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Real-world treatment patterns and overall survival in patients with HR+/HER2- metastatic breast cancer treated with chemotherapy following endocrine therapy in the US

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KEY FINDINGS

This study provides contemporary real-world treatment patterns and estimates of overall survival in patients with HR+/HER2– metastatic breast cancer (mBC) treated with chemotherapy following progression on at least two lines of endocrine therapy (ET)-based treatment or with primary endocrine resistance

- More than half of patients (54.7%) were observed to receive a next line of therapy (LOT) after initiating a chemotherapy
- Real-world overall survival (rwOS) remains poor with median survival of approximately 1.5 years

CONCLUSION

This study highlights a need for more effective therapies with tolerable safety profiles to improve outcomes among patients with HR+ and HER2– or HER2-low mBC expression profiles who progress on ET-based treatments

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BACKGROUND

- Current therapeutic approaches for patients with HR+/HER2-low metastatic breast cancer (mBC) do not differ from patients with HR+/HER2– mBC, with systemic chemotherapy remaining the standard of care (SOC) following progression on multiple lines of endocrine therapy (ET)-based treatment or in cases of primary endocrine resistance[1]
- Given the scarcity of United States (US) real-world data on treatment patterns and real-world overall survival (rwOS) in this population, further research is essential to inform decision making and better understand the effectiveness of SOC treatments

STUDY OBJECTIVE

Among US patients initiating chemotherapy following ET for **HR+/HER2- mBC**

1. Describe real-world treatment patterns
2. Describe rwOS

METHODS

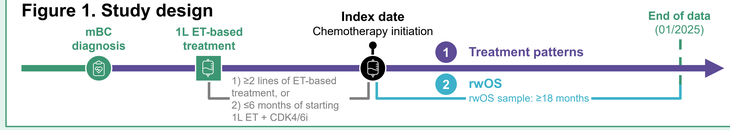
Study design

- Retrospective cohort study in Komodo Research Data (KRD+; 1/2016-1/2025)
- Index line of therapy (LOT) was defined as the initiation of chemotherapy in the mBC setting
- Treatment sequences in the mBC setting were described around the index LOT
- rwOS was assessed from chemotherapy initiation to end of follow-up among patients initiating chemotherapy between 1/2017-7/2023 using the Kaplan-Meier method

HR+/HER2- mBC identification algorithm

- A claims-based algorithm was developed based on medical expert guidance (Dr. Tiffany Traina) to identify patients with HR+/HER2- mBC receiving chemotherapy (index date) after ≥2 lines of ET-based treatment or in cases of primary endocrine resistance (**Figure 1**)
- HR+/HER2- statuses were inferred from treatments received based on expert's input. As such, HER2 expression profile below the threshold for positivity was not further stratified

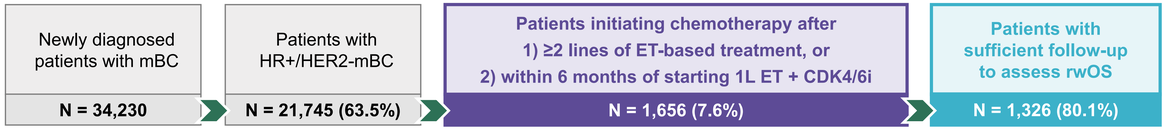
Figure 1. Study design



ET: endocrine therapy; mBC: metastatic breast cancer; rwOS: real-world overall survival
Note: Diagnosis of incident mBC was based on the presence of ≥2 medical claims with diagnosis codes for primary BC followed by ≥2 claims with diagnosis codes for secondary neoplasms, excluding breast, skin, or lymph nodes. Patients were required to have ≥12 months of continuous health plan enrollment prior to their first mBC diagnosis without diagnoses of other neoplasms and without prior chemotherapy only approved in the mBC setting.

RESULTS

Figure 2. Sample selection



ET: endocrine therapy; mBC: metastatic breast cancer; rwOS: real-world overall survival

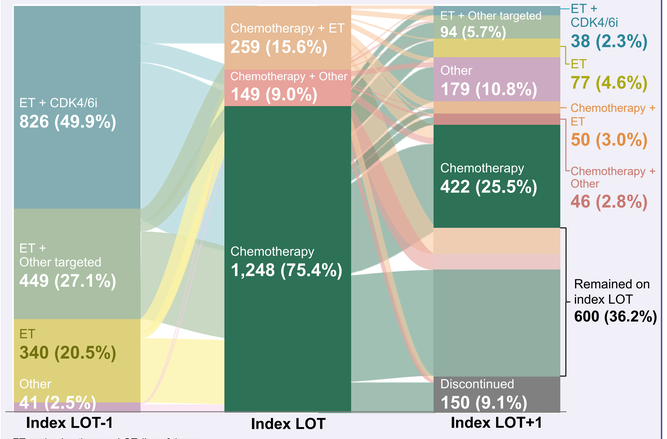
Table 1. Demographics

	Patients with HR+/HER2- mBC N = 1,656
Demographics (on index date)	
Age (years), mean ± SD [median]	59.3 ± 11.5 [59.0]
Sex[a], N (%)	
Female	1,628 (98.3%)
Male	16 (1.0%)
Race & ethnicity known, N (%)	1,314 (79.3%)
White	949 (72.2%)
Black or African American	158 (12.0%)
Hispanic or Latino	117 (8.9%)
Asian or Pacific Islander	49 (3.7%)
Other	41 (3.1%)
Payer type[b], N (%)	
Commercial	1,101 (66.5%)
Medicare	414 (25.0%)
Medicaid	139 (8.4%)
Clinical characteristics (within ± 3 months of index)	
Most common comorbidities, N (%)	
Liver disease	498 (30.1%)
Diabetes	362 (21.9%)
Cardiovascular disease	346 (20.9%)
Chronic obstructive pulmonary disease	273 (16.5%)
Months from mBC 1L initiation to end of follow-up[c], mean ± SD [median]	36.1 ± 19.5 [32.8]

1L; first-line; mBC: metastatic breast cancer; SD: standard deviation
Notes: [a]12 patients had unknown sex. [b]Two patients had unknown payer type. [c]End of follow-up was defined at the earliest of 1) end of continuous health plan enrollment, 2) end of data, or 3) death.

