Poster RWD149

Real-World Burden of Illness in Patients With ER+/HER2- ABC Receiving Second-Line Treatment: Interim Results of Longitudinal Health Utility Data

Chakraborti P[1], Atkinson C[2], Lambert V[3], Barry AL[4], Cappelleri JC[3], Chandiwana D[5], Cooper C[2], Gillespie-Akar L[2], Mycock K[2], Grace Rose C[3]

[1]Stoke Mandeville Hospital, Aylsebury, UK; [2]Adelphi Real World, Bollington, UK

[3]Pfizer Inc., New York, NY, US; [4]Pfizer Ltd., Surrey, UK.; [5]Arvinas Inc., New Haven, CT, US

Objective

- To estimate health status for patients with estrogen receptor-positive (ER+) human epidermal growth factor receptor 2-negative (HER2-) advanced/metastatic breast cancer (aBC) receiving second-line (2L) treatment in a real-world setting.

Key Findings

- This interim analysis demonstrates real-world health utility is lower for patients with ER+/HER2- aBC, receiving 2L TT±ET or ET-monotherapy, compared with prior published estimates. Side effects from treatment may be negatively impacting patient HRQoL

References

1. Elfgen, C. & Bjelic-Radisic, V. (2021). Targeted therapy in HR+ HER2- metastatic breast cancer. Cancers, 13(23), 5994.
2. Hernández Alava, M., Pudney, S. & Wailoo, A. (2023). EQ-5D-5L and EQ-5D-3L relationship. Pharmacoeconomics, 41(2), 199–207.
3. Mycock, K. et al. (2022). Palbociclib combination therapy: real-world outcomes. Clin Ther, 44(12), 1588–1601.
4. Lam, C. et al. (2025). HER2+ metastatic breast cancer treatment patterns. The Oncologist, 30(4).
5. Lloyd, A. et al. (2006). Health state utilities in metastatic breast cancer. Br J Cancer, 95(6), 683–690.
6. Wood, R. et al. (2017). Quality of life in HR+/HER2- metastatic breast cancer. Clin Ther, 39(8), 1719–1728.
7. Clarke, N.A. et al. (2024). NFBSI-16 validation and responsiveness. J Patient Rep Outcomes, 8(1), 97.
8. Garcia, S.F. et al. (2012). Development of NFBSI-16. Value Health, 15(1), 183–190.
9. Pearman, T.P. et al. (2018). Single-item measure of treatment side effect bother. Cancer, 124(5), 991–997

Acknowledgments

We gratefully acknowledge Dr. Andrew Eicholz of Stoke Mandeville Hospital for his leadership and contributions as the initial Principal Investigator of this study. We would also like to acknowledge all participating sites from the UK (Stoke Mandeville Hospital, Leeds Teaching Hospital, Royal Cornwall Hospital, Princess Alexandra Hospital, Royal Stoke University Hospital, Clatterbridge Cancer Centre) and Canada (Centre hospitalier universitaire de Québec, Sir Mortimer B. Davis Jewish General Hospital).

ISPOR Europe 2025, Glasgow, Scotland - November 9–12, 2025

Background

- Estrogen receptor–positive (ER+)/human epidermal growth factor receptor-2–negative (HER2-) is the most common type of breast cancer (BC)(approximately 70% of cases).
- Advanced/metastatic BC (aBC) is largely incurable, with a 5-year survival rate of 26% [1].
- Minimizing disease burden and optimizing health-related quality of life (HRQoL) is essential.
- Data on HRQoL in the (second-line) 2L setting are limited, particularly following first line standard-of-care treatment with a CDK4/6i. Few real-world studies have reported patient outcomes in this context.

