Bristol Myers Squibb™

December 29, 2020

Anu Santhanagopal, PhD
Director, Oncology WW Scientific Content & Market Capabilities
Bristol Myers Squibb
3401 Princeton Pike
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NCCN Guidelines® Panel: Small Cell Lung Cancer Panel

Dear Panel Members,

On behalf of Bristol Myers Squibb, we are informing the Small Cell Lung Cancer Panel of the U.S. withdrawal of the indication for OPDIVO® (nivolumab) for the treatment of patients with small cell lung cancer (SCLC) whose disease has progressed after platinum-based chemotherapy and at least one other line of therapy.

This decision was made in consultation with the U.S. Food & Drug Administration (FDA), in accordance with the Agency's standard procedures for evaluating accelerated approvals that have not met their post-marketing requirements. In 2018, the FDA granted OPDIVO® this indication under accelerated approval based on the effect of OPDIVO® on surrogate endpoints from the Phase 1/2 CheckMate 032 trial of patients with advanced or metastatic solid tumors. Subsequent confirmatory studies in different treatment settings, CheckMate 451 and CheckMate 331, did not meet their primary endpoints of overall survival.

FDA Clearance:

The use of OPDIVO® (nivolumab) for the treatment of SCLC is considered investigational.[1]

Rationale: This submission is being made in response to a standing request from NCCN® for new information.

Previous submissions to NCCN regarding data from CheckMate 032 were made on June 4, 2016 and December 4, 2019. Previous submissions to NCCN regarding data from CheckMate 331 and 451 were made on December 20, 2018 and April 11, 2019, respectively.

As part of this submission, the following resource is enclosed for your review:

1. Product Information, OPDIVO® (nivolumab) injection for intravenous infusion. Bristol Myers Squibb, Princeton, NJ. December 2020.

Thank you for your consideration.

Sincerely,

Anu Santhanagopal, PhD
Director, Oncology WW Scientific Content & Market Capabilities

Samantha Gothelf, PharmD
Vice President & Head, US Medical Oncology