UPDATED APPENDIX C¹: COLLABORATIVE FUNDING PARTNER OVERVIEW AND CONTACT INFORMATION: CANCER STEM CELL CONSORTIUM, CANADA

THE FOLLOWING MATERIAL IN UPDATED APPENDIX C WAS PREPARED BY THE CANCER STEM CELL CONSORTIUM (CSCC):

I. PURPOSE

The purpose of this funding opportunity is to facilitate development of novel therapies based on cancer stem cells for the benefit of persons with cancer. This objective will be met through the support of research teams, co-led by Canadian and Californian Principal Investigators (PIs), who will move stem-cell based therapies toward the clinic. This document provides CSCC relevant information about participating in a Disease Team Therapy Development Research Award.

Canadians who plan to participate in this RFA must have informed the CSCC at the Letter of Intent for the Planning Award stage.

II. FUNDS AVAILABLE

Under this RFA 10-05, the CSCC intends to commit up to CDN\$11 million to support the Canadian component of Research Awards funded through the Collaborative Funding Partner Program. Additional funds will also be sought from other Canadian funding agencies and organizations. Research Award projects will be funded for up to four (4) years and CSCC funding is conditional upon CIRM providing funding to support the Californian component.

III. BACKGROUND

Cancer stem cells represent an exciting and promising new avenue for cancer research as their presence, in many malignancies studied so far, may explain the ability of tumours to proliferate, metastasize and survive traditional chemotherapy and radiation treatments. The ability to extract, culture and expand cancer stem or progenitor cell populations is central to advancing research and to enabling a rigorous investigation of the potential of cancer stem cells as targets for new, more specific, therapeutics. The Cancer Stem Cell Consortium (CSCC) is a not-for-profit corporation formed in 2007 and committed to:

- Developing and implementing an international strategy for cancer stem cell research, technology development, clinical translation activities, and commercialization opportunities to allow the biomedical community to move quickly and effectively from discoveries to application in the clinic;
- ii) Establishing partnerships among organizations in Canada, California, and other jurisdictions; and
- iii) Securing investments to fund the activities of the CSCC.

¹ This Updated Appendix C supersedes the Appendix B posted in July, 2010 in its entirety.

Current members of the CSCC include the Canada Foundation for Innovation (CFI), Genome Canada, the Canadian Institutes of Health Research (CIHR), the Ontario Institute for Cancer Research (OICR), the Stem Cell Network of Centres of Excellence (SCN), the National Research Council (NRC) of Canada, and the Michael Smith Foundation for Health Research (MSFHR). CSCC is dedicated to identifying and developing partnerships with other funding organizations and stakeholders to enhance the availability of funding for cancer stem cell research. As additional partnerships for this initiative are identified, the relevant information will be posted on the CSCC website (http://www.cancerstemcellconsortium.ca/).

In June 2008 the CSCC established a formal partnership with California through the signing of a Memorandum of Understanding (MOU) with the California Institute for Regenerative Medicine (CIRM) to explore possible collaborative funding of cancer stem cell research projects undertaken by Canadian and Californian research teams. The first opportunity for CSCC and CIRM collaborative funding of cancer stem cell research arising in the context of this MOU was CIRM's RFA 09-01 Disease Team I Research Awards Competition. Proposals were required to include a description of milestones on a path to an Investigational New Drug (IND) filing at the end of the four year grant. Through the Disease Team initiative two projects were funded, with a total investment of almost \$40M to each project (\$20M to the Californian scientists and \$20M to the Canadian scientists, with funds for the Californians provided by CIRM and funds for the Canadians provided by CIHR and Genome Canada). The Project Leaders for the two projects are: Dr. Tak Mak, Princess Margaret Hospital, University Health Network, Toronto and Dr. Dennis Slamon, University of California, Los Angeles; and Dr. John Dick, University Health Network, Toronto and Dr. Dennis Carson, University of California, San Diego.

IV. AWARD INFORMATION

The second collaborative funding opportunity between CSCC and CIRM is through the CIRM RFA 10-05 Disease Team Therapy Development Awards competition. Teams of Canadian and Californian scientists submitting Research Award applications through CIRM's Collaborative Funding Partner Program must complete both the CIRM requirements and any additional requirements put forth by the CSCC.

CSCC requests that teams of Canadian and Californian scientists designate a Californian PI ("CIRM PI") (accountable to CIRM for performance) and a Canadian PI ("CSCC PI") (accountable to CSCC for performance). All communications about successfully funded grants should cite both PIs.

A. Eligibility

Only Canadians who had informed the CSCC at the Letter of Intent stage for the Planning Award, January 2011, and were part of a successful Planning Award are eligible to apply for this funding with one exception: recipients of Disease Team I Research Awards (RFA 09-01) may apply for an exemption from the Planning Award requirement, subject to the conditions outlined in the Supplement to RFA 10-05: CIRM Disease Team Therapy Development Awards section V.F. (Special note for recipients of Disease Team I awards.)

