

SCEMBLIX - Efficacy - HCP

[Prescribing information](#)

Image



Image



 **SCSEMBLIX**[®] ▼
(asciminib) 20 mg, 40 mg tablets

SCSEMBLIX▼ (asciminib) is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph + CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors, and without a known T315I mutation.¹

The below content is for healthcare professionals in Great Britain only. If you require information for Northern Ireland please refer to the [Northern Ireland prescribing information](#).

Efficacy

SCEMBLIX® showed superior efficacy vs bosutinib as early as Week 24^{1,2}

ASCEMBL is the first head-to-head Phase III study comparing a STAMP inhibitor vs an ATP-competitive TKI.^{2,3}

A multicentre, randomised, active-controlled and open-label Phase III study of SCEMBLIX vs bosutinib, assessing MMR at 24 and 96 weeks, and other endpoints including time to and duration of MMR, CCyR and safety profile.²

The ASCEMBL trial population was not restricted to Ph+ patients with CML-CP.² SCEMBLIX is indicated in adults with Ph+ CML-CP previously treated with two or more TKIs and without a known T315I mutation.¹



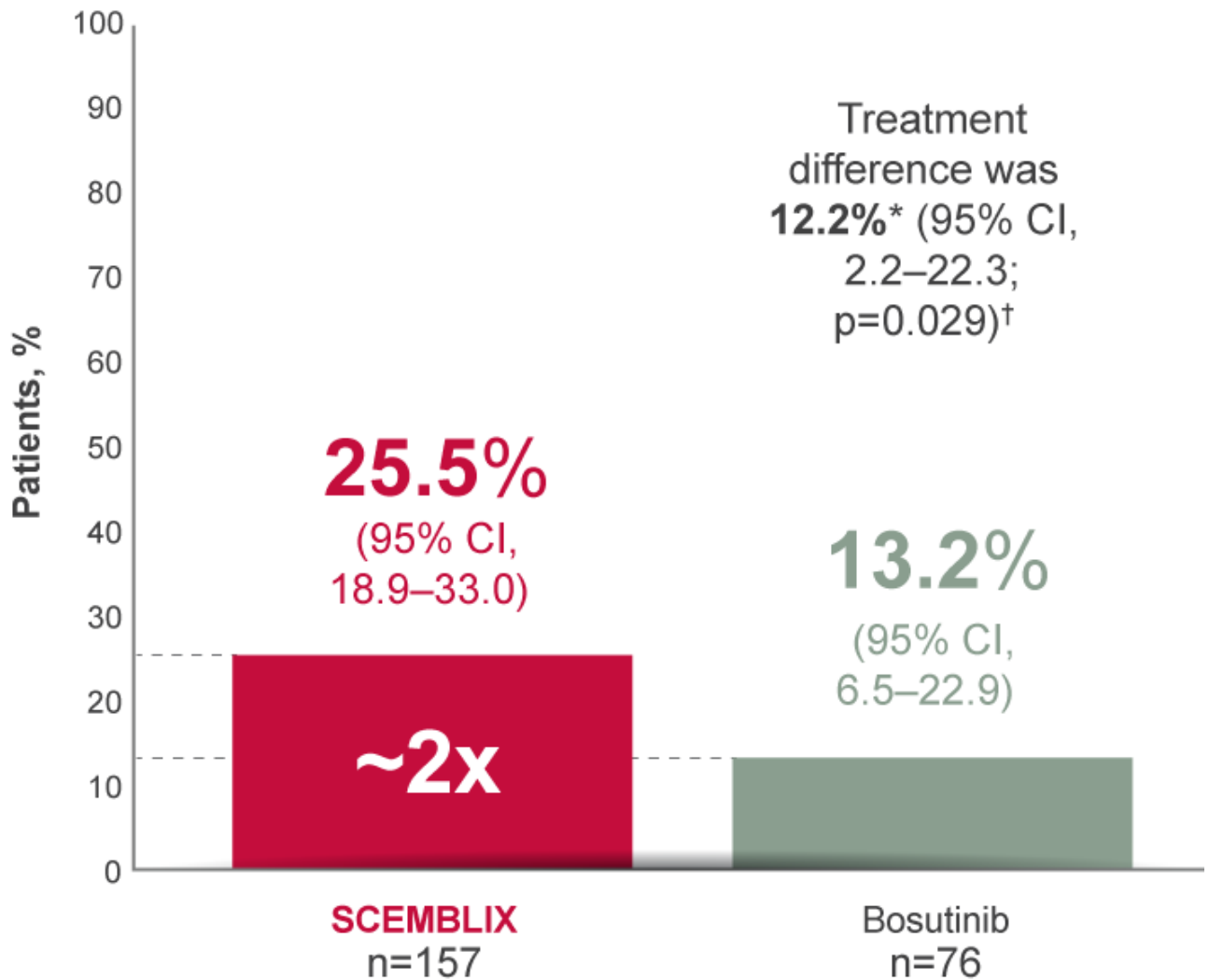
- MMR at Week 24
- MMR at Week 96
- MMR at Week 156



SCEMBLIX nearly doubled the MMR rate vs bosutinib at Week 24 (primary endpoint)^{2,4}

MMR at Week 24
Primary endpoint^{2,4}

Image



*On adjustment for the baseline major cytogenetic response status.

