

Medera's Novoheart partners with AstraZeneca on First Bioengineered Human Models of Heart Failure

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- Heart failure is a global pandemic affecting at least 64 million people worldwide and costing over US\$100B per year
- Heart failure with preserved ejection fraction (HFpEF) accounts for half of all heart failure cases, and is a growing problem with limited treatment options
- There is a lack of effective human-specific models for preclinical testing of targeted therapeutic candidates for HFpEF
- The Novoheart-AstraZeneca collaboration has successfully generated the world's first bioengineered HFpEF miniature human heart models
- Forced expression of a down-regulated gene product identified in HFpEF reverses the disease phenotype in our bioengineered heart models
- HFpEF mini-hearts could provide a powerful tool for discovery, screening, and advancement to clinical trials of novel therapeutics for heart failure

Medera Biopharmaceutical (Medera), a clinical-stage gene and cell therapy company, and Novoheart, its fully owned subsidiary for disease modelling and drug discovery, together with AstraZeneca, are delighted to announce that their ongoing collaboration has led to the successful development of the world's first human-specific in vitro, functional models of heart failure with preserved ejection fraction (HFpEF), a steadily worsening condition especially common among the elderly.¹

Heart failure (HF) is a global pandemic,² with an increasing trend in prevalence.³ The annual global economic burden of HF is estimated at over US\$100 billion.⁴ HFpEF accounts for approximately [50%](#) of HF cases and is a major and growing public health problem worldwide. However, the pathological mechanisms and diverse causes of HFpEF remain poorly understood. Due to these complexities, previous models of the disease, including various investigational models, have shown limited ability to mimic the clinical presentation of HFpEF.⁵ Therefore, drug developers have lacked predictive tools for preclinical testing of drug candidates for efficacy. As a result, clinical outcomes for HFpEF have hardly improved over the last several decades and limited treatment options are available to patients.

Medera's Novoheart has worked with the Cardiovascular, Renal and Metabolism therapy area of

AstraZeneca to use its proprietary mini-Heart™ Platform for human cardiac tissue engineering to successfully establish novel in vitro models that reproduce key phenotypic characteristics, including relaxation defects, fibrosis and hypertrophy, as seen in HFpEF patients. Also known as “human heart-in-a-jar”, the 3-D human ventricular cardiac organoid chamber (hvCOC) is the only human-engineered heart tissue available on the market that enables clinically informative assessments of human cardiac pump performance including ejection fraction and developed pressure.⁶ Unlike animal models, engineered human heart-in-a-jar can be fabricated with specific cellular and matrix compositions, and patient-specific human induced pluripotent stem cells (iPSCs), that allow control over the physical and mechanical properties to uniquely mimic those observed in HFpEF patient hearts. Novoheart has also developed human cardiac fiber-like HFpEF cardiac tissue strips (CTS) that recapitulate the effects of HFpEF on cardiac muscle stiffness and contractility.

To facilitate the research, Novoheart has also developed CTScreen™ proprietary hardware and software for automation that increases the throughput, accuracy and sensitivity of phenotypic and drug screening experiments using the engineered human heart-in-a-jar and hvCTS assays.

Collectively, these innovative HFpEF human heart models and related tools have provided a unique assay for understanding the mechanisms of HFpEF, identifying new therapeutic targets, and assessing novel therapeutics for treating HFpEF patients. Novoheart exclusively owns the intellectual property rights to the newly developed HFpEF models. This work is being submitted for publication in a peer-reviewed scientific journal.

“These new HFpEF versions of our human heart-in-a-jar and hvCTS assays, developed in our ongoing collaboration with AstraZeneca, demonstrate the capability and versatility of Novoheart’s mini-Heart™ Platform for modelling complex acquired diseases such as heart failure, that are even more challenging than well-defined and rare genetic mutations,” said Novoheart CSO, Dr. Kevin Costa.

Regina Fritsche Danielson, Senior Vice President, Head of Research and Early Development, Cardiovascular, Renal and Metabolism, BioPharmaceuticals R&D, AstraZeneca, said, “At AstraZeneca, we recognize the urgent need to learn more about the underlying mechanisms of HFpEF in our ambition to develop targeted therapies for this population of patients. Our collaboration with Novoheart to build the first in vitro HFpEF models will help us bridge the gap between animal models and clinical trials to accelerate the drug discovery process by providing human-specific preclinical data.”

“The US FDA Modernization Act 2.0 aims to accelerate innovation and get safer, more effective drugs to patients more quickly by encouraging the use of scientifically superior, human-based technologies to replace animal testing for improved human accuracy and therefore better successes. Along this line, we are totally excited about the new HFpEF human mini-heart models. We are now focusing on their translation into tangible patient benefits,” said Medera CEO, Dr. Ronald Li.

¹ [Heart Fail Clin. 2014; 10\(3\):377-388.](#)

² [Lancet 2017; 390\(10100\):1211-59.](#)

³ Lancet. 2018; 392:1789-1858.

⁴ Int J Cardiol. 2014; 171(3):368-76.

⁵ JACC Basic Transl Sci. 2017; 2(6):770-789.

⁶ Biomaterials. 2018;163:116-127.

Medera

Founded in 2014, Medera is a leading clinical-stage company dedicated to next-generation therapeutics for difficult-to-treat and incurable diseases. Medera has two subsidiaries, Novoheart and Sardocor. Novoheart capitalizes on the world's first and award-winning "mini-Heart" Technology for revolutionary disease modelling and drug discovery, enabling us to uniquely model human-specific diseases and discover therapeutic candidates free from species-specific differences. Before privatisation by Medera, Novoheart was dually listed on the Toronto Stock Exchange and Frankfurt Stock Exchange. Sardocor aspires to create the shortest regulatory path to clinic for advancing next-generation cell and gene therapies. Building upon Novoheart's bioengineered human tissue-based assays for disease modelling and drug discovery, Sardocor has developed one of the world's largest gene and cell-based therapeutic pipelines for a range of cardiac, vascular and muscular diseases including heart failure with preserved ejection fraction, Duchenne muscular dystrophy and pulmonary hypertension. For more information, visit www.medera.bio.

AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit www.astrazeneca.com.

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