IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports – Commission No. A16-53

Necitumumab (lung cancer) –

Addendum to Commission A16-17[1]

Addendum

Commission: A16-53
Version: 1.0
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[1] Translation of addendum A16-53 *Necitumumab (Lungenkarzinom) – Addendum zum Auftrag A16-17* (Version 1.0; Status: 22 August 2016). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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Keywords: necitumumab, carcinoma – non-small-cell lung, benefit assessment

[2] Due to legal data protection regulations, employees have the right not to be named.

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Abbreviation	Meaning
EGFR	epidermal growth factor receptor
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
NSCLC	non-small cell lung cancer
RCT	randomized controlled trial
SGB	Sozialgesetzbuch (Social Code Book)

1 Background

On 8 August 2016, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to conduct supplementary assessments for Commission A16-17 (Necitumumab [lung cancer] – Benefit assessment according to §35a Social Code Book (SGB) V [1]).

In the framework of the oral hearing on 8 August 2016 on the benefit assessment of necitumumab, one of the persons submitting comments referred to the survival time curve of the SQUIRE study and particularly highlighted the long-term survival under necitumumab. As an example, the person stated that at the time point of 3 years, twice as many patients survived under necitumumab than under the control treatment. This conclusion was challenged in the hearing because estimations from the right side of survival time curves from oncological studies are mostly very uncertain because generally at these time points only few patients are still under observation. This uncertainty could not be estimated on the basis of the available figure because the pharmaceutical company (hereinafter referred to as "the company") in the dossier provided no information on the number of patients at risk at different time points [2]. This deviated from the requirements in the dossier template [3]. The company's comment [4] also did not contain the corresponding information.

After the oral hearing, the company submitted supplementary information on the proportion of patients at risk. The G-BA commissioned IQWiG to assess this information regarding validity and plausibility.

The responsibility for the present assessment and the results of the assessment lies exclusively with IQWiG. The assessment is forwarded to the G-BA. The G-BA decides on the added benefit.

2 Assessment

Figure 1 shows the survival time curve of the SQUIRE study on the comparison of necitumumab in combination with gemcitabine and cisplatin versus gemcitabine and cisplatin in patients with metastatic epidermal growth factor receptor (EGFR) expressing squamous non-small cell lung cancer (NSCLC) who have not received prior chemotherapy for this stage of the disease. This figure was already submitted with the dossier [2] and presented in dossier assessment A16-17.