[†]Cochran-Mantel-Haenszel two-sided test stratified by baseline major cytogenetic response status.

Adapted from Réa D, et al. 2021² and Mauro M, et al. 2023.⁴

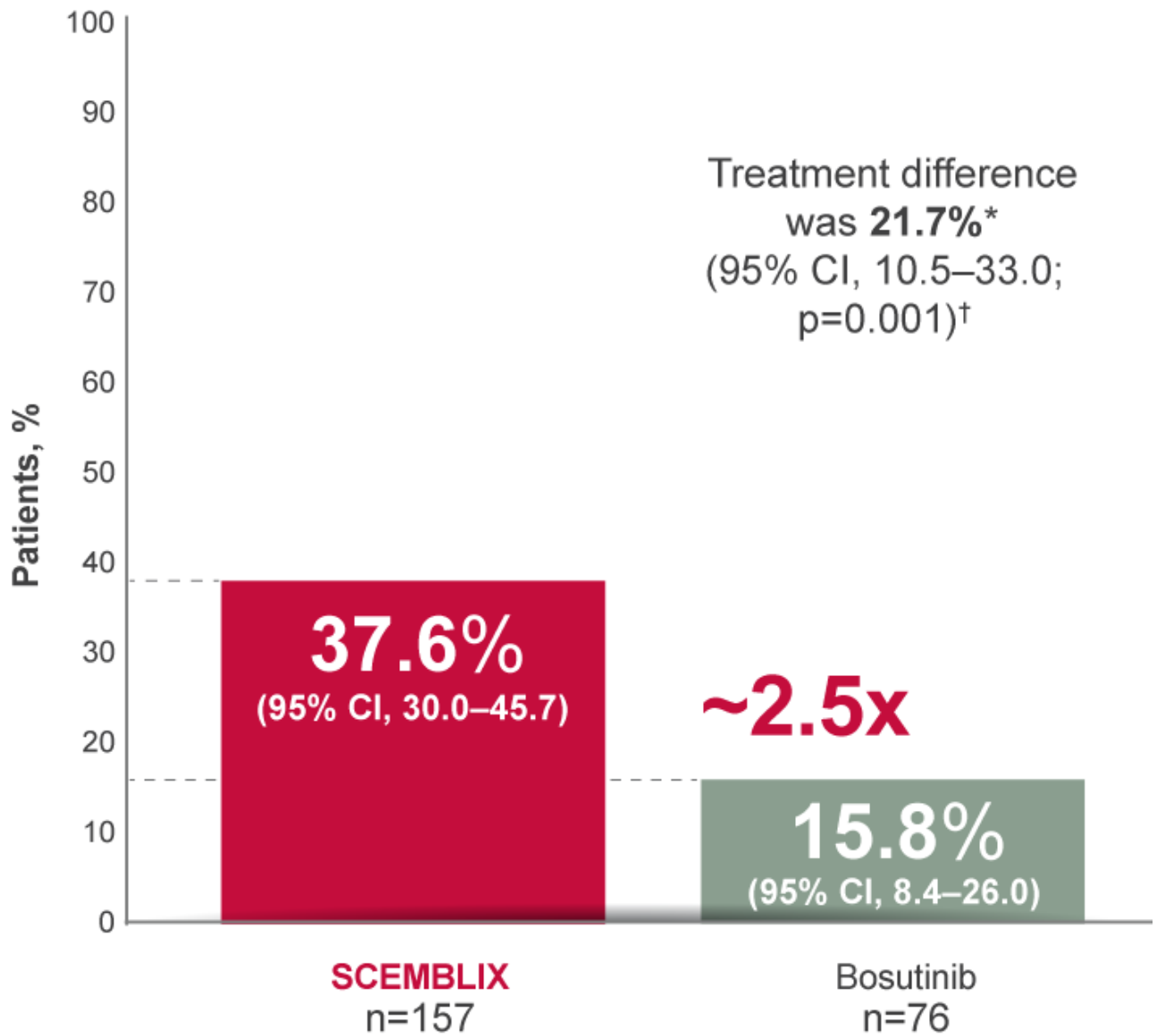
Achieving MMR has been associated with more favourable long-term outcomes, including survival and progression-free survival.^{2,5,6}

Key secondary endpoint

Reported after a follow-up of 2.3 years^{2,4}

MMR at Week 96^{2,4}

Image



*On adjustment for the baseline major cytogenetic response status.

