AstraZeneca update on Fasenra PIII trial in COPD

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AstraZeneca provides update on GALATHEA Phase III trial for *Fasenra* in chronic obstructive pulmonary disease

GALATHEA Phase III trial did not meet the primary endpoint of a statistically-significant reduction of exacerbations in patients with COPD

Second Phase III trial TERRANOVA is ongoing with results expected later this quarter

AstraZeneca and MedImmune, its global biologics research and development arm, today announced top-line results from the GALATHEA Phase III trial for *Fasenra* (benralizumab) in patients with moderate to very severe chronic obstructive pulmonary disease (COPD). The trial did not meet the primary endpoint of a statistically-significant reduction of exacerbations in patients with COPD.

Dr. Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "COPD is a debilitating disease with significant unmet need among patients whose disease remains uncontrolled despite treatment with existing inhaled therapies. We will now await the results of TERRANOVA and a full evaluation of both trials to determine next steps for *Fasenra* in COPD."

The pivotal Phase III trials GALATHEA and TERRANOVA are randomised, double-blinded, 56-week placebo-controlled, multi-centre trials assessing the safety and efficacy of *Fasenra* as an add-on to dual or triple inhaled therapy compared to placebo in patients with moderate to very severe COPD with a history of exacerbations across a range of baseline blood eosinophils.1

The safety and tolerability findings in GALATHEA were consistent with those observed in previous trials with *Fasenra*. A full evaluation of the data is ongoing and the results will be submitted for presentation at a forthcoming medical meeting.

Fasenra is AstraZeneca's first respiratory biologic and is currently approved as an add-on treatment for severe eosinophilic asthma in the US, EU, Japan and several other countries.

The results of the GALATHEA trial do not impact the approved indication in severe eosinophilic asthma.

About COPD

COPD is a progressive disease which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness.2 It affects an estimated 384 million people worldwide and is predicted to be the third-leading cause of death by 2020.2,3 At initial diagnosis, approximately one-third of COPD patients have severe or very severe forms of this disease.4 Improving lung function, reducing exacerbations and managing daily symptoms such as breathlessness are important to the management of COPD.2

About 30-40% of moderate to severe COPD patients on triple inhaled therapy (ICS/LAMA/LABA) remain uncontrolled and continue to experience exacerbations.5,6 COPD exacerbations significantly impair quality of life and are linked to disease progression, accelerated decline in lung function, and increased hospitalisations and mortality.7,8,9

About *Fasenra*

Fasenra (benralizumab) is a monoclonal antibody that recruits natural killer cells to induce rapid and near-complete depletion of eosinophils, a type of white blood cell that are a normal part of the body's immune system.10,11 Depletion of circulating eosinophils is rapid, with an onset of action within 24 hours as confirmed in Phase I/II severe asthma trials.10,11,12

Fasenra is AstraZeneca's first respiratory biologic now approved in severe eosinophilic asthma in the US, EU, Japan, Canada and Australia and under regulatory review in several other jurisdictions.

Fasenra was developed by AstraZeneca with MedImmune, the company's global biologics research and development arm and is in-licensed from BioWa, Inc., a wholly-owned subsidiary of Kyowa Hakko Kirin Co., Ltd., Japan.

About the VOYAGER Programme

VOYAGER is AstraZeneca's Phase III *Fasenra* clinical trial programme in COPD and, with close to 4,000 patients, it is currently the largest COPD biologics development programme in the world.13 The VOYAGER programme includes two trials, GALATHEA and TERRANOVA, evaluating *Fasenra* in patients with moderate to very severe COPD with a history of exacerbations across a range of baseline blood eosinophils.13

About AstraZeneca in Respiratory Disease

Respiratory diseaseis one of AstraZeneca'smain 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 treatmentthrough 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-5rα), now approved for severe eosinophilic asthma, and tezepelumab (anti-TSLP), which achieved its Phase IIb primary and secondary endpoints and is continuing development in the Phase III PATHFINDER clinical trial programme. AstraZeneca's research is focused on addressing underlying disease drivers focusing on the lung epithelium, lung immunity and lung regeneration.

About MedImmune

MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Oncology, Respiratory, Cardiovascular & Metabolic Diseases, and Infection and Vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK and Mountain View, Calif. For more information, please visit www.medimmune.com

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 & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

For more information, please visit www.astrazeneca.com and follow us on Twitter @AstraZeneca.

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