



March 10, 2026
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Notice Regarding the Publication of the Research Article on Our HGF Gene Therapy Product in *Circulation*

Our research article on the investigational HGF gene therapy product has been officially accepted and published in *Circulation: Cardiovascular Interventions* (Volume 19, Number 1, January 2026). However, due to the publisher's policy, access to the full original article requires a paid subscription. Accordingly, this notice provides a general, easy-to-understand summary of the article's content for the public.

What Is CLTI (Chronic Limb-Threatening Ischemia)?

- CLTI represents the most advanced stage of peripheral artery disease (PAD).
- It carries a high risk of lower-limb amputation and is associated with very poor prognosis and high mortality rates—comparable to many high-grade malignancies.

Treatment of CLTI

- As noted above, CLTI is a severe condition associated with chronic, non-healing wounds, risk of limb loss, reduced quality of life, and increased mortality.
- Treatment approaches mainly include wound management, risk-factor control, infection treatment, and—when appropriate—revascularization (endovascular intervention or surgical bypass).
- Revascularization is generally the first-line option due to its high limb-salvage rates. However, even when successful, ulcer healing often takes considerable time, sometimes extending beyond several months.
- For moderate CLTI—characterized by moderate ischemia, persistent ulcers, and cases where revascularization is borderline or unsuitable—effective non-surgical treatments are limited, and no FDA-approved standard pharmacologic therapy currently exists.

Note: This notice does not describe detailed numerical or statistical outcomes. For the precise data, please refer to the original article (DOI: 10.1161/CIRCINTERVENTIONS.125.015648).

Summary and Significance of the Clinical Trial

- This study evaluated the effect of AMG0001 (HGF gene therapy product) on ulcer healing in patients with moderate CLTI. The results suggested that:
 - There was a trend toward shortening the time required for ulcer healing.
 - Favorable trends were also observed in healing outcomes at 12 months.
- These findings indicate that AMG0001 may represent a promising new therapeutic option for patients with moderate CLTI.

(Note) This document has been translated from the Japanese original for reference purposes only.
In the event of any discrepancy between this translation and the Japanese original, the original shall prevail.

- This trial is particularly meaningful because it explored a new therapeutic concept: “gene therapy at the moderate ischemia stage.” The study demonstrated the potential of this approach to promote ulcer healing. AMG0001 has been granted FDA Breakthrough Therapy designation.

Based on these results and ongoing discussions with the FDA, our company is currently preparing a Biologics License Application (BLA).