Elderly patients treated with afatinib in clinical practice – results from the prospective non-interventional study GIDEON

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Purpose

This post-hoc analysis of the GIDEON study was conducted to evaluate the efficacy and safety of afatinib in elderly patients aged ≥70 years, when administered according to the approved label. All comparisons were descriptive.

Methods

- Patients were enrolled in a non-interventional study, and the data was collected from routine clinical practice.
- The study included patients aged ≥70 years who received afatinib.
- The data was analyzed retrospectively.

Results

Patient demographics and baseline characteristics

- Among the 151 patients included in the GIDEON study, 15% were aged ≥70 years.

Efficacy

- The median PFS (95% CI) was 54.6% (47.1–62.2 months) in patients aged ≥70 years.

Safety

- The most common adverse events were rash maculo-papular, diarrhea, and dyspnoea.

Conclusion

Afatinib showed manageable safety and efficacy in elderly patients aged ≥70 years, providing an opportunity to study the real-world use of afatinib in elderly patients.

References

1. European Medicines Agency (EMA). GIDEON summary of product characteristics. May 2018
5. GIDERON NIS: the GIDEON non-interventional study. Presented at the European Lung Cancer Congress (ELCC), Geneva, Switzerland, 10 April 2019
6. Kortsik E, Laack E, Brüch W. Scan the QR code for an electronic copy of the poster and supplementary content

Presented at the European Lung Cancer Congress (ELCC), Geneva, Switzerland, 10–13 April 2019

#125P

Efficacy (cont’d)

Figure 5. ORR and DCR in different age groups

<table>
<thead>
<tr>
<th>Age group</th>
<th>ORR (%)</th>
<th>DCR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;70 years</td>
<td>100</td>
<td>55</td>
</tr>
<tr>
<td>≥70 years</td>
<td>86</td>
<td>53</td>
</tr>
</tbody>
</table>

Safety

- Treatment-emergent adverse events (TEAEs) in the GIDEON study were consistent with the known safety profile of afatinib.

Key findings and conclusions

- Data from the GIDEON NIS provide important information on the routine clinical use of afatinib in elderly patients.
- Elderly patients were well represented in this study.
- The safety profile of afatinib in elderly patients was comparable to that seen in the younger subgroup.

Table 1. 12-month PFS rate

<table>
<thead>
<tr>
<th>Patient subgroup</th>
<th>12-month PFS rate (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥70 years</td>
<td>49.1 (37.3–58.9)</td>
</tr>
<tr>
<td>&gt;70 years</td>
<td>62.0 (48.7–73.6)</td>
</tr>
</tbody>
</table>

ORR was 78% (95% CI: 67.6–85.3) and 51% (95% CI: 41.0–60.0) in patients aged <70 years and ≥70 years, respectively.

*Nine patients were not evaluable.

Key patient baseline characteristics are shown in Table 1.
Elderly patients treated with afatinib in clinical practice – results from the prospective non-interventional study GIDEON

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Introduction

• Afatinib, an irreversible ErbB family blocker, is approved for the first-line treatment of patients with locally advanced or metastatic NSCLC with activating EGFR mutation(s)\(^1\)

• Numerous randomised clinical trials have shown significantly improved efficacy outcomes with afatinib compared with chemotherapy or the first-generation EGFR tyrosine kinase inhibitor, gefitinib, and a manageable safety profile\(^2-5\)

• The prospective, non-interventional study (NIS), GIDEON, was undertaken to investigate the effectiveness and tolerability of first-line afatinib treatment when used in routine clinical practice in Germany\(^6\)

• Elderly patients are often under-represented in clinical trials, which can lead to uncertainties regarding optimal treatment of such patients in routine clinical practice

• The GIDEON NIS enrolled a high proportion of patients aged \(\geq 70\) years, providing an opportunity to study the real-world use of afatinib in older individuals\(^6\)

• Here, we report the results from a post-hoc analysis of elderly patients in the first interim analysis of the GIDEON NIS
The GIDEON study

- One hundred and sixty patients with confirmed EGFR mutation-positive NSCLC were recruited at 49 centres across Germany, between April 2014 and December 2016

