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for the sound mind and body

January 15, 2021

Company: DyDo Group Holdings, Inc.
Representative: Tomiya Takamatsu, President
(Code 2590 on the First Section of the Tokyo Stock Exchange)
Inquiries: Naokazu Hasegawa, Corporate Officer
and General Manager of Corporate Communication Department

Notice of a Consolidated Subsidiary's Entry into a Licensing Agreement

DyDo Pharma, Inc., a consolidated subsidiary of DyDo Group Holdings, has entered, effective today, into a licensing agreement with CellGenTech, Inc., for commercialization of LCAT-GMAC (genetically modified human adipocyte of LCAT), a promising novel treatment for familial LCAT deficiency.

Having identified the healthcare market, including the rapidly-growing life science field, as its next growth domain, the DyDo Group established DyDo Pharma in January 2019 in an effort to focus on pharmaceuticals for treating rare diseases (diseases which affect 50,000 or fewer patients in Japan). Such diseases, for which there are as yet no effective treatment options, have become a social issue. The licensing agreement is the first for DyDo Pharma, which has been working to secure a promising product pipeline in an effort to develop pharmaceutical drugs for rare congenital diseases and ultra-rare diseases, which have even fewer patients, in order to address this issue.

Please see the separate press release for more information about the agreement.

As the effect of this licensing agreement on consolidated performance during the fiscal year ending January 2021 has already been incorporated into the full-year performance outlook that was announced on November 26, 2020, that outlook remains unchanged.

January 15, 2021

For immediate release

CellGenTech, Inc.
DyDo Pharma, Inc.

Notice of Licensing Agreement for LCAT-GMAC (genetically modified human adipocyte of LCAT)

CellGenTech, Inc., (head office: Chuo-ku, Chiba; president & CEO: Masayuki Aso) and DyDo Pharma, Inc., (head office: Kita-ku, Osaka; president and representative director: Yasunori Inaoka) are pleased to announce that they have entered, effective today, into a licensing agreement under which they will jointly and exclusively pursue the development and sale in Japan of LCAT-GMAC (genetically modified human adipocyte of LCAT), a promising treatment for familial LCAT deficiency that is being developed by CellGenTech.

LCAT-GMAC is being developed by CellGenTech with research support from "Medical Research and Development Programs Focused on Technology Transfer Adaptable and Seamless Technology Transfer Program through Target-Driven Research and Development," a program of the Japan Agency for Medical Research and Development (AMED). By entering into this agreement with AMED and other entities, CellGenTech and DyDo Pharma entered have acquired a license to commercialize the results of that R&D effort.

Founded in 2003, CellGenTech, a biotech venture with an origin in Chiba University, has pioneered development of pharmaceuticals using human adipocytes. The company, which is dedicated to helping improve quality of life for patients suffering from difficult-to-treat diseases and their family members, offers treatment using genetically modified human adipocytes ("GMACs"), which are created by transfection of genes that supply proteins used to treat disease to human adipocytes, in order to treat disorders caused by genetic or acquired deficiency or reduced functionality of proteins with physiological functions.

CellGenTech president and CEO Masayuki Aso described the licensing agreement as follows:

"LCAT deficiency is a rare and difficult-to-treat disease. Currently, Chiba University is conducting the clinical trials for LCAT-GMAC in cooperation with us in order to develop a gene therapy and regenerative medicine as the world's first treatment for LCAT deficiency. By taking advantage of the life span of human adipocytes, LCAT-GMAC will be expected that it secrets normal LCAT in the body for several years and improves or halts the progression of various symptoms caused by LCAT deficiency and reduced function by its once implantation/administration. LCAT-GMAC will be a medicine that realizes true regenerative medicine. By entering into a license agreement that covers joint development and sales with DyDo Pharma, which is dedicated to contributing to the treatment of rare diseases, we will add momentum to the development of the product, allowing us to offer it to healthcare providers sooner so that we can make a contribution to patients and their families. We at CellGenTech look forward to contributing to healthcare by applying the basic technology underlying GMAC to the development of treatments for other rare and difficult-to-treat diseases."

DyDo Pharma president and representative director Yasunori Inaoka amplified President Aso's comments:

"We expect that partnering with CellGenTech in the joint development and sale of LCAT-GMAC will help us offer a new treatment option to patients suffering from familial LCAT deficiency for which there is no cure yet, and their families. Going forward, we'll be pursuing joint development with CellGenTech to obtain marketing authorization approval so that we can supply this cell and gene therapy to patients as soon as possible."

(Reference information)

Familial LCAT deficiency

Familial LCAT (Lecithin Cholesterol Acyltransferase) deficiency is a disease in which the LCAT enzyme, which plays a role in the process by which cholesterol that is not needed in the body is captured by HDL cholesterol and sent to the liver for processing, fails to function sufficiently due to a genetic deficiency or mutation. As a result, unnecessary cholesterol that remains unprocessed has an adverse effect on bodily tissues, causing symptoms such as corneal opacity, hemolytic anemia, and renal dysfunction. In particular, the condition brings increased risk of serious conditions such as visual field constriction due to corneal opacity and renal failure due to renal dysfunction. The disease, which is caused by an abnormality of the LCAT gene on the chromosomes, affects about one in a million people. Currently, there are no effective treatments for familial LCAT deficiency, leaving only dietary therapy, which seeks to delay progression of the disease through a low-fat diet.

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