



Press Release

for  
**immediate**  
release

## **Teva Launches AirDuo™ RespiClick® and its Authorized Generic, Two Inhalers Containing Fluticasone Propionate and Salmeterol**

*First and Only Generic Fluticasone Propionate and Salmeterol (ICS/LABA) Inhaler Available in the U.S.*

**JERUSALEM, April 20, 2017** – Teva Pharmaceutical Industries Ltd., (NYSE and TASE: TEVA) today announced the simultaneous launch of AirDuo™ RespiClick® (fluticasone propionate and salmeterol) inhalation powder and its authorized generic for the treatment of asthma in patients aged 12 years and older who are uncontrolled on an inhaled corticosteroid (ICS) or whose disease severity clearly warrants the use of an ICS/long-acting beta<sub>2</sub>-adrenergic agonist (LABA) combination.

AirDuo™ RespiClick® and its authorized generic are fixed-dose combination asthma therapies containing an ICS and a LABA, the same active ingredients as Advair®. The authorized generic is known as fluticasone propionate and salmeterol inhalation powder (multidose dry powder inhaler). Teva is launching both products at the same time in an effort to address the need for more affordable asthma treatment options in the U.S. Teva expects that sales of the authorized generic will represent most of the sales of the two products.

“With the launch of AirDuo™ RespiClick® and its authorized generic, our intent is to meet the needs of patients, providers, and payers in the U.S. seeking greater access to lower-cost asthma inhaler technology, while also allowing Teva to compete in the highly competitive asthma combination controller market,” said Rob Koremans, M.D., President and CEO of Global Specialty Medicines at Teva. “This important launch marks not only the first available generic ICS/LABA product in the U.S., but also the continued expansion of our RespiClick® family of products, which now includes breath-activated inhaler options for both maintenance treatment and rescue medication.”

AirDuo™ RespiClick® was approved by the U.S. Food and Drug Administration (FDA) in January 2017 in three doses: 55/14 mcg, 113/14 mcg and 232/14 mcg administered as one inhalation twice daily. AirDuo™ RespiClick® contains medication delivered via Teva’s RespiClick® breath-activated, multi-dose dry powder inhaler (MDPI), which is used with other approved medicines in Teva’s respiratory product portfolio.

### **About AirDuo™ RespiClick® (Fluticasone Propionate and Salmeterol) Inhalation Powder and authorized generic fluticasone propionate and salmeterol inhalation powder (multidose dry powder inhaler)**

The following Indication and Important Safety Information are applicable to both AirDuo RespiClick and its authorized generic.

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AirDuo™ RespiClick® is indicated for the treatment of asthma in patients aged 12 years and older. AirDuo™ RespiClick® is only for patients uncontrolled on an ICS or whose disease severity clearly warrants an ICS/LABA.

Important Limitation of Use: AirDuo™ RespiClick® is NOT indicated for the relief of acute bronchospasm.

## IMPORTANT SAFETY INFORMATION

### WARNING: ASTHMA-RELATED DEATH

- **Long-acting beta<sub>2</sub>-adrenergic agonists (LABA), such as salmeterol, one of the active ingredients in AirDuo RespiClick, increase the risk of asthma-related death. Data from a large placebo-controlled US trial that compared the safety of salmeterol with placebo added to usual asthma therapy showed an increase in asthma-related deaths in subjects receiving salmeterol (13 deaths out of 13,176 subjects treated for 28 weeks on salmeterol versus 3 deaths out of 13,179 subjects on placebo). Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients**
- **Therefore, when treating patients with asthma, physicians should only prescribe AirDuo RespiClick for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid, or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and a LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue AirDuo RespiClick) if possible without loss of asthma control and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use AirDuo RespiClick for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids**

- **Contraindications:** AirDuo RespiClick is contraindicated in
  - Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required
  - Patients with known severe hypersensitivity to milk proteins or known hypersensitivity to fluticasone propionate or any of the excipients
- **Deterioration of Disease and Acute Episodes:** Serious acute respiratory events, including fatalities, have been reported when salmeterol, a component of AirDuo RespiClick, has been initiated in patients with significantly worsening or acutely deteriorating asthma. AirDuo RespiClick should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma. AirDuo RespiClick is not indicated for the relief of acute bronchospasm. An inhaled, short-acting beta<sub>2</sub>-agonist, not AirDuo RespiClick, should be used to relieve acute symptoms such as shortness of breath
- **Excessive Use and Use with Other Long acting Beta<sub>2</sub>-Agonists:** AirDuo RespiClick should not be used more often than recommended, at higher doses than recommended, or in conjunction with other

