FDA Approves Trelegy Ellipta as the First Once-Daily Single Inhaler Triple Therapy for the Treatment of Both Asthma and COPD in the US

September 9, 2020

New asthma indication for Trelegy Ellipta introduces an important option for patients to the current treatment paradigm

LONDON & BURLINGAME, Calif.--(BUSINESS WIRE)--Sep. 9, 2020-- GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) announced the US Food and Drug Administration (FDA) has approved a new indication for Trelegy Ellipta (fluticasone furoate / umeclidinium / vilanterol 'FF/UMEC/VI') for the treatment of asthma in patients aged 18 years and older adding to its current license for use in patients with chronic obstructive pulmonary disease (COPD). Trelegy Ellipta is not indicated for relief of acute bronchospasm.

The FDA-approved strength for both COPD and asthma is fluticasone furoate / umeclidinium / vilanterol 100/62.5/25mcg. There is an additional strength for asthma alone which is fluticasone furoate / umeclidinium / vilanterol 200/62.5/25mcg.

The approval means Trelegy is the first single inhaler triple therapy approved for the maintenance treatment of both asthma and COPD and is the only single inhaler triple therapy available for patients in a convenient once-daily inhalation in the US. Today's announcement marks GSK's sixth major medicine approval in 2020 across areas of significant unmet medical need including cancer, HIV, respiratory and chronic kidney disease.

Dr Hal Barron, Chief Scientific Officer and President R&D, GSK, said: "Millions of asthma patients in the US rely on multiple inhalers to help control their condition and manage their symptoms. Today's approval is an important advance for these patients as it allows them to benefit from triple therapy by using one inhaler, once-a-day."

Trelegy's approval for the maintenance treatment of asthma in patients aged 18 years and older introduces a new paradigm for managing the approximately 30% of adult asthma patients who still experience symptoms despite being adherent to inhaled corticosteroids/ long-acting beta agonist (ICS/LABA) combination therapy.

Tonya Winders, President, Global Allergy and Airways Patient Platform (GAAPP) commented: "In the US there are almost 20 million adults [i] living with asthma and we know that many of those continue to live with and adapt their lives around ongoing symptoms, despite taking medication as prescribed by their physician. We welcome the news that for appropriate patients, Trelegy Ellipta will now be available as a new treatment option."

Today's approval was based on a supplemental New Drug Application which included data from the CAPTAIN study showing that in patients uncontrolled on ICS/LABA, the additional bronchodilation provided by Trelegy demonstrated significant improvements in lung function compared with FF/VI, in a single daily dose in an easy-to-use inhaler. The results from CAPTAIN were presented at the European Respiratory Society (ERS) Congress this week, reinforcing the potential of once-daily single inhaler triple therapy in asthma management.

Pavel Raifeld, Chief Executive Officer of Innoviva, said: "In 2017, Trelegy Ellipta was approved in the US as the first once-daily single inhaler triple therapy for the treatment of COPD, and it remains the market leader with strong continued growth. Today's approval in asthma is another successful outcome for our long-standing partnership with GSK and a testament to our commitment to make innovative medicines accessible to patients with respiratory diseases."

About asthma

Asthma is a chronic lung disease that inflames and narrows the airways. Asthma affects 358 million people worldwide. Despite medical advances, more than half of patients continue to experience poor control and significant symptoms impacting their daily lives.

The causes of asthma are not completely understood but likely involve an interaction between a person's genetic make-up and the environment. Key risk factors are inhaled substances that provoke allergic reactions or irritate the airways.

About the CAPTAIN Study

CAPTAIN (Clinical study of Asthma Patients receiving Triple therapy through A single INhaler) was a randomised, double-blind, active controlled, six-arm parallel group, global multicentre study evaluating FF/UMEC/VI (100/62.5/25 mcg, 200/62.5/25 mcg, 100/31.25/25 mcg, and 200/31.25/25 mcg) versus FF/VI (100/25 mcg and 200/25 mcg) given once-daily to patients whose asthma was inadequately controlled despite treatment with ICS/LABA (>250 mcg/day fluticasone propionate, or equivalent) maintenance asthma medication.

About Trelegy Ellipta (FF/UMEC/VI) in the US

FF/UMEC/VI is a combination of three molecules in a single inhaler that only needs to be taken in a single inhalation, once a day. It contains fluticasone furoate, an inhaled corticosteroid, umeclidinium, a long-acting muscarinic antagonist; and vilanterol, a long-acting beta2-adrenergic agonist, delivered in GSK's Ellipta dry powder inhaler.

FF/UMEC/VI was approved in the US under the brand name Trelegy Ellipta in September 2017 for the long-term, once-daily maintenance treatment of patients with COPD. Trelegy Ellipta was approved in the US on 9 September 2020 for the maintenance treatment of asthma in patients aged 18 years and older. Trelegy Ellipta is not indicated for relief of acute bronchospasm.

US Prescribing Information for Trelegy Ellipta.

Important Safety Information (ISI) for Trelegy Ellipta

The following ISI is based on the Highlights section of the US Prescribing Information for Trelegy Ellipta. Please consult the full Prescribing Information for all the labelled safety information.

Trelegy Ellipta is NOT indicated for the relief of acute bronchospasm.

