

Press Release

Establishing New Manufacturing Lines for Aseptic Drug Products at Yaizu Technology Center

- Establishing setup for stable global supply and accelerating development and commercialization of new drugs -

TOKYO, January 25, 2021 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) today announced that construction of new manufacturing lines for aseptic drug products utilizing new modalities and technologies has commenced at Yaizu Technology Center of Astellas Pharma Tech Co., Ltd., a production subsidiary of Astellas.

Astellas will expand manufacturing capabilities for aseptic drug products, to reinforce stable production for global supply, and to accelerate the development and commercialization of new drugs by the new lines. The Yaizu Technology Center currently mainly manufactures solid preparations of both commercial drug products and clinical trial materials. The new aseptic drug product manufacturing lines will be newly installed for commercial antibody drugs and clinical trial materials in the existing buildings. The construction of the commercial production line for antibody drugs has started today, and the construction of the manufacturing line for clinical trial materials is scheduled to begin in July 2021. The total cost of construction is approximately ¥ 18 billion.

Astellas is developing new drugs utilizing new modalities and technologies based on its Focus Area approach. These new lines for aseptic drug products allow flexibility to manufacture not only antibodies, but also new modalities that require high technology in the future with some modification of the facility. With these new production lines, Astellas aims to improve its own manufacturing capabilities and strengthen its seamless and stable manufacturing system from development to commercialization phases.

As announced on November 11, 2020 (<https://www.astellas.com/jp/en/news/22971>), Astellas will absorb and merge Astellas Pharma Tech Co., Ltd. by April 1, 2022, aiming to accelerate the fusion of process development and production technology of the two companies.

These capital expenditures will have no impact on the financial forecasts of the current fiscal year ending March 31, 2021.

Outlines of the manufacturing facilities for aseptic drug products

Commercial production line

- Location: No. 5 Building of Yaizu Technology Center
(Address: 180, Ozumi, Yaizu-shi, Shizuoka prefecture)
- Outline of No. 5 Building: Total floor area 30,000 m², 6-story building, Building area 8,000 m²
- Construction area: 2,100 m²
- Construction period: Construction will start on January 2021, and is expected to be completed by February 2022

No. 5 Building



Investigational drug production line

- Location: ATC Building, Yaizu Technology Center
(Address: 180, Ozumi, Yaizu-shi, Shizuoka prefecture)
- Outline of ATC Building: Total floor space 7,000 m², 4-story building, Building area 1,800 m²
- Construction area: 1,100 m²
- Construction period: Construction will start on July 2021 and is expected to be completed by August 2022

ATC building



About Astellas

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+[®] healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into value for patients. 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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