<u>Celgene Corporation Request for Proposal</u> 2015 Psoriasis Live and/or Multimedia Programming

Therapeutic Area: Immunology

Disease State: Psoriasis

Grant applications must be submitted through Celgene website:

www.celgene.com

Submission Timeframe:	Deadline <i>April 30, 2015</i> by 5PM EST. Please include Psoriasis 2015 RFP as part of the title of application.
Proposal:	Support for CME based educational programming focusing on psoriasis and understanding the role different factors have on treatment decision making
Educational Audience:	 Primary Dermatologists Secondary Dermatology NPs and PAs Primary care physician Other HCPs who manage patients with psoriasis
Program Format:	Live programming and/or web-based platforms.
Outcomes	At a minimum, the educational outcomes plan must
Measurement:	be designed to objectively measure improvements in HCP competence (Level 4), and/or performance (Level 5), patient health (Level 6), and/or community health (Level 7).
Available Funding:	Up to \$300,000.

Celgene Corporation is interested in providing grant support for independent educational programming in the area of psoriasis designed to increase awareness of this disease and improve understanding of treatment decisions that may be based on several factors including, for example: severity of the disease (mild, moderate, or severe), location of the disease, therapeutic efficacy, potential for adverse events, prior treatments, patient preference, duration of disease, medical risk factors, comorbidities, and the potential for improvement in quality of life.

Synopsis of Healthcare Gap

In the United States, psoriasis affects approximately 3.2% (7.5 million) of US adults, with plaque psoriasis being the most common form, and can significantly impact patients' quality of life. According to published studies sponsored by the National Psoriasis Foundation (NPF), 38% of people with psoriasis have mild disease (<3% body surface area or BSA), 41% have moderate disease (3%-10% BSA), with another 21% reporting they have severe psoriasis (>10% BSA).

Unfortunately, the majority of psoriasis patients are not being treated to the established standards of care published by the American Academy of Dermatology (AAD), or receive no treatment for their disease at all. Psoriasis is associated with a "strong psychosocial component" that influences the patient's perceived degree of

disease severity in a way that often does not correspond with the clinician's severity assessment.³ Physicians often consider the severity of skin lesions as well as their location (e.g., difficult to treat areas such as scalp, nail, and palmoplantar) when planning treatment for patients with psoriasis.³ It has been reported that approximately 80% of patients have scalp psoriasis, 50% have nail psoriasis, and 5% have palmoplantar psoriasis.⁴⁻⁶ As part of the 2011 release of AAD's most recent psoriasis guidelines, Ronald L. Moy, MD, then president of the AAD, stated that disease severity is just one of many factors that needs to be considered when developing a treatment plan for psoriasis.

According to the latest position statement developed by the AAD, treatment decisions should be based on efficacy, potential adverse effects, prior treatments, patient preference, duration and severity of disease, medical risk factors, comorbidities, and potential impact on quality of life. A 2014 survey identified that 47% of psoriasis patients had not seen an HCP in the previous 12 months for their psoriasis with 19% stating that this was because they did not believe their HCP could help. Additionally, more than 80% of moderate patients are not receiving treatment or are receiving treatment only with a topical therapy.

Newer agents are providing additional treatment options for patients with psoriasis, but several of these agents were FDA approved after clinical guideline recommendations were updated in 2011 causing uncertainty as to their appropriate use among certain psoriasis patients. In fact, the majority of dermatologists do not routinely use systemics to treat psoriasis. A 2008 survey of dermatologists noted that many patients with psoriasis are frustrated with the management of their disease and perceive their treatment to be ineffective. Furthermore, psoriasis affecting certain areas of the body like scalp, nails, palms and soles remains difficult to treat. Despite the work of AAD and NPF, the under-treatment of psoriasis continues to be a serious concern.

