treatment for severe 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

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Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions used by 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 2015 amounted to \$19.7 billion. For more information, visit [www.tevapharm.com](http://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® (which faces competition from orally-administered alternatives and a generic version); our ability to consummate the acquisition of Allergan plc's worldwide generic pharmaceuticals business ("Actavis Generics") and to realize the anticipated benefits of such acquisition (and the timing of realizing such benefits); the fact that following the consummation of the Actavis Generics acquisition, we will be dependent to a much larger extent than previously on our generic pharmaceutical business; potential restrictions on our ability to engage in additional transactions or incur additional indebtedness as a result of the substantial amount of debt we will incur to finance the Actavis Generics acquisition; the fact that for a period of time following the consummation of the Actavis Generics acquisition, we will have significantly less cash on hand than previously, which could adversely affect our ability to grow; 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 investments in our pipeline of specialty and other products; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; 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; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; 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*

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*our complex manufacturing processes; significant disruptions of our information technology systems or breaches of our data security; 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, 2015 and in our other filings with the U.S. Securities and Exchange Commission (the "SEC"). Forward-looking statements speak only as of the date on which they are made and we assume no obligation to update or revise any forward-looking statements or other information, whether as a result of new information, future events or otherwise.*

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## טבע מודיעה על קבלת אישור ה-FDA לאבקת האינהלציה (Albuterol Sulfate) ProAir RespiClick®

### לטיפול בילדים חולי אסטמה בגילאים 4 עד 11

ההתוויה החדשה מעניקה אפשרות לטיפול בילדים המבטלת את הצורך במרווח (Spacer) ובתיאום בין לחיצה לשאיפה בעת הפעלת המשאף

ירושלים, 29 באפריל 2016 – טבע תעשיות פרמצבטיות בע"מ (NYSE ו-TASE: TEVA) הודיעה היום כי מנהל המזון והתרופות האמריקאי (FDA) אישר את אבקת האינהלציה (Albuterol Sulfate) ProAir RespiClick® לטיפול או למניעה של ברונוכספאזם בקרב ילדים בגיל 4 עד 11 שנים הסובלים ממחלת ריאות חסימתית הפיכה, ולמניעת ברונוכספאזם הנגרם בעקבות מאמץ (EIB).

במרץ 2015, ProAir RespiClick® קיבל את אישור ה-FDA לשימוש במטופלים בני 12 ומעלה. זהו משאף בטה אגוניסט קצר-טווח (SABA), בעל אבקה יבשה, רב-מינון, המופעל באמצעות נשימה, שנשאר עד היום היחיד מסוגו בשוק בארה"ב.

"השכיחות של אסטמה בקרב ילדים בארצות הברית היא גבוהה ועומדת על יותר מ-10 מיליון מטופלים, ומספר זה ממשיך לעלות בהתמדה", אמר ד"ר ארווין גלפנד, יו"ר מחלקת הילדים במרכז היהודי הלאומי לרפואה ולמחקר. "ילדים קטנים החולים באסטמה מתקשים ללמוד כיצד להשתמש במשאף בצורה הנכונה. מהסיבה הזו, ההתוויה של ProAir RespiClick® לטיפול בילדים היא חשובה במיוחד, משום שזו אפשרות חדשה של טיפול במשאף לשעת חירום למטופלים צעירים, שבה אין צורך בתיאום בין פעולת הלחיצה לשאיפה בעת הפעלת המשאף, והיא נועדה לשימוש ללא מרווח (Spacer)".

האישור של ProAir RespiClick® לטיפול בילדים התקבל לאחר שה-FDA בדק את הנתונים מתכנית המחקרים הקליניים שלב 3 של טבע, להערכת הבטיחות והיעילות של הטיפול במטופלים מגיל 4 ומעלה הסובלים מאסטמה. הנתונים הראו כי הטיפול ב-ProAir RespiClick® הביא לשיפור ניכר בנפח נשימה מאומצת (FEV<sub>1</sub>) בהשוואה לפלצבו. תופעות הלוואי הנפוצות ביותר הקשורות לטיפול ב-ProAir RespiClick® כוללות דלקות בדרכי הנשימה העליונות, כאבים בפה ובגרון והקאות.

"אנחנו שמחים מאוד שה-FDA החליט להרחיב את ההתוויה של ProAir RespiClick® לטיפול בחולים מגיל 4 ומעלה", אמר ד"ר טושאר שאה, סמנכ"ל בכיר, מחקר ופיתוח נשימתי גלובלי בטבע. "הפיכת אפשרות הטיפול הזו לזמינה לחולים צעירים יותר היא צעד נוסף במימוש המחויבות של טבע לשיפור הטיפולים הקיימים למחלות בדרכי הנשימה על ידי פיתוח מערכות חדשות של מתן תרופה, העונות על הצרכים הקיימים בשוק".

### התוויות שימוש מאושרות

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ההתוויה של אבקת האינהלציה ProAir® RespiClick (Albuterol Sulfate) היא לטיפול או למניעה של בرونכוספאזם המתרחש במחלת ריאות חסימתית הפיכה ולמניעת בرونכוספאזם בעקבות מאמץ בקרב חולים בגיל ארבע ומעלה.

### Important Safety Information

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- You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088

[Please click here for Full Prescribing Information](#)

### 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 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-

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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 המשמשים מיליוני 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 ברוב התחומים הטיפוליים. בתחום התרופות הייחודיות, טבע הינה חברה מובילה בטיפולים חדשניים למחלות מערכת העצבים המרכזית, כולל כאב, והיא מחזיקה גם צבר 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 2015 הסתכמו ב-\$19.7 מיליארד. למידע נוסף על החברה, בקרו באתר [www.tevapharm.com](http://www.tevapharm.com).

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*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; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; 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 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, 2015 and in our other filings with the U.S. Securities and Exchange Commission (the "SEC"). Forward-looking statements speak only as of the date on which they are made and we assume no obligation to update or revise any forward-looking statements or other information, whether as a result of new information, future events or otherwise.*

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