November 22, 2019
Company Name: AnGes Inc.
Presentative: Ei Yamada, President & CEO
(Code Number 4563, Mothers of the TSE)

HGF Gene Therapy Product "Collategene®"
Notice regarding the start of a clinical study for arteriosclerosis obliterans based on new global guidelines

AnGes, Inc. (Head Office: Ibaraki City, Osaka; President and CEO: Ei Yamada) will commence a clinical study in the U.S. of the HGF gene therapy product beperminogene perplasmid (Collategene® intramuscular injection 4 mg; the product, hereafter) in patients with arteriosclerosis obliterans with lower limb ulcers.

Global vascular guidelines[1)] regarding the treatment of chronic limb-threatening ischemia by arteriosclelosis obliterans were jointly published by vascular surgery societies in the U.S., Europe, Asia, and Oceania in June of this year, indicating treatment in accordance with the progression of the disease from the perspective of the patients' quality of life (QOL).

Based on the global vascular guidelines, the study will target patients with a lower risk of lower limb amputation than patients targeted in the past clinical study of the HGF gene therapy product, aiming to obtain approval in the U.S. Prior to the Phase III study, effectiveness in alleviating lower limb ulcers in the patients in question will be confirmed in a small-scale clinical study. Approximately 60 subjects are scheduled to be recruited for this study. The company has conducted deliberations with the U.S. Food and Drug Administration and reached an agreement with regards to the development plan.

Collategene® received conditional approval in Japan on March 26, 2019 for the improvement of ulcers in patients with chronic arterial occlusive diseases (arteriosclerosis obliterans and Buerger's disease), and Mitsubishi Tanabe Pharma Corporation began launch Collategene® from September 10, 2019.

The impact this will have on the full-year consolidated results for this fiscal year is currently being examined, and if there is determined to be a need to revise the earnings forecast, including other elements, prompt disclosure will be ensured.

1) Global Vascular Guidelines (GVG): These guidelines recommend improving patient QOL by providing appropriate therapeutic management from the initial stages of CLTI (chronic limb-threatening ischemia: the new term for critical limb ischemia). The guidelines divide the disease into four clinical stages (clinical stages 1 to 4), indicating treatment guidelines for the respective stages. This study will target patients in clinical stages 1 and 2 with low risk of lower limb amputation. For patients in these stages, the guidelines recommend first considering treatment of ulcers, and according to experts, approximately 60% of all patients fall under this category.

AnGes, Inc.
Public Relations & Investor Relations Group
TEL: +81-3-5730-2641, FAX: +81-3-5730-2635
https://www.anges.co.jp/en/