NOVARTIS

SCEMBLIX - The unmet need in CML - HCP

Scemblix® (asciminib) prescribing information Glivec® (imatinib) 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]

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.

The unmet need in chronic myeloid

leukaemia

Tyrosine kinase inhibitors (TKIs) have improved CML prognosis, yet survival remains poor in patients on ≥3rd line therapy.[2,3]

Many patients on TKIs face treatment failure or discontinuation due to intolerance, with up to half of patients discontinuing 1st line imatinib within 5 years.[3]

During 2nd line treatment:[3]

Image

of patients fail to achieve major molecular response (MMR) (n=1279)*[3]

Image

of patients fail to achieve complete cytogenetic response (CCyR) within 2 years (n=958)*[3]

*Results for MMR and CCyR rates are taken from multiple studies including different 2L medications. This is a meta-analysis.[3]

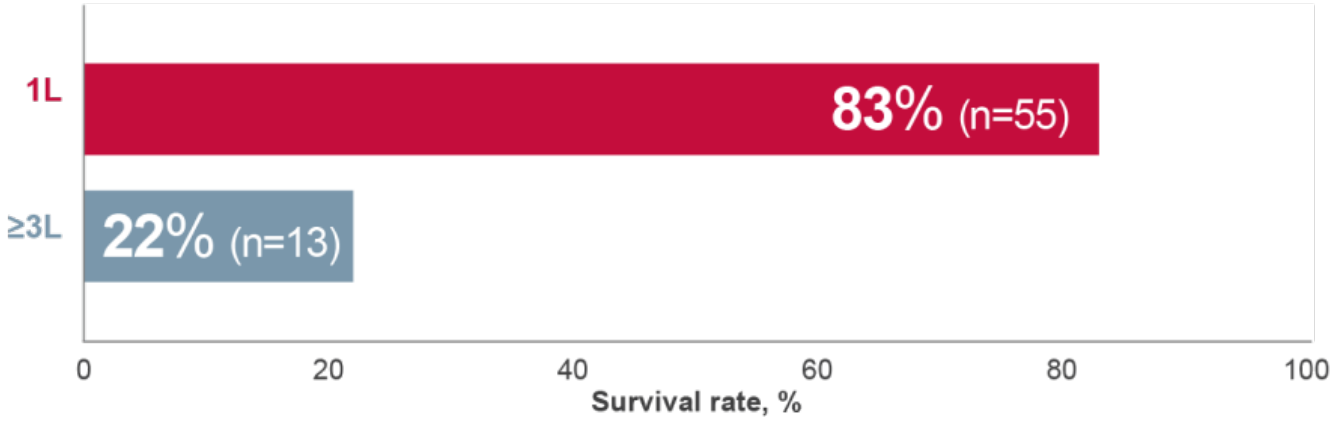
In CML patients, a low 8-year overall survival was associated with being on ≥3rd line of treatment.[†2]

Image

Approximately 2/3 of those who had at least 1 TKI switch was due to **resistance**[†4] (n=73/113)

8-year overall survival, N=902

Image



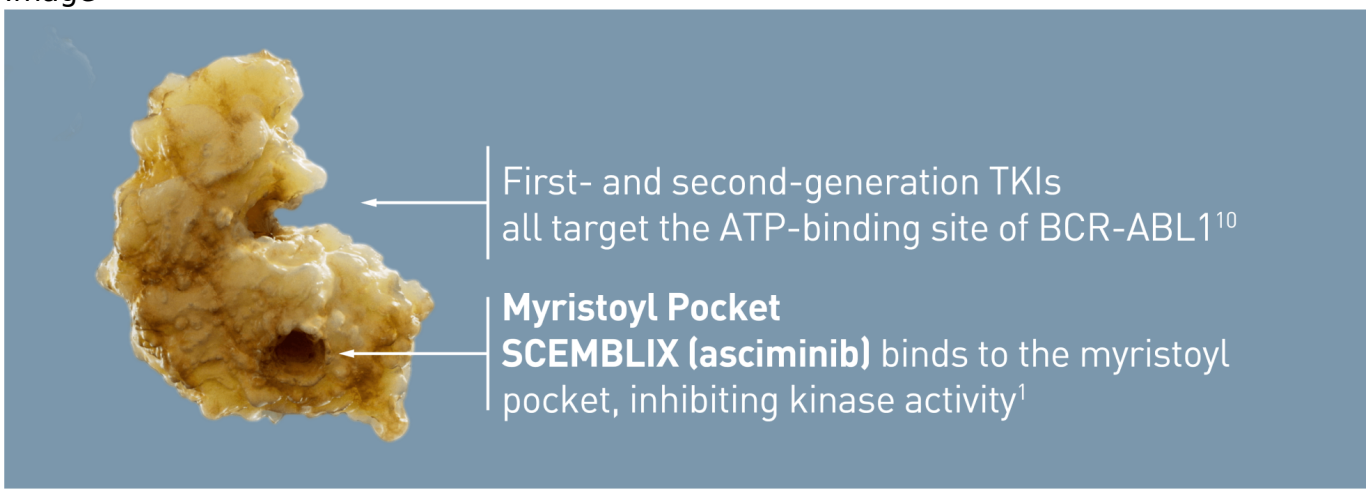
Adapted from Bosi GR, et al. 2019.[2]

Image

Optimal monitoring is important to assess treatment benefits and inform the decision to switch.[5,6] When a TKI fails, timely switching can limit the progression of disease[6]

A 2nd generation TKI may have limited benefit in a ≥3L setting, after the failure of another 2nd generation TKI and 1st generation TKI prior.[3] Patients in ≥3L of treatment may need a different mechanism of action to optimise outcomes.[2,7–9]

Image



"You can end up running out of options for patients who experience side effects. Then you need to consider transplant after 4th line or chemotherapy options"

Adapted from haematologist quote[11]

"In a year I had gone from taking one drug and living a normal life to having zero options"

Adapted from 5L CML patient quote[12]

SCEMBLIX is the first and only STAMP inhibitor, specifically targeting the ABL1 myristoyl pocket[10,13,14]

Discover the MOA

The ASCEMBL trial did not restrict to Ph+ patients with CP-CML. SCEMBLIX is indicated in adult with Ph+ CP-CML previously treated with two or more tyrosine kinase inhibitors and without a known T315I mutation.[1,13]

[†]Data from a retrospective, non-interventional study conducted at 21 UK NHS secondary and tertiary care centres on 257 patients with CML.[4]

ATP, adenosine triphosphate; CCyR, complete cytogenetic response; CI, confidence interval; CML, chronic myeloid leukaemia; MCyR, major cytogenetic response; MMR, major molecular response; MOA, mechanism of action; NHS, National Health Service; 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) SmPC, 2023.

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4. Milojkovic D, et al. *Br J Haematol* 2021;192:62–74.

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6. Hochhaus A, et al. *Leukaemia* 2020;34:1495–1502.

7. Soverini S, et al. *Blood* 2009;114(10):2168–2171.

8. Garg RJ, et al. *Blood* 2009;114(20):4361–4368.

9. Ibrahim AR, et al. *Blood* 2010;116(25):5497–5500.

10. Schoepfer J, et al. *J Med Chem* 2018;61(18):8120–8135.

11. Novartis data on file; Asc001.

12. Novartis data on file; Hae003.

13. Réa D, et al. *Blood* 2021;138(21):2031–2041.

14. Redaelli S, et al. *J Clin Oncol* 2009;27(3):469–471.

UK | October 2024 | 444668

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.

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