Few immuno-oncology agents reach ASCO efficacy thresholds

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(HealthDay)—Few modern, U.S. Food and Drug Administration-

approved immuno-oncology agents have durable survival and response rates that are deemed significant by the American Society of Clinical Oncology (ASCO) value framework, according to a study published online Dec. 28 in *JAMA Oncology*.

Omer Ben-Aharon, M.B.A., M.H.A., from Bar Ilan University in Ramat Gan, Israel, and colleagues reviewed all FDA approvals for immuno-oncology agents between March 2011 and August 2017. Data were collected; specifically, improvement in the proportion of patients alive with the test regimen and the survival rate with standard treatment.

The researchers found that 23 metastatic indications were approved by the FDA for six immuno-oncology agents (ipilimumab, pembrolizumab, nivolumab, atezolizumab, avelumab, and durvalumab). Ten and 13 of the approvals (43 and 57 percent) were based on survival end points and response rates, respectively. Only three drug indications met the minimum 20 percent threshold defined for the survival rate of patients receiving standard care. Nine indications achieved the required (>50 percent) improvement in the proportion of patients alive in the test regimen versus the standard. For three drug indications there was overlap between these two criteria, allowing them to gain the durable survival bonus points that the ASCO framework awards.

"Durable survival and response rates of modern immuno-oncology agents are rarely recognized as significant by current oncology value frameworks," the authors write. "This may be due to insufficient demonstration of efficacy of such agents or inappropriately calibrated value frameworks."

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Editorial