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Part I. Overview Information:

Section 1. Funding Opportunity Title: The Lawrence and Isabel Barnett Drug Development Program

Section 2. Key Dates:

Request for Application Open: March 15, 2021

Letter of Intent Due Date, if applicable: April 23, 2021, 5 p.m. US ET

Full Application Due Date (by invite only): June 25, 2021, 5 p.m. US ET

Anticipated Award Decision: September 2021

Anticipated Earliest Start Date: October 2021*

***Note: The start date should be prior to January 31, 2022.**

Part 2. Full Text of the Announcement

Section I. Funding Opportunity Description:

1. **Overview:** There is an urgent need for new and improved therapies for ALS, as there is still no cure. The Lawrence and Isabel Barnett Drug Development Program is open to industry and academic investigators proposing to develop novel or repositioning approaches for ALS. The Association seeks applications for the

preclinical assessment of therapeutics for ALS that have a high probability of reaching the clinic within three years.

2. **Topics of Interest:** We are especially interested in drug discovery projects supporting the following:
 - In vivo efficacy testing of lead molecules from pharmacological treatments, biological therapies, or gene therapy in animal models of ALS. Both novel programs and repurposing of approved or clinically safe therapies from other disease indications are appropriate for this RFA.
 - Determination of dose-range finding, target engagement, pharmacokinetics, pharmacodynamics, and preclinical toxicology/safety.
 - Development of pharmacologic agents through Adsorption, Distribution, Metabolism, Excretion, and Toxicity (ADMET) phase; This can be performed by a contract research organization in collaboration with the PI.

Please Note: Clinical trials will not be supported with this funding opportunity. Early drug discovery studies proposing high-throughput screening, hit-to-lead, and lead optimization will also not be supported through this funding opportunity.

Section II. Award Information:

1. **Funding Instrument:**
 - Grant: A support mechanism providing money to an eligible entity to carry out an approved project or activity.
2. **Funds Available and Anticipated Number of Awards:**
 - The number of awards is contingent upon The ALS Association's budget allocation and the submission of a sufficient number of meritorious applications.
3. **Award Budget:**
 - Budgets for direct and indirect costs up to \$250,000 per year may be requested.
4. **Award Period of Performance:**
 - The maximum period of performance is two (2) years.

Section III. Eligibility

1. **Eligible Individuals:**
 - Individuals with the skills, knowledge, and resources necessary to carry out the proposed research may apply as a principal investigator.
 - Post-doctoral fellows are not eligible to apply as a principal investigator.
2. **Eligible applicants:**
 - U.S. and non-U.S. biotechnology/pharmaceutical companies, or other publicly or privately held for-profit entities.

- U.S. and non-U.S. public and private non-profit entities, such as universities, colleges, hospitals, laboratories, units of state and local governments and eligible agencies of the federal government.

Section IV. Application and Submission Information

1. Content and Form of Application Submission

- It is critical that applicants follow the instruction of the application guide. Applications that are out of compliance with these instructions may be delayed or not accepted for review.
- **Letter of Intent:** By the date listed in Part I Overview Information, prospective applicants are required to submit a letter of intent that includes the following information:
 - a. Descriptive title of proposed activity
 - b. Name, address, and telephone number of the Principal Investigator
 - c. Names of other key personnel
 - d. Participating Institution(s)
 - e. Number and title of this funding opportunity
 - f. A scientific rationale for the proposed study and its relevance to ALS
 - g. A brief description of the study hypothesis and/or objectives and overall experimental plan to meet those objectives

The Letter of Intent should be submitted per the application instructions at this [link](#). The letter of intent can either be accepted or declined. If the letter of intent is accepted, the applicant will be invited to submit a full application. Results from the letter of intent review phase will not be provided to the applicant.

2. Page Limitations

- All page limitations described in the Research Plan instructions must be followed.

3. Submission Dates and Times

- Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date.
- Organizations must submit applications by accessing the application and instructions [here](#).