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medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using AirDuo RespiClick should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason

- **Local Effects of Inhaled Corticosteroids:** Oropharyngeal candidiasis has occurred in patients treated with AirDuo RespiClick. Advise patients to rinse the mouth with water without swallowing following inhalation
- **Immunosuppression:** Patients who use corticosteroids are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients. Use with caution, if at all, in patients with the above because of the potential for worsening of these infections
- **Transferring Patients from Systemic Corticosteroid Therapy:** Particular care is needed for patients who have been transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to AirDuo RespiClick
- **Hypercorticism and Adrenal Suppression:** Because of the possibility of significant systemic absorption of inhaled corticosteroids, patients treated with AirDuo RespiClick should be observed carefully for any evidence of systemic corticosteroid effects. If such effects occur, the dosage of AirDuo RespiClick should be reduced slowly, consistent with accepted procedures for reducing systemic corticosteroids, and for management of asthma symptoms
- **Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors:** The use of strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, telithromycin) with AirDuo RespiClick is not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur
- **Paradoxical Bronchospasm and Upper Airway Symptoms:** AirDuo RespiClick can produce paradoxical bronchospasm, which may be life-threatening. If paradoxical bronchospasm occurs following dosing with inhaled fluticasone propionate/salmeterol medicines, it should be treated immediately with an inhaled, short-acting bronchodilator; inhaled fluticasone propionate/salmeterol medicines should be discontinued immediately; and alternative therapy should be instituted. Upper airway symptoms of laryngeal spasm, irritation, or swelling, such as stridor and choking, have been reported
- **Hypersensitivity Reactions, Including Anaphylaxis:** Immediate hypersensitivity reactions (e.g., urticaria, angioedema, rash, bronchospasm, hypotension), including anaphylaxis, may occur after administration of AirDuo RespiClick. Discontinue AirDuo RespiClick if such reactions occur
- **Cardiovascular and Central Nervous System Effects:** AirDuo RespiClick should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension. Salmeterol, a component of AirDuo RespiClick, can produce clinically significant cardiovascular effects in some patients as measured by pulse rate, blood pressure, and/or symptoms. If such effects occur, AirDuo RespiClick may need to be discontinued
- **Reduction in Bone Mineral Density (BMD):** Decreases in BMD have been observed with long-term administration of products containing inhaled corticosteroids. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, or

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chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care

- **Effect on Growth:** Inhaled corticosteroids, including AirDuo RespiClick, may cause a reduction in growth velocity when administered to pediatric patients. Monitor the growth of pediatric patients receiving AirDuo RespiClick routinely (e.g., via stadiometry). Titrate each patient's dosage to the lowest dosage that effectively controls his/her symptoms
- **Glaucoma and Cataracts:** Glaucoma, increased intraocular pressure, and cataracts have been reported in patients with asthma following the long-term administration of inhaled corticosteroids, including fluticasone propionate. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts
- **Eosinophilic Conditions and Churg-Strauss Syndrome:** Systemic eosinophilic conditions, such as Churg-Strauss syndrome, may occur. These events usually, but not always, have been associated with the reduction and/or withdrawal of oral corticosteroid therapy following the introduction of fluticasone propionate. Be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy
- **Coexisting Conditions:** Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines
- **Hypokalemia and Hyperglycemia:** Be alert to hypokalemia and hyperglycemia
- **Adverse Reactions:** Most common adverse reactions ( $\geq 3\%$ ) in patients taking AirDuo RespiClick 55/14 mcg twice daily, 113/14 mcg twice daily, 232/14 mcg twice daily, and placebo, respectively, were nasopharyngitis (8.6%, 4.8%, 6.9%, 4.4%), oral candidiasis (1.6%, 2.2%, 3.4%, 0.7%), back pain (3.1%, 0.7%, 0%, 1.8%), headache (5.5%, 4.8%, 2.8%, 4.4%), and cough (2.3%, 3.7%, 0.7%, 2.6%)
- **Drug Interactions:**
  - **Inhibitors of Cytochrome P450 3A4:** The use of strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, telithromycin) with AirDuo RespiClick is not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur
  - **Monoamine Oxidase Inhibitors and Tricyclic Antidepressants:** AirDuo RespiClick should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of salmeterol, a component of AirDuo RespiClick, on the vascular system may be potentiated by these agents
  - **Beta-Adrenergic Receptor Blocking Agents:** Beta-blockers not only block the pulmonary effect of beta-agonists, such as salmeterol, a component of AirDuo RespiClick, but may also produce severe bronchospasm in patients with asthma. Therefore, patients with asthma should not normally be treated with beta-blockers
  - **Non-Potassium-Sparing Diuretics:** The ECG changes and/or hypokalemia that may result from the administration of non-potassium-sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, such as salmeterol, a component of AirDuo RespiClick. Caution is advised in the coadministration of AirDuo RespiClick with non-potassium-sparing diuretics
- **Use in Specific Populations:** Since both fluticasone propionate and salmeterol are predominantly cleared by hepatic metabolism, impairment of liver function may lead to accumulation of fluticasone

