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

Date	January 9, 2023
RFE Requestor Information	Name: Maria Deutsch E-mail: maria.deutsch@bms.com
RFE Code	RFE-23-ONC-101
Therapeutic Area	Oncology – Lung Cancer
Area of Interest	Immunotherapy in early to late/advanced stage lung cancer
Educational Design	Bristol Myers Squibb is interested in supporting an innovative, comprehensive educational initiative that includes the following: • Virtual – A live video web broadcast presentation and panel discussion with live Q&A/interaction with faculty held during 2023 ASCO Meeting, June 2-6, 2023 • On-demand – Web-based enduring activity leveraging the content from the live webcast presentation • Online resources and tools Knowledge and competency-based objective outcome measures according to Moore's Level 5 is preferred.
Intended Audience (may include, but not limited to)	Medical oncologists, pulmonologists, thoracic surgeons, pathologists, and other allied HCPs involved in the treatment of patients with NSCLC
Budget/Budget Range	The anticipated program is expected to be achieved with a BMS budget of no more than $185K. Single and multi-supported initiatives will be considered.
Accreditation	ACCME and others as appropriate to the audience(s).
Geographic Coverage	United States
Deadline for Submission (Date and Time)	2/10/2023 EOB 5pm EST

Background:

Lung (early disease)

Despite approved immunotherapies in locally advanced and adjuvant settings, an urgent need exists to improve prognosis in stage I to III NSCLC, but past attempts with various treatment approaches have usually failed, resulting in a lack in significant progress.[1] Among different reasons for the slow progress in resectable cancers have been the operational challenges of multimodality clinical trials and the long wait for overall survival results. One strategy to expedite clinical trials, including those assessing immunotherapies in early-stage cancer settings, is the use of newer, innovative surrogate measurements for endpoints.[2–6]

The first immunotherapy approved in early-stage settings was atezolizumab for adjuvant treatment after resection and platinum-based chemotherapy in patients with stage II to IIIA NSCLC whose tumors have PD-L1 expression on ≥1% of tumor cells, as determined by an FDA-approved test.[7] The FDA also approved the VENTANA PD-L1 (SP263) Assay as a companion diagnostic device to select patients with NSCLC for adjuvant treatment with atezolizumab. The approval was based on data from the IMpower010 trial, which demonstrated disease-free survival (DFS) benefit with adjuvant atezolizumab versus best supportive care after adjuvant chemotherapy in patients with resected Stage II-IIIA NSCLC, with a greater benefit observed in tumors with PD-L1 TC ≥1%.[8] This makes IMpower010 the first phase 3 study of cancer immunotherapy to demonstrate DFS improvement in the adjuvant NSCLC setting after platinum-based chemotherapy.[9]

Neoadjuvant therapy provides the ability to assess pathologic response as an early surrogate marker for survival outcomes. Pathologic response criteria such as pathologic complete response (pCR) and major pathological response (MPR) have been assessed in neoadjuvant immunotherapy trials. Although definitions vary, MPR is generally defined as ≤10% residual viable tumor cells in the surgical specimen, whereas pCR is the absence of any viable tumor cells at the time of resection. For example, in the CheckMate-816 study, neoadjuvant treatment with 3 cycles of nivolumab plus chemotherapy significantly improved pCR, a primary endpoint in the trial, compared with chemotherapy alone in patients with resectable stage Ib to IIIa NSCLC.[10,11] According to a recent press release, in addition to the pCR, event-free survival (EFS) was significantly improved as well. Several trials have correlated pCR with disease-free survival (DFS), relapse-free survival (RFS), and OS, including a recent study presented at ESMO 2021 on neoadjuvant durvalumab,[12] although some experts believe that additional studies are needed to definitively confirm that pCR and MPR after neoadjuvant ICI are valid surrogate endpoints that can predict survival similar to neoadjuvant chemotherapy, evidence to that end is starting to accumulate.

In addition to IMpower010 and CheckMate-816, the phase 3 KEYNOTE-091 trial met one of its dual primary endpoints of DFS with pembrolizumab for the adjuvant treatment of patients with stage IB-IIIA NSCLC following surgical resection regardless of PD-L1 expression.[13] A recent post-hoc analysis of the trial data showed DFS benefit with pembrolizumab regardless of surgery type, lymph node involvement, tumor size, and chemotherapy type and extent, further supporting the benefit of pembrolizumab as adjuvant therapy for early-stage NSCLC.[14]

Recently, immune-related pathologic response criteria (irPRC) have also been developed with the aim of assessing the full spectrum of response to immunotherapy in the complete resection specimen.[15] Over recent years, dozens of clinical trials have been initiated to examine the potential benefits and optimal use of immunotherapies and rational immunotherapy-based combinations as part of multimodal therapy in early-stage NSCLC, including as neoadjuvant, adjuvant, or perioperative approaches.[11,16–28]

Lung (advanced)

Therapeutic choice for the first-line treatment of advanced NSCLC is informed by tumor expression of PD-L1 and the presence of oncogenic driver mutations. For patients eligible for immunotherapy, approved indications and practice guidelines allocate recommended first-line treatment regimens into three categories using PD-L1 expression level cutoffs (<1%, 1%-49%, ≥50%).[29-33]

