



Powerful thinking advances the cure.

Multiple Myeloma Research Foundation

BIOTECH INVESTMENT AWARD

PROGRAM GUIDELINES AND APPLICATION INSTRUCTIONS

PROGRAM DESCRIPTION:

July 7, 2010: The Multiple Myeloma Research Foundation (MMRF) seeks proposals for its Biotech Investment Award program (BIA). The goal of this initiative is to drive and accelerate the development of innovative and effective treatments for myeloma. By funding the early stages of drug discovery and development, BIA will have significant impact on future myeloma treatments. To date, more than \$7M has been awarded to biopharmaceutical companies in programs aimed at this objective. This program is designed to: a) provide resources necessary for biotechnology and pharmaceutical companies to rapidly test therapeutics in multiple myeloma; and b) to foster collaboration with academic myeloma experts, as needed. BIA aims to remove barriers that limit the development of novel drugs for myeloma. *This is a milestone-driven initiative.* Payments will be made after successful completion of milestones as outlined in each applicant's proposal.

KEY DATES:

July 7:	Program launch
August 24:	Required Letter of Intent due to MMRF (5pm EDT)
Mid-September:	Selected applicants to be invited to submit full proposal
October 19:	Full proposals due to MMRF (5pm EDT)
December:	Applicants to be notified of review/award decisions
March 2011:	Anticipated completion of negotiations and start date

BACKGROUND:

The Multiple Myeloma Research Foundation was founded in 1998 and has raised more than **\$140 million** to fund the most promising research in the field of multiple myeloma. The MMRF BIA program is intended to assist biotechnology, pharmaceutical, and other for-profit (either public or privately-held) entities through the “Valley of Death”— the funding gap between laboratory discovery and commercialization. Ultimately, the goal is for the MMRF to help biotechnology/pharmaceutical organizations successfully develop new treatments for people battling multiple myeloma.

PRIORITY AREAS:

Applications may seek support for the following:

- Phase I or II clinical trials in multiple myeloma
- To advance pre-clinical candidates for myeloma clinical trials into studies to support formulation, pharmacokinetics, toxicology, and scale-up
- Advance promising therapeutic entities currently under study for other disease indications into myeloma

Certain targets and pathways of particular interest to the MMRF include, but are not limited to, the following:

- Akt/PI3K
- Cyclin D/cdks
- FGFR3
- Hedgehog/Notch
- Maf
- mTOR
- NF-kB
- Proteasome
- Ras/MAPK
- STAT3/IL6/JAK

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 by the second half of 2013.

FUNDS AVAILABLE:

The MMRF will commit up to \$1 million per application over a two year period to support BIA projects in 2010. The number of awards granted in 2010 is contingent upon the availability of funds and the receipt of a sufficient number of applications of high scientific merit that meet the RFP requirements.

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 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 wholly within the scope of this initiative. It is anticipated that broader proposals i.e. bringing an early phase study into the clinic environment, will require funding outside the parameters of BIA. Therefore, it will be important for applicants to demonstrate access to third-party resources as a means of sustainability and viability for their proposed study in addition to sufficient corporate expertise and manpower to enable success.

SUBMISSION PROCESS:

Step 1-Submission of LOI and Abbreviated Grant Proposal:

Applicants are required to submit a Letter of Intent Package with an Abbreviated Grant Proposal by **August 24, 2010** which will then be sent out for external peer review. The LOI is a statement of project intent and must include an accompanying abbreviated grant proposal containing the following information. The Abbreviated Grant Proposal is not to exceed **four pages and will contain:**

- a) Scientific rationale in multiple myeloma and proposed scope of work
- b) Summarized scientific achievements (preliminary studies that support the work plan; milestones achieved to date on this project)
- c) Name, Title, and Institution of academic collaborators/consultants (if applicable) and key personnel (required)

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

- d) Most recent year's audited financials (if not available, please contact Nicole Morgan at 203-652-0228)
- e) Signed Good Faith Agreement for future negotiations
- f) Company's summarized business plan
- g) Signed Non-Disclosure Agreement

Samples of the following are available at <http://www.themmr.org/research-programs/for-academic-researchers/>:

- Letter of Intent (LOI) Template
- MMRF Non-Disclosure Agreement
- MMRF Good Faith Agreement for Future Negotiations
- Sample Letter of Support

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, or if applicable, with the full proposal.

