



Siltuximab (Sylvant®)

Morbus Castleman » idiopathic multicentric Morbus Castleman

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

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Siltuximab (Sylvant®)

Dokument: Fact Sheet

Spezifizierung: Morbus Castleman » idiopathic multicentric Morbus Castleman

Stand: Juli 2022

1 Siltuximab, idiopathic multicentric Morbus Castleman

| Siltuximab, idiopathic multicentric Morbus Castleman | | | | EU Approval 2014 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|------------------------|--------------------|---|---|------------------|-----------|--------------|------------|------------------|-----------|--------------|-------|---------------------------|----|----|----------------|--|--|--|--|--|--|--|--|--|--|------------------------------|--|---|---|---|---|---|
| onkopedia | | | Facts | Appraisal | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Parameter | Results¹⁵ | HR¹⁶ | p value | <table border="1" style="width: 100%; text-align: center;"> <tr> <td colspan="2"></td> <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="2">Evidence (LoE)</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 colspan="2">Clinical benefit (ESMO MCBS)</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td> </tr> </table> <p> ■ curative ■ non-curative </p> | | | | 5 | 4 | 3b | 3a | 2c | 2b | 2a | 1b | 1a | Evidence (LoE) | | | | | | | | | | | Clinical benefit (ESMO MCBS) | | 1 | 2 | 3 | 4 | 5 |
| | | 5 | 4 | | | 3b | 3a | 2c | 2b | 2a | 1b | 1a | | | | | | | | | | | | | | | | | | | | | | |
| Evidence (LoE) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clinical benefit (ESMO MCBS) | | 1 | 2 | 3 | 4 | 5 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RR ² | 0 ²¹ vs 34 ²¹ | | p = 0.0012 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| SAE ⁷ | 19 vs 23 | | n.s. ¹⁷ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| TTF ¹⁴ | 134 ²² vs n.e. ²⁰ | | p = 0.0084 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Patients | Idiopathic multicentric Morbus Castleman | | | <table border="1" style="width: 100%; text-align: center;"> <tr> <td colspan="2"></td> <td>lower</td><td>not proven</td><td>not quantifiable</td><td>not minor</td><td>considerable</td><td>major</td> </tr> <tr> <td colspan="2">Additional benefit (G-BA)</td> <td></td><td></td><td style="background-color: black;"></td><td></td><td></td><td></td> </tr> </table> | | | | lower | not proven | not quantifiable | not minor | considerable | major | Additional benefit (G-BA) | | | | | | | | | | | | | | | | | | | | |
| | | lower | not proven | | | not quantifiable | not minor | considerable | major | | | | | | | | | | | | | | | | | | | | | | | | | |
| Additional benefit (G-BA) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Trial | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Randomisation | 2 : 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| N¹ | 79 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| New Therapy | Siltuximab | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Control | Placebo | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Publication | DOI:10.1016/S1470-2045(14)70319-5 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Legende:

¹ N - number of patients

² RR - remission rate, in %

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

¹⁴ TTF - time to treatment failure

¹⁵ results for control, results for new therapy

¹⁶ hazard ratio for new therapy

¹⁷ n. s. not significant

²⁰ n. e.

²¹ durable tumour and symptomatic response for at least 18 weeks

²² time to treatment failure, in days