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Fasenra (benralizumab) receives US FDA approval for severe eosinophilic asthma

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Fasenra distinctively targets and rapidly depletes eosinophils and is the first respiratory biologic with an 8-week maintenance dosing schedule

FDA approval based on Phase III programme demonstrating up to 51% reduction in asthma exacerbations, significant improvement in lung function and a 75% reduction in daily oral steroid use

AstraZeneca and its global biologics research and development arm, MedImmune, today announced that the US Food and Drug Administration (FDA) has approved *Fasenra* (benralizumab) for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Pascal Soriot, Chief Executive Officer of AstraZeneca, said: “We’re excited to offer *Fasenra* as a new precision biologic to help improve the lives of severe asthma patients whose disease is driven by eosinophilic inflammation. This is the first approval from our respiratory biologics portfolio and the latest in a series of significant milestones for our company as we deliver on our pipeline-driven transformation.”

The FDA approval is based on results from the WINDWARD programme, including the pivotal Phase III exacerbation trials, SIROCCO and CALIMA, and the Phase III oral corticosteroid (OCS)-sparing trial, ZONDA. Results for the 8-week benralizumab dosing regimen from these trials showed:

- Up to 51% reduction in the annual asthma exacerbation rate (AAER) versus placebo
- Significant improvement in lung function as measured by forced expiratory volume in one second (FEV_1) of up to 159mL versus placebo. Differences were seen as early as 4 weeks after the first dose, providing an early indication of effectiveness
- 75% median reduction in daily OCS use and discontinuation of OCS use in 52% of eligible patients
- An overall adverse event profile similar to that of placebo

Eugene Bleecker, MD, Professor and Co-Director, Genetics, Genomics and Precision Medicine, University of Arizona Health Sciences, and lead investigator of the pivotal Phase III SIROCCO study, said: “This is an important day for severe, eosinophilic asthma patients who have had limited treatment options for far too long, with many relying on oral steroids to manage their symptoms. *Fasenra* has a strong clinical profile which includes the ability to show lung function improvement after the first dose, the potential to reduce – or even stop - oral steroid use, and the convenience of 8-week dosing. *Fasenra* also treats a distinct patient phenotype, helping physicians select the right patient in clinical practice with more confidence.”

Fasenra is the only respiratory biologic that provides direct, rapid and near-complete depletion of eosinophils within 24 hours. Eosinophils are a type of white blood cell that are a normal part of the body's immune system. Elevated levels of eosinophils, seen in about half of severe asthma patients, impact airway inflammation and airway hyper-responsiveness, resulting in increased asthma severity and symptoms, decreased lung function and increased risk of exacerbations.

Fasenra binds directly to the IL-5α receptor on an eosinophil and uniquely attracts natural

killer cells to induce apoptosis (programmed cell death). *Fasenra* will be available as a once every 8-week fixed-dose subcutaneous injection via a prefilled syringe.

On 10 November, 2017, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the marketing authorisation of benralizumab. Benralizumab is also under regulatory review in Japan and several other countries.

NOTES TO EDITORS

About Severe Asthma

Asthma affects 315 million individuals worldwide, and up to 10% of asthma patients have severe asthma which may be uncontrolled despite high doses of standard-of-care asthma controller medicines and can require the use of chronic OCS.

Severe, uncontrolled asthma is debilitating and potentially fatal with patients experiencing frequent exacerbations and significant limitations on lung function and quality of life. Severe, uncontrolled asthma has higher risk of mortality than severe asthma.

Severe, uncontrolled asthma can lead to a dependence on OCS, with systemic steroid exposure potentially leading to serious short- and long-term adverse effects, including weight gain, diabetes, osteoporosis, glaucoma, anxiety, depression, cardiovascular disease and immunosuppression. There is also a significant physical and socio-economic burden of severe, uncontrolled asthma with these patients accounting for 50% of asthma-related costs.

About *Fasenra* (benralizumab)

Fasenra is a monoclonal antibody that recruits natural killer cells to induce direct, rapid and near-complete depletion of eosinophils. Depletion of circulating eosinophils is rapid, with an onset of action within 24 hours as confirmed in an early Phase II trial. In the pivotal Phase III trials, SIROCCO and CALIMA, *Fasenra* demonstrated significant reduction in exacerbations and improved lung function and asthma symptoms in severe, uncontrolled eosinophilic asthma patients. Eosinophils are the biological effector cells in approximately 50% of asthma patients, leading to frequent exacerbations, impaired lung function and asthma symptoms. *Fasenra* will be available as a subcutaneous injection via a prefilled syringe administered once every 4 weeks for the first 3 doses, and then once every 8-weeks thereafter.

Fasenra is now approved in the US, and under regulatory review in the EU, Japan and several other countries.

Fasenra is the foundation of AstraZeneca's respiratory biologics portfolio of potential new medicines targeting underlying causes of respiratory disease. *Fasenra* is also being evaluated in chronic obstructive pulmonary disease (COPD).

Fasenra was developed by AstraZeneca with MedImmune, AstraZeneca'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 WINDWARD Programme

The WINDWARD programme in asthma is made up of six Phase III trials, including SIROCCO, CALIMA, ZONDA, BISE, BORA and GREGALE. The two pivotal trials SIROCCO and CALIMA, are randomised, double-blinded, parallel-group, placebo-controlled trials designed to evaluate the efficacy and safety of subcutaneous administration of *Fasenra* (fixed 30mg dose) for up to 56-weeks in exacerbation-prone adult and adolescent patients 12 years of age and older.

A total of 2,510 patients (1,204 in SIROCCO and 1,306 in CALIMA) received standard-of-care medicine (including high-dosage inhaled corticosteroids and long-acting $beta_2$-agonists) and were randomised globally to receive either *Fasenra* 30mg every 4 weeks; *Fasenra* 30mg every 4 weeks for the first three doses followed by 30mg every 8 weeks; or placebo administered via subcutaneous injection using an accessorised pre-filled syringe.

A recent pooled *post-hoc* analysis of the SIROCCO and CALIMA studies demonstrated an association between enhanced *Fasenra* efficacy and certain easily identifiable clinical features of severe eosinophilic asthma, including higher baseline blood eosinophil counts, history of more frequent exacerbations, chronic OCS use and a history of nasal polyposis.

The third registrational trial, ZONDA, demonstrated a statistically-significant and clinically-meaningful reduction in daily-maintenance, OCS use compared with placebo for patients with severe, uncontrolled OCS-dependent eosinophilic asthma receiving *Fasenra*. Patients treated with *Fasenra* achieved a median reduction in OCS dose of 75%, and were more than four times as likely to reduce their OCS dose than those on placebo. The results were published in *the New England Journal of Medicine* in May 2017.

In addition to WINDWARD, the Phase III VOYAGER programme is currently underway, which is evaluating the efficacy and safety of *Fasenra* in patients with severe chronic obstructive pulmonary disease (COPD).

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 2016. 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 both pMDIs and dry powder inhalers, as well as the innovative *Aerosphere* Delivery Technology. The company's biologics include *Fasenra* (anti-eosinophil, anti-IL-5Rα), which is now approved in the US, received a positive CHMP opinion in the EU and is under regulatory review in Japan, tralokinumab (anti-IL-13), which has completed Phase III trials, and tezepelumab (anti-TSLP), which successfully achieved its Phase IIb primary and secondary endpoints. 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 commercialization 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, CA. 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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This announcement contains inside information.

Adrian Kemp
Company Secretary
AstraZeneca PLC

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