National Multiple Sclerosis Society

FALL 2017 REQUEST FOR PROPOSALS

Fast Forward

Therapeutic Development Opportunities for Neuroprotection and Neuroregeneration in Multiple Sclerosis

Background

The National Multiple Sclerosis Society invests in promising research to drive breakthroughs that will stop MS, restore function and end MS forever. Research breakthroughs fuel the treatments and solutions people with MS need to overcome the challenges of MS today with confidence and hope for a world free of MS tomorrow. As part of its commitment to addressing the needs of individuals affected by MS, the Society invites proposals to establish research partnerships with Fast Forward, LLC to accelerate and support development of therapeutic strategies relevant to MS.

Purpose of this RFP

The purpose of this request for proposals (RFP) is to fund drug development opportunities for therapies promoting neuroprotection and repair. New treatment strategies are needed to stop disease worsening by preventing neurodegeneration and reversing neuronal damage so that lost function can be restored. Although it is recognized that animal models of MS provide only limited insight into the pathophysiology of neurodegenerative process, studies to evaluate impact on demyelination, remyelination, neuroprotection, neural plasticity, and repair are considered appropriate for this RFP.

Areas of high impact include:

- Therapeutic approaches that directly promote remyelination and/or neuroprotection (including stimulation of endogenous repair and cell-based approaches)
- Proof of concept studies with repurposed FDA-approved therapies that have defensible intellectual property or strong commercial viability

Research areas supported by this RFP include, but are not limited to:

- Early-stage target validation
- Optimization of pre-clinical compounds
- PK/ADMET studies for valid compounds in development
- Imaging studies to measure target occupancy or target-related pharmacodynamic effects that could support a future clinical trial

Research areas NOT supported by this RFP:

- Assay development
- Target identification studies
- High-throughput screening efforts
- Animal studies where the primary effect of a drug or drug candidate targets an immune-based anti-inflammatory pathway that would primarily be relevant to relapsing-remitting MS

Mechanisms of support:
This RFP is open to global commercial organizations and not-for-profit research institutions collaborating with a commercial organization. Consistent with our goal to support research and development conducted with a high level of quality control typical of the pharmaceutical industry, proposals from not-for-profit institutions will be considered if a majority of the work is conducted at reputable Contract Research Organizations with appropriate expertise relevant to the proposal. The project period should be 1 to 2 years.

Funding: Up to $300,000 will be provided and must be justified based on the scientific and development work plan. In the case of proposals or clinical trials where the cost exceeds the budget limitations of this RFP, Fast Forward may consider such a proposal with evidence that additional financial resources will be provided in-kind or by third parties.

Submission guidelines and process: Important dates:

- Pre-applications will be accepted beginning **November 8th, 2017**
- Final date for acceptance of pre-applications: **December 6th, 2017**
- Final date for receipt of completed full applications: **December 20th, 2017**

A brief pre-application is required to determine if a proposal is aligned with the objectives of the RFP. Inquiries with Fast Forward staff are strongly encouraged (see contact information below). Proposals are to be submitted through the National MS Society's online grant submission portal - MSGrants. All proposal information, including instructions for accessing MSGrants, can be found at http://www.nationalmssociety.org/For-Professionals/Researchers/Society-Funding/Commercial-Research-Funding. Upon review of pre-applications by staff, only those applicants proposing work aligned with the RFP objectives will be invited to submit full proposals for review. If selected, applicants will be provided access to the full application and a set of document requests to enable Fast Forward to conduct a due diligence review of the proposal.

Applicants invited into full review will have until December 20th, 2017 to complete the application and submit all required documents. Proposals will undergo evaluation by Fast Forward's Scientific and Business Advisory Committee (SBAC) and only selected proposals will advance to the next stage to conduct a teleconference with the Fast Forward SBAC for a presentation in early 2018.

Fast Forward will review proposals based on the following criteria:
A. Scientific Considerations:

- **Rationale**: Does the proposal address an important aspect of the RFP?
- **Innovation:** Does the project challenge existing paradigms or address an innovative hypothesis, novel target or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies for this area?
- **Research Team**: Are the lead investigator and collaborators qualified and well-suited to carry out the proposed research?
- **Scientific Plan:** Is the research plan sufficiently developed and appropriate to the project? Are the specific aims clearly defined? Are milestones and go/no go decision points articulated? Are the milestones and timeline realistic?

- **Environment**: Is the research environment appropriate and likely to contribute to the success of the proposed research? Does the environment foster collaborative arrangements that may support the proposed research activities? Is the research environment compliant with appropriate rules and regulations for study conduct?
- **Budget**: Is the proposed budget reasonable and justified relative to the proposed research?

B. Commercial Considerations:

- **Commercial Feasibility**: Does the proposal define a potential path to the marketplace? What are key milestones or barriers to achieve commercialization?
- **Therapeutic Strategy**: Does the proposed therapeutic approach address unmet needs relative to existing alternatives/therapies for treatment of MS? Is the strategy feasible and appropriate to MS?
- **Development Potential**: Is there a development path that enables the drug candidate to advance through preclinical and/or clinical development?
- **Intellectual Property**: Has the applicant secured intellectual property for the technology? If not, is it in the process of doing so?
- **Funding by Third Parties**: Has the proposed research program been evaluated by other entities that have provided external support?

Applications that do not advance to the next stage of the review process and are not selected for funding will receive a summary of comments provided by the Fast Forward SBAC.

Funding decisions will be made based on the recommendations of the SBAC with advice from the Fast Forward Board of Managers. Applicants will be notified of final funding recommendations in Q2 of 2018. Each award will be provided pursuant to a Sponsored Research Agreement covering details of milestone-based project support and terms of revenue sharing.

Inquiries:

Applicants are encouraged to contact Fast Forward staff for clarification of any issues or questions regarding this invitation.

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