Tumor uptake of antibody FF-21101 confirmed by imaging of advanced solid cancer patients

June 28 2016

Fujifilm Corporation is announcing the progress in a Phase I clinical trial of radioimmunotherapeutic anti-cancer agent FF-21101 in the United States in patients with advanced solid cancers. In imaging, tumor uptake of antibody FF-21101 was demonstrated in administered patients. Taking these results, it is expected to treat diseases with emission from the radiolabeled antibody. Fujifilm will proceed with the clinical trial and evaluate FF-21101 as an anti-cancer agent.

FF-21101 is an anti-cancer agent consisting of a radioisotope labeled antibody (armed antibody), and uses radiation emitted by the radioisotope to directly attack cancer cells. This is why it is expected to have a higher level of efficacy, regardless of the state of patient's immune system. In addition, its accumulation in cancer tissue can be confirmed by imaging with an administration of antibodies labeled with a radioisotope. To date, tumor uptake of antibody was demonstrated in three of four patients who have undergone imaging with an administration of radiolabeled FF-21101.

These results were presented on June 27th at the World Innovative Networking in Personalized Cancer Medicine Symposium 2016 (Paris, France) by principal investigator, Vivek Subbiah MD, of The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center, hereafter), Houston, TX, USA.

Fujifilm has organized the technologies of its Group companies to develop FF-21101. The bio-venture, Perseus Proteomics, has contributed to antibody drug discovery, while the biopharmaceutical contract manufacturer, FUJIFILM Diosynth Biotechnologies, has taken charge of antibody production. The radiopharmaceutical company, FUJIFILM RI Pharma, utilized its technology for developing the diagnostic and therapeutic radiopharmaceuticals.

Fujifilm initiated the Phase I clinical trial of radiolabeled FF-21101 in patients with advanced solid cancers at MD Anderson Cancer Center in the United States, one of the world's most distinguished facilities for cancer research and treatment, in January 2016. In this trial, FF-21101(111In), antibodies labeled with Indium-111, were administered prior to therapy and its biodistribution to normal and cancerous tissues were visualized and quantified by imaging procedures. In addition, for safety estimation in advance, radiation absorbed doses of Yttrium-90 in organs were calculated from these data, after which, patients were moved on to the therapeutic dosing of FF-21101($_{90}$Y), antibodies labeled with Yttrium-90.

Although the trial is still underway, preliminary observations include:

- Imaging revealed tumor uptake in 3 of 4 patients administered FF-21101(111In).
- FF-21101 was well tolerated in all patients who went on to receive the therapeutic dose of FF-21101($_{90}$Y).

Fujifilm will continue the study to further evaluate tolerability and efficacy in multiple advanced solid tumors at MD Anderson Cancer Center, and will move on to the phase IIa study.

Fujifilm is working on the R&D of innovative pharmaceutical products and creation of their production processes by combining the

technologies and know-how accumulated in the photographic film business including analysis technology, nanotechnology, and production technology, with the technological expertise of its core pharmaceutical affiliates such as Toyama Chemical. Defining oncology, a field with numerous unmet medical needs as its focal area, the company will actively promote R&D to expand business deployment and supply innovative pharmaceutical products so as to contribute to resolving challenges social issues.

About anti-cancer agent FF-21101:

FF-21101 uses antibodies that target P-cadherin, which is overexpressed on the surface of solid cancer cells, including lung, pancreatic and colon cancers, and is implicated in tumor growth and cancer metastasis. For the clinical application of FF-21101, tumor uptake will be confirmed in patients administered antibodies radiolabeled with emitter, such as Indium-111 or other radioisotopes. Antibodies labeled with Yttrium-90 namely FF-21101($_{90}$Y), will be subsequently administered and directly attacks cancer cells by radiation emitted from the $_{90}$Y radioisotope. FF-21101 is expected to be more effective than therapy using the P-cadherin targeted antibody without the $_{90}$Y. In animal testing, it has already demonstrated a high efficacy in shrinking human tumors implanted in mice.

Provided by Fujifilm

provided for information purposes only.