July 17 2026

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

Notice Regarding the Pre-BLA Meeting and BLA Submission for the HGF Gene Therapy Product

AnGes, Inc. hereby announces that it had been scheduled to hold a Pre-BLA Meeting with the U.S. Food and Drug Administration (FDA) on July 16 in preparation for the submission of a Biologics License Application (BLA) for its HGF gene therapy product in the United States. However, through the exchange of written communications in advance of the meeting, the Company received positive feedback from the FDA. As a result, the Company has proceeded to the process of submitting its BLA.

Previously, in its announcement dated August 8, 2025, titled“Notice Regarding the Determination of the U.S. Development Strategy for the HGF Gene Therapy Product and the Active Pharmaceutical Ingredient Supply Agreement with Boehringer Ingelheim BioPharmaceuticals GmbH,” the Company disclosed its decision to complete clinical development of the product in the United States and to proceed with preparations for a BLA submission. Subsequently, on January 6, 2026, the Company announced the holding of a Type B Clinical Meeting, and on May 14, 2026, it announced the holding of a Type B CMC Meeting. Through these meetings, the Company discussed clinical and CMC (Chemistry, Manufacturing and Controls) matters with the FDA and reached agreement on the overall submission strategy for the BLA.

AnGes is pleased to announce the receipt of positive responses from the U.S. Food and Drug Administration (FDA) prior to the preBLA meeting. AnGes’ questions were sufficiently addressed, and FDA concurred with our Rolling Submission and content plans. Accordingly, no FDA meeting was required and AnGes will proceed with the BLA submission.

HGF Gene Therapy Product(beperminogene perplasmid) is intended to treat chronic limb-threatening ischemia (CLTI) in patients with peripheral artery 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 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. Treatment of CLTI with HGF Gene Therapy Product in patients with PAD may contribute to increased ulcer- and amputation-free days, thereby improving the patient's quality of life.

The cancellation of the Pre-BLA Meeting will have no impact on the Company’s consolidated

financial results.

Rolling Submission: A regulatory process that allows products designated by the FDA under programs such as Fast Track or Breakthrough Therapy to submit completed sections of a marketing application for review on a rolling basis, rather than waiting until the entire application is complete.

About the HGF Gene Therapy Product

The HGF gene therapy product consists of plasmid DNA expressing **hepatocyte growth factor (HGF)**, a factor originally identified in the liver, which possesses the highest regenerative capacity among human organs. When administered to ischemic tissue, the product induces the production and secretion of HGF, promotes collateral vessel formation, increases local blood flow, and thereby improves ischemic conditions.
HGF plays a key role not only in the liver but also in the formation and regeneration of various tissues and organs, including blood vessels, lymphatic vessels, and nerves. Recognizing HGF's ability to stimulate angiogenesis, AnGes developed this innovative therapy as a novel treatment for ischemic diseases caused by impaired blood flow due to vascular occlusion. This development effort has culminated in the commercialization of the product.

*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