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MD Anderson, Astellas Pharma Sign Option Agreement for Monoclonal Antibody Drug Targeting Acute Myeloid Leukemia

TOKYO and HOUSTON – April 3, 2015 – Astellas Pharma Inc. (TSE: 4503) and The University of Texas MD Anderson Cancer Center today announced the signing of an option agreement to research and develop a new treatment for patients with acute myeloid leukemia (AML).

The collaboration grants Astellas an option to firstly negotiate an exclusive, worldwide license at the end of Phase Ib, with both Phase Ia and Phase Ib studies to be conducted by MD Anderson. The agreement also includes up to \$26 million as an option premium and research and development funding.

The collaboration will focus on h8F4 technology, a humanized monoclonal antibody invented by Jeffrey Molldrem, M.D., professor of Stem Cell Transplantation and Cellular Therapy at MD Anderson. The antibody h8F4 targets an HLA-restricted peptide called PR1/HLA-A2, which is expressed in cancer cells and cancer stem cells. Molldrem will lead these research efforts with Carlo Toniatti, M.D., Ph.D., executive director of MD Anderson's Oncology Research for Biologics and Immunotherapy Translation (ORBIT) platform.

“Current treatments for aggressive leukemias are often toxic,” said Molldrem. “We desired to develop a safer, yet more potent, therapy for these aggressive cancer types that currently have poor survival outcomes. Unfortunately, advancing novel discoveries from the laboratory to drug development has been historically challenging. We hope that this important collaboration will allow us to deliver much-needed antibody-based treatment to the patient’s bedside more quickly.”

“h8F4 has a radically novel anti-tumor activity and this collaboration provides MD Anderson and Astellas with a great opportunity to potentially deliver a first-in-class antibody drug to patients with AML,” commented Yoshihiko Hatanaka, president and CEO of Astellas. “Astellas continues to focus on developing novel therapies in areas of unmet medical need through in-house developments and external collaborations.”

While monoclonal antibodies are very common in oncology, generating antibodies against HLA-restricted peptides has proven difficult. To develop viable antibody drugs, MD Anderson created ORBIT for its Moon Shots Program to centralize this type of research. The program is an ambitious initiative to accelerate the conversion of scientific discoveries into clinical advances and significantly reduce cancer deaths.

“This is an outstanding addition to MD Anderson’s Moon Shots Program to deliver accelerated solutions for cancer treatment,” said Ronald DePinho, M.D., president of MD Anderson. “These are exciting times for cancer drug development and I’m proud that eminent scientists like Drs. Molldrem and Toniatti are leading the way. While it’s true that myeloid cancer has not responded well to standard therapies, this novel solution looks promising.”

About Astellas Pharma Inc.

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious diseases, Oncology, Neuroscience and Diabetes Mellitus (DM) Complications and Kidney diseases. For more information on Astellas Pharma Inc., please visit the company website at www.astellas.com/en.

About MD Anderson

[The University of Texas MD Anderson Cancer Center](http://www.mdanderson.org) in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. MD Anderson is one of only 41 comprehensive cancer centers designated by the National Cancer Institute (NCI). For the past 25 years, MD Anderson has ranked as one of the nation's top two cancer centers in [U.S. News & World Report's](http://www.usnews.com) annual "Best Hospitals" survey. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

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