# Cardior Announces CE Marking of CardiorHealth miR-132 PCR Kit Used in Ongoing HF-REVERT Phase 2 Clinical Study

***Hanover, Germany, September 8, 2022*** – Cardior Pharmaceuticals, a clinical-stage biotech company developing non-coding RNA (ncRNA)-based therapeutics for patients with cardiac diseases, today announced the CE marking of its PCR kit which measures circulating microRNA-132 (miR-132) levels in the blood of patients receiving the company's lead candidate CDR132L, an oligonucleotide-based miR-132 inhibitor. The company is currently conducting its Phase 2 clinical study, HF-REVERT (NCT05350969), to evaluate the safety and efficacy of CDR132L in patients with heart failure and reduced left ventricular ejection fraction (LVEF) after a myocardial infarction. By using the CardiorHealth miR-132 PCR kit, Cardior ensures consistent measurement of miR-132 levels following CDR132L treatment across all clinical trial centers as an indicator of the target engagement and the compound's mechanism of action.

Cardior is developing CDR132L as a therapeutic candidate to improve cardiac systolic and diastolic function in patients with heart failure. By selectively blocking aberrant miR-132 levels, CDR132L has the potential to reverse cellular pathology and restore normal cardiac function. The CardiorHealth miR-132 PCR kit is the first PCR kit designed to monitor the treatment with a non-coding RNA-based therapeutic.

*"Receiving the CE mark for our CardiorHealth miR-132 Plasma PCR kit is another demonstration of our ongoing commitment to pioneering a paradigm shift in the treatment of cardiac disease,"* ***said Prof. Dr. Dr. Thomas Thum, CSO and Founder of Cardior.*** *"The kit allows us to monitor the effect of our lead candidate in patients and provides us and participating clinicians with valuable information at a high level of certainty."*

The blocking of abnormal miR-132 levels by CDR132L as measured with the PCR kit will be an exploratory parameter in the Phase 2 HF-REVERT trial. CE mark approval of the kit was based on the clinical evaluation of the test in patients receiving various doses of CDR132L or placebo, where the kit demonstrated comparable results to a similar testing protocol used in Cardior's Phase 1b clinical study. The CE mark confirms that Cardior's proprietary kit meets the essential requirements of the European *in vitro* diagnostic regulation (EU) 2017/746 for its intended use.

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**About HF-REVERT**

HF-REVERT (NCT05350969) is a multicenter, randomized, parallel, three-arm, placebo-controlled clinical proof-of-concept study designed to evaluate the safety and efficacy of CDR132L in 280 patients with heart failure and reduced left ventricular ejection fraction (LVEF) after a myocardial infarction. The primary endpoint of the study is defined as percentage change from baseline in the left ventricular end-systolic volume assessed by echocardiography (ECHO). Patients enrolled in the Phase 2 study will be randomized to receive intravenous CDR132L infusions with either 5 mg/kg or 10 mg/kg or placebo, administered 28 days apart as an add-on to Standard of Care (SoC) treatment. The study will be conducted at approximately 60 clinical study centers across Europe.

**About CDR132L**

CDR132L is a synthetic antisense oligonucleotide-based inhibitor directed against the microRNA-132 (miR-132). miR-132 is up-regulated in cardiac tissue of heart failure patients causing an aberrant expression of genes that are crucially involved in cardiac function and lead to pathological cardiac remodeling. By blocking miR-132 with its selective inhibitor

CDR132L, Cardior is able to restore healthy levels of miR-132 and trigger a concerted therapeutic effect against key hallmarks of heart disease including pathological remodeling processes, impaired contractility and fibrosis. CDR132L has the potential to restore heart function thereby prolonging the patient's life span as well as improving quality of life. The candidate is currently under evaluation in the company's Phase 2 HF-REVERT trial and has successfully completed Phase 1b clinical studies demonstrating a favorable safety profile and beneficial cardiac effects in heart failure patients. Results were published in the *European Heart Journal* in 2021.

**About Cardior**
Cardior Pharmaceuticals is a leading clinical-stage biopharmaceutical company pioneering the discovery and development of RNA-based therapeutics designed to prevent, repair and reverse diseases of the heart. Cardior's therapeutic approach uses distinctive non-coding RNAs as an innovative platform for addressing the root causes of cardiac dysfunctions. The company aspires to bring transformative therapeutics and diagnostics to patients and thereby make a lasting impact on the treatment of cardiac diseases worldwide.

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