Poster# **CML-636**

Christopher Benton, MD | Christopher.Benton@USOncology.com

Real-world evaluation of treatment patterns among patients with chronic-phrase chronic myeloid leukemia (CML-CP) in a large community oncology setting

Ira Zackon, MD[1]; Courtney McDermott, PhD[2] ; April Beeks, MPH[1]; Chuck Wentworth, MS[1]; Jinhong Guo,PhD[1]; Kejal Jadhav, MS[2]; David Wei, PhD[2]; Andrea Damon, PhD[2]; Islam Sadek, MD[2]; Christopher Benton, MD[3]

[1]Ontada, Boston, USA; [2]Novartis Pharmaceuticals Corporation, East Hanover, USA; [3]The US Oncology Network, Rocky Mountain Cancer Center, Aurora, USA

BACKGROUND

- Chronic-Phase chronic myeloid leukemia (CML-CP) marks one of the earliest successes in rational drug design, where treatment is developed based on knowledge of the biological target.[1]
- BCR-ABL1 tyrosine kinase inhibitors (TKIs) are highly effective in reducing the disease burden in CML-CP and are a mainstay of CML-CP treatment.[2]
- Despite tremendous improvement in patient outcomes from TKI treatments, some patients still experience non-optimal treatment response and low quality of life due to TKI resistance and intolerance.[3,4]
- Monitoring the evolution of real-world TKI therapy utilization and patient safety is vital to understanding treatment choices for patients with CML-CP in the community oncology setting.

OBJECTIVE

The objective of this study was to describe characteristics and treatment patterns of patients with CML-CP initiating TKIs as their first treatment in a US community oncology setting.

METHODS

Study Design: Retrospective observational cohort study using structured and unstructured electronic health record (EHR) data from with The US Oncology Network. Structured data were obtained programmatically, while unstructured data were obtained via chart abstraction.

Study Population (Figure 1): 300 adult patients newly diagnosed with CML-CP initiating TKI treatment (imatinib, dasatinib, bosutinib, or nilotinib) (index date) from January 1, 2016, - December 31, 2022, and followed through earliest of last patient contact or death prior to November 30, 2023.

Study Measures: Patient characteristics and treatment patterns were descriptively summarized**.** The duration of index treatment was defined as the time from first TKI treatment initiation to treatment discontinuation, date of death, or last patient record.

Attrition: Structured data variables, including diagnosis, stage, and treatment indicators, were used to screen patients based on the inclusion and exclusion criteria. From those deemed eligible based on this initial screening, patients were randomly selected for further verification through chart abstraction using unstructured data.

Database: iKnowMed (iKM) is an oncology-specific EHR system that captures the outpatient practice encounter history for patients receiving treatment within The US Oncology Network. The US Oncology Network is affiliated with approximately 2,500 physicians in more than 600 sites of care across 31 states in the US, with approximately 1.4 million US patients with cancer treated annually.

Key Data Elements: Demographics and clinical characteristics, healthcare visits and treatments, reasons for discontinuations or switches.

TFR is defined as patients discontinuing their first TKI without other treatment while still being monitored afterwards during the observation period.

RESULTS

Patient attrition

- Overall, 1,480 adult patients with CML initiated treatment with a TKI during the study period (structured data); of these, 300 patients who fit the inclusion/exclusion criteria were randomly selected (unstructured data) (**Figure 1**)

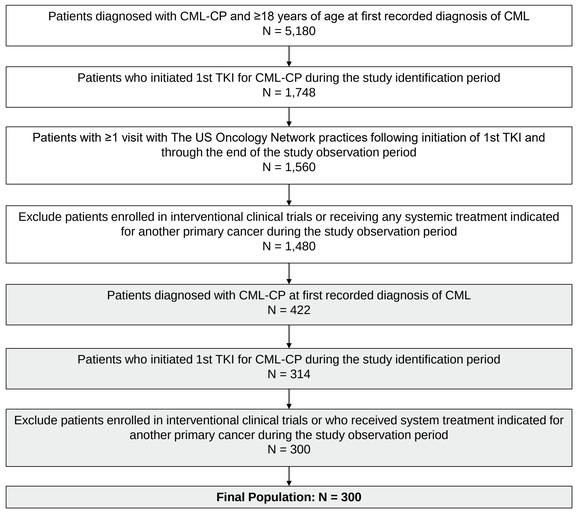
Baseline demographics and clinical characteristics

- Mean age at index was 58.2 years. Patients were primarily male (52.7%) and White (73.0%), with a baseline ECOG score of 0 or 1 (61.3%) (**Table 1**).
- Median follow-up post index was 44.8 months.

