September 18, 2024

Company Name: AnGes Inc.
Presentative: Ei Yamada, President & CEO

Collategene (HGF gene therapy product) was granted Breakthrough Therapy designation by FDA

AnGes is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to Collategene, (HGF gene therapy product) that we are developing in the United States for the treatment of Peripheral Arterial Disease (PAD)

PAD 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.In addition, The Global Vascular Guidelines*4 recommend initiation of treatment in the early stages of PAD. Therefore, starting treatment with Collategene for patients with PAD in a relatively early stage may contribute to increased ulcer- and amputation-free days, thereby improving the patient's quality of life and therefore prevent infections and amputations.

Breakthrough Therapy designation is a process designed by the FDA to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on clinically significant endpoint(s).

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Although there is no change in our consolidated earnings forecast for the current fiscal year as a result of this Breakthrough Therapy designation, we believe that this matter will accelerate the development of “Collategene” and contribute to the enhancement of our medium-term corporate value.

*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