Sanofi Genzyme and Regeneron Alliance
Medical Affairs
Request for Proposal

**Date:** April 18, 2016
**Disease State:** Atopic Dermatitis
**Therapeutic Area:** Immunology
**Area of Interest:** Atopic Dermatitis

**Internal Requestor Information:**
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**TAG ID #:** PL-WKSN1  
**Due Date:** no later than 5PM EST on Wednesday, May 25, 2016

**Health Care Gap**

Atopic dermatitis (AD) is a common inflammatory disorder, driven by immune dysregulation, allergen exposure, skin barrier disruptions, and infection. Moderate-to-severe disease is present in as many as a third of patients with AD and is associated with markedly reduced quality of life and overall well-being. In a study of adults with AD, stress and emotional state are common triggers of AD flares; these patients reported that their emotional response to these episodes was as important of a concern as their disease itself. Moreover, a recent update to the American Academy of Dermatology guidelines of care for the management of adult and pediatric patients recommends a proactive approach for long-term disease management versus episodic management of flares with an emphasis on clinical assessment of disease severity. The resulting shift in care of this patient population has resulted in an increased awareness leading to an identification of a need to ensure education of both healthcare practitioners (HCPs) and patients with regards to new and emerging treatment options for these individuals.

Currently available FDA-approved therapeutic options adequately treat most patients with mild AD, but have demonstrated limited long-term or sustained efficacy in patients with moderate-to-severe disease. Recent investigation into the underlying mechanisms of AD have revealed specific T-cell cytokines and cytokine receptors as primary drivers of the inflammatory response and data from trials examining the clinical effects of targeted agents directed against these and other key molecules involved in modulating T-cell signaling are emerging. Specifically, several monoclonal antibodies in phase 2 and phase 3 clinical trials have shown an ability to block various proteins that mediate inflammation and immune responses potentially arresting development and progression of the disease at various pathogenic steps. As these new and emerging treatment options are made available to HCPs and patients, education on the safety, efficacy and attributes of these therapies will be necessary to ensure appropriate product utilization as HCPs adopt a proactive treatment approach to help individuals with AD to reduce severity and maintain treatment success for overall improvement in quality of life.
The Sanofi Genzyme and Regeneron Alliance is seeking proposals to close these independently defined healthcare gaps.

- Preference will be given to proposals that recommend a format likely to enhance a practitioner’s performance in assessment and treatment of atopic dermatitis, and familiarity with new and emerging therapies including monoclonal antibody treatment options to ensure appropriate utilization as required.
  - Preference will be given to programs that demonstrate a sequential implementation and assessment of these independently identified educational gaps

- Preference will also be given to proposals that develop content customized to the specialists in dermatology and in allergy (those treating moderate-to-severe atopic dermatitis).

- Preference will be given to proposals that recommend a format likely to enhance a practitioner’s knowledge in the gaps identified above.

- Preference will also be given to proposals that develop content customized to the different audiences attending the following meetings or other recommended meetings/activities.

Please note that proposals are expected to include the perspectives of patients in the analysis of the barriers and root causes for these educational gaps and appropriately designed educational interventions.

The Sanofi Genzyme and Regeneron Alliance will consider proposals including, but not limited to, the following meetings:

- The American Academy of Dermatology (AAD) announced the possibility of satellite symposia for accredited educational activities during their 2016 Summer AAD meeting.

- Academy of Managed Care Pharmacy (AMCP) announced the possibility of satellite symposia for accredited educational activities including AMCP Nexus 2016 and the 2017 Annual Meeting.

- The Skin Disease Education Foundation has announced the possibility of accredited educational activities during the 17th Annual Las Vegas Dermatology Seminar in 2016.

- National Association of Managed Care Physicians (NAMCP) announced the possibility of accredited educational activities at the 2016 Fall Managed Care Forum and the 2017 Spring Managed Care Forum.

- The 2016 Fall Clinical Dermatology Conference and 2017 Winter Dermatology Conference announced the possibility of accredited educational activities during these annual meetings.

- The American College of Asthma, Allergy and Immunology (ACAAI) announced the possibility of satellite symposia for accredited educational activities during their 2016 Annual Scientific Meeting.

- The American Society of Health System Pharmacists (ASHP) announced the possibility of accredited educational activities during their 2016 Midyear Clinical Meeting.

- The Western Society of Allergy, Asthma and Immunology (WSAAI) announced the possibility of accredited educational activities during their 2017 Scientific Sessions.

