

**Bristol-Myers Squibb**  
**Independent Medical Education**  
**Request for Educational Support (RFE)**

<b>Date</b>	8/14/2017
<b>RFE Requestor Information</b>	Name: Maria Deutsch E-mail: maria.deutsch@bms.com
<b>RFE Code</b>	<b>RFE-17-ONC-123</b>
<b>Therapeutic Area</b>	<ul style="list-style-type: none"> <li>• Immuno-Oncology</li> </ul>
<b>Area of Interest</b>	<ul style="list-style-type: none"> <li>• Cancer immunotherapy</li> <li>• Immune checkpoint inhibitors</li> <li>• Recurrent and metastatic Squamous Cell Carcinoma of the Head &amp; Neck (SCCHN)</li> <li>• Immune-related adverse events (irAEs) and management</li> </ul>
<b>Educational Design</b>	<p>BMS is interested in supporting a comprehensive, innovative, educational activity at the <b>2018 Multidisciplinary Head &amp; Neck Cancers Symposium</b>, February 15-17, 2018, in Scottsdale, AZ.</p> <p>The activity will include the following:</p> <ul style="list-style-type: none"> <li>• Live interactive satellite symposium</li> <li>• Live simulcast during the live meeting</li> <li>• Web-based enduring activity leveraging the medical content from the live meeting</li> </ul> <p>Knowledge, performance and competency based outcome measures according to Moore's Levels 4 is required; Level 5 outcomes are highly favored</p>
<b>Intended Audience (may include, but not limited to)</b>	<ul style="list-style-type: none"> <li>• Community/Academic Oncologists, Medical Oncologists, Radiation Oncologists, Surgical Oncologists, H&amp;N Surgeons</li> <li>• Multidisciplinary H&amp;N Oncology Team: NPs/PAs, PharmDs, Pharmacists, Nurses, etc</li> </ul>
<b>Accreditation</b>	ACCME, ANCC, ACPE, CEU, and others as appropriate

<b>Budget/Budget Range</b>	The anticipated program is expected to be achieved with a budget of no more than \$235,000.
<b>Geographic Coverage</b>	United States
<b>Deadline for Submission (Date and Time)</b>	September 29, 2017 EOB 5pm EST

**Background:**

Oncology clinicians are in need of education that improves their abilities to select evidence-based, multimodal treatment regimens for their patients with advanced head and neck cancer, and that assists them with incorporating new and emerging agents into these regimens as they become available.

Due to the large amount of clinical data available in immuno-oncology for advanced head and neck cancer, an integration of the data in a live setting for a broad audience at a key professional meetings is warranted. Since many community oncologists and other healthcare professionals working in a multidisciplinary oncology team do not have the opportunity to attend live meetings, it is necessary and important to make the activities/education correlated with the live meeting available through both a web-based simulcast of the live event, and an internet/computer-based activity.

**Educational needs and professional practice gaps:**

BMS is seeking proposals to close the following independently identified educational gaps for oncology HCPs that treat recurrent or metastatic head & neck cancer.

- **Comprehensive knowledge:** Understand the latest science and clinical trial data on the use of multimodal regimens, including immuno-oncology agents, in recurrent or metastatic head & neck cancer; Understand the role of the immune system in cancer and the MOA of immunomodulatory agents
- **Implementation of cancer immunotherapy treatment:** Apply practice guideline recommendations on the use of immunotherapy in the treatment of recurrent or metastatic head & neck cancer; Describe the potential impact of HPV, PD-L1 status, and expression profiling (ie, IFN $\gamma$ ) on a patient’s clinical response to immune checkpoint inhibitors
- **Treatment algorithms for irAEs:** Increasing the awareness and understanding of the symptoms and treatment options of irAEs and implementing best practices into routine clinical practice.
- **Improving patient outcomes:** Identify appropriate candidates for approved and emerging cancer immunotherapies for recurrent or metastatic head & neck

cancer; Outline methods to incorporate the multidisciplinary care team in the treatment of patients with recurrent or metastatic head & neck cancer

