CIRM CLIN2 Wound Healing grant script

Hi, my name is Antoni Ribas and I am a professor of medicine at UCLA. We have submitted a full length CLIN2 proposal twice since the priorities were established, and both times the 82-page grant has been returned without scientific review.

The proposal is to conduct a first-in-human clinical trial of a topical therapy for wound healing. The treatment target is the stimulation of skin stem cells. One percent of Californians have chronic leg wounds, with higher incidence in marginalized populations. There is no existing drug therapy for this condition, and we propose to clinically develop a gel that regenerates skin stem cells.

The mechanism of action is based on a pharmacological property of a class of drugs to treat the skin cancer melanoma. It was noted that they had a peculiar side effect of making skin cells proliferate. Therefore, we hypothesized that we could take this side effect and turn it into a treatment for skin wounds if we applied the drug topically.

We tested this mechanism of action in four mouse models and in minipigs, and in all cases the topical therapy accelerated wound healing, including in a diabetic mouse model.

Based on this data we were granted a CLIN1 grant from CIRM that has allowed us to produce 70 Kg of the clinical grade LUT017 gel. The grant was for $5M and we achieved all four milestones, which included 9 drug metabolism and pharmacokinetic studies, and 20 toxicology studies. These investigator new drug-enabling studies led to the successful IND filing with the FDA, and getting approval by the UCLA institutional review board to initiate the phase 1 clinical trial.

We organized our CLIN2 application to seamlessly move from the phase 1 to a randomized cohort study to obtain fast track approval by the FDA, with the goal of bringing this therapy to Californians as soon as possible. We included in the CLIN2 application a detailed affordability and commercialization plan designed with our collaborators at the UCLA Anderson School of Management.

However, none of this was scientifically reviewed by CIRM, as we were told we only met two preferences, building on a prior CIRM grant and being in California, and therefore the grant did not fit the CIRM preferences to be reviewed. Why would an already manufactured gel using prior CIRM funding not get a preference for being affordable? If the goal of CIRM is to develop regenerative medicines for diseases that affect Californians, why would this grant only check two preferences checkboxes and not be reviewed scientifically?