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# Update on the RESOLUTE Phase III trial for *Fasenra* in chronic obstructive pulmonary disease

The RESOLUTE Phase III trial of AstraZeneca's *Fasenra* (benralizumab), despite showing numerical improvement, did not achieve statistical significance in the primary endpoint in patients with chronic obstructive pulmonary disease (COPD).[i]

Sharon Barr, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca, said: "COPD, which remains a leading cause of death worldwide, is a complex, heterogeneous disease and we continue to advance other promising approaches in our pipeline to address the unmet needs of patients. With its well-established ability to target and eliminate eosinophils, *Fasenra* has helped transform treatment of severe asthma, and more recently has demonstrated a significant effect in eosinophilic granulomatosis with polyangiitis and hypereosinophilic syndrome."

The safety and tolerability profile for *Fasenra* in the trial was consistent with the known profile of the medicine.[1] The Company will analyse the full data set from RESOLUTE to further understand the results, which will be shared with the scientific community in the future.

*Fasenra* is currently approved as an add-on maintenance treatment for severe eosinophilic asthma (SEA) in more than 80 countries, including the US, Japan, EU and China.[2-5] It is also approved for SEA in children and adolescents ages six and above in the US and Japan.[6] *Fasenra* is also approved in more than 60 countries for the adult treatment of eosinophilic granulomatosis with polyangiitis (EGPA),[7] and is under regulatory review for the treatment of hypereosinophilic syndrome (HES).

## Notes

**COPD**
COPD is a debilitating, irreversible and progressive disease.[8-11] COPD exacerbations are life-threatening and accelerate disease progression, irreversible lung damage, increased hospitalisations, subsequent exacerbations and death.[8-12] COPD is one of the most common chronic respiratory diseases, affecting 391 million people globally,[8] and is among the highest causes of morbidity and mortality globally.[13]

**RESOLUTE**
RESOLUTE is a randomised, double-blind, placebo-controlled Phase III trial to evaluate the efficacy and safety of benralizumab 100 mg in people with moderate to very severe COPD with a history of frequent COPD exacerbations and an elevated blood eosinophil count (BEC) ≥ 300 cells/µL.[1,4] Participants in the trial had a history of at least two COPD exacerbations in the year prior to enrolment, were on background treatment with ICS/LABA/LAMA and were a current or former smoker.[14] The primary endpoint was the annualised rate of moderate or severe exacerbations in patients with three or more exacerbations in the previous year. The RESOLUTE trial population was informed by the analysis from the Phase III GALATHEA and TERRANOVA trials.

Participants (n=689) were randomised to receive placebo-solution or *Fasenra* (100 mg every four weeks for the first three doses and then every eight weeks thereafter).[14] All participants remained on their background therapy, ICS/LABA/LAMA.[14]

In the trial, moderate COPD exacerbations were defined by symptomatic worsening of COPD requiring the use of systemic corticosteroids for at least three days and use of antibiotics.[14] Severe exacerbations were defined by hospitalisation or death due to COPD.[14] Key secondary endpoints included the annualised rate of severe exacerbations, change from baseline in SGRQ total score; and change from baseline in pre-dose/pre-bronchodilator FEV1 at Week 56.[14]

***Fasenra***
*Fasenra* (benralizumab) is currently approved as an add-on maintenance treatment for adults with SEA in more than 80 countries, including the US, Japan, EU and China.[2-5] More than 150,000 patients globally are currently taking *Fasenra*.[15] In the US and Japan, *Fasenra* is also approved in SEA patients six years and older.[6] *Fasenra* is also approved in more than 60 countries for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in adults.[7]

The NATRON Phase III trial evaluating *Fasenra* (benralizumab) in people with hypereosinophilic syndrome (HES) successfully met the primary endpoint. *Fasenra*, dosed monthly in a single injection, demonstrated a statistically significant increase in the time to first worsening or flare compared to placebo.[16]

*Fasenra* was developed by AstraZeneca and is in-licensed from BioWa, Inc., a wholly owned subsidiary of Kyowa Kirin Co., Ltd., Japan.

**AstraZeneca in Respiratory & Immunology**
Respiratory & Immunology, part of AstraZeneca BioPharmaceuticals, is a key disease area and growth driver to the Company.

AstraZeneca is an established leader in respiratory care with a 50-year heritage and a growing portfolio of medicines in immune-mediated diseases. The Company is committed to addressing the vast unmet needs of these chronic, often debilitating, diseases with a pipeline and portfolio of inhaled medicines, biologics and new modalities aimed at

previously unreachable biologic targets. Our ambition is to deliver life-changing medicines that help eliminate COPD as a leading cause of death, eliminate asthma attacks and achieve clinical remission in immune-mediated diseases.

**AstraZeneca**
AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca's innovative medicines are sold in more than 125 countries and used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on social media @AstraZeneca.

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[i] The primary endpoint was the annualised rate of moderate or severe chronic obstructive pulmonary disease (COPD) exacerbations.


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