

SCEMBLIX - Efficacy - HCP

[Prescribing information](#)

Image



Image



 **SCSEMBLIX**<sup>®</sup> ▼  
(asciminib) 20 mg, 40 mg tablets

SCSEMBLIX<sup>®</sup> ▼ (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.<sup>1</sup>

## Efficacy

**SCSEMBLIX<sup>®</sup> ▼ (asciminib) showed superior efficacy vs bosutinib as early as Week 24<sup>1,2</sup>**

ASCEMBL is the first head-to-head Phase III study comparing a STAMP inhibitor vs an ATP-competitive TKI.<sup>2,3</sup>

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.<sup>2</sup>

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

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

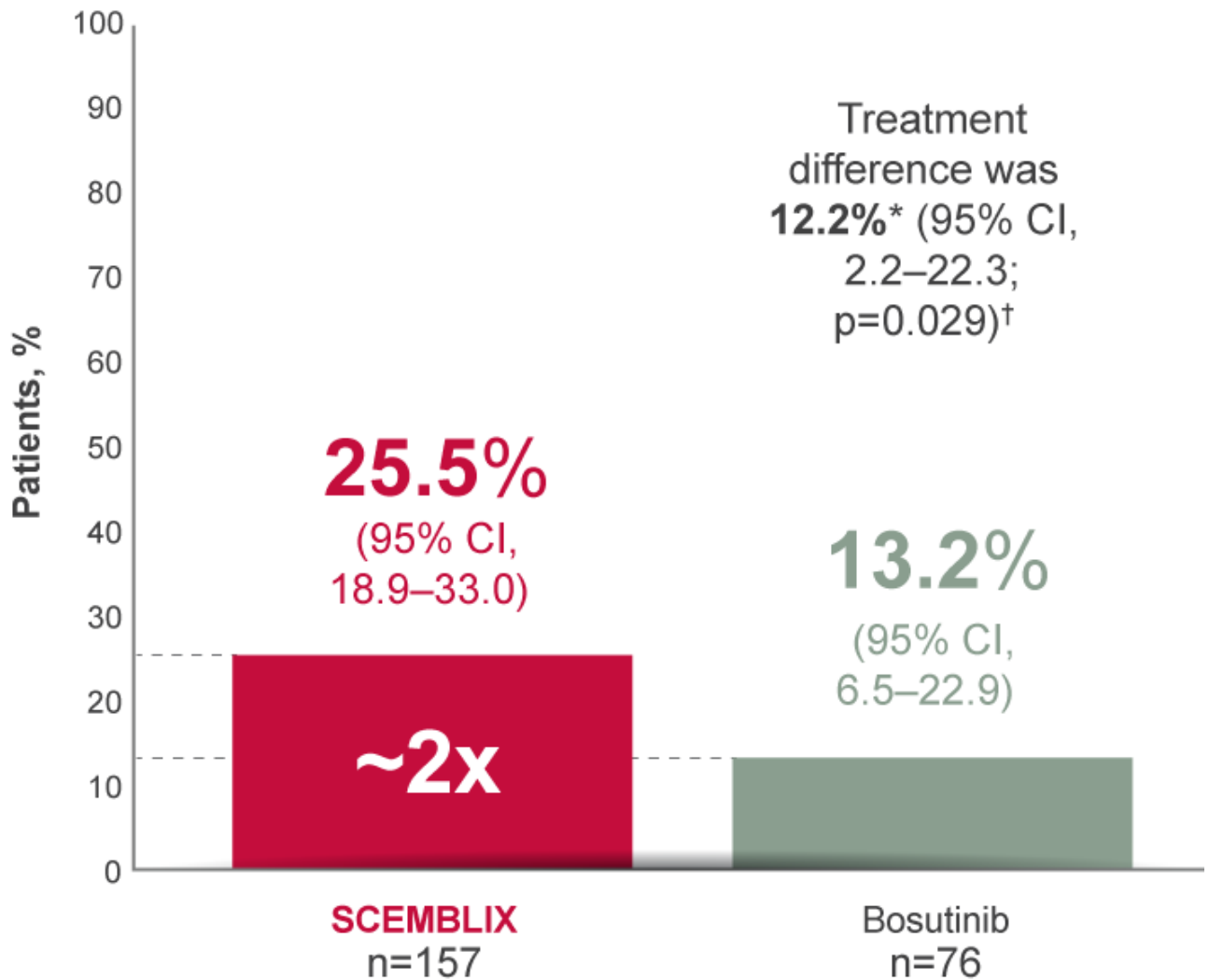


**SCEMBLIX nearly doubled the MMR rate vs bosutinib at Week 24 (primary endpoint)<sup>2,4</sup>**

**MMR at Week 24**

Primary endpoint<sup>2,4</sup>

Image



\*On adjustment for the baseline major cytogenetic response status.