†Cochran-Mantel-Haenszel two-sided test stratified by baseline major cytogenetic response status.

Adapted from Réa D, et al. 2021² and Mauro M, et al. 2023.⁴

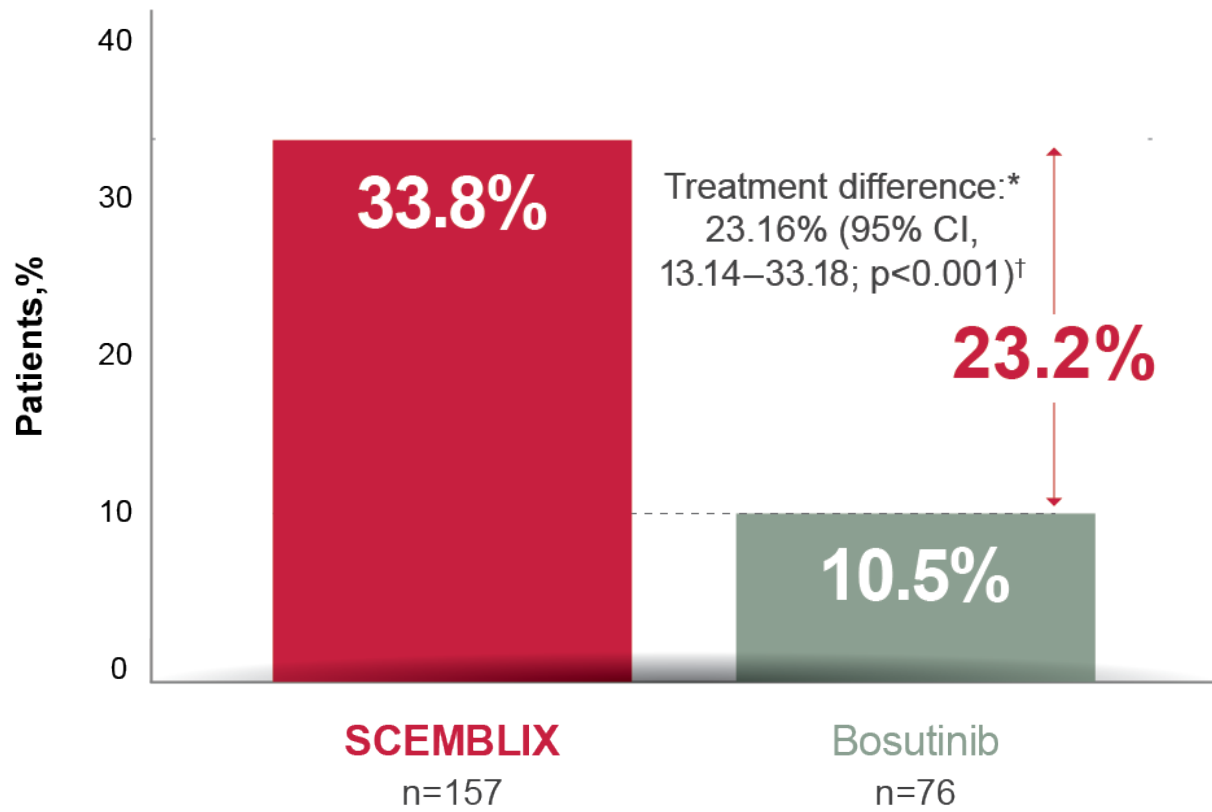
MMR continued to be higher with SCEMBLIX vs bosutinib at Week 96.^{2,4}

End of study treatment

MMR at Week 156^{2,4}

Image

Week 156



*On adjustment for the baseline major cytogenetic response status.

†Cochran-Mantel-Haenszel two-sided test stratified by baseline major cytogenetic response status.

Adapted from Réa D, et al. 2021,² and Mauro M, et al. 2023.⁴



- CCyR at Week 24 and Week 96
- MR4 at Weeks 24, 96 and 156
- Cumulative incidence of MMR

