NCCN Request for Proposals (RFP): NCCN Pfizer Investigator-Sponsored Research Project to Evaluate the Effectiveness of Elranatamab in the Treatment of Multiple Myeloma

Date Issued: March 29, 2023

1.0 Purpose

The National Comprehensive Cancer Network® (NCCN) and Pfizer Global Medical Grants are collaborating to offer a new grant opportunity seeking proposals for investigator-sponsored research with elranatamab. Pfizer (hereafter, "Grantor") is providing up to $5 Million Dollars in research grants to support clinical research studies to further evaluate the effectiveness of elranatamab in the treatment of Multiple Myeloma. The Grantor will serve as the funding organization. Grants are available to all investigators from institutions within the United States.

2.0 Organization Information

National Comprehensive Cancer Network

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit alliance of 32 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, efficient, and equitable cancer care so patients can live better lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. By defining and advancing high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers around the world.

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.

This RFP is being issued by both organizations. NCCN is the lead organization for review and evaluation of proposals. A Scientific Review Committee (SRC), led by NCCN, will make decisions on which proposals will receive funding. **Grant funding and general oversight of the funded projects will be provided directly from Pfizer.**

For all 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. NCCN and Pfizer must not be involved in any aspect of study protocol or project development, nor the conduct or monitoring of the project.

3.0 Background

Multiple Myeloma (MM) is a plasma cell neoplasm characterized by dysregulated proliferation of bone marrow (BM) plasma cells with B-cell maturation antigen (BCMA) overexpression.[1] Globally, there are approximately 176,000 new cases and 117,000 deaths per year attributed to MM.[2] In 2023, the American Cancer Society estimates that for the US, approximately 35,730 new MM cases will be diagnosed and

approximately 12,590 MM-related deaths will occur.[3] While a reduction in deaths is predicted in 2023, MM remains an incurable disease and almost all patients, even those who initially respond to treatment, are expected to relapse. MM patients typically cycle through many lines of treatment, having become relapsed/refractory (RR) to various therapeutic approaches.[4-7] Real world data from the MAMMOTH study show that patients who are triple-class refractory with prior PI-, IMiD- or anti-CD38-based combination regimens, can expect a median overall survival of 8.6 months.[6] Additionally, a recent analysis from the ConnectMM registry of 232 patients who were refractory to three classes of medications (1 PI, 1 IMiD, and 1 anti-CD38 antibody) further elucidated the need for more effective treatments in this population as patients experienced a median overall survival of just 9.9 months.[7]

BCMA has emerged as an effective therapeutic target in the last few years for patients with heavily pretreated MM.[8-11] Both cellular and non-cellular BCMA modalities are commercially available in the US, including chimeric antigen receptor T-cell (CAR T) therapy (ide-cel and cilta-cel) and bispecific antibodies (teclistamab).[9-11] Response rates with BCMA CAR T are impressive in patients with heavily pretreated RRMM, but the majority of patients with RRMM are unable to access CAR T due to manufacturing limitations and/or proximity to a certified site of administration.[12] BCMA bispecific antibodies also provide improvements in objective response rates as monotherapy in patients with heavily pretreated RRMM.[11] The purpose of this grant is to further advance the scientific understanding of the BCMA bispecific antibody elranatamab alone or in combination with novel therapies in MM.

Mechanism of Action of Elranatamab

Elranatamab (PF-06863135) is a heterodimeric humanized full-length bispecific IgG2 kappa monoclonal antibody (mAb) against BCMA and CD3. Targeted T-cell-mediated cytotoxicity follows the binding of one arm of elranatamab to CD3-expressing T-cells and a second arm to BCMA-expressing MM cells.[13]

Preclinical Data

In vitro, elranatamab has been shown to induce cytokine release by human T-cells and to redirect patients T-cells to lyse tumor cells from MM patients in a concentration-dependent manner. Elranatamab also showed robust anti-tumor activity in vivo following a single dose in 3 different orthotopic human MM models established in immunodeficient mice engrafted with human T-cells, and greater potency was correlated with higher BCMA expression levels. In another orthotopic tumor model with low BCMA expression levels, a second dosing of elranatamab was found to delay tumor progression. As part of a secondary pharmacology assessment, elranatamab induced cytokine release in human whole blood, which was expected due to the presence of BCMA-expressing target cells, confirming the mechanism of action. Finally, toxicology studies in cynomolgus monkeys showed mechanism-based effects, including increased T-cell activation, increased cytokines, and microscopic findings in the secondary lymphoid tissues.[13-14]

Clinical Data

The safety, efficacy, and PK of elranatamab as a single agent were initially evaluated in a Phase 1 study (C1071001) as monotherapy (IV and SC) or in combination with lenalidomide or pomalidomide. This study is ongoing, but enrollment is complete.

