

CALIFORNIA'S STEM CELL AGENCY

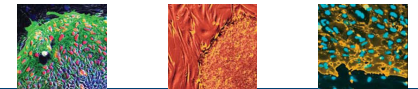


CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Bridging Supplement Awards

**ICOC Meeting, July 24, 2014
Agenda Items #11, 12**

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Bridging Supplement Awards



- In December 2011, the ICOC approved a total of \$12 MM for Bridging Supplements
- Program Goal: Accelerate development of stem cell therapies by providing a funding mechanism for the efficient and seamless advancement of promising CIRM-funded translational and development projects towards and through clinical development
- A “bridge” to future funding.

Bridging Supplement



- **Project Eligibility and Scope**
 - Open to promising projects from CIRM translational and development awards programs
 - Show good progress on project
 - Active at time of CIRM approval for submission of a full application
 - CIRM is particularly interested in promising projects that address an unmet medical need
- **Award Features**
 - Funding
 - Up to \$ 3MM for individual total project costs, in exceptional circumstances, more routinely, less than \$1MM for up to 12 months.
 - \$12 MM allocated to program

Bridging Supplement: Application & Review Process



- PI submits a brief proposal that summarizes the proposed research and addresses how it meets the goal of the bridging funding program
- Proposal assessed internally by staff for eligibility and responsiveness
- CIRM President makes decision to invite submission of a full application upon review of proposal and with staff input.
- If invited, PI submits full application
- Full application is reviewed by:
 - External experts if proposed activities are within scope of original award/RFA
 - GWG if proposed activities are outside of scope of the original award/RFA, or, if requested funding of \geq \$1MM
- ICOC Application Review Subcommittee makes funding decision

Bridging Supplement: Review Criteria

- Review criteria include:
 - Impact, Significance and Responsiveness
 - Feasibility and Design
 - Team, Assets, Collaborations, Resources and Environment
 - Additional specific criteria may apply depending on the nature of the proposal

BF1-01768

- Parent Award: Develop an animal component - free culture system for expansion of autologous limbal stem cells (LSC) to treat limbal stem cell deficiency, a blinding eye disorder caused by corneal injury
- Request for bridging funding to conduct studies to further assess and optimize reproducibility of key components for LSC expansion
- Requested funding: \$699,983
- Reviewed by external experts (n=3); average score 80; Tier 1
- CIRM recommendation: Fund
 - Clinically validated approach ex-US.

BF1-01841

- Parent award: Identify an hESC-derived neural stem (NSC) or progenitor development candidate (DC) to treat Huntington's Disease (HD), a neurodegenerative disease for which there are no disease-modifying treatments
- Request for bridging funding to test the hESC-NSC DC
 - to further establish dose range
 - in models of HD that have a slower onset to assess over time cell survival and functional outcomes
- Requested funding: \$505,717
- Reviewed by external experts (n=4); average score = 72
➔ Tier 2

BF1-01841

- CIRM recommendation: Fund
 - Further strengthens encouraging results achieved to date
 - 1 of 3 portfolio projects targeting HD; approach and mechanism distinct

Bridging Fund – Request for Funding Approval



- BF1-01768 - \$699,983
- BF1-01841 - \$505,717