Choice of Taxane and Outcomes in the KEYNOTE-407 Study of Pembrolizumab plus Chemotherapy for Metastatic Squamous NSCLC

Balazs Halmos, 1 Alexander Luft, 2 Margarita Majem, 3 Rina Hui, 4 Romain Corre, 5 Mahmut Gümüş, 6 Konstantin Laktionov, 7 Barbara Hermes, 8 Irfan Cicin, 9 Andrew G. Robinson, 10 Terufumi Kato, 11 Ying Cheng, 12 Dariusz Kowalski, 13 Xiaodong Li, 14 Gregory M. Lubiniecki, 14 Bilal Piperdi, 14 Luis Paz-Ares15

1Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, NY, USA; 2Leningrad Regional Clinical Hospital, St. Petersburg, Russia; 3Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; 4Westmead Hospital and University of Sydney, Sydney, Australia; 5CHU Rennes, Rennes, France; 6Istanbul Medeniyet University Hospital, Istanbul, Turkey; 7N.N. Blokhin Russian Cancer Research Center, Moscow, Russia; 8Universitätsklinikum Tübingen, Tübingen, Germany; 9Trakya University, Edirne, Turkey; 10Cancer Centre of Southeastern Ontario at Kingston General Hospital, Kingston, ON, Canada; 11Kanagawa Cancer Center, Yokohama, Japan; 12Jilin Cancer Hospital, Changchun, China; 13Maria Skłodowska-Curie Institute of Oncology, Warsaw, Poland; 14Merck & Co., Inc., Kenilworth, NJ, USA; 15Hospital Universitario 12 de Octubre, CNIO, Universidad Complutense and Ciberonc, Madrid, Spain

Balazs Halmos, Montefiore Medical Center/Albert Einstein College of Medicine, USA

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KEYNOTE-407 (NCT02775435)

Key Eligibility Criteria
- Untreated stage IV NSCLC with squamous histology
- ECOG PS 0 or 1
- Provision of a sample for PD-L1 assessment
- No symptomatic brain metastases
- No pneumonitis requiring systemic steroids

Pembrolizumab 200 mg Q3W + Carboplatin AUC 6 Q3W + Paclitaxel 200 mg/m² Q3W OR nab-Paclitaxel 100 mg/m² Q1W for 4 cycles (each 3 wk)

Placebo (normal saline) Q3W + Carboplatin AUC 6 Q3W + Paclitaxel 200 mg/m² Q3W OR nab-Paclitaxel 100 mg/m² Q1W for 4 cycles (each 3 wk)

Optional Crossover
- Pembrolizumab 200 mg Q3W for up to 35 cycles

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Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Paclitaxel and Carboplatin</th>
<th>Nab-Paclitaxel and Carboplatin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pembrolizumab n = 169</td>
<td>Pembrolizumab n = 109</td>
</tr>
<tr>
<td>Age, median (range), yrs</td>
<td>65.0 (29-82)</td>
<td>65.0 (34-87)</td>
</tr>
<tr>
<td>Male</td>
<td>79.3%</td>
<td>78.9%</td>
</tr>
<tr>
<td>ECOG PS 1</td>
<td>74.6%</td>
<td>72.5%</td>
</tr>
<tr>
<td>Stable brain metastases</td>
<td>7.7%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Current/former smoker</td>
<td>92.9%</td>
<td>90.8%</td>
</tr>
<tr>
<td>Enrolled in east Asia</td>
<td>15.4%</td>
<td>25.7%</td>
</tr>
<tr>
<td>PD-L1 TPS ≥1%</td>
<td>62.7%</td>
<td>64.2%</td>
</tr>
</tbody>
</table>

*Along with choice of taxane (paclitaxel vs nab-paclitaxel), region of enrollment (east Asia vs rest of world) and PD-L1 TPS (<1% vs ≥1%) were randomization stratification factors.
Data cutoff date: Apr 3, 2018.
Overall survival

### Paclitaxel

<table>
<thead>
<tr>
<th>Events</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pembro + Chemo</td>
<td>34.9%</td>
</tr>
<tr>
<td>Placebo + Chemo</td>
<td>48.5%</td>
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<tr>
<td></td>
<td><strong>0.67 (0.48-0.93)</strong></td>
</tr>
</tbody>
</table>

Median (95% CI): 14.0 mo (12.9-16.6) for Pembro + Chemo, 10.3 mo (8.2-14.8) for Placebo + Chemo

### Nab-Paclitaxel

<table>
<thead>
<tr>
<th>Events</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pembro + Chemo</td>
<td>23.9%</td>
</tr>
<tr>
<td>Placebo + Chemo</td>
<td>34.2%</td>
</tr>
<tr>
<td></td>
<td><strong>0.59 (0.36-0.98)</strong></td>
</tr>
</tbody>
</table>

Median (95% CI): NR (NE-NE) for Pembro + Chemo, 12.6 mo (9.6-NE) for Placebo + Chemo

No. at Risk

- **Paclitaxel**
  - 169
  - 156
  - 112
  - 76
  - 42
  - 14
  - 2
  - 0

- **Nab-Paclitaxel**
  - 109
  - 100
  - 76
  - 48
  - 20
  - 3
  - 0
  - 0

Data cutoff date: Apr 3, 2018.

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Immune-Mediated AEs and Infusion Reactions

Presented on: WCLC, September 23-26, 2018, Toronto, Canada

Data cutoff date: Apr 3, 2018.
Summary and Conclusions

- In the first-line, metastatic, squamous NSCLC setting:
  - Pembrolizumab plus chemotherapy improved OS, PFS, and ORR over chemotherapy alone, regardless of whether paclitaxel or nab-paclitaxel was given with carboplatin.
  - Pembrolizumab plus carboplatin and paclitaxel and pembrolizumab plus carboplatin and nab-paclitaxel were both generally tolerable.

- Data support the addition of pembrolizumab to carboplatin and paclitaxel or to carboplatin and nab-paclitaxel for patients with previously untreated, metastatic, squamous NSCLC.

We thank the patients and their families and all investigators and site personnel from 166 sites in 17 countries.