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AnGes MG, Inc.

“Active Osaka Promotion Fund” Adopts AnGes’ Project

Development of Companion Diagnostic for Collatogene[®] as a Lymphedema Treatment
After Lumpectomy

AnGes MG, Inc. (AnGes) announced that the company’s project to develop an “in-blood miRNA screening test to examine c-Met expression in breast cancer” was selected for “Active Osaka Promotion Fund, priority project grant (promotion projects for pharmaceutical, medical devices, and iPS cell [regeneration medicine and drug-discovery] business).”

Under this project, AnGes aims to establish a simple screening test, which examines c-Met expressing breast cancer tumors by detecting micro (mi) RNA in the blood as a diagnostic marker.

By applying this examination method as a companion diagnostic product for Collatogene[®] (gene therapy with hepatocyte growth factor [HGF] plasmid) as a treatment for lymphedema, it can detect those patients with lymphedema caused by lumpectomy who are at risk of having theoretical adverse effects of HGF gene therapy, such as relapse and metastasis. Thus, the theoretical treatment risks of Collatogene[®] may be substantially reduced.

Lymphedema is an intractable disease in which a compromised lymphatic system causes severe swelling and fluid retention in the limbs. There are 2 types of lymphedema:

(1) “primary lymphedema,” which has an unidentified pathogenesis, and (2) “secondary lymphedema,” which occurs due to the after-effects of cancer surgery. There are no definitive treatments available for lymphedema and Collatogene[®], with its function to regenerate lymph vessels, is expected to become the world’s first drug treatment for lymphedema. AnGes has entered the Phase I/II development stage of Collatogene[®] as a treatment for primary lymphedema. After obtaining the proof of concept (POC) from the clinical study, AnGes intends to expand the indication to secondary lymphedema. However, it is considered that a small percentage of patients with breast cancer tumors express c-Met, which is a receptor of HGF and is related to cancer proliferation. Thus, realization of a companion diagnostic product that can detect c-Met positive tumors may prevent the risk of having such theoretical adverse effects as relapse and metastasis derived from HGF gene therapy.

It is estimated that there are approximately 3,000 patients with primary lymphedema in Japan. The number of patients with cancer-related secondary lymphedema, however, is relatively large. It is thought that there are 100,000 to 200,000 patients who develop secondary lymphedema in the United States (US) and Europe every year. AnGes aims to improve the quality of life (QOL) of patients with lymphedema by developing Collatogene[®], the world's first drug treatment for lymphedema, along with the companion diagnostic agent.

Non-operating income is expected to occur beginning fiscal year 2014 by receipt of this grant; however, it has no effect on business performance for the fiscal year 2013.

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Disclaimer: This is a translation of the news release posted in Japanese. In case of any deviations between the two language versions, the original document in Japanese shall take precedence.

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