



BERLIN HEALS Announces results of first-in-human study for its Implantable C-MIC device for the Treatment of Heart Failure with Electrical Microcurrent and the Launch of a pivotal CE Mark Study

BERLIN and ZUG, Switzerland, March 04, 2021 (GLOBE NEWSWIRE) -- BERLIN HEALS, a company dedicated to developing and offering novel and life-saving treatments for patients suffering from heart failure, announces results of a first-in-human study published in *ESC Heart Failure*, in patients with dilated cardiomyopathy for its proprietary C-MIC device. The C-MIC is a small implantable device that delivers a minimal constant electrical DC current to the heart. The results show significant, rapid improvements in heart function, heart size and quality of life of patients. Thus, this treatment has the potential to become the first sustainable, almost curative, treatment for heart failure in patients with unmet medical needs.

Results from the first-in-human study involving 10 patients show that the C-MIC device significantly improved cardiac performance by two levels of the New York Heart Association (NYHA) classification and quality of life of patients with NYHA class III heart failure. Heart failure is the world's most lethal disease, accounting for 16% of all deaths globally. As of today, no therapy, drug or method has been developed and made available to treat cardiac failure for a patient to be enabled a normal and mobile life. The last hope for most of these seriously ill patients are Ventricular Assist Devices (VAD) which are very often associated with significant side effects and a statistically short life expectancy. They serve at most as a "bridge to transplant," that is, if a transplant becomes available at all.

Since 2014, the Berlin Heals team has been developing a new and revolutionary technology to treat heart failure. After confirmation from preclinical trials that microcurrents have a regenerative and anti-inflammatory effect on heart cells, the company developed and widely tested its proprietary C-MIC device which restores endogenous electric potential gradients using microcurrents, leading to improved myocardial function. The C-MIC is a small implantable device that delivers a constant electrical DC current equivalent to physiological strength to the heart via two leads, one placed on the epicardium of the left ventricle, and the other in the right ventricular cavity. Extensive preclinical trials confirmed that microcurrent application via C-MIC promotes reverse remodeling of heart muscle tissue and a strong anti-inflammatory effect in a safe and effective manner. Following this work, Berlin Heals moved on to test their technology in patients.

The results of the first-in-human study of 10 patients are extremely positive, demonstrating rapid and lasting improvement in heart function within days of C-MIC placement. Patients' mean 6-minute walking distance improved by almost 100% in 14 days and all of the patients' hearts, which were typically enlarged in dilated cardiomyopathies, had shrunk. All patients saw NYHA classification drop by two classes. The electrical microcurrent remained completely undetectable to the patients and did not interfere with the heart rhythm. No device-specific side-medication or follow-up procedures were required. The patients maintained and increased these improvements for 6 months after implantation and at least another 6 months post deactivation of C-MIC.

"We were very pleased to see that our patients, who previously could barely walk 200 meters during the 6-minute walk test, were now able to walk more than 400 meters only two weeks after the C-MIC device had been implanted - almost reaching the level of healthy patients," says Marko Bagaric, CEO of Berlin Heals. "We continue to see stable parameters after now more than 12 months and above all, happy and mobile patients. Our new method has a realistic potential to almost cure heart failure, rather than just delaying the progression of the disease."

"It is of utmost importance to note that our C-MIC device can be implanted with pacemakers or VAD pumps and will work independently or in parallel to such implants without any cross-interferences," explains Dr. Johannes Müller, Scientific Director and Chairman of the Board of Directors of Berlin Heals. "Even in the case of seriously ill patients with already very low pumping capacity, a VAD together with our C-MIC device can be implanted and remain until the patient's heart recovers. We are talking about a real paradigm shift in the treatment of heart failure, which millions of patients will benefit from. And in combination with VADs, the microcurrent method will be a 'bridge to the regeneration' of the heart, rather than a 'bridge to transplantation'."

Berlin Heals has now launched a CE mark study with its C-MIC device to confirm the successful results obtained in the first-in-human study within a larger group of patients, and preliminary data is confirming data from the pilot study.

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. After the completion of the CE-study, the company intends to test the efficacy of its technology also with patients suffering from heart failure with preserved ejection fractions (HFpEF-patients).

About Heart Failure

In the US alone, 1 in every 4 deaths are due to heart disease, resulting in attributable disease costs of about \$220 billion annually. It has shown the largest increase amongst all fatal diseases since 2000, rising by more than 2 million to 8.9 million deaths in 2019.

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Contact: Björn Peters – No. +41 78 811 06 77 / email: bjoern.peters@2908.ch