Trelegy Ellipta is contraindicated in primary treatment of status asthmaticus or acute episodes of asthma requiring intensive measures and in patients with severe hypersensitivity to milk proteins or any of the ingredients.

LABA monotherapy increases the risk of serious asthma-related events.

Trelegy Ellipta should not be initiated in patients experiencing episodes of acutely deteriorating COPD or asthma. Do not use Trelegy Ellipta to treat acute symptoms

Trelegy Ellipta should not be used in combination with other medicines containing LABA because of risk of overdose.

Candida albicans infection of the mouth and pharynx has occurred in patients treated with fluticasone furoate, a component of Trelegy Ellipta. Monitor patients periodically. Advise the patient to rinse his/her mouth with water without swallowing after inhalation to help reduce the risk.

There is an increased risk of pneumonia in patients with COPD taking Trelegy Ellipta. Monitor patients for signs and symptoms of pneumonia.

Patients who use corticosteroids are at risk for potential worsening of infections (e.g. existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex). Use Trelegy Ellipta with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.

There is a risk of impaired adrenal function when transferring from systemic corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to Trelegy Ellipta.

Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage of Trelegy Ellipta in susceptible individuals. If such changes occur, discontinue Trelegy Ellipta slowly.

If paradoxical bronchospasm occurs, discontinue Trelegy Ellipta and institute alternative therapy.

Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of TRELEGY. Discontinue TRELEGY if such reactions occur.

Use Trelegy Ellipta with caution in patients with cardiovascular disorders because of beta-adrenergic stimulation.

Assess patients for decrease in bone mineral density initially and periodically thereafter after prescribing Trelegy Ellipta.

Consider referral to an ophthalmologist in patients who develop ocular symptoms or use TRELEGY ELLIPTA long term. Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a healthcare provider immediately if symptoms occur.

Worsening of urinary retention may occur in patients taking Trelegy Ellipta. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

Use Trelegy Ellipta with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis.

Be alert to hypokalemia and hyperglycemia in patients taking Trelegy Ellipta.

Orally inhaled corticosteroids may reduce growth velocity in children and adolescents. Trelegy Ellipta is not indicated for use in children and adolescents.

COPD: The most common adverse reactions reported for Trelegy Ellipta 100/62.5/25 mcg (incidence ≥1%) are upper respiratory tract infection, pneumonia, bronchitis, oral candidiasis, headache, back pain, arthralgia, influenza, sinusitis, pharyngitis, rhinitis, dysgeusia, constipation, urinary tract infection, diarrhoea, gastroenteritis, oropharyngeal pain, cough, and dysphonia.

Asthma: The most common adverse reactions (incidence ≥2%) are nasopharyngitis, upper respiratory tract infection, bronchitis, viral respiratory tract infection, sinusitis, urinary tract infection, rhinitis, influenza, headache, and back pain.

GSK's commitment to respiratory disease

For 50 years, GSK has led the way in developing medicines that advance the management of asthma and COPD. From introducing the world's first selective short-acting beta agonist in 1969, to launching six treatments in five years to create today's industry-leading respiratory portfolio, we continue to innovate so we can reach the right patients, with the right treatment. Working together with the healthcare community, we apply world-class science to discover and understand the molecules that become the medicines of tomorrow. We won't stand still until the simple act of breathing is made easier for everyone.

About GSK

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com/about-us.

Editor's Note: In addition to the FDA's approval of Trelegy Ellipta in asthma, GSK has received five major medicine approvals to date in 2020 for CABENUVA (cabotegravir and rilpivirine) in Canada, DUVROQ (daprodustat) in Japan, and ZEJULA (niraparib), RUKOBIA (fostemsavir) and BLENREP (belantamab mafodotin) in the US.

About Innoviva

Innoviva, Inc. (referred to as "Innoviva", the "Company", or "we" and other similar pronouns), is a company with a portfolio of royalties that include

respiratory assets partnered with Glaxo Group Limited (“GSK”), including RELVAR ®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, “FF/VI”), ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, “UMEC/VI”) and TRELEGY ® ELLIPTA® (the combination FF/UMEC/VI). Under the Long-Acting Beta2 Agonist (“LABA”) Collaboration Agreement, Innoviva is entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. Innoviva is also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC (“TRC”), relating to TRELEGY ® ELLIPTA® and any other product or combination of products that may be discovered and developed in the future under the LABA Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the “GSK Agreements”), which have been assigned to TRC other than RELVAR ®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk Factors" in the company's Annual Report on Form 20-F for 2019 and as set out in GSK’s Principal risks and uncertainties” section of the Q2 Results and any impacts of the COVID-19 pandemic.

Innoviva forward-looking statements

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives and future events, including the development, regulatory and commercial plans for closed triple combination therapy and the potential benefits and mechanisms of action of closed triple combination therapy. Innoviva intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve substantial risks, uncertainties and assumptions. These statements are based on the current estimates and assumptions of the management of Innoviva as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Innoviva to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Innoviva's Annual Report on Form 10-K for the year ended December 31, 2018, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors are described in those sections of Innoviva's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019. In addition to the risks described above and in Innoviva's other filings with the SEC, other unknown or unpredictable factors also could affect Innoviva's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The information in this press release is provided only as of the date hereof, and Innoviva assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

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[i] https://www.cdc.gov/nchs/fastats/asthma.htm

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Source: Innoviva, Inc.