Terms of Reference

CUA-CUOG Astellas Research Grant Program
2017-2018

Background

Astellas Pharma Canada, Inc. ("Astellas") is continuing its commitment to supporting research and development in prostate cancer through the funding of a research grant program with the Canadian Urological Association (CUA) and the Canadian Urological Oncology Group (CUOG). In addition to the ongoing CUA Astellas Research Grant Program, the CUA-CUOG Astellas Research Grant Program (the "Program") has been established to support high quality, independent and innovative investigator-sponsored research in prostate cancer that will be peer reviewed by the CUOG Board of Directors. Astellas' involvement is limited to providing the funding for the Program. As an affiliate of the CUA, CUOG will provide the receipt, processing, evaluation and decision-making infrastructure for the Program and will administer the funds and enter into investigator-initiated study agreements with the successful applicants.

Key Dates

Application deadline	April 3, 2018
Notification Date	Annual General Meeting of CUOG and during the CUA Annual Meeting
Submission of study update to CUOG	12 months following receipt of the grant

Objectives and Scope

The objective of the Program is to support peer-reviewed research that promotes excellence in prostate cancer research with the ultimate goal of improving patient care.

The primary focus of the Program is to support research in prostate cancer.

Grant recipients are expected to demonstrate improved understanding of the specific research area and/or contribute to improving patient care.

Grants will be awarded to the successful applicant (or applicant's institution on behalf of the applicant, if applicable). It is anticipated that 2 grants of $50,000 and 2 grants of $25,000 will be provided over a 12-month performance period.

Eligibility

The CUOG Board of Directors shall receive, process, and evaluate the submitted proposals. Proposals will be selected to receive a Program grant based on the following:

Eligible Applicants

- Must be a current resident/fellow/student in a Canadian urology, radiation oncology or oncology program sponsored by an active member of CUOG.
- The sponsoring active member of CUOG must also be a member of the CUA.
- Agrees to execute an Investigator-Initiated Study Agreement with the CUOG/CUA.
- If successful, agrees to have their application shared in confidence with Astellas for internal documentation and auditing purposes
- Agrees that Astellas may disclose the amount and nature of the grant payment publicly on its website and in connection with any other public disclosure of payments/funding to healthcare professionals and health organizations.
- Agrees to provide a progress report, including a publication/congress plan, to the CUOG for dissemination of study results.

Eligible Research Proposals

In 2018, the research proposals being considered will be in prostate cancer. Preference will be given to junior investigators and to new/pilot projects that have not been previously funded.

The research proposal may belong to one of the following categories:

- Clinical, translational, interventional studies
- Basic research, genetic studies
- Epidemiology, health outcomes, and quality of life studies

The study must be completed within 12 months of receipt of funding; no renewals will be considered. The submitted proposal should include a 'standalone' project. Program grants are not meant to

complete funding for larger projects.

Non-eligible Research Proposals

The following types of proposals will not be eligible:

- Proposals for projects that have received funding from another source, including government or industry sponsors, will not be eligible to receive a Program grant unless said funding is shown by the applicant to be directed to a portion of the overall project/research that is separate and distinguishable from the portion to which the proposal relates.

- Proposal budgets in excess of the amount of the intended grant ($50,000 or $25,000) CDN will not be considered unless there are available matching funds from the applicant's institution.

- Proposals for pharmaceutical product development (including studies on non-approved indications for drugs) and/or product comparison, or product promotion will not be considered.

Review Criteria

The proposals will be reviewed and approved by the CUOG Board of Directors. Research proposals will be evaluated based on the following criteria:

Significance

- Scientific merit (validity, integrity, originality)
- Contribution to advancement of scientific knowledge in relevant therapeutic field
- Clinical relevance or potential clinical value and applicability

Feasibility

- Feasibility of study design, methodology, analysis
- Adequate power and sample size
- Study budget
- Proposed timelines

Guidelines for Application Submission

- Original, previously unpublished; Pilot project
- Application to be generated and submitted by a Resident or Fellow and sponsored by an active member of CUOG
- The sponsoring active member of CUOG must also be a member of the CUA
- Magnitude of the project should match size award; the award is not intended to supplement a more major grant. A proposed budget should accompany the application
- Funds will be administered by the sponsor/supervisor

All applications must include the following:

- Completed Application Form
- Research Proposal not exceeding five (5) single spaced pages
- One (1) page summary of the research proposal
- Curriculum Vitae (Please submit a pdf version of your Common (CHIR) CV)
- A maximum of three (3) published reprints or pre-prints
- Project budget
- Letter of support from the Department/Division Chair agreeing to conform to the Terms of Reference. The letter should indicate the level of support and commitment by the university/institution for the candidate.
- Name and contact information for three (3) external reviewers
- Evidence of appropriate Ethics Committee approval or application for approval must be included along with the consent forms where human subjects are involved in the study

The following are suggestions for preparation of the research proposal. The headings suggested include 1) Statement of Objective(s), 2) Recent relevant research by applicant, 3) Brief review of literature and background information, 4) Hypothesis(es), 5) Design and Methodology, 6) Analysis of Data, 7) Anticipated Timeline, 8) Impact, and 9) Budget.

