Berlin Heals Initiates International Randomized, Double-Blind, Sham-Controlled C-MIC IV Trial

Zug, Switzerland, 18th November 2026 (PRNewswire) -- Berlin Heals Holding AG, a clinical-stage medical device company developing a first-in-class microcurrent therapy for heart failure, today announced the initiation of the international C-MIC IV trial and the first patient implantation. This new trial builds on the C-MIC III study, which introduced a less invasive implantation approach performed as an outpatient procedure in a cardiac catheterization laboratory. C-MIC IV marks the first evaluation of microcurrent therapy in a double-blind sham-controlled trial, with patients randomized 1:1 to active treatment or sham control.

The study will enroll 60 patients across six European countries: Spain, Belgium, Netherlands, Denmark, Serbia and Bosnia & Herzegovina. Participants will have symptomatic heart failure of either non-ischemic or ischemic etiology with a reduced ejection fraction above 20%. This represents a substantial broadening of the study population compared with previous studies. All patients will have devices implanted but will be blinded to whether therapy is on or off. With the completion of CMIC-IV, Berlin Heals will increase the clinical experience of microcurrent technology to over 120 heart failure patients.

The first patient was implanted in Kragujevac, Serbia and treated by Dr. Miodrag Sreckovic, Head of Interventional Cardiology at the University Clinical Center Kragujevac.

John Brumfield, CEO of Berlin Heals, said: “Initiation of the international CMIC-IV trial marks a pivotal moment for Berlin Heals as we continue to build a robust body of evidence for this novel therapy. “

Dr Faouzi Kallel, Chief Scientific Officer of Berlin Heals, added “CMIC-IV is the second randomized trial of microcurrent therapy, further characterizing safety and efficacy to inform the design of our planned pivotal IDE trial.”

“Randomized, double-blind, sham-controlled trials can be challenging to conduct with implantable medical devices because of the difficulty of maintaining blinding”, said

Global Principal Investigator Stefan Anker, Professor of Medicine Charite, “because microcurrent therapy is not perceived by the patient and treatment allocation can be concealed from assessing clinicians, CMIC-IV allows us to evaluate the therapy using a rigorous, double-blind, sham-controlled design.”

Berlin Heals Holding AG is a Swiss joint-stock company founded in 2014. The company's C-MIC technology delivers a constant electrical microcurrent to the heart, generating a localized electrical field designed to improve cardiac function. Clinical findings to date suggest that this approach may provide early and sustained improvements in patients suffering from chronic heart failure.