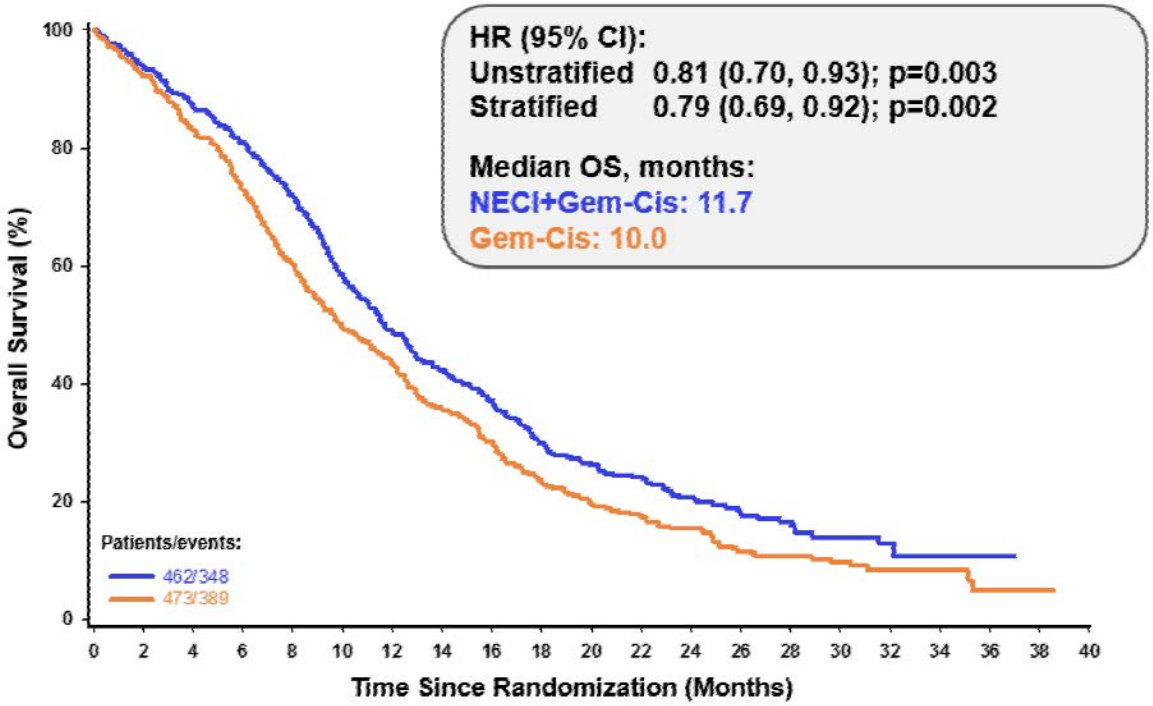

Figure 1: Kaplan-Meier curve for overall survival – RCT, direct comparison: necitumumab + gemcitabine + cisplatin vs. gemcitabine + cisplatin (EGFR+ population)

After the oral hearing, the company subsequently submitted the information on the number of patients at risk at several time points. These are shown in Figure 2.

Patients at Risk - SQUIRE EGFR+ Population

Month	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
Gem/Cis+Nec	462	421	381	353	311	253	211	180	156	114	87	73	56	38	28	18	12	3	3	0	0
Gem/Cis	473	429	380	331	270	221	193	158	133	96	66	54	42	29	24	17	8	7	3	1	0

Figure 2: Number of patients at risk at different time points – RCT, direct comparison: necitumumab + gemcitabine + cisplatin vs. gemcitabine + cisplatin (EGFR+ population)

Firstly, it should be noted that the company subsequently submitted only the information in Figure 2 and not, as customary, the complete Kaplan-Meier curve including the information on the patients at risk. This does not ensure a direct relation to the survival curve in Figure 1.

Figure 2 shows that the number of patients at risk decreases in the course of the study, which is due to patients with event, in this case deaths, and censorings. In the time after 2 years, at the latest after month 30, the number of patients at risk is very small, however. At the time point of 3 years (36 months) mentioned in the hearing, there were only 3 patients at risk in each treatment group. No conclusions on a survival advantage in one of the groups can be derived from these small numbers of patients on the basis of the risk estimations for survival in the treatment groups at this time point.

The data subsequently submitted did not influence the result of the assessment of dossier assessment A16-17.

3 References

1. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Necitumumab (Lungenkarzinom): Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung; Auftrag A16-10 [online]. 28.06.2016 [Accessed: 12.08.2016]. (IQWiG-Berichte; Volume 404). URL: https://www.iqwig.de/download/A16-17_Necitumumab_Nutzenbewertung-35a-SGB-V.pdf.

2. Lilly Deutschland. Dossier zur Nutzenbewertung gemäß § 35a SGB V; Necitumumab (Portrazza): Erwachsene Patienten mit lokal fortgeschrittenem oder metastasiertem, den EGFR exprimierenden, plattenepithelialem NSCLC, wenn diese bislang keine Chemotherapie für dieses Stadium der Erkrankung erhalten haben; Modul 4 A: medizinischer Nutzen und medizinischer Zusatznutzen, Patientengruppen mit therapeutisch bedeutsamem Zusatznutzen [online]. 29.03.2016 [Accessed: 12.08.2016]. URL: https://www.g-ba.de/downloads/92-975-1430/2016-03-29_Modul4A_Necitumumab.pdf.

3. Gemeinsamer Bundesausschuss. Verfahrensordnung des Gemeinsamen Bundesausschusses [online]. 16.04.2015 [Accessed: 29.04.2015]. URL: https://www.g-ba.de/downloads/62-492-1002/VerfO_2014-12-18_iK-2015-04-16.pdf.

4. Lilly Deutschland. Stellungnahme zum IQWiG-Bericht Nr. 404: Necitumumab (Lungenkarzinom); Nutzenbewertung gemäß §35a SGBV; Dossierbewertung; Auftrag A16-17. [Soon available under: https://www.g-ba.de/informationen/nutzenbewertung/227/#tab/beschluesse in the document "Zusammenfassende Dokumentation"].