The completed application must be submitted via email to the office of the CUOG Secretary no later than **April 3, 2018**. Late documentation received after the closing date will be returned to the applicant. Incomplete applications will be disqualified and returned to the applicant.

Conditions of the CUA-CUOG Astellas Research Grant Program

Financial Considerations

The budget for each proposal should include direct costs (labour and study costs), institutional overhead costs (if any), study drug costs (if applicable), and indirect costs (publication, software license fees, and REB fees). Payments will be made in installments according to milestones, with a maximum of 50% of the funding delivered at the beginning of the project. Institutions are expected to waive overhead fees that might otherwise apply to industry-funded research.

Contract Administration

A copy of the Template Grant Agreement, signed by the Program grant recipient and his/her affiliated institution (if applicable) must be returned to CUOG prior to disbursement of funds. Studies must be designed to be completed within 12 months after receipt of funding, yielding results that would merit submission as an abstract to a scientific meeting and subsequent publication in a peer-reviewed journal.

Progress Reports

At one year after receipt of The Grant, the recipient must provide a progress report to the CUOG secretary, summarizing work done, including any publications, as well as an accounting of funds. If the Board of Directors deems that the recipient has not made sufficient progress, further

payment/ installments maybe withheld. A site visit may also be recommended by the Chair/Secretary of the CUOG Board of Directors, during the year of the Program, where appropriate.

Publications

Grant recipients are expected to present their findings at the CUA annual meeting as well as other scientific meetings and to submit their work for publication in peer-reviewed journals. CUOG shall require a copy of all proposed publications upon submission for publication or other public disclosure and CUOG shall provide said information to Astellas forthwith. All publications that result from a project supported by the Program should carry the following acknowledgement:

> "This research was supported by the *CUA-CUOG Astellas Research Grant Program,* managed by the Canadian Urological Association and the Canadian Urological Oncology with funding provided by Astellas Pharma Canada, Inc. through a grant to the CUA-CUOG."

Grant Recipient Responsibilities

The following responsibilities must be assumed and carried out by the grant recipient:

- Study contract review and execution
- Research Ethics Board submission and approval (if applicable)
- Health Canada Clinical Trial Application (CTA) submission and approval (if applicable)
- Study-related activities such as data management, statistical analysis, medical writing, monitoring, etc.
- Registration and posting of study results on http://prsinfo.clinicaltrials.gov
- Safety Reporting to Health Canada and Astellas Pharma Global Development – Please refer to the Serious Adverse Events and other Product Safety Information Reporting section
- Communication of progress updates to the CUOG
- Forward copy of abstract(s)/manuscripts(s) to the CUOG upon submission to congress/journal

Serious Adverse Events and other Product Safety Information Reporting

1. As sponsor of the study, the grant recipient is responsible for reporting SAEs and Lack of Therapeutic Efficacy directly to **Health Canada (**pursuant to the Canadian *Food and Drug Regulations*) and to the local REB, as required.

2. If a drug product is involved, the grant recipient is also required to notify the Product Safety/Pharmacovigilance group for the appropriate company.[1]

[1] If the research involves a drug product marketed by Astellas Pharma Canada, Inc., the Grant recipient is required to notify **Astellas Pharma Global Development – Product Safety & Pharmacovigilance (PSP)** at fax: 1-847-317-1241 or Email: Safety-us@astellas.com within twenty-four (24) hours of receiving a SAE or Lack of Therapeutic Efficacy report.

Also Required to be Collected by the Independent Investigator

Product Safety Information ***("PSI")*** including but not necessarily limited to:

1. *Death (always considered serious)*
2. Abuse/Misuse/Overdose

A ***Serious Adverse Event*** is any untoward adverse event/adverse drug reaction that at any dose, results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, is a congenital anomaly/birth defect, or results in other medically important events.

Lack of Therapeutic Efficacy – If a health product fails to produce the expected intended effect, there may be an adverse outcome for the patient, including an exacerbation of the condition for which the health product is being used. Clinical judgment should be exercised by a qualified health care professional to determine if the problem reported is related to the product itself, rather than one of treatment selection or disease progression since health products cannot be expected to be effective in 100% of the patients.

Notification of CUA-CUOG Astellas Research Grant

Notification of the selected grant recipients will be made at the CUOG Annual General Meeting. Both successful and unsuccessful applicants will receive a summary and a constructive critique.

Address for Submissions
Canadian Urological Association
c/o Marfisa DeFrancesco
185 Dorval Avenue, Suite 401
Dorval, QC H9S 5J9

Completed submissions should be submitted by email to:
marfisa.defrancesco@cua.org

3. Medication Errors (in prescribing, dispensing, or administration)
4. Drug Exposure during impregnation, pregnancy, breastfeeding or as a result of one's occupation
5. AEs reported in association with suspected or confirmed quality defects or counterfeit reports
6. Suspected transmission of an infectious agent