Methods

- Data were prospectively collected (November 2023-April 2025) from patients with ER+/HER2- aBC, previously treated with a CDK4/6i, initiating 2L treatment with endocrine monotherapy (ET) or targeted-therapies (TT)±ET at 9 sites in the UK and Canada.
- Patient demographic and clinical characteristics were extracted from medical records.
- Health-related quality of life (HRQoL) data were collected using the EQ-5D-5L, and National Comprehensive Cancer Network – Functional Assessment of Cancer Therapy Breast Symptom Index [NFBSI-16]) instruments. Health utilities (EQ-5D scores) were derived using the UK EQ-5D-5L crosswalk [2] value set.
- Data were collected at baseline (prior to 2L initiation) and months 1, 2, 4, and 6 following 2L initiation, and are reported by collection timepoint (baseline and pre-progression observations) and as mean on-treatment score (pooled pre-progression observations).

Results

Patients

- At time of this analysis, 22 patients were included, having contributed at least 1 survey observation at baseline, for a total of 73 longitudinal observations across baseline to month 6.
- Average patient age was 62.2 years, and mean time since aBC diagnosis was 40.6 months.
- 23% (n=5) were expected to start 2L endocrine monotherapy, while 77% (n=17) were to receive 2L targeted therapy (with or without endocrine therapy). Comorbid conditions are summarized in **Table 1**.
- Survey response distribution is shown in **Figure 1**. All invited patients completed at least one survey; completion rate across all time points was 80%.

NFBSI-16

- The mean on-treatment NFBSI-16 score (scale: 0-64) was 39.9 (95% CI: 37.3-42.6) (**Table 2**), and varied minimally over time (range: 39.1-42.1) (**Figure 2**)
- Mean NFBSI-16 GP5 (“I am bothered by side effects of treatment”; scale 0-4) was 2.4 (95% CI: 2.1-2.7) (**Table 2**).

Table 1: Patient demographics and clinical characteristics (n=22)

Patient age at enrolment	
Mean (SD)	62.2 (13.55)
Min, Max	38, 85
Patient menopausal status*	
Post-menopausal	20 (95%)
Unknown	1 (5%)
BMI	
Mean (SD)	31.7 (7.57)
Min, Max	20, 53
Ethnicity*	
White (incl. Hispanic, Latin, Spanish)	19 (90%)
Black, African or Caribbean	1 (5%)
Middle Eastern or North African	1 (5%)
Is the patient of Hispanic, Latin or Spanish origin?	
No	21 (95%)
Unknown	1 (5%)
Yes	0
Stage at study enrolment	
Stage IIIb	1 (5%)
Stage IIIc	0
Stage IV	21 (95%)
Not known/not recorded	0
Months from diagnosis of metastatic aBC to index date*	
Mean (SD)	40.6 (33.9)
Min, Max	9.8, 169.4
Diagnosed concomitant conditions	
Other	8 (36%)
Not diagnosed with any concomitant conditions per medical records	9 (41%)
Renal disease	2 (9%)
Congestive heart failure	1 (5%)
Peripheral vascular disease	1 (5%)
Chronic pulmonary disease	1 (5%)
Rheumatologic disease	1 (5%)
Diabetes without chronic complications	1 (5%)
Diabetes with chronic complications	1 (5%)
Mild liver disease	1 (5%)
Other autoimmune condition(s)	1 (5%)
Second line treatment	
Endocrine monotherapy	5 (23%)
Targeted therapy (with or without endocrine therapy)	17 (77%)

