POSB400

Real World Treatment Patterns and Clinical Outcomes Associated with Palbociclib Combination Therapy across Europe, North and South America, and Asia: A Pooled Analysis from the IRIS Study

Katie Mycock[1], Kent Hanson[2], Kieran Hart[1], Gavin Taylor-Stokes[1], Gary Milligan[1], Christian Atkinson[1], Debanjali Mitra[2], Salena Preciado[2], Ernest Law[2]

[1]Adelphi Real World, Bollington, UK; [2]Pfizer Inc., 235 East 42nd Street, New York, US

Objective

The Ibrance Real World Insights (IRIS) study collected data from patients with hormone receptor-positive (HR+), human epidermal growth factor 2-negative (HER2-) advanced breast cancer (ABC) receiving palbociclib combination therapy in the real-world clinical setting across Europe, North and South America, and Asia.

The present study aimed to examine real-world patient characteristics, treatment patterns, and clinical outcomes for the global cohort and patient subgroups in a pooled analysis of data collected from IRIS.

Conclusion

This study represents the largest multinational assessment of real-world treatment patterns and outcomes associated with palbociclib. Effectiveness data were comparable at 12 months regardless of partner therapy; consistently high 12-month PFR and SRs were observed across all subgroups. This data provides valuable insight to physicians and healthcare stakeholders to better inform treatment decisions.

Study Limitations: Data were collected from physicians who were willing to participate, introducing a potential selection bias; however physicians included in this study came from a wide range of practice settings and covered all major geographic regions.
Results were limited to patients who had potential for at least 3 and 6 months of follow-up following chart abstraction for patients receiving P+F and P+AI, respectively.

Conflicts of interest: The first author Katie Mycock is an employee of Adelphi Real World, who were paid consultants to Pfizer in connection with the development of this publication. No other conflicts of interest to declare.

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Presenting Author: Katie Mycock; katie.mycock@adelphigroup.com

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Materials and Methods

STUDY DESIGN

- IRIS was a multinational, retrospective cohort study that used a standardized approach to collect data for patients diagnosed with HR+/HER2- ABC receiving palbociclib combined with an aromatase inhibitor (P+AI) or fulvestrant (P+F) between July 2017 and May 2020.
- Medical charts were reviewed and data was pooled from 13 countries (Argentina (AR), Belgium (BE), Canada (CA), France (FR), Germany (DE), Italy (IT), Japan (JP), the Netherlands (NL), Portugal (PT), Spain (ES), Switzerland (CH), United Kingdom (UK), United States (US))
- Patient characteristics, treatment patterns and outcomes were summarized. Subgroup analyses were conducted including age, ethnicity, disease-free interval (DFI), performance status (ECOG), visceral status, metastases and line of therapy.

PHYSICIAN INCLUSION CRITERIA

- Oncologists, Hematologists, Gynecologists, and Surgeons, based on country-specific studies;
- Responsible for treating ≥ 2-6 (depending on country) ABC/MBC patients who meet the eligibility criteria.

PATIENT INCLUSION CRITERIA

- ≥18 years old, female;
- Confirmed HR+/HER2- ABC/MBC diagnosis;
- Received P+AI or P+F in line with country-specific labelled indications;
- No prior or current enrolment in an interventional clinical trial for ABC/MBC;
- Minimum of six months of potential follow up data following P+AI initiation, and three months for P+F;
- Japan only: inoperable or recurrent breast cancer.

STUDY MEASURES

- Best response was measured using the definitions in Table 1. Definitions for clinical endpoints were presented to physicians, detailed in Table 2.

Table 1. Clinical Response Definitions

Response	Definition / Variables
Complete response (CR)	Where 'Complete Response' has been recorded at any time (no 24-week minimum)
Partial Response (PR)	Where 'Partial Response' has been recorded at any time (no 24-week minimum)
Stable disease (SD) ≥24 weeks	Patient remained on palbociclib for a minimum of 24 weeks, without complete or partial response, death, treatment switch or progression
Stable Disease (SD) <24 weeks	Stable disease recorded for initial response, with a subsequent progression recorded <24 weeks or treatment switch for reason other than progression <24 weeks or death without recorded progression <24 weeks
Progressive Disease (PD)	Progression recorded for initial response without a subsequent partial or complete response recorded

ANALYSES

- Analyses were descriptive and no formal hypotheses were tested. Missing data were not imputed. Descriptive analyses were performed in STATA statistical software version 17 (StataCorp, 2019).
- Time to event outcomes at 6, 12, 18 and 24 months were calculated using Kaplan-Meier estimators.
- Disease-free interval was defined as the time from the end of adjuvant endocrine therapy and diagnosis of ABC/MBC.