- The South Beach Symposium is expected to announce the possibility of accredited educational activities during their 2017 annual meeting.

- The Skin Disease Education Foundation is expected to announce the possibility of accredited educational activities for the 16th Caribbean Dermatology Symposium, and the 41st Annual Hawaii Dermatology Seminar to be held in 2017.

- The American Academy of Dermatology (AAD) announced the possibility of satellite symposia for accredited educational activities during their 2017 Annual Meeting.

- The American Academy of Allergy, Asthma and Immunology (AAAAI) announced the possibility of satellite symposia for accredited educational activities during their 2017 Annual Meeting.
Advances in Cosmetic and Medical Dermatology is expected to announce the possibility of satellite symposia for accredited educational activities during the 13th Annual Maui Derm Meeting in 2017.

Web-based and other non-symposium, live activities (such as society chapter meetings), that are aligned to the described educational gaps above will be considered.

Proposal should include the following information:

- **Needs Assessment/Gaps/Barriers:** Include a comprehensive needs assessment that is well referenced and demonstrates an understanding of the specific gaps and barriers of the target audiences. The needs assessment must be independently developed and validated by the accredited provider.

- **Target Audience and Audience Generation:** Describe the target audience(s) and provide a rationale for how and why this target audience is important to closing the identified healthcare gap. In addition, please describe methods for reaching the target audience(s) including description of and rationale for recruitment and placement strategies to maximize participation according to need. Any unique recruitment efforts specific to the target audience should be highlighted.

- **Learning Objectives and Content Accuracy:** Provide clearly defined and measurable learning objectives framed as expected practice improvements in relation to the identified gaps and barriers. Include an overview of program content and explanation of criteria that will guide content selection, considering level of evidence and other variables. The Sanofi Genzyme and Regeneron Alliance is committed to the highest standards in ensuring patient safety; the applicant should describe methods to ensure complete, accurate, evidence-based review of key safety and efficacy data for any therapeutic entities discussed in the activity. Explain how content will be updated if necessary throughout the program period, and how accuracy will be ensured.

- **Educational Methods:** The ACCME calls for educational methods that are clearly designed to address the knowledge, competence and/or performance gaps that may underlie an identified healthcare gap. Your proposal should demonstrate an understanding of instructional design issues as they relate to the gaps in the knowledge, competence, or performance of the targeted audience. Education methods and design should be based on current literature in CME best practice and consistent with ACCME accreditation criteria. For example, systematic reviews have suggested that the most effective continuing education is clearly linked to clinical practice, uses methods including interaction, reflection, strategies that ensure reinforcement through use of multiple educational interventions, and more. Preference will be given to applications that utilize methods that have been shown to result in practice improvements, and/or with data on the effectiveness of other programs of the same type. ACCME criteria recognize that barriers may be related to systems, lack of resources, or tools etc. and these may be included, if relevant, in your discussion of the gap and the educational methods you propose. In addition, the educational preferences of the target audience(s) may be considered to maximize attendance/participation and lead to practice improvements.

- **Faculty Recruitment and Development:** Provide information on the expected qualifications of contributors and description of methods to ensure recruitment of course directors and faculty who meet the qualifications. Explain any methods that will be used to ensure that faculty are fully trained in the program expectations and any skills that may be needed to ensure effective delivery of intended education.

- **Program Evaluation and Outcomes:** Provide a description of the approach to evaluate the reach and quality of program delivery; methods for monitoring individual activities and for ensuring ongoing quality improvements. Describe methods that will be used to determine the extent to which the activity has served to close the identified healthcare gap and the qualifications of those involved in the design and analysis of the outcomes. Preference will be given to programs with Objectives and Outcomes Plans of Moore level 3-6.
• **Budget:** Include a detailed budget with rationale including breakdown of costs, clear explanation of the units, and calculations of:
  - Content cost per activity
  - Out-of-pocket cost per activity
  - Management cost per activity

• **Accreditation:** Programs must be accredited by the appropriate accrediting bodies and fully compliant with all ACCME criteria and Standards for Commercial Support. *If you are a non-accredited provider, the accredited provider must be involved from the concept origin, fully knowledgeable of the grant submission and documentation should be provided on the website grant application section entitled, “Other Information”.*

• **Resolution of Conflict:** The proposal should briefly describe methods for ensuring fair and balanced content, identification and resolution of conflict of interest.

• **Communication and Publication Plan:** Provide a description of how the provider will keep the supporter informed of progress. Include description of how the results of this educational intervention will be presented, published or disseminated.

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