Press Release

Astellas Announces Construction of New Research, Development and Manufacturing Facilities for Drugs Using Innovative Modalities/Technologies Including Antibodies and Cell Therapies

TOKYO, October 31, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that construction and renovation of new facilities for the research, development and manufacture of new drugs using new Modality/Technology has begun in Toyama and Tsukuba, Japan as well as Massachusetts, United States.

Astellas is focused on creating innovative healthcare solutions for patients with high unmet medical needs through unique combinations of Biology and Modality/Technology based on emerging science. In addition to the small molecules from which we discovered a large number of new drugs, Astellas is engaged in research and development (R&D) of new drugs that utilize not only antibody approaches but new modalities such as cell therapy, next generation vaccines and gene therapy. Astellas currently has multiple development programs utilizing these approaches at the clinical and pre-clinical stage. Therefore, Astellas has, with a view to the future progress of development and commercialization of these programs, decided to construct R&D facilities in Japan and overseas, as well as facilities for the manufacture of clinical trial materials (CTM) and for the initial commercial production of these products

The details of the new research, development and manufacturing facilities are summarized below.

- Construction of the Center for Active Ingredient for Biopharmaceuticals (provisional name) in Japan.

The Center for Active Ingredient for Biopharmaceuticals will be constructed inside the premises of Toyama Technology Center of Astellas Pharma Tech Co., Ltd., a production subsidiary of Astellas. It will be capable of manufacturing antibodies for use in both CTM and commercial products in Japan, the United States ("U.S.") and Europe, while also manufacturing products that include other modalities such as cell therapy. Through the construction of the Center, which will have four above ground floors and total floor area of approximately 8,000 m², the company's ability to manufacture biopharmaceuticals for CTM and commercial usage will be greatly enhanced, creating the global supply framework necessary to respond flexibly to future environment changes. The total cost of the facility is approximately ¥10.0 billion. Work will begin in November 2018 and is scheduled for completion during September 2019.

- Construction of the Center for Multimodality Clinical Trial Materials (provisional name) in Japan.

The Center for Multimodality CTM, which will be constructed inside the Tsukuba Biotechnology Research Center of Astellas in Japan, will bear responsibility for the manufacture of CTM for use in early-stage clinical trials (Phase 1 and Phase 2) designed for the purpose of developing cell therapies and gene therapies for patients in Japan, U.S. and Europe. Through the construction of the Center, which will have two above ground floors and total floor area of approximately 1,800 m², it will become possible for the company to supply CTM in a flexible and timely manner necessary to progress development programs in various modalities. This is expected to contribute to the shortening of the total time from development to product launch. The total cost of the facility is approximately ¥5.0 billion. Work began in September 2018 and is scheduled for completion during March 2019.

- Relocation and renovation of the AIRM in the U.S.

The Astellas Institute for Regenerative Medicine (AIRM), a subsidiary of Astellas and a center of the research and development of regenerative medicine and cell therapy located in Massachusetts, U.S., will move to a new location within the state of Massachusetts with two above ground floors and a total floor area of 24,000 m². In addition, the facility will be upgraded. As a result of this relocation and renovation, the new facility will enable AIRM to accelerate research and development in the field of regenerative medicine and cell therapy. In addition, the enhancement of the production facilities will also make it possible to smoothly supply CTM. Furthermore, designed with the consideration of future progress of development, the facilitity will enable Astellas to meet the demands of commercial production. The total cost of the facility is approximately ¥14.0 billion. Work began in September 2018 and is scheduled for completion during January 2020.

Astellas reflected the impact from these capital expenditures in its financial forecasts for the current fiscal year ending March 31, 2019.

Reference Information

Summary of Center for Active Ingredient for Biopharmaceuticals (provisional name)

(1) Location：Toyama Technical Center, Astellas Pharma Tech Co., Ltd. (Kojinmachi 2-178, Toyama City, Toyama Prefecture, Japan)
(2) Number of floors, total floor area: Four above ground floors and a total floor area of approximately 8,000 m²,
(3) Total construction cost：Approximately ¥10.0 billion
(4) Construction period：Starting in November 2018, scheduled for completion in September 2019

CG image of completed building



Summary of Center for Multimodality Clinical Trials Materials (provisional name)

(1) Location：Tsukuba Biotechnology Research Center, Astellas Pharma Co., Ltd. (Tokodai 5-2-3, Tsukuba City, Ibaraki Prefecture, Japan)
(2) Numeber of floors, total floor area: Two above ground floors and a total floor area of approximately 1,800 m²,
(3) Total construction cost：Approximately ¥5.0 billion
(4) Construction period：Starting in September 2018, scheduled for completion in March 2019

CG image of completed building



Summary of AIRM Relocation and Renovation

(1) New address：9, Technology Drive, Westborough, Massachusetts, U.S.
(2) Number of floors, total floor area: Two above ground floors and a total floor area of approximately 24,000 m²,
(3) Total construction cost：Approx. ¥14.0 billion
(4) Construction period：Starting in September 2018, scheduled for completion in January 2020

About Astellas Institute for Regenerative Medicine (AIRM)
The Astellas Institute for Regenerative Medicine (AIRM) was established in May 2016 following Astellas' acquisition of Ocata Therapeutics Inc. Headquartered in Marlborough, Mass., and work together with a research team in Tsukuba, Japan, AIRM is a wholly-owned subsidiary of Astellas and serves as the Company's global hub for regenerative medicine and cell therapy research in ophthalmology and other therapeutic areas that have few or no available treatment options.

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. For more information, please visit our website at https://www.astellas.com/en

Cautionary Notes
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.

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.

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