

**Fujifilm Starts a U.S. Phase I Clinical Trial of Anti-Cancer Agent “FF-10850”  
on Advanced Solid Tumors**

Clinical Development of a Novel Liposome Drug with Mechanism of Selective Delivery of Anti-Cancer Agent to Tumors

Tokyo, November 18, 2019 — FUJIFILM Corporation (President: Kenji Sukeno) announced the start of a U.S. Phase I clinical trial of FF-10850, an anti-cancer agent targeting advanced solid tumors. FF-10850 is a liposome-based agent in which topotecan<sup>\*1</sup>, an approved anti-cancer agent, has been encapsulated in the newly developed liposome. The study will evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of FF-10850.

As a drug delivery system (DDS), liposomes are artificially constructed vesicles made from the organic phospholipids which make up cellular membranes and biomembranes. Liposomes can deliver the required amount of a drug to the specific area of the body on predetermined schedule. Anti-cancer agents can act on normal cells, in addition to cancer which can induce strong adverse reactions. By encapsulating a drug in liposomes it is expected to selectively deliver the drug to cancer cells, suppress adverse reactions, and improve pharmacological efficacy.

FF-10850 is a liposome formulation with the purpose of delivering anti-cancer agent to cancerous cells, with the aim of reducing bone marrow suppression<sup>\*2</sup> and other adverse reactions of topotecan indicated for the treatment of ovarian cancer, etc., and to improve pharmacological efficacy. In the past, liposome encapsulation of topotecan was ineffective because the drug would leak from the liposome prior to reaching the cancerous area. By adding new materials to liposome ingredients and enhancing the strength of the liposome membrane, Fujifilm solved the challenges associated with drug delivery and in preclinical studies it successfully encapsulated topotecan in a stable manner for FF-10850.

Preclinical studies of FF-10850 in mice have shown stable encapsulation of Topotecan in the blood and reduced bone marrow suppression when compared with using Topotecan alone. The study also showed improved efficacy of FF-10850 (3 mg/m<sup>2</sup>) when compared to Topotecan (30 mg/m<sup>2</sup>) alone – demonstrating that FF-10850 can have the equivalent effect of Topotecan at just 1/10<sup>th</sup> the dose. Furthermore, the study showed that FF-10850 (8 mg/m<sup>2</sup>) demonstrated tumor regression.

Fujifilm has actively promoted the research and development of liposome formulations by harnessing its advanced nano-dispersion technology, analysis technology, and process technology cultivated and evolved through its wide range of product development. In 2017, the company began a U.S. Phase I clinical trial of FF-10832, a liposome-based agent that encapsulates the approved anti-cancer agent gemcitabine<sup>\*3</sup>.

In the preclinical mice studies on FF-10850 and FF-10832<sup>\*4</sup> Fujifilm has observed the extension of the survival period as a result of immune checkpoint inhibitor<sup>\*5</sup> combination therapy. In addition, Fujifilm has been promoting the application of liposome for use with next-generation drugs such as nucleic acid drugs and gene therapy drugs. Looking towards future growth, in order to ensure a stable supply of high-quality liposome formulations, Fujifilm is developing a manufacturing facility for producing investigational and commercial drugs through its subsidiary, FUJIFILM Toyama Chemical Co., Ltd. The facility is planned to begin operations in February 2020.

Fujifilm is harnessing its unique technologies to undertake the development of new drugs in the priority areas including oncology. The company is also focusing on developing DDS technologies to create new value and contributing to the resolution of social issues.

- \*1: An anti-cancer agent (generic name: topotecan, product name: Hycamtin) developed by GlaxoSmithKline plc. Currently, the drug is being sold by Novartis. It is used as a treatment for ovarian cancer, small-cell lung cancer, cervical cancer, etc.
- \*2: Because of the adverse reaction of anti-cancer agents, the functions of bone marrow are suppressed, and the production of white blood cells, platelets, and red blood cells is reduced, leading to increased risk of infection, bleeding and anemia. With topotecan, severe bone marrow suppression is seen in over 80% of the patients.
- \*3: An anti-cancer drug (generic name: gemcitabine, product name: Gemzar) developed by Eli Lilly and Company. It is used as the first-line drug for the treatment of pancreatic cancer, and is also indicated for the treatment of a wide range of other cancers (such as lung cancer and ovarian cancer).
- \*4: The results on preclinical studies on FF-10850 and FF-10832 were presented at 30th EORTC-NCI-AACR SYMPOSIUM  
<https://www.fujifilm.com/news/n181112.html>  
<https://www.fujifilm.com/news/n181113.html>
- \*5: 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.

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