Clinical trial identification: NCT01296113.

10.36), p = 0.0001) were significantly associated to PFS and, PS 2 vs. 0-1 (HR 4.10 (1.62-9.99), p = 0.0006) to OS. Similar differences only in a few of the items explored (particularly afebrile neutropenia), but no significant differences in the overall comparison.

Background: The goal of the CLOVER study is to perform a pairwise comparison of 4 tests based on the same patient population: 3 validated PD-L1 IHC assays [Ventana SP142 (aterolizumab), Ventana SP263 (durvalumab), Dako 22C3 (pembrolizumab)] and one PCR test.

Methods: 473 NSCLC samples (including 81 EGFR+, 36 ALK+, 131 squamous cell carcinoma) were stained with PD-L1 IHC assays. Four pathologists independently evaluated the percentages of tumor (TC) and tumor infiltrating immune cells (IC) staining positive at any intensity. PD-L1 transcripts were quantified by Taqman RT-PCR assay using SDHA as a gene-reference; dCT = 2 was chosen as a threshold between positive and negative RNA expression. The concordance analysis was performed to assess (1) correlation of IC and TC between different assays, (2) the predictive properties of one test of another. One test-specific cutoff rule for each assay was pre-specified as: for first-line TC or IC ≥ 5% for SP142, TC ≥ 25% for SP263, TC ≥ 50% for 22C3, and for second-line TC ≥ 50% or IC ≥ 10% for SP142, TC ≥ 25% for SP263, TC ≥ 1% for 22C3.

Results: Pearson Correlation Coefficients (PCC) for TC were: 0.71, 0.87 and 0.75 between SP142/22C3, SP263/22C3 and SP142/SP263, respectively. PCC for IC were: 0.45, 0.61 and 0.68 for the same pairs. Low correlation was observed between PCR test and any of the IHC assays for TC and IC. Table represents how well one assay can predict the same outcome (positivity or negativity) of another assay using recommended individual cutoffs for each test. Among patients who were positive by PCR, 92%-99% of the patients were negative by any of the three IHC assays using corresponding recommended cutoff. Among patients who were positive by PCR, 9-45% of them were positive by IHC assays.

Table: 1406P Probability of negative test B, given negative test A

<table>
<thead>
<tr>
<th>Test A</th>
<th>SP142</th>
<th>SP263</th>
<th>22C3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First-line</td>
<td>Second-line</td>
<td>First-line</td>
</tr>
<tr>
<td>SP142</td>
<td>-</td>
<td>92%</td>
<td>85%</td>
</tr>
<tr>
<td>SP263</td>
<td>91%</td>
<td>98%</td>
<td>-</td>
</tr>
<tr>
<td>22C3</td>
<td>88%</td>
<td>99%</td>
<td>91%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Probability of Positive Test B, given Positive Test A</th>
</tr>
</thead>
<tbody>
<tr>
<td>SP142</td>
</tr>
<tr>
<td>SP263</td>
</tr>
<tr>
<td>22C3</td>
</tr>
</tbody>
</table>

Conclusions: PCR should not be recommended as a substitute for a PD-L1 IHC assay due to high probability of false positive prediction and low PCC. 22C3 could be considered as a substitute for SP263 in first-line.

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