

arzneimittel



Axitinib (Inlyta®)

Nierenzellkarzinom (Hypernephrom) » + Pembrolizumab (Keytruda®) » fortgeschritten, Erstlinie, niedriges / intermediäres Risiko

Empfehlungen der Fachgesellschaft zum Einsatz neuer Arzneimittel

Herausgeber

DGHO Deutsche Gesellschaft für Hämatologie und
Medizinische Onkologie e.V.
Alexanderplatz 1
10178 Berlin

Geschäftsführender Vorsitzender: Prof. Dr. med. Lorenz Trümper

Telefon: +49 (0)30 27 87 60 89 - 0
Telefax: +49 (0)30 27 87 60 89 - 18

info@dgho.de
www.dgho.de

Ansprechpartner

Prof. Dr. med. Bernhard Wörmann
Medizinischer Leiter

Quelle

www.onkopedia.com

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Inhaltsverzeichnis

1 Axitinib + Pembrolizumab, RCC, advanced, first line, low/in- ... 2
termediate risk


Axitinib (Inlyta®)

Dokument: Fact Sheet

Spezifizierung: Nierenzellkarzinom (Hypernephrom) » + Pembrolizumab (Keytruda®) » fortgeschritten, Erstlinie, niedriges / intermediäres Risiko

Stand: Mai 2020

1 Axitinib + Pembrolizumab, RCC, advanced, first line, low/intermediate risk

Axitinib + Pembrolizumab, RCC, advanced, first line, low/intermediate risk																							
		Facts	Appraisal																				
EU Approval 2019																							
Parameter	Results⁶	HR⁹	p value																				
RR ²	42 vs 63		p < 0.001																				
PFS ³	12.5 vs 18.0	0.70	p < 0.001																				
OS ⁵	n.r. vs n.r.	0.57	p = 0.001																				
SAE ⁷	71 vs 76																						
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Evidence (LoE)</td> <td style="width: 15%; text-align: center;">5</td> <td style="width: 15%; text-align: center;">4</td> <td style="width: 15%; text-align: center;">3b</td> <td style="width: 15%; text-align: center;">3a</td> <td style="width: 15%; text-align: center;">2c</td> <td style="width: 15%; text-align: center;">2b</td> <td style="width: 15%; text-align: center;">2a</td> <td style="width: 15%; text-align: center;">1b</td> <td style="width: 15%; text-align: center;">1a</td> </tr> <tr> <td></td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> </table>				Evidence (LoE)	5	4	3b	3a	2c	2b	2a	1b	1a		[]	[]	[]	[]	[]	[]	[]	[]	[]
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	[]	[]	[]	[]	[]	[]																	
Patients	advanced/metastatic, low/intermediate risk																						
Trial	KEYNOTE 426, phase 3																						
Randomisation	1 : 1																						
N¹	753																						
New Therapy	Axitinib + Pembrolizumab																						
Control	Sunitinib																						
Publication	DOI:10.1056/NEJMoa1816714																						

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

⁸ results for control, results for new therapy

⁹ hazard ratio for new therapy