Fujifilm Concludes a Manufacturing Contract Agreement with VLP Therapeutics, for a COVID-19 Vaccine Formulation

-Process development and manufacture of formulations using lipid nanoparticles Drug Delivery System technology-

TOKYO, October 1, 2020—FUJIFILM Corporation (President: Kenji Sukeno) announces the conclusion of a manufacturing contract agreement with biotechnology company, VLP Therapeutics Japan LLC (Representative Executor: Wataru Akahata, hereinafter "VLP Therapeutics") regarding COVID-19 vaccine formulation developed by VLP Therapeutics.

VLP Therapeutics' COVID-19 vaccine is self-amplifying (replicon) RNA[*1] vaccine and uses a formulation (lipid nanoparticle)[*2], which is a type of Drug Delivery System (DDS) technology[*3]. Fujifilm will utilize its manufacturing facilities and infrastructure for lipid nanoparticle to handle operations relating to VLP Therapeutics' COVID-19 vaccine formulations, from process development to manufacturing for the clinical trials.

VLP Therapeutics is the Japanese subsidiary of VLP Therapeutics, LLC (Chief Executive Officer: Wataru Akahata), a U.S. biotechnology company engaged in the development of next-generation COVID-19 vaccine, aiming to prevent infections for which no effective treatment methods exist. Research is currently under way at VLP Therapeutics LLC to produce next-generation COVID-19 vaccines that, by using replicons, can demonstrate high effects even with inoculation in small amounts, reduce the risk of adverse reactions, and cope with some genetic mutation.

This COVID-19 vaccine R&D project was selected for funding by the Japan Agency for Medical Research and Development (AMED). VLP Therapeutics will proceed in Japan with pre-clinical and clinical trials of this vaccine in collaboration with the National Center for Global Health and Medicine; the National Institutes of Biomedical Innovation, Health and Nutrition; Oita University; and Osaka City University

In March of this year, Fujifilm concluded a strategic partnership agreement with Canada's Precision NanoSystems Inc. (hereinafter "PNI"), a leading company in the development, manufacture and sales of lipid nanoparticle manufacturing equipment. By utilizing FUJIFILM Toyama Chemical's state-of-the-art 701 Factory, NanoAssemblr (GMP[*4]-compatible), which is a lipid nanoparticle manufacturing device produced by PNI that was introduced into this factory, as well as PNI's strong customer base, Fujifilm is promoting the process development and contract manufacturing business for active ingredients, nucleic acid drugs and RNA. Under the agreement with VLP Therapeutics, Fujifilm will develop the production process for VLP Therapeutics' COVID-19 vaccine formulation and also manufacture it for the clinical trials.

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 technologies, manufacturing facilities and other resources.

*1 RNA (ribonucleic acid) is a biopolymer composed of a base, sugar, and phosphoric acid. It is a type of nucleic acid that governs genetic information. RNA that was added with a function that causes temporary RNA proliferation in vivo after administration is called self-amplifying RNA, or replicon.

*2 A nanoparticle that is composed by using, as a primary ingredient, phospholipid, etc., an organic component of cell membranes and biomembranes.

*3 A technology to deliver the necessary amount of drugs to the necessary sites at the necessary timing.

*4 Good Manufacturing Practice defines quality measures for production and quality control to supply high-quality pharmaceuticals and medical devices.

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