Fujifilm collaborates with Merck & Co., Inc., Kenilworth, N.J., U.S.A. in a clinical trial for advanced solid tumor in combination therapy of FF-10832, a liposome drug candidate with KEYTRUDA® (pembrolizumab)

TOKYO, May 26, 2020 —FUJIFILM Corporation (President: Kenji Sukeno) announced that it will collaborate with Merck & Co., Inc., Kenilworth, N.J., U.S.A. (NYSE: MRK), known as MSD outside the United States and Canada. It signed a clinical collaboration agreement with MSD International GmbH, effective May 25, for the implementation of a clinical trial that evaluates a combination therapy with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, and Fujifilm's drug candidate FF-10832, a liposome drug candidate. The liposome formulation is designed to utilize drug delivery system (DDS) technology to deliver drugs to affected sites.

Based on this agreement, Fujifilm plans to initiate a U.S. clinical trial in the fiscal year 2020 ending March 2021 to evaluate combination therapy using its FF-10832, a liposome formulation drug candidate, and KEYTRUDA® (pembrolizumab). The goal of the study will be to confirm the combination tolerability, pharmacokinetics and preliminary estimates of clinical activity of FF-10832 with Keytruda in selected tumor types.

A liposome formulation is a preparation that encapsulates active ingredients in liposomes, which are artificially constructed vesicles made from an organic substance such as phospholipids which make up cell and biological membranes. Liposomes are expected to deliver active ingredients efficiently to affected sites.

Fujifilm's drug candidate, FF-10832, is a liposome formulation which encapsulates gemcitabine[*1], an approved anti-cancer agent indicated for the treatment of a variety of solid tumors including pancreatic cancer. The clinical phase I study of FF-10832 targeting advanced solid tumors is currently underway in the U.S. Preclinical studies in mice have demonstrated that a combination[*2] of FF-10832 and immune checkpoint inhibitors increased CD8-positive cytotoxic T cells[*3], leading to longer survival compared to monotherapy.

Fujifilm will leverage its established proprietary technologies to tackle the development of new drugs responding to unmet medical needs, and also develop new DDS technologies, thereby creating new value and enhancing medical care worldwide.

*1: An anti-cancer agent developed by Eli Lilly and Company (generic name: gemcitabine; brand name: Gemzar). It is used as the first-line drug for pancreatic cancer, and is also being used for treating a wide range of other cancers such as lung and ovarian cancers.

*2: Combined administration of FF-10832 and anti-CTLA-4 antibody. Anti CTLA-4 antibody and anti PD-1 antibody are immune checkpoint inhibitors which inhibit the mechanism that weakens the actions of immune cells ("immune checkpoint") and activated immune cells attack cancer cells.

*3: A type of T-cell that makes immune responses. It recognizes cells that become a foreign body to the host, and destroys them.

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