



February 21, 2019

AnGes, Inc.

Japanese approval of HGF gene therapy drug, as the first gene therapy product to be launched in Japan

AnGes Inc. (Head office: Osaka, Japan, President: Ei Yamada, "AnGes") has been developing HGF gene therapy drug^{*1*2} for critical limb ischemia ("CLI"). Our product was discussed at the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) Committee for Regenerative Medicine and Biologics etc. on Feb. 20, and the committee recommended the product for conditional and time limited approval.

We have been developing this HGF gene therapy drug as our main project since the foundation of our company. We filed application for Marketing Approval for Cellular and Tissue-based Products^{*3} to the Japanese Ministry of Health and Welfare ("MHLW") on January 22, 2018.

Based on this conditional and time-limited approval, the following conditions need to be met within 5 years:

- (1) The product should be used by physicians who have sufficient knowledge and therapeutic experience in severe chronic arterial occlusive diseases, at facilities where wound management is implemented by collaboration among multiple departments.
- (2) During the period between the conditional and time-limited approval up to filing for official marketing approval, a post approval evaluation should be performed for all patients receiving treatment

In addition, although in our filing we aimed for treatment of pain at rest and improvement of ulcers in patients with chronic arterial occlusive disease, the recommendation for approval was granted only for improvement of ulcers. We are planning to conduct a clinical study to further confirm efficacy in improvement of pain at rest.

The product will be marketed by Mitsubishi Tanabe Pharmaceuticals in Japan, based on an exclusive partnership with them for the sales and distribution of our HGF gene therapy drug for peripheral artery diseases including CLI in Japan and in USA.

We will continue to be fully committed to advancing our pipeline projects including this HGF gene therapy drug, to aim to become “a global leader in gene-based medicine”, and to continue to work on our corporate mission, “realizing healthy and hopeful life”.

As we explained at our financial announcement on Feb 1, 2019, the launch and sales of this product is considered in the earnings forecast for the current fiscal year ending Dec 2019.

*1: HGF gene therapy drug: JAN/INN: Bepermingene Perplasmid, Code name: AMG001

*2: Gene therapy drug: A drug that uses genes or part of the genes as the active ingredient

*3: Cellular and Tissue-based Products: Gene therapy products are also included. For cellular and tissue-based products, a conditional and time-limited approval system is introduced under certain circumstances to allow quick approval of the product.

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

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