



“It’s breakthrough time.” —TOM BROKAW

# Multiple Myeloma Research Foundation **2018 Biotech Investment Awards: Advancing Immune Therapeutic Approaches in Myeloma**

*October 2018*

The MMRF is in the top 1% of nonprofits:





# MULTIPLE MYELOMA Research Foundation

## **BIOTECH INVESTMENT AWARD: ADVANCING NOVEL IMMUNE THERAPEUTIC APPROACHES IN MYELOMA**

### **PROGRAM GUIDELINES AND LOI INSTRUCTIONS**

#### **PROGRAM DESCRIPTION:**

**October 12, 2018:** The Multiple Myeloma Research Foundation (MMRF) seeks proposals for its Biotech Investment Award program (BIA) which this year is specifically directed at advancing novel immune therapeutic approaches to the clinic for myeloma patients. As clinical advancements with various antibody based approaches have recently been demonstrated in myeloma patients, the MMRF recognizes the need to bring other promising immune therapeutics, both novel and those currently under investigation for other cancers, into myeloma focused clinical trials. Given the successes in other malignancies, it is time to explore and advance additional strategies within the myeloma patient population using these classes of agents. These include but are not limited to novel antibodies directed toward checkpoint inhibitors or co-stimulatory factors, autologous and allogenic engineered T-cells and other adaptive cell therapies, bispecifics, cancer vaccines and immune monitoring tests and technologies.

This BIA program is designed to: (a) provide resources necessary for early-stage biotechnology companies to rapidly test immune therapeutics and their use in multiple myeloma, (b) to foster collaboration with academic myeloma experts to support tumor and immune correlative studies as part of the clinical trial, and as needed, (c) to aid in preclinical work to define appropriate combination approaches and improved patient targeting.

The BIA *is a milestone-driven initiative* and therefore payments will be made after successful completion of milestones as outlined in each applicant's proposal.

#### **KEY DATES:**

October 12, 2018:	Program launch; Call for LOIs
November 16, 2018:	Letter of Intent Package due to MMRF (5pm EDT)
December 10, 2018:	Selected applicants to be invited to submit full proposal
February 4, 2019:	Full proposals of invited applicants due to MMRF
February 28, 2019:	Finalists invited to present at the MMRF
March 1, 2019:	Applicants to be notified of review/award decisions

#### **BACKGROUND:**

The Multiple Myeloma Research Foundation was founded in 1998 and has raised more than \$400 million to fund the most promising research in the field of multiple myeloma. The MMRF BIA program is intended to assist biotechnology and other for-profit (either public or privately-held) entities through the critical funding phase between laboratory discovery and commercialization. It is expected that companies supported by the MMRF BIA program will require additional funding and resources for successful completion of the proposal. The MMRF, through its BIA program, has provided more than \$12 million in financial support to biopharmaceutical companies to advance agents from early drug discovery and development through Phase I/IIa clinical trials. The purpose of the 2018 BIA is to support the advancement of **novel, advanced immune therapeutics into the clinic as a single agent or combination for the treatment of myeloma**

#### **Immune Therapy Focus:**

**The 2018 MMRF BIA program is focused on accelerating the development of promising immune therapeutic or diagnostic candidates into multiple myeloma clinical trials starting on or before July 2020 .** Applications may seek support for:

- Phase I or IIa immune therapy or diagnostic focused clinical trials in multiple myeloma

- IND-enabling studies to advance a late-stage development candidate for myeloma into clinical trials with the intent of IND submission no later than July 2020.

