



November 24, 2021

## **Notice of Conclusion of Joint Venture Agreement Regarding the Establishment of a Joint Venture for Contract Development and Manufacturing of Active Pharmaceutical Ingredients and Intermediates**

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The six companies of Shionogi Pharma Co., Ltd. (headquartered in Settsu, Osaka; President & CEO: Ryuichi Kume; “Shionogi Pharma”), Chiyoda Corporation (headquartered in Yokohama, Kanagawa Pref.; President: Masaji Santo; “Chiyoda”), Taisei Corporation (headquartered in Shinjuku-ku, Tokyo; President & CEO: Yoshiro Aikawa; “Taisei”), Fujimoto Chemicals Co., Ltd. (headquartered in Chuo-ku, Osaka; President & CEO: Kazumasa Fujimoto; hereinafter “Fujimoto Chemicals”), Takenaka Corporation (headquartered in Chuo-ku, Osaka; President: Masato Sasaki; “Takenaka”), and Nagase & Co., Ltd. (headquartered in Chuo-ku, Tokyo; Representative Director and President: Kenji Asakura; “Nagase”) are pleased to announce that we have concluded a joint venture agreement regarding the establishment of a joint venture (hereinafter the “joint venture”) to develop a technology for Continuous Manufacturing (CM) of active pharmaceutical ingredients (APIs) and intermediates and to conduct a contract development and manufacturing business using CM technology.

### 1. Purpose of the establishment of the joint venture

The environment surrounding APIs and intermediates is undergoing major changes. Under such circumstances, it is necessary to establish an advanced quality control system and thoroughly control the regulated substances in response to tightened laws and regulations, as well as to strengthen the ability to offer globally competitive prices and meet delivery dates. Furthermore, it is also desired to establish a sustainable manufacturing method that takes into consideration the protection of workers in the handling of chemical substances, energy saving and environmental protection. Especially under the COVID-19 pandemic, which has raged on since last year, it is also required to further accelerate pharmaceutical development and build a stable supply network for APIs. By introducing CM technology\*<sup>1</sup> in response to these environmental changes, it is expected that the time required for development of manufacturing methods in the

pharmaceutical development stage will be shortened. CM technology is also expected to improve the efficiency of commercial production of pharmaceutical ingredients by conserving manpower and space and to enable advanced quality assurance for high-quality pharmaceutical products. Aiming to realize effective CM of APIs and intermediates, the six companies with specialized technologies and functions have come together to establish the joint venture to provide contract development and manufacturing services of APIs and intermediates. The joint venture is to be established as per the “Agreement between Chiyoda Corporation and Shionogi Pharma on the Development of Continuous Manufacturing Technology for APIs and Intermediates and to Study the Establishment of a Joint Venture for commercialization of the technology,” announced in the press release dated May 31, 2021.

## 2. Outline of the joint venture

The joint venture will provide full-range, one-stop manufacturing services of APIs and intermediates, from manufacture of APIs for clinical trials to commercial production. In order to meet diverse customer needs, Shionogi Pharma will transfer to the joint venture the business of manufacturing APIs for clinical trials using GMP- and USP/EP/JP-compliant batch manufacturing technology\*2 with a proven track record, aiming to conduct pharmaceutical development and manufacturing using both CM technology and the already well-established batch manufacturing technology. This will make it possible to apply CM to the processes that will have significant benefits by switching to CM. In addition, by applying CM from the development stage, it is also possible to accelerate the development of pharmaceutical products while ensuring high quality and process safety.

By actively developing technologies and introducing new technologies through strengthened industry-government-academia collaboration and cooperation with various partner companies, including invested companies, we will strive to expand our business and provide CM-based contract development and manufacturing services ahead of the rest of the world, thereby promoting an API manufacturing revolution.

Currently, we are also conducting discussions with one of our partner companies, Yokogawa Electric Corporation (headquartered in Musashino City, Tokyo), regarding the development of CM technology for APIs and intermediates.

