NOVARTIS

SCEMBLIX - Efficacy - HCP

Prescribing information

Image


Image


SCEMBLIX®▼ (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]

# Efficacy

### SCEMBLIX®▼ (asciminib) 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]

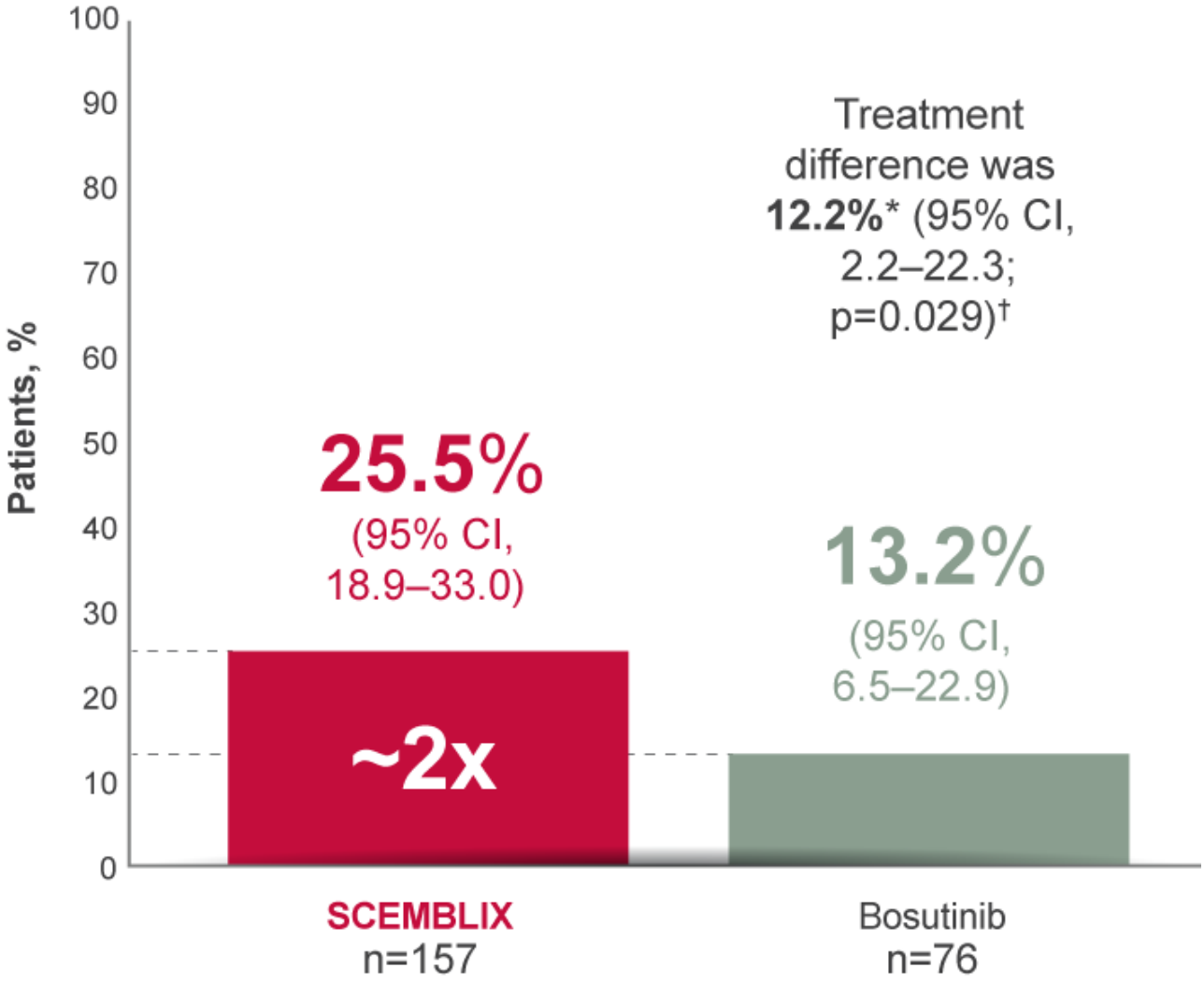
---

- 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. 2021[2] and Mauro M, et al. 2023.[4]

