CALIFORNIA'S STEM CELL AGENCY

TO: Members of the Science Subcommittee of the ICOC

FROM: C. Scott Tocher, Deputy General Counsel

DATE: September 2, 2016

RE: ATP3 Review Steps

Executive Summary

The Grants Working Group ("GWG") will meet in the first quarter of 2017 to evaluate applications for the "Accelerating Therapies: Public-Private Partnership" program, known as ATP3. The GWG and Application Review Subcommittee's review of applications for the ATP3 award and subsequent in-licensed projects will occur in two steps. The goal of the first review will be to identify and select a single awardee, referred to as "Newco." The review of projects that Newco seeks to in-license will occur at subsequent reviews once those projects are identified by Newco. The level of GWG review of the in-licensed projects will depend on the status of the project to be licensed, as described below.

Step 1 – Identifying Newco – Making the Award

The GWG will convene to review applications for the ATP3 award and make funding recommendations to the Application Review Subcommittee, which will choose a single awardee. The primary focus of the GWG will be to weigh the qualifications of the team and the proposed business plan, including an assessment of the team's ability to execute the business plan. The review will de-emphasize discussion of specific CIRM projects to avoid the distraction of a scientific evaluation of such projects. That being said, potential Newco applicants will be required to present a business plan that describes their strategy for bringing regenerative medicine therapies to the market and they will be encouraged to examine CIRM's portfolio and engage in preliminary discussions with CIRM awardees to ensure the Newco awardee will be able to proceed rapidly to in-license and advance projects toward commercialization. Shifting the scientific evaluation of specific projects to a future review will allow the GWG to focus on whether: (1) the qualifications of the proposed management team; (2) applicants have put forth a viable business plan to achieve the objectives of the RFA and have an appropriate strategy for in-licensing CIRM-funded technology to create a compelling value proposition; and

(3) the business plan is likely to create value for both patients and shareholders, and will support growth of the business beyond the five-year award period.

Step 2 – In-Licensed Projects Review

After the Application Review Subcommittee has made the award to Newco, Newco will be encouraged to expeditiously identify specific CIRM projects to in-license. Development milestones will be agreed to in the Research and Financing Agreement to ensure that Newco adheres to appropriate timelines for in-licensing projects. All proposed projects for in-licensing must undergo a review by the GWG, and the Application Review Subcommittee, as follows:

1. Bucket 1 – Active New Projects: Active CIRM-funded projects that have been approved by the Application Review Subcommittee within the preceding 12 months will not require a new GWG review unless CIRM, in its sole discretion, determines that a review is warranted based on the status of the project, in which case the project will be subject to a good-standing review, described in paragraph (2).

2. Bucket 2 – Active Mature Projects: Active CIRM-funded projects approved by the Board more than 12 months earlier will require a new GWG review, limited to the question of whether the project is in good standing, e.g., has met or is on target to meet milestones, or if the project has not met milestones, has a viable path to accomplish them.

3. Bucket 3 – Non-CIRM or Inactive Projects: These projects will be subject to a full GWG CLIN-style review if Newco wants to use CIRM ATP3 funds – limited to $75m.

Requested Action: CIRM requests the Science Subcommittee recommend the ICOC approve this policy for the review of ATP3 applications and subsequent in-licensing of projects.