

arzneimittel



# Gilteritinib (Xospata®)

Akute Myeloische Leukämie (AML) » rezidiert/refraktär » FLT3 mutiert

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.

# Inhaltsverzeichnis

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# Gilteritinib (Xospata®)

**Dokument:** Fact Sheet

**Spezifizierung:** Akute Myeloische Leukämie (AML) » rezidiert/refraktär » FLT3 mutiert

**Stand:** Januar 2022

## 1 Gilteritinib, AML, relapsed/refractory, FLT3mut

Gilteritinib, AML, relapsed/refractory, FLT3mut																																																	
		<b>Facts</b>	<b>Appraisal</b>																																														
		<b>EU Approval 2019</b>																																															
<b>Parameter</b>	<b>Results<sup>14</sup></b>	<b>HR<sup>15</sup></b>	<b>p value</b>																																														
RR <sup>2</sup>	10.5 <sup>19</sup> vs 21.1 <sup>19</sup>		n.s. <sup>16</sup>																																														
OS <sup>5</sup>	5.6 vs 9.3	0.64	p < 0.001																																														
EFS <sup>8</sup>	0.7 vs 2.8	0.79	n.s. <sup>16</sup>																																														
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <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 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;"> <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%; 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)					<span style="color: blue;">■</span> curative <span style="color: yellow;">■</span> non-curative								
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<b>Patients</b> AML, relapsed/refractory, FLT3mut <b>Trial</b> ADMIRAL <b>Randomisation</b> 2 : 1 <b>N<sup>1</sup></b> 371 <b>New Therapy</b> Gilteritinib <b>Control</b> Chemotherapy <b>Publication</b> DOI:10.1056/NEJMoa1902688		<b>Additional benefit (G-BA)</b> lower    proven    not quantifiable    not minor    considerable    major <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td> </tr> <tr> <td colspan="9" style="text-align: center;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;"></td><td style="width: 20%;"></td><td style="width: 20%;"></td><td style="width: 20%;"></td><td style="width: 20%;"></td> </tr> </table> </td> </tr> </table>											<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;"></td><td style="width: 20%;"></td><td style="width: 20%;"></td><td style="width: 20%;"></td><td style="width: 20%;"></td> </tr> </table>																																				
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Legende:

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

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

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

<sup>8</sup> EFS - Event-Free Survival

<sup>14</sup> results for control, results for new therapy

<sup>15</sup> hazard ratio for new therapy

<sup>16</sup> n. s. not significant

<sup>19</sup> Complete Remission Rate (CR + CRp)