SOMETHING BETTER THAN HOPE

GWG Recommendations

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July 10, 2020



COVID-19 Program

- Given the urgent need to develop treatments for COVID-19, CIRM launched a solicitation in support of promising discovery, translational, preclinical and clinical trial stage projects that could quickly advance treatments to patients in need.
- CIRM is utilizing its established partnering opportunities in Discovery (DISC1, DISC2), Translational (TRAN1), and Clinical (CLIN1,CLIN2) stages to facilitate the application, review and funding process.
- The CIRM Governing Board approved a total allocation of \$5 million to support this new program.

COVID-19 Program

Support under the DISC2, TRAN1, CLIN1, and CLIN2 program announcements is provided with the following award limitations:

| Project Stage | Specific Program | Award Amount* | Award Duration |
|---------------------------|------------------|---------------|----------------|
| Clinical trial | CLIN2 | \$750,000 | 24 months |
| Late stage preclinical | CLIN1 | \$400,000 | 12 months |
| Translational | TRAN1 | \$350,000 | 12 months |
| Discovery | DISC2 | \$250,000 | 12 months |
| Early Discovery | DISC1 | \$150,000 | 12 months |

*Award limits are for Total Funds Requested (i.e., limit includes direct facilities costs and indirect costs)

COVID-19 Program

All projects must propose to achieve a clear deliverable within <u>six months</u> of project initiation to demonstrate progress toward the goal.

| Program | Ready to Start | Six-Month Goal | |
|---------|--|--|--|
| CLIN2 | IND filed/approval to treat patients | Initiate enrollment and data collection | |
| CLIN1 | Pre-IND with FDA completed | File IND with FDA | |
| TRAN1 | Therapeutic candidate w/ disease-modifying activity | Conduct pre-IND or equivalent interaction w/ FDA | |
| DISC2 | Proposal to identify a candidate for development | Have data for a viable candidate that could progress quickly to the clinic | |
| DISC1 | Great new idea | Data to confirm or reject hypothesis | |

Addressing Needs of the Underserved

- COVID-19 has a disproportionate impact on minority and underserved communities in California and the nation.
- CIRM clinical trial (CLIN2) projects are already required to include a plan for outreach and inclusion of minority and underserved populations in their studies.
- CIRM is asking all other applicants how their overall study plan and design has considered the disproportional impact of COVID-19 on underserved populations and the limitations, advantages and/or challenges of the proposed study in developing a product or tool that will broadly serve all populations.

GWG Recommendations

| | Number of Apps | Total Applicant Request | Funds Available |
|--|-------------------|----------------------------|--------------------|
| Recommended for funding Score 85-100 | 2 | \$399,999 | \$922,356 |
| Not recommended for funding Score 1-84 | 6 | | |

For each award, the final award amount shall not exceed the amount approved by the ICOC Application Review Subcommittee and may be reduced contingent on CIRM's assessment of allowable costs and activities.

Recommended Applications

| Application | Score (Median) | Project Type | Therapeutic Product | Applicant Request |
|------------------------|-------------------|-----------------|------------------------|----------------------|
| DISC1COVID19- 12047 | 90 | Discovery | Biologic | \$150,000 |
| DISC2COVID19- 12022 | 90 | Discovery | Small molecule | \$249,999 |