MagnetisMM-3 is an open-label, multicenter, non-randomized, phase 2 study to evaluate the safety and efficacy of elranatamab monotherapy in patients with RRMM. MagnetisMM-3 enrolled 123 patients refractory to at least 1 proteasome inhibitor (PI), 1 immunomodulatory agent (IMiD) drug, and 1 anti-CD38 mAb. Patients received SC elranatamab 76 mg QW on a 28-day cycle with a 2-step-up priming

dose regimen (12 mg and 32 mg) administered during the first week. In a cohort of patients, had not received previous BCMA-directed therapy, the ORR by BICR was 61.0% (95% CI, 51.8−69.6), with response > VGPR of 55.3% and > CR of 27.6% (primary endpoint was ORR by BICR per IMWG criteria) after a median follow-up of 10.4 months (range, 0.2−20.1). The median duration of objective response, median progression free survival and median overall survival have not been reached. Among patients who received the 2-step-up priming regimen (n=119), cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity syndrome (ICANS), respectively, were reported in 56.3% and 3.4% of patients, respectively. All CRS and ICANS were grade 1 or 2 and CRS events were primarily confined to the first 2 priming doses (90.6%) and the first 3 doses (98.8%). Grade 3/4 neutropenia was reported in 48.0% of patients, grade 3/4 thrombocytopenia was reported in 22.0% of patients, Grade 3/4 anemia was reported in 36.6% of patients, Grade 3/4 lymphopenia was reported in 24.4% of patients. Infections were reported in 66.7% (grade 3/4, 35.0%) of patients.[15-16]

There are ongoing registrational-intent trials that explore elranatamab both as monotherapy and in combination with standard or novel therapies, spanning multiple patient populations, from newly diagnosed MM to RRMM. This includes MagnetisMM-5 (NCT05020236) in the double class exposed setting, MagnetisMM-6 (NCT05623020) in transplant ineligible newly diagnosed patients, and MagnetisMM-7 (NCT05317416) as maintenance treatment in newly diagnosed patients after transplant, all of which are currently enrolling.

While this summary of safety data is representative of a small amount of study data for elranatamab, this agent is being investigated in clinical trials in various MM disease settings, and in different combinations/regimens. These clinical trials are in different phases of conduct. Applicants are encouraged to review appropriate clinical trial data from clinicaltrials.gov, as well as previously presented data at meetings, for a more comprehensive and specific safety profile that may be applicable.

4.0 Aims and Eligibility

Aim:	Support innovative studies evaluating the BCMA bispecific antibody elranatamab to advance the treatment of multiple myeloma and toxicity management.
Geographic Scope:	United States
Eligibility Criteria: *Investigators from the following organizations may apply*	• PIs must be from US Institutions only; ex-US sub-sites are allowed. • Academic health care centers. • Community health care centers. • Health care professional organizations and other organizations related to health care improvement. • Health technology companies if partnered with a health care delivery organization who must serve as lead applicant.
Additional Eligibility Information:	• Collaboration between Institutions is strongly encouraged to foster interactive sharing of knowledge and expertise, and to utilize the combined clinical strengths of both Institutions. • Proposal submissions from junior faculty are encouraged. • Trainees may participate as a sub-investigator under appropriate mentorship from a PI.

5.0 Letters of Intent (LOI)

This RFP model employs a 2-stage process: Stage 1 is the submission of a 3-page LOI (see Section 8). If a LOI is selected, the applicant will be invited to Stage 2 and will submit a full program proposal into Pfizer's web-based system (additional information for full proposal submission will be provided at the time of notification).

6.0 Requirements

Clinical Area:	Multiple Myeloma (MM)
Target Audience:	Medical Oncologists, Hematologists, Infectious Disease Specialists, and scientists with an interest in MM.
Funding Considerations:	• There is up to $5 million available for funding of all projects. • The intent is to fund 3-5 studies. There is a funding cap of $1.25 million per study. Exceptional studies with budgets above this amount will be considered based on scientific merit and must contain a robust justification. • Overhead (indirect cost) rates of up to 28% of the total proposed project budget are allowed and *must* be included in the total grant request amount. • The decision relative to funding is deferred to the members of the Scientific Review Committee (SRC) as chosen by NCCN and independent of Grantor.

