

October 2, 2025

To whom it may concern,

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Notice of submission of clinical trial notification for Phase I/II study of cardiac remuscularization therapy HS-005 (catheter administration) targeting severe heart failure due to ischemic heart disease and dilated cardiomyopathy

Heartseed Inc. (hereinafter "the Company") is pleased to announce that it has completed the submission of a clinical trial notification to the Pharmaceuticals and Medical Devices Agency (PMDA) regarding the commencement of the Japan clinical trial for HS-005 (catheter-based administration therapeutic program of allogeneic iPS cell-derived cardiomyocyte spheroids). This submission was successfully completed as targeted within the year.

The Company's sponsored trial aims at treating severe heart failure with underlying ischemic heart disease as well as dilated cardiomyopathy. The Company plans to enroll 7 patients in each cohort, for a total of 14 patients, to evaluate the safety and efficacy of the therapy.

The prior notification to PMDA regarding the delivery catheter system, which was the most critical aspect for initiating the clinical trial, had been completed. Going forward, provided there are no particular comments from PMDA during their document review, the Company will proceed to formally contract with the candidate clinical trial sites once the discussions in the Institutional Review Boards (IRBs) at each site are finalized. The Company plans to begin administering the therapies to patients in the clinical trial in 2026.

Please note that, there is no revision to the latest earnings forecast for the fiscal year ending December 31, 2025.

(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.