STEP ONE CHECKLIST:

Due: August 24, 2010

- Letter of Intent (signed by officer of the company) _____
- Scientific rationale, scope of work, scientific achievements and key personnel (Abbreviated Grant Proposal/limit of four pages)

- Audited Financials _____
- Signed Good Faith Agreement for Future Negotiations _____
- Summarized Business Plan _____
- Non-Disclosure Agreement _____
- Letter(s) of Support (optional) _____

Companies may submit their applications electronically to morgann@themmr.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.

Hard copies may be mailed to:
Multiple Myeloma Research Foundation
Attn: Nicole Morgan
383 Main Avenue, 5th Floor
Norwalk, CT 06851

REVIEW PROCESS FOR STEP ONE:

Each Letter of Intent package will undergo a review process by individuals under confidentiality and a small number of companies will be invited to submit full proposals. Decisions regarding invitations to submit full proposals will be made in mid-September and selected applicants will be notified by MMRF staff by phone and in writing.

Step 2-Submission of Full Application (by invitation only):

Companies who have been asked to submit a full proposal will be notified by mid-September and will be provided with a full application. Completed applications will be due by October 19 at 5:00 pm EDT, either electronically to Nicole Morgan at morgann@themmrf.org, or in hard copy to:

Multiple Myeloma Research Foundation
Attn: Nicole Morgan
383 Main Avenue, 5th Floor
Norwalk, CT 06851

STEP TWO CHECKLIST:

Due: October 19, 2010

- Completed Application (signed by officer of the company) _____
- Letter(s) of Support (optional) _____
- Comprehensive Business Plan _____
- Additional Supporting Documents (optional) _____

REVIEW PROCESS FOR STEP 2:

Full proposals will be sent out for scientific review by a team of experts in drug discovery and development. The reviewers will score each proposal and assign its weight based upon the following:

- 40% Scientific Narrative including background and significance, goals and objectives, scope of work and potential for meaningful contribution to the field of multiple myeloma
- 25% Clear and measureable milestones with feasible timelines for deliverables to trigger corresponding payments
- 25% Human and Institutional Resources
 - Experience of Principal Investigator
 - Appropriate/Suitable Facilities
 - Company's experience in cancer drug discovery/development
 - Institutional commitment to study multiple myeloma
- 10% Budget and Budget Justification must be appropriate to conduct the study in the proposed timeframe. The company must demonstrate that its infrastructure is viable and its finances sound.

Award Notification:

Applicants will be notified of their award status during **December 2010**. If awarded a Biotech Investment Award, the MMRF will coordinate press releases and other public announcements in concert with the grantee. Applicants who do not receive funding will be eligible to receive verbal feedback from MMRF based upon external reviewers' comments. In the past, this has proved a useful mechanism for enhancing future grant applications.

Contracting:

Awardees will be required to enter into contract agreements with the MMRF.

Funding will be provided in installments following milestone achievement.

Regular project meetings must be held during the award period that will include company representatives, academic collaborators, and MMRF staff. All parties will be required to sign confidentiality agreements and all data and information will be held in the strictest of confidence. **Contracting must be completed within 90 of the award notice.**

Additional Applicant Information:

- No application's proposed project timeframe may exceed a period of two (2) years although the study may extend beyond the grant period.
- If invited to submit a full application, applicants must identify aggressive yet likely achievable milestones and timelines, incorporating go and no-go decision points.
- Multi-year funding is contingent upon successful milestone achievement as determined by the Scientific Review Committee.
- Funds cannot be used for equipment purchases or travel expenses.
- Indirect costs will not be paid to a for-profit entity but indirect costs up to 10% may be allocated to an academic collaborator.
- The results of the research will be published as rapidly as possible, at a maximum of 12 months from the date of the project's completion or early termination, in the open scientific literature, consistent with high standards of scientific excellence and rigor, and include acknowledgement of the funding provided by the Multiple Myeloma Research Foundation.

INQUIRIES:

For more information on the MMRF please visit www.multiplemyeloma.org or contact:

Administrative/Fiscal

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383 Main Avenue, 5th Floor
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Scientific

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