PS5-05-09

Treatment Persistence and Dose Modifications in US Patients With HR+, HER2-, Node-Positive, Early Breast Cancer Treated With Adjuvant Abemaciclib

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Study was sponsored by Eli Lilly and Company

OBJECTIVE

To describe 6-month treatment persistence and dose-reduction patterns in patients with hormone receptor-positive (HR+), human epidermal growth factor receptor-negative (HER2-), node-positive early breast cancer (EBC) initiating adjuvant abemaciclib 150 mg twice daily (BID) in US clinical practice

CONCLUSIONS

- In US clinical practice, a majority (75%) of patients with HR+, HER2-, node-positive EBC who initiated adjuvant abemaciclib 150 mg BID continued abemaciclib beyond 6 months
- The proportion of patients who discontinued due to an adverse event (AE) within the first 90 days was 4 times lower for those with ≥1 dose reduction vs. those with no dose reduction (5.6% vs. 22.4%)
- Treatment persistence in patients meeting monarchE high-risk criteria (Cohort 1) was consistent with that in the overall study population
- These additional real-world data support the use of early dose reductions in patients experiencing AEs
  - Given the known onset time of diarrhea,[7] dose reductions may improve tolerability and treatment persistence with abemaciclib in patients with EBC at high risk of recurrence, without compromising efficacy[8]

San Antonio Breast Cancer Symposium (SABCS) 48th Annual Meeting; San Antonio, TX; December 9-12, 2025

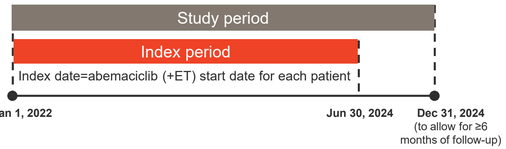
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BACKGROUND

- Abemaciclib, a selective inhibitor of CDK4/6, in combination with endocrine therapy (ET), is approved and recommended by international guidelines for adjuvant treatment of adult patients with HR+, HER2-, node-positive EBC who are at a high risk of recurrence[1-4]
- In the monarchE trial, 2 years of adjuvant abemaciclib + ET resulted in sustained benefit in invasive disease-free survival (IDFS) (hazard ratio [HR], 0.68; 95% confidence interval [CI], 0.60-0.77) and distant relapse-free survival (DRFS) (HR, 0.68; 95% CI, 0.59-0.77)[5]
  - At 7 years, adjuvant abemaciclib + ET continued to show sustained benefit (absolute benefit vs. ET alone, IDFS: 6.5% [HR, 0.73; 95% CI, 0.66-0.82]; DRFS: 5.1% [HR, 0.75; 95% CI, 0.66-0.84]), with consistent results across subgroups[6]
  - Adjuvant abemaciclib + ET resulted in 15.8% reduced risk of death vs. ET (HR, 0.84; 95% CI, 0.72-0.98; p=0.027) at the pre-specified primary overall survival analysis, demonstrating a statistically significant benefit (median follow-up, 6.3 years)[6]
- In monarchE, 18.5% of patients discontinued abemaciclib due to AEs; diarrhea was the most common AE leading to discontinuation and occurred early (median days to onset, 8 days)[7]
- Abemaciclib is dosed at 150 mg BID[1] for 2 years with a recommendation for dose reductions to improve tolerability; efficacy of adjuvant abemaciclib is not compromised by dose reductions[8]
- Previous real-world results show that the majority (88%) of patients with EBC continue taking abemaciclib beyond 3 months,[8] suggesting that it is well tolerated in clinical practice, supported by dose reductions when needed
  - Persistence was higher among patients with dose reductions vs. those without[9]
  - Among patients meeting monarchE high-risk criteria, 91% of patients with dose reductions continued abemaciclib beyond 3 months[9]
- In a further real-world analysis, patients with dose reductions spent a longer time on abemaciclib treatment than those without dose reductions[10]
- Understanding utilization and dose modification of adjuvant abemaciclib in the real-world setting can provide insights into treatment patterns beyond the clinical trial setting and help inform AE management strategies to improve tolerability and support persistence with treatment

METHODS

- **Study design:** Observational retrospective study
- **Data source:** US Flatiron Health electronic health records–derived de-identified database[11] with supplemental abstraction of details on abemaciclib doses and reasons for dose modifications



Patient Selection

- **Inclusion criteria:** Age ≥18 years; diagnosed with HR+, HER2-, node-positive, stage I-III EBC; prescribed ET and initiated adjuvant abemaciclib 150 mg BID in index period
- **Exclusion criteria:** (Neo)adjuvant clinical trial participation; prior use of any CDK4/6 inhibitor; any other primary malignancy (except non-melanoma skin cancer and other benign in situ neoplasm) while on treatment for EBC

Descriptive Analyses

- Baseline patient demographics and clinical characteristics, 6-month treatment persistence, reasons for discontinuation, and time to dose modifications, with subgroup analysis for no dose reduction vs. ≥1 dose reduction
  - Persistence was estimated using Kaplan-Meier survival curves
  - Persistence rate=proportion of patients on abemaciclib at 6 months, allowing for ≤60-day medication gap

Additional Subgroup Analyses (see Supplemental Materials)

- Conducted in patients meeting monarchE high-risk criteria (Cohort 1) consistent with FDA-approved population and dose reductions consistent with FDA label
  - ≥4 positive axillary lymph nodes, or 1-3 positive axillary lymph nodes and tumor ≥5 cm[a] and/or Grade 3 disease[12]
  - Dose reductions were limited to 100 mg BID (then 50 mg BID, if needed)

[a]Tumor ≥5 cm was defined as T3 or T4 for this analysis.

RESULTS

Patient Demographics and Clinical Characteristics

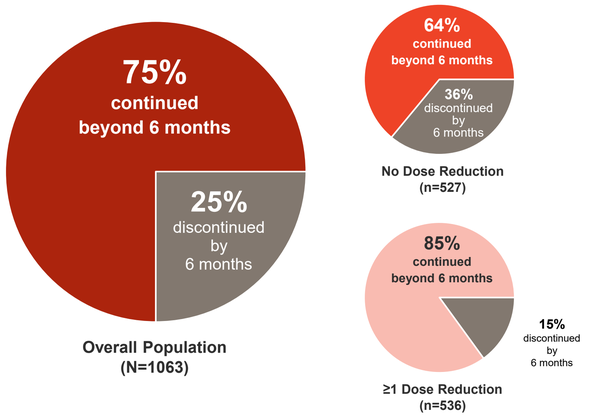
Characteristic	Overall (N=1063)	No Dose Reduction (n=527)	≥1 Dose Reduction (n=536)
Age,[a] median (IQR), years	56 (47-65)	54 (46-64)	59 (49-66)
Female	1053 (99.1)	519 (98.5)	534 (99.6)
Race			
White	698 (65.7)	350 (66.4)	348 (64.9)
Black or African American	110 (10.3)	47 (8.9)	63 (11.8)
Asian	34 (3.2)	18 (3.4)	16 (3.0)
Other race[b]	79 (7.4)	40 (7.6)	39 (7.3)
ECOG performance status[a]			
0	542 (51.0)	254 (48.2)	288 (53.7)
1	268 (25.2)	136 (25.8)	132 (24.6)
≥2	24 (2.3)	15 (2.8)	9 (1.7)
Unknown	229 (21.5)	122 (23.1)	107 (20.0)
Menopausal status			
Premenopausal	414 (38.9)	231 (43.8)	183 (34.1)
Postmenopausal	615 (57.9)	280 (53.1)	335 (62.5)
N/A, patient is male	10 (0.9)	8 (1.5)	2 (0.4)
Unknown/not documented	24 (2.3)	8 (1.5)	16 (3.0)
Practice setting			
Community	860 (80.9)	428 (81.2)	432 (80.6)
Academic	154 (14.5)	74 (14.0)	80 (14.9)
Community and academic	49 (4.6)	25 (4.7)	24 (4.5)
Stage			
Stage I	152 (14.3)	71 (13.5)	81 (15.1)
Stage II	499 (46.9)	230 (43.6)	269 (50.2)
Stage III	412 (38.8)	226 (42.9)	186 (34.7)
Pathological T status[c]			
T0	23 (2.2)	15 (2.8)	8 (1.5)
T1	352 (33.1)	167 (31.7)	185 (34.5)
T2	441 (41.5)	217 (41.2)	224 (41.8)
T3	211 (19.8)	111 (21.1)	100 (18.7)
T4	25 (2.4)	13 (2.5)	12 (2.2)
Pathologic nodal status[c]			
N0[d]	55 (5.2)	27 (5.1)	28 (5.2)
N1/N1mi	509 (47.9)	249 (47.2)	260 (48.5)
N2	359 (33.8)	174 (33.0)	185 (34.5)
N3	133 (12.5)	73 (13.9)	60 (11.2)
Histological grade[c]			
Grade 1	75 (7.1)	36 (6.8)	39 (7.3)
Grade 2	609 (57.3)	301 (57.1)	308 (57.5)
Grade 3	375 (35.3)	188 (35.7)	187 (34.9)
Prior neoadjuvant chemotherapy	432 (40.6)	223 (42.3)	209 (39.0)
Adjuvant chemotherapy	418 (39.3)	202 (38.3)	216 (40.3)
ET[a,c]			
Anastrozole	497 (46.8)	239 (45.4)	258 (48.1)
Exemestane	56 (5.3)	20 (3.8)	36 (6.7)
Letrozole	415 (39.0)	217 (41.2)	198 (36.9)
Tamoxifen	84 (7.9)	45 (8.5)	39 (7.3)
Follow-up time, median (IQR), months	17.5 (11.0-25.0)	16.3 (10.4-25.0)	18.2 (12.0-25.1)

