

## **JDRF Requests Expressions of Interest for the Discovery and Development of Antigen Specific Therapies for Type 1 Diabetes**

### **Purpose of Request**

JDRF is soliciting expressions of interest (EOI) for the identification, development or pre-clinical testing of novel antigen specific therapeutic approaches designed to reverse type 1 diabetes (T1D). JDRF is committed to translation of research findings towards clinical results and is most interested in translationally relevant projects.

### **Background**

Immunotherapeutic approaches for preventing or halting T1D have involved both antigen-specific and antigen non-specific interventions. Because T1D results from a failure to maintain immune tolerance to islet autoantigens, targeting these autoantigens should provide not only an effective means of controlling the autoimmune response but should also avoid the harmful effects associated with non-specific immunosuppression. Recent clinical data from several independent trials has provided compelling evidence that immunomodulation alone will not cure T1D permanently. In addition, islet transplantation trials show resilient recurrence of islet antigen specific autoreactivity. Thus, antigen specific therapies will likely be required to induce long-lasting disease remission in the absence of adverse side effects.

### **Specific Goals of Request**

Expressions of interest are sought from investigators interested in identifying and further developing, in pre-clinical models, novel antigen specific therapies for treatment of recent onset T1D. The clinical translation potential of the investigations should be emphasized. Of particular interest are also mechanistic studies conducted in collaboration with ongoing antigen-specific T1D clinical trials aiming to correlate blood markers and T cell responses with clinical outcome, glycemic control, and response to therapy. Projects involving close cooperation between clinical results and pre-clinical models to allow for targeted prediction of optimal biomarkers are also deemed of high interest.

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

- Apply novel strategies, as opposed to classical approaches, for identifying novel human  $\beta$ -cell autoantigens
- Discover novel antigen-specific therapeutics for T1D including novel antigen delivery approaches and tolerogenic adjuvants
- Validate and further develop existing antigen-specific approaches to enable and accelerate their clinical translation
- Dose finding studies, including optimization of treatment regimens and in silico modeling
- Elucidate mechanisms of action of antigen-specific approaches to improve efficacy and refine the therapeutic strategy
- Mechanistic studies for ongoing or recently completed antigen specific clinical trials in T1D
- Using human samples, identify novel biomarkers of antigen-specific therapeutic efficacy to expedite product development and clinical assessment of efficacy
- Pre-clinical testing of combination therapies for halting and reversing T1D by combining antigen specific with anti-inflammatory or immunomodulatory approaches
- Investigators with ideas or resources that might benefit this initiative should also submit their ideas via an expression of interest

### **Expressions of intent should be no more than two pages in length including the following information:**

- Name, title and institution of principal investigator (PI), co-investigator and/or key collaborator(s)
- Brief details of approach proposed, including hypothesis, scientific rationale and references to published or preliminary data (preliminary data need not be presented in detail)
- Description of potential for translation into therapies including short and long-term development goals
- Biosketches of PI and co-investigators/collaborators (does not count towards page limit)
- Total estimated budget and project duration (not to exceed 24 months)

Inquiries in this area should be referred to Teodora Staeva Ph.D. [tstaeva@jdrf.org](mailto:tstaeva@jdrf.org); tel: +1-917-216-1047

### **Key Dates:**

- Expressions of interest should be submitted as attached pdf via e-mail to Teodora Staeva ([tstaeva@jdrf.org](mailto:tstaeva@jdrf.org)) under the subject line "EOI-Ag Specific Therapies" no later than March 2, 2009 at noon EST.
- Submitted expressions of interest will be acknowledged with brief responses as to their suitability for further development by the JDRF Autoimmunity Program no later than March 13, 2009.

**Note:** Please be reminded that there are research resources for pre-clinical testing and manufacture of therapeutic agents for T1D through NIH: [NOT-DK-08-012](#) and [NOT-KD-07-009](#).