



# Nivolumab (Opdivo®)

Nierenzellkarzinom (Hypernephrom) » fortgeschritten » ab  
Zweitlinientherapie

Empfehlungen der Fachgesellschaft zum Einsatz neuer Arzneimittel

## **Herausgeber**

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## **Quelle**

[www.onkopedia.com](http://www.onkopedia.com)

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# Nivolumab (Opdivo®)

**Dokument:** Fact Sheet

**Spezifizierung:** Nierenzellkarzinom (Hypernephrom) » fortgeschritten » ab Zweitlinientherapie

**Stand:** Mai 2020

## 1 Nivolumab, RCC, advanced, second line

### Nivolumab, RCC, advanced, second line

onkopedia				Facts	Appraisal	EU Approval 2016																																														
<b>Parameter</b>	<b>Results<sup>8</sup></b>	<b>HR<sup>9</sup></b>	<b>p value</b>	<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></td><td></td><td></td><td></td><td></td><td></td><td></td><td style="background-color: black;"></td><td></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></td> <td></td><td></td><td></td><td></td><td style="background-color: yellow;"></td> <td colspan="4"></td> </tr> <tr> <td></td> <td colspan="2"> <div style="display: flex; justify-content: space-between; width: 100%;"> <span style="color: blue;">■</span> curative                             <span style="color: yellow;">■</span> non-curative                         </div> </td> <td colspan="3"></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-between; width: 100%;"> <span style="color: blue;">■</span> curative                             <span style="color: yellow;">■</span> non-curative                         </div>				
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<b>RR<sup>2</sup></b>	<b>5</b> vs <b>25</b>		<b>p &lt; 0.001</b>																																																	
<b>PFS<sup>3</sup></b>	<b>4.4</b> vs <b>4.6</b>		<b>n.s.<sup>10</sup></b>																																																	
<b>OS<sup>5</sup></b>	<b>19.6</b> vs <b>25.0</b>	<b>0.73</b>	<b>p = 0.002</b>																																																	
<b>SAE<sup>7</sup></b>	<b>37</b> vs <b>19</b>																																																			
<b>Patients</b>	advanced/metastatic																																																			
<b>Trial</b>	CheckMate 025, phase 3																																																			
<b>Randomisation</b>	1 : 1																																																			
<b>N<sup>1</sup></b>	812																																																			
<b>New Therapy</b>	Nivolumab																																																			
<b>Control</b>	Everolimus																																																			
<b>Publication</b>	DOI:10.1056/NEJMoa1510665																																																			
<b>Additional benefits (G-BA)</b>				<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;">lower</td> <td style="width: 15%;">not proven</td> <td style="width: 15%;">not quantifiable</td> <td style="width: 15%;">minor</td> <td style="width: 15%;">considerable</td> <td style="width: 15%;">major</td> </tr> <tr> <td>following antiangiogenic therapy</td> <td></td><td></td><td></td><td></td><td style="background-color: black;"></td><td></td> </tr> <tr> <td>following tamsulosin</td> <td></td><td style="background-color: black;"></td><td></td><td></td><td></td><td></td> </tr> </table>		lower	not proven	not quantifiable	minor	considerable	major	following antiangiogenic therapy							following tamsulosin																																	
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Legende:

<sup>1</sup> N - number of patients

<sup>2</sup> RR - remission rate, in %

<sup>3</sup> PFS - progression-free survival in months

<sup>5</sup> OS - overall survival in months

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

<sup>8</sup> results for control, results for new therapy

<sup>9</sup> hazard ratio for new therapy

<sup>10</sup> n. s. not significant