



Ibrutinib (Imbruvica®)

Chronische Lymphatische Leukämie (CLL) » + Rituximab » Erstlinie,
≤70 Jahre, IGHV unmutiert

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. Lorenz Trümper

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 Ibrutinib + Rituximab, CLL, first line, ≤70 years, IGHV un- mutated | ... 2 |
|--|--------------|

Ibrutinib (Imbruvica®)

Dokument: Fact Sheet

Spezifizierung: Chronische Lymphatische Leukämie (CLL) » + Rituximab » Erstlinie, ≤70 Jahre, IGHV unmutiert

Stand: Oktober 2020

1 Ibrutinib + Rituximab, CLL, first line, ≤70 years, IGHV unmutated

| Ibrutinib + Rituximab, CLL, first line, ≤70 years, IGHV unmutated | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|------------------------|---|----|----|----|----|----|----|----|----|----|----------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|--|--|
| onkopedia Facts | | | Appraisal EU Approval 2019 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Parameter | Results¹¹ | HR¹² | p value | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| PFS ³ | | 0.26 (0.14 - 0.50) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <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%; background-color: black;">1b</td><td style="width: 10%;">1a</td> </tr> <tr> <td colspan="9">Evidence (LoE)</td> </tr> <tr> <td colspan="9"> </td> </tr> <tr> <td colspan="9">Clinical benefit (ESMO MCBS)</td> </tr> <tr> <td colspan="9"> </td> </tr> <tr> <td colspan="9"> ■ curative ■ non-curative </td> </tr> </table> | | | | 5 | 4 | 3b | 3a | 2c | 2b | 2a | 1b | 1a | Evidence (LoE) | | | | | | | | | | | | | | | | | | Clinical benefit (ESMO MCBS) | | | | | | | | | | | | | | | | | | ■ curative ■ non-curative | | | | | | | | |
| 5 | 4 | 3b | 3a | 2c | 2b | 2a | 1b | 1a | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Evidence (LoE) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clinical benefit (ESMO MCBS) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ■ curative ■ non-curative | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Patients | ≤70 years, no del17p/TP53mut, IGHV unmutated | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Trial | E1912, phase 3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Randomisation | 2 : 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| N¹ | 281 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| New Therapy | Ibrutinib + Rituximab | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Control | Fludarabine / Cyclophosphamide / Rituximab (FCR) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Publication | DOI:10.1056/NEJMoa1815281 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Legende:

¹ N - number of patients

³ PFS - progression-free survival in months

¹¹ results for control, results for new therapy

¹² hazard ratio for new therapy