August 8, 2025

Company Name: AnGes Inc.

Presentative: Ei Yamada, President & CEO

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

At the board meeting held today, our company has decided to complete the clinical trials of the HGF gene therapy product currently being developed in the United States (hereinafter referred to as "the Product") and proceed with preparation for a Biologics License Application (BLA). In addition, we would like to inform you that, as a result of this decision, we have also decided to make final arrangements with Boehringer Ingelheim Biopharmaceuticals GmbH (Germany, hereinafter referred to as "BI") concerning the conclusion of an agreement for the supply of the active pharmaceutical ingredient for this product.

As the product showed favorable results in Phase II clinical trials in the United States, it was publicly announced in the "Notice of FDA Breakthrough Therapy Designation for Gene Therapy Product 'Collategene' dated September 18, 2024" that it received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA). This designation is intended to apply a system that accelerates the development and review of drugs for serious illnesses, and it means that the FDA has recognized that the drug is expected to provide significant improvement over existing treatments in clinically important endpoints. Based on past cases, it is expected that the review period will be shortened, and the likelihood of approval will increase.

Thereafter, our company held ongoing consultations with the FDA and continued to address the issues that were presented. As the environment for advancing discussions with the FDA has now been established, we have officially decided to complete the clinical trial for this product and move forward with preparations for a BLA application. Going forward, we will continue discussions with the FDA while preparing the application documents and related materials. If the clinical trials are deemed complete and the BLA application becomes possible, we expect a significant reduction in development costs and time.

In addition, with this decision, we have decided to begin final preparations for entering into a contract with BI concerning the supply of active pharmaceutical ingredients after the approval of this product. The details of the contract will be decided through future discussions with BI.

Furthermore, there is no change to the consolidated earnings forecast for this fiscal year as a result of this development policy decision and the discussions with BI.