CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

M E M O R A N D U M

TO: Members Of The Independent Citizens Oversight Committee

FROM: Patricia Olson, PhD

SUBJECT: Consideration of Extraordinary Supplement Award To Viacyte Inc.

DATE: December 3, 2012

Background

On October 25, 2012, CIRM's governing board, the Independent Citizens Oversight Committee ("ICOC"), approved the concept proposal for Extraordinary Supplements to Existing Awards. The concept provided for "Level 1: Minor Supplements" as well as "Level 2: Major Supplements." The Level 2: Major Supplements are intended to "support grantees [in order] to enhance the probability of conversion of funded projects to unexpected and transformational benefits, and raise projects to a high probability of clinical benefit." This award provides for up to $3 million. CIRM is proposing that a Level 2 Major Supplement award in the amount of $3 million be provided to Viacyte.

In 2010, Viacyte received a Disease Team I award in the amount of $20 million. The Disease Team 1 program is developing a human embryonic stem cell derived therapy for patients with Type 1 diabetes, and at its periodic assessments by CIRM's Clinical Development Advisor panel, the program has received strong endorsement for the outstanding caliber of its progress. At the May 2012 CIRM presentation to the ICOC on the progress of the 14 Disease Team I programs, CIRM noted there would be a need for supplement funding to

the Viacyte Disease Team I award to enable them to continue their strong progress towards filing an IND to enter first in human clinical trials. In September 2012, Viacyte's Strategic Partnership 1 application, building upon the progress from its Disease Team 1 award and defining the activities needed to advance towards completing an early phase clinical trial and clinical proof of concept, was reviewed by the Grants Working Group. It received the highest scientific score, with the Grants Working Group noting the project was the "holy grail" of diabetes treatments. At the October 2012 ICOC meeting, Viacyte was awarded $10M under the Strategic Partnership I program. Applicants were qualified under the Strategic Partnership RFA by showing evidence of (i) having raised $15M in the past two years and having one year of operating cash or (ii) having a term sheet or letter of intent entered into with a biopharmaceutical company for joint development. Pursuant to the RFA, funding will not be disbursed until execution of the joint development agreement.

At the October 25th ICOC meeting a representative from GlaxoSmithKline (GSK) acknowledged ViaCyte's "tremendous progress in [the] field" and informed the Board that GSK had already conducted "intense technical and financial diligence of the program [which was] reviewed by multiple [GSK] committees" and that pending final approval, GSK was interested in "an alliance to enable GSK, ViaCyte and CIRM to progress the program." We have recently been informed that GSK was not able to obtain the final approval required due to business reasons in the context of GSK's overall research and development portfolio and investment needs and not as a result of any scientific or technical assessment of ViaCyte's program.

Most recently, on November 29, 2012, Viacyte was assessed at its regularly scheduled session with the Clinical Development Advisory Panel ("CDAP"). Again, the advisors were extremely positive, stating that the program is viewed as one of the top programs they have seen, with an ability to establish early in clinical development proof on concept and with a strong potential to proceed to a commercial therapeutic. The CDAP strongly recommended providing supplemental funding in order to ensure that the project stays on the critical path while additional funding sources are secured.

Description of Project Status and Proposed Use of Funded Activities

Viacyte's therapeutic approach involves differentiation of human embryonic stem cells into pancreatic progenitor cells. These cells are encapsulated in a device that protects them from immune rejection when implanted subcutaneously into patients, where they mature into pancreatic cells that secrete insulin in response

to glucose.

Viacyte has recently held a pre-IND meeting with the FDA prior to conducting critical activities for filing an approvable IND in approximately 12 months. The FDA had some specific recommendations for activities to be undertaken and/or completed prior to IND filing. These activities were discussed by CDAP with Viacyte in the November 29 meeting, endorsed by the CDAP and it is these activities that the requested supplement would be used to fund over a period of approximately six months.

Recommendation

Following endorsement by the Clinical Development Advisors, CIRM recommends that a Level 2 Major Supplement in the amount of $3M be awarded to Viacyte so that it may continue to conduct research that is on the critical path for an IND, as recommended by the FDA in its recent pre-IND meeting.