

This announcement contains inside information

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Update on US regulatory review of PT010 in COPD

AstraZeneca today announced that the US Food and Drug Administration (FDA) has issued a complete response letter regarding the New Drug Application (NDA) for PT010 (budesonide/glycopyrronium/formoterol fumarate), an inhaled triple-combination therapy and potential new medicine for patients with chronic obstructive pulmonary disease (COPD).

The NDA submitted to the FDA by AstraZeneca included data from the Phase III trial KRONOS. The Company will now work closely with the FDA regarding next steps, including submitting for review recent results from the second positive Phase III trial, ETHOS, which was not completed at the time the NDA was submitted.

PT010 was [approved in Japan](#) in June 2019 as *Breztri Aerosphere*, a triple-combination therapy to relieve symptoms of COPD. PT010 is under regulatory review in China where it has been granted priority review by the National Medical Products Administration, and is also under regulatory review in the EU.

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 ATHENA

ATHENA is PT010's global clinical trial programme, including 11 completed Phase III trials with more than 15,500 patients.^{3,4,5,6} The four key trials are ETHOS, KRONOS, TELOS and SOPHOS.^{3,4,5,6} The ETHOS and KRONOS trials assessed the efficacy and safety of PT010.^{3,4} The TELOS and SOPHOS trials characterised PT009 and substantiated it as an active comparator in the PT010 clinical trial programme.^{5,6}

In the Phase III ETHOS trial, PT010 demonstrated a statistically-significant reduction in the rate of moderate or severe exacerbations compared with dual-combination therapies *Bevespi Aerosphere*(glycopyrronium/formoterol fumarate) and PT009 (budesonide/formoterol fumarate). The safety and tolerability of PT010 in the trial were consistent with the known profiles of the dual comparators.⁷

About PT010

PT010 is a fixed-dose triple-combination of budesonide, an inhaled corticosteroid with glycopyrronium, a long-acting muscarinic agonist, and formoterol fumarate, a long-acting beta2-agonist, delivered in a pressurised metered-dose inhaler.

Under the terms of the agreement to acquire Pearl Therapeutics Inc., AstraZeneca anticipates making a \$150m milestone payment upon US regulatory approval of PT010 for COPD. This payment would be the final development and regulatory milestone under that agreement.

About AstraZeneca in respiratory diseases

Respiratory is one of AstraZeneca's three therapy areas, and our medicines reached more than 18 million patients as maintenance therapy in 2018. 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-IL5 receptor alpha), now approved for severe eosinophilic asthma and in development for severe nasal polyposis and COPD and a number of other potential indications, 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 and Metabolism (CVRM) and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow us on Twitter [@AstraZeneca](https://twitter.com/AstraZeneca).

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