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Renovacor Announces Data from Pilot Pig Study Showing Successful Cardiac Transduction with REN-001 Delivered Via Low-Dose Retrograde Coronary Sinus Infusion Published in Journal of the American College of Cardiology: Basic to Translational Research

REN-001 delivered locally via low-dose retrograde coronary sinus infusion demonstrated robust, diffuse cardiomyocyte transduction in a large animal heart

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Renovacor, Inc. (NYSE: RCOR), a biotechnology company focused on delivering innovative precision therapies to improve the lives of patients and families battling genetically-driven cardiovascular and mechanistically-related diseases, today announced the publication of the results of a preclinical study demonstrating cardiac transduction with low-doses of REN-001 delivered via retrograde coronary sinus infusion (RCSI) in healthy Yucatan pigs. The paper, titled, “Cardiac Transduction in Mini-Pigs After Low-Dose Retrograde Coronary Sinus Infusion of AAV9-BAG3: A Pilot Study,” was published in the peer-reviewed *Journal of the American College of Cardiology: Basic to Translational Science (JACC: BTS)*.

REN-001 is an AAV-based gene therapy designed to directly address the underlying cause of *BAG3*-associated dilated cardiomyopathy (*BAG3-DCM*) by using a validated AAV9 capsid to deliver a functional copy of the *BAG3* gene to cardiac tissue. In the pilot Yucatan pig study featured in *JACC: BTS*, low doses (<1e13 vector genome (vg) per kilogram (kg)) of REN-001 delivered locally to the heart using RCSI resulted in each evaluated cardiomyocyte containing, on average, at least one copy of the delivered *BAG3* gene (i.e., vector copy number threshold ≥1). The study also demonstrated diffuse transduction patterns across multiple regions of the heart and documented the presence of vector mRNA / transcript. Additionally, all animals tolerated the procedure without evidence of heart injury (e.g., arrythmia, presence of myocardial scar, or coronary sinus injury at necropsy).

The pilot Yucatan pig study published in *JACC: BTS* included three dose groups. Group A evaluated a 1.46e12 vg/kg dose, Group B evaluated a 3.45e12 vg/kg dose and Group C evaluated a 7.58e12 vg/kg dose (based on median pig weights for each group). Levels of vector genomes and corresponding RNA transcripts were quantified. A summary of the data is shown below.

Group	Vector Genomes/Porcine Cardiomyocyte (mean ± SEM)	Vector Transcripts* (Relative Quantities; mean ± SEM)
Group A (n=4)	0.7 ± 0.2	4.1 ± 1.0
Group B (n=2)	2.0 ± 0.8	9.0 ± 4.5
Group C (n=1)	1.3	8.5

*Vector mRNA was assessed using qPCR targeting vector cDNA and expressed as relative quantities (rq) to the 18S housekeeping gene

“We believe this publication provides important validation of the RCSI delivery method, which is a key differentiator of our REN-001 program,” said Marc Semigran, M.D., Chief Medical Officer of Renovacor and a co-author of the paper. “By delivering vector directly to the heart via the coronary venous circulation using a percutaneously placed catheter, we observed what we believe to be clinically therapeutic levels of cardiomyocyte transduction by our viral vector at lower doses than those used for systemic delivery of AAV gene therapies for other genetic diseases. We believe that RCSI delivery of our gene therapy candidate has the potential to provide safety and manufacturing advantages compared to systemic approaches, which may require higher vector doses to attain similar levels of cardiac transduction as those seen in this animal study. We look forward to advancing REN-001 by using the learnings from the newly published pilot study and are working expeditiously towards a planned IND application submission in the second half of the year.”

Arthur M. Feldman, M.D., Ph.D., Renovacor’s founder, Laura H. Carnell Professor of Medicine at the Lewis Katz School of Medicine at Temple University, and the paper’s senior author added, “The transduction levels achieved with low-dose RCSI in this pre-clinical study are promising and we believe strongly support the advancement of REN-001 into the clinic. Over 80% of *BAG3-DCM* patients have truncating variants of the *BAG3* gene, which reduce levels of functional *BAG3* protein in the heart. We believe the data showing successful cardiac delivery and transcription of *BAG3* in Yucatan pigs provide strong evidence of REN-001’s ability to potentially correct this genetic abnormality. Given *BAG3*-DCM’s devastating nature and the lack of effective therapies, this represents an important step toward addressing an urgent unmet medical need.”

This paper was published, in its entirety, in the June 2022 issue of JACC: BTS. The paper will also be published, in its entirety, in the September 2022 issue of JACC: BTS that is dedicated to DNA and RNA cardiovascular therapeutics.

About Renovacor

Renovacor is a biotechnology company focused on delivering innovative precision therapies to improve the lives of patients and families battling genetically-driven cardiovascular and mechanistically-related diseases. The company’s lead program in *BAG3*-associated dilated cardiomyopathy (DCM) uses gene transfer technology to address the monogenic cause of this severe form of heart failure. Renovacor’s vision is to bring life-changing therapies to patients living with serious genetic cardiovascular and related diseases, by developing medicines that target the underlying cause of disease and provide a transformative benefit and significant improvement to quality of life.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of the “safe harbor” provisions of the United States Private Securities Litigation Reform Act of 1995, as amended, including statements regarding the anticipated development of Renovacor’s product candidates and clinical development timelines. These forward-looking statements generally are identified by the words “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “strategy,” “future,” “opportunity,” “plan,” “may,” “should,” “will,” “would,” “will be,” “will continue,” “will likely result,” and similar expressions. These forward-looking statements are based upon current estimates and assumptions of the Company and its management and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: competition, the ability of the company to grow and manage growth, maintain relationships with customers and suppliers and retain its management and key employees; the Company's ability to successfully advance its current and future product candidates through development activities, preclinical studies and clinical trials and costs related thereto; the

timing, scope and likelihood of regulatory filings and approvals, including final regulatory approval of our product candidates; changes in applicable laws or regulations; the possibility that the Company may be adversely affected by other economic, business or competitive factors; the Company's estimates of expenses and profitability; the evolution of the markets in which the Company competes; the ability of the Company to implement its strategic initiatives and continue to innovate its existing products; the ability of the Company to defend its intellectual property; the impact of the COVID-19 pandemic on the Company's business, supply chain and labor force; and the risks and uncertainties described in the "Risk Factors" section of the Company's annual and quarterly and reports filed the Securities Exchange Commission. These filings identify and address important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and Renovacor assumes no obligation and does not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. Renovacor gives no assurance that it will achieve its expectations.

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