



Crizotinib (Xalkori®)

Lungenkarzinom, nicht-kleinzellig (NSCLC) » ALK+ » Erstlinie

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+ » Erstlinie

Stand: Juli 2021

1 Crizotinib, NSCLC, ALK+, first line

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onkopedia				Facts	Appraisal	EU Approval 2015																																						
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: 10%;">5</td><td style="width: 10%;">4</td><td style="width: 10%;">3b</td><td style="width: 10%;">3a</td><td style="width: 10%;">2c</td><td style="width: 10%;">2b</td><td style="width: 10%;">2a</td><td style="width: 10%;">1b</td><td style="width: 10%;">1a</td> </tr> <tr> <td></td> <td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: black;"></td><td style="background-color: black;"></td> </tr> <tr> <td>Clinical benefit (ESMO MCBS)</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td> </tr> <tr> <td></td> <td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: yellow;"></td><td style="background-color: #cccccc;"></td> </tr> <tr> <td></td> <td colspan="5"> <div style="display: flex; justify-content: space-around;"> ■ curative ■ non-curative </div> </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>				
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RR ²	45 vs 74		p < 0.0001																																									
PFS ³	7.0 vs 10.9	0.454	p < 0.0001																																									
OS ⁵	47.5 vs n.r. ¹⁸	0.760	p = 0.0978																																									
SAE ⁷	53.3 vs 50.3																																											
Remarks: 63% of patients in the control arm received Crizotinib at a later stage (crossover/switching).																																												
Patients	ALK+, first line			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Additional benefit (G-BA)</td> <td style="width: 10%;">lower</td><td style="width: 10%;">not proven</td><td style="width: 10%;">not quantifiable</td><td style="width: 10%;">minor</td><td style="width: 10%;">considerable</td><td style="width: 10%;">major</td> </tr> <tr> <td></td> <td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: #cccccc;"></td><td style="background-color: black;"></td><td style="background-color: #cccccc;"></td> </tr> </table>			Additional benefit (G-BA)	lower	not proven	not quantifiable	minor	considerable	major																															
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Trial	PROFILE 1014, phase 3																																											
Randomisation	1 : 1																																											
N¹	343																																											
New Therapy	Crizotinib																																											
Control	Platin+Pemetrexed																																											
Publication	DOI: 10.1056/NEJMoa1408440 DOI:10.1200/JCO.2017.77.4794																																											

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

¹⁸ n. r. - median not reached