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

Adapted from Réa D, et al. 2021<sup>2</sup> and Mauro M, et al. 2023.<sup>4</sup>

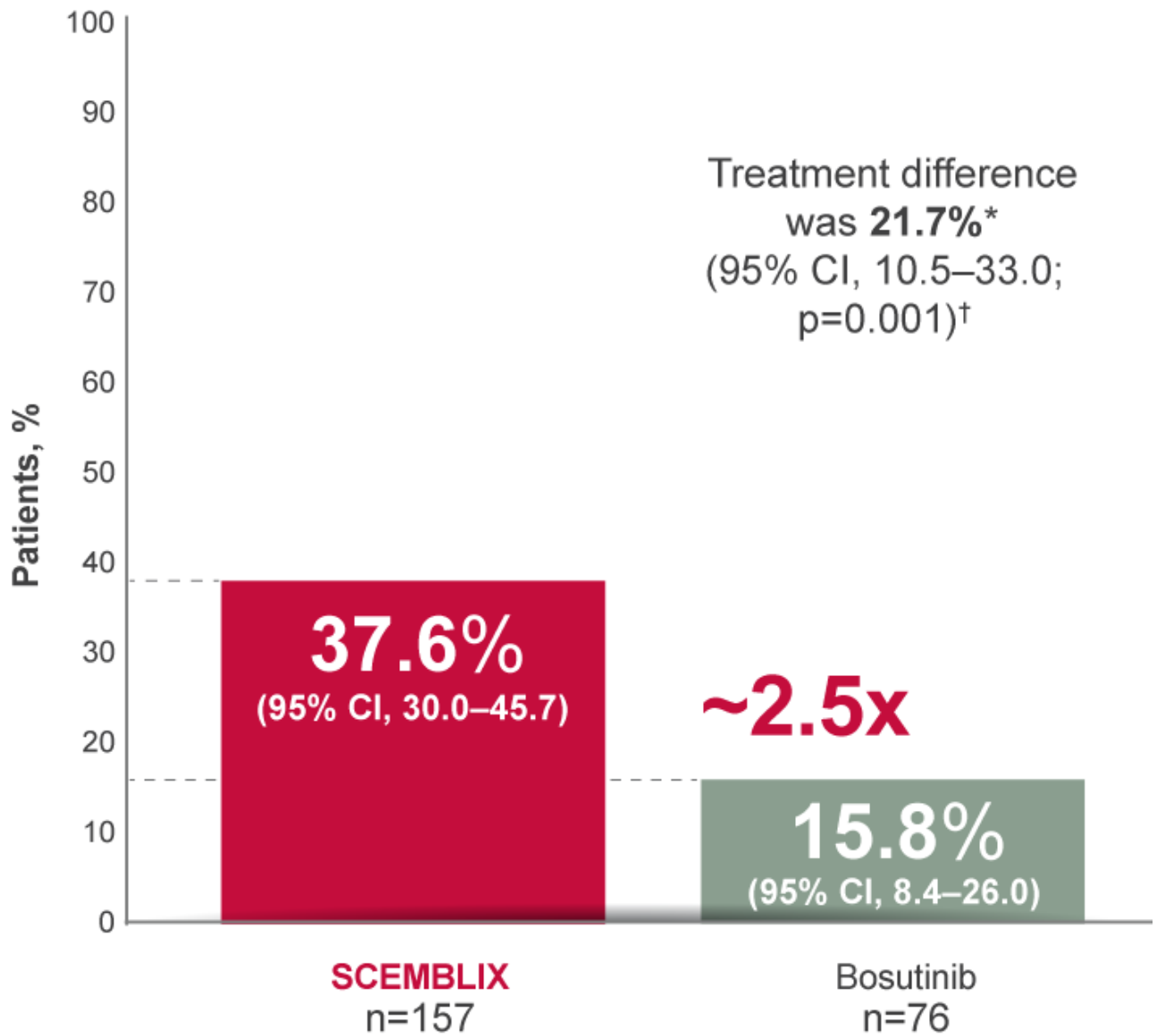
**Achieving MMR has been associated with more favourable long-term outcomes, including survival and progression-free survival.**<sup>2,5,6</sup>

