

EVALUATING FIRST-LINE ENDOCRINE-BASED PALBOCICLIB THERAPY FOR PATIENTS WITH HR+/ HER2- ADVANCED BREAST CANCER IN REAL WORLD

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BACKGROUND

Endocrine (ET)-based CDK4/6 inhibitor treatment (e.g., palbociclib) is the 1st-line standard of care for patients with hormone receptor-positive (HR+) and human-epidermal-growth-factor-receptor 2-negative (HER2-) advanced breast cancer (ABC). Randomized clinical trials as well as a current meta-analysis^{1,2,3,4} have presented high efficacy and a consistent safety profile. Nevertheless, insights into real-world longitudinal treatment patterns, effectiveness, and patient-reported outcomes (PRO) are crucial and complement clinical trial data. The non-interventional study PERFORM examines treatment sequences that are initiated with palbociclib/ET combination treatment in the 1st-line setting in routine clinical practice and aims to document clinical evidence to gain new real-world insights.

METHODS

In 320 sites across Germany and Austria, 1,900 patients receiving 1st-line palbociclib/ET will be prospectively enrolled. Primary endpoint is progression-free survival supplemented with secondary endpoints including treatment patterns, effectiveness along with second- and third-line effectiveness and PRO beyond progression. The first interim analysis approximately 12 months after first-patient-in focusses on baseline characteristics, socioeconomic status (SES, ALLBUS 2018) and treatment expectation/ satisfaction using descriptive statistics.

RESULTS

Between 10/2020 and 09/2021, 342 patients were enrolled, 209 patients were observed >3 months and 179 patients were evaluable for this analysis. Median age was 69 years. 26% of the patients were ≥75 years at start of 1st-line treatment, 99% were female and 90% were postmenopausal. In total 36% of patients presented with de novo ABC at inclusion and 64% with relapsed disease. Metastases were present in 96% of patients at ABC diagnosis, mainly visceral (43%) and bone only (41%). Only 3% of patients were included with a locoregionally advanced tumor only (Table 1).

Regarding SES, 51% were married and living together with their partner, 15% full-time employed and 55% not gainfully employed. Health insurance status was in 89% statutory and in 11% private (Table 2). 83% of the patients expected treatment benefits from 1st-line treatment.

3 months after treatment start treatment benefit met (51%) or exceeded (10%) expectations for the majority of patients. Only 9% stated that benefits did not meet their prior expectations (Figure 1). Regarding individual therapy decision factors of the physician (Figure 2), good efficacy, tumor board decision and guideline recommendations as well as the maintenance of quality of life were the most important factors.

Characteristics	Total (n=179)
Age (years), median (range)	69 (33.0-89.0)
<75 years, n (%)	132 (73.7)
≥75 years, n (%)	47 (26.3)
Menopausal Status, n (%)	
Premenopausal	12 (6.7)
Perimenopausal	4 (2.2)
Postmenopausal	161 (89.9)
Missing	1 (0.6)
Male Patient	1 (0.6)
ECOG performance status^a	
Median (range)	1 (0-3)
Mean ± SD	0.67 ± 0.72
CCI, n (%)	
0	149 (83.1)
1	8 (4.5)
2	8 (4.5)
≥3	13 (7.3)
Missing	1 (0.6)
De novo advanced/ metastatic disease, n (%)	
Yes	65 (36.3)
No	114 (63.7)
Time since initial diagnosis for patients with non de novo advanced disease (years), median (range)	7.1 (0-39)
Tumor stage at ABC diagnosis, n (%)	
Locoregionally advanced	6 (3.3)
Metastatic	172 (96.1)
Missing	1 (0.6)
Disease site, n (%)	
Visceral	76 (42.5)
Non-visceral only (excl. bone-only)	18 (10.1)
Bone-only	73 (40.7)
No metastases present at inclusion ^b	12 (6.7)

Characteristics	n (%)
Kind of health insurance	
Private health insurance	20 (11.17)
Statutory health insurance	159 (88.83)
Occupation	
Full-time employed	27 (15.08)
Part-time employed, part-time	13 (7.26)
Part-time employed	6 (3.35)
Not gainfully employed	98 (54.75)
Missing	35 (19.55)
Marital status	
Married/ in a partnership, living together	91 (50.84)
Married/ in a partnership, living apart	6 (3.35)
Widowed/ Divorced	41 (22.91)
Single	12 (6.7)
Missing	29 (16.2)
Nr. of persons in household	
No other person	54 (30.17)
Less/ exactly 3 other persons	85 (48.04)
More than 3 other persons	5 (2.79)
Missing	34 (18.99)
Nr. of children	
No children	28 (15.64)
1 or 2 children	89 (49.72)
3 or 4 children	18 (10.06)
More than 5 children	5 (2.79)
Missing	39 (21.79)
Age of the youngest child (years)	
n	114
Mean ± SD	38.55 ± 14.89
Median (Q1-Q3)	39.67 (29.27 - 47.92)
Min-Max	3.71 - 90.98 ^c
Missing	65
Distance to oncologist	
<5 km	37 (20.67)
5-10 km	36 (20.11)
10-20 km	41 (22.91)
20-50 km	27 (15.08)
>50 km	5 (2.79)
Missing	33 (18.44)

^aMaximum value of 90-98 years might be according to a potential documentation error since this is a patient questionnaire.