Immune therapeutic strategies include but are not limited to:

- New antibody therapies targeting myeloma
- New antibody or small molecule therapies intended to modulate host immunity, including, e.g. immune checkpoint inhibitors and co-stimulatory factors
- Engineered T cell and other immune cell approaches
- Bispecific therapies
- Vaccine approaches
- Immune monitoring diagnostics

The proposed studies could be immune therapeutic strategies as single agents or in combination with standard of care and/or other novel agents or prospective diagnostic trials to demonstrate clinical utility. The clinical studies are intended for the following patient populations:

- Relapsed/refractory myeloma
- Newly diagnosed symptomatic myeloma
- Smoldering myeloma

#### **ELIGIBILITY REQUIREMENTS:**

The applicant organization must be for-profit. While not required, the MMRF encourages applications from companies proposing collaboration with academic researchers. Responsibility for the planning, direction and execution of the proposed studies will be solely that of the principal investigator who must be an employee of the company. Academic investigators may have an advisory role but the operational and strategic ownership of the project must reside with the company. Proposed projects must be ready to move into clinical testing for multiple myeloma patients starting on or before July 2020

#### **FUNDS AVAILABLE:**

The MMRF will commit to support BIA projects in 2018-2019 with up to \$3 million per successful application over a two year period. The number and financial support of awards to be granted is contingent upon the availability of funds and the receipt of applications of high scientific merit that meet the RFP requirements.

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MMRF reserves the right not to fund any BIA in 2018-2019 if the proposals submitted do not meet the RFP requirements or if the submitted applications are not of high scientific merit.

The MMRF expects that the projects supported through BIA will require additional financial and other resources from the applicant. The BIA program has been developed as a mechanism to enable companies to leverage other sources of funding. Applications will therefore need to demonstrate solvency in the form of existing and anticipated resources. Applicants should provide a business plan that identifies sources of revenue/capital, as well as their most recent audited financial documents.

Applicants with finite goals, i.e. toxicology testing, scale-up, etc. should indicate vendors and partners with whom they choose to sub-contract. These applications are within the scope of this initiative even though IND filing should be no later than July, 2020. It is anticipated that broader proposals i.e. bringing an early phase study into the clinic environment, will require funding outside the scope of the BIA. Therefore, in addition to sufficient corporate expertise and manpower to enable success, it will be important for applicants to demonstrate access to third-party resources as a means of sustainability and viability for their proposed study.

## **CALL FOR LETTER-OF-INTENT (LOI) PACKAGES:**

### **Submission of LOI Package Including Abbreviated Grant**

#### **Proposal:**

Applicants are required to submit a **Letter of Intent (LOI) Package** with an **Abbreviated Grant Proposal** by **November 16, 2018** for review. The following information must be included in the LOI package:

**LOI:** Cover letter stating overall goal and intent of the proposal and signed by an officer of the company. A sample cover letter is provided at the end of these guidelines.

**Abbreviated Grant Proposal:** (the following information is limited to **4 pages; single spaced/Arial or Times New Roman font 11 or 12**. The 4 page limitation excludes figures, tables and publications).

- a) Scientific rationale/preliminary studies in multiple myeloma and proposed scope of work
- b) Summarized scientific achievements to date and proposed milestones associated with scope of work
- c) Principal investigator and key personnel from the Company included in proposal (required)
- d) Name, Title, and Institution of academic collaborators/consultants and brief description of their role in project and intended studies (if applicable)

**LOI Supporting Documentation:**

In addition, the following LOI Supporting Documentation should accompany the Letter of Intent Abbreviated Grant Proposal (not subject to page limitations):

- e) Most recent year's audited financials (if not available, please contact **Christopher Williams at 203-652-0206** to determine how to proceed)
- f) One page summary of Company's business plan
- g) Signed Confidentiality Agreement (agreement template at end of these guidelines)

**Supplementary Information:**

Letters of support from past or potential partners are a means of demonstrating peer recognition. Letters of Support from third-party investigators are encouraged and may be submitted with the Letter of Intent.

**STEP ONE CHECKLIST:**

**Due: November 16, 2018**

- Letter of Intent (signed by an officer of the company) \_\_\_\_\_
- Abbreviated Grant Proposal: limit of four pages  
(Scientific rationale, scope of work, scientific achievements, Milestones and key personnel) \_\_\_\_\_
- Audited Financials \_\_\_\_\_
- Summarized Business Plan \_\_\_\_\_
- Signed Confidentiality Agreement \_\_\_\_\_
- Letter(s) of Support (optional) \_\_\_\_\_

Companies may submit their applications electronically to [williamsc@themmrf.org](mailto:williamsc@themmrf.org). However, given the proprietary nature of some of the content, the MMRF will accept hard-copies in order to ensure the confidentiality of its applicants. However please be aware of the due date of **November 16, 2018**.

