Poster # CML – 692

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Asciminib in Newly Diagnosed Philadelphia Chromosome-Positive Chronic Myeloid Leukemia in Chronic Phase (Ph+ CML-CP): A Retrospective Chart Review Study in the US

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KEY FINDINGS & CONCLUSIONS

- This first, diverse real-world cohort of newly diagnosed patients with CML-CP treated with asciminib demonstrated efficacy outcomes, including molecular response and discontinuation rates consistent with ASC4FIRST[4]
- Asciminib was well-tolerated, with nearly all patients remaining on asciminib by 48 weeks post-treatment initiation
- These findings support asciminib's favorable risk-benefit profile and its role as a standard of care in 1L treatment for CML management in US clinical practice

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This study was sponsored by Novartis Pharmaceuticals Corporation.

Poster presented at the Society of Hematologic Oncology (SOHO 2026) Annual Meeting, September 9th to September 12th, 2026.

BACKGROUND

- Tyrosine kinase inhibitors (TKIs) are the cornerstone for treatment of patients diagnosed with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic phase (CML-CP)[1]
- However, intolerance and treatment failure with available ATP-competitive TKIs remain common in patients with CML-CP[2, 3]
- Asciminib, the first BCR::ABL1 inhibitor specifically targeting the ABL myristoyl pocket (STAMP), received initial US FDA approval in October 2021. Its indication was expanded in October 2024, based on results from the pivotal phase 3 ASC4FIRST study, and currently include adults with newly diagnosed or previously treated CML-CP, as well as those with CML-CP harboring the T315I mutation[4, 5]

Objective

- To describe real-world clinical outcomes of patients with newly diagnosed CML-CP treated with asciminib as first-line (1L) therapy in the US clinical practice, representing the first study to evaluate outcomes with 1L asciminib in a real-world setting

METHODS

- This study was a retrospective physician panel-based chart review study conducted from June to September 2025 using an online case report form (eCRF) completed by hematologists/oncologists from community and academic practices across US census regions
- Retrospective collection of de-identified patient-level data was performed from medical charts of newly diagnosed adult patients with CML-CP initiated on 1L asciminib between January 2024 and October 2024
  - Based on physician-reported clinical assessment and payer authorization, patients initiated asciminib as off-label 1L therapy during the index period
- Institutional review board exemption was obtained from the Pearl IRB under 45 CFR 46.104(d)
- Time-to-treatment discontinuation (TTD): time from asciminib initiation (index date) until treatment discontinuation (physician assessment; event) or date of eCRF completion / loss to follow-up (censor); evaluated using Kaplan-Meier (KM) analyses
- Time-to-MR[2] (BCR::ABL1 ≤1%) / MR[3] (BCR::ABL1 ≤0.1%) / MR4 (BCR::ABL1 ≤0.01%), separately: time from asciminib initiation until the first MR assessment documenting MR[2] / MR[3] / MR[4] or better (event) or the earliest occurrence of treatment discontinuation or date of eCRF completion/loss to follow-up (censor); evaluated using KM analyses
- Cardiovascular-related adverse events (AEs) observed during 1L treatment (physician assessment) were described regardless of their severity

RESULTS

Physician and patient characteristics

- A total of 30 physicians (**Figure 1**) provided data for 98 patients with newly diagnosed CML-CP who initiated 1L asciminib (**Figure 2**)
- Median follow-up post-asciminib initiation was 51.3 weeks (range: 28.1-81.1 weeks)

Figure 1. Physician characteristics (N = 30)

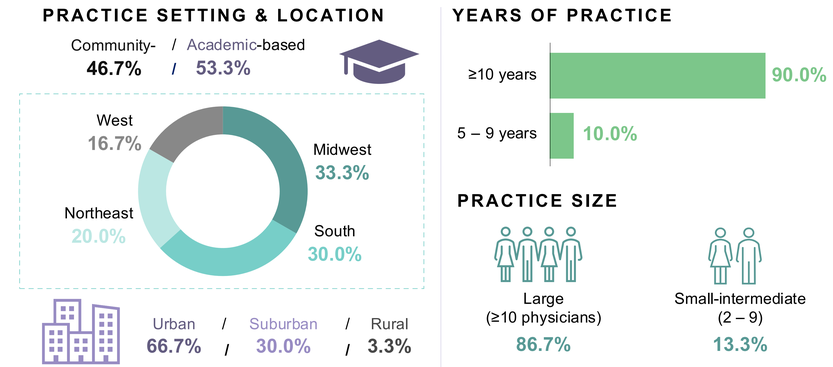
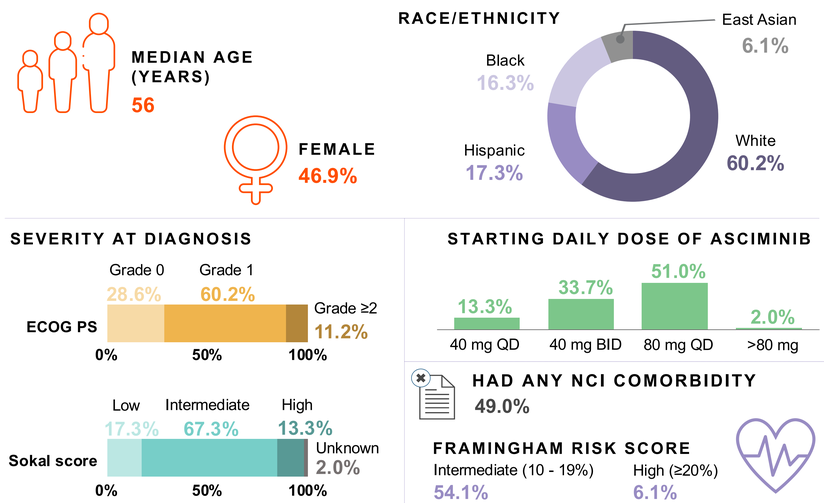


