Sanofi Genzyme and Regeneron Alliance Medical Affairs
Request for Proposal

Date: May 11, 2017
Disease State: Asthma
Therapeutic Area: Immunology
Area of Interest: Asthma
Geographic Scope: US

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Due Date: no later than 5PM ET on June 23, 2017
Submission Portal: https://sgrants.envisionpharma.com/vt_sgrants

Health Care Gap
Asthma is a chronic inflammatory disease of the airways that is characterized by recurrent episodes of wheeze, cough, chest tightness, and/or shortness of breath, usually accompanied by widespread but variable airflow obstruction.1,2

Worldwide, up to 300 million people are affected with asthma.3 The disease remains symptomatic and inadequately controlled.5 In these patients, asthma symptoms can be worsened by concomitant comorbidities including allergic rhinitis, sinusitis, and nasal polyposis.4

Patients with uncontrolled persistent asthma experience more exacerbations (including emergency visits, hospitalizations, and additional need for drugs for recurrent exacerbations), are associated with a rapid decline in lung function, and can have increased morbidity and mortality compared to patients with well-controlled asthma.5,6,7,8 Furthermore, uncontrolled persistent asthma can have a negative impact on patients and their families, affecting their lives physically, functionally, and psychologically.9,10,11,12 Therefore, alternate therapeutic approaches are urgently required for those individuals who have poorly controlled asthma, including improvements in health care delivery and novel therapeutics.

In 2009, uncontrolled asthma in the US led to half a million hospitalizations, 1.9 million emergency room visits and 24 million days of absenteeism from school or work.13 Despite increasing adoption of inhaled corticosteroids and other controller medicines in primary care and specialty practices, the burden of asthma continues to rise in the US. In both children and adults, the burden of asthma falls disproportionately on vulnerable and marginalized communities.

Traditionally, asthma and allergic diseases have been defined by broad definitions and treated with nonspecific medications, including corticosteroids and bronchodilators. There is an increasing appreciation of heterogeneity within asthma and allergic diseases based primarily on recent cluster analyses, molecular phenotyping, biomarkers, and differential responses to targeted and non-targeted therapies.14,15,16 The identification of particular asthma phenotypes with distinct pathophysiologic mechanisms has opened up a new era for patient populations not well served by current therapies, especially patients with severe asthma.

Recent investigation into the underlying mechanisms involved in Type 2 Asthma phenotype have revealed specific T-cell cytokines and cytokine receptors as primary drivers of the inflammatory response. The Type 2 inflammatory process involves the activation of multiple cell types, including Type 2 helper T cells, Group 2 innate lymphoid cells, mast cells, eosinophils, epithelial cells, smooth muscle cells and mucus-producing cells. Recent publications have advanced our understanding of the complex interactions between these cell populations and the relationship between the pathophysiology and the clinical manifestations of asthma. Data from trials examining the clinical effects of targeted agents directed against specific Type 2 cytokines and other key targets are emerging17, including inhibitors of Interleukin-5, interleukin-13, interleukin 4α receptor and Immunoglobulin E. Additionally it is increasingly recognized that there exist multiple comorbid disease entities mediated by the Type 2 inflammatory phenotype such as allergic rhinitis, CRSwNP, atopic dermatitis or food allergy. Identification of one Type 2 mediated disease should prompt clinicians to look for clinical evidence of comorbid atopic diseases.18,19,20

As recently approved and emerging biologic therapies 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 asthma to reduce exacerbations, improve lung function and improve symptoms and health related quality of life and patient related outcomes.

The initial target for this educational outreach should be physicians who are frequently encountering patients with uncontrolled asthma in their practice, who are already familiar with the guidelines for the appropriate use of inhaled steroids either as monotherapy or in combination with a long acting beta agonist (i.e., Steps I through 3 of the Global Initiative for Asthma (GINA) guidelines) and who are interested in learning about management of patients with more difficult to control asthma (i.e., GINA Steps 4 and 5 therapy).1


The Alliance (Sanofi Genzyme and Regeneron Pharmaceuticals) is seeking proposals to close these independently defined healthcare gaps, and provide education for health care providers on the problem of uncontrolled asthma with focus on understanding trends in the burden of uncontrolled asthma in the US, recognition of uncontrolled asthma, identification and addressing of remediable causes of poor control including environmental triggers, lack adherence to treatment plans and comorbidities, and understanding the pathophysiology of Type 2 inflammation in asthma and approved and emerging biologic therapies that target Type 2 inflammation not adequately controlled on inhaled corticosteroids and bronchodilators. This education would be targeted to appropriate clinicians (e.g., Physicians [Allergists and Pulmonologists]) to optimize patient outcomes. The grant committee will consider independent medical education applications designed to close these gaps according to well-referenced learner preferences.

Please note that proposals are expected to include an analysis of the barriers and root causes for this gap and how the educational intervention would address this gap.

• Preference will be given to proposals that recommend a format likely to enhance 1) a practitioner’s performance in assessment and management of uncontrolled asthma, and 2) understanding of recent advances in the pathophysiology of asthma with specific reference to the role of Type 2 inflammatory pathways, and the development of novel therapies that target these pathways. The role of specific inflammatory and effector cell types should be discussed in a manner that seeks to explore the relationship of the pathophysiology to the clinical manifestations of disease.

• Preference will be given to multi-modal programs that demonstrate a sequential implementation (compounded learning) and assessment of these independently identified educational gaps.

• Preference will be given to proposals that develop content customized to specialists in pulmonology and in allergy (those treating uncontrolled persistent asthma).
• 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.

Single supported and multi-supported proposals will be considered with a maximum request not to exceed $400,000, although preference will be given to grants with opportunities for support from multiple funders.

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

• The American Thoracic Society (ATS) has announced the possibility of non-accredited satellite symposia at their 2018 annual meeting

• Satellite Symposia at AAAAI 2018

• Satellite Symposia at CHEST (American College of Chest Physicians) 2018

• Non-symposium, live activities (such as regional or society chapter meetings), that are aligned to the described educational gaps above will be considered

• Web-based, online, or other enduring activities that are aligned to the educational gaps described will be considered

Proposals 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 (http://www.accme.org/requirements/accreditation-requirements-cme-providers/accreditation-criteria. Accreditation Criteria. Accessed April 8, 2016).¹ The needs assessment must be independently developed and validated by the accredited provider.

• Target Audience and Audience Generation: Proposal should 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 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 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 continuing education best practice and consistent with ACCME accreditation elements (http://www.accme.org/requirements/accreditation-requirements-cme-providers/accreditation-criteria. Accreditation Criteria. Accessed April 8, 2016).¹ 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.²,³,⁴,⁵ 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.


- **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”.


- **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.