Hard copies may be mailed to:  
Christopher Williams  
Multiple Myeloma Research Foundation  
383 Main Avenue, 5<sup>th</sup> Floor  
Norwalk, CT 06851  
Attn: BIA Program

**REVIEW PROCESS FOR LOI Submission:**

Each Letter of Intent package will undergo a confidential review process and a small number of companies will be invited to submit full proposals. Decisions regarding invitations to submit full proposals will be made on or about December 10, 2018 and selected applicants will be notified by MMRF staff by phone and via email. Guidelines for the full application will be provided at the time the company is invited to apply.

**INQUIRIES:**

For more information on the MMRF please contact:

Christopher Williams  
VP Business Development  
Multiple Myeloma Research Foundation  
383 Main Avenue, 5<sup>th</sup> Floor  
Norwalk, CT 06851-1543  
(203) 652-0206  
williamsc@themmrff.org

## Sample Letter of Intent

Date

Christopher Williams

VP Business Development

Multiple Myeloma Research Foundation  
383 Main Avenue, 5<sup>th</sup> Floor  
Norwalk, CT 06851-1543  
(203) 652-0206  
williamsc@themmrf.org

Dear Mr. Williams

On behalf of (*insert name of company*), I am writing to inform you of our request to submit an application for funding through the Multiple Myeloma Research Foundation's Biotech Investment Award (BIA) program. We understand this letter is subject to peer review and not all companies will be invited to submit a full proposal. We also appreciate that the information provided within this Letter of Intent is proprietary and that the Multiple Myeloma Research Foundation is bound by the terms of confidentiality as specified in the mutually-signed Non-Disclosure Agreement for the duration of the review.

Enclosed please find:

- a. Scientific rationale/preliminary studies in multiple myeloma and proposed scope of work
- b. Summarized scientific achievements to date and proposed milestones associated with scope of work
- c. PI and key personnel from Company included in proposal (required)
- d. Name, Title, and Institution of academic collaborators/consultants and brief description of their role in project and intended studies (if applicable)
- e. Most recent year's audited financials (*if not available, please contact Christopher Williams at 203-652-0206*)
- f. One page summary of Company's business plan
- g. Signed Confidentiality Agreement

(Items a-d may not exceed four pages. Items e-g are not subject to page limitations.)

If invited, we look forward to developing this application into a full proposal according to the guidelines that will accompany the invitation.

Sincerely,

(*Name and Title*)



## **MUTUAL CONFIDENTIAL DISCLOSURE AGREEMENT**

THIS MUTUAL CONFIDENTIAL DISCLOSURE AGREEMENT, effective as of the date of the last signature hereto (“Effective Date”) by and between \_\_\_\_\_, having its principal place of business at \_\_\_\_\_ (“Company”) and the Multiple Myeloma Research Foundation, Inc., on behalf of its wholly owned subsidiaries, its and its wholly owned subsidiaries officers, directors, employees, agents, volunteers, and consultants, having an address at 383 Main Avenue, Norwalk, CT 06851 (“MMRF”), shall govern the conditions of disclosure by the parties of proprietary and/or confidential information (“Information” as further defined below).

The parties are willing to furnish such Information to each other. As used herein, “Information” shall mean proprietary and/or confidential financial, technical, business, clinical, scientific, or other confidential information disclosed by any party, which is designated as being confidential non-public information, including without limitation, information relating to a party’s projects, plans, procedures, development, research, and finances.