### Key secondary endpoint

Reported after a follow-up of 2.3 years<sup>2,4</sup>

### MMR at Week 96<sup>2,4</sup>

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<sup>2</sup> and Mauro M, et al. 2023.<sup>4</sup>

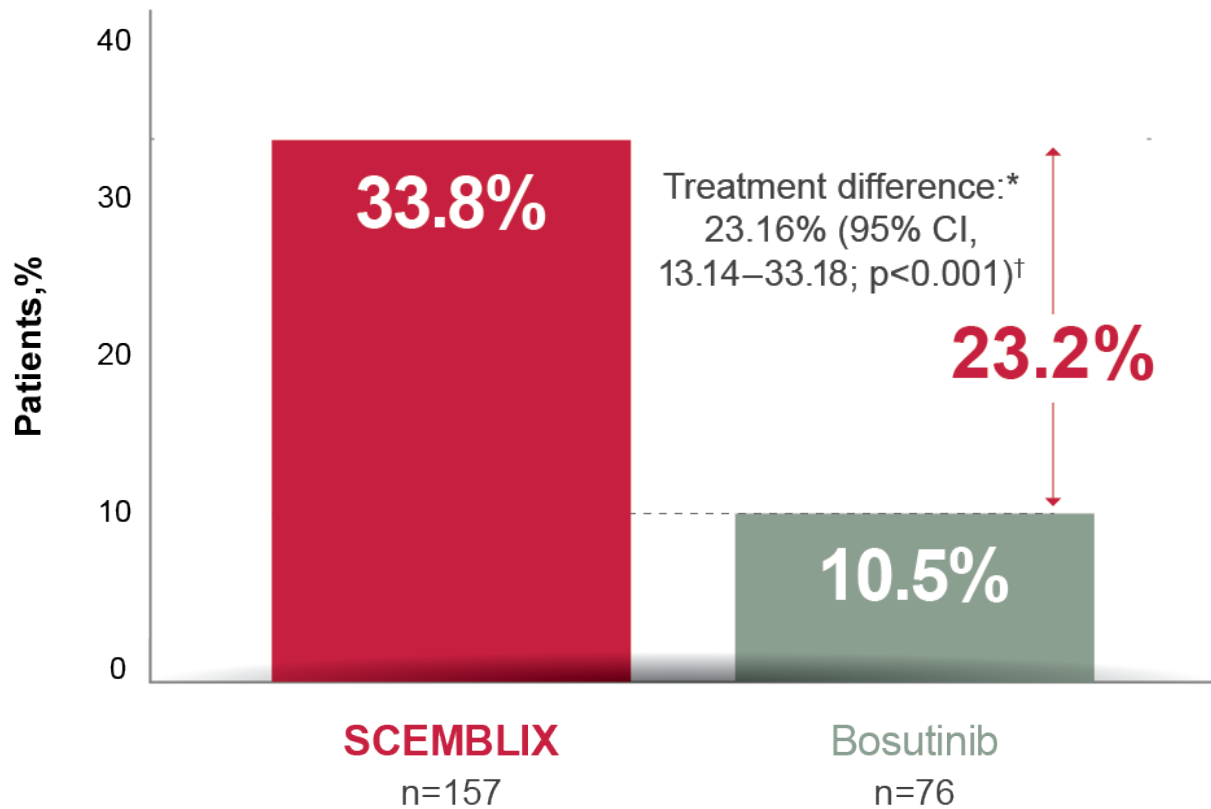
**MMR continued to be higher with SCEMBLIX vs bosutinib at Week 96.<sup>2,4</sup>**

**End of study treatment**

**MMR at Week 156<sup>2,4</sup>**

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,<sup>2</sup> and Mauro M, et al. 2023.<sup>4</sup>