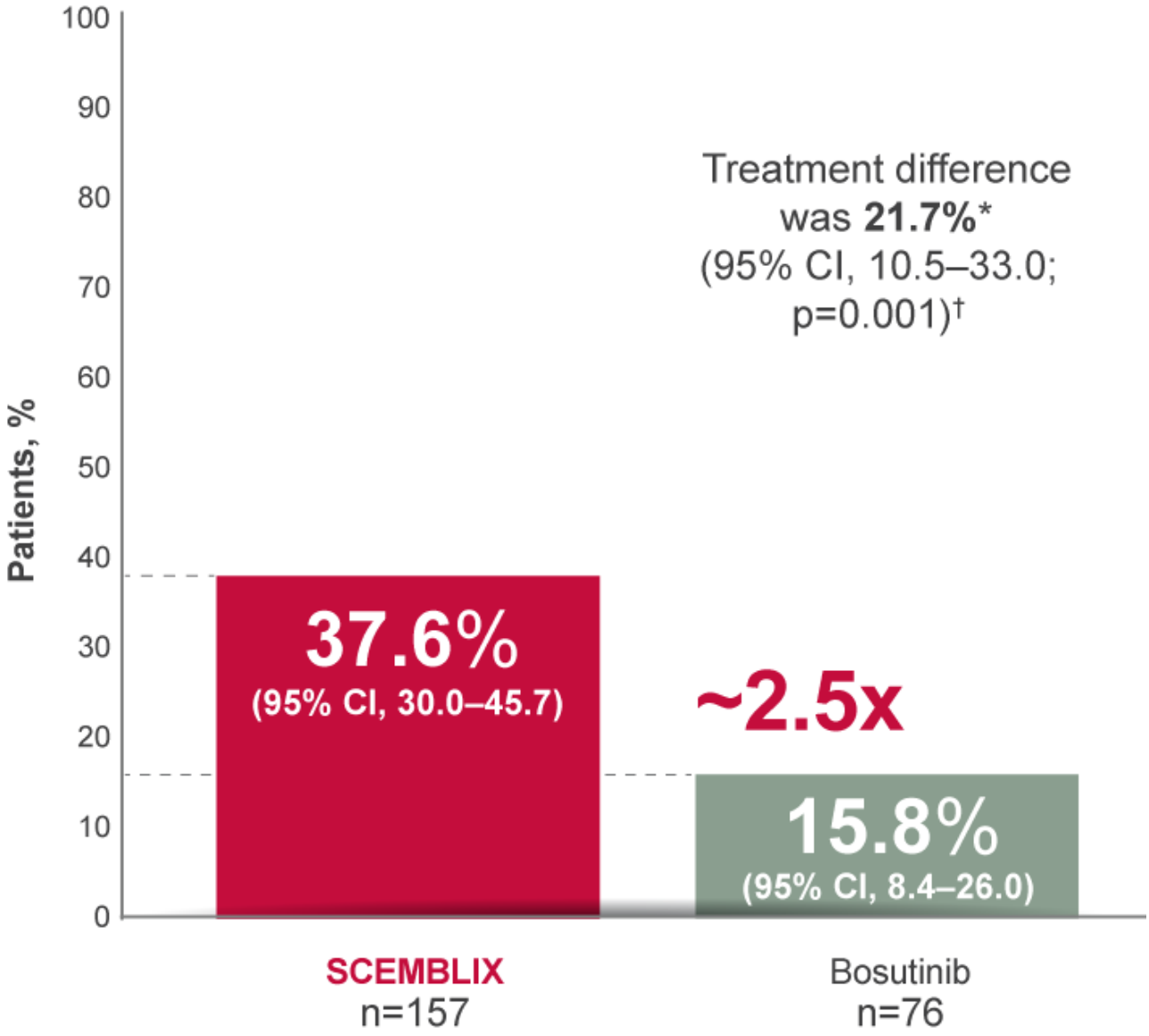
**Achieving MMR has been associated with more favourable long-term outcomes, including survival and progression-free survival.[2,5,6]**

