Elderly patients treated with afatinib in clinical practice – final results of the GIDEON study in *EGFR* mutated NSCLC in Germany

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Introduction

- Afatinib is an irreversible ErbB family blocker approved for the first-line treatment of patients with locally advanced or metastatic NSCLC with activating *EGFR* mutation(s)[1]
- Data from randomised clinical trials have shown that afatinib significantly improves efficacy outcomes compared with chemotherapy or the EGFR tyrosine kinase inhibitor gefitinib, and has a manageable safety profile[2–5]
- The prospective GIDEON non-interventional study (NIS) investigated the effectiveness and tolerability of first-line afatinib treatment in routine clinical practice in Germany.[6] Key findings were (in the treated population, n=152):
  - **Primary endpoint** 1-year PFS rate: 50.2%
  - Median PFS/OS: 12.2/30.4 months
  - ORR: 74.6% (88/118)
  - DCR: 91.5% (108/118)
- Elderly patients are often under-represented in clinical trials, which can lead to uncertainty regarding the optimal treatment of this patient group in the routine practice setting
- The GIDEON NIS enrolled a high proportion of patients aged ≥70 years;[6] this provided an opportunity to study outcomes in older patients
- Here, we report the final results of a post-hoc analysis of elderly participants in the GIDEON NIS

DCR, disease control rate; EGFR, epidermal growth factor receptor; NSCLC, non-small cell lung cancer; ORR, overall response rate; OS, overall survival; PFS, progression-free survival

Objectives

- This post-hoc analysis aimed to investigate the efficacy and safety of afatinib in patients aged ≥70 years when administered according to the approved label

Methods

- In GIDEON, patients (N=161) with confirmed *EGFR* mutation-positive NSCLC were recruited at 41 centres across Germany, between March 2014 and December 2016
- Data were reported via eCRF during routine clinical practice
- All comparisons were descriptive

Primary endpoint
PFS rate at 12 months

Other key endpoints
PFS | ORR (CR + PR)
OS | DCR (CR+PR+SD)

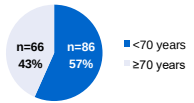
CR, complete response; eCRF, electronic case report form; PR, partial response; SD, stable disease

Results

- 152 patients were treated
- Median age: 67 years (range 38–89)

Age group	*EGFR* mutation status		
	Del19	L858R	Uncommon*
<70 years	65%	26%	9%
≥70 years	64%	18%	18%

*Uncommon mutations include exon 18–21 mutations. Del19, exon 19 deletion



Proportion of patients aged ≥70 and <70 years

Key findings and conclusions

- Data from the GIDEON NIS provide important information on the routine clinical use of afatinib in elderly patients
- Elderly patients (≥70 years) were well represented in the GIDEON NIS, comprising 43% of the population
- Although elderly patients tended to have a worse ECOG PS, and a higher proportion had a Charlson Comorbidity Index of ≥1, this seemed not to compromise efficacy
- Furthermore, the safety profile of afatinib in elderly patients was similar to that seen in the younger subgroup, with no new safety signals identified

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Baseline characteristics

Age group	ECOG PS			Charlson Comorbidity Index			Starting dose	
	0	1	≥2	0	1	>1	40 mg	<40 mg
<70 years	53%	41%	1%	74%	16%	9%	84%	16%
≥70 years	41%	45%	9%	38%	26%	36%	62%	38%

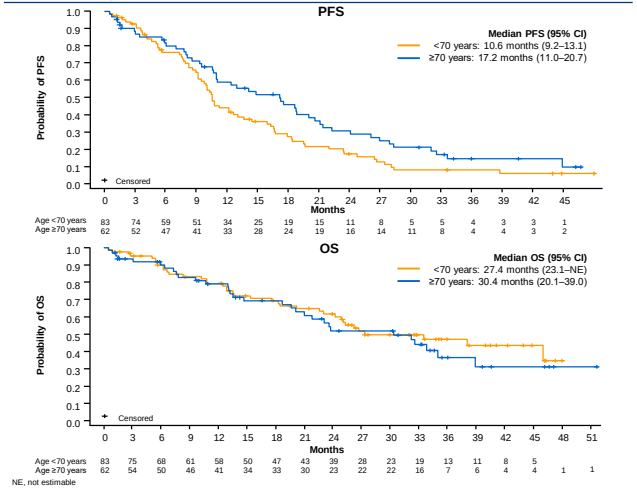
ECOG PS, Eastern Cooperative Oncology Group performance status

Efficacy

Age group*	PFS rate at 12 months (95% CI)	ORR (%)	DCR (%)
<70 years, n=83	43.9% (32.8–54.5)	76	88
≥70 years, n=62	58.9% (45.1–70.3)	72	96

*PFS: n=145; ORR and DCR: n=118. CI, confidence interval

Efficacy



Safety

- AE were consistent with the known safety profile of afatinib[2–4,6]
- Afatinib-related grade ≥3 AEs were similar in patients aged ≥70 years and <70 years; diarrhoea was most common
- In patients aged ≥70 and <70 years, 57.6% and 61.6% required dose reductions, respectively
- In patients aged ≥70 and <70 years, discontinuation due to adverse drug reactions was required in 13 (19.7%) and 12 (14.0%), respectively

ADR, n (%)*	<70 years		≥70 years	
	Any	Grade ≥3	Any	Grade ≥3
Diarrhoea	70 (81)	12 (14)	56 (85)	9 (14)
Acneiform dermatitis	35 (41)	6 (7)	22 (33)	5 (8)
Paronychia	24 (28)	1 (1)	15 (23)	0
Stomatitis	18 (21)	4 (5)	10 (15)	1 (2)
Maculopapular rash	15 (17)	4 (5)	12 (18)	1 (2)
Nausea	11 (13)	3 (3)	8 (12)	2 (3)
Fatigue	4 (5)	0	9 (14)	1 (2)
Vomiting	6 (7)	1 (1)	7 (11)	1 (2)

*ADRs shown were reported in ≥10% of the patient population with at least one grade ≥3 event reported. ADR, adverse drug reaction; AE, adverse event

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