## Real-World Outcomes of Patients Receiving Oral Specialty Therapy for the Treatment of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia at an Integrated Health System in the United States

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n (%)

#### Purpose

Evaluate treatment outcomes (adherence, persistence, switching and discontinuation of therapy) in patients on an oral oncolytic therapy for CLL/SLL at an integrated health-system specialty pharmacy (IHSSP) focused on patient outcomes.

#### **Study Design and Setting**

Single-center, retrospective cohort analysis of data collected from electronic medication records and specialty pharmacy management

Vanderbilt Health System outpatient oncology and hematology clinics from 1/1/19 – 6/30/22 with patients having a minimum of 6 months of follow-up

#### **Study Methods**

#### Inclusion and **Exclusion** Criteria

Inclusion: Patients prescribed acalabrutinib ibrutinib, or venetoclax for treatment of CLL/SLL

**Exclusion**: Clinical trial participation, off-label use, lost to follow-up, received a stem cell transplant, or transferred care outside of VUMC

## Sample

157 patients were identified for inclusion 12 patients were excluded (off-label indication [n=2], lost to follow-up [n=1], stem cell transplant [n=1], and transferred care outside of VUMC [n=5]) 145 patients included for analysis

## Outcome Measures

1) Adherence (calculated as proportion of days covered [PDC]); 2) Persistence (defined as a >30-day gap in treatment); **3)** Therapy discontinuation or switch; 4) Reasons for discontinuation or switch in therapy

## Data **Analysis**

Patients with 3+ fills were included in the adherence and persistence analyses. PDC was calculated as the number of days with medication available between the date of the first fill and the last fill in the study period. Excess supply from overlap was carried forward and truncated at the date of the last fill.

#### Results

#### Table 1. Baseline Demographics (n=145)

Characteristic

Age (at start of medication use), median [IQR]	69 [60-76]
Male	96 (66)
Female	49 (34)
White	130 (90)
Black	7 (5)
Duration of disease in years (at start of medication use), median [IQR]	6 [2-10]
Medicare insurance	74 (51)
CLL/SLL Treatment	n (%)
Ibrutinib	77 (53)
Venetoclax	46 (32)
Acalabrutinib	22 (15)
Comorbid Conditions	n (%)
Hypertension	74 (51)
GERD	45 (31)
Atrial fibrillation/arrhythmia	26 (18)
Cerebrovascular disease	7 (5)
Headache	7 (5)
Migraine	3 (2)
Genetic Testing	n (%)
Del (13q)	77 (53)
Del (11q)	24 (17)
Del (17p)	15 (10)
No testing available	46 (32)

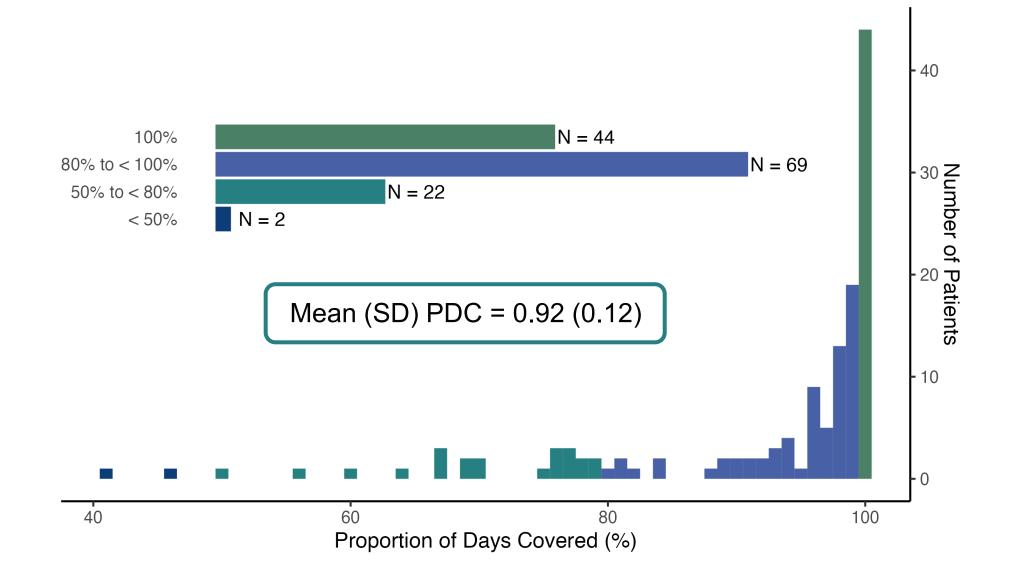
## Conclusion

- In a population of patients initiating CLL/SLL therapy through an integrated health-system specialty pharmacy, adherence to therapy was high (mean PDC = 92%).
- Adverse effects contributed to 36% of therapy discontinuations and 72% of therapy switches, indicating a continued opportunity for specialty pharmacists to help manage and mitigate adverse effects.

