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Preliminary results comparing PD-L1 IHC diagnostic assays in lung cancer released

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A pre-competitive consortia of pharmaceutical companies, diagnostic companies, and academic associations, including the International Association for the Study of Lung Cancer (IASLC), announced phase I results of the "BLUEPRINT PD-L1 IHC ASSAY COMPARISON PROJECT" at the Annual Meeting of the American Association for Cancer Research (AACR) on April 19. The study compared four PD-L1 IHC diagnostic assays developed in conjunction with four PD-1/PD-L1 immune checkpoint inhibitors, which are used in non-small cell lung cancer (NSCLC) clinical trials.

To validate the results from the phase I (feasibility) study, the IASLC will conduct phase II. The overall goal of the study (phase I and II) is to give a better understanding of the current PD-L1 IHC assays, and their similarities and differences.

"This study provides key information regarding the four diagnostic PD-L1 assays, which hopefully will add significant value to further research and application," said Fred R. Hirsch, MD, PhD, Professor of Medicine and Pathology at the University of Colorado Cancer Center and School of Medicine and CEO of the IASLC.

The results of the phase I study, presented by Dr. Hirsch et al at the recent 2016 Annual Meeting of the AACR and to be published shortly, clearly demonstrated similarities and differences between the four assays. Until further research gathers additional data, it is recommended that each assay should be utilized for its specific indication according to

its distinct scoring algorithm for PD-L1 clinical diagnostic status.

Doctors diagnose more than 1.6 million new patients with lung cancer each year around the world, more than breast, colon and prostate cancer combined. Immunotherapy represents new hope for these patients, and doctors already see great success with the treatments for many patients with NSCLC. A better understanding of how to best select patients for these treatments is still an ongoing effort.

The IASLC is part of a unique cross-industry academic collaboration initiated by the AACR, Merck, Bristol-Myers Squibb, Genentech, Astra Zeneca, Dako, and Ventana and designed to provide additional clarity on the analytic performance of the PD-L1 assays. The assays being compared in this study are being developed for evaluation and approval as either companion or complementary diagnostics by the US Food and Drug Administration (FDA).

The blueprint consortium was created in recognition of the fact that multiple drug-diagnostic combinations for medical products in the same class could pose a unique challenge to medical professionals and patients. It aims to provide clarity in these matters through collaborative evidence generation to enable informed treatment decision making.

"Immunotherapy treatments offer enormous promise in the treatment of lung cancer. The progress in lung cancer treatment brings us closer to the goal of making lung cancer a curable or chronic condition," Dr. Hirsch said.

Provided by International Association for the Study of Lung Cancer