



May 14 2026

Company Name: AnGes Inc.

Presentative: Ei Yamada, President & CEO

## **Notice Regarding the Conduct of a Type B CMC Meeting for the HGF gene therapy product**

AnGes Inc. is pleased to announce the successful results of a type B CMC meeting with the FDA to discuss the manufacturing of HGF gene therapy product for the upcoming Biological Licensing Application (BLA) Filing.

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. And on January 6, 2026, in the press release titled *"Notice Regarding the Type B Clinical Meeting for the HGF Gene Therapy Product,"* the Company held discussions with the FDA regarding clinical aspects in preparation for the BLA submission and reached agreement on the clinical regulatory strategy.

The FDA agreed with our plans and we have a clear path forward for the CMC portion of our submission.

Ei Yamada, PhD is quoted as saying that; "We are very enthusiastic with the further progress of our program and the continued positive interaction with the FDA" Further updates will be provided along with a Pre-BLA meeting in the near future during the summer of 2026.

This Type "B" meeting will have no impact on the Company's consolidated financial results.

### **\*About the HGF Gene Therapy Product**

The HGF gene therapy product is a plasmid DNA that expresses hepatocyte growth factor (HGF), which was originally discovered in the liver, the organ with the highest regenerative capacity. When administered to ischemic tissue, the product induces the production and secretion of HGF, promotes the development of collateral blood vessels at the ischemic site, increases local blood flow, and thereby improves ischemic conditions. HGF plays a major role not only in the liver but also in the formation and regeneration of various organs and tissues throughout the body, including blood vessels, lymphatic vessels, and nerves. Focusing on HGF's ability to induce angiogenesis, the Company has developed this product as a novel therapeutic agent for ischemic diseases caused by vascular occlusion and reduced blood flow, offering a novel mechanism of action through the promotion of new blood vessel formation, and has brought it to commercialization.

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