Terms of Reference

CUA Astellas Research Grant Program 2018

Background

Astellas Pharma Canada, Inc. ("Astellas") is continuing its commitment to supporting research and development within the Canadian urology scientific community through the funding of a research grant program with the Canadian Urological Association (CUA). The CUA Astellas Research Grant Program (the "Program") has been established to support high quality, independent and innovative investigator sponsored research in urology that will be peer reviewed by the Scientific Council of the Canadian Urological Association Scientific Foundation (CUASF). Astellas' involvement is limited to providing the funding for the Program. The CUASF 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	**February 28, 2018**
Notification Date	Annual Meeting of the CUA
Study update submitted to CUASF	Within 6 months of receipt of the grant

Objectives and Scope

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

The primary focus of the Program is to support research in the area of functional urology such as over-active bladder (OAB), lower urinary tract symptoms (LUTS), pelvic floor disorders, voiding dysfunctions, and neurogenic bladder, among others. The secondary focus is to support other urological areas, with the exception of urologic cancer (these proposals should be submitted to the CUA-CUOG Astellas research grant program), such as community-based research, practice improvement, multidisciplinary management, basic research, etc.

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 3 grants of $50,000 CDN/each will be provided over a 12-month performance period.

Eligibility

The CUASF shall receive, process, and evaluate the submitted proposals. Proposals will selected to receive a Program grant based on the following:

Eligible Applicants

- Canadian residents
- M.D. or Ph.D. trained individuals
- The main applicant must be an active member of the Canadian Urological Association (CUA)
- Agrees to execute an Investigator-Initiated Study Agreement with the CUASF
- 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 CUASF for dissemination of study results

Eligible Research Proposals

In 2018, the research proposals being considered will be in functional urology such as OAB, LUTS, pelvic floor disorders, voiding dysfunctions, neurogenic bladder, or other urology areas (excluding urologic cancer), such as community-based research, practice improvement, multidisciplinary management, basic research, etc.

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 $50,000 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 Executive Council of the CUASF after recommendation from the Chair of the Scientific Council.

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

The research proposal must be electronically submitted, including the budget and references, and should not exceed five (5) pages. Proposals should be written in the standard 12 font. The completed application must be received at the Office of the Chair of the CUASF no later than **February 28, 2018**. Each applicant must arrange for a letter of support from the Chair of the University Department/Division affiliated with the research. The letter should indicate the level of support and commitment by the University and/or affiliated institution for the application.

Documentation received after the submission deadline will be returned to the applicant.

Applicants must submit their applications electronically to the CUASF office via this online submission system: http://www.cua.org/en/astellas.

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, 9) Budget and 10) References.

Each application must include the following: 1) completed application form, 2) research proposal, 3) evidence of appropriate Ethics Committee approval or application for approval along with consent forms where human subjects are involved in the study, and 4) letter of support and commitment from the Chair of the Department/Division indicating the level of institutional and/or university support. Incomplete applications will be disqualified and returned to the applicant.

Conditions of the CUA 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 the CUASF 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

The grant recipient must provide a progress report to the Chair of the Scientific Council within 6 months of receipt of initial funding. If the Scientific Council deems that the recipient has not made sufficient progress, further payment/installments may be withheld. A site visit may also be recommended by the Chair of the Scientific Council, if 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. CUASF shall require a copy of all proposed publications upon submission for publication or other public disclosure and CUASF 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 Astellas Research Grant Program,* managed by the Canadian Urological Association with funding provided by Astellas Pharma Canada, Inc. through a grant to the Canadian Urological Association."

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 (if applicable). Please refer to the Serious Adverse Events Reporting section.
- Communication of progress updates to the CUASF
- Forward copy of abstract(s)/manuscripts(s) to the CUASF 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]

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[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
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

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 judgement 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 Astellas Research Grant

Notification of the selected grant recipients will be made at the CUA Annual Meeting. Both successful and unsuccessful applicants will receive a summary and a constructive critique from the Scientific Council of the CUASF.

Complete applications must be submitted online: http://www.cua.org/en/astellas**.**

Questions should be directed to:

Canadian Urological Association Scholarship Foundation
Jonathan Izawa, MD, FRCSC
Chair, Scientific Council
c/o Ms. Marfisa Defrancesco
marfisa.defrancesco@cua.org