**SANOFI GENZYME**  
**Medical Affairs**  
**Request for Proposals**

<table>
<thead>
<tr>
<th><strong>Date:</strong></th>
<th>August 4, 2021</th>
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<tbody>
<tr>
<td><strong>Disease State:</strong></td>
<td>Dermatology</td>
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<td><strong>Therapeutic Area:</strong></td>
<td>Immunology/RBD</td>
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<td><strong>Area of Interest:</strong></td>
<td>Pemphigus Vulgaris (PV)</td>
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<td><strong>Geographic Scope:</strong></td>
<td>Global/US</td>
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<th><strong>Internal Requestor Information:</strong></th>
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<tr>
<td><strong>Name:</strong> Malika Wicks, EMBA</td>
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<td><strong>Title:</strong> Grant Manager, IME</td>
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<td><strong>Company:</strong> Sanofi Genzyme</td>
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| **Due Date:** | 5:00 pm ET September 9, 2021 |
| **Maximum Funds Available:** | $290,000 |
| **Submission Portal:** | [https://sgrants.envisionpharma.com/vt_sgrants/](https://sgrants.envisionpharma.com/vt_sgrants/) |
| **RFP Title (to include in request):** | Global/US PV incl AAD22 |

**Burden of Disease**

PV is a rare autoimmune disease that causes blistering of the skin and mucous membranes. If left untreated it is almost always fatal. While mortality has significantly declined with the availability of treatment, PV patients still have a 3-fold higher risk of mortality. Today, the main causes of death in PV are associated with the disease and/or treatments such as corticosteroids and immunosuppressive therapy. PV therapies are associated with significant adverse events including diabetes, high blood pressure, cardiac insufficiency, myopathy, osteoporosis, avascular bone necrosis, glaucoma, and cataracts due to corticosteroids; infections, notably, respiratory infections, hepatitis, or hematologic abnormalities (leukopenia) as a result of immunosuppression; and mental disorders. In addition to increased mortality, PV patients suffer significant morbidity as PV can negatively impact quality of life, even in patients with quiescent disease, reduce work productivity, and result in significant healthcare costs.

The pathogenesis of PV involves both the innate and adaptive immune systems. While innate immune cells (monocytes and granulocytes) are present in pemphigus lesions, their pathogenic role is less clear. Emerging data suggests cytokines, chemokines, intracellular mediators, and other immune cells also play a role in pathogenesis.

**Health Care Gap**

While, there are multiple therapies used to treat PV, currently there is only one FDA approved therapy. The most commonly used therapies for PV have shown complete remission rates between 0% and 89%. However, a significant portion of patients experience relapse ranging from 30%-81% with currently approved treatment. Relapse is also of particular concern for patients. The cyclical nature of PV and the potential for unexpected relapse is associated with worse quality of life.
Current treatments also provide some challenges in managing PV. Although approved therapy has reduced the corticosteroid burden for patients, the cumulative corticosteroid burden remains high.\textsuperscript{21-22} Current treatments may also increase risk of infection, worsen outcomes in patients with infections and inhibit vaccine response.\textsuperscript{24-31} Thus, multiple new therapeutic targets and modalities are currently being investigated, including BAFF, BTK, PI3K, FcRn and CAR-T therapy.\textsuperscript{3}

SANOFI GENZYME is seeking proposals to close this independently defined healthcare gap to improve clinician knowledge of new treatment strategies in Pemphigus Vulgaris (PV) at the American Academy of Dermatology (AAD) annual meeting 2022 and other global congress symposia, virtual and enduring activities through independent medical education. Proposals can target one or multiple audiences.

Preference will be given to proposals that recommend appropriately designed interventions that are likely to enhance a learner’s knowledge of the unmet needs and employ proven strategies to overcome knowledge and performance gaps and barriers. Single and multi-supported proposals will be considered with a maximum request not to exceed $290,000. Multi-support proposals are highly encouraged. Applicants must secure their own slot times at AAD and other Congresses.

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.

- **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. Sanofi Genzyme 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 12 July 2021).8

- 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 and breakdown of costs, per unit, and description of each budget line item. In addition, please include any registrations fees paid by the learner, and how the fees will be applied.
  - Single and multi-supported proposals will be considered, with a maximum request not to exceed $290,000. Please select Global/US PV incl AAD22 from the RFP dropdown panel within the grant portal upon submitting your applicant for this RFP.

- Accreditation: If proposal involves an accredited program, the accreditation must be provided by an appropriate accrediting body and fully compliant with the accrediting body’s criteria and applicable government guidelines and regulations.

- Fair Balance: The proposal should briefly describe methods for ensuring fair and balanced content, identification and resolution of conflict of interest, in alignment with applicable ACCME criteria.

- Communication and Publication Plan: Provide a description of how the provider will keep Sanofi Genzyme informed of progress. If applicable, include description of how the results of this educational intervention will be presented, published or disseminated.

32. Kasperkiewicz, M et al. Pemphigus Nat Rev Dis Primer, 2017 May 11;3;17026