Innovation all for the patients

CHUGAI

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Construction of New Bio API Plant for Early Clinical Trials to Accelerate the Initiation of Clinical Development

- Decided to construct a plant for biopharmaceutical API specializing in the production of investigational drugs for early clinical trials
- Reinforce the foundation to swiftly initiate clinical development and accelerate RED SHIFT

TOKYO, October 22, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its decision to construct a new manufacturing building (UK4), in the Ukima Site (Kita-ku, Tokyo), for active pharmaceutical ingredients (APIs) of biopharmaceuticals for early clinical trials.

UK4 specializes in the production of investigational drugs for early clinical trials. By expanding supply capacity and enhancing manufacturing speed and flexibility with a dedicated facility, Chugai aims to enable the earliest start of First in Human clinical trials (FIH), which are the first stage in clinical development, for biopharmaceutical projects including antibodies and to rapidly achieve early PoC (Proof of Concept)[1]. UK4 will become an important foundation to support RED SHIFT[2], which is one of the key drivers in Chugai's growth strategy "TOP I 2030."

"Speedy manufacturing of investigational drugs is a major challenge in transitioning molecules from research to clinical development. In order to achieve the two targets stated in TOP I 2030 – 'Double R&D output' and 'Launch in-house global products every year,' – we must establish manufacturing methods of investigational drugs and initiate FIH trials as early as possible for those new drug candidates arising from our research consistently," said Chugai's President and CEO, Dr. Osamu Okuda. "The establishment of the new UK4 will ensure the capacity to manufacture investigational drugs for early clinical trials with speed and flexibility, which will further strengthen our foundation to pursue challenging projects using our proprietary antibody engineering technologies. Through UK4, Chugai will accelerate the development of therapeutic antibodies, which are expected to evolve, and strive to provide our innovation to patients worldwide."

Chugai has been actively investing in manufacturing facilities in anticipation of the consecutive launch of innovative biopharmaceuticals using its antibody engineering technologies. Besides existing API manufacturing buildings for biopharmaceuticals (UK1 and UK2), Chugai constructed a new manufacturing building (UK3) for late-stage investigational drugs and initial commercial products, which started to operate in 2018. The addition of UK4 will reinforce Chugai's streamlined manufacturing capability, from investigational drugs for early clinical development to initial commercial products. This will provide a more robust foundation to support the development and launch of innovative drug candidates.

In pursuit of sustainability, UK4 will implement measures to reduce environmental burdens, including chlorofluorocarbons-free operation and energy saving systems. Also, as part of the digital transformation in

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manufacturing functions announced in January this year, actions that have been taken at the Ukima Plant in advance will be laid out at UK4.

Chugai aims to address the unmet medical needs of the world by achieving world-class biopharmaceutical manufacturing capabilities.

1) PoC: A demonstration that the therapeutic effect conceived in the research stage is effective in humans. Early PoC means that, in addition to safety, signs of efficacy or pharmacological effect have been confirmed in a limited number of cases.
2) RED SHIFT: RED stands for Research & Early Development, and RED functions correspond to the initial development stages of research, early clinical development, and pharmaceutical technology functions. By focusing resources and expanding investment in RED functions, Chugai aims to enhance capabilities from drug discovery, the source of its value creation, to translational research for acquiring PoC, and to increase R&D outputs.

[Overview of the Ukima Site]

1. Location: 5-5-1 Ukima, Kita-ku, Tokyo
2. Site area: 54,958 m^2
3. Business activities: Research on API manufacturing process, production of investigational drugs and commercial products

[Overview of construction plan of UK4]

1. Total investment: 12.1 billion yen
2. Start of construction: February, 2022
3. Completion of construction: April, 2023
4. Completion of building: September, 2023
5. Start of operation: January, 2024
6. Construction area: 1,220 m^2 (4-story base isolated building)
7. Total floor area: 3,705 m^2
8. Overview of facility: 2,000 L×2 single-use bioreactors + 1 purification line

[Overview of Antibody API Production Facilities in the Ukima Site]

Building	Target	Bioreacters	Features
UK1, UK2	Commercial products/ Investigational drugs (Small-scale)	2,000 L x 4 (Single-use)	・Improve capacity utilization through the application of single-use bioreactor technology
UK3	Commercial products/ Investigational drugs (Large-to -medium-scale)	6,000 L x 6 (Stainless steel tanks)	・Emphasis on flexibility ・Can handle high-mix, low-volume production
UK4 (New building)	Investigational drugs (Small-scale)	2,000 L x 2 (Single-use)	・Specializing in the production of investigational drugs for early clinical trials ・Improve speed and flexibility by application of strengthened single use bioreactor technology

[Conceptual drawing of UK4]

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