Table 2. Clinical Endpoint Definitions

Response	Definition / Variables
Objective Response Rate (ORR)	Proportion of patients who achieved a complete or partial response as assessed by the physician
Clinical Benefit Rate (CBR)	Proportion of patients who achieved a complete or partial response or had stable disease for at least 24 weeks as assessed by the physician
Progression free rate (PFR)	Proportion of patients who do not have evidence of disease progression or death at various time points
Survival rate (SR)	Proportion of patients alive at various time points

Results

PHYSICIAN AND PATIENT CHARACTERISTICS

- 417 physicians completed 2954 electronic chart record forms (eCRF) across BE [n=9 physicians/151 eCRFs]; FR: 41/283; DE: 35/251; IT: 33/260; NL: 14/64; PT: 15/100; ES: 37/259; CH: 20/100; UK: 34/255; AR: 41/162; CA: 33/247; US: 76/652; JP: 29/170 .
- Medical/Clinical Oncologists (75.8 %), Oncologist Haematologists (10.1 %), Gynaecologists (6.5 %), Breast Surgeons (4.8 %), Oncologists (1.9 %), Surgical Oncologists (0.8 %) and Gastro-Surgeons (0.2 %), participated.
- Patient demographics and clinical characteristics are shown in Table 3.

Table 3. Patient Demographics & Characteristics

	Overall (n=2954)		P+AI (n=1748)		P+F (n=1206)	
Age at Palbociclib Initiation, years						
Mean	63.3		63.0		63.7	
Median	64.0		64.0		64.0	
Ethnic Origin n, %						
White	2119	71.7	1257	71.9	862	71.5
Black	156	5.2	99	5.6	57	4.8
Hispanic/Latino	214	7.2	132	7.6	82	6.8
Middle Eastern	77	2.6	42	2.4	35	2.9
Asian	284	9.6	161	9.2	123	10.2
Other*	104	3.5	57	3.3	47	3.9
Disease-Free Interval n, %						
n	2815		1729		1086	
De novo	1679	59.6	1343	77.7	336	30.9
≤12 months	757	26.9	176	10.2	581	53.5
>12 months	379	13.5	210	12.1	169	15.6
ECOG PS† at Palbociclib Initiation n, %						
0	1092	37.0	684	39.1	408	33.8
1	1448	49.0	821	47.0	627	52.0
2+	369	12.5	220	12.6	149	12.3
Unknown/not assessed	45	1.5	23	1.3	22	1.8
Visceral Status n, %						
Visceral disease‡	1242	48.3	765	49.7	477	46.2
Non visceral disease	1329	51.7	773	50.3	556	53.8
Metastases n, %						
Bone only	1120	43.6	671	43.6	449	43.5
Liver only	339	11.5	192	11.0	147	12.2
Lines prior ABC/MBC Treatment n, %						
1	1919	65.0	1443	82.6	476	39.5
2	807	27.3	233	13.3	574	47.6
3+	228	7.7	72	4.1	156	12.9

* Other includes Native American, Mixed Race, and Other (specify)
† 0 = Fully active, able to carry on all pre-disease performance without restriction
1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2 = Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50 % of waking hours
3 = Capable of only limited selfcare; confined to bed or chair more than 50 % of waking hours
‡ Patients with stage IV/mBC defined as having metastases to lung, brain, liver or ovaries.

PALBOCICLIB TREATMENT PATTERNS AND DOSING

- The majority of patients received palbociclib as first line therapy (P+AI: 1st line 92.7 %; ≥2nd line or later 7.3 %; P+F: 1st line 45.8 %; ≥2nd line or later 54.2 %).
- Median follow-up duration from palbociclib initiation was 10.0 months for P+AI and 7.4 months for P+F patients. Overall, 80.3 % P+AI and 78.4 % P+F pts were still on treatment at the time of data collection.
- Most patients initiated palbociclib on 125mg/day (P+AI: 88.0 %; P+F: 85.0 %), of those, dose reductions were observed in 18.5 % P+AI and 14.8 % P+F patients, respectively.