0.25

## Results

Figure 1. Adherence (n = 137)





# Figure 2. Persistence (n = 135)

**72 patients (53.3%)** were found to be nonpersistent with a median time to non-persistence of 375 (IQR 180-526)

#### Reasons for non-persistence:

- Treatment progression (n=22; 31%) Adverse effects
- (n=20; 28%) Treatment completed
- (n=23; 32%) Patient deceased
- (n=4; 6%)Unknown (n=9: 13%)

#### **Table 2. Discontinuation** Reasons (n = 81)

Discontinuation Reason	n (%)
Adverse events	29 (36)
Treatment completed	28 (35)
Treatment progression	25 (31)
Patient deceased	5 (6)
ncludes all patients in study regardless of # of fills. Patients may	

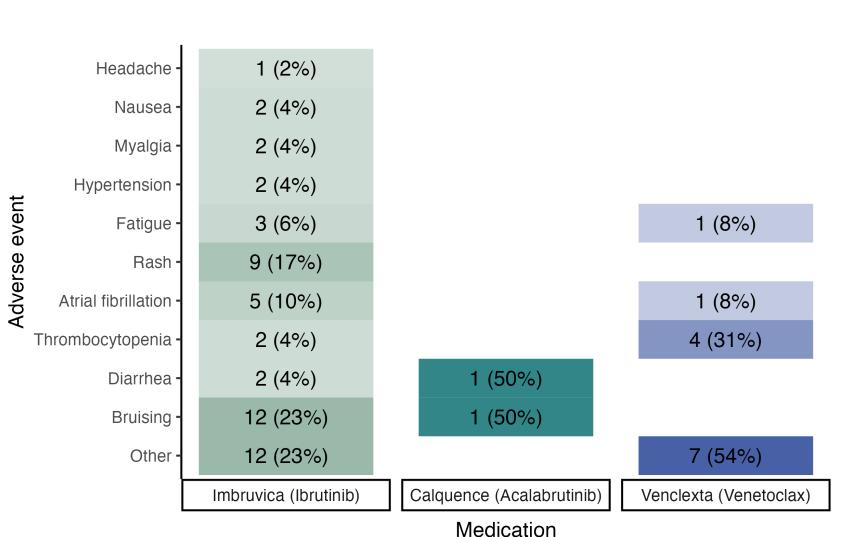
**Primary Adverse Events (≥10%) Leading to Discontinuation (n,%)** 

have more than one reason documented for discontinuation.

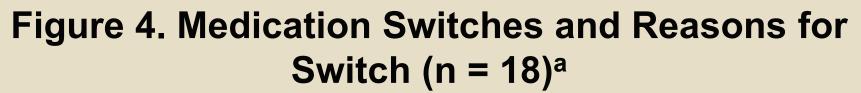
- **Ibrutinib** (n=21): atrial fibrillation (3,14); bruising (2,10); fatigue (2,10); nail splitting (2,10); rash (2,10)
- Acalabrutinib (n=2): bruising (1,50); diarrhea (1,50)
- Venetoclax (n=6): pancytopenia (4,66); itching (1,17); nausea (1,17)

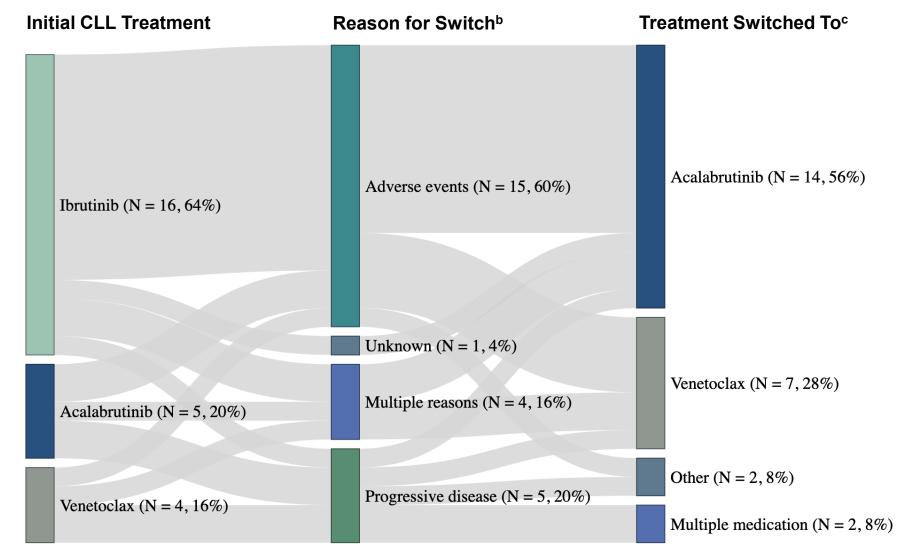
## Figure 3. Patient Reported Adverse Events for

Patients who Discontinued Medication (n = 67)



Includes all adverse events experienced by patients who discontinued the study medication.





- <sup>a</sup>Numbers will not add up to 18 as some patients switched treatment more than once
- bMultiple reasons: No clinical response + Adverse events (n=1); No clinical response + Progressive disease (n=1); No clinical response + Adverse events + Progressive disease (n=1); Progressive disease + Adverse events (n=1)
- <sup>c</sup>Multiple medications: Acalabrutinib + Venetoclax (n=1); Venetoclax + Obinutuzumab (n=1)

CLL = Chronic Lymphocytic Leukemia; SLL = Small Lymphocytic Leukemia; VSP = Vanderbilt Specialty Pharmacy \*Disclosure-this study was supported by a grant from BeiGene USA, Inc.