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Application Review Subcommittee (ARS)
Independent Citizens Oversight Committee (ICOC)
California Institute for Regenerative Medicine (CIRM)

Re: TRAN1-15291: Pro-regenerative infusible extra-cellular matrix (iECM) biomaterial for treating acute myocardial infarction

Dear ARS and ICOC Members,

I am writing to request funding for TRAN1-15291 during the current review cycle. We are in a unique position at the current time to accelerate our pro-regenerative Infusible Extracellular Matrix (iECM) biomaterial into acute myocardial infarction (heart attack) patients. Below I explain the reasoning why this project warrants funding at this time.

Uniquely related to the timing of this grant, last month (September) Ventrix Bio, Inc., our collaborator and subcontractor for manufacturing on the TRAN1-15291 application, was awarded an NIH National, Heart, Lung, Blood Institute (NHLBI) SBIR grant, in which I serve as Co-investigator, to further support development of the iECM product in myocardial infarction patients (1R44HL169072). The SBIR grant is funded from September 2023 to July 2025.

If TRAN1-15291 is funded at this time, both UC San Diego and Ventrix, are in a unique position with complimentary grants that would quickly accelerate the preclinical development of the product. In our experience, a limiting step for finalizing preclinical work and submitting an IND is performing biocompatibility analysis on product that is manufactured according to the scaled up, eventual cGMP manufacturing process. TRAN1-15291 provides key funding for developing the manufacturing of the iECM product that is not possible under the NIH SBIR guidelines. Funding TRAN1-15291 now will enable us to do all preclinical studies under both TRAN1-15291 and the SBIR using an engineering batch of iECM that is produced with the same process for the final clinical grade material.

Based on our history with a similar product, VentriGel, which is regulated as a biologic by CBER, not as a medical device, TRAN1-15291 will accelerate our IND filing and path to patient by at least 12 months. In addition, by working with Ventrix who are in the process of licensing the IP from UC San Diego for the iECM, we can reduce the budget for TRAN1-15291 by ~$125,000 Direct Costs by eliminating extra biocompatibility analysis that would need to be repeated later with manufactured material if TRAN1-15291 is funded at a later time.

It is our understanding that TRAN applications have been funded with similar scores in the past. For example, in the very recent review cycles TRAN1-13996 received a final score of 83 with 6 votes for funding and TRAN1-14710 received a score of 80 with 5 votes for funding; both were approved for funding. Our application received a final score of 83 with 5 yes votes for funding. In addition, in our discussions the CIRM Alpha Clinic at UC San Diego, they are very interested in cardiovascular products, as they mentioned there is a lack of cardiovascular products funded by CIRM in the clinic. Therefore, this project would fill a major gap given the high prevalence of myocardial infarction amongst Californians.

We truly appreciate your consideration during this funding cycle. In short, we believe we have a very unique opportunity to accelerate iECM into patients through the synergy with current SBIR funding that can accelerate product development by 12 months or more. This benefits the State of California by allowing project acceleration to patients for an indication with high prevalence and one that is not well represented currently in the CIRM portfolio. Furthermore, this can be accomplished with a reduction in the TRAN1 budget. This opportunity may be lost if funding is delayed by 6 months on a resubmittal.

Thank you in advance for your consideration.

Sincerely,

Karen L. Christman, PhD
Professor of Bioengineering
Associate Dean for Faculty Affairs & Welfare
Jacobs School of Engineering
University of California San Diego