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Agilent Technologies announces expanded use for PD-L1 IHC 28-8 pharmDx diagnostic in Europe

15 May 2017 | News

Approved for use in Europe to identify head and neck cancer patients most likely to benefit from Opdivo(nivolumab) Therapy

Agilent Technologies Inc. recently announced the expanded use of Agilent´s Dako PD-L1 IHC 28-8 pharmDx test for squamous cell carcinoma of the head and neck (SCCHN), the most prevalent type of head and neck cancer.

Europe is the first region to launch a PD-L1 CE-IVD test for SCCHN globally. The CE marking demonstrates that the product meets all relevant European Medical Device Directives. The PD-L1 IHC 28-8 pharmDx test has broad utility, as it has already been previously CE marked for tumor cell PD-L1 expression for non-squamous, non-small-cell lung cancer (ns-NSCLC) and melanoma.

With this latest indication, pathologists in Europe now have access to a clinically validated test to determine tumor PD-L1 status PD-L1, in patients with SCCHN.

There are currently few treatment options for SCCHN, but this new test can identify which patients could most likely benefit from treatment with *Opdivo* (nivolumab), an immunotherapy developed by Bristol-Myers Squibb. *Opdivo* as monotherapy is indicated for the treatment of squamous cell cancer of the head and neck in adults progressing on, or after platinum-based therapy

Immunotherapies are designed to help an individual´s immune system detect and kill cancer cells. Because individual patients often respond differently to the same treatment, scientists have been focusing emphasis on personalized medicine, which is where Agilent´s Dako brand of diagnostics comes into play, providing important information about the status of key biomarkers in individual cancer patients.

Jacob Thaysen, president of Agilent's Diagnostics and Genomics Group said, “It is encouraging to see new indications validated both analytically and clinically, for the PD-L1 28-8 assay,”

“We recently saw the first approval for the PD-L1 IHC 28-8 pharmDx test, in head and neck cancer in Japan, and are now pleased that the CE marked indication has been extended to Europe. Head and neck cancer has few treatment options, and tumor PD-L1 testing can identify patients with this devastating disease who are most likely to benefit from *Opdivo* therapy",

he added

PD-L1 IHC 28-8 pharmDx is the first and only diagnostic assay approved to assess the survival benefit with *Opdivo* in patients with SCCHN and was developed in collaboration with Bristol-Myers Squibb.