Press Release

Cardior Pharmaceuticals Announces Positive Phase Ib Results of its Lead Compound CDR132L in Heart Failure

- *First-in-class compound showed excellent tolerability and safety*
- *Unique mode of action in chronic heart failure confirmed by data on cardiac function and biomarkers*
- *Phase II studies in subacute and chronic heart failure planned*

Hanover, Germany, November 12, 2020 - Cardior Pharmaceuticals GmbH, a clinical-stage biotech company focused on the development of non-coding RNA (ncRNA) based therapeutics for patients with cardiovascular diseases, announced today positive results of a Phase Ib study with its lead compound CDR132L. The compound is an antisense oligonucleotide inhibiting the non-coding microRNA-132 (miR132) that directly regulates adverse cardiac remodeling. This first-in-human study was performed in cooperation with Richmond Pharmacology Ltd., London, UK (clinicaltrials.gov: NCT04045405). Results were published in the European Heart Journal (doi:10.1093/eurheartj/ehaa898).

In the trial, CDR132L met all endpoints and showed excellent tolerability and safety. The randomized, double-blind, placebo-controlled, dose-escalating study was designed to assess safety, pharmacokinetic (PK) and pharmacodynamic (PD) properties of CDR132L in patients with stable heart failure (HF) of ischemic origin (NYHA 1-3). The study design combined dose escalation with repeat dosing (day 1 and 28) at 4 dose levels. 28 patients received CDR132L or placebo (5:2 randomized in 4 cohorts) via short-term intravenous infusions as add-on therapy to standard of care.

Primary endpoint was safety and tolerability of CDR132L as assessed during the 120-day study period. The characterization of CDR132L's PK profile in heart failure patients served as secondary endpoint. In addition, the effect of CDR132L on the target miR132 and on certain HF-relevant PD parameters was analyzed in an exploratory manner.

The infusion was very well tolerated by all patients with no injection-related signs. No safety signals or unexpected adverse events were observed for CDR132L. PK data showed strong dose-dependent linearity and specific target engagement could be confirmed. Exploratory analysis of multiple pharmacodynamic parameters, including measurement of NT-proBNP blood levels, showed beneficial effects on top of standard of care and will be used for planning Phase II proof-of-concept studies.

"CDR132L did not show any signs of toxicity regardless of dose level. As expected, the pharmacokinetic characteristics were found to be dose-dependently linear," said Dr. Thomas Thum, Professor at Hannover Medical School and CSO of Cardior. "In addition, the target engagement data confirmed the mode of action of CDR132L. We also observed positive changes of various markers which in our preclinical models were strong signs of efficacy. In sum, the analysis of relevant surrogate pharmacodynamic parameters showed promising beneficial results in these patients, even after only two administrations of CDR132L.

He added that the observed pharmacodynamic effects of CDR132L are planned to be further investigated in upcoming Phase II studies.

“We are very pleased with the outcome of our clinical study, the first-ever trial of an oligonucleotide-based drug in heart failure patients,” said Claudia Ulbrich, CEO of Cardior. “These encouraging results are an excellent basis for starting Phase II studies in subacute and chronic heart failure patients. The outcome of this trial also underlines the potential of RNA-based therapies as a causal approach to treat complex diseases.”

###

About CDR132L

CDR132L is an antisense oligonucleotide developed by Cardior Pharmaceuticals inhibiting the microRNA-132 (miR132), a non-coding microRNA that regulates cardiac hypertrophy and remodeling in cardiomyocytes by targeting well-defined pathways. miR132 is a regulatory master switch to control cardiac function and a promising, causal therapeutic target in heart failure therapy. Expression of miR132 is increased in various pathological cardiac conditions in both animals and humans, and previous preclinical studies have shown that miR-132 is essential for driving the pathological growth of cardiomyocytes.

About Cardior

Cardior Pharmaceuticals is a privately held German biopharmaceutical company pioneering the development of curative and preventive heart failure therapeutics based on non-coding RNAs (ncRNAs). Cardior’s therapeutic approach is using distinctive ncRNA signatures driving the molecular reprogramming that causes maladaptive remodeling and heart failure. Drug candidates developed by Cardior represent first-in-class ncRNA therapeutics and diagnostics for patients with myocardial infarction and various forms of heart failure. Founded in 2016 based on the work of cardiologist Prof. Dr. Dr. Thomas Thum of Hannover Medical School, the Company has raised EUR 15 Mio. from international investors LSP, BioMedPartners, Boehringer Ingelheim Venture Fund (BIVF), Bristol-Myers Squibb (BMS) and High-Tech Gründerfonds (HTGF).

Contact Cardior

Dr. Claudia Ulbrich / Barbara Gaertner-Rupprecht
Cardior Pharmaceuticals GmbH
Feodor-Lynen-Str. 15
30625 Hanover Germany
Tel: +49 511 33 85 99 30

Media Inquiries

akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64
Tel. +49 30 23 63 27 6