EMD Serono

Grant for Oncology Innovation:
Program description and rules

The following rules apply to all proposals received from and grants awarded to researchers as part of the Grant for Oncology Innovation (GOI) program. The grant rules and procedures may be changed by EMD Serono for projects based in the United States and by Merck Serono, Darmstadt, Germany to those based in the rest of the world at any time, without notice, in order to comply with applicable laws, rules, regulations, company policies or industry codes.

If you have any questions regarding the grant rules please contact goi@emdserono.com or visit www.grantforoncologyinnovation.org

1. Program description

As part of EMD Serono's commitment to advance science and medicine, the Grant for Oncology Innovation will be launched in 2013. The aim of the grant is to support the advancement of science and medical research in the field of personalised treatment for patients with solid tumours. Potential research topics which could be funded through the Grant for Oncology Innovation include: Research on molecular biomarkers or new targeted treatments, technology platforms for the routine analysis of molecular biomarkers, side effect management and platforms or tools which allow patients to access individualized treatment.

EMD Serono and its affiliates believe that medical research and dissemination of scientific and educational information are worthy undertakings deserving support. Support for research, however, must be carried out in an appropriate manner. Research grants awarded by the company must be consistent with all applicable laws, rules, regulations, company policies and industry codes and may not be used as a price concession, reward, or inducement to prescribe or purchase our company products.

2. Award criteria

The following criteria must be met for all Grant for Oncology Innovation awards:

a. The research must take the form of short-term research with relevance to clinical practice. Some examples of this would include molecular biomarkers for treatment response, development of new targeted treatments, technology platforms for the routine analysis of molecular biomarkers and side effect management.

c. The research must be of legitimate scientific value to the company or the medical/scientific community at large and must be designed to provide meaningful information or conclusions.

d. The research must be innovative, feasible, have a strong scientific rationale, have the potential for practical utility and the potential for personalisation.

e. The research must not compete with any research and development or clinical projects sponsored by EMD Serono or any of its global affiliates.

f. No preference will be given to individuals or entities for prescribing or purchasing EMD Serono products or to induce the prescription or purchase of EMD Serono products in the future. Grant recipients are not expected or obliged to prescribe or purchase EMD Serono products.

g. The amount awarded for the research must not exceed the legitimate costs to be incurred in carrying out the research to be funded by the grant, and must be commensurate with and not exceed fair market value for the research activities.

h. All applicable regulatory requirements must be observed, including, as appropriate, regulatory filings and ethics committee/Institutional Review Board review and approval.

i. The selected researchers must not be currently excluded, debarred, suspended or otherwise ineligible to participate in their respective countries of citizenship, residence and/or practice. Any selected U.S.-based researcher must not be currently excluded, debarred, suspended or otherwise ineligible to participate in currently any U.S. Federal health care programs or in Federal procurement or non-procurement programs by the Office of Inspector General or the General Services Administration.

j. The selected researchers must have the appropriate training and expertise to conduct the research, as determined by the Grant for Oncology Innovation assessment committee.

k. Awarding research grants to an individual researcher not affiliated with an institution, as opposed to an institution or organization with a tax identification number, is discouraged but not prohibited, provided all other requirements of the innovation award are followed.

l. In addition to the rules set forth above, all grants must comply with all applicable laws, rules or regulations.

3. Audit and monitoring

All research activities carried out in connection with a Grant for Oncology Innovation are subject to audit and monitoring by EMD Serono to help ensure that the research programs comply with law and applicable EMD Serono policy. In addition, the name of the grant recipient and amount of the grant will be publicly disclosed to the extent required by law and applicable EMD Serono policy.

4. Researcher obligations

Progress Reports
In order to ensure the appropriate progress of innovation award research projects, grant recipients must provide the company with periodic updates on the progress of each project, including updated budget information and substantiation of expenses, before any relevant milestone payments are made. All grant recipients must provide an annual progress report.

If a research project is not progressing satisfactorily, appropriate action will be taken, including but not limited to withdrawing any remaining funding and terminating the research project.

Final Report and Publication

EMD Serono desires to ensure that research undertaken as part of the Grant for Oncology Innovation program is completed and analysed. All grant recipients must provide the company with final study results in the form of a final report or a publication (manuscript or abstract) in a peer reviewed journal.

EMD Serono supports the exercise of academic freedom by researchers and expects the results of research to be published, whether or not the results are favorable to EMD Serono.

5. Certification

When a research project is completed or terminated, the researcher and/or institution conducting the research must certify to EMD Serono that: (i) the research was conducted in accordance with the terms of the grant agreement, (ii) any unused funds provided by EMD Serono have been returned to the company, (iii) all safety reporting obligations were met, and (iv) if required, a manuscript or abstract has been submitted for publication, or the research was terminated early and a publication is not appropriate.

6. Reconciliation

At the end of the research project, reconciliation will take place to ensure that funds were used solely for the purpose stated in the Grant for Oncology Innovation application and any unused funds are returned to EMD Serono.