

November 19, 2021

California Institute for Regenerative Medicine (CIRM) 1999 Harrison Street, Suite 1650 Oakland, CA 94612

RE: Application Review Subcommittee Meeting for TRAN1-12889 Application

Dear Members of the Independent Citizens Oversight Committee,

I am leading the CMC program at Ray Therapeutics. By way of background, I have over thirty years of global experience in biologics product development from concept to market approval. In 2000 as CEO and co-founder I established a CDMO building world class biologics development and clinical manufacturing facilities before a trade sale to Watson Pharmaceuticals Inc. Most recently, as Allergan's SVP Biologics and Small Molecule R & D I had accountability for all aspects of process development managing laboratories in Irvine, Ca, Madison NJ and Liverpool UK. Relevant to Ray-001 this included leading CMC teams engaged in optogenetics and CRISPR-Cas9 viral gene therapy. During my time in Allergan I had the opportunity to meet patient advocates that exposed me to the life challenges patients face with these conditions hence I am very motivated and excited to be working with the Ray team.

Paul Bresge, CEO of Ray Therapeutics, has asked me to attend the subcommittee meeting on November 23rd to address any questions you may have regarding Ray's revised development timelines, which reflect real-time information from our CDMO partner. I understand that I will only have three minutes to speak about our current plans for Ray-001, so I thought that it would be best to provide our updated project schedule in advance. Please see the following page.

I look forward to the subcommittee meeting and hope that Ray receives funding for this important therapy.

Sincerely,

Crawford Brown, PhD Ray Therapeutics



	Activity	2021	2022	2023	2024
In Scope Activities for TRAN1	Mouse dose range/safety				
	NHP Safety and Biodistribution				Future GLP Phase
	In Vitro human retinal explant study				
	CDMO Contracting	\square			
	Research Grade Plasmids				
	Process Development				
	GMP Source Plasmids				
	Process Scale-up				
	Analytical Development				
	CDMO Audit				
	Tox Batch				
	Stability				
	Compatibility Studies				
	Process and Specification Lock				
	Process Confirmation Batch				
	Clinical Batch				
	Clinical Development Planning				
	Pre-IND prep and meeting				
	3-month mouse tox				
	6-month NHP tox	F	uture GLP Phase		
	IND prep, submission				