



Astellas Pharma Inc. & Harvard University REQUEST FOR PROPOSALS

Proposal Submission Deadline: July 16, 2020

Harvard's Office of Technology Development (<http://otd.harvard.edu>) is pleased to announce the **2020 Request for Proposals (RFP)** under the strategic research alliance recently established between **Harvard University** and **Astellas Pharma Inc.** This three-year strategic research alliance will support multi-year research projects initiated by Harvard faculty, focused on the research and development of innovative therapeutics and technologies of mutual interest.

Astellas Pharma Inc., established in 2005 and based in Tokyo, Japan, has a primary vision to turn innovative science into value for patients around the world, through the development of novel drugs and state-of-the-art medical solutions. Astellas uses a Focus Area Approach to strategically build a sustainable and expandable drug discovery pipeline with primary areas of interest including: Blindness and Regeneration, Antigen-Specific Immune Modulation Biology and Multi-immune Regulation, and Mitochondria Biology. For more information, please visit <https://www.astellas.com/en>.

FRAMEWORK AND FUNDING

This Request for Proposals (RFP) is seeking novel and innovative project proposals, based on strong scientific rationale and projected impact on value for patients, **within the scope of the scientific challenges proposed by Astellas, found in Appendix A.**

Astellas will provide meaningful funding, **anticipated to be \$500,000 per year for 2-3 years** (including direct and indirect costs), to support research projects.

APPLICATION PROCESS

Applicants should develop a 2-4 page, Non-Confidential Short Proposal that describes the research objectives, relevant preliminary results and an overview of the planned implementation of the proposed project, **as outlined in Appendix B.** Applicants can submit more than one proposal. The deadline for submission of Short Proposals is **July 16, 2020**. Please contact us at otdalliances@harvard.edu to request a Microsoft Word version of the 2020 Astellas – Harvard

RFP short proposal template. *We recommend that you reach out to your OTD contact to discuss your idea for a proposal **before** preparing or submitting a proposal.*

REVIEW PROCESS AND SELECTION OF FINAL AWARD RECIPIENTS

Astellas will review the Non-Confidential Short Proposals and determine further interest in the development of Confidential Detailed Proposals. Feedback on Short Proposals may be informally provided by Astellas upon request. Confidential Detailed Proposals will include a more refined and detailed research plan and budget and will be developed by the applicants in collaboration with Astellas’ R&D leadership. The development of Confidential Detailed Proposals may involve meetings between the selected proposal finalists and Astellas’ R&D leadership. Astellas will select the final project award recipients after submission of the Confidential Detailed Proposals.

APPLICATION TIMELINES

Date	Action
Thursday, July 16, 2020	Deadline for the submission of Short Proposals
Thursday, August 13, 2020	Announcement of Short Proposals advanced to submission of Detailed Proposals
August 13, 2020 – October 7, 2020	Development of Detailed Proposals in collaboration with Astellas- may involve meeting between proposal finalists and Astellas’ R&D leadership
Wednesday, October 7, 2020	Deadline for the submission of Detailed Proposals
Friday, November 6, 2020	Announcement of Final Project Award Recipients
Wednesday February 10, 2021	Latest start date of projects

ELIGIBILITY AND RESTRICTIONS

Anyone with rights as a Principal Investigator, whose employer is Harvard University and who has an obligation to assign intellectual property rights to Harvard, is eligible to apply. Investigators with Harvard academic appointments but who are not employed by Harvard University are not eligible. Post-docs and research scientists who are interested in applying should discuss with their PI and apply jointly. Collaborations within Harvard University are highly encouraged. Please reach out to your contact within OTD or to otdalliances@harvard.edu to discuss projects that may involve collaborators with Harvard-affiliated hospitals or outside of Harvard University.

AWARD TERMS AND CONDITIONS

Project Team: A scientific Project Team will be established for each Project, which will include representatives from Astellas and Harvard. The Astellas Project Manager and Harvard Alliance Manager will be the primary points of contact for the Project Teams. Project Teams will meet quarterly to discuss project progress and results.

Publications: Publication of the research project results is permitted, although Principal Investigators will need to comply with a short pre-disclosure period for all research publications and presentations resulting from the funded work, to determine if any publications contain company confidential information or if the publications contain patentable subject matter.

Reporting Requirements: Progress reports will be required twice each calendar year during the funding period, and a final report is due no later than 60 days of the end of the funding period. Each report should summarize research results relevant to the specific aims of the project.

