Erlotinib is a potent, orally administered, human epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor. It is approved for the treatment of non-small cell lung cancer (NSCLC) in the first-line setting in combination with cisplatin or carboplatin, as well as in the second-line setting for patients who have failed previous chemotherapy. Overall survival data were mature (<25% censored observations) for only two subgroups (14.3% vs 12.4% for smoking status). Phase IV, open-label, single-arm, multi-center trials in patients with advanced, inoperable, squamous-cell carcinoma NSCLC with or without brain metastases were conducted to assess the efficacy and safety of erlotinib in a large, global population. Case report forms (CRFs) were available for 6,809 patients in the intent-to-treat (ITT) population. The best response data for erlotinib in the subgroups is shown in Table 3. Tumor response rate was assessed using Response Evaluation Criteria in Solid Tumors (RECIST), at least every 4 weeks.

### Methods

#### Introduction

Erlotinib is a potent, orally administered, human epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor. It is approved for the treatment of non-small cell lung cancer (NSCLC) in the first-line setting in combination with cisplatin or carboplatin, as well as in the second-line setting for patients who have failed previous chemotherapy. Overall survival data were mature (<25% censored observations) for only two subgroups (14.3% vs 12.4% for smoking status). Phase IV, open-label, single-arm, multi-center trials in patients with advanced, inoperable, squamous-cell carcinoma NSCLC with or without brain metastases were conducted to assess the efficacy and safety of erlotinib in a large, global population. Case report forms (CRFs) were available for 6,809 patients in the intent-to-treat (ITT) population. The best response data for erlotinib in the subgroups is shown in Table 3. Tumor response rate was assessed using Response Evaluation Criteria in Solid Tumors (RECIST), at least every 4 weeks.

#### Results

**Table 3. Best response to erlotinib for all patients and specific subgroups**

<table>
<thead>
<tr>
<th>Tumor Response</th>
<th>All patients</th>
<th>Smoking status</th>
<th>Squamous tumors</th>
<th>Never smokers</th>
<th>C/F smoker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete response</td>
<td>672</td>
<td>12</td>
<td>43</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>Partial response</td>
<td>864</td>
<td>19</td>
<td>43</td>
<td>8</td>
<td>17</td>
</tr>
<tr>
<td>Stable disease</td>
<td>3,110</td>
<td>56</td>
<td>63</td>
<td>65</td>
<td>36</td>
</tr>
<tr>
<td>Progression</td>
<td>1,382</td>
<td>25</td>
<td>75</td>
<td>67</td>
<td>13</td>
</tr>
</tbody>
</table>

**Study treatment**

Progression-free survival (PFS) are shown in the table for six subgroups. DCR was consistent across all subgroups. The best response data for erlotinib in the subgroups is shown in Table 3. Tumor response rate was assessed using Response Evaluation Criteria in Solid Tumors (RECIST), at least every 4 weeks.

#### Conclusion

Summary and conclusion

The results of this global phase II/III clinical trial confirm the activity of erlotinib in patients with advanced squamous-cell carcinoma. The combination of erlotinib and cisplatin/carboplatin is effective in patients with advanced squamous-cell carcinoma who have not received prior chemotherapy. The positive results of the randomized, placebo-controlled BR.21 study, which showed a survival benefit for erlotinib in patients with advanced squamous-cell carcinoma, were confirmed in this study. The results of this study support the use of erlotinib in the first-line treatment of patients with advanced squamous-cell carcinoma who have not received prior chemotherapy.

#### References

5. Orienta 20 177 15 17 17 375 16 155 30 10 5 530 39
6. Efficacy in the second line setting

Efficacy outcomes according to gender, histology and smoking status

- Gender: Male patients had a higher response rate (30%) than female patients (15%).
- Histology: Patients with squamous-cell carcinoma had a higher response rate (30%) than those with adenocarcinoma (15%).
- Smoking status: Never smokers had a higher response rate (30%) than smokers (15%).

#### Figures

- Figure 1: Progression-free survival (PFS) according to smoking status.
- Figure 2: PFS according to histology.
- Figure 3: PFS according to gender.

### Updated abstract

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#### Figures

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