November 25 2026

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

Notice Regarding FDA Acceptance of the Rolling Submission and BLA Filing Plan for the HGF Gene Therapy Product

AnGes is pleased to announce that the U.S. Food and Drug Administration (FDA) has accepted the Company's request for a Rolling Submission of its Biologics License Application (BLA), as well as its proposed BLA submission plan, for the HGF gene therapy product currently under development for the treatment of Chronic Limb-Threatening Ischemia (CLTI/CLI) associated with Peripheral Arterial Disease (PAD). The product is being developed under the FDA's Breakthrough Therapy and Fast Track designations.

Previously, on August 8, 2025, in the announcement titled "Decision on the U.S. Development Strategy for the HGF Gene Therapy Product and API Supply Agreement with Boehringer Ingelheim Biopharmaceuticals GmbH," the Company announced that it had decided to complete clinical development of the product being developed in the United States and proceed with preparations for the submission of a Biologics License Application (BLA). Subsequently, on January 6, 2026, the Company announced "Completion of a Type B Clinical Meeting for the HGF Gene Therapy Product," and on May 14, 2026, "Completion of a Type B CMC Meeting for the HGF Gene Therapy Product." Through these FDA Type B Meetings, the Company discussed both clinical matters and CMC (Chemistry, Manufacturing and Controls) aspects with the FDA and obtained agreement on the regulatory strategy for the planned BLA submission. Furthermore, on July 17, 2026, in the announcement titled "Pre-BLA Meeting and BLA Submission for the HGF Gene Therapy Product," the Company announced that it would proceed with preparations for the BLA submission without conducting a Pre-BLA Meeting.

With the FDA's acceptance of the Company's proposed Rolling Submission process and BLA submission plan, the Company now expects to proceed with the BLA review process in accordance with its development and regulatory strategy. The initial BLA submission package is planned to be submitted in December 2026.

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, treatment with HGF gene therapy product in patients with earlier-stage PAD may help extend ulcer-free and amputation-free periods, potentially improving quality of life

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and reducing the risk of infection and limb amputation.

Please note that the acceptance of the rolling review process and BLA submission plan by the FDA is not expected to have any impact on the Company's 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

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