NEW CELL STUDY PRESENTS GROUNDBREAKING PRE-CLINICAL WORK: DEVELOPING IMMUNE THERAPY TO POTENTIALLY TREAT SERIOUS INFLUENZA A

*MEDI8852 blocked all influenza A with unique binding properties*

Bellinzona, 21.07.2016 – A paper published today by *Cell* presents pre-clinical work to develop a promising new antibody, MEDI8852, as a potential therapy to treat influenza caused by numerous type A strains – the source of seasonal and pandemic outbreaks. The findings also highlight the mechanisms of action of MEDI8852, which along with its unique binding properties, point to valuable implications for the design of a universal influenza vaccine that can address the unpredictable nature of the flu virus.

“The results of this study confirm how MEDI8852’s unique molecular features have the potential to differentiate it from current treatment options for influenza, with the potential to become an important anti-influenza candidate during pandemic periods,” said JoAnn Suzich, Vice President, R&D, MedImmune.

The paper results from international collaboration among researchers at MedImmune, the global biologics research and development arm of AstraZeneca; Humabs BioMed; the Institute for Research in Biomedicine (Università della Svizzera italiana); and, the Francis Crick Institute in London.

**Study highlights include:**

- MEDI8852 exhibits multiple mechanisms of action, including blocking essential steps of the viral lifecycle; it also engages the immune system to eliminate virus-infected cells.
- MEDI8852 provides an extended therapeutic window in animal models when compared to the standard of care.
- Structural analyses reveal that MEDI8852 targets a unique and highly conserved epitope in the stem region of influenza in two distinct hemagglutinin (HA) subtypes, H5 and H7, distinguishing it from other structurally characterized cross-reactive antibodies.

“We compared the binding activity of MEDI8852 with other antibodies, as well as its precursor, and found it has the highest activity and the widest breadth of coverage,” said co-author Davide Corti, Chief Scientific Officer, Humabs BioMed. “This antibody targets a unique epitope in the stem of the influenza HA and can attack the virus’ entry and exit by blocking multiple mechanisms.”

John Skehel, one of the lead authors from the Francis Crick Institute, said: “This new antibody binds to numerous different influenza viruses to block their infectivity. Our studies show how this is achieved and highlight differences between this and other antibodies to explain its potential as an anti-influenza therapeutic.”
MEDI8852: Potential for high unmet medical need for influenza treatment
Despite advances in vaccines and antiviral therapeutics, a high unmet medical need remains for additional treatment options of influenza in populations at high risk for morbidity and mortality. In these patients, influenza infection can lead to severe complications and causes a significant burden to the overall healthcare system. The current standard of care for the treatment of influenza, the neuraminidase inhibitors (NAIs) oseltamivir and zanamivir, have many limitations, including a limited therapeutic window and the potential for resistance.

MEDI8852 received Fast Track designation from the US Food and Drug Administration (FDA) in March 2016. The FDA’s Fast Track program is designed to expedite the development and review of drugs to treat serious conditions and fill an unmet medical need.

MEDI8852 is currently being evaluated in a Phase Ib/IIa clinical trial to investigate the safety and preliminary efficacy of a single intravenous dose in combination with oseltamivir, and as a monotherapy in adult patients with confirmed acute, uncomplicated influenza caused by Type A strains prior to studying it in hospitalized patients. A recently completed Phase I study in healthy adult subjects demonstrated that MEDI8852 had an acceptable safety and pharmacokinetics profile, which supported continued development in patients with influenza.

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NOTE TO EDITORS

About MEDI8852
MEDI8852 is an investigational human IgG1 kappa monoclonal antibody (mAb) administered via infusion. The precursor to MEDI8852 was isolated from human memory B cells by Humabs BioMed, and further optimized for enhanced neutralization activity at MedImmune. MEDI8852 binds to a region within the stalk of the hemagglutinin protein that is highly conserved amongst all influenza A subtypes. MEDI8852 is being developed as a treatment for patients hospitalized with influenza caused by Type A strains in conjunction with local standard of care. While MEDI8852 is being developed as a treatment for seasonal influenza disease, it is anticipated that it could also be used in the pandemic setting.

About Influenza
Influenza virus infection remains a serious threat to global health and world economy. Annual epidemics result in a substantial number of hospitalizations, with an estimated 3-5 million cases of severe disease and 250,000-500,000 deaths globally, and higher mortality rates are possible during pandemics. Given the emergence of drug-resistance, the short treatment window of antivirals and the lack of universal or broadly cross-protective vaccines, there is a significant unmet medical need for new therapeutic agents that can effectively treat influenza infection.
About Influenza A
Influenza A, which is responsible for most influenza hospitalizations and is the only type to cause pandemics, is subtyped by its surface protein hemagglutinin (HA). HA is the main target of neutralizing antibodies. It is composed of a globular head domain and a stem. A conserved site within the stem has been the target of a new class of influenza-neutralizing antibodies.

About Humabs BioMed
Humabs BioMed is a leading Swiss antibody therapeutics company that discovers and develops antibodies directly derived from individuals who have successfully overcome major diseases. These "winner antibodies" have already passed natural selection by the immune system in response to disease and can be developed for standardized therapeutic use. Humabs BioMed has established a unique technology platform and know-how allowing the selection of monoclonal antibodies from immortalized human memory B cells and plasma cells. To date, the company has closed four major licensing deals with top pharmaceutical companies generating significant revenues. Two of these partnered programs are currently in clinical development.

About the Francis Crick Institute
The Francis Crick Institute is a unique partnership between the Medical Research Council (MRC), Cancer Research UK, the Wellcome Trust, UCL (University College London), Imperial College London and King’s College London.

About the Institute for Research in Biomedicine
The Institute for Research in Biomedicine was founded in 2000 with the clear and ambitious goal of advancing the study of human immunology, with particular emphasis on the mechanisms of host defense. The IRB benefits from a wide international network of collaborations. In addition, the IRB provides teaching and training programs for graduate students from Swiss and foreign Universities.

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 key therapeutic areas, including oncology; respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; and infection and vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca’s three global R&D centers, with additional sites in Cambridge, UK and Mountain View, CA. For more information, please visit www.medimmune.com.

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