## **References**

1. Economopoulou P, Kotsantis I, Psyrri A. Checkpoint inhibitors in head and neck cancer: rationale, clinical activity, and potential biomarkers. *Curr Treat Options Oncol.* 2016;17:40.
2. Fay AP, et al. The management of immune-related adverse events associated with immune checkpoint blockade. *Exp Rev Qual Life Cancer Care.* 2016;1(1):89-97.
3. Ferris RL. Immunology and Immunotherapy of Head and Neck Cancer. *J Clin Oncol.* 2015;33(29):3293-304
4. Ferris RL, Blumenschein G Jr, Fayette J, et al. Nivolumab for Recurrent Squamous-Cell Carcinoma of the Head and Neck. *N Engl J Med* 2016; 375:1856-1867.
5. Hamid et al. Epacadostat plus pembrolizumab in patients with SCCHN: Preliminary phase I/II results from ECHO-202/KEYNOTE-037. Presented at: 2017 ASCO Annual Meeting; June 5, 2017; Chicago, Illinois. Oral Abstract 6010
6. Harrington KJ, et al. *Lancet Oncol.* 2017; Jun 23. doi: 10.1016/S1470-2045(17)30421-7.
7. Howell M, Lee R, Bowyer S, et al. Optimal management of immune-related toxicities associated with checkpoint inhibitors in lung cancer. *Lung Cancer.* 2015;88:117-123.
8. Leidner R, Kang H, Haddad R, et al. Preliminary efficacy from a phase 1/2 study of the natural killer cell-targeted antibody, lirilumab in combination with nivolumab in squamous cell carcinoma of the head and neck. Presented at: 2016 SITC Annual Meeting; November 9-13, 2016; National Harbor, MD. Abstract 456
9. Pai SI, Zandberg DP, Strome SE. The role of antagonists of the PD-1:PD-L1/PD-L2 axis in head and neck cancer treatment. *Oral Oncol.* 2016;61:152-158.

10. Perez RP, et al. Phase I/II study of the safety, tolerability, and efficacy of epacadostat (INCB24360) with nivolumab in advanced cancers. Presented at: 2017 ASCO Annual Meeting; June 5, 2017; Chicago, Illinois. Oral Abstract 3003
11. Seiwert TY, Burtness B, Mehra R, et al. Safety and clinical activity of pembrolizumab for treatment of recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-012): an open-label, multicentre, phase 1b trial. *Lancet Oncol.* 2016;17:956-965
12. Segal NH, Ou SI, Balmanoukian AS, et al. Safety and efficacy of MEDI4736, an anti-PD-L1 antibody, in patients from a squamous cell carcinoma of the head and neck (SCCHN) expansion cohort. *J Clin Oncol* 33, 2015 (suppl; abstr 3011).
13. Zandberg DP, Strome SE. The role of the PD-L1:PD-1 pathway in squamous cell carcinoma of the head and neck. *Oral Oncol.* 2014;50:627-632.

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.

**Note:** The accredited provider and, if applicable, the medical education provider (MEP) or other third party executing the activities are expected to comply with current ethical codes and regulations. They must have a conflict-of-interest policy in place to identify and resolve all conflicts of interest from all contributors and staff developing the content of the activity prior to delivery of the program, and must have a separate company providing/accrediting independent medical education if they are also performing promotional activities.

*If your organization wishes to submit an educational grant request, please use the online application available on the Bristol-Myers Squibb Independent Medical Education website.*

<http://www.bms.com/responsibility/grantsandgiving>

Grant Proposals should include, but not be limited to, the following information:

- **Executive Summary:** The Executive Summary should consist of 1-2 pages and highlight the key areas as described below.
- **Needs Assessment/Gaps/Barriers:** Needs assessment should be referenced and demonstrate

an understanding of the specific gaps and barriers of the target audiences. The needs assessment must be independently developed and validated by the educational provider.

- **Target Audience and Audience Generation:** Target audience for educational program must be identified within the proposal. In addition, please describe methods for reaching target audience(s) and any unique recruitment methods that will be utilized. The anticipated or estimated participant reach should also be included, with a breakdown for each modality included in the proposal, as applicable (e.g., number of participants for the live activity, the live webcast, and enduring activity).
- **Learning Objectives:** The learning objectives must be written in terms of what the learner will achieve as a result of attending. The objectives must be clearly defined, measurable, attainable and address the identified gaps and barriers.
- **Educational Design and Methods:** Describe the approach used to address knowledge, competence, and performance gaps that underlie identified healthcare gaps. The proposal should include strategies that ensure reinforcement of learning through use of multiple educational interventions and include practice resources and tools, as applicable.

**Communication and Publication Plan:** Provide a description of how the provider will communicate the progress and outcomes of the educational program to the supporter. It is highly recommended to describe how the results of the activity will be presented, published, or disseminated.

- **Program Evaluation and Outcomes Reporting:** Description of the approach to evaluate the reach and quality of the educational program. Describe methods used for determining the impact of the educational program on closing identified healthcare gaps.
  - Please refer to “Guidance for Outcomes Report” (on the BMS grants website) for a detailed explanation of preferred outcomes reporting methods and timelines.
- **Budget:** Detailed budget with rationale of expenses, including breakdown of costs, content cost per activity, out-of-pocket cost per activity, and management cost per activity.