4. Funding Restrictions

- The ALS Association awards are subject to the terms and conditions described in The ALS Association Grants Policy Statement (GPS) and the award Agreement. The ALS Association GPS and a sample award Agreement template are available at <https://www.als.org/research/funding-opportunities/research-policies>.
- Awards will be limited \$500,000 total costs for the entire 2-year period of performance.
- Salary and wages and fringe benefits of personnel other than the salary of the Principal Investigator
- Salary and wages and fringe benefits of the Principal Investigator only when indirect costs are waived
- Direct salary for individuals not to exceed the salary limitation for Executive Level II of the Federal Executive pay scale provided at https://grants.nih.gov/grants/policy/salcap_summary.htm.

- Indirect costs for award and reimbursement is limited to 10 percent of the total funds awarded.
- Economy travel up to \$2,000 per year to attend scientific conferences.
- Moveable equipment costs not to exceed 20 percent of the annual budget.
- Computer hardware and software costs up to \$2,000.
- Recurring annual cost-of-living/inflationary increase up to 3% for personnel and consumable supplies.
- All funds must be expended within the approved period of support.
- All unexpended funds remaining at the end of the project must be returned to The ALS Association.

5. Requirements

- Therapeutics for ALS that have a high probability of reaching the clinic within three years.
- Successful applications will provide strong and compelling data supporting the biological rationale for the proposed treatment and a clear plan, including essential “Go/No-Go” decision milestones, for moving the approach through the essential stages of development.
- Applicants must address at least one of the areas of programmatic interest listed in the eligible topics section above. Applications that do not focus on at least one of the topic areas will be administratively withdrawn.

6. Collaborations

- The preclinical drug development process will likely require resources beyond those available at a single organization. *Therefore, applications are open to investigators participating in synergistic collaborations, focused testing and developing lead agents for the treatment of ALS.*
- *If a collaboration is proposed, letters confirming/supporting the collaboration are required.* Specific roles and responsibilities for each collaborator need to be clearly articulated. If the collaboration is multi-organizational, participating organizations will ensure the success of the collaboration by resolving potential intellectual and material property issues and by removing organizational barriers that might interfere with achieving high levels of cooperation.

7. Administrative and National Policy Requirements

All ALS Association grants include The ALS Association Grants Policy Statement as part of the Research Grant Agreement. The Grants Policy Statement includes the requirements applicable to animal welfare, human subject protections, data sharing, research resource sharing, publications, etc.

- **Animal Welfare Requirements:** The ALS Association requires its grantees to establish appropriate policies and procedures to ensure the humane care and use of animals. Domestic grantees also bear the ultimate responsibility for compliance with The *Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals*. Foreign grantees also bear the responsibility to comply with applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and a commitment to follow the [International Guiding Principles for Biomedical Research Involving Animals](#) developed by the Council for International Organizations of Medical Sciences.
- **Human Subject Requirements:** The ALS Association requires its grantees to establish appropriate policies and procedures to ensure the protection of human subjects used in research supported by The ALS Association. The ALS Association grantee must comply with the Department of Health and Human Services (HHS) regulation Title 45 Code of Federal Regulation Part 46. Clinical research involving

investigational drugs and devices or products regulated by the Food and Drug Administration (FDA), must comply with all FDA requirements in 21 CFR Parts 50, 56, 312 and 812.

- **Health Insurance Portability and Accountability Act (HIPAA):** The ALS Association requires its domestic grantees to comply with the requirements of HIPAA to ensure the protection of individually identifiable health information for ensuring confidentiality of patient records.
- **General Data Protection Regulation (E.U. 2016/679):** The ALS Association requires its foreign grantees to comply with the Regulation E.U. 2016/679, or its amended regulation, of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to processing of personal data and on the free movement of such data.
- **Intellectual Property/Royalty:** The ALS Association expects a royalty from discoveries in proportion to its contribution to the direct activity leading to the discovery, invention, or idea, if applicable. Grantees shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain all registerable rights in Intellectual Property arising from implementation of the Research Scope of Work at its sole expense. The grantee shall notify The ALS Association if it does not intend to pursue patent protection from any invention, discovery, or idea arising from the implementation of the Research Scope of Work and assign all rights to The ALS Association. Successful applicants will be accountable for providing The ALS Association its portion of the royalty received during and after termination of the award. Remittance of The ALS Association's share of the royalty must be made to The ALS Association per the instructions provided within the Research Grant Agreement.