**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.

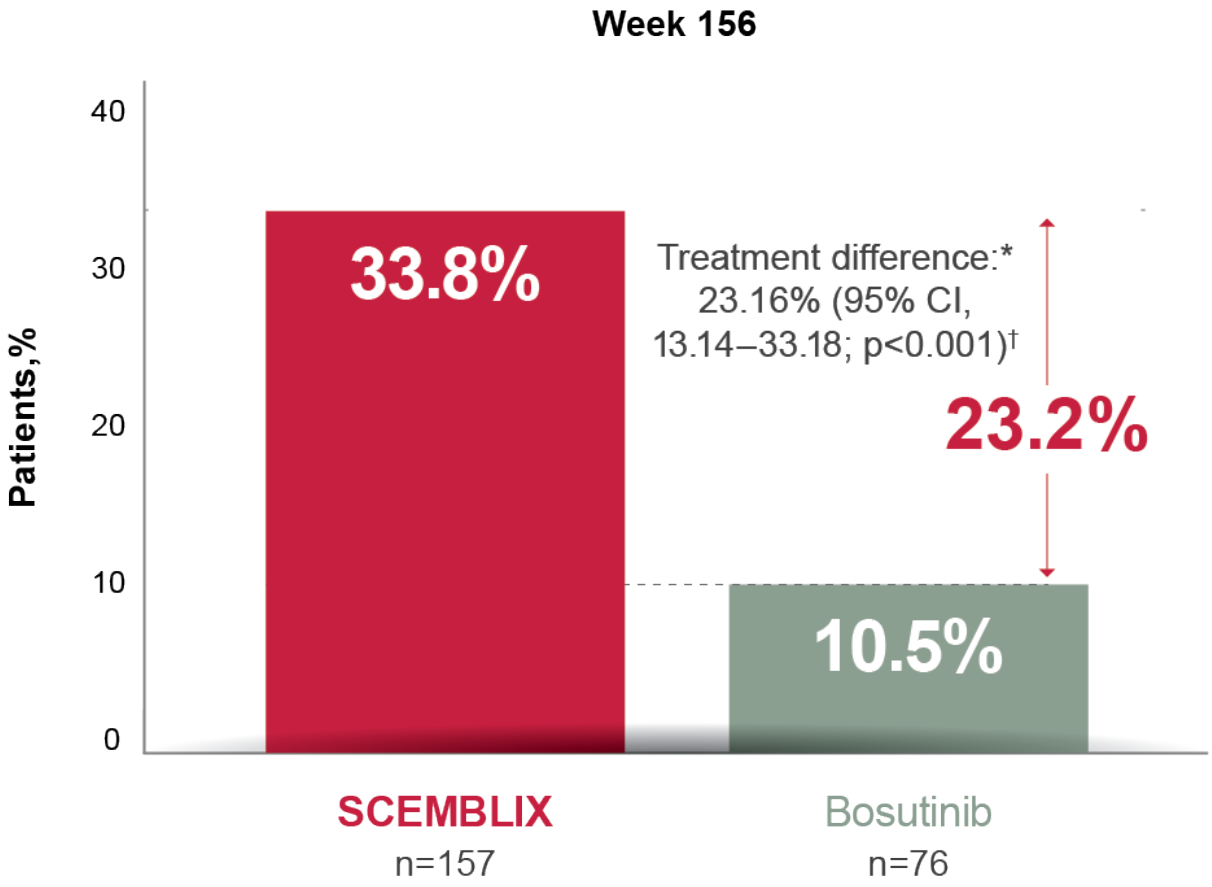
Adapted from Réa D, et al. 2021[2] and Mauro M, et al. 2023.[4]

**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




*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]

