FDA-approved test for NSCLC, 12/15

Dako announced FDA approval of a test that can identify PD-L1 expression levels on the surface of non-small cell lung cancer tumor cells and provide information on the survival benefit with Opdivo (nivolumab) for patients with nonsquamous NSCLC.

Dako developed the diagnostic, known as PD-L1 IHC 28-8 pharmDx, through a collaboration with Bristol-Myers Squibb, the maker of Opdivo, an immuno-oncology therapy approved by the FDA for the treatment of all patients with previously treated NSCLC. The diagnostic was used to assess PD-L1 expression in the phase three CheckMate 057 trial. The FDA expanded the indication for Opdivo to include previously treated nonsquamous NSCLC in addition to the squamous NSCLC indication.

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