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



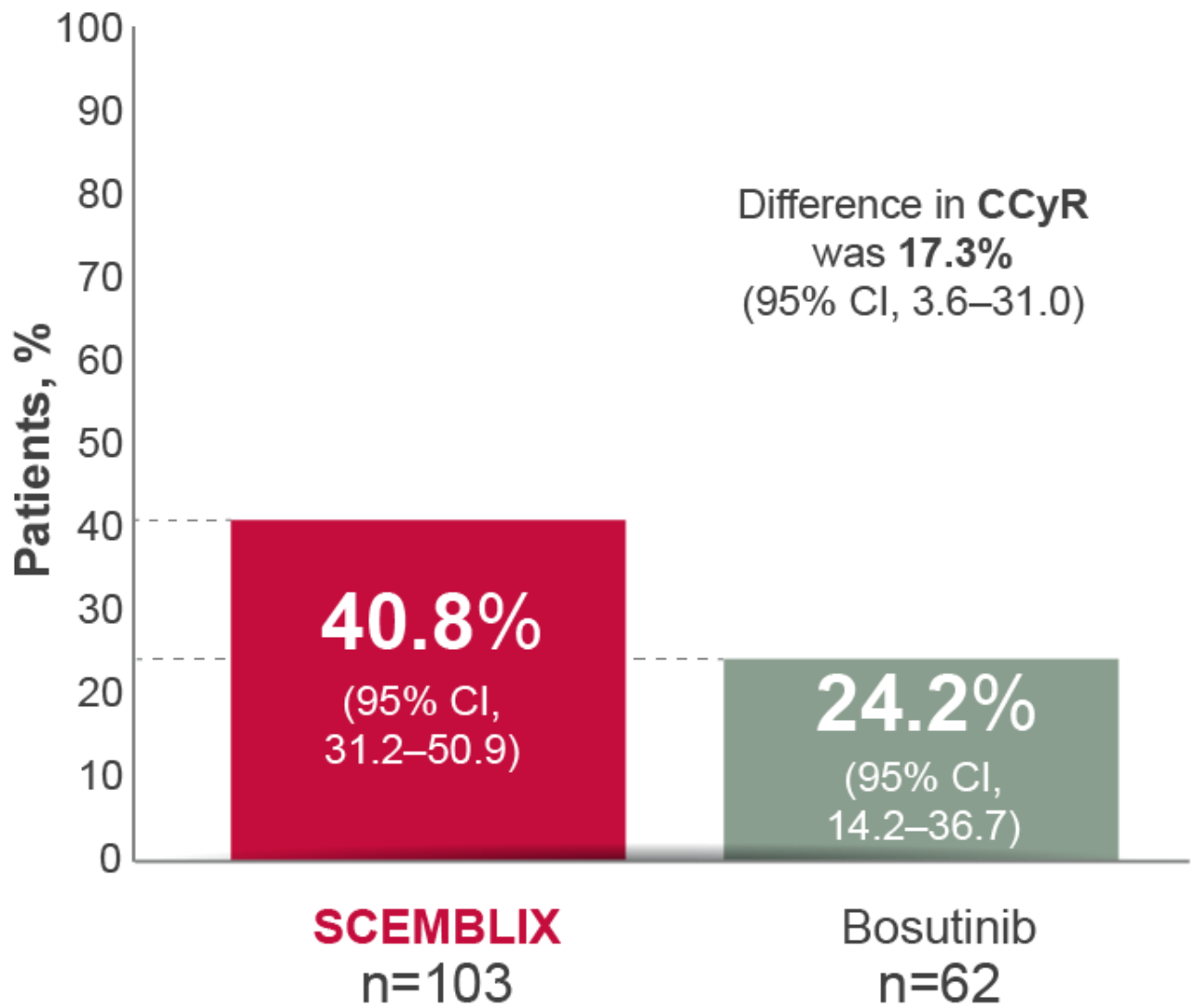


**More patients receiving SCEMBLIX may yield CCyR status over time vs bosutinib<sup>1</sup>**

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

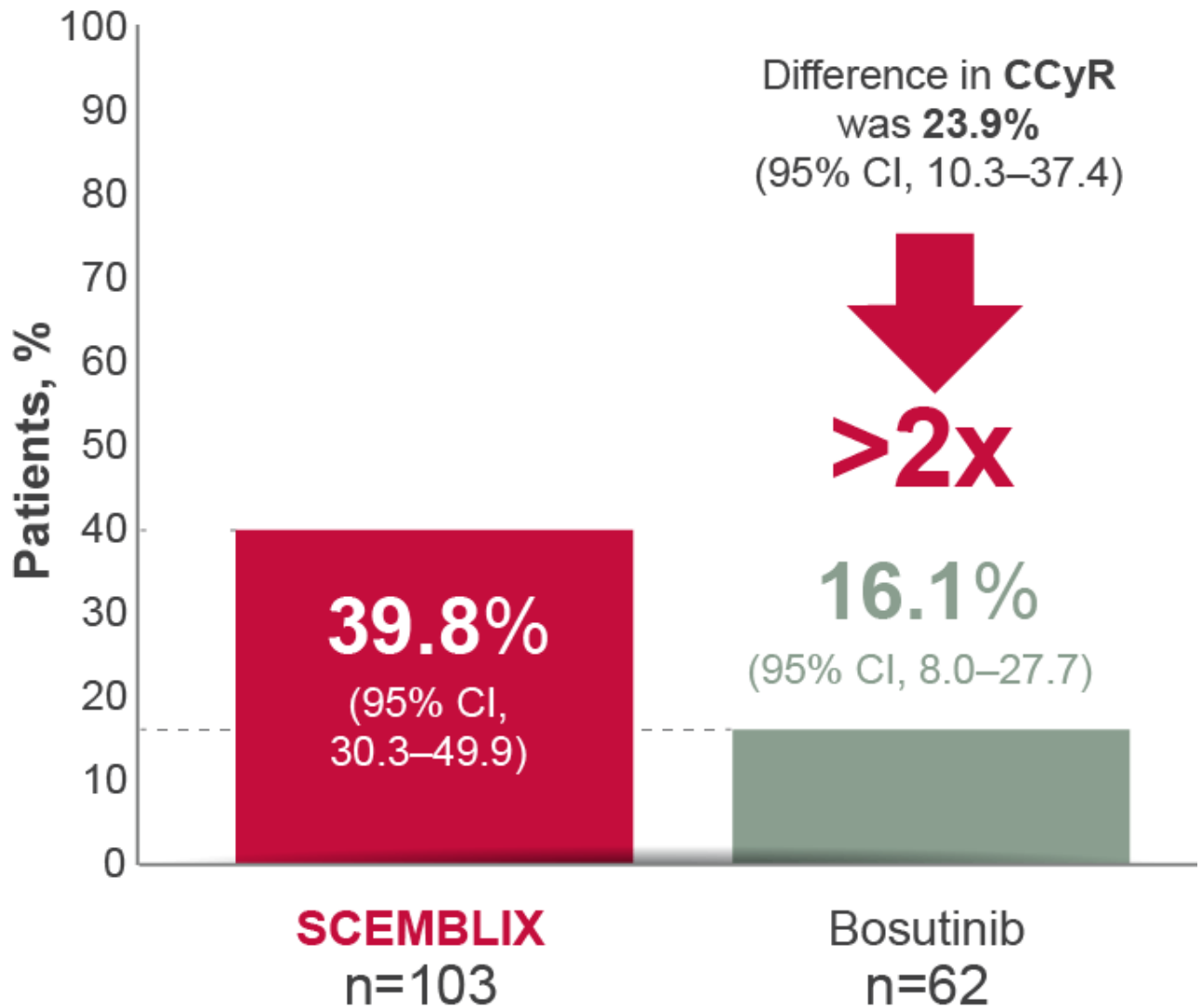
**CCyR at Week 24\*<sup>1,2</sup>**

Image



CCyR at Week 96\*<sup>1-3</sup>

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).<sup>2</sup>

Adapted from Réa D et al. 2021,<sup>2</sup> Hochhaus A et al. 2023<sup>3</sup> and the SCEMBLIX SmPC.<sup>1</sup>