CONTACT INFORMATION

For additional information on the program and the application process, please contact the Director of Business Development at OTD that supports you or contact us at otdalliances@harvard.edu.

Appendix A: Scientific Challenges /// Short Proposal Submission Deadline: July 16, 2020

Cell Therapy

- Novel, controllable methods to induce cell-specific apoptosis, applicable for use in cell-based therapies
- Methods or technologies to manipulate extracellular vesicle cargo loading
- Methods, including identification of specific regulators or pathways, to induce reprogramming of induced pluripotent stem cells, embryonic stem cells or fibroblasts into cell types of interest including:
 - Photoreceptor progenitors, hepatocytes, cardiomyocytes, corneal endothelial cells
- Methods or technologies to enhance engraftment, survival, and functionality of transplanted cells
- Targeting technologies or approaches to maintain localization of cell therapies to target tissues or to sites of injury
- Organoid/biomaterials/tissue engineering-based approaches to maintain primary human hepatocytes in culture
- Key factors or cell signaling pathways involved in driving maturation of corneal endothelial cells
- Approaches to enhance neuronal synapse formation or axon generation upon tissue transplantation

Phage Therapy

- Identification of novel pathogenic bacteria or bacterial targets, amenable to phage therapy, for microbiome-related diseases

Immunology

- Validated targets, regulators, pathways, therapeutic modalities or technologies focused on cell-specific immune tolerance
 - Disease areas of interest include multiple sclerosis, type 1 diabetes, transplantation, rheumatoid arthritis, inflammatory bowel syndrome, systemic lupus erythematosus
- Novel regulators of immunity and tolerance in human dendritic cells and macrophages
- Validated targets or therapeutic modalities that modulate activity/plasticity of innate lymphoid cells (ILCs) in autoimmune diseases, allergy or cancer
- Expertise in Interferon-inducible protein, AIM2:
 - Strategies for recombinant protein purification of full-length monomeric AIM2 protein
 - Techniques to determine AIM2 structure and conformational changes related to its mechanism of activation

Autophagy / Mitochondria

- Validated targets, regulators, pathways, therapeutic modalities or technologies to improve disease outcomes related to the following biological processes:
 - Autophagy
 - Chaperone biology
 - Proteostasis
 - Mitochondria biology
- Disease areas of interest include:

- Muscle diseases: Duchenne muscular dystrophy, myotonic dystrophy, frailty/disuse atrophy, sarcopenia
- Kidney diseases: acute kidney injury, chronic kidney disease, autosomal dominant polycystic kidney disease
- Ischemic reperfusion injury
- Eye diseases: glaucoma, age-related macular degeneration, corneal wound healing
- Neurodegeneration: amyotrophic lateral sclerosis, Huntington's disease, Parkinson's disease, Alzheimer's disease
- Immuno-oncology: T cell activation via modulation of metabolism/mitochondria

Sensorineural hearing loss

- Small molecules, targets or pathways to induce ribbon synapse regeneration, preferably mechanisms other than tropomyosin-receptor kinase, TrkB/TrkC pathways
- Small molecules, targets or pathways to induce hair cell regeneration, excluding Wnt signal pathway regulation
- Animal models to study idiopathic sudden hearing loss
- Biomarker identification or indicators to quantify age-related hearing loss
- Development of antisense oligonucleotide approaches as a treatment modality in otology
- Methods or technologies to reduce toxicity of antisense oligonucleotide therapeutics in otology
- Drug delivery technology/device targeting the inner ear

Appendix B: Short Proposal Outline /// **Short Proposal Submission Deadline: July 16, 2020**

Applicants are advised to work with OTD to develop their proposal. Please contact us at otdalliances@harvard.edu for a Microsoft Word version of the proposal template.

Cover Page:

- Project title
- Affiliation details of lead PI
- Names and affiliation details of any collaborators
- Total budget request (including indirect costs)
- Project term
- Keywords
- Final deliverable
- Non-confidential executive summary (250 words maximum)

Non- Confidential Research Plan

The Research Plan should not exceed 4 pages (this limit does include figures but does not include references). Please do not include any structures of chemical matter in your proposal.

1. Background and significance
2. Research objectives, including rationale and preliminary results for each aim
3. Experimental plan
4. Anticipated milestones and timelines
5. References
6. Publications

Proposal submission: Proposals should be submitted as a single Microsoft Word file, with the exception of supporting publications, which should be provided as PDF files. Please submit proposals via e-mail to otdalliances@harvard.edu. Please include in the subject line the words "Astellas RFP" and the PI's last name.