The CSCC will review the proposals for eligibility and only those satisfying the CSCC eligibility criteria will be put forward by the CSCC for consideration in this competition.

A1. Eligibility Criteria

The CSCC will **only** support pan-Canadian proposals involving a clinical trials network that engages sites in more than one province. Proposals for consideration for support by the CSCC must also meet the following eligibility criteria:

- 1. Focus on cancer stem cells;
- 2. Support Objectives 2 and/or 3 of the RFA, i.e., work in support of Objective 1, filing an IND (CTA in Canada), is not eligible;
- 3. Inclusion of a significant genomics component in the research plan;
- 4. Be submitted by a CSCC eligible investigator (see A1.1 below);
- 5. Comply with general guidelines of each of the participating partners (see A1.2 below); and
- 6. All other conditions set out in the RFA

Each funded Research Award will support a project for a <u>single</u> development candidate. However, for the CSCC funded research, the therapeutic agent may be tested for different clinical indications, and if justified, a combination with a second agent may be considered in trials conducted in Canada.

A1.1 Canadian Investigator Eligibility

To submit a proposal, Canadian investigators must be eligible to receive grant funding from the participating funding agencies relevant to the RFA.

In general, eligible lead applicants include Canadian researchers, scholars and health professionals affiliated with the following institutions and organizations:

- Canadian post-secondary institutions and their affiliated institutions including hospitals and research institutes;
- Canadian non-governmental, not-for-profit organizations (including community or charitable organizations) with an explicit research or knowledge translation mandate;
- Canadian non-federal government departments or agencies, including regional health authorities, when specific programs of those departments or agencies do not fund the activity that forms the subject matter of the grant.

A1.2 General Guidelines

The general guidelines of each of the participating partner agencies must be followed. At this time, funding is available from Genome Canada, the Ontario Institute for Cancer Research (OICR) and the Canadian Institutes of Health Research (CIHR).

Relevant general guidelines for the individual funding organizations are below:

Genome Canada: http://www.genomecanada.ca/en/portfolio/program.aspx

OICR: http://oicr.on.ca/oicr-programs-and-platforms/research-grants/policies

CIHR: http://www.cihr.ca/e/805.html

A1.3 Specific Conditions

In addition, the following special conditions apply:

- i) Members of the team may pursue other avenues of research in addition to their commitment to the *Disease Team Therapy Development Award*; however, each individual investigator must contribute sufficient time to the Research Award project to ensure the achievement of its research objectives. The CSCC PI must commit a minimum of thirty percent (30%) and CSCC co-PIs a minimum of twenty percent (20%) effort to the Research Award project.
- ii) Grant holders receiving funding from the CSCC under the Canadian component of the CSCC-CIRM Collaborative Funding Partner Program must agree to follow all provisions for intellectual property found in the document "Terms and Conditions for Grants made by the Canadian component of the CSCC-CIRM Collaborative Funding Partner Program for CIRM's RFA 10-05 Disease Team Therapy Development Award".
- iii) Members of a team may be located in one or more departments, faculties or eligible institutions in Canada and California. As well, teams may include international, private sector (for-profit organizations), or federal laboratory scientists. However, CSCC funding is restricted to work performed within CSCC-eligible institutions, i.e., the CSCC will not support research to be undertaken outside Canada, in for-profit organizations (see exception below for OICR funds) or in federal laboratories.
- iv) The CSCC will require that funded teams of Canadian and Californian scientists engage in information exchange within the Consortium, adhere to all Consortium policies and principles and participate in other CSCC-wide annual activities and events, including annual meetings, networking activities and training programs.
- v) The applicants must have documented commitment from the host institution to provide space and shared resources sufficient to carry out the proposed research.
- vi) Committed funds (of up to CDN \$5 million/4 years) from the OICR must be spent in Ontario. Consideration may be given to providing funds to an Ontario-based for-profit company that would: 1) provide services to the project; and/or 2) support a project team member that is in an Ontario-based for-profit company. Project applications that would necessitate disbursement of OICR funds to a for-profit company need to contact OICR two months prior to submission of the application of the Part II Research Application, in order to confirm eligibility of OICR funds).

B. Eligible Costs

Support for Canadian scientists will primarily be for operating funds, but may include reasonable requests for minor equipment essential for the proposed research. However, funds will not be available for major equipment, infrastructure, renovation, or facilities.

Guidelines for eligible use of funds from specific agencies can be found on their web-sites at the links below:

Genome Canada: http://www.genomecanada.ca/medias/PDF/en/guidelines-competition-2010.pdf

OICR: http://oicr.on.ca/oicr-programs-and-platforms/research-grants/policies

CIHR: http://www.nserc-crsng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/index_eng.asp

V. APPLICATION PROCEDURE

Disease Team I applicants must inform the CSCC of their intent to request an exemption from the planning award requirement by October 4, 2011.

VI. CSCC CONTACT

For more information.

Please contact:

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