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Company Name: AnGes Inc.

Presentative: Ei Yamada, President & CEO

AnGes Announces Discontinuation of Development of HGF Gene Therapy Product for Additional Indication of Chronic Arterial Occlusive Disease with Rest Pain in Japan

AnGes, Inc. hereby announces that it has decided to discontinue the development of an HGF gene therapy product it has been working on for the additional indication of chronic arterial occlusive disease with rest pain in Japan. Details are as follows.

1. Background to development of HGF gene therapy product

The HGF gene therapy product is the first gene therapy product to be approved in Japan. It is a core project we have been involved in since our foundation. In March 2019, we obtained marketing approval with conditions and time limit in Japan, claiming improvement of arteriosclerosis obliterans with lower limb ulcer as the efficacy, effect, or performance, and we started selling the product in September 2019. We subsequently completed enrollment of the target number of patients to conduct an approval condition-based post-marketing evaluation for this indication. Furthermore, in December 2021, we also completed administration for a Phase 3 Clinical Trial for approval of the additional indication of chronic arterial occlusive disease with rest pain in Japan.

In addition, a Phase 2 Clinical Trial in the US of the HGF gene therapy product for arteriosclerosis obliterans with lower limb ulcer in patients with chronic arterial occlusion has also been progressing largely according to plan.

2. Discontinuation of development for additional indication of rest pain in patients suffering from chronic arterial occlusion in Japan

We completed administration for the Phase 3 Clinical Trial of the HGF gene therapy product for the additional indication of chronic arterial occlusive disease with rest pain and have been organizing and analyzing the data. As a result, we found that the results are such that we failed to meet the primary endpoints for rest pain. Based on these results, AnGes decided to discontinue development for approval of the HGF gene therapy product in Japan for the additional indication of chronic arterial occlusive disease with rest pain.

3. Future development plans for HGF gene therapy product

AnGes will push ahead as planned with preparations to apply to obtain the approval of the HGF gene therapy product in Japan, with improvement of arteriosclerosis obliterans with lower limb ulcer as the stated efficacy, effect, or performance.

We will also continue with the Phase 2 Clinical Trial in the US of the HGF gene therapy product for arteriosclerosis obliterans with lower limb ulcer and push ahead with development aiming to quickly progress through the clinical trial stages.

4. Future outlook

The impact that discontinuation of the development of the HGF gene therapy product for the additional indication of chronic arterial occlusive disease with rest pain in Japan will have on our full-year consolidated financial results and financial position for the current fiscal year will be minimal. AnGes will promptly disclose any future material developments.

AnGes, Inc.
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