ASTRAZENECA PLC
Form 6-K
December 20, 2018

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of December 2018

Commission File Number: 001-11960

AstraZeneca PLC

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F X Form 40-F __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

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Yes __ No X

If “Yes” is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1.
Bevespi Aerosphere approved in the EU for COPD

20 December 2018 13:45 GMT

Bevespi Aerosphere approved in the EU for chronic obstructive pulmonary disease

AstraZeneca today announced that the European Commission (EC) has approved Bevespi Aerosphere(glycopyrronium/formoterol fumarate) in a pressurised metered-dose inhaler (pMDI) as a maintenance dual bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Bevespi Aerosphere is the first medicine in its class to be approved by the EC in a pMDI. The approval offers patients with COPD an important new choice of inhaler device.

Dr Colin Reisner, Head of Respiratory, Global Medicines Development, said: "Bevespi Aerosphere is already available to COPD patients in the US and other countries, and this approval means we can now bring this new medicine to patients in Europe. Bevespi Aerosphere is the first dual-bronchodilator treatment delivered in our next-generation pressurised metered-dose inhaler using Aerosphere Delivery Technology."

Dr Omar Usmani, Consultant Physician in Respiratory Medicine at the National Heart & Lung Institute, Imperial College London and Royal Brompton Hospital, UK, said: "Bevespi Aerosphere is an important treatment option in COPD, particularly for patients with limited lung function and advanced age who may benefit from using a pMDI. The efficacy and safety profile of Bevespi Aerosphere has been well established in the Phase III PINNACLE programme."

Bevespi Aerosphere is a twice-daily, fixed-dose dual bronchodilator combining glycopyrronium, a long-acting muscarinic antagonist (LAMA), and formoterol fumarate, a long-acting beta2-agonist (LABA). The EC approval is based on the Phase III PINNACLE trial programme which evaluated the efficacy and safety of Bevespi Aerosphere and involved more than 5,000 patients with moderate to very-severe COPD.

Bevespi Aerosphere is also approved in the US, Canada, Australia, Turkey and Taiwan as a dual bronchodilator for the long-term maintenance treatment of COPD.

About COPD
COPD is a progressive disease which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness.1 It affects an estimated 384 million people worldwide and is predicted to be the third leading cause of death by 2020.1,2 Improving lung function, reducing exacerbations and managing daily symptoms such as breathlessness are important treatment goals in the management of COPD.1

About the Phase III PINNACLE programme
PINNACLE 1/2/4 were randomised, double-blinded, multi-centre, placebo-controlled trials conducted over 24 weeks, which compared the efficacy and safety of Bevespi Aerosphere administered twice daily via a pMDI, compared to its monotherapy components (glycopyrronium and formoterol fumarate) and to placebo.3,4,5 In PINNACLE 1, open-label tiotropium was included as an active control.3PINNACLE 3 was a multi-centre, randomised, double-blinded, parallel-group, chronic-dosing, active-controlled, 28-week safety extension trial of PINNACLE 1/2, which evaluated the long-term safety, tolerability, and efficacy of Bevespi Aerosphere administered twice daily via a pMDI compared to its monotherapy components.6 All the trials were conducted in patients with moderate to very-severe COPD.

About Bevespi Aerosphere
Bevespi Aerosphere is a fixed-dose dual bronchodilator combining glycopyrronium, a long-acting muscarinic antagonist (LAMA), and formoterol fumarate, a long-acting beta2-agonist (LABA) in a pMDI. Pressurised metered-dose inhalers are an important choice for COPD patients where limited lung function, advanced age and reduced dexterity or cognition are significant considerations for patients to achieve therapeutic benefits from their medicines.7,8 Bevespi Aerosphere is the only LAMA/LABA with AerosphereDelivery Technology. Results from an imaging trial have shown that Bevespi Aerosphere effectively delivers medicine to both the large and small airways.9 Aerosphere Delivery Technology is also the platform for the potential new medicine PT010, AstraZeneca's triple combination of budesonide /glycopyrronium/formoterol fumarate.

About AstraZeneca in Respiratory Disease
Respiratory disease is one of AstraZeneca's main therapy areas, and the Company has a growing portfolio of medicines that reached more than 18 million patients in 2017. AstraZeneca's aim is to transform asthma and COPD treatment through inhaled combinations at the core of care, biologics for the unmet needs of specific patient populations, and scientific advancements in disease modification.

The Company is building on a 40-year heritage in respiratory disease and AstraZeneca's capability in inhalation technology spans pressurised metered-dose inhalers and dry powder inhalers, as well as the Aerosphere Delivery Technology. The company also has a growing portfolio of respiratory biologics including Fasenra (anti-eosinophil, anti-IL-5r), approved for severe eosinophilic asthma and in development for severe nasal polyposis, and tezepelumab (anti-TSLP), which has been granted Breakthrough Therapy designation by the US Food and Drug Administration in patients with severe asthma and is in Phase III trials. AstraZeneca's research is focused on addressing underlying disease drivers focusing on the lung epithelium, lung immunity and lung regeneration.

About AstraZeneca
AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit astrazeneca.com and follow us on Twitter @AstraZeneca.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

References

1. GOLD. Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2018. [Online]. Available at: http://goldcopd.org. Last accessed: November 2018.
2. Adeloye D, Chua S, Lee C, et al. Global Health Epidemiology Reference Group (GHERG). Global and regional estimates of COPD prevalence: Systematic review and meta-analysis. J Glob Health. 2015; 5 (2): 020415.
3. Clinicaltrials.gov. Efficacy and Safety of PT003, PT005, and PT001 in Subjects With Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD); (PINNACLE 1). [Online]. Available at: https://clinicaltrials.gov/ct2/show/NCT01854645. Last accessed: November 2018.
4. Clinicaltrials.gov. Multi-Center Study to Assess the Efficacy and Safety of PT003, PT005, and PT001 in Subjects With Moderate to Very Severe COPD (PINNACLE 2). [Online]. Available at: https://clinicaltrials.gov/ct2/show/NCT01854658. Last accessed: November 2018.
5. AstraZeneca plc. Bevespi Aerosphere demonstrates statistically significant improvement in lung function in patients with COPD. [Online]. Available at: https://www.astrazeneca.com/media-centre/press-releases/2017/bevespi-aerosphere-demonstrates-statistically-significant-im accessed: November 2018
6. Clinicaltrials.gov. Extension Study to Evaluate the Safety and Efficacy of PT003, PT001, and PT005 in Subjects With Moderate to Very Severe COPD, With Spiriva® Handihaler® (PINNACLE 3). [Online]. Available at: https://clinicaltrials.gov/ct2/show/NCT01970878. Last accessed: November 2018.
7. Usmani O, Capstick T, Chowhan H, et al. Inhaler choice guideline. March 2017 [Online]. Available at:https://www.guidelines.co.uk/respiratory/inhaler-choice-guideline/252870.article. Last accessed: November 2018.
8. Bonini and Usmani. The importance of inhaler devices in the treatment of COPD. COPD Research & Practice. 2015: 1: 9
9. AstraZeneca. Aerosphere Delivery Technology - Global Core Claims Guide.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 20 December 2018

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary