VANDERBILT HEALTH | Specialty Pharmacy

Abemaciclib Dose Escalation in Early Breast Cancer: 12-Month Evaluation of Off-Label Dosing Along with Modifications

Christopher Rodriguez, PharmD Candidate[1] | Stephanie G. White, PharmD[2] | Jared Crumb, PharmD[2] | Josh DeClercq, MS[3] | Chelsea P. Renfro, PharmD[2]

[1]Vanderbilt Specialty Pharmacy Student Research Program | [2]Vanderbilt Specialty Pharmacy, Vanderbilt University Medical Center | [3]Department of Biostatistics, Vanderbilt University Medical Center

PURPOSE

To describe the initial dose, modifications, and time to dose modification in patients with early breast cancer (EBC) who initiate lower than FDA-approved doses of abemaciclib.

STUDY DESIGN

Single-center, retrospective cohort analysis of data collected from an electronic medical record and specialty pharmacy management system at one academic medical center. Patients were followed for 12 months from the initiation of abemaciclib.

STUDY POPULATION

Inclusion criteria:
Starting abemaciclib at an initial dose less than 150mg twice daily for HR+, HER2- early high-risk breast cancer between 10/12/2021 and 8/31/2023

Exclusion criteria:
Evidence of any other primary malignancy; documented prior use of any cyclin-dependent kinase (CDK) 4/6 inhibitor; participation in a clinical trial

OUTCOMES

- Initial doses
- Frequency of dose modifications (both escalations and reductions)
- Reasons for dose reductions
- Time to the first dose modification
- Occurrence of dose holds
- Number of patients who achieved FDA-approved dosing

Figure 1. Study Timeline

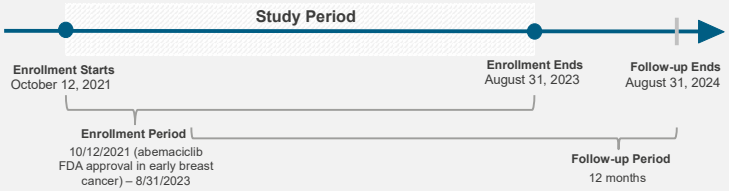


Figure 2. Study Attrition

*Patients may have met more than one exclusion criteria

Abbreviations: FDA = Food and Drug Administration; HR = hormone receptors; HER = human epidermal growth factor receptor; CCI = Charlson Comorbidity Index; GI = gastrointestinal; BID = twice daily; QAM = once daily in the morning; QPM = once daily in the evening; IQR = interquartile range; EBC = Early Breast Cancer

HIGHLIGHTS

- Dose modifications were common during the first twelve months on therapy, with 96% (n=44/46) of patients with a dose modification having at least one dose increase and 46% (n=21/46) having at least one dose decrease.
- Within the first year, 28 patients (60%) reached the FDA-approved dose of 150 mg twice daily.

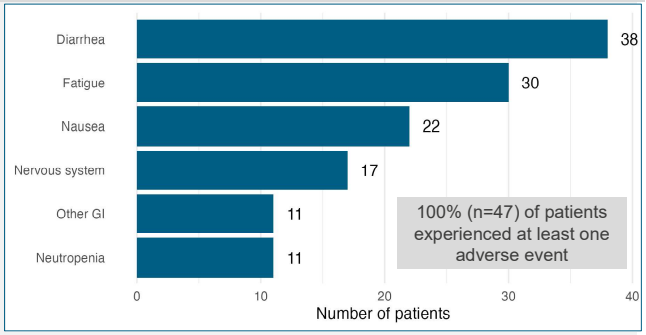
RESULTS

Table 1. Baseline Demographics

Characteristic	Patients, (N = 47) n (%)
Age, years - median (IQR)	56 (44–66)
Sex, female	47 (100)
Race	
White	38 (81)
Black	4 (9)
Other*	5 (10)
ECOG Performance Status prior to start	
0	14 (28)
1	33 (72)
2	0 (0)
CCI, median (IQR)	4 (2–5)
Pre-existing GI condition, yes	27 (57)
Menopausal status	
Pre-menopause	17 (37)
Post-menopause	27 (57)
Peri-menopause	2 (4)
Undocumented	1 (2)
Previous treatment, yes	46 (98)

*Other: American Indian/Alaska Native, Hispanic/Latino(a), Middle Eastern or North African, Unknown

Figure 3. Most Common Adverse Events[a]



[a]Display of AE experienced in >10 patients, not all categories are displayed

Figure 4. Dose Modification and Time to Modification

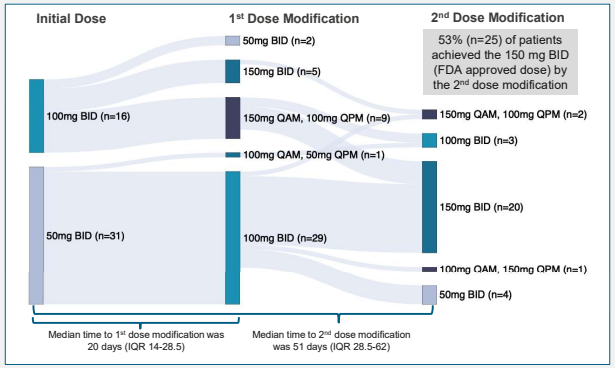
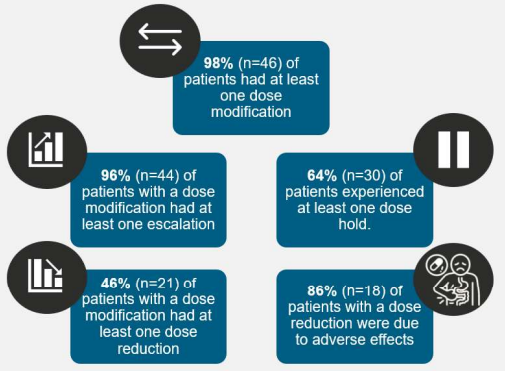



Figure 5. Summary of Modifications