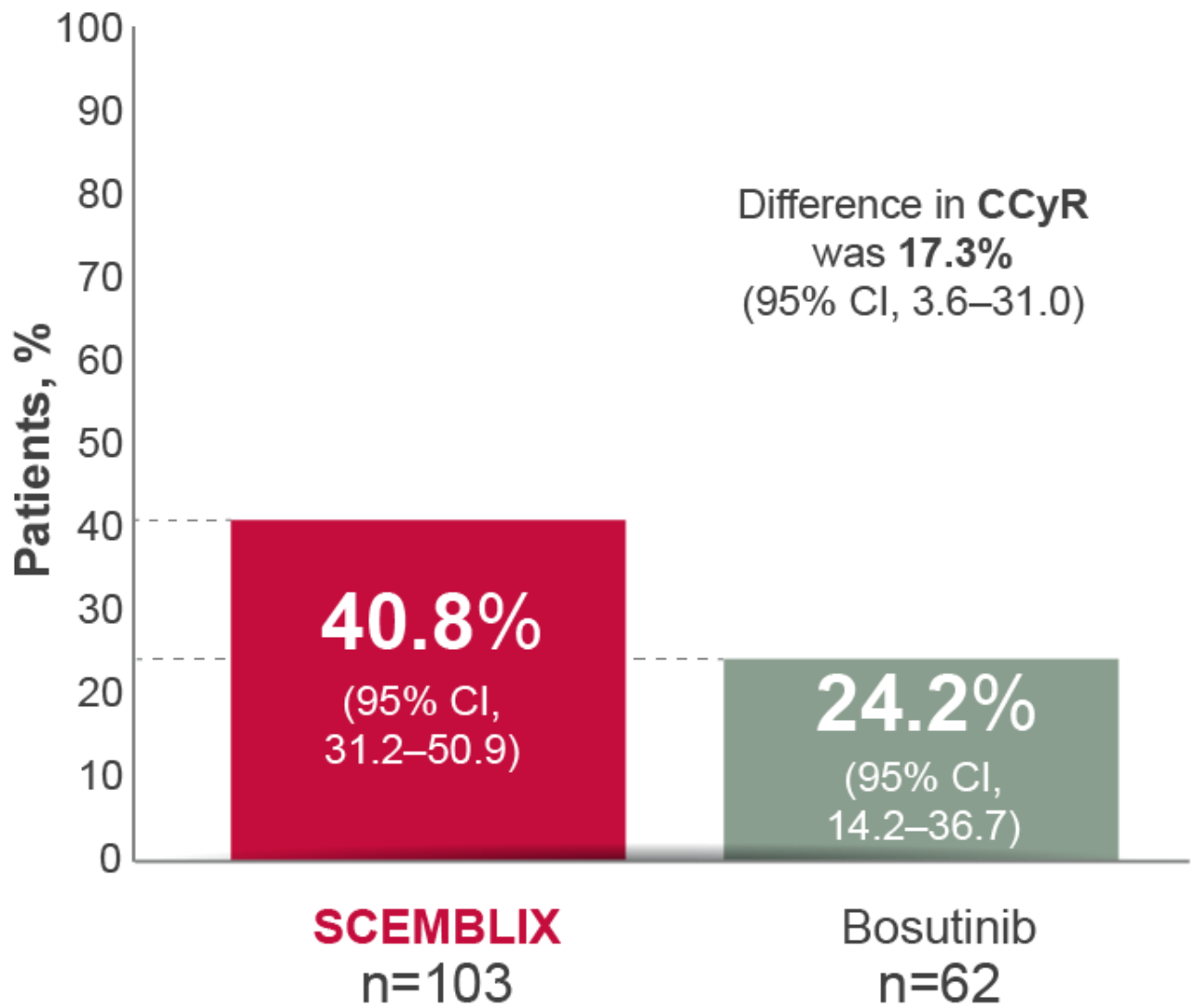


More patients receiving SCEMBLIX may yield CCyR status over time vs bosutinib¹

Please note that p values were not formally tested for this analysis

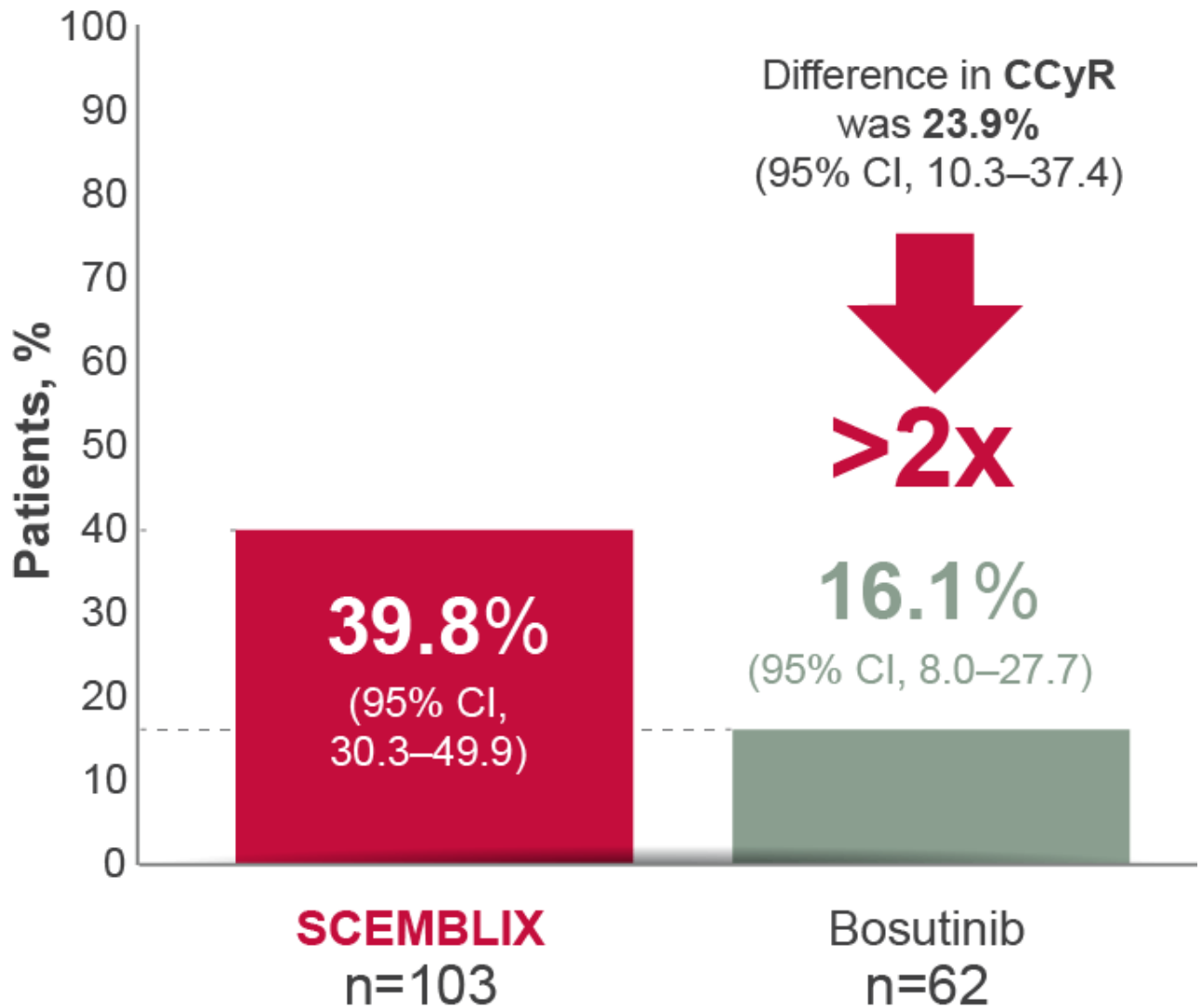
CCyR at Week 24*^{1,2}

Image



CCyR at Week 96^{*1-3}

Image



*CCyR analysis based on 103 of 157 patients (65.6%) receiving SCEMBLIX and 62 of 76 (81.6%) receiving bosutinib who did not have this level of response at baseline. Key secondary efficacy and safety results were reported after a median follow-up of 2.3 years (16.5 months of additional follow-up since primary analysis).²

