



BERLIN HEALS Receive Breakthrough Device Designation from FDA for its C-MIC Heart Failure Device and Initiates Early Feasibility Study in the United States

BERLIN and ZUG, Switzerland, March 11, 2021 (GLOBE NEWSWIRE) -- BERLIN HEALS, a company developing novel life-saving treatments for heart failure, announced today that the US Food and Drug Administration (FDA) has granted a Breakthrough Device Designation for its proprietary Cardiac Microcurrent Therapy Device ("C-MIC"). The C-MIC is an implantable device that delivers a constant but minimal electrical DC-current to the heart via two electrodes. Based on results of first-in-human studies in 2019/20, the C-MIC device has shown potential to become the first near-curative heart failure therapy. Berlin Heals, which has already launched a European-wide CE-study, is now about to file an Investigational Device Exemption (IDE) - Application with the FDA for an Early Feasibility Study (EFS) to commence in the US later this year.

The FDA's Breakthrough Devices program accelerates the development of medical devices with the potential to effectively treat or diagnose life-threatening or irreversibly debilitating diseases. Heart failure, the world's most lethal disease, is a chronic inflammatory disorder affecting millions of patients globally. It is responsible for 16% of all deaths and has shown the largest increase amongst all fatal diseases since 2000, rising by more than 2 million to 8.9 million deaths in 2019. The C-MIC device has shown potential to be the first treatment to enable patients of cardiac failure to lead a normal and mobile life and has consequently been assigned as a breakthrough device by the FDA.

As of today, no therapy, drug, or method has been developed and made available to reverse cardiac failure. Designation of the C-MIC as a breakthrough device by the FDA allows significant acceleration in the development and review of the technology, providing patients faster access. Marko Bagaric, CEO of Berlin Heals said, "Our completely novel therapeutic approach has the potential to almost cure heart failure rather than just delaying the progression of the disease. The *FDA Breakthrough Designation* is a tremendous turning point in the approval process for the US, enabling us to make our device available to patients with life-threatening heart disease much faster."

Since 2014, Berlin Heals has been developing novel and revolutionary technology to treat heart failure. The proprietary C-MIC method was developed following results of pre-clinical trials in an intensive scientific cooperation with the Medical University of Vienna which confirmed that microcurrents have an extremely positive effect on cardiac cells. The C-MIC is a small implantable device that propagates reverse remodeling of the cardiac muscle tissue by delivering a constant but minimal electrical DC current to the heart. Not only did extensive preclinical trials confirm the efficacy and safety of microcurrent application via C-MIC, but also a strong anti-inflammatory effect with significant improvement in cardiac function. After confirming the clearly beneficial effects of microcurrent in preclinical studies, Berlin Heals started first implantations in patients under study conditions.

Berlin Heals successfully completed a pilot study with 10 patients in April 2020. The electrical microcurrent remained completely undetectable to the patients, did not interfere with the heart rhythm, and lead to significant improvements in heart function within a few days. All of the patients' hearts, which are typically enlarged in dilated cardiomyopathies, had shrunk and all patients decreased by 2 NYHA classes. No device-specific side-medication or follow-up procedures were required.

Berlin Heals has now launched a European CE-multi-center-study with its C-MIC device in Germany, Serbia, Austria, and Poland which is expected to be complete by the end of 2022. The company will also commence an *Early Feasibility Study (EFS)* in the US which includes 10 patients in mid-2021. It will then confirm the successful results of the first human study in a much larger group of more than 100 patients in a randomized two-arm multicenter trial. Marketing of the C-MIC system could start in Europe in 2022, in the US in 2025, and globally in 2025.

About BERLIN HEALS

Berlin Heals Holding AG, a Swiss company operating an R&D subsidiary in Berlin, Germany, was founded in 2014 as an innovative life science company with the mission to develop its proprietary C-MIC technology to treat heart failure. The C-MIC device is a novel cardiac implant using constant microcurrent to treat heart failure and meanwhile has turned out to represent a breakthrough near-curative treatment for patients with systematic and refractory heart failure.

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