Press Release

Astellas Research & Development Meeting Highlights

- Turning Innovative Science into Value for Patients -

Tokyo, December 8, 2016 – Astellas Pharma Inc. (Tokyo: 4503, President and CEO: Yoshihiko Hatanaka, "the Company") announced that it is holding a research and development (R&D) meeting for securities analysts, institutional investors and the press today on December 8, 2016.

"The environment surrounding the pharmaceutical industry continues to undergo changes. Also, the daily advances in scientific innovation represent new opportunities for Astellas. Against the social issue of expanding healthcare cost, Astellas conducts proactive efforts to achieve a balance between patients' access to medicines and innovation as a pharmaceutical company." said Yoshihiko Hatanaka, President and CEO of Astellas. "We endeavor to achieve sustained growth by making ongoing investments in R&D to create innovative medical solutions and efforts to deliver such innovation to patients around the world. Astellas is on the forefront of healthcare change to turn innovative science into value for patients."

R&D Meeting highlights are described as follows.

1. Projects Contributing to Short to Medium Term Growth (Development Strategy)

Clinical development resources are concentrated on high-priority projects, to promote more efficient and expedited development, and to maximize product value.

Development Project Update

In the oncology area, Astellas is advancing development projects that will establish its position of leadership. Efforts are being made to evaluate the efficacy and safety in treatment-resistant populations and areas of highest unmet medical need and to expand into earlier stages of disease and/or other tumor types if appropriate as typified by ongoing studies of enzalutamide.
In addition, Astellas is focusing its efforts on several specific areas for which there is strong demand in unmet medical needs. Gilteritinib (ASP2215), is being developed as a potential treatment for acute myeloid leukemia (AML) and results of phase I and II clinical trials were announced at a symposium of the American Society of Hematology. Trials are being conducted to evaluate the compound as a potential treatment option in multiple AML patient populations, including currently ongoing phase III clinical trials. Phase III clinical trials also are currently being conducted for ASP8273 to examine its potential as a first line drug in non-small cell lung cancer applications. The Company is exploring enfortumab vedotin (ASG-22ME) in urothelial cancer based upon the results of phase I clinical trials. Furthermore, the Company plans to include IMAB362 (Target indication: Gastroesophageal adenocarcinoma) in the oncology therapeutic area after the acquisition of Ganymed Pharmaceuticals AG, which was announced in October 2016, is concluded.

With respect to development projects in other therapeutic areas, roxadustat (ASP1517), which is being developed for anemia associated with chronic kidney disease in patients not on dialysis and on dialysis, is currently undergoing a phase III clinical trial. In addition, we also have numerous other projects in the latter stages of development.

2. Projects Supporting Medium to Long Term Growth (Research Strategy)

Astellas is strengthening its new drug discovery capabilities and cultivating new opportunities by leveraging its network research system based upon the principles of "Best Science, Best Talent, Best Place."

Efforts to Improve Productivity

Astellas reshaped its research structure in 2013 and is actively leveraging external innovation and promoting open innovation based upon its research network to achieve further improvements in productivity. Furthermore, the Company has created a supervisory system called "FAST-Ex-NEW-standard" (FASTEN), which segments R&D projects into three types of processes in pre-clinical and early clinical testing stages. These efforts have achieved significant results in cost and time reductions between the initiation of research and the completion of phase I clinical trials and in significant increase of number of projects, which advance to the clinical studies.

Strengthening Our Research Infrastructure

In order to promote further innovation, Astellas implemented the following human resources and hiring systems:

- aiPaths (Astellas Research Multi-Career Paths): Researchers are given human resources training based upon their characteristics and capabilities designed to provide several career paths and to support innovation.
- Drug Discovery Innovator Selection Camp (DISC): This five-day camp system has been introduced to secure additional talent. Astellas seeks out participants with the ability to share diverse values and create new value, in addition to the ability to leverage resources including specialization, experience, information and human networks to solve various issues.

Strategy in Various Therapeutic Areas

Astellas promotes research in select areas where the potential for scientific feasibility is high and where demand in unmet medical needs also is high. The Company also promote innovation by utilizing new approaches and technologies that leverage not only our own research but also resources from networks outside of our Company.

- **Oncology Area**

The Company is creating a new immuno-oncology pipeline designed to control the tumor microenvironment by leveraging network research systems formed in collaboration with Potenza Therapeutics, Inc., the University of Texas MD Anderson Cancer Center (MD Anderson), and other institutions.
The Company plans to apply for an investigational new drug application (IND) for 2 programs targeting the checkpoint inhibitor and regulatory T cell modulator in 2017, in collaboration with Potenza Therapeutics, Inc. The Company is also conducting research program of a T-cell receptor like antibody, h8F4 against PR1/HLA-A2 which eliminates the target positive human AML cells with MD Anderson, and the Company plans to apply for IND of h8F4 in 2017.

- **Muscle Disease Area**
  Joint research and innovation discovery is being conducted with Cytokinetics, Inc. and Mitobridge, Inc. based upon the approach of improving muscle function. Furthermore, new internal drug discovery engines are being leveraged to create muscle disease therapeutic treatments.
  With respect to the joint research with Cytokinetics, Inc., research on the next-generation activator CK-3672889 is being conducted with the aim of initiating development as early as possible.
  Furthermore, with respect to the joint research project with Mitobridge, Inc., a gene regulator “MTB-1” for clinical trial was identified. The Company plans to apply for IND of MTB-1 in 2017.

- **Immunology Area**
  Joint research is being conducted with biopharmaceutical companies like Immunomic Therapeutics, Inc. and academic institutions such as the University of Tokyo to develop innovative drug discovery platforms that make antigen specific immunity suppression possible, and for R&D activities to create fundamental treatments for allergies, autoimmune disease and infections.

Regenerative Medicine
Astellas Institute for Regenerative Medicine is conducting multiple programs including a retinal pigment epithelium (RPE) cell program, which is in the clinical stage, as part of its efforts to pursue the potential of regenerative medicine as a new treatment method, and Phase-Ib/II dose-ranging and proof-of-concept trial for dry age-related macular degeneration is planned to start with a new cell line and formulation in 1H/2017.
Moreover, the Company’s Regenerative Medicine Labs based in Tsukuba is conducting joint research with Center for iPS Cell Research and Application (CiRA), Kyoto University, Osaka University and others.

NOTE: For further information on our R&D Meeting, please refer to the Astellas website.

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About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

Cautionary Notes

The safety and efficacy of the agents discussed herein are under investigation and have not been established. There is no guarantee that the agents will receive regulatory approval and become commercially available for uses being investigated. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

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