Adapted from Réa D et al. 2021,² Hochhaus A et al. 2023³ and the SCEMBLIX SmPC.¹

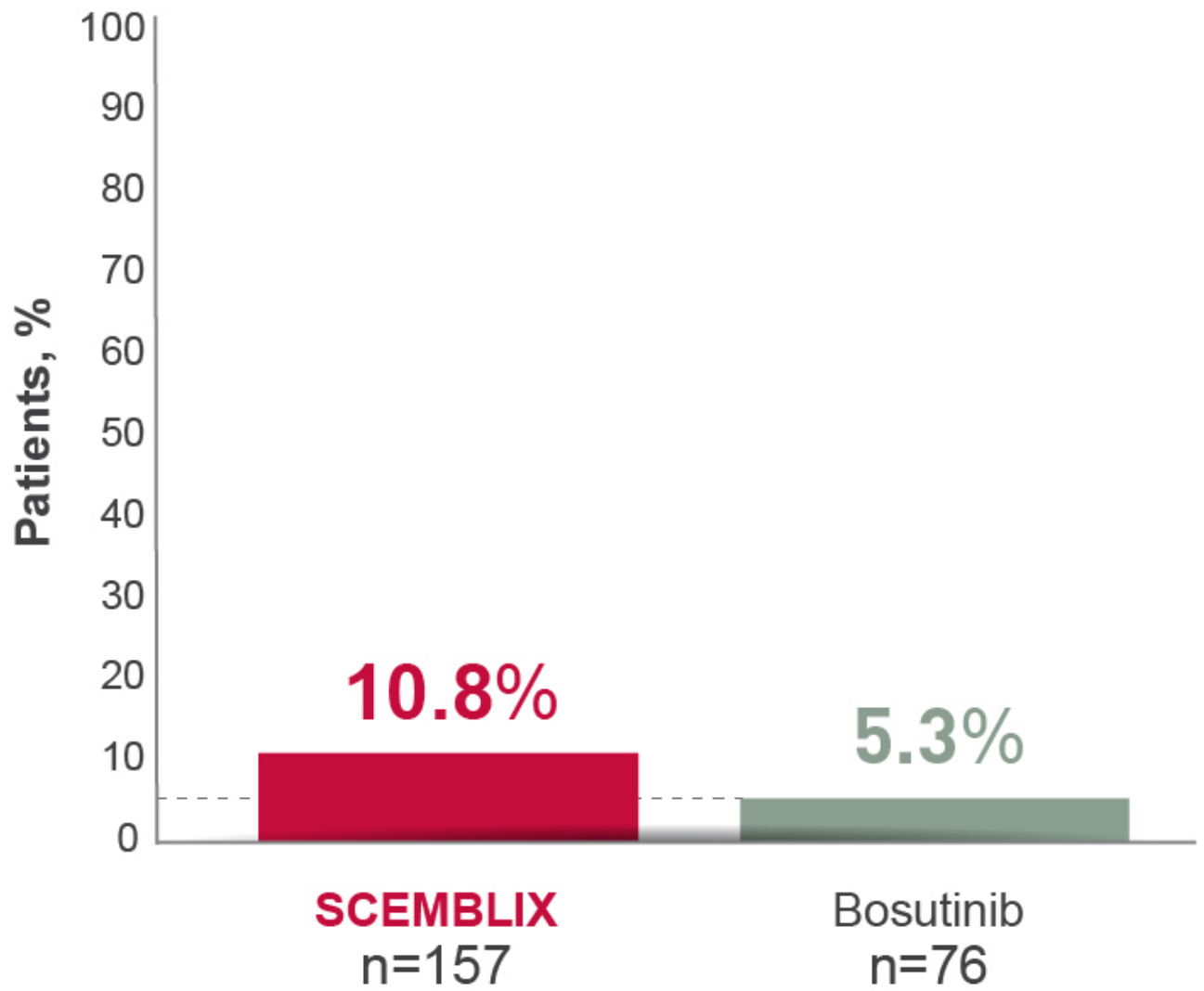
CCyR is a predictor of better long-term outcomes.⁷

With SCEMBLIX, more patients achieved deep MR vs bosutinib at Week 24 through to Week 156^{2,8}