With regard to a party’s Information, the receiving party shall use reasonable efforts (i) not to use such Information except for the purpose of discussions between the parties and (ii) not to disclose such Information to any person without the express written permission of the disclosing party, except that the receiving party shall not be prevented from using or disclosing Information that the receiving party can demonstrate by competent evidence:

1. was previously properly known to the receiving party without any restriction on use or disclosure;
2. is now public knowledge, or becomes public knowledge in the future, other than through breach of the Agreement by the receiving party;
3. is lawfully obtained by the receiving party without any restriction on use and disclosure from sources independent of the disclosing party who have a lawful right to disclose such Information; or
4. is developed by the receiving party independently of the disclosing party and can be proven through written documentation.

Receiving party may disclose Information to its directors, partners, officers, employees, independent contractors, consultants, or affiliates who are actively and directly involved with the business relationship and consequently need to know such Information.

Disclosing party shall mark all Information provided to the receiving party hereunder with a “Confidential” label or other similar notation to indicate the confidential nature thereof. With respect to Information that disclosing party provides to the receiving party by means other than in written or documentary form, disclosing party shall within thirty (30) days thereafter, summarize such Information in writing to the receiving party, with a marking indicating its confidential nature.

Upon request by the disclosing party, the receiving party will promptly return to disclosing party all of disclosing party’s Information and all copies and extracts of disclosing party’s Information furnished to the receiving party hereunder, and shall discontinue any further use of disclosing party’s Information provided, however, that the receiving party may retain one copy of all documents solely for use in connection with regulatory requirements and as evidence of the receiving party’s performance of its obligations hereunder. Receiving party shall not be required to destroy electronic files containing Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information provided that such electronic files remain subject to the confidentiality restrictions set forth herein. Any notes, summaries or extracts of or containing Information made by receiving party shall be kept confidential in accordance with the terms of this Agreement.

The parties agree that neither furnishing Information to the other party, nor anything contained in this Agreement shall constitute any grant, option, or license to the other party under any patent or other rights now or hereinafter held by any party. Nothing contained in this Agreement shall be construed, by implication or otherwise, as an obligation upon any party to disclose any particular information to the other or to negotiate or enter into any further agreement or arrangement with the other party relating to any of the Information or any other matter This provision

may only be modified or waived by a separate writing signed by all parties expressly so modifying or waiving this provision.

If a receiving party becomes obligated to disclose any of disclosing party's Information to comply with an applicable governmental law, regulation, or court order, the receiving party agrees to provide disclosing party with written notice of such requirement as far in advance of disclosure as is reasonably possible so that disclosing party may take any action it deems appropriate to prevent or limit disclosure, and the receiving party agrees to provide reasonable cooperation with such actions.

This Agreement constitutes the entire agreement between the parties, regarding the subject matter hereof and supersedes any and all other agreements and understandings between said parties, whether oral or written, with respect to the subject matter hereof. No waivers or modifications to this Agreement will be effective unless in writing and signed by all parties. If any provision of this Agreement is declared void or unenforceable, such provision shall be deemed modified to the extent necessary to allow enforcement, and all other portions of this Agreement shall remain in full force and effect.

Notwithstanding the foregoing, this Agreement shall not alter, modify, or supersede any previous Confidential Disclosure Agreement(s) entered into by and between any of the parties.

The term of this Agreement shall commence on the Effective Date and shall expire on \_\_\_\_\_, unless terminated earlier as provided herein. Notwithstanding the foregoing, the obligations of the recipient party under the terms of this Agreement with respect to any Information that the recipient party retains following the Effective Date shall remain in effect for five (5) years from the date of disclosure.

Any party may terminate this agreement without cause at any time by providing prior written notice within thirty (30) days to the other parties.

The parties agree that this Agreement may be executed and delivered by facsimile, electronic mail, internet, or any other suitable electronic means, and the parties agree that signatures delivered by any of the aforementioned means shall be deemed to be original, valid, and binding upon the parties.

IN WITNESS WHEREOF, the parties have caused their duly authorized representatives to execute this Agreement on the Effective Date set forth above.

**Multiple Myeloma Research Foundation, Inc.**

**NAME:**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Authorized Signatory

Authorized Signatory

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_