

Press Release

Initiation of cell therapy research and development program for adult T-Cell leukemia / lymphoma (ATLL)

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National Cancer Center
ARC Therapies Inc.

Overview:

The National Cancer Center (Tokyo, Japan) and The University of Pennsylvania (Philadelphia, PA, USA) have licensed patent rights directed to a chimeric antigen receptor T cell therapy that targets the chemokine receptor CCR4^{*1} (CCR4 CAR-T cell therapy^{*2}) to ARC Therapies Inc. (CEO: Rami Suzuki, Headquarters: Shinjuku-ku, Tokyo), a startup originating from the National Cancer Center. This agreement marks the commencement of ARC Therapies, Inc.'s research and development of a cell therapy targeting T-cell cancers, including adult T-cell leukemia/lymphoma (ATLL)^{*3}, which is prevalent in Japan. Furthermore, the potential application of CCR4 CAR-T cell therapy to solid cancers will also be pursued.

The National Cancer Center, established in 1962, is a leading cancer institute in Japan. The University of Pennsylvania pioneered the foundational research and co-development activities that led to the first CAR-T cell approved by the FDA in 2017 and continues to be a leader in CAR-T cell research, including next-generation therapies. ARC Therapies Inc., established in May 2022, is a National Cancer Center Japan-certified startup that promotes the research and clinical development of new cell therapies using cutting-edge research.

Hiroyuki Mano, Director of the National Cancer Center Research Institute, commented: "At the National Cancer Center, we are consistently promoting a comprehensive approach from understanding the mechanisms of carcinogenesis to the development of treatment and diagnostic methods for various cancers. We are pleased that one of the outcomes of our international collaborative research, the CCR4 CAR-T cell therapy, has led to a licensing arrangement for the development of potential new treatments by a startup originating from the National Cancer Center. We expect this arrangement to accelerate the practical application of new T-cell therapies originating from the National Cancer Center."

Rami Suzuki, CEO of ARC Therapies Inc., commented: "We are committed to the research and development of the CCR4 CAR-T cell therapy licensed from the National Cancer Center and the University of Pennsylvania. The potential long-lasting efficacy of chimeric antigen receptor T cell therapy is well-known, and we hope that our efforts will provide valuable treatment options for cancer patients."

Glossary:

*1 CCR4:

CCR4 is a chemokine receptor primarily expressed on lymphocytes that migrate to the skin. It is found on the surface of cells in Adult T-Cell Leukemia/Lymphoma (ATLL), Peripheral T-Cell Lymphoma (PTCL), and Cutaneous T-Cell Lymphoma (CTCL). The anti-CCR4 antibody "mogamulizumab" is approved as a therapeutic drug for the aforementioned three types of cancer. Additionally, CCR4 is expressed on regulatory T cells surrounding tumors, indicating potential for solid cancer treatment through regulatory T cell removal therapy.

*2 CCR4 CAR-T cell therapy:

Recombinant T cells will be created by introducing a gene that combines an antibody (single chain) that binds specifically to CCR4 with an intracellular signal transduction domain into

leukocytes collected from the patient. When injected into the patient, it is hoped that these cells will migrate and accumulate in tumor tissues expressing CCR4, become activated, and attack the cancer.

*3 Adult T-Cell Leukemia/Lymphoma (ATLL):

A rare and intractable lymphoma/lymphoid malignancy (neoplasm) caused by Human T-Cell Leukemia Virus Type 1 (HTLV-1) infection. HTLV-1 infection is observed in Japan, comprehensive HTLV-1 countermeasures are included in the Basic Plan to Promote Cancer Control Programs (Term4), and are being promoted as a national policy. Although anti-CCR4 antibody treatment has been successful for acute and chronic-type ATLL, recurrence remains a problem, currently without effective treatments for lymphoma-type ATLL.

University of Pennsylvania Financial Disclosure:

Penn may receive forward-looking financial consideration related to the licensing of certain Penn intellectual property to ARC Therapies, Inc.

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