Celgene Corporation Request for Proposal

2016/2017 AML Continuing Professional Educational Programming

Therapeutic Area: Hematology

Disease State: Acute Myelogenous Leukemia (AML)

Grant applications must be submitted through Celgene website:

www.celgene.com

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<th>Submission Timeframe</th>
<th>Deadline August 22, 2016 by 5PM EST. Please include AML RFP as part of the title of application.</th>
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<tr>
<td>Proposal</td>
<td>Independent CME/CE certified educational programming that improves HCP’s awareness of evidence based clinical information that can be used to better diagnose and manage AML while improving quality of care for their patients.</td>
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| Educational Audience | • Community based hematologist/oncologists  
• Pathologists, hematopathologists  
• HCPs who manage patients with AML. |
| Program Format       | Independent CME/CE certified educational programming that utilizes formats with innovative educational design that improves HCP’s awareness of evidence based clinical information that can be used to better manage patients under their care. |
| Outcomes Measurement | Submissions should include a description of measures, metrics and/or strategies for measuring impact of educational design on improving awareness of new clinical information and/or application of evidence-based medicine (if relevant) that will be incorporated into the educational design, initiative execution and/or measurement process. |

Celgene Corporation is interested in providing funding to support quality independent education that addresses bona fide educational gaps in the diagnosis and management of patients with AML that is evidence-based and in accordance with ACCME, AMA, PhRMA Code, OIG and FDA guidance.

Introduction and Background

The combined advent of new agents and discoveries of predictive and prognostic factors are changing the treatment paradigm for AML, and these approaches are rapidly being incorporated into treatment guidelines including those developed by the NCCN, the World Health Organization and ASH/CAP. However, many clinicians are not fully aware of new and upcoming guideline recommendations and may not be prepared to discuss them with patients. In addition, multiple promising new agents are in late-phase clinical trials and promise to change practice in the near future. Clinicians need to be apprised of these developments in order to be poised to evaluate new agents and validated markers in the treatment of AML to make diagnosis and treatment decisions as quickly and effectively as possible.¹
Acute myeloid leukemia (AML) is the most common form of leukemia among adults, and in 2016 an estimated 19,950 cases will be diagnosed and 10,430 individuals will die from this disease. Untreated AML is a fatal disease, and even with adequate therapy, the five-year survival rate among all risk groups combined is approximately 22%. Chemotherapy has been a cornerstone of treatment for AML for decades and much dismay has been expressed over the lack of progress in the management of this disease. In addition to the history of slow progress, many patients have suboptimal outcomes with standard regimens, in part due to disease heterogeneity. The past 15 years have seen major leaps in scientific understanding of the molecular genetic mutations that act as drivers of AML and mounting excitement surrounding the utility of molecular diagnostics have led to improvements not only in risk stratification but also led to the availability and potential emergence of more effective targeted therapies allowing for more individualized approach to patient management.

The ability to identify mutations that carry prognostic impact is increasing with molecular profiling. Testing for these molecular markers is becoming more common in commercial reference laboratories and in referral centers. Therefore, it is important for physicians to confer with the local pathologist on how to optimize sample collection from the time of diagnosis for subsequent molecular diagnostic tests, particularly in patients with normal karyotype. Recent advances in gene-expression analyses and next-generation sequencing which has lead to the identification of unique biomarkers associated with some myeloid neoplasms and acute leukemias has prompted the World Health Organization (WHO) to update its 2008 publication on the classification of tumors of the hematopoietic and lymphoid tissues. With respect to myeloid neoplasms, many novel molecular findings with diagnostic and/or prognostic importance have been incorporated into the 2016 revision. The authors credit the revision to the efforts of pathologists working closely with clinicians and geneticists. The revised recommendation is necessary due to the discoveries in diagnostic and prognostic markers; improved characterization and standardization of morphologic features; and the clinical-pathologic studies that call for an integrated approach incorporating hematologic, morphologic, cytogenetic, and molecular genetic findings.

In a commentary from a recently published review article, Mikkael A. Sekeres, MD from The Cleveland Clinic stated that “emerging biologic insights and new molecular and immunotherapeutic approaches are generating exciting results for AML patients, and while preliminary, may result in improvement in outcomes, in particular for those patients most in need: older patients and those with high-risk disease. The challenge is how to match molecular and clinical information with emerging compounds in order to select the best treatment for individual patients. The success of personalized approaches in AML is likely to depend on our ability to readily attain molecular information and on access to new drugs.”

The aim of this RFP is to support educational programming that increases understanding of available data on emerging predictive and prognostic factors, current and future therapies in late stage development, and the emerging safety and efficacy data of new and investigational therapies for the management of patients with AML.

References:


3 Stein E., Molecularly targeted therapies for acute myeloid leukemia. ASH Education Book; December 5, 2015 vol. 2015 no. 1 579-583.


7 Khaled, Malki and Marcucci, Acute Myeloid Leukemia: Biologic, Prognostic, and Therapeutic Insights, April 15, 2016, Leukemia & Lymphoma.

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. Proposals which do not appear to provide balanced view of available and/or potential future therapeutic options will not be considered.