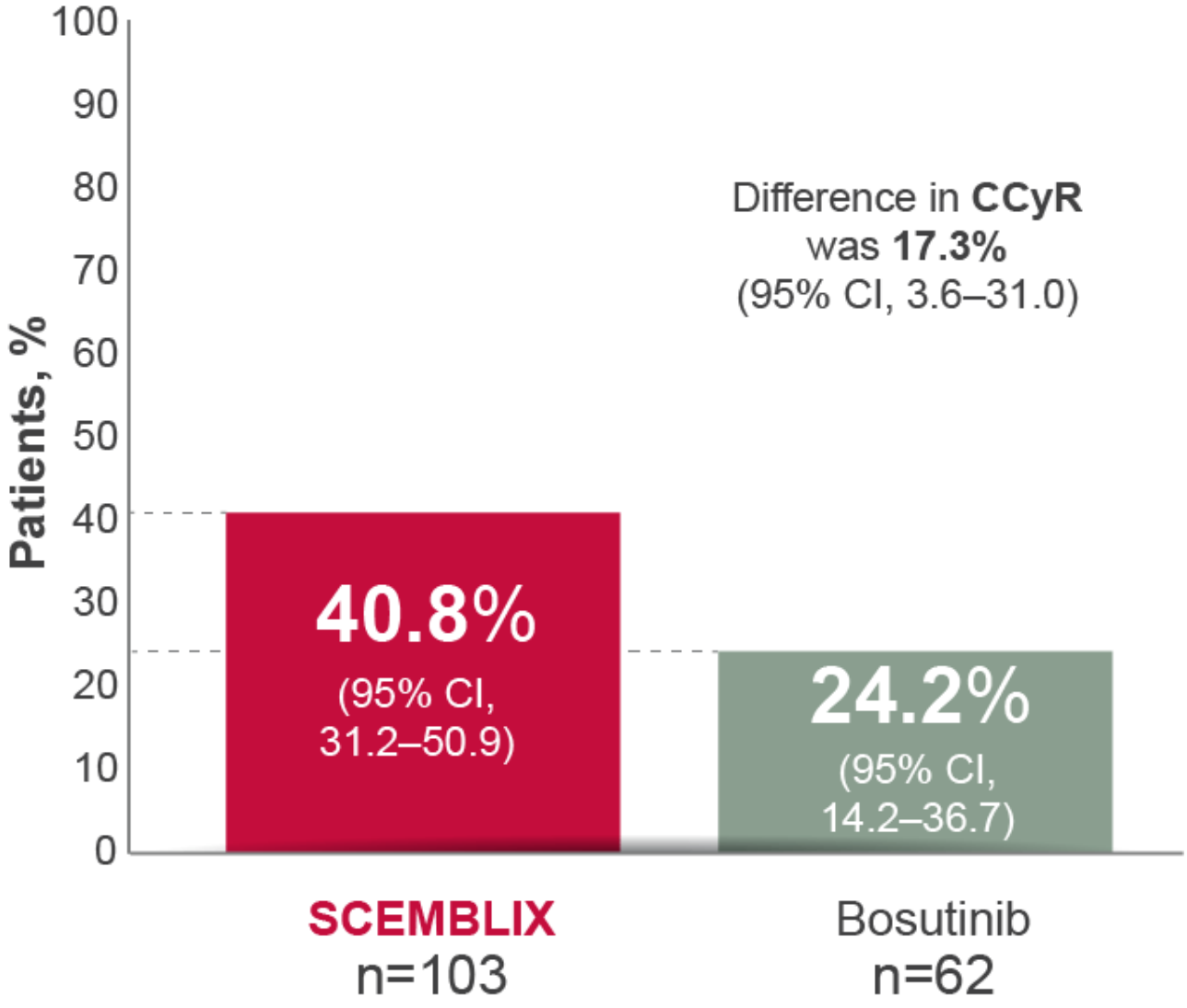
- CCyR at Week 24 and Week 96
- MR4 at Weeks 24, 96 and 156
- Cumulative incidence of MMR