8. Other Submission Requirements and Information

- Applications must be submitted electronically following the instruction described in [create application guideline](#). Paper applications will not be accepted.
- Upon receipt, applications will be evaluated for completeness and compliance with application instructions. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Review Criteria for Letter of Intent

- **Fit:** The letter of intent should allow the ALS Association staff to assess whether there is a good match between The ALS Association's interest and the project.
- **Relevance & Rationale:** The Letter of intent should provide appropriate scientific rationale for the proposed study and its relevance to ALS.
- **Overall Experimental Objectives:** The letter of intent should provide study hypothesis and/or objectives and overall experimental plan to meet those objectives.

2. Review Criteria for Proposals:

- **Impact/contribution to ALS:** Potential for the proposed studies to make an important contribution to ALS therapeutic development and how does the approach fit the current landscape of ALS treatments in development.
- **Target/Pathway:** Rationale for developing compounds against the given target/pathway.
- **Research Plan:** Feasibility, timeline and design of experiments, and whether the development plan will result in go-no go decisions in moving the therapeutic forward.
- **Research Team:** Qualifications of the PI, key personnel, and collaborators/consultants are appropriate to perform the proposed research project.

- **IP/Patent landscape:** Impact on future development/commercialization of the therapeutic.
3. **Peer Review and Selection Process**
 - All applications are peer reviewed by an ad hoc Scientific Review Committee constituted by The ALS Association to determine the application's scientific merit, and relevance to ALS.
 - The Scientific Review Committee's priority scores are forwarded only to The ALS Association Board of Trustees, which has the sole authority for approving the funding of research grants.
 4. **Anticipated Announcement and Award Dates**
 - After the peer review of the application is completed and a selection is made of the application, The ALS Association will send the combined review results of the grant proposal. To the extent practical and within the scope of the budget, The ALS Association recommends that the PI integrate any recommendations that the reviewers may have suggested to further optimize the project and outcomes.
 - See Part I, Section II, for dates of peer review, Scientific Review Committee and earliest start date.

Section VI. Award Administration Information

1. **Award (Agreement) Notice and Payment Schedule**
 - A formal notification in the form of an ALS Association Research Grant Agreement (Agreement) is the authorizing document and will be provided to the applicant organization for successful applicants.
 - The Agreement, signed by the applicant's authorized organizational representative (AOR), principal investigator and The ALS Association, will include the negotiated terms and conditions of the award between The ALS Association and the Grantee.
 - Award payments will be made to the Grantee on an annual or semi-annual basis as outlined within the Agreement.
2. **Administrative Requirements.**
 - The Grantee is expected to utilize The ALS Association funds in direct support of the research project and expend funds in accordance with the established organizational policies and procedures.
 - Funds charged to The ALS Association award must be for allowable project costs that are determined to be reasonable, allocable, consistently applied and conform to the program guidelines and/or limitations outlined in The ALS Association Funding Opportunity Announcement and the Agreement.
 - The Grantee is expected to seek The ALS Association's prior approval before making certain types of post-award changes.
 - Requests for prior approval should be submitted via email to researchgrants@alsa-national.org at least 30 days before the proposed change.
3. **Reporting Requirements**
 - The Grantee will be required to submit semi-annual Research Progress Reports and annual Grant Expenditure Reports during the period of an award unless otherwise noted in the Agreement.
 - Future grant payments are contingent upon the grantee's submission of and The ALS Association's acceptance of the report(s).
 - The ALS Association's issuance of the next award payment, when applicable, serves as confirmation that the information provided has been reviewed and approved by The ALS Association.

- Final closeout reports (i.e., final research progress and expenditure reports) are due within 90 days following the termination date of the Agreement.

Section VII. ALS Association Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Submit general questions and other related correspondence to researchgrants@alsa-national.org.