In 2020, the first dual ICI combination therapy available for the first-line setting received FDA approval.[34] Nivolumab plus ipilimumab is the only chemotherapy-free regimen recommended for first-line treatment of patients with advanced NSCLC with PD-L1 <1%, a population with a high unmet need, and the only first-line, chemotherapy-free regimen recommended for patients with tumors expressing any level of PD-L1 (<1%, 1%-49%, ≥50%).[29] The efficacy and safety of frontline treatment with nivolumab plus ipilimumab was explored in the CheckMate 227 trial that enrolled patients with metastatic NSCLC without ALK or EGFR mutations.[35] Patients were randomized and stratified according to expression of PD-L1, using 1% as the cutoff. In primary analysis, median OS was significantly improved with nivolumab plus ipilimumab compared with chemotherapy in patients with PD-L1-expressing (≥1%) tumors (17.1 months vs 14.9 months; HR, 0.79). Median OS was also prolonged among all trial participants regardless of PD-L1 tumor expression level (HR, 0.73) and among patients with PD-L1 <1% tumors (HR, 0.62). Comparable benefits with the regimen were observed regardless of tumor histology or TMB. Clinical improvements were sustained with longer follow up. More patients who were treated with nivolumab plus ipilimumab were alive at 4 years than patients who were treated with chemotherapy (24% vs 18% in the PD-L1 ≥1% population, 24% and 10% in the PD-L1 <1% population).[36] Responses were notably durable in the dual ICI arm and ongoing in about one third of responders, despite discontinuation of ICI therapy for at least 2 years. Although the nivolumab/ipilimumab combination in the first-line setting is beneficial regardless of PD-L1 status, the regimen lacks an FDA indication for patients with tumors expressing PD-L1 <1%.

Pembrolizumab is available as a single agent for stage III or metastatic NSCLC with PD-L1 ≥1% and no EGFR or ALK aberrations or in combination with chemotherapy for metastatic squamous NSCLC and metastatic nonsquamous NSCLC with no EGFR or ALK aberrations.[32] Pembrolizumab approval as monotherapy for PD-L1-positive (≥1%) NSCLC was based on data from KEYNOTE-042 that showed significantly improved OS compared with chemotherapy.[37] Single-agent pembrolizumab has also been evaluated in a population of patients with PD-L1 ≥50% NSCLC in the KEYNOTE-024 trial. Median OS was significantly longer with pembrolizumab than with chemotherapy (HR, 0.63).[38] At 5 years, 32% of patients who received pembrolizumab

were alive, compared with 16% of patients who received chemotherapy.[39] Combination pembrolizumab and chemotherapy was compared with chemotherapy alone in patients with metastatic nonsquamous NSCLC (no EGFR or ALK mutations) unselected for PD-L1 expression in the KEYNOTE-189 trial that showed significantly longer median OS (22.0 vs 10.6 months) and median progression-free survival (PFS; 9.0 vs 4.9 months) in the pembrolizumab arm.[40] Longer-term results of KEYNOTE-189 showed 3-year OS rate of 31.3% with pembrolizumab vs 17.4% for control.[41] Clinical benefit and response rates were greatest in patients with PD-L1 ≥50%, but patients with <1% PDL1 expression also benefited. In the KEYNOTE-407 trial, the ICI-chemotherapy combination demonstrated significantly longer OS regardless of PD-L1 expression in patients with metastatic squamous NSCLC.[42]

Atezolizumab is also available as a single agent for the first-line treatment of patients with metastatic NSCLC with high PD-L1 expression (≥50%) without EGFR or ALK genomic tumor aberrations based on results from the IMpower110 study, a phase III trial.[43] Compared with chemotherapy, median OS was significantly longer with atezolizumab treatment (HR, 0.59; P = .0106).[44] Median PFS and ORR were also significantly improved. Atezolizumab in combination with chemotherapy is also a first-line treatment option for metastatic nonsquamous NSCLC without EGFR or ALK aberrations based on results from the phase III IMpower130 study.[45] The combination showed significantly improved median OS compared with chemotherapy alone (18.6 months vs 13.9 months; HR, 0.79).[46] Atezolizumab in combination with bevacizumab and chemotherapy is also approved for this indication.[31]

Education Needs:

Medically accurate, fair-balanced learning programs are required to maximize transparency and minimize clinician bias in the provision of medical education. Applying evidence-based scientific knowledge significantly contributes to professional competencies of HCPs and improves patient outcomes.

This virtual, live stream webcast will ensure timely and effective communication of the latest science and clinical trial data surrounding current and emerging immunotherapies from early to late/advanced stage NSCLC.

The following educational needs should be addressed through this educational program:

- Describe latest evidence supporting the use of current and emerging immune checkpoint inhibitors (ICIs) and combinations in locally advanced or metastatic and early-stage non-small cell lung cancer (NSCLC) without actionable molecular mutations based on the current clinical evidence
- Select the most appropriate ICI-based treatment for eligible patients with locally advanced/metastatic and early-stage NSCLC without actionable molecular mutations based on the current clinical evidence, considering the disease presentation, tumor characteristics, current evidence and guidelines, and other relevant factors
- Identify potential predictive biomarkers and surrogate endpoints to assess treatment response and evaluate the prognosis of patients with resectable lung cancer who are receiving immunotherapy
- Collaborate with the multidisciplinary team to integrate immunotherapy into individualized multimodal treatment plans for eligible patients with NSCLC

- Implement patient-centric approaches to ensure optimal and equitable use of immunotherapies in the care of all eligible patients with NSCLC
- Apply current guidelines and best practices for monitoring and management of immune related adverse events (irAEs) in patients with NSCLC who are receiving or have received immunotherapy

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23. Nivolumab With or Without Ipilimumab or Chemotherapy in Treating Patients With Previously Untreated Stage I-IIIA Non-small Cell Lung Cancer - Full Text View - ClinicalTrials.gov.
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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/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.

- **Innovation:** Describe how this project is innovative and engages the learners to improve knowledge, competence and/or performance. Further describe how this project might build on existing work, pilot projects or ongoing projects developed either by your institution or other institutions related to this topic.

- **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.
    - Remember that knowledge, performance and competency based outcome measures according to Moore’s Levels 4 & 5 are required. Level 6 outcomes are highly favored and recommended when possible.

- **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.