**More patients receiving SCEMBLIX may yield CCyR status over time vs bosutinib[1]**

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

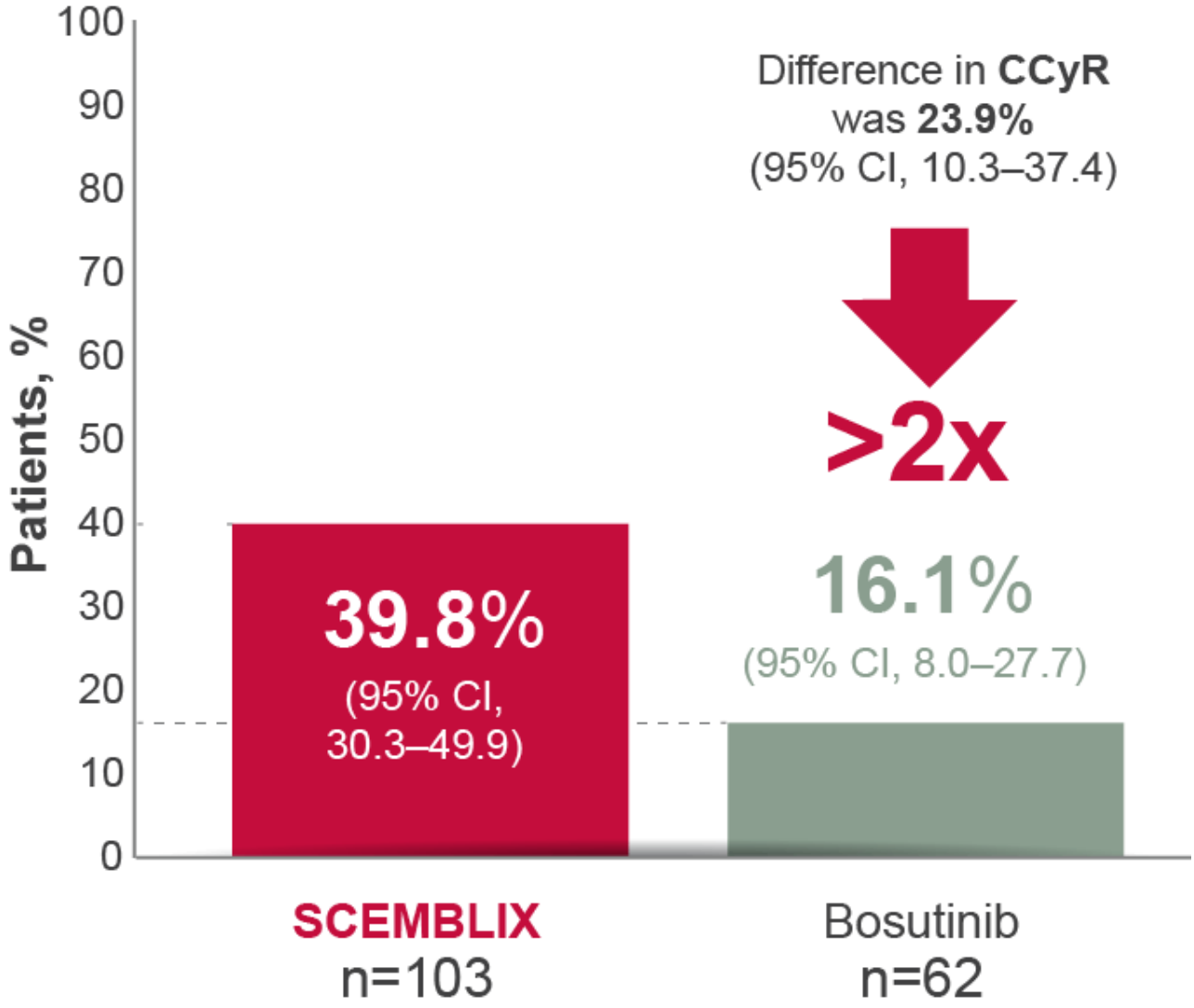
**CCyR at Week 24*[1,2]**

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. 2023[3] and the SCEMBLIX SmPC.[1]

