



Decision to Invest over 20 Billion Yen in Bio Drug Substance Manufacturing Building “UK3” to Expand its Production Capacity and towards Realizing Halogenated Hydrocarbon-Free

- Expanding production capacity by approximately 3 times to strengthen our in-house production foundation to support “Double R&D output” and “Launch global in-house products every year,” which we aim to achieve in TOP I 2030
- Renew various equipment to achieve zero halogenated hydrocarbons as we aim in our Mid-Term Environmental Goals 2030

TOKYO, December 19, 2023 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced its decision today to invest in its Bio drug substance (DS) manufacturing facility “UK3” in the Ukima Plant (Kita-ku, Tokyo) of Chugai Pharma Manufacturing Co., Ltd. (Head office: Tokyo, President: Shinya Takuma), a member of the Chugai Group. UK3 covers DS production for phase 3 clinical trials, through to early commercial production after initial launch. This investment will expand UK3’s production capacity and also contribute to realizing halogenated hydrocarbons-free, aiming to further strengthen Chugai’s in-house supply foundation, which is essential for achieving the goals in the growth strategy TOP I 2030.

Chugai has its strength in its proprietary antibody engineering technologies, and thus the majority of its in-house development projects and drugs are highly difficult to manufacture because of their complex structure. In order to achieve rapid and adequate supply in-house, Chugai has been aggressively making investments to build a consistent supply platform from clinical development to early commercial production. In addition, under Chugai’s growth strategy TOP I 2030, development projects and drugs coming from its research laboratories are expected to increase, which will require further increased in-house supply capacity as well as improvement in efficiency.

This investment will approximately triple the production capacity of UK3 and increase the speed and flexibility in the supply of Bio DS, by adopting innovative technologies that has advanced in recent years, contributing to faster launches of in-house products. At the same time, as an environmental measure, Chugai will upgrade various types of equipment to eliminate halogenated hydrocarbons and take steps to achieve the target of zero halogenated hydrocarbons* in our Mid-Term Environmental Goals 2030. Both the enhancement of production capacity and the implementation of environmental measures are important pillars in Chugai’s growth strategy. By conducting these measures at the same time, Chugai aims to shorten the period of suspension of manufacturing due to construction.

*100% reduction in the use of halogenated hydrocarbons (Base year 2020)

“Chugai has set the challenging goal of “Double R&D output” and “Launch global in-house products every year” toward 2030. To achieve this goal, our company must build a strong supply foundation that supports the increased output generated by its proprietary drug discovery technologies from the

manufacturing perspective” said Chugai’s President and CEO, Dr. Osamu Okuda. “Chugai also aims to become a global role model, and it is essential to step up environmental measures in addition to increasing production capacity. The elimination of halogenated hydrocarbons in UK3 which was planned prior to the formulation of our Mid-Term Environmental Goals 2030, will contribute to the achievement of halogenated hydrocarbons reduction targets for the Chugai Group as a whole. Through the UK3 modification, the Group will work as one to realize sustainable manufacturing facilities in terms of both environmental friendliness and ensuring supply of our products, and deliver innovative medicines to patients as quickly as possible.”

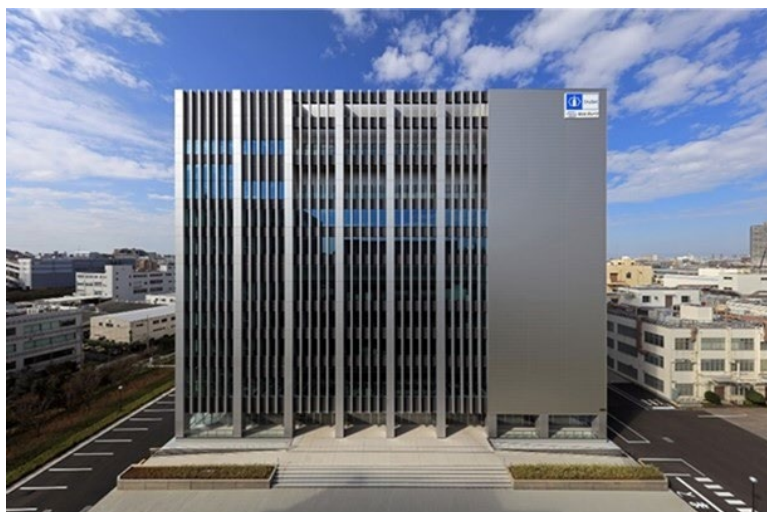
[Overview of Ukima Plant]