*Base equals n=21 due to missing data

Figure 1: Response distribution by patient

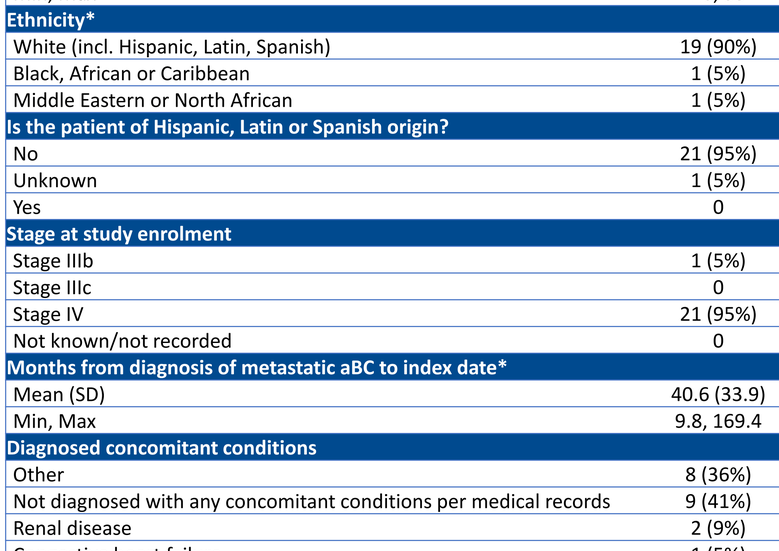
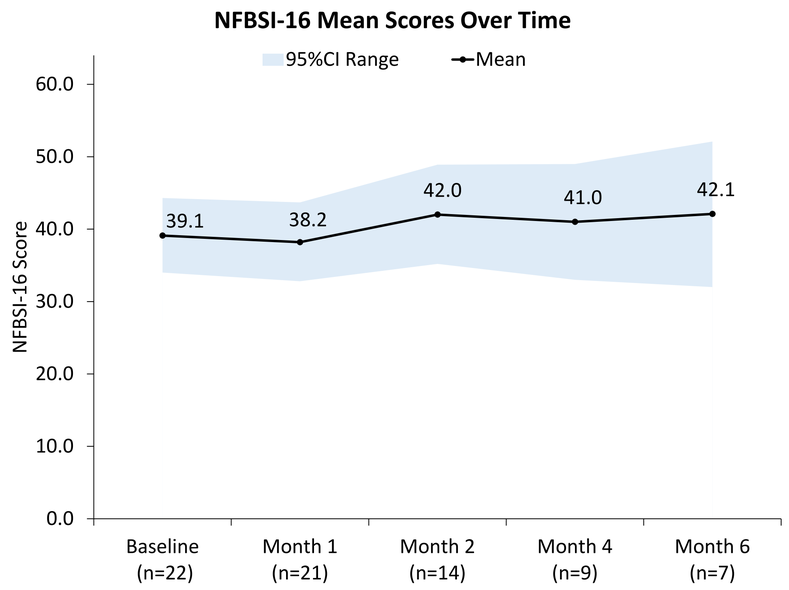


Table 2: NFBSI-16 score and subscales (n=73)

NFBSI-16 score (0-64)	
Mean (SD)	39.9 (11.3)
Min, Max	12.2 , 61.2
NFBSI-Disease-Related Symptom-Physical (DRS-P) subscale (0-32)	
Mean (SD)	19.6 (7.0)
Min, Max	3.0 , 32.0
NFBSI-Disease-Related Symptom-Emotional (DRS-E) subscale (0-4)	
Mean (SD)	1.6 (1.4)
Min, Max	0.0 , 4.0
GP2 (Nausea) NFBSI-Treatment Side-Effect (TSE) item (0-4)	
Mean (SD)	3.5 (0.9)
Min, Max	0.0 , 4.0
N6 (Mouth sores) NFBSI-Treatment Side-Effect (TSE) item (0-4)	
Mean (SD)	3.2 (1.2)
Min, Max	0.0 , 4.0
GP5 (Side effects) NFBSI-Treatment Side-Effect (TSE) item (0-4)	
Mean (SD)	2.4 (1.3)
Min, Max	0.0 , 4.0
B5 (Hair loss) NFBSI-Treatment Side-Effect (TSE) item (0-4)	
Mean (SD)	3.3 (1.2)
Min, Max	0.0 , 4.0
NFBSI- General Function and Well-Being (F/WB) subscale (0-28)	
Mean (SD)	6.8 (3.0)
Min, Max	0.0 , 12.0