No statistical analysis was available at the time of publication

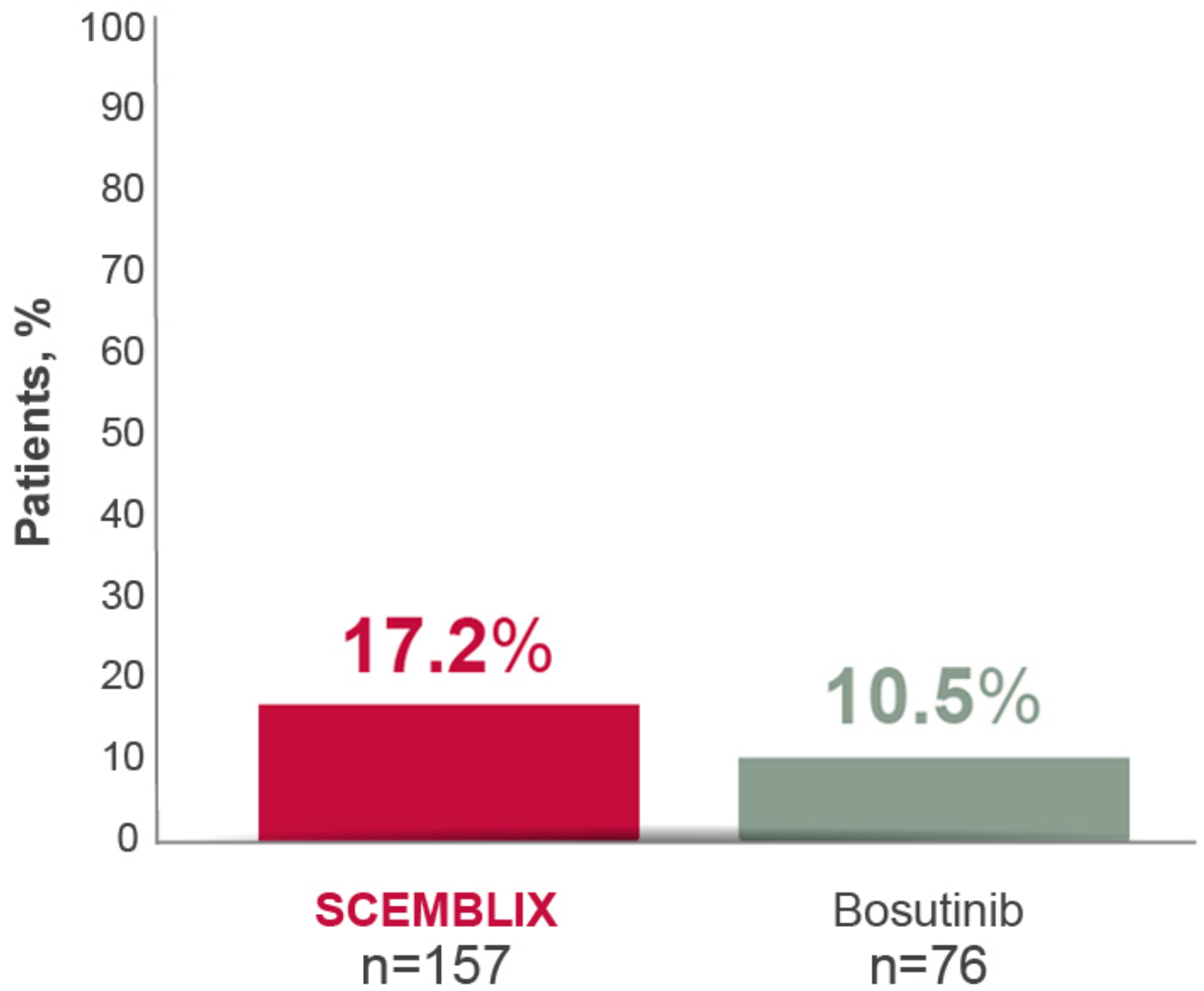
MR4 at week 24^{2,8}

Image



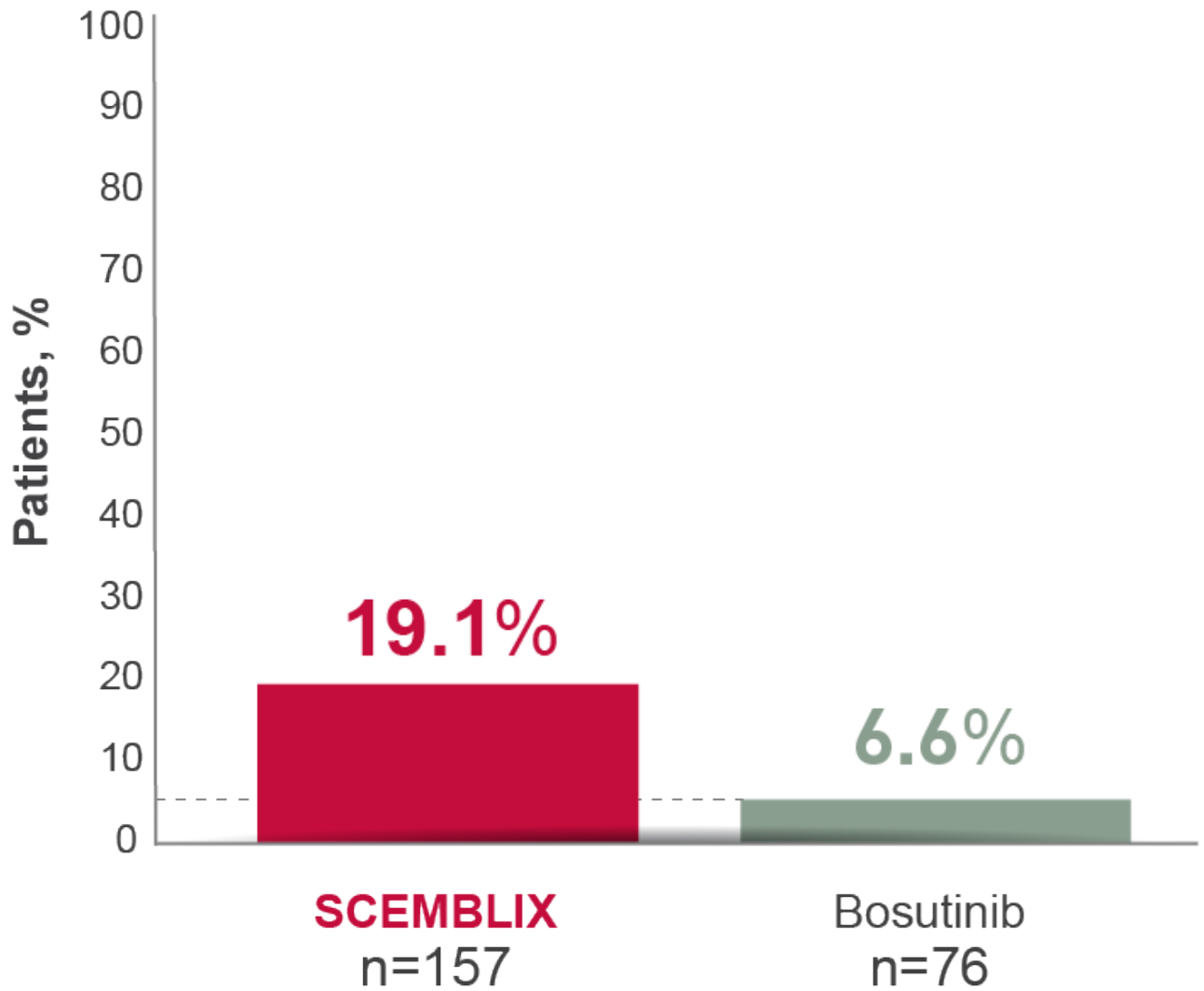
MR4 at week 96⁸

Image



MR4 at Week 156⁸

Image



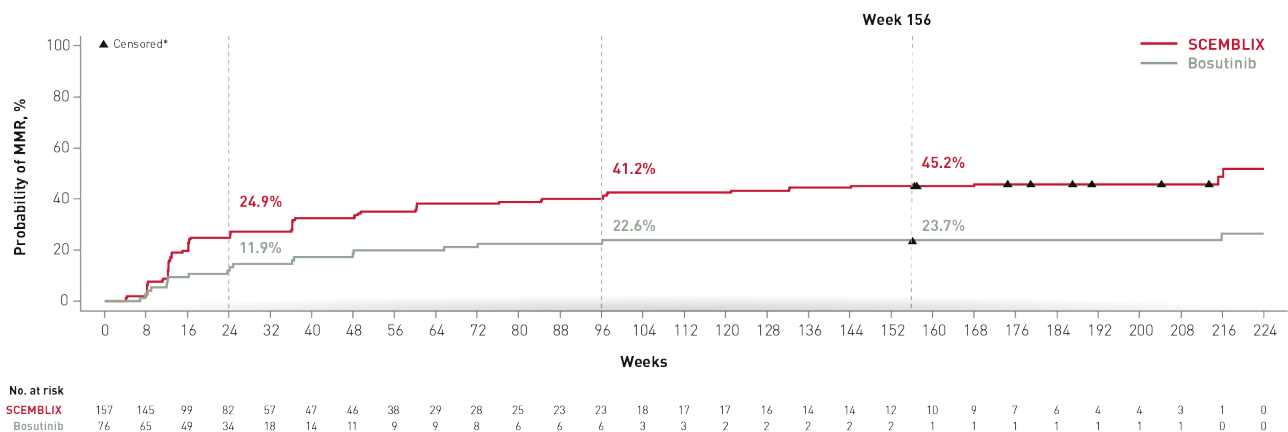
Adapted from Réa D, et al. 2021² and Mauro M, et al. 2023.⁸

Deep molecular response is defined as MR4 (BCR-ABL1^{IS} ≤0.01%) or better (with MR4.5 BCR-ABL1^{IS} ≤0.0032%).⁵

SCEMBLIX consistently increased cumulative MMR vs bosutinib over time^{2,4,8}

Cumulative incidence of MMR

Image



*Non-responders were censored at their last molecular assessment date.

Adapted from Réa D, et al. 2021,² Mauro M, et al. 2023⁴ and Mauro M, et al. 2023.⁸

SCSEMBLIX achieved higher MMR rates vs bosutinib throughout the duration of the study.^{2,4}

SCSEMBLIX resulted in fewer all-grade and grade ≥ 3 AEs vs bosutinib^{2,3}

[Learn more about safety information on SCSEMBLIX](#)

AE, adverse event; ATP, adenosine triphosphate; BCR-ABL, breakpoint cluster region and Abelson murine leukaemia viral oncogene homologue; CCyR, complete cytogenetic remission; CI, confidence