Treatment Patterns

- Most common index treatments were imatinib (46.0%), dasatinib (37.0%), nilotinib (15.3%), and bosutinib (1.7%).
- 40.0% of patients did not receive a second treatment during the follow-up period. (**Figure 2**).

Figure 1: Study attrition (N=300)



Abbreviations: CML, chronic myeloid leukemia; CML-CP, chronic-phase chronic myeloid leukemia; TKI, tyrosine kinase inhibitors

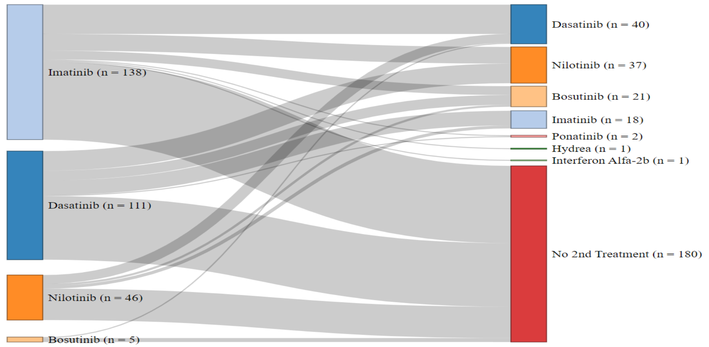
Table 1. Baseline Demographic and Clinical Characteristics (N=300)

Characteristic	N (%)
Mean (SD) Age at Index (Years)	58.2 (15.8)
18-34 Years	25 (8.3%)
35-44 Years	35 (11.7%)
45-54 Years	57 (19.0%)
55-64 Years	72 (24.0%)
65-74 Years	63 (21.0%)
75+ Years	48 (16.0%)
Male, n (%)	158 (52.7%)
Race, n (%)	
African American	28 (9.3%)
White	219 (73.0%)
Other	17 (5.7%)
Not documented	36 (12.0%)
Median (IQR) Patient Follow-Up Time (Months)	44.8 (22.0, 62.1)
ECOG at Baseline, n (%)	
0	81 (27%)
1	103 (34.3%)
2	9 (3.0%)
≥ 3	1 (0.3%)
Not documented	106 (35.3%)

Treatment Discontinuations (n=154)

- 51.3% of patients (n=154) discontinued their first TKI treatment.
- Among these patients, 76.6% (n=118) switched to a new TKI, 14.3% (n=22) were lost to follow-up, 6.5% (n=10) achieved treatment free remission (TFR), and 2.6% (n=4) died. (**Table 2**).

Figure 2. Treatment Sequence from 1st TKI Treatment for Overall Population (N=300)*



*Out of the 180 patients who did not receive a second treatment, 146 were still undergoing their initial TKI treatment.

Treatment Switches (n=118)

- Most common treatment switches were from imatinib to dasatinib (25.4%, n=30), dasatinib to nilotinib (16.9%, n=20), imatinib to nilotinib (14.4%, n=17), and dasatinib to imatinib (12.7%, n=15) (**Figure 2**).
- Median (IQR) duration of index treatment among patients who switched to a new TKI was 11.5 (4, 18.9) months, versus 42.2 (20.3, 61.2) months for patients who remained on index treatment until end of follow-up. (**Table 2**).
- Reasons for index treatment discontinuation included adverse events (59.3%), disease progression (24.6%), physician preference (14.4%), and other¥ (9.3%). (**Figure 3**).

