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Company Name: AnGes Inc.

Presentative: Ei Yamada, President & CEO

Strategic Change in Product Development -Collategene (HGF gene therapy product)

Anges is pleased to announce promising US data for the use of Collategene (HGF gene therapy product) in patients with mild to moderate peripheral vascular disease. Preliminary results of the late phase II clinical trial establish both safety and efficacy with the trial meeting its efficacy endpoints. Based on these promising results Anges has made the decision to withdraw it's application for full approval for Collategene for use in patients with severe peripheral vascular disease, along with this the current product will be removed from the Japanese market and Anges will be submitting a new application for peripheral arterial disease in Japan using the global mutli-regional development strategy. As a result, we expect to expand the target patient population for Collategen.

Peripheral vascular disease is a complex medical condition that affects 200 million people worldwide and can lead to extremely devastating complications in the lower extremity, including ulceration, infection, and ultimately limb amputation.*1 When compared to cancer, as reported by Armstrong et. al. the 5-year mortality rate following a major (proximal to ankle) lower extremity amputation (57%) is second only to lung cancer (80%).*2,3. Starting treatment for such poor prognosis arteriosclerosis obliterans at a relatively early stage can be expected to prevent future deterioration of the patient's quality of life, and is recommended in treatment guidelines that have reached a global consensus*4.

Detailed results of the late phase II clinical trial in the U.S. are currently being analyzed and will be announced once the analysis is completed.

1. Withdrawal of Application in Japan and Consideration for Future Applications

In March 2019, AnGes obtained conditional and time-limited marketing approval in Japan for Collategene, an HGF gene therapy product, and submitted full an application in May 2023.

Since the post-marketing surveillance conducted under open-label conditions could not reproduce the results of the double-blind domestic Phase III clinical trial, the above application was temporarily withdrawn, and we will build an application data package centered on the results of the domestic Phase III clinical trial and the late Phase II clinical trial in the U.S., both conducted under double-blind conditions, and prepare to submit a new application for manufacturing and marketing approval by the end of 2024.

2. Response to Withdrawal of an Application for Approval in Japan

Currently, Collategene, an HGF gene therapy product, is marketed in Japan based on the manufacturing and marketing approval with conditions and time limits. With the withdrawal of the

application for the manufacturing and marketing approval, the approval will expire and the sales of the product will also be terminated. Accordingly, products currently in the market will be recalled.

3. Future Outlook

The impact of the withdrawal of the application for approval in Japan on our consolidated results for the current fiscal year is a decrease in sales of the product (23 million yen in the previous fiscal year) and expenses related to the product recall and new application, but the details are under investigation. The Company will promptly disclose the cost estimate for this event when it becomes available.

*1. Allison MA, et al. Health Disparities in Peripheral Artery Disease: A Scientific Statement from the American Heart Association. Circulation. 2023 Jul 18;148(3):286-296.

*2. Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. N Engl J Med. 2017 Jun 15;376(24):2367-2375.

*3. Armstrong DG, et al. Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer. Journal of foot and ankle research. 2020;13(1):1-4

*4. Michael S. Conte, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. Journal of Vascular Surgery. 2019;Volume 69, Number 6S