Press Release

For media and investors only

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Trelegy Ellipta approved in China for use in adults with uncontrolled asthma

- Asthma indication introduces an important option for patients with uncontrolled symptoms
- Approval adds to existing indication in COPD, making *Trelegy Ellipta* the only single inhaler triple therapy available for both respiratory conditions in China
- Approximately 46 million adults in China have asthma[1], with around half experiencing uncontrolled symptoms, putting them at increased risk of exacerbations[2]

GSK plc (LSE/NYSE: GSK) today announced that China's National Medical Products Administration (NMPA) has approved a new indication for *Trelegy Ellipta* (fluticasone furoate / umeclidinium / vilanterol 'FF/UMEC/VI') for the treatment of patients with asthma aged 18 years and older, adding to its current license for use in patients with chronic obstructive pulmonary disease (COPD). The approval means that FF/UMEC/VI is the first and only single inhaler triple therapy (SITT) approved for the maintenance treatment of both respiratory conditions in the country.

Approval was based on GSK's CAPTAIN study which showed that in patients uncontrolled on inhaled corticosteroids/long-acting beta agonist (ICS/LABA), the additional bronchodilation provided by FF/UMEC/VI demonstrated significant improvements in lung function compared with FF/VI.

Kaivan Khavandi, Senior Vice President, Global Head, Respiratory, Immunology and Inflammation, R&D said: "Early intervention with a single inhaler triple therapy can improve clinical outcomes for suitable patients with uncontrolled asthma. Today's approval gives patients whose condition is not optimally managed, and therefore at increased risk of experiencing exacerbations, an important option in their care. As a company, we are committed to help change the course of disease and make clinical remission, where patients' disease has sustained control, an ambitious but attainable treatment goal."

Asthma is one of the most prevalent chronic respiratory diseases in China, with approximately 46 million adults affected nationwide[1]. Despite established treatment recommendations, around half of patients experience uncontrolled symptoms, increasing the likelihood of exacerbations and reduced quality of life.[2,3,4] This new indication for our already established SITT in COPD presents an important option for patients with uncontrolled asthma in China who would benefit from an ICS/LAMA/LABA in a once-daily inhalation.

FF/UMEC/VI is now approved by NMPA in 100/62.5/25mcg strength for both asthma and COPD indications and in 200/62.5/25mcg strength for asthma only.

About *Trelegy Ellipta* (FF/UMEC/VI)
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 (FF), an inhaled corticosteroid, umeclidinium (UMEC), a long-acting muscarinic antagonist; and vilanterol (VI), a long-acting beta2-adrenergic agonist, delivered in GSK's *Ellipta* dry powder inhaler.

FF/UMEC/VI was approved in China under the brand name *Trelegy Ellipta* in 2019 for the long-term, once-daily maintenance treatment of patients with COPD.

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. In the study, 2,436 patients were treated across 15 countries with approximately 400 patients randomly assigned to each of the six treatment arms.

Data from the study demonstrated mean (95% confidence interval) improvements in FEV_1 change from baseline of 110ml for FF/UMEC/VI 100/62.5/25 µg versus FF/VI 100/25 µg (95% CI 66-153; p<0.0001) and 92ml for FF/UMEC/VI 200/62.5/25 µg versus FF/VI 200/25 µg (49-135; p<0.0001).

About GSK in respiratory
GSK continues to build on decades of pioneering work to deliver more ambitious treatment goals, develop the next generation standard of care, and redefine the future of respiratory medicine for hundreds of millions of people with respiratory diseases. With an industry-leading respiratory portfolio and pipeline of vaccines, targeted biologics, and inhaled medicines, GSK is focused on improving outcomes and the lives of people living with all types of asthma and COPD along with less understood refractory chronic cough or rarer conditions like systemic sclerosis with interstitial lung disease. GSK is harnessing the latest science and technology with the aim of modifying the underlying disease dysfunction and preventing progression.

About GSK
GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

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