DISCLAIMER: This document has been translated from a part of the Japanese original for reference purposes only. In the event of any discrepancy between this translated document and the Japanese original, the original shall prevail.

November 10, 2026

To whom it may concern,

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Notice Regarding Designation of Allogeneic iPSC-Derived Cardiomyocyte Spheroids "HS-001" as an "Orphan Regenerative Medical Product" by the MHLW

Heartseed Inc. (the “Company”) hereby announces that its lead pipeline product, allogeneic iPS cell-derived cardiomyocyte spheroids (development code: HS-001; hereafter “HS-001”), received orphan regenerative medical product designation from the Ministry of Health, Labour and Welfare (MHLW) on November 9, 2026.

1. Overview of the designation

Target product:	Allogeneic iPS cell-derived cardiomyocyte spheroids "HS-001"
Non-proprietary name:	remumiocel
Expected efficacy/effects:	Treatment of severe heart failure secondary to ischemic heart disease with inadequate response to standard drug therapy, limited to patients who satisfy both of the following criteria: • Patients undergoing coronary artery bypass grafting (CABG) • Patients with a resting left ventricular ejection fraction (LVEF) of 40% or less
Designation date:	November 9, 2026

2. Overview of the orphan designation system for regenerative medical product and "HS-001"

This designation system provides administrative support measures—including financial subsidies, priority consultation, priority review, tax incentives, and extension of the re-examination period (up to 10 years)—to regenerative medical products that meet criteria regarding the target patient population, medical need, and development feasibility.

"HS-001" is a regenerative medical product composed of micro-tissues called "cardiomyocyte spheroids" formed from highly purified cardiomyocytes derived from allogeneic iPS cells. The product is directly transplanted into the myocardium during CABG. The engrafted cardiomyocytes contract synchronously with the patient's myocardium, aiming to improve reduced cardiac function.

Please note that there is no revision to the latest earnings forecast for the fiscal year ending December 31, 2026.

(Cautionary notice on forward-looking information)

The financial results forecasts and other forward-looking information contained in this document are based on the information currently available to the Company and certain assumptions considered reasonable by the Company. It is not a guarantee that the forecasts will be achieved, and actual results may differ significantly from such forecasts depending on various factors.