# Landmark Trial Demonstrates Efficacy of Microcurrent Therapy in Heart Failure: C-MIC II Results Published in the European Journal of Heart Failure

ZUG, Switzerland, July 23, 2025 /PRNewswire/ -- Berlin Heals and the C-MIC II Investigators today announced the publication of the C-MIC II trial results in the *European Journal of Heart Failure*. The study, titled *"Cardio-microcurrent Device Treatment for Heart Failure with Reduced Ejection Fraction: Results from the C-MIC II Open Label Randomized Controlled Trial,"* was previously presented as a Late-Breaking Clinical Trial (LBCT) at the 2025 ESC-HFA Congress in Belgrade.

The findings mark a major advancement in the field of bioelectronic medicine for heart failure, highlighting the potential of the Cardio-Microcurrent (C-MIC) device—a novel implantable system that delivers low-intensity microcurrent to the failing myocardium.

**Study Summary**

In this open-label, randomized controlled trial, 70 ambulatory patients with non-ischemic dilated cardiomyopathy, LVEF 25–35%, and NYHA Class III–IV symptoms were randomized 1:1 to receive C-MIC therapy plus guideline-directed medical therapy (GDMT) or GDMT alone. The primary endpoint was the difference in change in LVEF at 6 months. Secondary endpoints included change in NYHA class, 6-minute walk distance (6MWD), and Kansas City Cardiomyopathy Questionnaire Overall Summary Score (KCCQ-OSS).

At six months, patients receiving C-MIC therapy experienced markedly greater improvements than controls across all prespecified endpoints. Left-ventricular ejection fraction (LVEF) rose by an average of 6.6% in the C-MIC group versus 1.5% in the control group, yielding a mean between-group difference of 5.1% (95 % CI 3.1–7.1; $p < 0.001$). Clinically meaningful functional gains were similarly superior: 84 % of C-MIC patients improved by at least one NYHA class compared with 15 % of controls—a risk difference of 68.9 % (95 % CI 50.6–87.2; $p < 0.001$). Quality-of-life also benefited, with 75 % of C-MIC patients achieving a ≥5-point increase in KCCQ Overall Summary Score versus 15 % in controls (risk difference 60.0 %, 95 % CI 42.3–77.6; $p < 0.001$). Finally, nearly half of treated patients (47 %) attained at least a 30 % rise in six-minute-walk distance compared with only 9 % of controls (risk difference 38.3 %, 95 % CI 14.4–62.2; $p = 0.002$), underscoring consistent benefit across structural, symptomatic, and functional outcomes. The therapy was well tolerated, with no device-related serious adverse events reported.

**Author and Investigator Quotes**

"This study offers compelling evidence that microcurrent therapy can enhance both cardiac function and patient-centered outcomes in individuals with HFrEF," said **Prof. Jesus E. Rame**, co-first author, The Louis R. Dinon MD Professor of Medicine and Surgery and Enterprise Chief of Advanced Cardiac and Pulmonary Vascular Disease at Thomas Jefferson University. "These findings introduce a promising new therapeutic avenue for patients who remain symptomatic despite receiving optimal medical therapy." Dr. Rame further noted, "This randomized controlled trial not only demonstrates the efficacy and safety of the therapy in patients with stable, chronic ambulatory heart failure, but also pioneers an entirely novel treatment paradigm aimed at restoring cardiac function in non-ischemic cardiomyopathy."

"This was a remarkable collaborative effort across all participating sites," said **Prof. Dragana N. Kosevic**, co-first author and co-Principal Investigator at Dedinje Cardiovascular Institute, Belgrade. "We observed meaningful improvements in symptoms and functional capacity among our patients—an encouraging sign for broader clinical adoption."

**Prof. Jan Schmitto**, Professor of Cardiac Surgery at the Department of Cardiac, Thoracic, Transplantation and Vascular Surgery, Hannover Medical School, co-first author and coordinating investigator of the trial, commented: "These results validate more than a decade of translational work. They suggest that restoring myocardial bioelectric signaling can have a direct and clinically meaningful impact on cardiac performance in patients with advanced heart failure."

**Prof. Stefan D. Anker**, senior author and Professor of Cardiology at Department of Cardiology (CVK) of German Heart Center Charité; German Centre for Cardiovascular Research (DZHK) partner site Berlin, Charité Universitätsmedizin, Berlin added: "This is the first randomized trial to demonstrate that low-level microcurrent stimulation can improve both structural heart function and quality of life. It establishes a strong foundation for future studies focused on long-term clinical outcomes."

"We are thrilled to see the C-MIC II results published in the *European Journal of Heart Failure*," said **John Brumfield**, CEO of Berlin Heals "These findings support our mission to develop breakthrough, bioelectronic therapies for chronic heart failure—targeting the disease at its electrical and cellular roots."