For all scores, higher scores indicate a lower symptom burden and better health-related quality of life
GP2 = I have nausea; **N6** = I have mouth sores; **GP5** = I am bothered by side effects of treatment; **B5** = I am bothered by hair loss

Figure 2: NFBSI-16 mean scores over time*

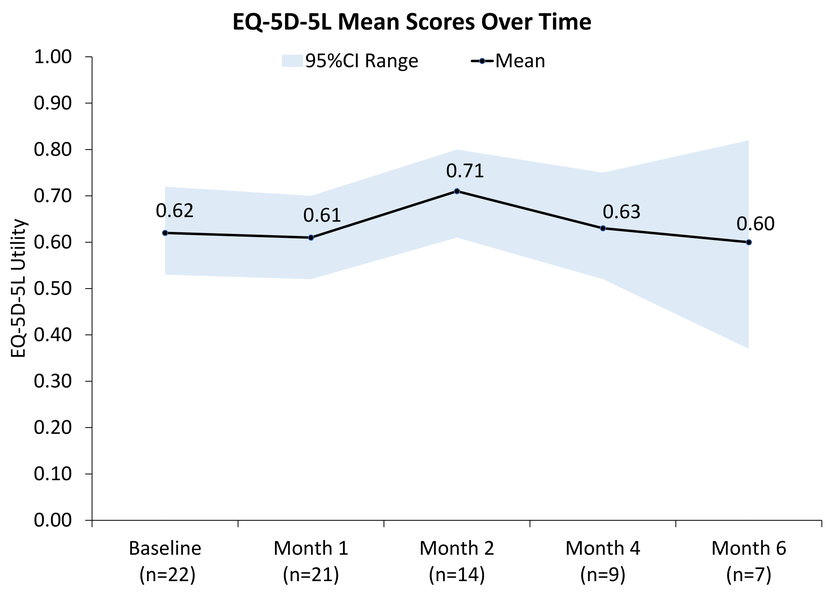


*Base at each time point describes number of available patients who responded.

