

arzneimittel



## Idelalisib (Zydelig®)

Chronische Lymphatische Leukämie (CLL) » ab Zweitlinientherapie »  
≥65 Jahre

Empfehlungen der Fachgesellschaft zum Einsatz neuer Arzneimittel

## **Herausgeber**

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## **Quelle**

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

Die Empfehlungen der DGHO für die Diagnostik und Therapie hämatologischer und onkologischer Erkrankungen entbinden die verantwortliche Ärztin / den verantwortlichen Arzt nicht davon, notwendige Diagnostik, Indikationen, Kontraindikationen und Dosierungen im Einzelfall zu überprüfen! Die DGHO übernimmt für Empfehlungen keine Gewähr.

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# Idelalisib (Zydelig®)

**Dokument:** Fact Sheet

**Spezifizierung:** Chronische Lymphatische Leukämie (CLL) » ab Zweitlinientherapie » ≥65 Jahre

**Stand:** Oktober 2020

## 1 Idelalisib, CLL, second line, ≥65 years

### Idelalisib, CLL, second line, ≥65 years

onkopedia				Facts	Appraisal	EU Approval 2016																																																							
<b>Parameter</b>	<b>Results<sup>11</sup></b>	<b>HR<sup>12</sup></b>	<b>p value</b>	<table border="1" style="width: 100%; text-align: center;"> <tr> <td colspan="9"></td> </tr> <tr> <td>5</td><td>4</td><td>3b</td><td>3a</td><td>2c</td><td>2b</td><td>2a</td><td>1b</td><td>1a</td> </tr> <tr> <td colspan="9" style="border: none;">Evidence (LoE)</td> </tr> <tr> <td colspan="9" style="border: none;"> <table border="1" style="width: 100%; text-align: center;"> <tr> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td> </tr> <tr> <td colspan="5" style="border: none;">Clinical benefit (ESMO MCBS)</td> </tr> </table> </td> </tr> <tr> <td colspan="9" style="border: none;"> <span style="color: blue;">■</span> curative    <span style="color: yellow;">■</span> non-curative                 </td> </tr> </table>												5	4	3b	3a	2c	2b	2a	1b	1a	Evidence (LoE)									<table border="1" style="width: 100%; text-align: center;"> <tr> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td> </tr> <tr> <td colspan="5" style="border: none;">Clinical benefit (ESMO MCBS)</td> </tr> </table>									1	2	3	4	5	Clinical benefit (ESMO MCBS)					<span style="color: blue;">■</span> curative <span style="color: yellow;">■</span> non-curative								
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RR <sup>2</sup>	16 vs 84		p < 0.001																																																										
PFS <sup>3</sup>	6.5 vs 19.4	0.27	p < 0.0001																																																										
OS <sup>5</sup>	34.6 vs 40.6		n.s. <sup>13</sup>																																																										
<b>Patients</b>	≥1 previous treatment			<table border="1" style="width: 100%; text-align: center;"> <tr> <td colspan="5"></td> </tr> <tr> <td>lower</td><td>not proven</td><td>not quantifiable</td><td>minor</td><td>considerablemajor</td> </tr> <tr> <td colspan="5" style="border: none;">Additional benefit (G-BA)</td> </tr> <tr> <td colspan="5" style="border: none;">suitable for chemotherapy</td> </tr> <tr> <td colspan="5" style="border: none;">not suitable for chemotherapy</td> </tr> </table>								lower	not proven	not quantifiable	minor	considerablemajor	Additional benefit (G-BA)					suitable for chemotherapy					not suitable for chemotherapy																																		
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<b>Trial</b>	phase 3																																																												
<b>Randomisation</b>	1 : 1																																																												
<b>N<sup>1</sup></b>	220																																																												
<b>New Therapy</b>	Idelalisib + Rituximab																																																												
<b>Control</b>	Rituximab																																																												
<b>Publication</b>	DOI:10.1056/NEJMoa1315226 DOI:10.1200/JCO.18.01460																																																												

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>11</sup> results for control, results for new therapy

<sup>12</sup> hazard ratio for new therapy

<sup>13</sup> n. s. not significant