Celgene Corporation Request for Proposal
2016/2017 Multiple Myeloma Continuing Professional Educational Programming

Therapeutic Area: Hematology
Disease State: Multiple Myeloma (MM)

Grant applications must be submitted through Celgene website:

www.celgene.com

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<th>Submission Timeframe:</th>
<th>Deadline by November 14, 2016 5PM EST. Please include MM RFP as part of the title of application.</th>
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<td>Proposal:</td>
<td>Independent CME/CE certified educational programming that improves HCP’s ability to better manage patients with relapsed/refractory multiple myeloma. Multi-support is preferred.</td>
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<td>Educational Audience:</td>
<td>Community-based hematologists, oncologists and other healthcare practitioners involved in the treatment and management of patients with relapsed/refractory multiple myeloma.</td>
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<td>Program Format:</td>
<td>Independent CME/CE certified educational programming that utilizes formats with innovative educational design in order to improve HCP’s ability to incorporate the latest clinical data and evidence-based recommendations into individualized care plans for patients with relapsed/refractory multiple myeloma that also have multiple co-morbidities. The content and/or the format of the CME/CE activity and its related materials must be designed in such a way that it addresses the educational needs of health care professionals and, if appropriate, tools/aids that can help health care practitioners communicate with or better manage their patients. Presentations and content must give a scientifically sound, fair and balanced overview of new and emerging therapeutic options currently available or in development to manage or prevent this disease.</td>
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<td>Commercial Support:</td>
<td>Program proposals should be structured to anticipate multiple commercial supporters.</td>
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<td>Outcomes Measurement:</td>
<td>Submissions should include a description of measures, metrics and/or strategies for measuring impact of educational design on translating clinical data and/or application of evidence-based medicine (if relevant) that will be incorporated into the educational design, initiative execution and/or measurement process.</td>
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Celgene Corporation is interested in providing funding to support quality independent education that addresses bona fide educational gaps in the management of patients with
multiple complex co-morbidities in the relapsed/refractory multiple myeloma therapeutic setting that is evidence-based and in accordance with ACCME, AMA, PhRMA Code, OIG and FDA guidance.

**Introduction and Background**

Multiple myeloma (MM) is a heterogeneous disease that results from uncontrolled proliferation of terminally differentiatated plasma cells. It accounts for 13% of all hematologic malignancies, with approximately 86,000 new cases each year. In 2016, it is estimated that 30,330 new cases will be diagnosed in the US alone in 2016, with 70 being the average age at diagnosis. The number of MM patients nationwide is expected to increase as a result of a growing elderly population. Although upfront treatment of multiple myeloma has become more effective, multiple myeloma is still incurable and, unfortunately, relapses are the norm. Recent trials have demonstrated the safety and efficacy of combination therapy also in the relapsed and refractory setting and supported the regulatory approval of several new agents. Despite these options, a majority of patients with MM present with co-morbidities such as renal insufficiency and older age which limit their treatment options and could lead to modified treatment goals over the continuum of care. It is important to note that these high risk populations, those patients experiencing renal dysfunction, bone disease, and infectious complications, may require modified treatment doses and schedules. In addition, recently approved novel agents have distinct administration routes, response to therapy, and toxicity profiles, which may further influence treatment decisions.

The MM field is rapidly evolving which has led to new and more inclusive diagnostic criteria, more accurate and reliable disease staging, and new and emerging agents that can offer patients improved outcomes. This has also increased the complexity of treatment and the need for HCPs to expand their knowledge base in MM, particularly for patients with co-morbid conditions, such as renal insufficiency, and the elderly population. Care teams therefore need to be aware of recommended therapeutic strategies for high risk populations, such as the frail, elderly and those with co-morbid conditions, so that they may appropriately tailor regimens, reduce treatment-related toxicities, avoid early treatment discontinuation, and improve quality of life.

**References:**

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 a balanced view of available and/or potential future therapeutic options will not be considered.