- Interim findings among the entire treated population (N=151) included:
  - 12-month PFS: 54.6%
  - Median PFS: 12.9 months
  - Median OS (preliminary): >33 months
  - ORR: 73%
  - DCR: 90%

CR, complete response; DCR, disease control rate; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; SD, stable disease
Methods

- This post-hoc analysis of the GIDEON study was conducted to investigate the efficacy and safety of afatinib in patients aged ≥70 years, when administered according to the approved label\(^1\)
- All comparisons were descriptive
Results

Patient demographics and baseline characteristics

- Among the 151 patients treated in the GIDEON study, median age was 67 years (range 38–89)
- In total, 67 patients (44%) were aged ≥70 years (Figure 1)

Figure 1. Age distribution in the overall GIDEON population (N=151)

- Key patient baseline characteristics are shown in Figure 2
Results (cont’d)

Figure 2. Key baseline characteristics among patients aged ≥70 years (n=67)

- **EGFR mutation**
  - Del19: 18%
  - L858R: 18%
  - Rare mutations: 64%

- **Brain metastases**
  - Brain metastases: 22%
  - No brain metastases: 78%

- **ECOG PS**
  - 0: 45%
  - 1: 42%
  - 2: 5%
  - 3: 6%
  - Missing: 3%

*Percentages do not total 100 due to rounding

ECOG PS, Eastern Cooperative Oncology Group performance score
Results (cont’d)

Afatinib starting dose and dose modifications

- There was a trend towards lower starting dose in patients aged ≥70 years, compared with those aged <70 years (Figure 3)

Figure 3. Starting dose of afatinib among patients aged <70 years and ≥70 years

*Missing: n=1, each group
Results (cont’d)

• The percentage of patients requiring dose reductions appeared similar between patients aged <70 years and ≥70 years (Figure 4)

Figure 4. Afatinib dose reductions among patients aged <70 years and ≥70 years
Efficacy

Response and survival
• Elderly patients had similar ORR and DCR compared to younger patients (Figure 5)

Figure 5. ORR and DCR in different age groups

• In patients aged ≥70 years:
  – ORR was 78%
  – DCR was 93%
Efficacy (cont’d)

- 12-month PFS rate in patients aged ≥70 years was 62% (Figure 6; Table 1)

Figure 6. PFS among patients aged ≥70 years

Median PFS (95% CI): 17.3 months (11.0–28.0)
Efficacy (cont’d)

Table 1. 12-month PFS rate

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<tr>
<th>Patient subgroup*</th>
<th>12-month PFS rate (95% CI)</th>
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<tbody>
<tr>
<td>Age &lt;70 years (n=80)</td>
<td>49.1% (37.3–59.8)</td>
</tr>
<tr>
<td>Age ≥70 years (n=62)</td>
<td>62.2% (48.0–73.6)</td>
</tr>
<tr>
<td>All patients (n=142)</td>
<td>54.6% (45.6–62.8)</td>
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</tbody>
</table>

*Nine patients were not evaluable
CI, confidence interval
Safety

- Treatment-emergent adverse events (TEAEs) in the GIDEON study were consistent with the known safety profile of afatinib, identified in the LUX-Lung 3, 6, and 7 clinical trials²–⁴
- Afatinib-related grade ≥3 TEAEs were similar in patients aged ≥70 years and <70 years, with diarrhoea being the most common (Figure 7)
- Eight patients aged ≥70 years (12%) and six patients aged <70 years (7%) discontinued due to serious adverse drug reactions

Figure 7. Afatinib-related grade ≥3 TEAEs occurring in at least 3 patients in any subgroup
Key findings and conclusions

• Data from the GIDEON NIS provide important information on the routine clinical use of afatinib in elderly patients

• As 44% of the GIDEON population were aged ≥70 years, elderly patients were well represented in this study

• With an ORR of 78% and 12-month PFS rate of 62%, these data support the use of afatinib in elderly patients

• Further, the safety profile of afatinib in elderly patients was comparable to that seen in the younger subgroup
References

6. Brueckl WM, et al. Poster #1449 at ESMO; 2018 October 19–21; Munich, Germany
Acknowledgments

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