ASTRAZENECA ADVANCES TRALOKINUMABTO PHASE III IN SEVERE ASTHMA

AstraZeneca today announced the start of the Phase III programme for tralokinumab, a potential treatment for patients with severe, inadequately controlled asthma, developed by MedImmune, the company's global biologics research and development arm.

The Phase III programme will evaluate the safety and effectiveness of tralokinumab in reducing the rate of asthma exacerbations (AER) in adults and adolescents with severe, inadequately controlled asthma despite receiving inhaled corticosteroids plus long-acting β2-agonist. The programme will also assess the effect of tralokinumab on lung function, patient-reported asthma symptoms and quality of life, as well as investigate whether potential clinical biomarkers could identify patients who are more likely to respond to tralokinumab.

Tralokinumab is an investigational human monoclonal antibody which potently and selectively neutralises interleukin-13 (IL-13). IL-13 is a key cytokine that is believed to contribute to the onset of severe and frequent asthma attacks, impaired lung function and other debilitating asthma symptoms by driving inflammation, airway hyper-responsiveness and excessive mucus production.

"We are pleased to begin the tralokinumab Phase III programme in severe asthma, further strengthening the breadth of our portfolio in respiratory disease, one of AstraZeneca's core therapy areas," said Bill Mezzanotte, Vice President and Head of Inflammation, Neuroscience and Respiratory in AstraZeneca's Global Medicines Development unit. "Patients with severe asthma currently have limited treatment options and need more effective therapies to control their disease. The development of tralokinumab underscores our commitment to a personalised treatment approach for these patients, to improve their lives. Severe asthma is highly heterogeneous; we are working to better understand patient subtypes, identify potential biomarkers, and tailor therapies to cellular and molecular phenotypes to achieve the best clinical outcomes."

Initiation of the Phase III programme is based on results from a Phase IIb study conducted by MedImmune. Results from that study were presented at the 2014 American Thoracic Society (ATS) International Conference in San Diego, California in May.

The efficacy and safety of tralokinumab is also being investigated in an ongoing Phase II study in patients with mild-to-moderate idiopathic pulmonary fibrosis (IPF) over a 72-week treatment period.

About tralokinumab

Tralokinumab is a human IgG4 monoclonal antibody that targets IL-13, a key cytokine that is believed to play a key role in the pathogenesis of asthma through the promotion of inflammation, airway hyper-responsiveness, mucus hyper-secretion, airway remodeling via fibrosis, increased IgE synthesis and mast cell activation.

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 key therapeutic areas, including respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; oncology; neuroscience; and infection and vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centers. For more information, please visit www.medimmune.com.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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.

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