TREATMENT PATTERNS (N = 1,656)

Figure 3. Treatment patterns before and after index LOT

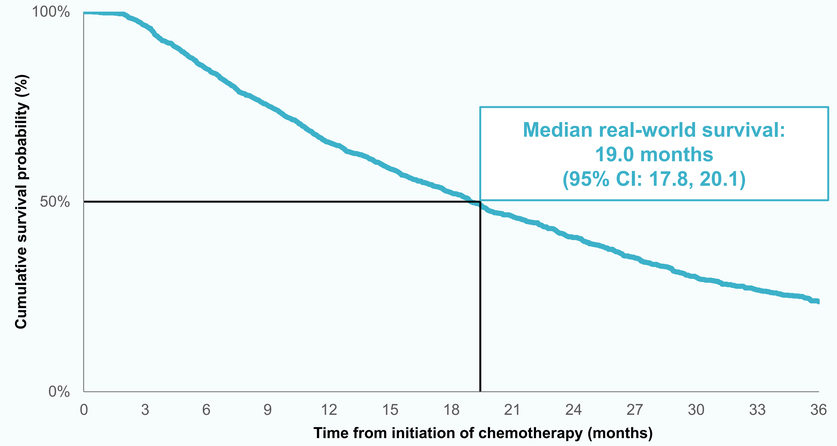


ET: endocrine therapy; LOT: line of therapy
Note: [a]All systemic BC treatments initiated within 60 days were part of the 1L regimen. Subsequent LOTs were defined as initiation of ≥1 new treatment or a treatment interruption of ≥90 consecutive days of all treatments followed by the initiation of any treatment.

- Chemotherapy was initiated for 23.2% after 1 LOT, 48.9% after 2 LOT, and 27.9% after ≥3 LOT, and most common treatment included capecitabine-based (60.9%), paclitaxel-based (16.0%) and albumin-bound paclitaxel-based (9.9%) regimens
- Overall, 36.2% remained on index LOT, 9.1% discontinued all LOT, and 54.7% received a next LOT

REAL-WORLD OVERALL SURVIVAL (N = 1,326)

Figure 4. rwOS from initiation of chemotherapy



	0 month	6 months	12 months	18 months	24 months	36 months
Patients at risk N (%)	1,326 (100.0%)	1,127 (85.0%)	870 (65.6%)	694 (52.3%)	468 (35.3%)	201 (15.2%)
Cumulative number of deaths[a] N (%)	0 (0.0%)	199 (15.0%)	456 (34.4%)	632 (47.7%)	779 (58.7%)	948 (71.5%)
Cumulative survival (%) (95% CI)	-	85.0 (83.0, 86.8)	65.6 (63.0, 68.1)	52.3 (49.6, 55.0)	40.6 (37.9, 43.3)	23.7 (21.2, 26.2)

CI: confidence interval; rwOS: real-world overall survival
Note: [a]Among N = 1,026 patients identified with a death date, N = 376 (36.6%) had a death date identified by the augmented claims-based algorithm, which included indicators of mortality such as any of the following: autopsy, necropsy, or death codes, or the last observed claim followed by ≥3 months without clinical activity (adapted from Joyce AT et al. 2004)[2]

References

1.Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Clinical Practice Guidelines in Oncology for Breast Cancer V.4.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed Sept 22, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
2.Joyce AT, Iacoviello JM, Nag S, et al. End-stage renal disease-associated managed care costs among patients with and without diabetes. Diabetes Care. 2004;27(12):2829-2835. doi:10.2337/diacare.27.12.2829

Limitations

- As clinical information (e.g., HR and HER2 statuses) is not directly available in claims data, the identification of the study sample and the LOT, and the description of rwOS, relied on algorithms developed with medical expert. rwOS analyses also incorporated imputed death dates to supplement death dates based on a claims-based algorithm
- This study is subject to common limitations of analyses using insurance claims databases, such as missing data and inaccurate insurance claims

Disclosures

- *Presenter:* T. A. Traina has received consulting/advisory fees from BioNTech SE, Genentech/Roche, Pfizer, AstraZeneca, Merck, Daiichi Sankyo, Gilead Sciences, GlaxoSmithKline, Tersera, Stemline Therapeutics, Exact Sciences, Veracyte, Aktis Oncology, and Ellipses Pharma; and research funding from BioNTech SE, Pfizer, AstraZeneca, Astellas Pharma, Genentech/Roche, and Daiichi Sankyo.
- *All authors:* C. Rossi, M. Levesque-Leroux, A. Tardif-Samson, P. Gagnon-Sanschagrin and A. Guérin are employees of Analysis Group ULC, a consulting company that has provided paid consulting services to BioNTech. S. Vlassak, V. Guan, and J. Salcedo are employed by BioNTech and own stocks
- This study was undertaken by Analysis Group ULC and sponsored by BioNTech SE

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