1. Location: 5-5-1 Ukima, Kita-ku, Tokyo
2. Site area: 54,958 m²
3. Business activities: Research on API manufacturing process, production of investigational drugs and commercial products

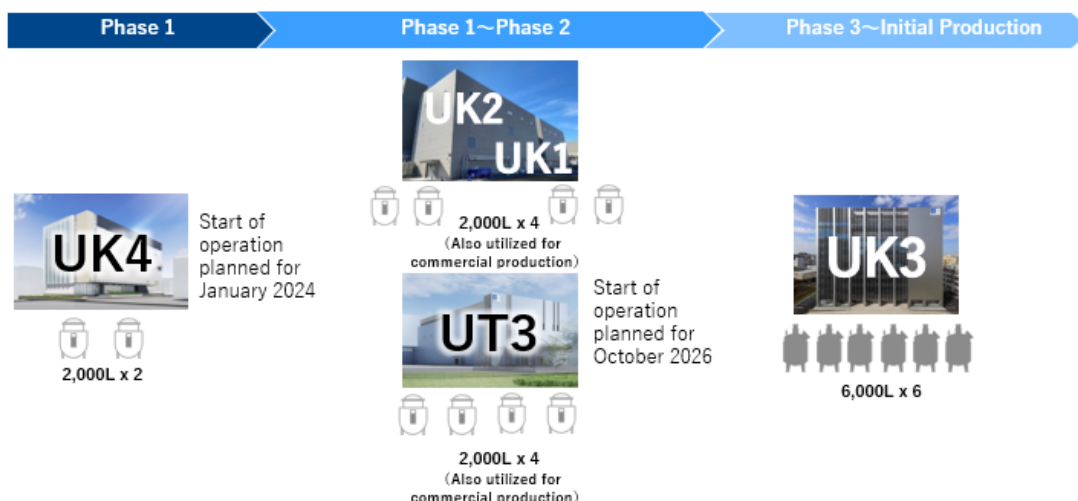
[Overview of construction plan of UK3 modification]

1. Total investment: 20.3 billion yen
2. Start of in-building construction: May 2026
3. Re-start of manufacturing: June 2027

[Picture of UK3]



[Framework of Antibody DS Production (Clinical Development to Initial Commercial Production)]



[Overview of Antibody DS Production Facilities]

Site	Building	Target	Bioreactors	Features
Ukima	UK1, UK2	Commercial products/ Investigational drugs (Small-scale)	2,000 L x 4 Single-use	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Emphasis on flexibility Can handle high-mix, low-volume production
	UK4 (Operation to be started in January 2024)	Investigational drugs (Small-scale)	2,000 L x 2 Single-use	<ul style="list-style-type: none"> Specializing in the production of investigational drugs for early clinical trials Improve speed and flexibility by application of strengthened single use bioreactor technology
Utsunomiya	UT1	Commercial products (Large-scale)	10,000 L x 2 Stainless steel tanks	<ul style="list-style-type: none"> Competitive low-cost production Dedicated facilities
	UT3 (Operation to be started in October 2026)	Commercial products/ Investigational drugs (Small-scale)	<ul style="list-style-type: none"> 2,000 L x 4 Single-use (For batch production), or 500 L x 1 Single-use (For continuous production) 	<ul style="list-style-type: none"> Improve capacity utilization and flexibility through the application of single-use bioreactor technology Partial installation of continuous production function

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