 меркс анонсировал результаты первоначального анализа из долгосрочного исследования безопасности LABA (mometasone furoate and formoterol fumarate dihydrate) Inhalation Aerosol, что показало, что добавление формотерола (LABA) к мометазону (the inhaled corticosteroid) терапии поддержания имеет схожий профиль безопасности, включая сопоставимый риск серьезных эпизодов астмы, в то время как снижая риск астматических обострений. Эти результаты являются предметом обсуждения в American Thoracic Society meeting in Washington, D.C. on May 22, 2017.

"Мы рады, что это исследование достигло обоих своих основных целей безопасности и ключевых вторичных целей эффективности," сказал доктор Синди Винстин, главный научный сотрудник, клинические исследования, дыхательная и иммунология, Меркс Рисерч Лабораторис. "Эти результаты решают важный вопрос общественного здравоохранения, заданный FDA о риске серьезных эпизодов астмы, связанных с смертью, астматических обострений, и подчеркивают важную роль Куранта в управлении астмой. Меркс благодарен всем исследователям и пациентам, которые приняли участие."
initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue DULERA) if possible without loss of asthma control, and maintain the patient on a long-term asthma controller medication, such as an inhaled corticosteroid. Do not use DULERA for patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids.

DULERA is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. DULERA is contraindicated in patients with known hypersensitivity to any of the ingredients in DULERA.

DULERA is NOT a rescue medication and does NOT replace fast-acting inhalers to treat acute symptoms. Increasing use of inhaled, short-acting beta₂-agonists is a marker for deteriorating asthma. In this situation, the patient requires immediate re-evaluation with reassessment of the treatment regimen.

Patients using DULERA should not use additional formoterol or other long-acting inhaled beta₂-agonists for any reason.

Oropharyngeal candidiasis may occur. If candidiasis develops, it should be treated with appropriate antifungal therapy, but at times therapy with DULERA may need to be interrupted. Advise patients to rinse the mouth after inhalation.

DULERA should be used with caution in patients with tuberculosis, fungal, bacterial, viral (including chicken pox or measles), or parasitic infections, or ocular herpes simplex infections because of the potential for worsening of these infections. A more serious or even fatal course of chickenpox or measles can occur in susceptible patients.

Particular care is needed for patients who are transferred from systemically active corticosteroids to DULERA. Deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids.

Hypercorticism and adrenal suppression may occur with very high dosages of DULERA or at the regular dosage in susceptible individuals. Patients treated with DULERA should be observed carefully for any evidence of systemic corticosteroid effects. If such changes occur, discontinue DULERA slowly.

Caution should be exercised when considering the coadministration of DULERA with long-term ketoconazole and other known strong CYP3A4 inhibitors, or in patients being treated with MAO inhibitors or tricyclic antidepressants.

There is an elevated risk of arrhythmias in patients receiving concomitant anesthesia with halogenated hydrocarbons.

Discontinue DULERA and institute alternative therapy if paradoxical bronchospasm occurs.

Excessive beta-adrenergic stimulation has been associated with central nervous system and cardiovascular effects. DULERA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids, including mometasone furoate, a component of DULERA. Patients with major risk factors for decreased BMD should be monitored and treated with established standards of care.

Inhaled corticosteroids, including DULERA, may cause a reduction in growth velocity when administered in pediatric patients.

Glucoma, increased intraocular pressure, and cataracts have been reported following the use of long-term inhaled corticosteroids, including mometasone furoate, a component of DULERA.

DULERA, like other medications containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines. Doses of the related beta₂-agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

Be alert to hypokalemia and hyperglycemia as beta₂-agonist medications such as DULERA have the potential to produce adverse cardiovascular effects.

The most common treatment-emergent adverse events reported in ≥3 percent of patients and more common than placebo included nasopharyngitis, sinusitis, and headache.

Dysphonia was reported in a longer-term treatment trial at an incidence of 5 percent in patients receiving DULERA 100 mcg/5 mcg and 3.8 percent in patients receiving DULERA 200 mcg/5 mcg.

About Merck

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This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within
the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s 2016 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).


CONTACTS

Media Contacts:
Pam Eisele
(267) 305-3558

Kate Prout
(267) 305-1971

Investor Contact:
Amy Klug
(908) 740-1898

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