

# Phase I clinical trial of anti-cancer drug FF-10101 in patients with relapsed or refractory acute myeloid leukemia

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FUJIFILM Corporation today announced to conduct a clinical trial of its anti-cancer drug FF-10101 in patients with relapsed or refractory acute myeloid leukemia (AML) in the United States next year. FF-10101 is a new drug candidate discovered by Fujifilm, tapping into its advanced technology to synthesize and design chemical compounds nurtured through the photographic film business.

AML is a type of hematological malignancy and considered as a refractory disease. The malignant transformation of [hematopoietic stem cells](#) into leukemia cells followed by their abnormal growth in bone marrow inhibits normal hematopoietic functions, leading to cytopenia. Organ dysfunctions are also caused by infiltration of the leukemia cells out of the [bone marrow](#). Fms-like tyrosine kinase 3 (FLT3) is a protein involved in proliferation of [hematopoietic cells](#). Approximately 30% of AML patients harbor FLT3 mutations such as internal tandem duplications (ITD) and tyrosine kinase domain (TKD) mutations, which induce abnormal growth of leukemia cells. Currently, FLT3 inhibitors resulting to inhibit leukemia cell proliferation are being developed, some of which show a favorable efficacy against leukemia cells with FLT3-ITD mutation. However, the TKD mutations are generally known to cause drastic decrease of efficacies of the FLT3 inhibitors.

FF-10101 is a FLT3 inhibitor which binds to an amino acid in FLT3 irreversibly. FF-10101 demonstrated a high efficacy in reducing

[leukemia cells](#) with the ITD or TKD mutation in a preclinical mouse model, hence the promising efficacy in [clinical trials](#) is expected. The results of the preclinical study will be presented at the 57th annual meeting of the American Society of Hematology, the world's largest hematology meeting, in Orlando, Florida the United States in December this year.

The development of FF-10101 was adopted as Next generation Technology Program (NexTEP) by the Japan Science and Technology Agency, which is in collaboration with Professor Hitoshi Kiyoi, M.D., Ph.D., Nagoya University, to investigate the efficacy and the safety profile of FF-10101. Findings from the research will be applied to the clinical study in an effort to further accelerate the development of FF-10101.

Fujifilm is defining oncology as its focal area and promoting the R&D of anti-cancer drugs by combining the technologies and experiences including chemical synthesis capacity, design ability, analysis technology accumulated through the development and production of photographic film. Fujifilm has initiated a Phase I clinical trial of FF-10501 in patients with relapsed or refractory myelodysplastic syndromes (MDS). The company will keep focusing on unmet medical needs in fields including oncology and actively promote R&D to expand business deployment and supply of innovative pharmaceutical products so as to contribute to resolving social issues.

Provided by FUJIFILM

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