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Construction of API Manufacturing Building for Late Stage Clinical Development and Early Commercial Production of Small and Mid-Size Molecule Drugs

TOKYO, July 26, 2021-- [Chugai Pharmaceutical Co., Ltd.](#) (hereafter, “Chugai”) announced the decision to construct a new manufacturing building for active pharmaceutical ingredients (APIs) of small and mid-size molecule drugs in the Fujieda Plant (Fujieda-shi, Shizuoka) of Chugai Pharma Manufacturing Co., Ltd. (Head office: Tokyo, President: Shinya Takuma), a manufacturing subsidiary of Chugai.

In recent years, Chugai's synthetic drug discovery is mostly based on compounds that are difficult to manufacture, including mid-size molecule drugs where Chugai focuses on as its third modality following small molecules and antibodies. In response to the increase in such compounds, Chugai started the construction of a manufacturing building for APIs (FJ2) in the Fujieda Plant in 2019, aiming for completion in 2022.

The new manufacturing building for APIs (FJ3) aims to address the manufacturing functions of small and mid-size molecule drugs with high potency, covering APIs for late-stage clinical trials and early production after launch. By adding FJ3 to the existing manufacturing building for APIs (FJ1) and FJ2 which is under construction in the Fujieda Plant, Chugai will gain the capability to consistently supply APIs throughout early clinical development to early commercial production, which will greatly strengthen the foundation that supports the rapid development and launch of innovative new drug candidates.

“In our growth strategy TOP I 2030, Chugai has positioned mid-size molecule drugs to constitute the mainstay for driving its medium- to long-term growth and has set a goal to realize the launch of global in-house products every year by 2030, by doubling our R&D output. The construction of FJ3 will enable us to establish our own stable supply capacity for those APIs that are difficult to manufacture on a large scale, including high potency APIs, covering all through early clinical development to market launch. With a steady stream of new projects expected to enter clinical trials, it will be a major force to support the speedy development of mid-size molecule drugs, and to gain a competitive edge” said Osamu Okuda, Chugai's President and CEO. “In order to realize a manufacturing function appropriate as the TOP Innovator which Chugai aims to become, FJ3 will be a world-class production facility with advanced production technologies and automate manufacturing operations which enable labor-saving and productivity improvements, as well as thoroughly considering environment and safety. We will put all our efforts into continuously pursuing innovation so that innovative drugs manufactured at FJ3 can be delivered to patients as quickly

as possible."

FJ3 will respond to the simultaneous development of drug candidates by installing multiple API production lines using advanced containment technologies. In addition, the building will be designed to realize chlorofluorocarbons-free operation, and used solvents will be recycled to make the facility environmentally friendly. At the same time, Chugai will thoroughly respond to safety issues, including earthquake countermeasures, by adopting seismic isolation structure and designing the facility to prepare for fires and other incidents.

Chugai aims to address unmet medical needs which cannot be solved by existing modalities, through advanced production technologies that support turning drug discovery ideas into drugs.

[Overview of Fujieda plant]

1. Location: 2500, Takayanagi, Fujieda-shi, Shizuoka
2. Site area: 216,804 m²
3. Business activities:
Production of APIs, manufacturing of solid formulations, packaging of pharmaceuticals, and manufacturing of APIs for clinical studies

[Overview of construction plan of the manufacturing building for APIs (FJ3) in the Fujieda plant]

1. Total investment: 55.5 billion yen
2. Start of construction: March, 2022
3. Completion of construction: February, 2024
4. Completion of building: October, 2024
5. Start of operation: March, 2025
6. Construction area: 2,211 m² (5-story base isolated building)
7. Total floor area: 10,250 m²

[Conceptual drawing of the manufacturing building for APIs (FJ3)]



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