### <Reference information> Benefits of the introduction of CM

- ✓ Shortened development period by reducing time for process development due to no need for scale-up
- ✓ Improved success rate for drug development process through accurate control of minute impurities (those subject to ICH M7, etc.)
- ✓ Reduced human errors and improved productivity through automation and manpower saving by introducing quality control tools that enable continuous inline quality monitoring (PAT\*<sup>3</sup>, RTRT\*<sup>4</sup>, etc.)
- ✓ Improved drug quality by removing nonconforming products based on RTD\*<sup>5</sup>
- ✓ Reduced construction costs of manufacturing plants due to compact size of equipment, and improved productivity through introduction of IT systems, including quality control tools
- ✓ Easier to own multiple production bases, enabling stable supply and diversification of production risks
- ✓ Reduced risks for workers through containment, and contribution to green chemistry by reducing waste and environmental impacts

\*1 A manufacturing method in which a certain amount of raw materials or their mixtures are continuously fed into the manufacturing process,

and products are continuously removed from the process after a certain period of time.

\*2 A conventional manufacturing method in which all or part of the raw materials are fed discontinuously into the manufacturing equipment, and products are removed all at once after the completion of each step.

\*3 PAT: Process Analytical Technology

\*4 RTRT: Real Time Release Testing

\*5 RTD: Residence Time Distribution

### 3. Basic information on the joint venture

Representative	Representative Director: Masanori Nishiwaki (currently Executive Officer and General Manager of the Technology Development Division of Shionogi Pharma)
Address	1-3 Kuise Terajima 2-chome, Amagasaki City, Hyogo Prefecture
Date of establishment	November 2021 (planned)
Commencement date of business	April 2022 (planned)
Shareholder composition	Shionogi Pharma: 50.6%, Chiyoda: 17.1%, Taisei: 16.1%, Fujimoto Chemicals: 10.1%, Takenaka: 5.4%, Nagase: 0.8%

\* The second decimal place has been rounded off.

### 4. Overview of each company that has concluded the joint venture agreement

#### Shionogi Pharma Co., Ltd

Shionogi Pharma Co., Ltd. launched its business on April 1, 2019 with the mission of becoming a “technology-development-oriented manufacturing company” trusted by customers. In addition to the development of manufacturing methods for APIs and formulation development, as well as commercial production, it has established a system to provide “full-range services,” including support for analytical method development and facility design using pharmaceutical engineering technology.

#### Chiyoda Corporation

Since its founding in 1948, Chiyoda Corporation has undertaken numerous projects worldwide, focusing on engineering, procurement and construction of plants (EPC) in the fields of energy (including oil and gas), chemistry, the environment, and life sciences.

#### Taisei Corporation

Taisei Corporation was founded in 1873 and performed the design-build works of API plant by establishing its Engineering Division in 1968. Since then, Taisei Corporation has been providing its customers with the production facilities in a wide range of fields, including life sciences such as pharmaceuticals and food products.

Under Taisei Group Philosophy “to create a vibrant environment for all members of society,” Taisei Corporation has

created “safe, secure, and attractive spaces” and “high value” in harmony with the nature, and has strived to build a global society filled with dreams and hopes for the next generation.

#### Fujimoto Chemicals Co., Ltd.

Since its establishment in 1953, Fujimoto Chemical Co., Ltd. has been engaged mainly in the production and sales of APIs and intermediates. By implementing a strict quality assurance system and by fully leveraging its multiple chemical synthesis manufacturing facilities, including highly potent API manufacturing facilities, the Company provides integrated services, from development to commercial manufacturing.

#### Takenaka Corporation

Since its founding, Takenaka Corporation has provided optimal solutions to meet the needs of the era based on its management philosophy: "Contribute to society by passing on the best works to future generations." By harnessing the strengths of the entire corporate group, the Company will contribute to urban creation by building cities and towns where people can live in safety and security while at the same time helping realize a sustainable society by addressing various issues, in cooperation with investing companies, to ensure stable supply of APIs.

#### NAGASE & CO., LTD.

Since its founding in 1832, NAGASE & CO., LTD. has been mainly engaged in the import and export of chemical products and has cultivated technological and information-gathering capabilities and built a global network. Going beyond the conventional framework of a chemicals trading company, NAGASE will strive as a business designer that creates a sustainable future to contribute to the development of a sustainable society.

#### [Contact Information]

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