interval; CML-CP, chronic myeloid leukaemia in chronic phase; IS, international scale; MCyR, major cytogenetic response; MMR, major molecular response; MR, molecular response; Ph+, Philadelphia chromosome positive; STAMP, specifically targeting the ABL1 myristoyl pocket; TKI, tyrosine kinase inhibitor.

For further information please refer to the [Summary of Product Characteristics](#).

References

1. SCSEMBLIX (asciminib) Summary of Product Characteristics.
2. Réa D, et al. *Blood* 2021;138(21):2031-2041 (and supplementary appendix).
3. Hochhaus A, et al. *Leukemia* 2023;37:617-626 (and supplementary appendix).
4. Mauro M, et al. *Blood* 2023;142 (Supplement 1):4536-4539.

5. Hehlmann R, et al. *Leukemia* 2017;31(11):2398–2406.
6. Castagnetti F, et al. *Leukemia* 2015;29(9):1823–1831.
7. Jabbour E, et al. *Blood* 2011;118(17):4541–4546.
8. Mauro M, et al. Poster 4536. 65th ASH Annual Meeting & Exposition; December 9–12, 2023; San Diego, California, & virtual.

UK | October 2024 | 444907

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.

Source URL:

<https://www.pro.novartis.com/uk-en/medicines/haematology/scemblix/efficacy>