

## MEMORANDUM

Date: May 18, 2012

From: Alan Trounson, PhD CIRM President

To: Independent Citizen's Oversight Committee

Subject: Extraordinary Petition for Application TR3-05730

Enclosed is a petition letter from Drs. Christopher Reyes and Peter Chu of Eclipse Therapeutics, an applicant for funding under RFA 11-02, CIRM Early Translational III Awards. This letter was received at CIRM on May 17, 2012 and we are forwarding it pursuant to the ICOC Policy Governing Extraordinary Petitions for ICOC Consideration of Applications for Funding.



## Dear CIRM ICOC:

## Re: RFA 11-02 TR3-05730: Monoclonal antibody therapeutic targeting human cancer stem cells

We are filing an extraordinary petition requesting special consideration for our RFA 11-02 grant TR3-05730 that recently scored a 58 and was not recommended for funding by the CIRM GWG.

This letter addresses the extraordinary circumstance that supports approval of this grant. This project is a highly innovative and unique opportunity for targeting a cancer stem cell (CSC) receptor that plays a key functional role in colorectal cancer (CRC) and many other important solid tumors. Our goal is to drive this project to clinical proof of concept in a Phase II clinical trial in four years and we would like to partner with CIRM to accomplish this.

**Extraordinary Circumstance:** Eclipse is a spin-out of Biogen Idec's oncology franchise. Our lead antibody CSC drug program began in 2004, and is the result of 3 years of basic CSC biology research and assay development plus an additional 4 years of target-focused discoveryphase drug research. This **research benefitted from millions of dollars of investment by Biogen Idec and a team of 15 scientists**. The project was reviewed and recommended for advancement on an annual basis by senior management under a highly competitive selection process. In 2010, Biogen Idec made a strategic business decision to end all oncology R&D. At the time we submitted this application, Eclipse had just completed a licensing and assignment agreement with Biogen Idec (10/26/11) for rights to all CSC assets from this research program. Material was transferred to our laboratories in San Diego in late November 2011. Therefore, we submitted our application in the wake of securing the CSC research assets from Biogen Idec, and just as our team initiated key CSC experiments relevant to this grant.

In the last 6 months since program materials were transferred to Eclipse, we have made **significant progress in generating data addressing the key issues brought up by the reviewers** - most specifically, confirming in multiple experiments that our lead antibody does indeed target cancer stem cells in vivo. In fact, we have already accomplished all of the **activities outlined in Milestone 1 including identification of a lead therapeutic candidate** and a number of activities from Milestones 2 and 3 of our grant application. We sent an email to CIRM on April 16, 2012 requesting to add this new data, but the application had already been reviewed.

Our progress has allowed us to accelerate our IND filing date by 1 year (**now H1 2014**). As such, <u>the budget needs for this grant will be reduced from the original \$3M.</u> This progress has been made possible by our ability to successfully raise \$2M of seed investment and the subsequent assembly of a top-notch team with specific expertise in cancer stem cell biology (**> 20 years combined cancer stem cell research experience**) and drug discovery (**>35 years combined industry experience**). Collectively, our Eclipse employees have led projects that have resulted in more than **15 INDs and 8 FDA approvals**, not including our highly expert panel of consultants and scientific advisors.

Eclipse has demonstrated the vision and track record to accomplish our drug development goals, and we welcome the opportunity to partner with CIRM to benefit cancer patients on this important therapeutic program.

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Thank you for your kind consideration and we look forward to your decision.

PI: Peter Chu, PhD President, Eclipse Therapeutics

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Co-PI: Christopher Reyes, PhD CSO, Eclipse Therapeutics