



Nivolumab (Opdivo®)

Nierenzellkarzinom (Hypernephrom) » + Ipilimumab (Yervoy®) »
fortgeschritten, Erstlinie, intermediäres Risiko

Empfehlungen der Fachgesellschaft zum Einsatz neuer Arzneimittel

Herausgeber

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www.onkopedia.com

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Inhaltsverzeichnis

1 Nivolumab + Ipilimumab, RCC, advanced, first line, intermediate risk	2
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Nivolumab (Opdivo®)

Dokument: Factsheet

Spezifizierung: Nierenzellkarzinom (Hypernephrom) » + Ipilimumab (Yervoy®) » fortgeschritten, Erstlinie, intermediäres Risiko

Stand: Mai 2020

1 Nivolumab + Ipilimumab, RCC, advanced, first line, intermediate risk

Nivolumab + Ipilimumab, RCC, advanced, first line, intermediate risk

onkopedia				Facts	Appraisal	EU Approval 2019																																																							
Parameter	Results⁶	HR⁹	p value	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="9"></td> </tr> <tr> <td style="width: 11%;">5</td><td style="width: 11%;">4</td><td style="width: 11%;">3b</td><td style="width: 11%;">3a</td><td style="width: 11%;">2c</td><td style="width: 11%;">2b</td><td style="width: 11%;">2a</td><td style="width: 11%;">1b</td><td style="width: 11%;">1a</td> </tr> <tr> <td colspan="9" style="text-align: center;">Evidence (LoE)</td> </tr> <tr> <td colspan="9" style="text-align: center;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">1</td><td style="width: 20%;">2</td><td style="width: 20%;">3</td><td style="width: 20%;">4</td><td style="width: 20%;">5</td> </tr> <tr> <td colspan="5" style="text-align: center;">Clinical benefit (ESMO MCBS)</td> </tr> </table> </td> </tr> <tr> <td colspan="9" style="text-align: center;"> <div style="display: flex; justify-content: center; gap: 10px;"> ■ curative ■ non-curative </div> </td> </tr> </table>												5	4	3b	3a	2c	2b	2a	1b	1a	Evidence (LoE)									<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">1</td><td style="width: 20%;">2</td><td style="width: 20%;">3</td><td style="width: 20%;">4</td><td style="width: 20%;">5</td> </tr> <tr> <td colspan="5" style="text-align: center;">Clinical benefit (ESMO MCBS)</td> </tr> </table>									1	2	3	4	5	Clinical benefit (ESMO MCBS)					<div style="display: flex; justify-content: center; gap: 10px;"> ■ curative ■ non-curative </div>								
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RR²	30 vs 42		p = 0.0014																																																										
PFS³	9.8 vs 12.5	0.89	n.s.¹⁰																																																										
OS⁵	34.8 vs n.r.	0.697	p = 0.0025																																																										
SAE⁷	63 vs 46																																																												
Patients	advanced/metastatic, intermediate risk																																																												
Trial	CheckMate 214, phase 3																																																												
Randomisation	1 : 1																																																												
N¹	667																																																												
New Therapy	Nivolumab + Ipilimumab																																																												
Control	Sunitinib																																																												
Publication	DOI:10.1056/NEJMoa1712126																																																												
Additional benefits (G-BA)				<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">lower</td><td style="width: 20%;">proven</td><td style="width: 20%;">not quantifiable</td><td style="width: 20%;">not minor</td><td style="width: 20%;">considerable</td><td style="width: 20%;">major</td> </tr> <tr> <td colspan="6" style="text-align: center;">intermediate risk (IMDC)¹⁹</td> </tr> <tr> <td colspan="6" style="text-align: center;">high risk (IMDC)²⁰</td> </tr> </table>	lower	proven	not quantifiable	not minor	considerable	major	intermediate risk (IMDC) ¹⁹						high risk (IMDC) ²⁰																																												
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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

¹⁰ n. s. not significant

¹⁹ International Metastatic Renal-Cell Carcinoma Database Consortium Score

²⁰ International Metastatic Renal-Cell Carcinoma Database Consortium Score