Thoracic cancer

Efficacy and safety of necitumumab (neci) in East Asian (EA) patients (pts) with stage IV squamous non-small-cell lung cancer (NSCLC): a subanalysis of the SQUIRE trial

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Aim/Background: The SQUIRE trial showed that neci added to gemcitabine + cisplatin (GC) improves overall survival (OS) in advanced squamous NSCLC pts. We report results of the EA subgroup.

Table: 436P

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<thead>
<tr>
<th>Variable</th>
<th>EA</th>
<th>Non-EA</th>
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<tbody>
<tr>
<td></td>
<td>Neci + GC</td>
<td>GC</td>
</tr>
<tr>
<td>Efficacy, median mos (95% CI)</td>
<td>n = 43</td>
<td>n = 41</td>
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<tr>
<td>OS</td>
<td>12.0 (7.3, 15.2)</td>
<td>11.5 (10.5, 12.6)</td>
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<tr>
<td>HR (95% CI)*</td>
<td>0.805 (0.484, 1.341)</td>
<td>0.839 (0.730, 0.964)</td>
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<tr>
<td>PFS</td>
<td>5.6 (4.7, 6.4)</td>
<td>5.7 (5.6, 6.0)</td>
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<tr>
<td>Safety, n (%)</td>
<td>n = 41</td>
<td>n = 39</td>
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Methods: Eligible pts were chemotherapy naive, ≥18 years, had stage IV squamous NSCLC, ECOG performance status 0-2, and unknown EGFR mutation status. Pts were randomly assigned to ≤ six 3-week cycles of G (1250 mg/m2) C (75 mg/m2) ± neci (800 mg). OS (median [months], 95% CI) and progression-free survival (PFS) of pts from EA (Korea, Taiwan, Singapore, Thailand, and Philippines) and non-EA countries treated with neci + GC or GC were estimated using the Kaplan-Meier method. Hazard ratios (HR) and 95% CIs of neci + GC vs GC were estimated from stratified Cox proportional hazards models.

Results: Baseline characteristics were similar between EA groups. OS and PFS were improved in EA pts treated with neci + GC vs GC, and were similar for EA vs non-EA pts treated with neci + GC vs GC (Table). The percentages of serious adverse events (SAEs), AEs Grade ≥3, and AEs with outcome of death were higher in EA pts treated with neci + GC vs GC, and in EA vs non-EA pts treated with neci + GC (Table). The percentages of AEs causally related to neci only were similar in EA and non-EA pts (Table).

Conclusions: The efficacy of neci in EA pts with advanced squamous NSCLC was consistent with those in non-EA pts. The overall percentage of AEs with neci + GC was higher in EA pts than in non-EA pts; however, the AEs related to neci were similar.

Clinical trial identification: NCT00981058

Disclosure: K. Park: consulted/advised for Astellas, Astra-Zeneca, AVEO, and Boehringer Ingelheim. M.-J. Ahn: consulted/advised for Eli Lilly and Company. V. Soldatenkova, H. Depenbrock, T. Puri, M. Orlando: employee of Eli Lilly and Company and own shares in Eli Lilly Pty Ltd. All other authors have declared no conflicts of interest.