The Prostate Cancer Foundation (PCF), Pfizer Inc. and Myovant Sciences GmbH announce

PCF-Pfizer-Myovant Relugolix Challenge Awards

Request for Proposals (RFP)

I. Background

About the Prostate Cancer Foundation

The Prostate Cancer Foundation (PCF) is the world's leading philanthropic organization dedicated to funding life-saving prostate cancer research. Founded in 1993, PCF has raised more than $865 million to support cutting-edge research by 2,200 scientists at 220 leading cancer centers in 22 countries around the world. Every FDA-approved life-extending treatment for prostate cancer was seeded and supported by PCF. The overall scientific goal of PCF is to cure prostate cancer. Learn more at pcf.org.

About Pfizer Global Medical Grants

Pfizer Global Medical Grants (GMG) supports the global healthcare community's independent initiatives (e.g., research, quality improvement or education) to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies. Pfizer's GMG competitive grant program involves a publicly posted Request for Proposal (RFP) that provides detail regarding a specific area of interest, sets timelines for review and approval, and uses an expert review panel (ERP) to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in research, practice or care as outlined in the specific RFP. For all Investigator Sponsored Research (ISRs) and general research grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. Pfizer and Myovant must not be involved in any aspect of study protocol or project development, nor the conduct or monitoring of the research program.

About Myovant Sciences

Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, we have two FDA-approved products. ORGOVYX™ (relugolix) was approved by the U.S. Food and Drug Administration in 2020 as the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist for the treatment of adult patients with advanced prostate cancer, and relugolix is also under regulatory review in Europe for men with advanced prostate cancer. MYFEMBREE® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) was approved in the U.S. in 2021 as the first once-daily treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women. Relugolix combination tablet (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) is under regulatory review in Europe for women with uterine fibroids, has completed Phase 3 registration-enabling studies for women with endometriosis, and is being assessed for contraceptive efficacy in healthy women ages

18-35 years who are at risk for pregnancy. We are also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for female infertility as part of assisted reproduction. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is our majority shareholder. For more information, please visit our website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn.

II. Eligibility

Geographic Scope:	United States
PCF-Pfizer-Myovant Challenge Award Team Eligibility Criteria	• The institutions and research team must be based in the United States. • Only organizations are eligible to receive grants, not individuals or medical practice groups. • Composed of a team of at least three (3) investigators from non-profit academic research centers, including one young investigator. Applicants (Principle Investigator; PI) must have a medical or doctoral degree (MD, PhD, or equivalent). • The young investigator may hold the title of Postdoctoral Fellow, Instructor, Research Associate, Assistant Professor, or equivalent and should be within six-years following completion of a professional degree (MD, DO, PhD, MD-PhD, DSc, ScD, DDM, DDS, DMD, MBBS, or equivalent) or subsequent mentored academic or clinical training program. • Both early career and experienced investigators are encouraged to apply and consideration will be given to all proposals meeting the selection criteria

III. Requirements

Date RFP Issued:	**June 7, 2021**
Clinical Area:	**Oncology – Genitourinary – Prostate Cancer**
Area of Interest for this RFP:	• The intent of this Request for Proposal (RFP) is to invite academic investigators to submit innovative proposals for clinical investigations with correlative research for relugolix in prostate cancer. **Research proposals in the following topic areas are preferred:** • Relugolix in combination with other standard-of-care or experimental systemic prostate cancer therapies (e.g. next-generation androgen axis-targeted therapies, taxane chemotherapy, etc.). Clinical settings of interest include loco-regional disease (N1/M0), hormone-sensitive metastatic disease, non-metastatic (M0) or metastatic (M1) castration-resistant prostate cancer (CRPC). • Use of relugolix as an intermittent therapy. Studies of interest in this setting include quality of life, safety, and survivorship impacts.

