Immunotherapy Shows Continued Survival Benefit for Advanced Melanoma

Researchers provide updates on the clinical trial of a new drug to improve the long-term survival of patients facing advanced melanoma

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When researchers submit a new drug to the FDA for approval, they submit a mountain of data regarding clinical trial results, information about how the drug is manufactured, data from any preclinical studies, and the proposed drug label which includes how it is to be used and any possible risks. The FDA then carefully reviews all available data before making its decision.

Over the last 10 years, the FDA has approved 13 new melanoma treatment options. However, this doesn't mean that researchers – and the pharmaceutical companies responsible for these drugs – are done once a therapy is approved. They continue to closely monitor patients involved in their clinical trials over time to ensure its safety and to determine how long patients respond to the treatment, what researchers call treatment durability.

At the annual meeting of the American Society of Clinical Oncology (ASCO) last month, Jedd Wolchok, MD, PhD – an MRA funded investigator and member of MRA's Grant Review Committee and Medical Advisory Panel – provided an important update on the long-term survival benefits of patients facing advanced melanoma in the Checkpoint 067 study.

After carefully following patients enrolled in Checkmate 067 over the last 6.5 years, he and the research team determined that 49% of patients treated with Opdivo + Yervoy were alive at 6.5 years and 77% of these patients remained treatment-free, meaning they were not treated with any other drug or treatment modality for their melanoma after completing the Opdivo + Yervoy treatment regimen. This represents the longest reported median overall survival in a phase 3 melanoma clinical trial – ever.

Dr. Wolchok also provided updates on progression free survival for each patient cohort in the study. Progression Free Survival, often abbreviated as PFS, is the length of time during and after treatment that a patient lives with the disease without it becoming worse. Patients treated with the combination of Opdivo + Yervoy demonstrated a progression free survival rate of 34% at 6.5 years, while patients treated with either Opdivo or Yervoy alone had a PFS of 29% and 7%,

respectively.

Of patients still alive and part of the current analysis, 77% of those who received the combination of Opdivo + Yervoy, 69% of those who received just Opdivo, and 43% of those who received Yervoy have been off treatment and never received subsequent systemic therapy for melanoma.

“The sustained overall survival and progression-free survival benefit shown with nivolumab-based treatment, particularly the nivolumab (Opdivo) plus ipilimumab (Yervoy) combination, has changed the way we look at long-term efficacy outcomes for patients with advanced melanoma,” said Jedd D. Wolchok, M.D., Ph.D., FASCO, Chief, Immuno-Oncology Service, Human Oncology and Pathogenesis Program, Memorial Sloan Kettering Cancer Center. “Durable clinical benefit was observed across clinically relevant subgroups, including BRAF mutation and baseline liver metastasis status.”

Consistent with previous studies, serious side effects were greatest among patients treated with the combination treatment compared to either monotherapy regimen alone. Grade 3 and 4 treatment-related adverse events were observed in over half of patients (59%) treated with combination Opdivo + Yervoy, and 24% and 28% of those treated with Opdivo and Yervoy monotherapy, respectively. No new safety signals were found beyond what has previously been reported.

Checkmate 067 is a randomized, double-blind, Phase 3 clinical trial that launched in 2013. It enrolled 1296 patients with advanced melanoma from across the world and was designed to compare the effectiveness of Opdivo + Yervoy or Opdivo alone against Yervoy alone. Since the trial launched, it has helped to answer a variety of questions for the melanoma field and was pivotal in the FDA approval of Opdivo + Yervoy for patients with advanced melanoma in 2015.

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