



Gemtuzumab Ozogamicin (Mylotarg®)

Akute Myeloische Leukämie (AML) » neu diagnostiziert » NPM1mut

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. Hermann Einsele

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

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

1 Gemtuzumab Ozogamicin, AML, newly diagnosed, NPM1mut ...	2
---	----------

Gemtuzumab Ozogamicin (Mylotarg®)

Dokument: Fact Sheet

Spezifizierung: Akute Myeloische Leukämie (AML) » neu diagnostiziert » NPM1mut

Stand: Januar 2021

1 Gemtuzumab Ozogamicin, AML, newly diagnosed, NPM1mut

Gemtuzumab Ozogamicin, AML, newly diagnosed, NPM1mut																																																			
onkopedia		Facts	Appraisal																																																
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Parameter</th> <th style="text-align: left;">Results¹⁴</th> <th style="text-align: left;">HR¹⁵</th> <th style="text-align: left;">p value</th> </tr> </thead> <tbody> <tr> <td>RFS¹⁰</td> <td>48.0¹⁹ vs 60.5¹⁹</td> <td></td> <td>p = 0.028</td> </tr> </tbody> </table>	Parameter	Results ¹⁴	HR ¹⁵	p value	RFS ¹⁰	48.0 ¹⁹ vs 60.5 ¹⁹		p = 0.028	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 5%;">5</th> <th style="width: 5%;">4</th> <th style="width: 5%;">3b</th> <th style="width: 5%;">3a</th> <th style="width: 5%;">2c</th> <th style="width: 5%;">2b</th> <th style="width: 5%;">2a</th> <th style="width: 5%;">1b</th> <th style="width: 5%;">1a</th> </tr> </thead> <tbody> <tr> <td>Evidence (LoE)</td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: black;"></td> <td style="background-color: #cccccc;"></td> </tr> <tr> <td>Clinical benefit (ESMO MCBS)</td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> </tr> <tr> <td></td> <td colspan="9"> <div style="display: flex; justify-content: space-between; align-items: center;"> ■ curative ■ non-curative </div> </td> </tr> </tbody> </table>				5	4	3b	3a	2c	2b	2a	1b	1a	Evidence (LoE)										Clinical benefit (ESMO MCBS)											<div style="display: flex; justify-content: space-between; align-items: center;"> ■ curative ■ non-curative </div>								
Parameter	Results ¹⁴	HR ¹⁵	p value																																																
RFS ¹⁰	48.0 ¹⁹ vs 60.5 ¹⁹		p = 0.028																																																
	5	4	3b	3a	2c	2b	2a	1b	1a																																										
Evidence (LoE)																																																			
Clinical benefit (ESMO MCBS)																																																			
	<div style="display: flex; justify-content: space-between; align-items: center;"> ■ curative ■ non-curative </div>																																																		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td>Patients</td> <td>AML, NPM1mut</td> </tr> <tr> <td>Trial</td> <td>AMLSG 09-09</td> </tr> <tr> <td>Randomisation</td> <td>1 : 1</td> </tr> <tr> <td>N¹</td> <td>386</td> </tr> <tr> <td>New Therapy</td> <td>Chemotherapy + Gemtuzumab Ozogamicin</td> </tr> <tr> <td>Control</td> <td>Chemotherapy</td> </tr> <tr> <td>Publication</td> <td>DOI:10.1182/blood.2020005998</td> </tr> </tbody> </table>	Patients	AML, NPM1mut	Trial	AMLSG 09-09	Randomisation	1 : 1	N ¹	386	New Therapy	Chemotherapy + Gemtuzumab Ozogamicin	Control	Chemotherapy	Publication	DOI:10.1182/blood.2020005998	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 15%;">lower</th> <th style="width: 15%;">proven</th> <th style="width: 15%;">not quantifiable</th> <th style="width: 15%;">not minor</th> <th style="width: 15%;">considerable</th> <th style="width: 15%;">major</th> </tr> </thead> <tbody> <tr> <td>Additional benefit (G-BA)</td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: black;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> <td style="background-color: #cccccc;"></td> </tr> </tbody> </table>				lower	proven	not quantifiable	not minor	considerable	major	Additional benefit (G-BA)																										
Patients	AML, NPM1mut																																																		
Trial	AMLSG 09-09																																																		
Randomisation	1 : 1																																																		
N ¹	386																																																		
New Therapy	Chemotherapy + Gemtuzumab Ozogamicin																																																		
Control	Chemotherapy																																																		
Publication	DOI:10.1182/blood.2020005998																																																		
	lower	proven	not quantifiable	not minor	considerable	major																																													
Additional benefit (G-BA)																																																			

EU Approval 2018

Legende:

¹ N - number of patients

¹⁰ RFS - Relapse-Free Survival

¹⁴ results for control, results for new therapy

¹⁵ hazard ratio for new therapy

¹⁹ Relapse-Free Survival after 4 years