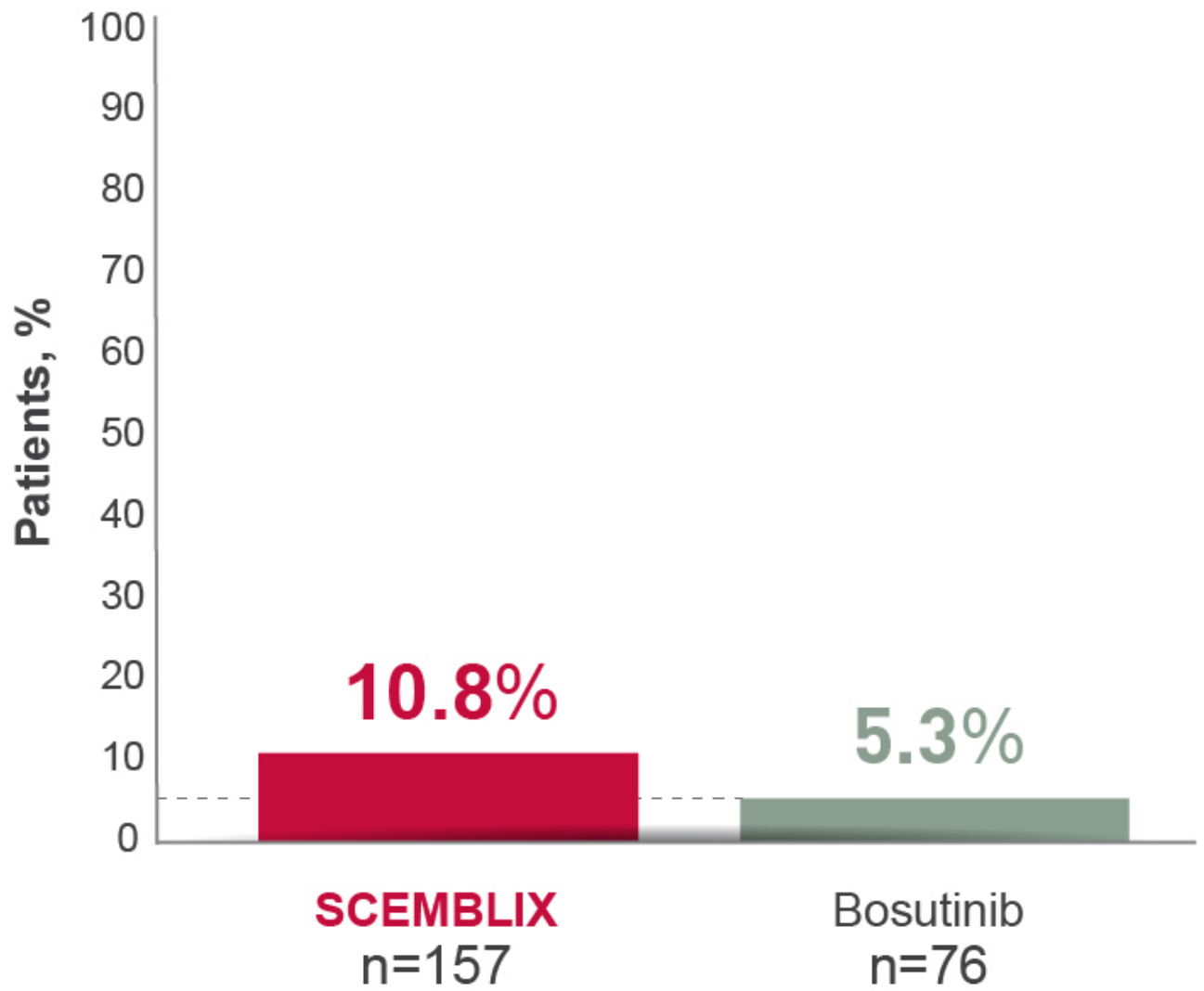
**CCyR is a predictor of better long-term outcomes.<sup>7</sup>**

