FUJIFILM Toyama Chemical announces completion of Japan's first manufacturing facility for liposome formulation capable of commercial production

Tokyo, December 9, 2019 — FUJIFILM Toyama Chemical Co., Ltd. (President: Junji Okada) is proud to announce the construction completion of a new manufacturing facility (facility name: 701) within its Toyama Second Factory for manufacturing liposome formulations. Liposome is a drug delivery system that has shown promising results in facilitating the drug delivery. The 701 facility is Japan's first[*1] manufacturing facility of liposome formulation capable of commercial-level production, and is due to go operational in February 2020.

Liposome formulation contains active ingredient such as drugs in artificially constructed vesicles (liposome) made from organic phospholipids which make up cellular membranes and biomembranes. They are expected to selectively deliver a drug to targeted areas.

The 701 facility will be the Fujifilm group's production hub for liposome. Designed to comply with GMP[*2] standards for Japan, the United States and Europe, the facility intends to supply liposome globally. FUJIFILM Toyama Chemical plans to use the new 701 facility to manufacture liposome-based investigational drugs and commercial-level drug.

The 701 facility features manufacturing equipment and containment facilities designed and developed based on production know-how that FUJIFILM Toyama Chemical has accumulated through its sterile production of injectable formulations and advanced production technology that FUJIFILM Corporation has fostered in a wide range of product development operations.

FUJIFILM Toyama Chemical also plans to provide services of production processes development and manufacturing of liposome formulation for other companies at the 701 facility, thereby achieving business further expansion.

At present, FUJIFILM Corporation through harnessing its advanced nano-dispersion technology, analysis technology and process technology, nurtured and evolved through its wide range of product development including the photographic film business, is conducting Phase I clinical trial of investigational liposome pipelines "FF-10832[*3]" and "FF-10850[*4]," i.e. even-sized liposomes containing existing anti-cancer drugs in a stable form. In preclinical studies of "FF-10832" and "FF-10850," the company observed the extension of survival period as a result of immune checkpoint inhibitor[*5] combination therapy. This has led to new cancer therapy research using liposomes. The company has been also working on researching further liposomes' application for use with next-generation pharmaceuticals such as nucleic acid drugs and gene therapy drugs.

FUJIFILM Toyama Chemical will continue to contribute to further medical advancement through developing, manufacturing and marketing pharmaceuticals of high added value.

*1 Japan's first manufacturing facility dedicated to liposome formulation production, according to Fujifilm data

*2 GMP stands for Good Manufacturing Practice, stipulating manufacturing management and quality control protocols for supplying high-quality pharmaceuticals and medical equipment.

*3 Liposome formulation containing anti-cancer drug "gemcitabine"; Gemcitabine is used as the first-line drug for pancreatic cancer and is also used to treat a wide range of cancers including lung cancer and ovarian cancer.

*4 Liposome formulation containing anti-cancer drug "topotecan"; Topotecan is used to treat ovarian cancer, small cell lung

cancer, cervical cancer, etc.

*5 Immune checkpoint inhibitor is a general term for drugs that demonstrate an efficacy by enabling immune cells to attack cancer cells by inhibiting the immune suppressive mechanisms (immune checkpoints). They are widely used in the treatment of malignant melanomas, lung cancer, stomach cancer, kidney cancer, etc.

[Overview of the 701 facility]

1. Facility name	701
2. Construction location	1-8-70 Chiharazaki, Toyama-shi, Toyama Prefecture (within the Toyama Second Factory)
3. Investment	Approx. 5 billion yen
4. Production description	Manufacturing liposome-based investigational drugs and commercial products
5. Total floor area	Approx. 3,400m^2 (two stories above ground)
6. Operation commencement	February 2020

[Exterior view of the 701 facility]

About FUJIFILM Toyama Chemical

FUJIFILM Toyama Chemical was launched by merging FUJIFILM RI Pharma Co., Ltd., a company that conducts research, development, manufactures, and sales of radiopharmaceuticals, and TOYAMA CHEMICAL CO., LTD., a company that conducts research, development, manufactures, and sales of small molecule pharmaceutical products. FUJIFILM Toyama Chemical dedicates efforts to developing innovative diagnostic and therapeutic radiopharmaceuticals and therapeutic drugs with unique action mechanisms in the fields of “oncology”, “central nervous system diseases”, and “infectious diseases” where significant unmet medical needs still exist, under close collaboration with FUJIFILM Corporation, which focuses on research of new medicines. The joining of FUJIFILM Toyama Chemical’s and Fujifilm’ know-how will also advance the development of new medicines utilizing drug delivery system (DDS) technologies that aims to deliver the required amount of a drug in a timely manner to a specific body area. Also, by exploring synergy with in vitro diagnostic (IVD) devices and reagents owned by Fujifilm group companies, the company will expand its offering of comprehensive solutions from “diagnosis” to “treatment”.

For more information of FUJIFILM Toyama Chemical, please visit http://fftc.fujifilm.co.jp/en/

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