



**Astellas, Daiichi Sankyo, and Takeda Announce Research Collaboration on
Establishing Biomarker Database on Healthy Adults**

*Three Pharmaceutical Companies with Research Bases in Japan Work Together to
Accelerate Innovation in Japan-Originated Drug Discovery*

Tokyo and Osaka, Japan, May 23, 2016 ---Astellas Pharma Inc. (President and CEO: Yoshihiko Hatanaka; Headquarters: Tokyo; TSE: 4503; "Astellas"), Daiichi Sankyo Company, Limited (President and CEO: Joji Nakayama; Headquarters: Tokyo; TSE: 4568; "Daiichi Sankyo"), and Takeda Pharmaceutical Company Limited (President and CEO: Christophe Weber; Headquarters: Osaka; TSE: 4502; "Takeda") announced today that they have entered into a joint research agreement. It is an agreement to comprehensively acquire and analyze fundamental biomarker^{*1} data on healthy adult volunteers in order to optimize and accelerate the development of innovative medicines.

Biomarkers are used in patient stratification, investigation of a drug's mechanism of action, and efficacy and safety indices, and are utilized in a wide variety of scenarios, ranging from the exploration stage of drug candidacy to clinical studies and daily diagnostics. However, fundamental biomarker data from healthy adults, which can be used for comparing and contrasting with patients in the preclinical and clinical stages, has not been sufficiently accumulated globally, and further enhancement of data construction is expected.

Based on this agreement, Astellas, Daiichi Sankyo, and Takeda will comprehensively acquire fundamental data from healthy adult volunteers that is required for clinical studies using protein and metabolite biomarkers, and undertake joint analysis thereon. Samples will be acquired at a clinical research organization associated with Leiden University in the Netherlands and be under the supervision of Dr. Thomas Hankemeier, Professor at Leiden University. The analysis results will be mainly utilized in the companies' therapeutic areas of focus^{*2}. Data gained from this analysis will be publicized so that it may be widely utilized in various types of drug discovery research to meet patients' unmet needs.

Astellas, Daiichi Sankyo, and Takeda aim to contribute to the enhancement of health and welfare of people around the world through creating innovative medicine. Through this joint research, it will become possible to establish a base of comprehensive biomarker data— something that is difficult for individual pharmaceutical companies to do— as well as lead to more effective drug discovery by using a translational research^{*3} approach. The three companies will contribute to the optimization and acceleration of innovation in Japan-originated drug discovery through this collaboration as pharmaceutical companies with research bases in Japan.

*1 Biomarkers are defined as characteristics that can be objectively measured and assessed as ordinary biological processes (in vivo biological changes), pathological processes (processes by which illnesses start or progress), or pharmacological responses to a therapeutic intervention. They include clinical laboratory test values and imaging diagnostic data such as biological testing, blood testing, and tumor markers. Biomarkers are used not just in daily diagnostics, but also in the development of pharmaceutical products including diagnostic medicines.

*2 Each company's therapeutic areas of focus are as below;

Astellas: Urology, Oncology, Immunology, Nephrology, Neuroscience, Muscle Diseases, and Ophthalmology

Daiichi Sankyo: Oncology and several new horizon areas (Pain, CNS disease, Heart • Kidney disease, and Rare diseases)

Takeda: GI (gastroenterology), Oncology, CNS (central nervous system), Vaccines

*3 Translational research is a research to lead discoveries in the preclinical phase to clinical applications. It can also be referred to as bench-to-bedside research.

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