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Subject: Public Comment – ICOC Board meeting

Dear Chairman Imbasciani and ICOC members,

My name is Cristina Puig Saus, and I'm an Assistant Professor at UCLA and a California resident. I write to the Board to provide public comment regarding the impact of CIRM's new funding preferences. My laboratory has developed a potent CAR-T cell therapy targeting TYRP1, a treatment designed for patients with cutaneous and rare melanomas, including acral, mucosal, and uveal melanoma. Cutaneous melanoma is caused by exposure to ultraviolet radiation; its incidence rises annually, and it is the third most common cancer in young adults. Notably, sunny California is among the highest-risk states in the US for melanoma. Despite the success of current treatments, 770 Californians will die this year from cutaneous melanoma. In addition, rare melanomas, which disproportionately impact minority populations, present high mortality rates due to poor responses to standard treatments and a lack of curative therapeutic options for these diseases. Furthermore, due to the low incidence of these rare melanomas, investment in the development of therapeutic approaches specifically targeting their biologic vulnerabilities is scarce.

With the support of a \$6M CIRM-TRAN1 grant, we have demonstrated that the TYRP1 CAR-T cell therapy is effective and safe, and developed a robust CAR-T cell therapy manufacturing protocol. With CIRM's support, we have successfully completed 10 efficacy studies, demonstrating robust CAR-T cell activity *in vitro* and *in vivo* across multiple patient-derived melanoma models. These studies utilized cells manufactured from 14 different healthy donors and 6 patients with melanoma. We have successfully completed 6 safety studies, including, among others, complete toxicology and histopathology studies in immunocompetent mice and cross-reactivity studies in human tissues. Finally, we have manufactured a GMP vector, qualified a GMP-compliant TYRP1 CAR-T cell manufacturing protocol, and developed a screening assay to select patients with high TYRP1 expression for inclusion in the phase 1 clinical trial. We completed a highly successful pre-IND meeting with the FDA and have minimal and feasible studies pending to execute before IND submission.

Our project was scientifically reviewed and deemed highly meritorious to advance the development of therapies to improve Californians' health. We have successfully achieved all proposed milestones, and the disease indication remains a high unmet medical need. Despite our accomplishments and the state of the field, we have submitted two Late PDEV pre-applications that have been triaged, without scientific review, based on CIRM's new funding preferences. Despite the prior investment in time and money, and the successful results obtained to date,

CIRM's preferences no longer align with autologous and virally engineered T-cell therapies for cancer treatment, a therapeutic approach extensively validated in other cancer types, with eight commercially available products. Given the current state of academic research funding, this new therapy for Californians will likely not proceed to clinical testing without CIRM support. I urge the ICOC board to conduct an objective review of the potential clinical impact lost by projects excluded due to the new funding preferences, and to reconsider the method by which proposals are selected for scientific review.

Thank you very much for your time and consideration.

*Cristina Puig Saus*

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