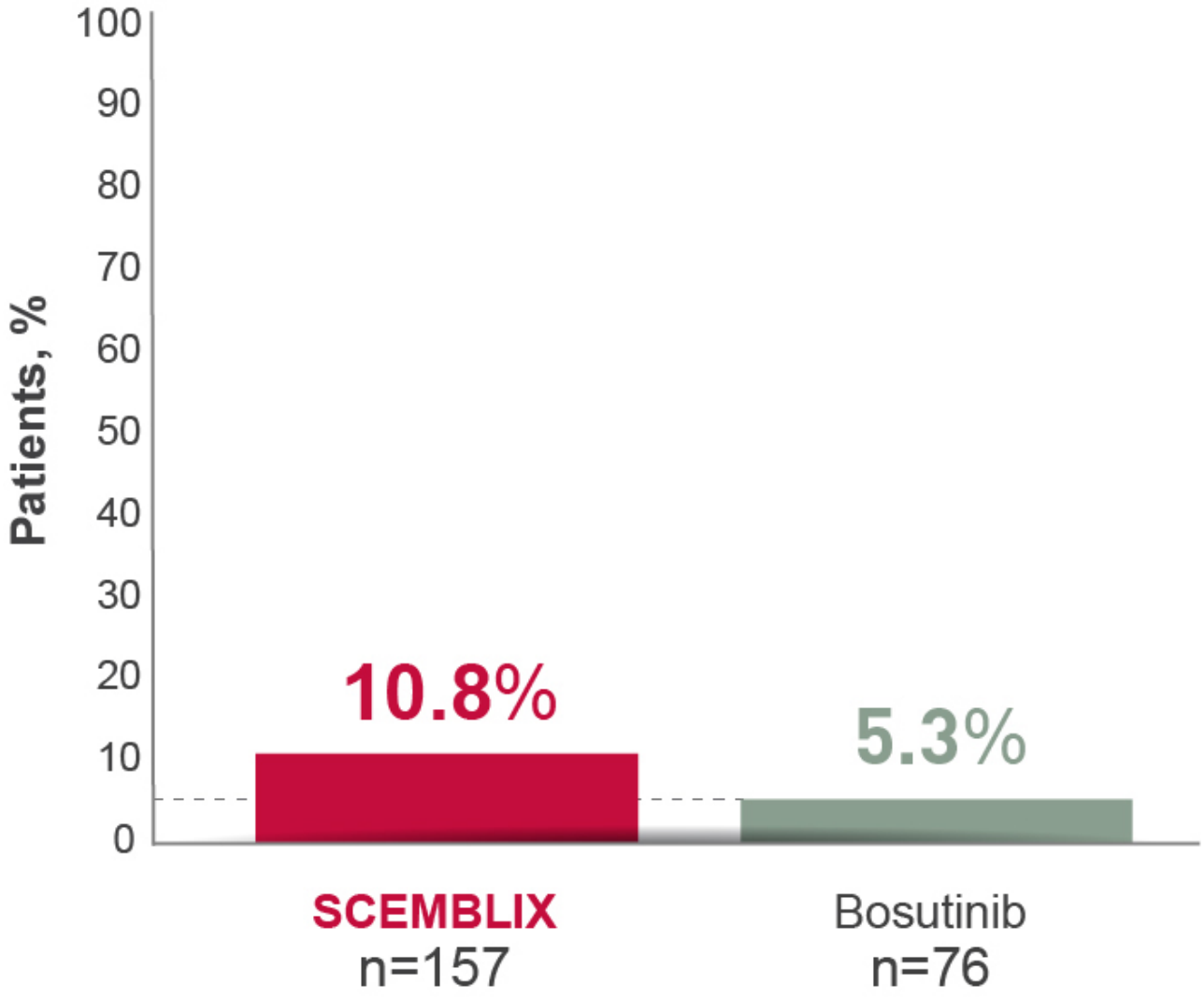
**CCyR is a predictor of better long-term outcomes.[7]**