Areas of research interest/emphasis:	Studies evaluating the BCMA bispecific antibody elranatamab to advance the treatment of MM and toxicity management including, but not limited to:
	• Studies exploring the optimal use of elranatamab;
	  • In combination, or optimal sequencing, with novel agents;
	  • Dose/schedule optimization and fixed duration;
	  • Administration and resource utilization;
	• Special populations;
	• Infection and CRS diagnosis, monitoring and management, including mitigation strategies;
	• Exploration of novel methods or alternative health care models that improve health equity and patient/care-giver experience during treatment with elranatamab, including technology for patient monitoring or toxicity assessment;
	  • Must be included/integrated within a clinical study; and
	  • Must be sustainable and reproducible.

Areas excluded or considered out of scope:	Specific areas considered out of scope or excluded include: • Exclusively preclinical/non-clinical studies (correlative studies included in a clinical study will be accepted); • Real World Evidence only studies; • Randomized, Phase 2/3 studies; • Studies dependent on access to banked samples from the MagnetisMM Clinical Development Program; • Studies evaluating elranatamab in smoldering MM or AL amyloidosis; • Studies looking at QOL only (studies including QOL and additional end points in a clinical study will be accepted); • Studies involving opioids; and • Studies not involving elranatamab. ***Proposals duplicative of completed, ongoing, or planned studies will not be considered****.*
Study Timeframes for Approved Studies:	• Commencement (defined as first patient receiving first dose of study drug): *no later than nine (9) months* of notice of study approval. • Complete accrual: *within five (5) years* of commencement. • Reporting/Dissemination of results in Manuscript Form: *no later than nine (9) months* after study endpoint achieved. ***All studies will require documentation of the feasibility of accruing the targeted study population; studies may be multi-institutional.***
Selection Criteria:	Proposals will be judged based on the following criteria: • Strategic Alignment to RFP • Innovation/Uniqueness • Methodology • Organizational Capability, Leadership & Staff Capacity Approach/Feasibility *The GRANTOR has the ability to reject any study with safety issues or if it is an already studied concept.*
Drug Supply:	Elranatamab will be supplied for all approved and funded studies by Grantor. If the proposal requires a second investigational drug, a letter of commitment for provision of that drug by supplier must be submitted with proposal.

Key Dates:	• RFP release date: March 29, 2023 • **LOI submission deadline: May 10, 2023** • LOI notification date: June 21, 2023 • Full Proposal submission deadline: August 2, 2023 • Anticipated grant award notification date: September 13, 2023 (Please note that the submission deadline is 5:00 PM Eastern)
Questions:	If you have questions regarding this RFP, please direct them in writing to Nicole Zion, Clinical Research Manager, at zion@nccn.org and Amanda Kaczerski, Director, Grant Officer Oncology, at amanda.kaczerski@pfizer.com with the subject **"NCCN Pfizer Elranatamab RFP"**.

How to Submit:	• Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW".
	• Select the following Competitive Grant Program Name: **2023 ONC US NCCN Multiple Myeloma RES**
	• Select the following Area of Interest: **Oncology-Hematologic**
	• Requirements for submission:
	  • Complete all required sections of the online application referring to the guide included in the Appendix.
	  • If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page.
	• IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.

Review and Approval Process	An NCCN Request for Proposals Development Team (RFPDT) has been formed to oversee this process and will utilize a formalized review procedure to select the proposals of highest scientific merit. The NCCN RFPDT oversaw the development of this RFP and will perform the peer review of applications. All reviews, evaluations, and award decisions are independent of Grantor.
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.

7.0 Terms and Conditions

1. RFP does not commit Pfizer, or their partners, to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.
2. 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. These terms have been drafted 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.
3. This RFP does not provide permission and license for the use (including the creation of derivative products) of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) or the NCCN Biomarkers Compendium for commercial use. Grant recipients will need to maintain a separate end-user or other license agreement directly with NCCN for use of the NCCN Guidelines or Biomarkers Compendium.

8.0 LOI Submission Requirements

The LOI will be accepted via the online application. When answering the LOI questions in the application please keep the following in mind:

Goals and Objectives	Briefly state the overall goal of the project. Describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s). List the *overall* objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.
Assessment of Need for the Project and Preliminary Data	Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), or a project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in *your* target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.
Target Audience	Describe the primary audience(s) targeted for this project. 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.
Project Design and Methods	Describe the planned project and the way it addresses the established need. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.

Innovation	Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed. 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	In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data. Quantify the amount of change expected from this project in terms of your target audience. Describe how the project outcomes will be broadly disseminated.
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.
Organization Detail **(Environment and Mentors)**	Describe the attributes of the institutions/organizations/associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.
Budget Detail	A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable. The budget amount requested must be in U.S. dollars (USD). While estimating your budget please keep the following items in mind: Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB/IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment. The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.

Budget Detail (continued)	It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non-prescription). Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.

9.0 References

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