	• Relugolix clinical studies on adherence/compliance in real world settings, including evaluations of the impact on clinical outcomes. • Biomarker studies with ADT (GnRH agonists and antagonists) to investigate mechanisms and reversibility of adverse cardiovascular (CV) events, including FSH-mediated outcomes. **Research proposals in the following topic areas are being investigated in other dedicated programs and are considered out-of-scope for this RFP:** • Relugolix in combination with radiation therapy. • Transition to relugolix • Relugolix in other cancer types (i.e. breast cancer) • Patient chart- or claims- based studies • Pre-clinical studies • Ex-US studies
Target Audience	Urologists, Medical Oncologists, Radio-Oncologists, Cardio-Oncologists, allied Prostate Cancer healthcare providers
Expected Approximate Monetary Range of Grant Applications:	• The target budget for each individual project grant is up to $500,000. However, individual projects requesting up to $750,000 will be considered. • The amount of the grant Pfizer-Myovant-PCF will be prepared to fund for any project will depend upon the expert review panel's (ERP) evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.
Key Dates	• RFP release date: **June 7, 2021** • Grant Application due date: **August 16, 2021.** Please note the deadline is 23:59 Eastern Time (New York, GMT -5). • Anticipated Grant Award Notification Date: **October 11, 2021** • Anticipated Project Start and End Dates: **December 2021 to November 2023**

How to Apply:	• Please go to www.cybergrants.com/pfizer/Research and sign in. First-time users should click "Create your password".
	• **In the application:**
	  • For the question "Are you replying to a Request for Proposal as part of the Competitive Grant Program?" select Yes
	  • Select the following Competitive Grant Program Name: **2021 Oncology PCF-Pfizer-Myovant Relugolix Challenge Awards**
	  • Select the following Primary Area of Interest: **Oncology – Genitourinary – Prostate Cancer**
	• Requirements for submission:
	  • Complete all required sections of the online application and upload your project proposal (see Appendix) in the Proposal/Protocol field.
	If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.
	IMPORTANT: Be advised applications submitted after the due date will not be reviewed.

Questions:	If you have questions regarding this RFP, please direct them in writing to Dewayne Brumlow at (Dewayne.Brumlow@Pfizer.com) or Jennifer Smith at (Jennifer.smith@Myovant.com) with the subject line **"2021 PCF-Pfizer-Myovant Relugolix Challenge Awards"**
Grant Agreements:	• If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click here to view the core terms of the agreement. • Pfizer has drafted the terms of these agreements to be balanced and reasonable and to further the goals of both parties. Negotiating grant agreements requires significant resources, so please ensure that your institution (including your legal department) is able and willing to abide by these terms before proceeding with submission of your application as they will need to be accepted in their entirety.

Review and Approval Process	• Grant requests received in response to a specific RFP are reviewed by an expert review panel (ERP) to make final grant decisions. • The panels are comprised of professionals from the medical community with advanced degrees and expertise in particular clinical areas, or specific needs of a geographic region/learner group, or expertise in research, continuing professional development or quality improvement.
Mechanism by which Applicants will be Notified:	• All applicants will be notified via email by the dates noted above • Applicants may be asked for additional clarification during the review period

Appendix A

General RFP Submission Requirements

Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references. Please include the following:

Goals and Objectives	• Provide the main goal of the study and the study population (if applicable). Provide a detailed definition that is directly linked to the primary objective
Assessment of Need for the Project	• This should reflect your study rationale. Provide a brief description of the medical/scientific question and the rationale of how this trial or study addresses the question
Target Audience	• Describe the primary audience(s) targeted for this project. For Investigator Sponsored Clinical Trials, please specify the age, gender and other demographic information for trial population • Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population • Trial designs that will assure inclusion of minority and historically underrepresented groups are encouraged
Project Design and Methods	• Describe concisely the research design and methods for achieving the stated goals. For a clinical interventional study, include inclusion/exclusion criteria, treatment plan and statistical plan
Innovation	• Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects. Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project
Evaluation and Outcomes	• Specify type and frequency of safety, efficacy, and/or outcome measures. Also indicate the method(s) used to assess measures • Provide a publication plan describing intended submission of abstracts to (a) congress(es) or intended submission of (a) publication(s) to peer-reviewed journals. All publications must follow ICH guidelines
Anticipated Project Timeline	• Provide an anticipated timeline for your project including project start/end dates
Additional Information	• If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here • Early-career applicants: Letter(s) of support from mentor(s) and

	collaborators describing how the award will advance the applicant's career.
Organization Detail	• Please list all team members, their institutions, and their roles in the project, including identification of the young investigator. In addition, identify the facilities to be used [laboratory, animal, clinical and "other"] at the team member institutions. Please indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. This information is used to assess the capability of the organizational resources available to perform the effort proposed.
References	• Bibliography of relevant references.