



M E M O R A N D U M

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From: Ellen G. Feigal, M.D., Senior Vice President, Research and Development
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To: Science Subcommittee, Independent Citizens Oversight Committee (ICOC)
Subject: Modification proposed for Strategic Partnership II

The specific modification to the approved concept (concept was approved by the ICOC on October 26, 2011 and amended on September 6th, 2012) is to **keep the total award amount per project at \$10M, but to allow the possibility to increase the award to \$15M per project, subject to ICOC approval and only under exceptional circumstances, and would have to be accompanied by budget and justification.**

The intent of the Strategic Partnership program is to create incentives and processes that will: (i) enhance the likelihood that CIRM-funded projects will obtain funding for Phase 3 clinical trials (e.g. follow-on financing), (ii) provide a source of co-funding in the earlier stages of clinical development, and (iii) enable CIRM- funded projects to access expertise within pharmaceutical and large biotechnology partners in the areas of discovery, preclinical, regulatory, clinical trial design and manufacturing process development.

The current concept directs CIRM to implement the program using a standard Request for Application process that has a defined submission period. Each RFA will define the scope of funded research which may be narrower than the currently approved concept scope which encompasses a broad range of research from basic to phase 2 clinical studies. The Strategic Partnership concept contains two unique features, in addition to the twice yearly solicitations, that distinguish it from the Disease Team concept. The Strategic Partnership i) requires applicants to show evidence of either having the financial capacity to move the project through development, or of being able to attract the capital to do so (commercial validation) and ii) requires co-funding from the applicant and/or their strategic partner, regardless of the stage of research.

The first RFA under the Strategic Partnership initiative (RFA 12-05: Strategic Partnership I) is anticipated for ICOC consideration on October, 25 2012. This program will issue repeat calls approximately every 6 to 9 months in fiscal year 2013.

Active management of these milestone-driven projects will include discussion with CIRM's Clinical Development Advisory Panel (CDAP) at key decision points, such as the transition from IND filing to initiation of a clinical trial.