



Alectinib (Alecensa®)

Lungenkarzinom, nicht-kleinzellig (NSCLC) » ALK+ » ab
Zweitlinientherapie

Empfehlungen der Fachgesellschaft zum Einsatz neuer Arzneimittel

Herausgeber

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Quelle

www.onkopedia.com

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Dokument: Fact Sheet

Spezifizierung: Lungenkarzinom, nicht-kleinzellig (NSCLC) » ALK+ » ab Zweitlinientherapie

Stand: Juli 2021

1 Alectinib, NSCLC, ALK+, second line

Alectinib, NSCLC, ALK+, second line

onkopedia				Facts	Appraisal	EU Approval 2017																																																																						
Parameter	Results¹⁴	HR¹⁵	p value	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Evidence (LoE)</td> <td style="width: 5%;">5</td><td style="width: 5%;">4</td><td style="width: 5%;">3b</td><td style="width: 5%;">3a</td><td style="width: 5%;">2c</td><td style="width: 5%;">2b</td><td style="width: 5%;">2a</td><td style="width: 5%;">1b</td><td style="width: 5%;">1a</td> </tr> <tr> <td>Clinical benefit (ESMO MCBS)</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td colspan="4"></td> </tr> <tr> <td colspan="10"> <div style="display: flex; justify-content: space-around;"> ■ curative ■ non-curative </div> </td> </tr> <tr> <td>Additional benefit (G-BA)</td> <td>lower</td><td>not proven</td><td>not quantifiable</td><td>minor</td><td>considerable</td><td>major</td><td colspan="3"></td> </tr> <tr> <td colspan="10"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">suitable for other systemic treatment²⁹</td> <td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td> </tr> <tr> <td>not suitable for other systemic treatment³⁰</td> <td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td> </tr> </table> </td> </tr> </table>			Evidence (LoE)	5	4	3b	3a	2c	2b	2a	1b	1a	Clinical benefit (ESMO MCBS)	1	2	3	4	5					<div style="display: flex; justify-content: space-around;"> ■ curative ■ non-curative </div>										Additional benefit (G-BA)	lower	not proven	not quantifiable	minor	considerable	major				<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">suitable for other systemic treatment²⁹</td> <td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td> </tr> <tr> <td>not suitable for other systemic treatment³⁰</td> <td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td> </tr> </table>										suitable for other systemic treatment ²⁹										not suitable for other systemic treatment ³⁰									
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RR ²	2.9 vs 37.5																																																																											
PFS ³	1.4 vs 9.6	0.15	p < 0.001																																																																									
OS ⁵	n.r. ¹⁸ vs 12.6		n.s. ¹⁶																																																																									
SAE ⁷	42.1 vs 27.1																																																																											
Remarks:	62.9% of patients in the control arm received Alectinib at a later stage (crossover/switching).																																																																											
Patients	ALK+, after Crizotinib																																																																											
Trial	ALUR, phase 3																																																																											
Randomisation	1 : 1																																																																											
N¹	107																																																																											
New Therapy	Alectinib																																																																											
Control	Docetaxel or Pemetrexed																																																																											
Publication	DOI:10.1093/annonc/mdy121																																																																											

Legende:

¹ N - number of patients

² RR - remission rate, in %

³ PFS - progression-free survival in months

⁵ OS - overall survival in months

⁷ SAE - serious adverse events, CTCAE grade 3/4

¹⁴ results for control, results for new therapy

¹⁵ hazard ratio for new therapy

¹⁶ n. s. not significant

¹⁸ n. r. - median not reached

²⁹ Pemetrexed, Docetaxel or Ceritinib

³⁰ Pemetrexed, Docetaxel or Ceritinib