JDRF REQUESTS EXPRESSIONS OF INTEREST FOR:

THERAPEUTIC DEVELOPMENT AND EARLY CLINICAL TESTING OF T CELL TARGETED IMMUNOTHERAPIES FOR THE TREATMENT OF TYPE 1 DIABETES.

PURPOSE

The purpose of this request for applications (RFA) is to facilitate faster translation of important type 1 diabetes (T1D) related research findings into viable immune therapeutic candidates for human testing. This RFA intends to specifically support late stage preclinical development of promising candidate immune drug and biologic therapies. It is JDRF's hope that projects successfully completed under this RFA will attract external partners for large scale trials towards regulatory approval of novel therapeutic candidates.

BACKGROUND

Type 1 diabetes (T1D) is a chronic autoimmune disorder in which auto-reactive T cells mediate the destruction of insulin-producing pancreatic β-cells, leading to lifelong dependence on exogenous insulin. To date, there are no approved immunotherapies for the prevention or treatment of T1D. Immune therapies that have shown promising results in T1D trials have included therapies aimed at enhancing the number and/or function of regulatory T cells (Treg) as well as those aimed at disabling or ablating auto-reactive effector T cells (Teff). To maximize efficacy and patient impact in T1D, a variety of Treg and Teff targeted therapies will be essential. To this end, in addition to pre-clinical development of novel lead candidates, existing clinical grade T cell targeted product candidates from industry pipelines may increase the number of therapies evaluated in T1D.

There are inherent challenges in translating findings from preclinical models to human T1D, especially with respect to the dose, route, and frequency of administration to result in clinically meaningful outcomes. These challenges make it difficult to compare candidate therapies head to head. There is therefore a dire need for standardized high quality preclinical testing of promising therapies. This RFA seeks proposals both from for-profit and non-profit sectors involving T cell targeted product candidates that require late stage pre-clinical development and also encourages projects to test clinical-stage compounds in proof-of-mechanism clinical trials in T1D.

OBJECTIVE/SCOPE

Examples of pertinent topics include, but are not limited to:

- IND-enabling studies of clinical candidates, including GLP/tox, studies if justified.
- Pre-clinical mechanistic and/or efficacy studies of candidate therapeutics in appropriate animal models (effectiveness in two orthogonal models is desirable).
- Optimization of lead candidate molecules.
- Pilot clinical studies to demonstrate proof-of-mechanism or effectiveness for existing clinical-stage drugs to define the expected MOA of different types of T cell targeted therapies.

To help ensure reproducibility and reliability of results, applicants are encouraged to work with appropriate Contract Research Organizations (CROs). A list of CROs with relevant expertise is available upon request.

Projects involving parties with complementary expertise are highly encouraged to submit to this RFA. Applicants are strongly encouraged to consult Subject Matter Experts (SME) while preparing their EOIs. This may include solicitation of scientific, clinical, regulatory and commercial advice. A clear vision of the Target Product Profile (TPP) of a therapeutic candidate is a plus.

This RFA is not intended to support: projects involving approved repositioned therapies not targeting Treg or Teff function, research on biomarker identification, studies without potential for near term translation, or for informing future clinical approaches, and discovery efforts.

Applicants who wish to consult with JDRF Program Staff to discuss the responsiveness of their proposal or to discuss ideas or resources that might benefit this initiative may do so. Enquiries should be succinct and made via email to contacts as shown below.

ANNOUNCEMENT INTRODUCTION AND PUBLIC Q&A

JDRF will hold an announcement introduction meeting via web and teleconference on Friday, **August 10th at 11 am-12 pm US Eastern Time** to which all interested prospective applicants are invited. JDRF scientists will give an overview of the goals of this initiative, explain the application process and answer initial questions on applications.

Join Webex meeting

Meeting number (access code): 734 175 042
Meeting password: Psqv6cwa

Join by phone
1-866-469-3239 Call-in toll-free number (US/Canada)
+1-650-429-3300 Call-in toll number (US/Canada)
Global call-in numbers | Toll-free calling restrictions

MECHANISM

Expressions of Interest (EOIs) are sought from academic investigators, biotechnology and pharmaceutical companies, or industry-academia partnerships who may have clinical grade product candidates relevant for T1D that are available for human testing or candidate Teff disabling or Treg enhancing immune therapies that require final stages of preclinical development in preparation for IND submission and initial clinical testing.

The level of funding for individual projects will vary depending on the scope and overall objectives of a project, and EOIs from strong cross functional teams will be given highest priority. Budgets proposed should be commensurate with project scope. Pilot and feasibility studies may also be proposed.

Under the terms of the grant award, written progress reports will be required from the funded investigator as a basis for continued support.

ELIGIBILITY

This RFA is open to academic investigators, biotechnology and pharmaceutical companies, or industry-academia partnerships, with preference given to collaborations between academic groups and commercial organizations.

Please note that additional information will be requested of applicants from for-profit entities or industry collaborations with academia if a full application is invited. Applications may be submitted by domestic and foreign for profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Applicants must hold an M.D., D.M.D., D.V.M., Ph.D., or equivalent and have a faculty position or equivalent at a college, university, medical school, or other research facility.

Please note that submissions from for-profit entities or collaborations involving for-profit entities will be reviewed by the JDRF T1D Fund (http://www.jdrf.org/about/t1dfund/) in addition to JDRF Research.

There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities, women, and members of minority groups underrepresented in the sciences.

EXPRESSIONS OF INTEREST

Prospective applicants should submit an expression of interest, [2 pages maximum] on line via RMS360 (http://jdrf.smartsimple.us) to be considered for a full proposal request. The EOI template provided in RMS360 must be used to complete the application.

PROPOSAL

An approved Expression of Interest is required prior to submission of a full proposal. JDRF staff will contact applicants of successful EOIs regarding next steps.

SCIENTIFIC REVIEW CRITERIA

Expressions of Interest will be evaluated based on the following criteria:

- Significance
- Relevance
- Approach
- Innovation
- Investigator Experience
- Environment
- Commercial Feasibility: Is there a potential path to the marketplace?
- Therapeutic Strategy: Does project address unmet needs relative to existing alternatives/therapies?
- 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?

PROJECTED DEADLINES

- RFA Release Date: .....July 19, 2018
- Announcement Intro Meeting.....August 10, 2018
- Expression of Interest Deadline.....October 8, 2018
- Notification of EOI Outcome.....November 15, 2018
- Full Proposal Deadline.....January 7, 2019

CONTACTS

PROGRAMMATIC

Primary contact:
Simi Ahmed, Ph.D.
Director, Immunotherapies
JDRF
26 Broadway, 14th Floor
New York, NY 10004
☎ 212-479-7679
💻 sahmed@jdrf.org

Secondary contact:
Carmen Fotino, Ph.D.
Scientist, Immunotherapies
JDRF
26 Broadway, 14th Floor
New York, NY 10004
☎ 212-401-2133
💻 cfotino@jdrf.org

ADMINISTRATIVE
Karen Ng
Program Administrator, Research Administration
JDRF
26 Broadway, 14th Floor
New York, NY 10004
☎ 212-479-7563
💻 kng@jdrf.org

RMS360 (http://jdrf.smartsimple.us)

If you have any grant-specific questions as you work within RMS360, please contact the administrative contact listed above.

For any non grant-specific inquiries or issues, please contact SmartSimple Support Services via email support@smartsimple.com or phone (866) 239 - 0991. Support hours are Monday through Friday between 5:00am and 9:00pm US Eastern Standard Time