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propionate and salmeterol in plasma. Therefore, patients with hepatic disease should be closely monitored

**Please click here for full Prescribing Information, including Boxed WARNING:**

- <http://airduorespiclick.com/assets/pdf/PI.pdf>
- [https://www.tevagerenics.com/assets/base/LaunchMaterials/Fluticasone/FluticasonePropionateSalmeterolInhalationPowder\\_PI.pdf](https://www.tevagerenics.com/assets/base/LaunchMaterials/Fluticasone/FluticasonePropionateSalmeterolInhalationPowder_PI.pdf)

### **About Asthma**

Asthma is a chronic (long term) disease usually characterized by airway inflammation and narrowing of the airways, which can vary over time. Asthma may cause recurring periods of wheezing (a whistling sound when you breathe), chest tightness, shortness of breath and coughing that often occurs at night or early in the morning. Without appropriate treatment, asthma symptoms may become more severe and result in an asthma attack, which can lead to hospitalization and even death.

### **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-activated 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**

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions used by approximately 200 million patients in 100 markets every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,800 molecules to produce a wide range of generic products in nearly every therapeutic area. In specialty medicines, Teva has the world-leading innovative treatment for multiple sclerosis as well as late-stage development programs for other disorders of the central nervous system, including movement disorders, migraine, pain and neurodegenerative conditions, as well as a broad portfolio of respiratory products. Teva is leveraging its generics and specialty capabilities in order to seek new ways of addressing unmet patient needs by combining drug development with devices, services and technologies. Teva's net revenues in 2016 were \$21.9 billion. For more information, visit [www.tevapharm.com](http://www.tevapharm.com).

### **Cautionary Note Regarding Forward-Looking Statements**

*This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 regarding the launch of AirDuo™ RespiClick® and its Authorized Generic,*

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which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to:

- the uncertainty of the commercial success of AirDuo™ RespiClick® and its Authorized Generic;
- our generics medicines business, including: that we are substantially more dependent on this business, with its significant attendant risks, following our acquisition of Allergan plc's worldwide generic pharmaceuticals business ("Actavis Generics"); our ability to realize the anticipated benefits of the acquisition (and any delay in realizing those benefits) or difficulties in integrating Actavis Generics; the increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products; price erosion relating to our generic products, both from competing products and as a result of increased governmental pricing pressures; and our ability to take advantage of high-value biosimilar opportunities;
- our specialty medicines business, including: competition for our specialty products, especially Copaxone®, our leading medicine, which faces competition from existing and potential additional generic versions and orally-administered alternatives; our ability to achieve expected results from investments in our product pipeline; competition from companies with greater resources and capabilities; and the effectiveness of our patents and other measures to protect our intellectual property rights;
- our business and operations in general, including: our ability to develop and commercialize additional pharmaceutical products; manufacturing or quality control problems, which may damage our reputation for quality production and require costly remediation; interruptions in our supply chain; disruptions of our or third party information technology systems or breaches of our data security; the restructuring of our manufacturing network, including potential related labor unrest; the impact of continuing consolidation of our distributors and customers; and variations in patent laws that may adversely affect our ability to manufacture our products;
- compliance, regulatory and litigation matters, including: costs and delays resulting from the extensive governmental regulation to which we are subject; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; potential additional adverse consequences following our resolution with the U.S. government of our FCPA investigation; governmental investigations into sales and marketing practices; potential liability for sales of generic products prior to a final resolution of outstanding patent litigation; product liability claims; increased government scrutiny of our patent settlement agreements; failure to comply with complex Medicare and Medicaid reporting and payment obligations; and environmental risks and other factors discussed in our Annual Report on Form 20-F for the year ended December 31, 2016 ("Annual Report"), including in the section captioned "Risk Factors," and in our other filings with the U.S. Securities and Exchange Commission, which are available at [www.sec.gov](http://www.sec.gov) and [www.tevapharm.com](http://www.tevapharm.com). 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 contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

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