Fujifilm signs an exclusive licensing agreement with Cynata for an allogeneic iPS-derived cell therapy of serious complication after bone marrow transplants

Tokyo, September 17, 2019 —FUJIFILM Corporation (President: Kenji Sukeno) today announced that it has signed an exclusive licensing agreement with Cynata Therapeutics Limited (Chief Executive Officer: Ross Macdonald), an Australian bio-venture(ASX:CYP), to obtain worldwide rights to develop, manufacture and market CYP-001 for the indication of graft-versus-host disease (GvHD)*[1], a complication that occurs after bone marrow transplants. Fujifilm plans to start a company-sponsored clinical trial in Japan, before the end of 2020.

CYP-001 is a regenerative medicine product that uses mesenchymal stem cells derived from allogeneic induced pluripotent stem cell(iPSC)*[2], and is manufactured based on the iPSCs supplied by FUJIFILM Cellular Dynamics, Inc (FCDI).

In January 2017, Fujifilm made a minority investment in Cynata, with the goal of obtaining the right to develop, manufacture and market CYP-001. In May 2017, Cynata began a phase 1 clinical trial of CYP-001 for the indication of GvHD in the U.K. and Australia as the first-ever company-sponsored clinical trial using an iPS-derived cell therapy product. Based on the results of the phase I study conducted by Cynata, which met safety endpoints and suggested improvement in GvHD associated symptoms such as skin eczema and disorder of digestive system, Fujifilm has decided to obtain CYP-001's license.

GvHD is a serious complication that occurs after bone marrow transplants for diseases including leukemia. Immune cells such as lymphocytes contained in the transplanted organs attack the patient's body as a foreign substance, causing inflammations throughout the body. Treatment is ordinarily provided with immunosuppressants and other drugs. However, approximately half of the patients fail to respond to treatment, and in the worst-case scenario, lose their lives, making GvHD a disease with high unmet medical needs.

Regenerative medicine is attracting attention as a new solution for unmet medical needs. iPSCs have the ability to self renew and to differentiate into a variety of cell types. As the source material for cell therapies, iPSCs have the potential to offer a more flexible approach and address the issues of limited availability and inconsistent quality associated with other source materials. Due to the promise of therapeutic products derived from iPS cells, expectations for its practical application continue to grow.

Fujifilm continues to advance its internal pipeline of cell therapies using products derived from iPSCs, focusing on diseases with high unmet needs such as age-related macular degeneration, retinal pigment degeneration, Parkinson's disease, as well as heart disease, through FCDI, a U.S. subsidiary and a leading company in the development and manufacture of iPSCs.

Fujifilm will contribute to the promotion of the regenerative medicine business to the industrialization stage by tapping into the technologies and expertise of FCDI as well as Fujifilm's other group companies such as Japan Tissue Engineering Co., Ltd., FUJIFILM Wako Pure Chemical Corporation, and FUJIFILM Irvine Scientific, Inc.

*1 Graft-versus-host disease. A general term for a symptom that occurs as a result of the white blood cells present in the organ of a donor recognizing the recipient's body cells as foreign and attacking them.

*2 Mesenchymal stem cells derived from iPSCs that have been produced from cells of human donors other than the patient himself/herself. Mesenchymal stem cells exist *in vivo,* and are stem cells having a set cell potency and proliferation capabilities. Clinical studies have been conducted with over 1,000 patients for the treatment of a variety of diseases such as cerebral infarction as well as cartilage injury, ischemic heart failure and lower limb ischemia. They are expected to demonstrate diverse effects, and, at the same time, have been verified to have a high level of safety.

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