**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**

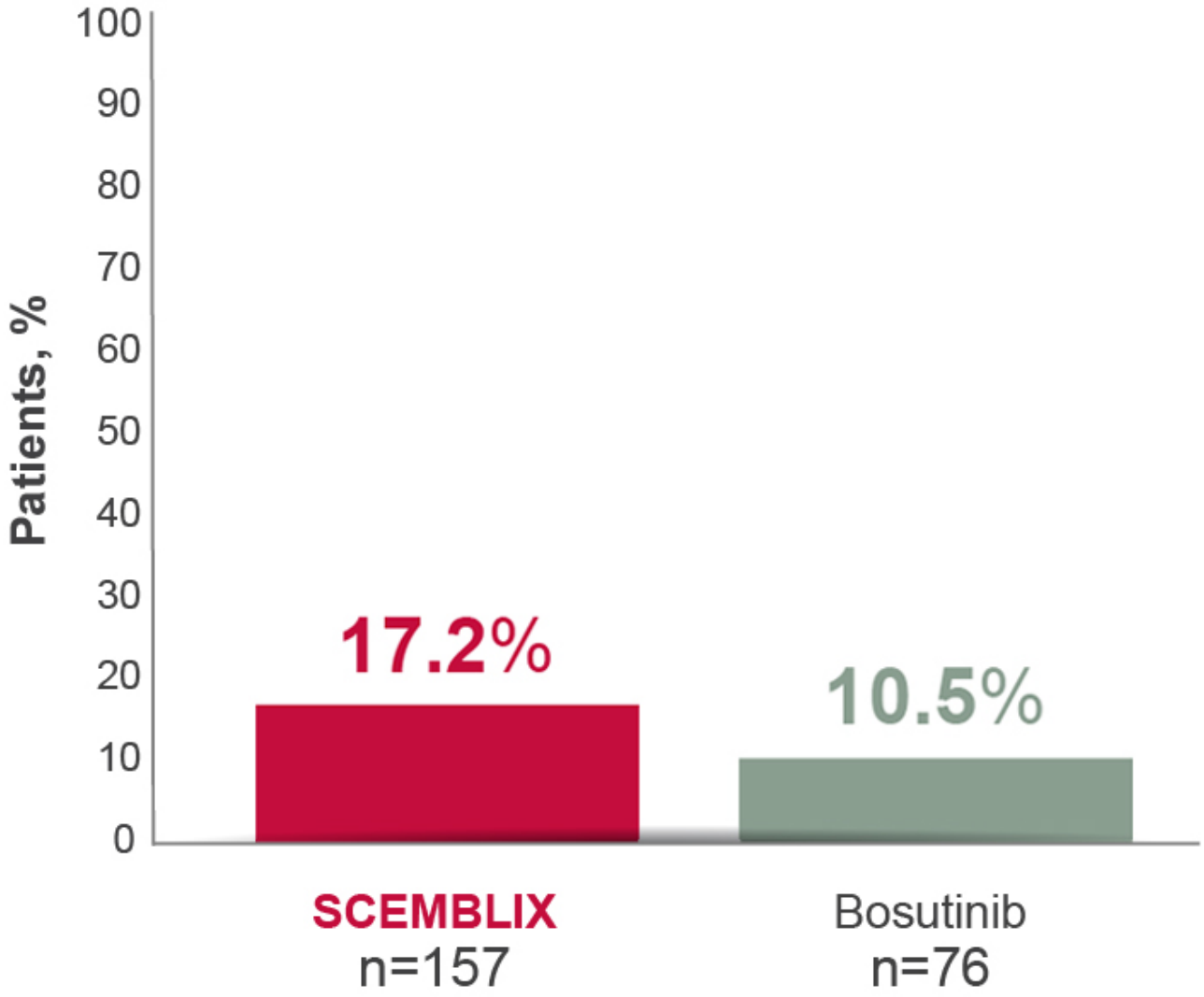
**MR4 at week 24[2,8]**

Image



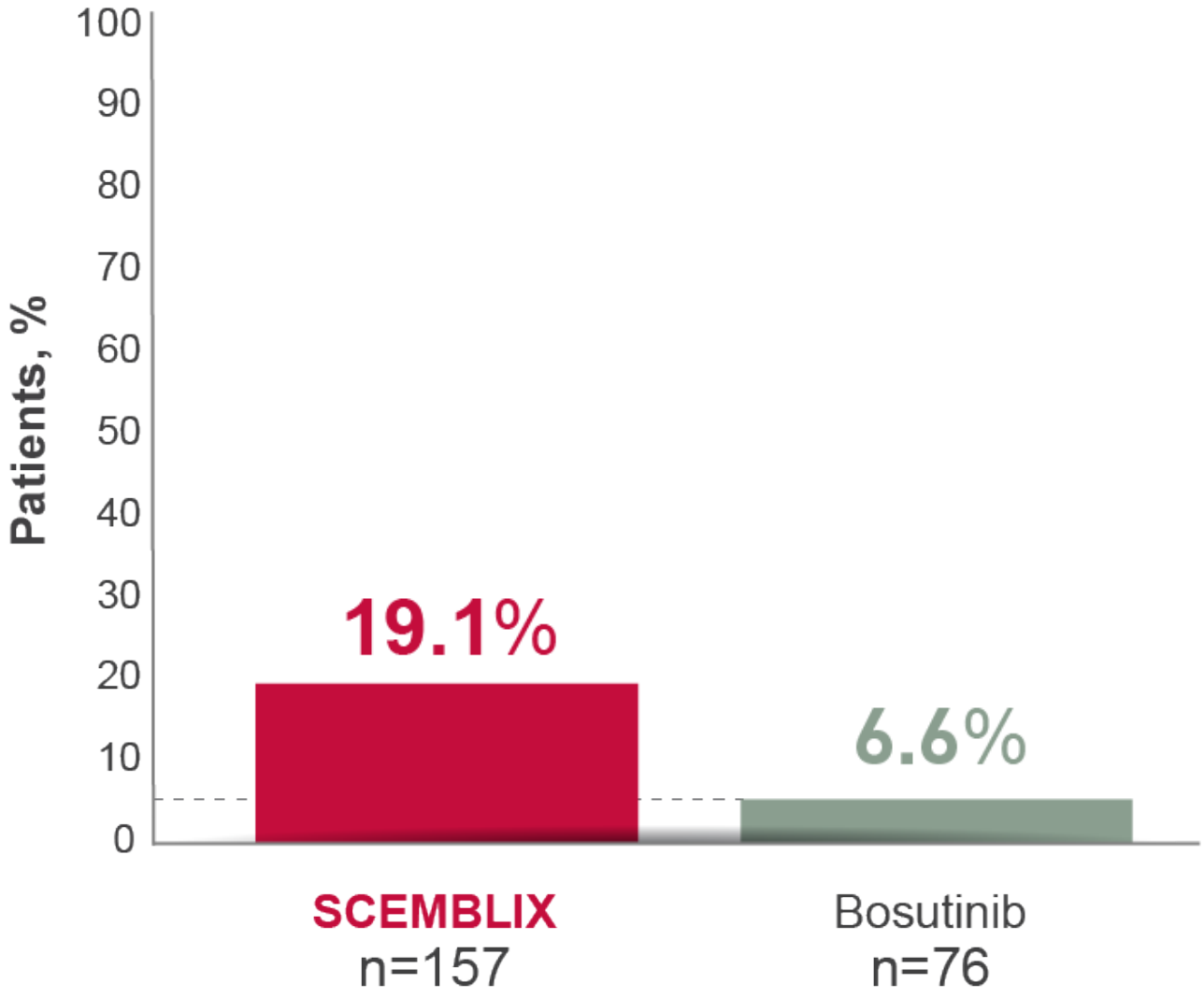

**MR4 at week 96[8]**

Image




**MR4 at Week 156[8]**

Image



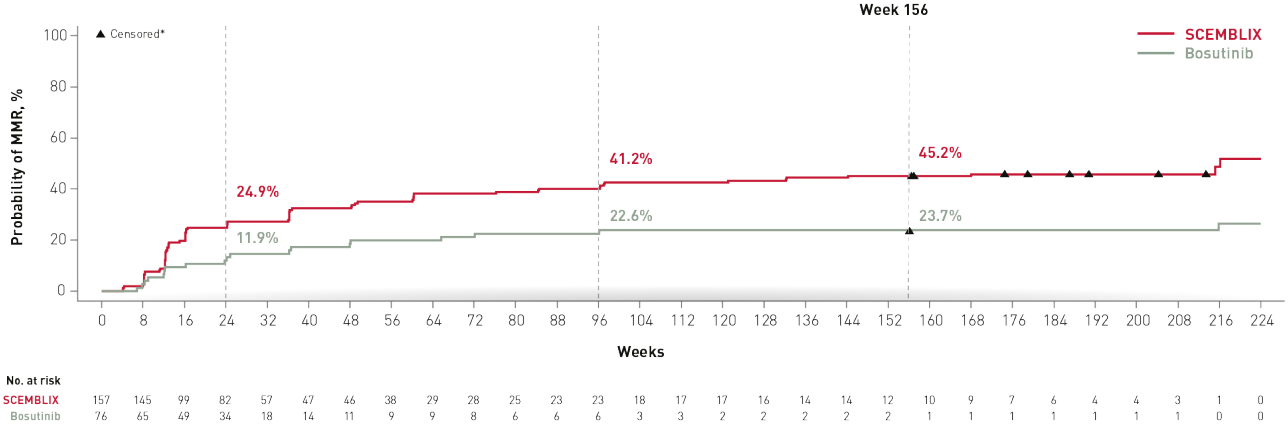

Adapted from Réa D, et al. 2021[2] and Mauro M, et al. 2023.[8]

**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. 2023[4] and Mauro M, et al. 2023.[8]

**SCEMBLIX achieved higher MMR rates vs bosutinib throughout the duration of the study.[2,4]**

**SCEMBLIX resulted in fewer all-grade and grade ≥3 AEs vs bosutinib[2,3]**

Learn more about safety information on SCEMBLIX

---

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. SCEMBLIX (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.

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*