CONCLUSION

The first interim analysis results of PERFORM show that a representative ABC patient population is enrolled in this study. Furthermore, patients treated with palbociclib/ET in the real-world setting report a high treatment satisfaction and factors like distance to the oncologist or higher age are not a barrier for palbociclib/ET treatment. For physicians, tumor board and guidelines recommendations, the effectiveness of endocrine-based therapy and the maintenance of quality of life are the most important

decision-making factors in the real world. While the group of elderly patients is well represented in the study, so far only one man has been enrolled to the date of database cut. Given the greater diversity of patients in the real-world setting compared to patients typically enrolled in randomized clinical trials a focus should be placed here during recruitment to be able to analyze rare subgroups and to answer clinically relevant questions for specific patient subgroups.

Figure 1

Treatment expectation before and treatment satisfaction 3 months after start of 1st-line treatment. (n = 179)

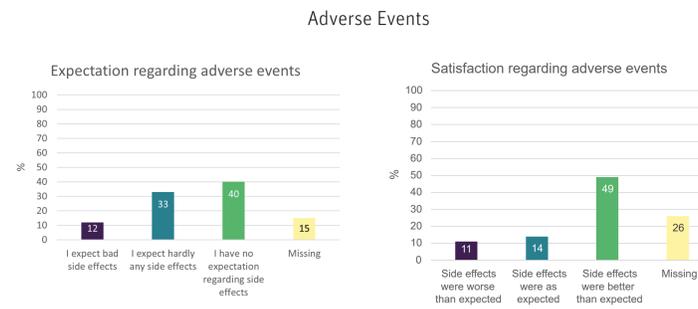
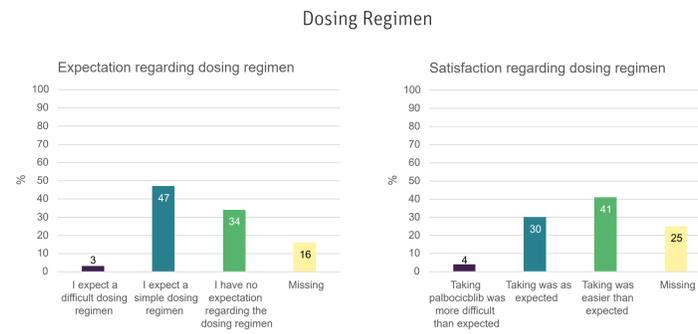
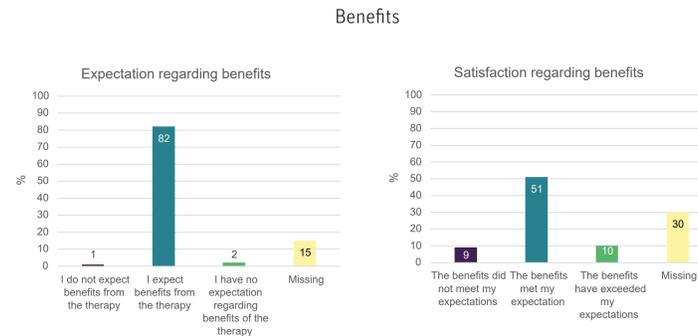


Figure 2

Factors influencing treatment decision (1 = not important, 6 = very important).



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Abbreviations
 ABC Advanced breast cancer
 CDK4/6 Cyclin-dependent-kinase 4/6
 CCI Charlson Comorbidity Index
 ECOG Eastern Cooperative Oncology Group
 ER Estrogen receptor
 ET Endocrine therapy
 HER2 Human-epidermal-growth-factor-receptor 2
 HR Hormone receptor
 km Kilometer
 PgR Progesterone receptor
 PRO Patient-reported outcomes
 Q Quartile
 QoL Quality of Life
 SD Standard deviation

Conflicts of Interest
 Thomas Fietz: Honoraria (Pfizer); Thomas Gabrysiak: Leadership position (Oncological Center WOB-HE MVZ); Shareholder/Stockholder/Stock options (Oncological Center WOB-HE MVZ); Michael Weigel: Honoraria (Pfizer, Roche, GSK, AstraZeneca, Lilly, Novartis); Denise Wrobel: Honoraria (Roche, Novartis, Pierre Fabre); Esther Glastetter: Leadership Role, Shareholder/Stockholder/Stock options, Employment; Leonie Berger: Employment; Anne Adams: Shareholder/Stockholder/Stock options, Employment; Achim Wöckel: Advisory/Consultancy (Amgen, Novartis, Eisai, Celgene, Pfizer, Tesaro, TEVA, Hexal, Lilly, Roche, AstraZeneca, Sirnex, MSD, Clovis, Pierre Fabre, Exact Sciences, Gilead, Seagen); Jochen Wilke, Mustafa Deryal, Björn Schöttker, Lutz Jacobasch, Volker Petersen, Melanie Frank, Sandra Maria Woerner: No conflicts of interest; Michael Patrick Lux: Leadership Position; Advisory Role; Honoraria self and institution; Medical Writer of Pfizer