[a]At index date. [b]Includes Hispanic or Latino and other race. [c]≤1% of patients have missing data. [d]Patients classified as node-positive based on clinical nodal status.
Note: Data are n (%) unless otherwise indicated.

- Patient demographics and clinical characteristics for the high-risk subgroup (Cohort 1; 60.2% [640/1063] of overall population) are included in the supplemental materials

Majority of Patients (75%) Continued Abemaciclib Beyond 6 Months; More Patients (85%) With ≥1 Dose Reduction vs. Patients With No Dose Reduction Continued Abemaciclib Beyond 6 Months

Abemaciclib Treatment Persistence at 6 Months by Dose Reduction Group



- Among patients who discontinued by 6 months, 70% did not have a dose reduction
- Abemaciclib treatment persistence in patients meeting monarchE high-risk criteria (Cohort 1) was consistent with that in the overall study population

Most Common Reason for Discontinuation Was AEs

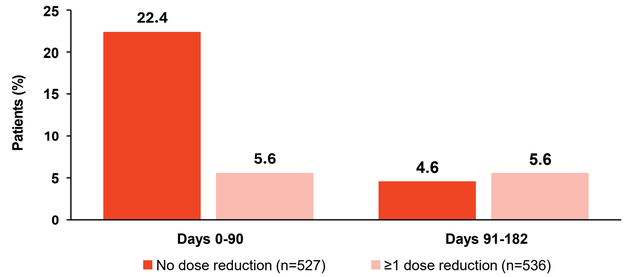
Reason for Treatment Discontinuation[a]	Overall Population (N=1063)	No Dose Reduction (n=527)	≥1 Dose Reduction (n=536)
AE	202 (19.0)	142 (26.9)	60 (11.2)
Non–cancer-related medical issues	34 (3.2)	26 (4.9)	8 (1.5)
Patient request	11 (1.0)	6 (1.1)	5 (0.9)
Disease recurrence	10 (0.9)	4 (0.8)	6 (1.1)
Other	23 (2.2)	17 (3.2)	6 (1.1)

[a]Patients could have more than 1 reason.
Note: Data are n (%).

- Proportion of patients who discontinued due to AEs was lower among those with ≥1 dose reduction vs. no dose reduction

Patients With Dose Reductions Had Lower Rates of Early Discontinuations Due to AEs vs. Patients With No Dose Reductions

Abemaciclib Discontinuation Due to AEs Over Time by Dose Reduction Group



Additional Dose Reduction Information

- Median time from start of abemaciclib to first dose change and/or hold was 49 days (IQR, 23-111)
- The most common reduction was to 100 mg BID (72%)

LIMITATIONS

- This was a descriptive study with no details on specific AEs that led to discontinuation or use of supportive care (eg, anti-diarrheal medications)
- Although most initial dose reductions occurred within the first 90 days, no direct causality with improved persistence can be determined

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ABBREVIATIONS AND ACKNOWLEDGMENTS

Abbreviations: *AE, adverse event; BID, twice daily; CI, confidence interval; DRFS, distant relapse-free survival; EBC, early breast cancer; ECOG, Eastern Cooperative Oncology Group; ET, endocrine therapy; FDA, Food and Drug Administration; HER2-, human epidermal growth factor receptor-negative; HR, hazard ratio, HR+, hormone receptor-positive; IDFS, invasive disease-free survival; IQR, interquartile range; N/A, not applicable*

Acknowledgments: Anja Becher, PhD, and Clare Weston, MSc, of Envision Catalyst, a part of Envision Pharma Group, provided medical writing support funded by Eli Lilly and Company

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