In an evolving era of healthcare shaped by the enactment of the Affordable Care Act (ACA) and the establishment of the National Quality Strategy (NQS) by the Secretary of the US Department of Health and Human Services, continuing medical education serves a valuable role in supporting the needs of healthcare professionals. Potential practice improvements associated with proposed activities should align to the NQS principle of addressing patients' unique treatment needs related to inducing and maintaining disease remission while including consideration of a number of factors such as disease severity, location of the disease, previous treatments and response to those treatments, risk of adverse effects, comorbidities as well as patient preference and quality of life. As data on newer psoriasis treatments continue to emerge, dermatologists need education on how to incorporate these new therapies into treatment strategies for their psoriasis patients based on clinical evidence and real world experience.

- Rachakonda TD, Schupp CW, Armstrong AW. Psoriasis prevalence among adults in the United States. J Am Acad Dermatol. 2014;70(3):512-6.
- 2. Armstrong AW, Robertson AD, Wu J, Schupp C, Lebwohl MG. Undertreatment, treatment trends, and treatment dissatisfaction among patients with psoriasis and psoriatic arthritis in the United States: findings From the National Psoriasis Foundation surveys, 2003-2011. JAMA Dermatol. 2013;149(10):1180-5.
- 3. Lee YW, Park EJ, Kwon IH, Kim KH, Kim KJ. Impact of psoriasis on quality of life: Relationship between clinical responses to therapy and change in health-related quality of life. Ann Dermatol. 2010;22(4):389-96.

- 4. Wozel G. Psoriasis treatment in difficult locations: scalp, nails, and intertriginous areas. Clin Dermatol. 2008;26(5):448-59.
- 5. Crowley JJ, Weinberg JM, Wu JJ, Robertson AD, Van Voorhees AS. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National Psoriasis Foundation. JAMA Dermatol. 2015;151(1):87-94.
- 6. Chung J, Callis Duffin K, et al. Palmoplantar psoriasis is associated with greater impairment of health-related quality of life compared with moderate to severe plaque psoriasis. J Am Acad Dermatol. 2014;71(4):623-32.
- 7. American Academy of Dermatology. Position statement on treatment of psoriatic patients. April 27, 2013. https://www.aad.org/Forms/Policies/Uploads/PS/PS%20on%20Treatment%20of %20Psoriatic%20Patients.pdf
- 8. Lebwohl MG, Bachelez H, Barker J, et al. Patient perspectives in the management of psoriasis: results from the population-based Multinational Assessment of Psoriasis and Psoriatic Arthritis Survey. J Am Acad Dermatol. 2014;70(5):871-81.
- 9. Agency for Healthcare Research and Quality. Evidence-based practice center systematic review protocol. Biologic and nonbiologic systemic agents and phototherapy for treatment of chronic plaque psoriasis. Amended September 1, 2011. http://effectivehealthcare.ahrq.gov/ehc/products/312/793/Psoriasis_AmendedProt ocol 20120110.pdf
- 10. Feldman SR. Disease burden and treatment adherence in psoriasis patients. Cutis. 2013;92(5):258-63.
- 11. Patel V, Horn EJ, Lobosco SJ, et al. Psoriasis treatment patterns: results of a cross-sectional survey of dermatologists. J Am Acad Dermatol. 2008;58(6):964-9.

Medical Educational Grants Guidelines

Medical Educational Grants are awarded in support of high quality, independent educational programs and materials, which demonstrate the potential to improve patient care and health outcomes. Each educational grant awarded must adhere to and be compliant with:

- FDA Final Guidance on Industry-Supported Scientific and Educational Activities,
- Office of Inspector General (OIG) Guidelines,
- Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support,
- Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals,
- American Medical Association (AMA) Ethical Guidelines for Gifts to Physicians from Industry, and
- Other relevant guidelines and regulations.

Supported programs must be independent, objective, balanced and scientifically rigorous. Grants cannot be tied, in any way, to past, present, or future prescribing, purchasing or recommending (including formulary recommendations) of any drug.