Fujifilm begins contract services of process development and manufacturing of liposome formulations, including small molecule drugs, nucleic acid medicines

Enters partnership agreement with Precision NanoSystems Inc.

TOKYO, March 25, 2020 — FUJIFILM Corporation (President: Kenji Sukeno) announces that it begins today to offer contract services of process development and manufacturing of liposome formulations to its partners seeking drug delivery formulations that are designed to deliver the therapeutic to the affected sites. The service will include both small molecule drugs and nucleic acid medicines[*1] which are poised to be therapies of the future. In order to offer the liposome formulation of nucleic acid medicines, Fujifilm also entered into a partnership agreement, on March 16, with Canada's Precision NanoSystems Inc. (hereinafter "PNI"), a leading technology provider for the development and manufacturing of nanoparticle-based therapeutics.

Liposomes are artificially constructed nanoparticles made from organic phospholipids that make up cellular membranes. They provide a type of Drug Delivery System (DDS) technology that is expected to improve the stability of the drug and, pass through the cell membrane and deliver drugs efficiently to the inside of cells. Thus research is currently being expanded to use liposome formulations not only for small molecule drugs but also for nucleic acid medicines.

Fujifilm has made use of advanced nano-dispersion, analysis, and process technologies that were cultivated and advanced through its development of wide-ranging products, to establish a manufacturing method to ensure the stable encapsulation of marketed anti-cancer agents[*2] in liposomes. The clinical phase I studies are currently under way in the U.S. for liposome formulations FF-10832 and FF-10850. In addition, the company established the first[*3] manufacturing facility (701 Facility) capable of commercial production of liposomes in Japan, a GMP[*4]-compliant facility, at FUJIFILM Toyama Chemical Co., Ltd., and began operation in February this year.

Fujifilm will offer its services by utilizing of the already established proprietary liposome manufacturing method as well as the 701 Facility. In addition, through its partnership with PNI, Fujifilm will install PNI's NanoAssemblr suite of instruments in the 701 Facility. With PNI's NanoAssemblr technology and Fujifilm's manufacturing facility and services, both companies will work together to serve their combined worldwide customer base.

Fujifilm is committed to developing new drugs that meet customers' unmet medical needs, and contribute to the further growth and development of the pharmaceutical industry by supporting the creation of drugs by utilizing DDS and other technologies that have been cultivated thus far.

*1 Nucleic acid medicines use, as their active ingredients, nucleic acid such as deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) that governs genetic information. Nucleic acid is a biopolymer composed of a base, sugar, and phosphoric acid.

*2 Examples include gemcitabine, an anticancer agent used as a first-line drug for the treatment of pancreatic cancer, as well as a wide range of other cancers, and topotecan, an anticancer agent used for ovarian cancer, small-cell lung

cancer, and cervical cancer, among others. FF-10832 and FF-10850 which are currently under development contain gemcitabine and topotecan, respectively, encapsulated inside the liposomes.

*3 Japan's first GMP compliant facility exclusively for manufacturing liposome formulations, according to Fujifilm survey.

*4 Good Manufacturing Practice defines quality measures for production and quality control to supply high-quality pharmaceuticals and medical devices. The facility was designed to comply with GMP standards of Japan, the U.S. and Europe.

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