Figure 2. Patient characteristics – Patients with CML-CP treated with 1L asciminib (N = 98)

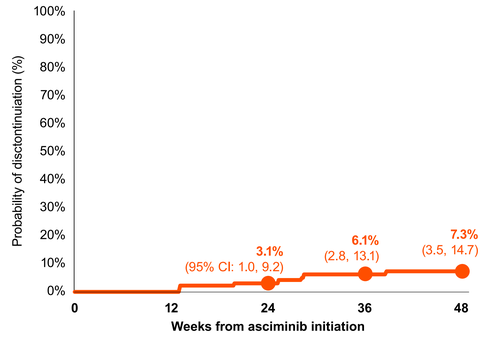


Abbreviations: BID: Twice daily; ECOG PS: Eastern Cooperative Oncology Group performance status; NCI: National Cancer Institute; QD: Once daily

Treatment patterns

- By 48 weeks post-index, the cumulative probability of discontinuation was 7.3% (**Figure 3**)
- Two patients discontinued asciminib due to resistance, and none due to AEs
- Cardiovascular-related AEs were uncommon (hypertension [4.1%], heart failure [3.1%], QTC prolongation [2.0%], cardiac arrhythmias [1.0%], myocardial infarction [1.0%])
- Progression to accelerated phase or blast crisis, or death was not observed

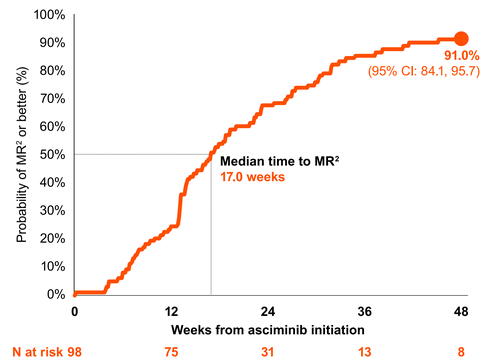
Figure 3. Cumulative probability of 1L asciminib discontinuation



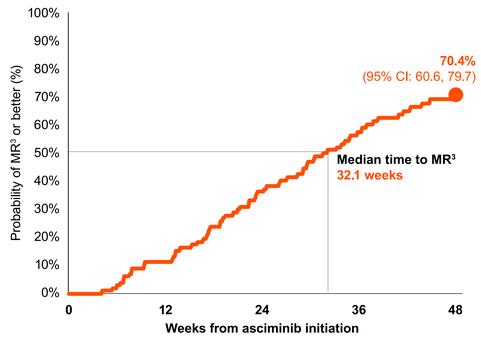
Abbreviations: 1L: first-line; CI: confidence interval; CML: chronic myeloid leukemia; CP: chronic phase; KM: Kaplan-Meier

Figure 4. Cumulative probability of achieving each assessed molecular response level

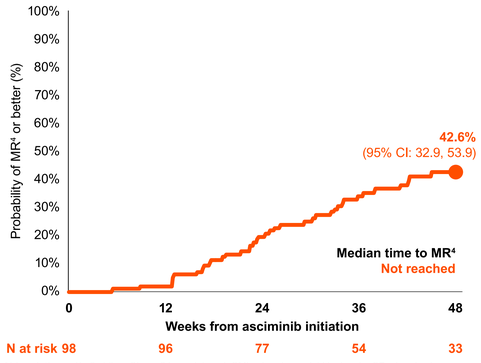
A. MR[2] or better



B. MR[3] or better



C. MR[4] or better



Abbreviations: 1L: first-line; CI: confidence interval; CML: chronic myeloid leukemia; CP: chronic phase; KM: Kaplan-Meier

Molecular response

- The cumulative probability of achieving each assessed molecular response level by 48 weeks was 91.0% for MR[2] (median: 17.0 weeks), 70.4% for MR[3] (median: 32.1 weeks), and 42.6% (median not reached) (**Figure 4A – C**)

Limitations

- Assessments of real-world molecular response may be based on heterogeneous assessment schedules
- The results may be subject to limitations inherent of retrospective chart reviews, and may not be generalizable to all US patients with CML-CP

References

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Acknowledgments

- Medical writing assistance was provided by Molly Gingrich, MSc, an employee of Analysis Group ULC, a consulting company which provided paid consulting services to Novartis Pharmaceutical Corporation during the development and conduct of this study and poster
- The authors would like to thank Fanny Jiang and Holly Arscott, employees of Analysis Group ULC, for their contribution to data analysis