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French Researchers Report out Harmonization Study for PD-L1 Immunohistochemistry Testing in NSCLC

Vienna, Austria—December 7, 2016—Immunology researchers strive to find a test that accurately and consistently predicts PD-L1 status so pathologists and clinicians can better predict which patients will benefit from immunotherapy. French researchers presented data today on how effective several laboratory-developed tests performed when compared against PD-L1 assays used in clinical trials. The data was presented at the **IASLC 17th World Conference on Lung Cancer (WCLC)** in Vienna, Austria.

PD-L1 immunohistochemistry (IHC) is considered as a predictive biomarker for most anti PD-1/PDL-1 therapies in non-small cell lung cancer, but different assays are used in clinical trials. Several studies have compared four assays (22C3, 28-8, SP142, SP263) performed in central laboratories on dedicated platforms. To compare these tests and make PD-L1 testing widely available on most IHC platforms and centers, Dr. Julien Adam of the Gustave Roussy Cancer Center in Villejuif and colleagues from 6 other centers in France compared PD-L1 Dako (22C3, 28-8) and Ventana (SP263) assays and laboratory-developed tests (LDT).

Dr. Adam and colleagues in 7 academic centers in France tested 41 non-small cell lung cancer specimens using IHC with five anti-PD-L1 clones (28-8, 22C3, E1L3N, SP142 and SP263) in various IHC platforms (Ventana BenchMark Ultra, Leica Bond or Dako Autostainer Link 48). For matching platforms, Dako or Ventana assays were performed with clones 22C3, 28-8 and SP263. LDT were developed in each center in non-matching platforms and with others antibodies. A total of 35 PD-L1 stainings (8 with PD-L1 assays and 28 with LDT) were performed across different platforms and antibodies for each case. Seven thoracic pathologists trained to PD-L1 scoring in expert courses scored tumor cell and immune cell staining.

The investigators found that 28-8, 22C3 and SP263 assays were highly concordant for tumor cell staining. 14 out of 27 (51.8 percent) LDT demonstrated similar concordance as compared to those 3 assays. Some differences were observed between antibodies and notably, LDT with clone SP263 achieved the highest concordance rate across all platforms. For immune cells staining, lower concordance rates were achieved for assays as well as LDT.

“We found that 28-8, 22C3 and SP263 assays gave comparable results for tumor cells staining, as well as half (51.8 percent) of laboratory-developed tests using 28-8, 22C3, SP263 and E1L3N clones” said Dr. Adam. “These results indicate that LDT can be an option for PD-L1 testing, but caution is required for validation and further use of these tests.” He emphasized that the requirement of LDT is dependent on clinical need, availability of

platforms and reimbursement issues. Next steps will include the validation of selected LDT to provide recommendations at the national level for the use of laboratory developed tests for PD-L1 testing in NSCLC.

About the WCLC:
The WCLC is the world's largest meeting dedicated to lung cancer and other thoracic malignancies, attracting more than 6,000 researchers, physicians, and specialists from more than 100 countries. The goal is to increase awareness, collaboration, and understanding of lung cancer, and to help participants implement the latest developments across the globe. Organized under the theme of "Together Against Lung Cancer," the conference will cover a wide range of disciplines and unveil several research studies and clinical trial results. For more information, visit http://wclc2016.iaslc.org/.

About the IASLC:
The International Association for the Study of Lung Cancer (IASLC) is the only global organization dedicated to the study of lung cancer. Founded in 1974, the association's membership includes more than 5,000 lung cancer specialists in over 100 countries. Visit www.iaslc.org for more information.

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