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Gene-Therapy Product for the Treatment of Malignant Pleural Mesothelioma adopted as Next generation Technology Transfer Program (NexTEP) by JST

TOKYO, JAPAN (July 1, 2014) — Kyorin Pharmaceutical Co., Ltd. (“Kyorin”) (Head office: Chiyoda-ku, Tokyo, President: Mitsutomo Miyashita), a wholly owned subsidiary of KYORIN Holdings, Inc., announced that the development of the gene-therapy product Ad-SGE-REIC will commence following the adoption of the program on the gene-therapy product^{*1} for the treatment of malignant pleural mesothelioma^{*2} (dated on June 23, 2014), which is part of the Next generation Technology Transfer Program (NexTEP)^{*3} of the Japan Science and Technology Agency (JST).

The adopted program of Ad-SGE-REIC (representative investigator: Hiromi Kumon, Professor of the Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences) is a gene-therapy product using a novel tumor suppressor gene of reduced expression in immortalized cells/ Dickkopf-3 (REIC/Dkk-3), which was discovered by researchers from Okayama University, as a therapeutic gene. It is expected to have direct effect on primary tumor lesions and indirect effect on metastatic tumor lesions as a gene-therapy product that simultaneously induces tumor cell-selective apoptosis and the activation of antitumor immunity respectively.

The legal environment for the development of gene-therapy product has improved markedly following the revision last year of the Pharmaceutical Affairs Act, which included the creation of the conditional/time limited approval system for prompt and effective practical application of products for regenerative medicine including gene-therapy product based on their characteristics. Given these circumstances, Kyorin has decided to develop the gene-therapy product Ad-SGE-REIC in collaboration with Okayama University, which has technologies and expertise related to Ad-SGE-REIC, and the drug discovery venture Momotaro-Gene Inc.,^{*4} which will promote its commercialization.

Kyorin will accelerate development of a practical application to provide a new therapeutic drug at the earliest time for patients with malignant pleural mesothelioma, the number of whom is expected to increase in Japan and overseas. Such patients at present have a poor prognosis with conventional treatment and thus high unmet medical needs.

[Reference]

*1 About gene-therapy product:

Gene therapy is defined as the administration of genes or gene-transfected cells into the human body for the treatment of disease. Pharmaceutical products that are used for gene therapy are called gene-therapy product. A vector is a carrier that is used to transfect target genes into cells or to administrate target genes into the human body and includes viruses and plasmids. Ad-SGE-REIC used in this project uses an adenovirus as a vector.

*2 About malignant pleural mesothelioma:

A disease in which malignant tumor cells develop in the membrane that lines the thoracic and abdominal cavity. It is thought to be caused by exposure to asbestos. According to the Vital Statistics by the Ministry of Health, Labour and Welfare, the number of deaths by mesothelioma in Japan was 500 in 1995, 953 in 2004, and 1400 in 2012, and expected to further increase toward the peak between 2030 and 2035. The prognosis of this disease is poor with conventional treatment and thus there is a strong need to develop a more effective new treatment.

*3 About the Next generation Technology Transfer Program (NexTEP):

A system through which the Japan Science and Technology Agency (JST) supports large-scale development that enterprises undertake using the seeds based on research results from academia and that may involve development risks to facilitate practical application.

*4 About Momotaro-Gene Inc.:

Momotaro-Gene Inc. is a drug discovery venture founded in 2007 that focuses on the strong potential of a tumor suppressor gene, reduced expression in immortalized cells (REIC), which was uniquely isolated and identified by researchers from Okayama University, to translate those research results for pharmaceutical companies by promoting the clinical development of REIC and related seeds.