EQ-5D-5L

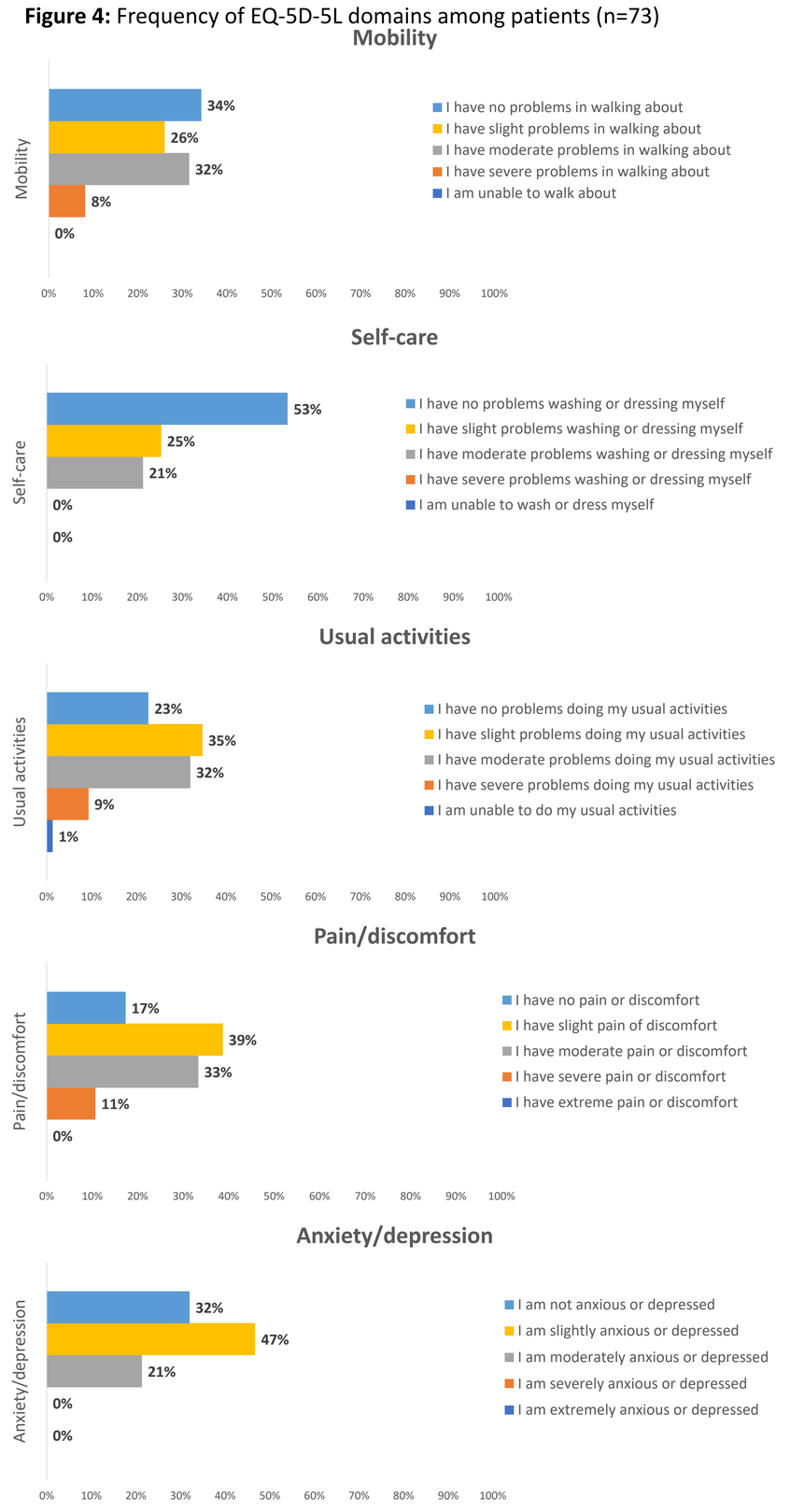
- Mean (95% CI) EQ-5D-5L utilities by timepoint ranged from 0.60 (month 6), to 0.71 (month 2). Utility score over time is shown in **Figure 3**.
- Frequency of responses to individual domains are reported in **Figure 4**.
- The mean on-treatment EQ-5D-5L utility score (mean [range] observations per patient: 3.32 [2-5]) was 0.64 (95% CI: 0.59-0.68).

Figure 3: EQ-5D-5L mean scores over time*



*Base at each time point describes number of available patients who responded.
Score of 0 is indicates a state as bad as being dead, and a score of 1.00 indicates no problems.

Figure 4: Frequency of EQ-5D-5L domains among patients (n=73)



Discussion

- The study sample is small (n=22) and around 1/3 patients were lost to follow up. Despite this, prospective data of this nature is rare and therefore valuable.
- Age, ethnicity, and time since diagnosis are consistent with the broader ER+/HER2- breast cancer population [3, 4].
- Over a third of the sample had moderate problems walking about, doing their usual activities, or experienced moderate pain/discomfort. Around 10% had severe problems walking about, doing their usual activities, or experienced severe pain/discomfort.
- Few prior studies have reported health utility for aBC patients, including: 0.72 for stable disease without toxicity [5] and 0.69 for HR+/HER2- aBC patients in 2L [6].
- Studies in similar populations report an overall NFBSI-16 score of 43.3 [7] and 42.3 [8], which is similar to this study. Increased burden on GP5 score has been associated with severity of adverse events [9].
- The mean GP5 score reported by patients in our study (2.4) could be indicative of adverse events in this population. The outcomes data from this study are similar or worse than previously published findings, highlighting the need for new therapies.