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February 15, 2024

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

Re: CLIN1-16396: Injectable pro-regenerative biomaterial for the treatment of patients with symptomlimiting intermittent claudication

Dear ICOC and ARS Members,

I am writing to request that the submitted grant application CLIN1-16396 be reviewed as originally intended for the February 29 CLIN1 deadline.

Broadly, I would like to advocate that CLIN1 grants be allowed to continue and not cause a big pause in the momentum of translating new technologies to patients. The pandemic put many trials on hold or delayed them and we are now finally gearing back up. It would be a shame to see a further delay in the translation of regenerative medicine therapies to patients especially for those technologies that have already been in the CIRM pipeline (i.e. through previous TRAN and CLIN1 grants).

In my particular case, this is a revised application (original submission was CLIN1-14768) that is the next stage in development after a successful TRAN grant (TRAN1- 09814). Our proposal seeks to obtain an IND for a cost effective, minimally-invasive, regenerative biomaterial therapy for treating patients with peripheral artery disease, which has a significant disease burden in California and nationwide. Although the initial review last year was a Tier 3, we were able to easily address all of the reviewer comments since the original submission. Over the past several months I continually updated CIRM on when to expect the resubmission, including late November and late January. After submitting the finished proposal on February 12 for feedback, I was notified on February 13 of the memo to the board proposing to suspend the CLIN1 program. While I would like to advocate for not suspending the program in general as mentioned above, I would like to respectfully request that if the program is to be suspended, it be done after the Feb 29 deadline and/or accept all resubmissions. I am sure many groups in addition to ours spent significant time and effort on proposals over the past month, which would be wasted if their applications are not allowed to be reviewed as planned.

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