January 6 2026

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

Notice Regarding the Type “B” Clinical Meeting for HGF Gene Therapy Product

AnGes is pleased to announce a successful Type “B” clinical meeting (Type "B" meeting)*1 with the U.S. Food and Drug Administration (FDA) in preparation for the Biologics License Application (BLA) for our HGF gene therapy product (the Product).

On August 8, 2025, the company announced in our release titled *“Decision on the Development Policy for the HGF Gene Therapy Product in the United States and Regarding the Contract with Boehringer Ingelheim Biopharmaceuticals Notification Regarding the Drug Substance Supply Agreement”* that the company had completed the clinical trials for the product under development in the United States and decided to proceed with preparations for the BLA submission.

The company has now conducted the Type “B” meeting with the FDA to discuss clinical matters related to the upcoming BLA submission. While minor adjustments to the analysis methods were suggested, we successfully reached an agreement with the FDA on the clinical submission strategy.

Commenting on the outcome, our President and CEO, Ei Yamada, stated:
“We are pleased that the FDA is positively considering the BLA submission for our Product. We will accelerate preparations for the submission, including the Pre-BLA Meeting scheduled for 2026.”

Peripheral artery disease (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 Dr. 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 the Product 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.

This Type “B” meeting will have no impact on our consolidated financial results.

(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

*1 **Type "B" meeting**: A formal meeting defined by the FDA, held at major milestones in the development of drugs and biologics. It serves as a forum to jointly review and discuss critical points related to clinical development, manufacturing, and quality control, ensuring clarity on data requirements for submission. These discussions help improve the quality of the application and resolve potential issues early in the review process.

*2 **Pre-BLA Meeting**: A formal meeting held immediately prior to the submission of a Biologics License Application (BLA). This meeting is an important opportunity to confirm with the FDA the content, structure, and data requirements of the documents to be submitted, and to identify and address any significant unresolved issues before filing.