PALBOCICLIB CLINICAL OUTCOMES

- The 12-month PFR was 87.5 % for P+AI patients (88.5 % 1L and 73.9 % ≥2L) and 79.2 % for P+F (83.3 % 1L and 76.2 % ≥2L). Twelve-month SR were 96.4 % for P+AI (96.8 % 1L and 91.5 % ≥2L) and 95.5 % for P+F patients (96.7 % 1L and 94.7 % ≥2L).
- An ORR of 80.4 % was achieved for patients treated with P+AI, and an ORR of 74.8 % for those treated with P+F (Figure 1).
- The 12-month PFR (Figure 2) and SRs (Figure 3) for most subgroups examined were clustered around the overall rate; trends were generally similar in patients treated with P+AI and P+F, irrespective of age, DFI, visceral or metastases status.
- White patients who receive P+AI tend to have more favorable 12-month PFR and SRs than P+F patients, the opposite trend is observed for black patients.
- PFR and SR were lower than the overall rate in patients who had an ECOG PS of 2+ prior to initiation, however outcomes were still favorable in populations with poor functional status.

Figure 1. Best Response in P+AI and P+F Patients

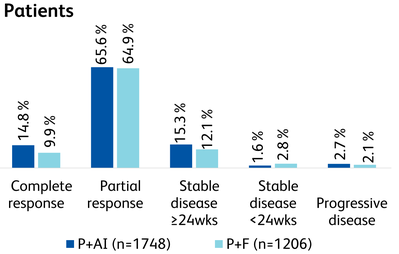
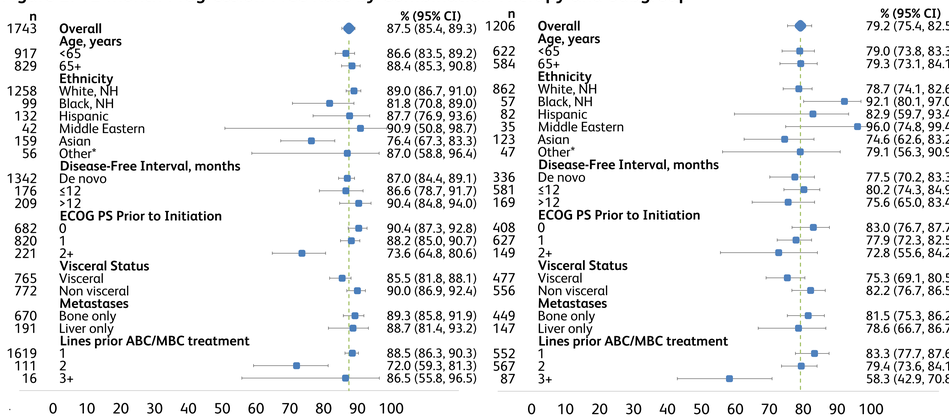


Figure 2. 12-month Progression-Free Rate by Combination Therapy and Subgroup



* Other includes Native American, Mixed Race, and Other (specify) .

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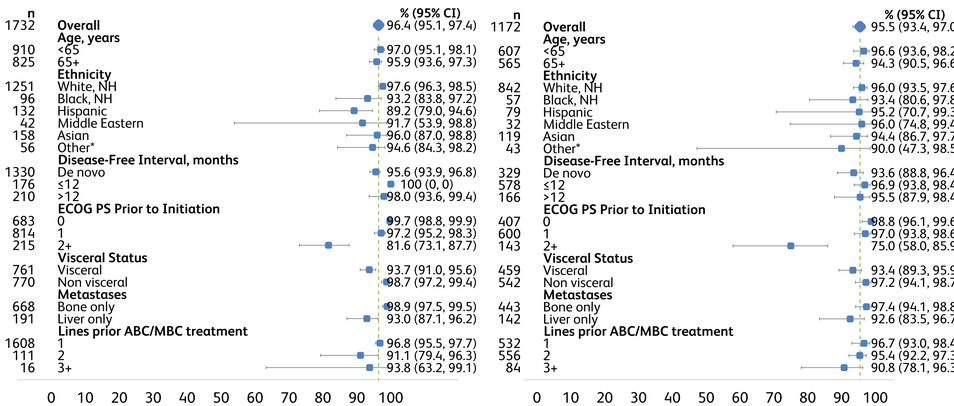
Figure 3. 12-month Survival Rate by Combination Therapy and Subgroup



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