**With SCEMBLIX, more patients achieved deep MR vs bosutinib at Week 24 through to Week 156<sup>2,8</sup>**

**No statistical analysis was available at the time of publication**

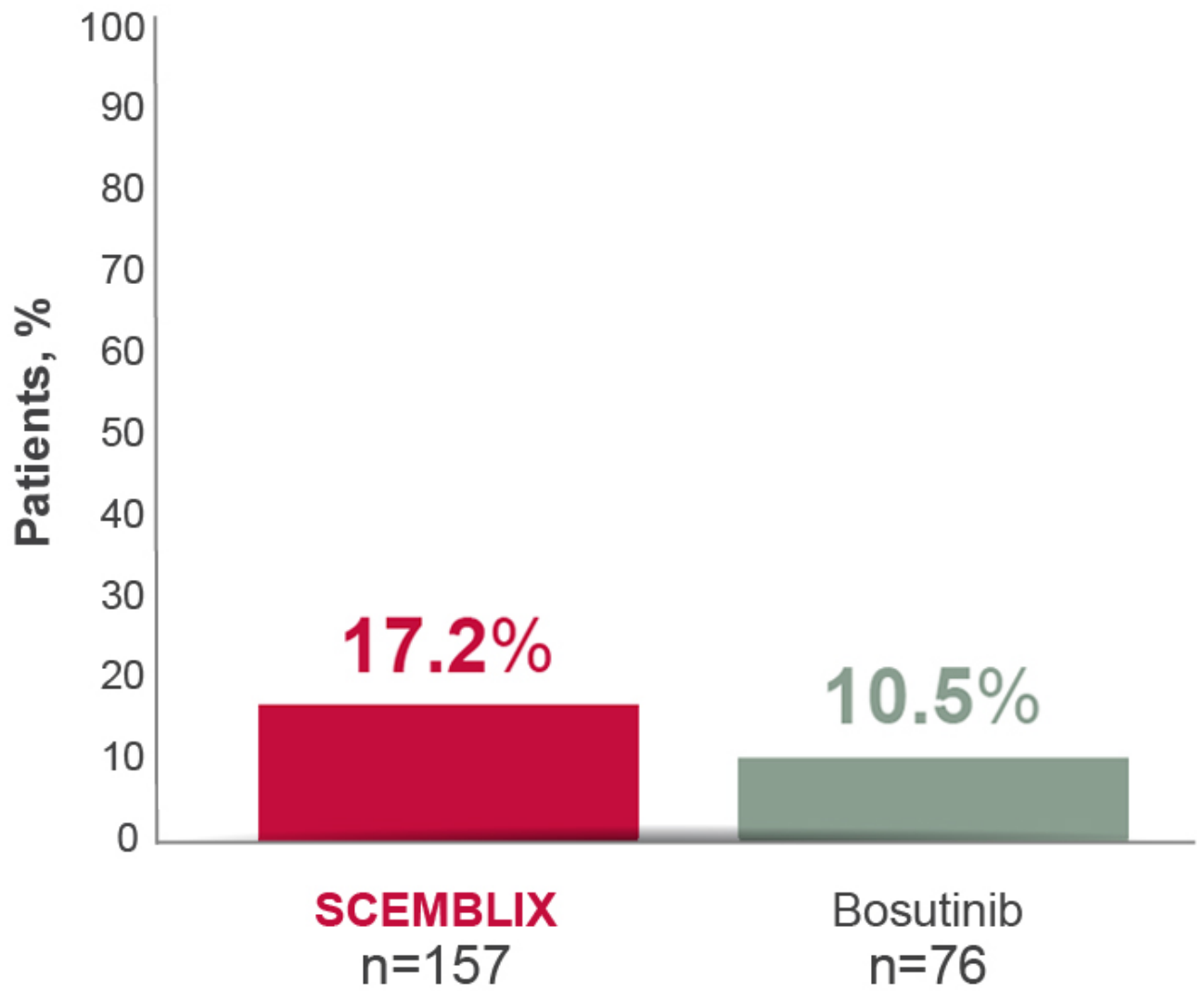
**MR4 at week 24<sup>2,8</sup>**

Image



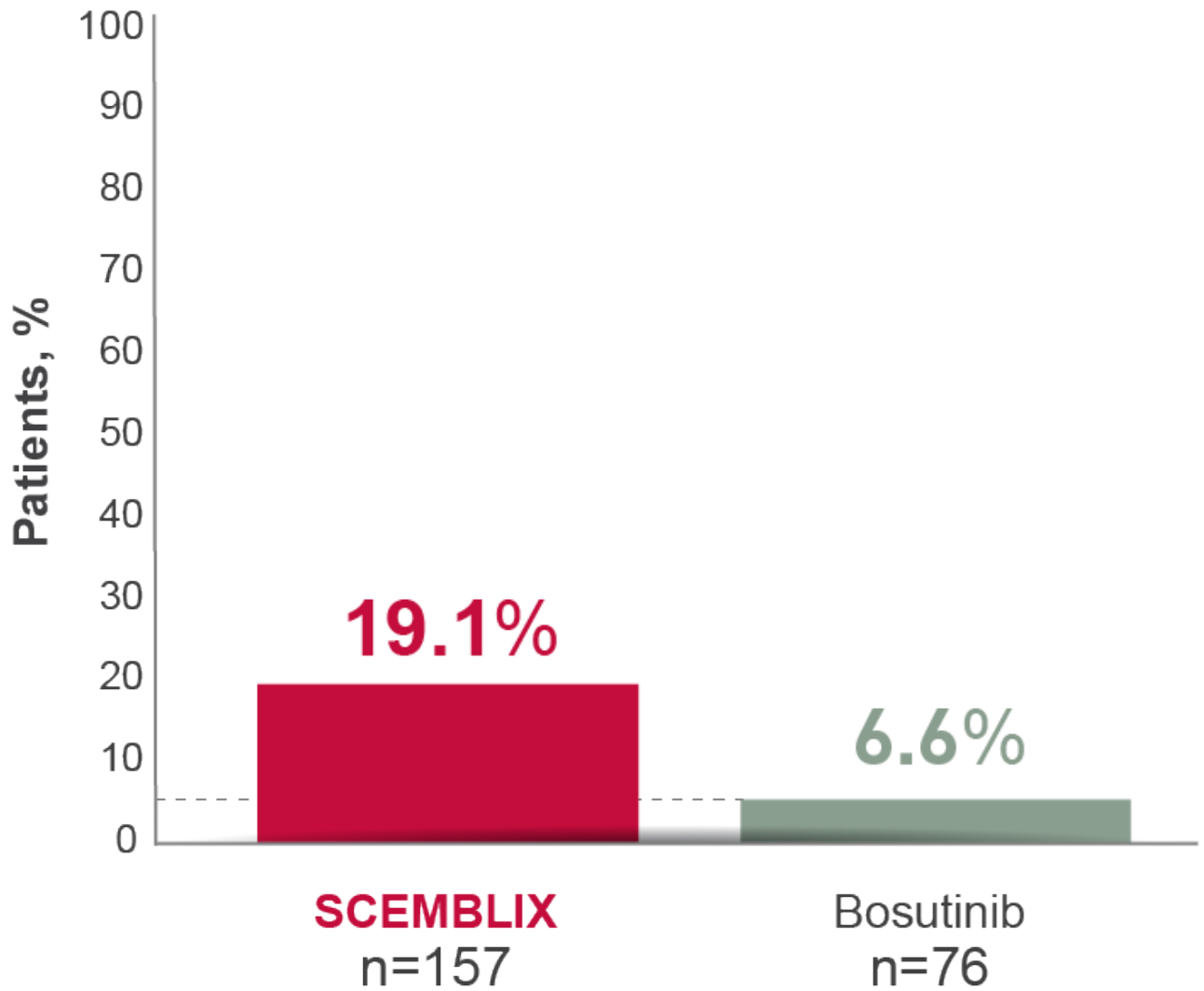
**MR4 at week 96<sup>8</sup>**

Image



**MR4 at Week 156<sup>8</sup>**

Image



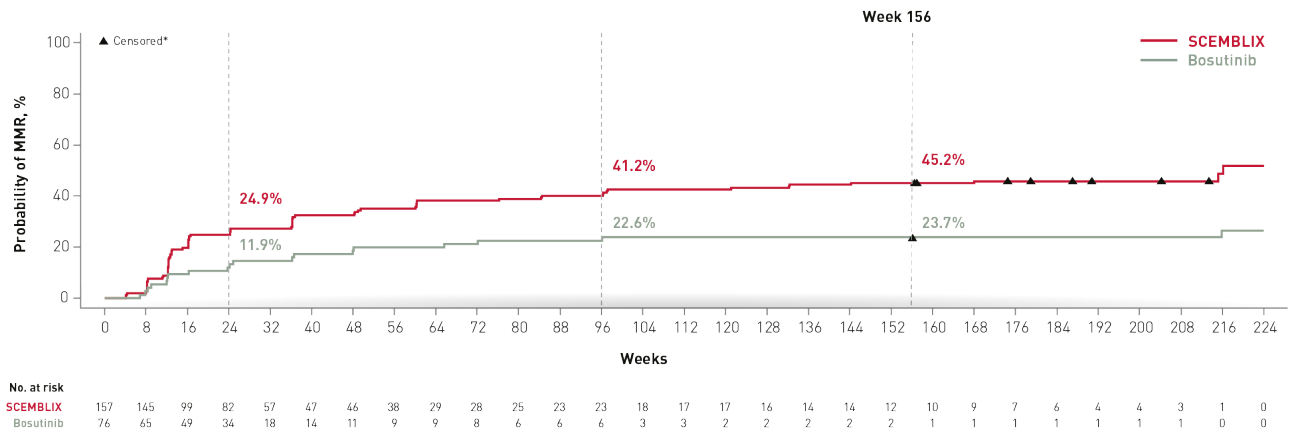
Adapted from Réa D, et al. 2021<sup>2</sup> and Mauro M, et al. 2023.<sup>8</sup>

**Deep molecular response is defined as MR4 (BCR-ABL1<sup>IS</sup> ≤0.01%) or better (with MR4.5 BCR-ABL1<sup>IS</sup> ≤0.0032%).<sup>5</sup>**

**SCEMBLIX consistently increased cumulative MMR vs bosutinib over time<sup>2,4,8</sup>**

**Cumulative incidence of MMR**

Image



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

Adapted from Réa D, et al. 2021,<sup>2</sup> Mauro M, et al. 2023<sup>4</sup> and Mauro M, et al. 2023.<sup>8</sup>

**SCSEMBLIX achieved higher MMR rates vs bosutinib throughout the duration of the study.<sup>2,4</sup>**

**SCSEMBLIX resulted in fewer all-grade and grade  $\geq 3$  AEs vs bosutinib<sup>2,3</sup>**

[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.

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