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BMS's Opdivo On Track For Esophageal Cancer Indication

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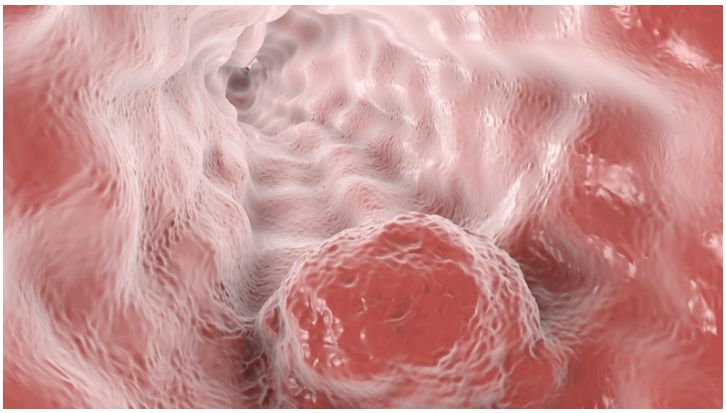
Executive Summary

Opdivo showed a 23% fall in the risk of death and 2.5-month improvement in median overall survival compared to chemotherapy in Phase III esophageal cancer trial.



OPDIVO EXTENDED OVERALL SURVIVAL IN ATTRACTION-3 TRIAL VERSUS CHEMO

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Results from Bristol-Myers Squibb Co.. and Ono Pharmaceutical Co. Ltd.'s Phase III ATTRACTION-3 trial showed Opdivo (nivolumab) 'significantly' extended overall survival (OS) compared with chemotherapy in patients with previously treated advanced esophageal squamous cell carcinoma, enhancing the PD-1 inhibitor's likelihood of approval in that indication.

The trial data, presented at the European Society for Medical Oncology (ESMO) 2019 Annual Congress in Barcelona, Spain, showed Opdivo resulted in a 23% fall in the risk of death and a 2.5-month improvement in median overall survival compared with chemotherapy.

The OS benefit with Opdivo was evident regardless of PD-L1 expression, the duo said.

The detailed ATTRACTION-3 results came just over nine months after topline data from the global, multi-center Phase III esophageal cancer study was released, in January 2019.

"These are very promising results for patients with advanced esophageal squamous cell carcinoma for whom prognosis is typically poor and are particularly important given Opdivo improved survival regardless of PD-L1 status," said Ian Waxman, who heads gastrointestinal cancer therapy development at Bristol-Myers Squibb. "We are encouraged to see important progress being made in this tumor type and look forward to broadening our research in gastrointestinal tumors," he added.

Analysts said the ATTRACTION-3 trial enhanced Opdivo's prospects of eventually being approved to treat esophageal cancer.

Its prime rival, Merck & Co. Inc.'s anti-PD-1 therapy Keytruda (pembrolizumab), was approved in July as monotherapy for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy.

That approval for Keytruda was made possible on the back of data maturing from the Phase III KEYNOTE-181, topline results from which Merck first announced in January this year. (Also see "Merck's Keytruda Shows Utility In Subset Of Esophageal Cancer" - Scrip, 15 Jan, 2019.)

Datamonitor Healthcare analyst Michael Ramirez noted that Opdivo in the latest ATTRACTION-3 data showed superiority to chemotherapy across all PD-L1 expression levels while OS benefit was only seen in high PD-L1 expressors in the KEYNOTE-181 Keytruda trial.

"The median OS of Opdivo [in ATTRACTION-3] was 10.9 months compared to 8.4 months including all PD-L1 expression levels. In contrast both Keytruda and chemotherapy showed a 7.1 month median OS across the entire ITT population in KEYNOTE-181," Ramirez told *Scrip*.

"Therefore, though Opdivo's potential approval will follow Keytruda's, Opdivo appears poised to gain approval in a larger previously-treated subset," he said.

However, Keytruda is in development for the first-line setting for treating esophageal cancer in the Phase III KEYNOTE-590 study, while Opdivo is not.

"That provides a way [for Keytruda] to make up for the potential difference in the size of the previously treated patient population," Ramirez said.