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Company Name: AnGes Inc.

Presentative: Ei Yamada, President & CEO

HGF Gene Therapy Product:
AnGes and Boehringer Enter Manufacturing Collaboration

Ingelheim and Tokyo – (August 20, 2025) - As disclosed on August 8, 2025, in the announcement by AnGes Inc., titled “Decision on the Development Policy for HGF Gene Therapy Product in the United States and Regarding the Contract with Boehringer Ingelheim Biopharmaceuticals”, AnGes now states it has completed clinical trials for the product to treat Peripheral Arterial Disease (PAD) being developed in the United States and will proceed with preparations for a Biologics License Application (BLA). AnGes also mentioned that final arrangements were underway for a supply agreement with Boehringer for the product’s drug substance. Today, we are pleased to announce that we have officially signed an agreement for the contract development and manufacturing of the product’s drug substance, and we will continue our collaboration toward regulatory approval.

Boehringer Ingelheim BioXcellence™, the biopharmaceutical contract manufacturing branch of the corporation, serves as a contract development and manufacturing organization (CDMO) for AnGes, responsible for manufacturing and supplying the active pharmaceutical ingredient of the Hepatocyte Growth Factor (HGF) gene therapy product. The plasmid DNA molecule has been manufactured using proprietary microbial technology in *E. coli* at Boehringer's site in Vienna, Austria, since the collaboration for clinical trial supply began nearly 20 years ago.

Ei Yamada, PhD, President & CEO, AnGes, says: “We proudly collaborate with Boehringer Ingelheim BioXcellence™, one of the top manufacturers of drugs and biologics in the world, and look forward to our mutual efforts toward a successful FDA approval.” Further updates regarding the Chemistry, Manufacturing, and Controls (CMC) will be provided to the FDA along with a pre-BLA meeting in the near future.

“At Boehringer Ingelheim BioXcellence™, we are committed to leveraging our expertise in biologics manufacturing. Therefore, we support our partners with high-quality, reliable manufacturing services to help them reach key regulatory milestones, such as FDA BLA approval, and to bring innovative therapies to patients worldwide. We deeply value the opportunity to collaborate with AnGes on their journey toward product launch, and we look forward to contributing to the future success of this important partnership,” says Ute Lehmann, Head of Key Account Management and Business Development at Boehringer Ingelheim BioXcellence™.

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 HGF gene therapy 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.

AnGes believes that the continued collaboration with Boehringer Ingelheim BioXcellence™ will accelerate the development of HGF gene therapy product and contribute to the enhancement of its 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

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Building on this, Boehringer Ingelheim BioXcellence™ collaborates with partners to reliably supply biopharmaceutical therapies. The companies' extensive experience in their contract development and manufacturing has resulted in supplying more than 45 commercial products to patients in need worldwide. It operates a global manufacturing network in key technologies such as mammalian and microbial, turning biologic innovations into commercial successes.
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