



## Chugai to Newly Construct an Antibody API Manufacturing Plant Capable of High-Mix Low-Volume Production in Preparation for the Consecutive Launch of Innovative Projects — React to the Development and Launch of Multiple Products with World-class Speed —

TOKYO, October 22, 2015 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today the decision to construct a new plant for manufacturing antibody active pharmaceutical ingredients (API) capable of high-mix low-volume production for late-stage investigational drugs and initial commercial products at the Ukima Plant (Kita-ku, Tokyo) of Chugai Pharma Manufacturing Co., Ltd., a manufacturing subsidiary of the company.

Chugai has been continuously conducting new drug development aiming for the world's highest level of quality and speed under the strategic alliance with F. Hoffman-La Roche Ltd. In 2012, it established a research laboratory in Singapore, Chugai Pharmabody Research Pte. Ltd. (CPR), focusing on drug discovery research applying its proprietary antibody engineering technologies. Furthermore, Chugai has adopted various measures to maximize the value of drug candidates arising from its research, such as the amendments to the out-licensing agreement of Chugai products to Roche and the establishment of the Translational Clinical Research Division.

The productivity to continuously generate innovative drug candidates is expected to increase as a consequence of these initiatives. Correspondingly, Chugai has also reinforced its production capacity for investigational drugs, and a capital investment of 2.9 billion yen is ongoing from 2013 to 2015 at Ukima Plant to double its production capacity of antibody drugs in order to accommodate the simultaneous development of drug candidates.

Since this reinforcement of production facility has been working successfully, Chugai made a decision to invest for a new production plant manufacturing antibody API to enlarge the capability to meet the demand of initial commercial products in the future. This new plant will enable seamless high-mix low-volume production of antibody API for investigational drugs in late-stage clinical studies to initial commercial products. Chugai is aiming to possess global top-class competitiveness by minimizing the time required from the development to launch of a new drug by handling the simultaneous development of multiple products.

“Chugai currently has several antibody projects under clinical development applying its proprietary innovative antibody engineering technologies. We are also actively conducting drug discovery research for antibody drugs at our domestic laboratories and CPR, and have several drug candidates close to the clinical phase. In order for us to promptly conduct simultaneous clinical development for these projects, we need to accommodate high-mix low-volume production of multiple investigational drugs,” said Dr. Hitoshi Kuboniwa, Senior Vice President and General Manager of the Pharmaceutical Technology Division. “It is very important to organize the supply system from the late stage of clinical development to realize a fast commercialization in order for us to survive the severe competition in drug development. The research center for

pharmaceutical process development is also located at the Ukima Office. Having technology development and production at a single site will enable increased efficiency in production processing.”

With this capital investment, six 6,000 L bioreactor tanks will be newly installed. Combined with the existing two 2,500 L tanks and four 2,000 L tanks, the Ukima Plant will have a total capacity of 49,000 L bioreactor tanks, with a consistent system from process development to production of antibody API of investigational drugs in late-stage clinical studies and initial commercial products at one site. Construction is scheduled to commence in January 2016, and the demolition of old facilities is currently underway. The total amount for this capital investment is 37.2 billion yen.

[Overview of the Ukima Plant]

1. Plant Location: 5-5-1 Ukima, Kita-ku, Tokyo
2. Site Area: 23,636 m<sup>2</sup>
3. Total Floor Area: 45,780 m<sup>2</sup> \*Includes the total floor area of the new plant
4. Business Activities: Production of antibody API, manufacturing of injection products, manufacturing of investigational drugs for clinical studies

[Overview of Construction Plan of Antibody API Production Plant at Ukima Plant]

1. Start of Construction: January 2016
2. Completion of Construction: December, 2017
3. Total Investment: 37.2 billion yen
4. Completion of Building: July, 2018
5. Start of Operation: June, 2019
6. Construction Area: 4,066 m<sup>2</sup>
7. Total Floor Area: 26,634 m<sup>2</sup>

[Overview of the Antibody Drug Production Facilities of Chugai]

1. Ukima Site: 2,500 L × 2 bioreactor tanks, 2,000 L × 4 bioreactor tanks for antibody API, production of antibody API for investigational drugs
2. Utsunomiya Site: 10,000 L × 8 bioreactor tanks for production of antibody API

[Conceptual Image of Antibody API Production Plant]