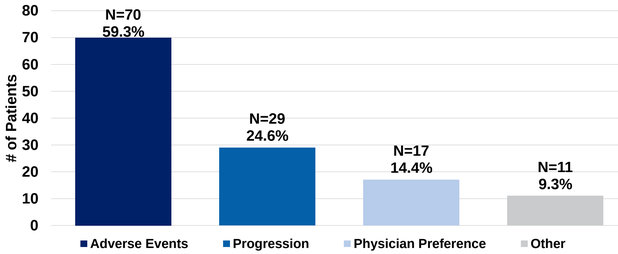
¥Reason "Other" for discontinuation consists of decline in performance status, financial/insurance, patient preference, and other

Table 2. Treatment Discontinuations and Duration of 1st TKI (months)

Characteristic	N (%)	
Number of Patients who Discontinued 1st TKI, n (%)	154 (51.3%)	
Patient Disposition following initiating 1st TKI, n (%)†	**N (%)**	**Duration of 1st TKI Median (IQR), months**
Ongoing treatment	146 (48.7%)	42.2 (20.3, 61.2)
Switched to a new TKI treatment	118 (39.3%)	11.5 (4.0, 18.9)
Lost to follow-up (LTF)	22 (7.3%)	28.6 (3.6, 58.3)
Treatment-free remission (TFR)	10 (3.3%)	38 (31.1, 42.6)
Death	4 (1.3%)	12.7 (1.8, 33.4)
Switched to a non-TKI treatment	2 (0.7%)	69.6 (50.3, 88.8)

†Not mutually exclusive – Two patients received interferon and hydrea during their first TKI treatment. Although the treatments were given, their first TKI treatment was considered ongoing.

Figure 3. Reasons for 1st TKI Treatment Discontinuation among Patients who Switched to a Different TKI (N=118)‡



‡Reasons for treatment discontinuation are not mutually exclusive.

¥Reason "Other" for discontinuation consists of decline in performance status, financial/insurance, patient preference, and other

KEY FINDINGS & CONCLUSIONS

- 51.3% of the patient population discontinued their first TKI.
- 76.6% of patients who discontinued their index treatment switched to a new TKI. Adverse events (59.6%) were the leading reason for a treatment switch.
- The median duration of first TKI treatment for patients who switched to a new TKI was almost four-times shorter than that for patients who remained on treatment.
- These results suggest remaining unmet treatment needs for patients with CML-CP receiving their first TKI treatment in the real-world community oncology setting.
- Novel therapies with reduced and manageable adverse effects are still needed to address tolerability, compliance, and duration of therapy, to further improve the quality of life and optimal outcomes in this patient population.

Limitations

This study utilized an oncology-specific EHR system that captures outpatient encounters for patients receiving treatment within The US Oncology Network practices. It is not used to collect data for research purposes but for clinical practice reasons.

References

1. Druker, B. Translation of the Philadelphia chromosome into therapy for CML. Blood. 2008;112:4804-4817. doi:10.1182/blood-2008-07-077958. **2.** Deeks, ED. Asciminib: First Approval. Drugs. 2022;82(2):219-226. doi:10.1007/s40265-021-01662-3. PMID: 35041175.**3.** Alves R, Gonçalves AC, Rutella S, Almeida AM, De Las Rivas J, Trougakos IP, Sarmento Ribeiro AB. Resistance to Tyrosine Kinase Inhibitors in Chronic Myeloid Leukemia—From Molecular Mechanisms to Clinical Relevance. Cancers. 2021; 13(19):4820. https://doi.org/10.3390/cancers13194820 **4.** Breccia M, Alimena G. Second-generation Tyrosine Kinase Inhibitors (TKI) as Salvage Therapy for Resistant or Intolerant Patients to Prior TKIS. Mediterr J Hematol Infect Dis. 2014; 6(1): e2014003. doi:10.4084/MJHID.2014.003

Disclosures

CM, KJ, DW, AD, and IS are employees of Novartis. IZ, AB, CW, JG are employees of Ontada. CB is an employee of The US Oncology Network.

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