# Phase 3 Nivolumab Trial Ends Early After Showing Better Survival Rates than Docetaxel in NSCLC

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A Phase 3 study comparing Opdivo (nivolumab) to Taxotere (docetaxel) in patients with advanced non-small cell lung cancer (NSCLC) who didn't respond to platinum-based chemotherapy was ended early after an independent monitoring committee found Obdivo had shown better overall survival rates and met the study's primary endpoint.

In the multinational study, called CheckMate-078 (NCT02613507), Opdivo also showed a similar safety profile as seen in previous studies with solid tumors. Obdivo is an inhibitor of the PD-1 protein that boosts the immune system's response to tumor cells.

Based on the results of CheckMate-078, which enrolled mostly Chinese patients, the China Food and Drug Administration (CFDA) accepted for review a Biologics License Application (BLA) for Opdivo from developer Bristol-Myers Squibb.

“It is exciting to see that the Phase 3 CheckMate -078 study met its primary endpoint early, which confirmed, for the first time, a superior overall survival benefit with a PD-1 inhibitor, nivolumab, in Chinese patients, compared with the standard treatment, docetaxel,” Yi-Long Wu, the trial’s lead investigator, said in a press release.

“The results of CheckMate -078 mark the third time Opdivo has demonstrated a survival advantage in previously treated metastatic non-small cell lung cancer,” added Nick Botwood, MD, development lead for thoracic cancers at Bristol-Myers Squibb. “In China, where lung cancer is the leading cause of cancer death, these results are especially important, as they represent the first Phase 3 trial to show an overall survival benefit with a PD-1 inhibitor in the Chinese patient population.”

The trial enrolled 504 patients with both squamous and non-squamous NSCLC. Of those, 451 patients were recruited in China, 45 in Russia, and eight in Singapore.

Patients were randomized to receive either 3mg/kg of Opdivo intravenously every two weeks or 75 mg/$m^2$ of Taxotere intravenously every three weeks until the first signs of disease progression or an unacceptable toxicity.

While the trial’s primary endpoint was overall survival, secondary measures included objective response rate, time to disease progression or death, and the rate of improvement of disease-related symptoms. Bristol-Myers is currently evaluating the trial’s results for future presentation.