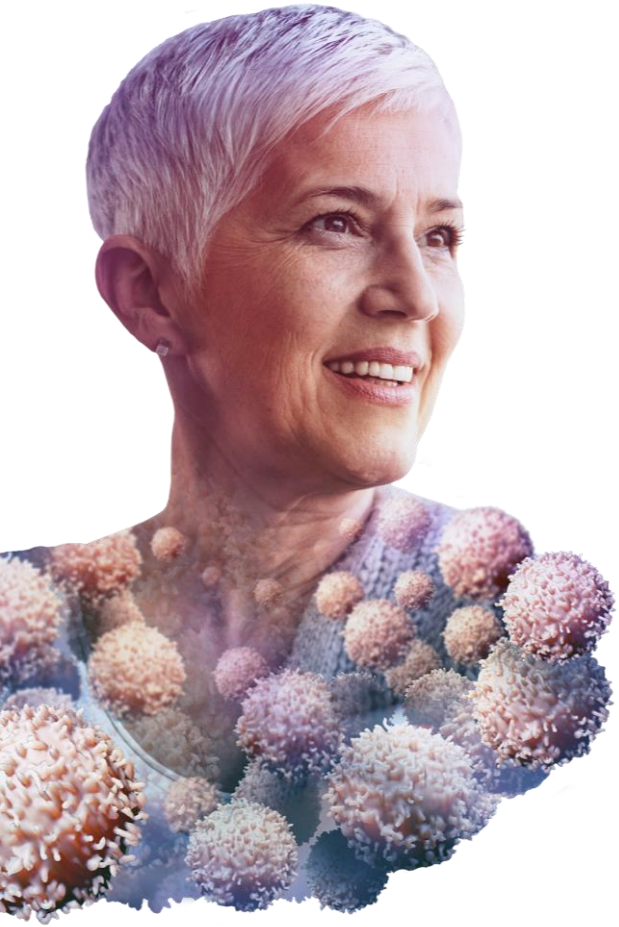

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HR+/HER2- Advanced breast cancer: what are the latest developments in CDK4/6 inhibition?

Professor Sibylle Loibl, Neu-Isenberg, Germany

Webinar recorded May 2019

This activity is supported by an educational grant from Eli Lilly and Company.

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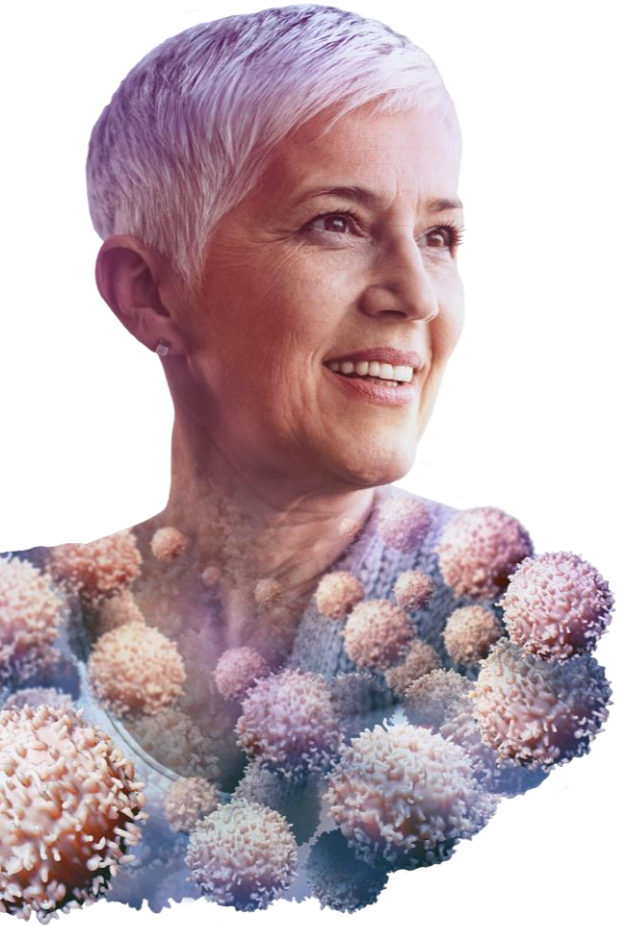

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HR+/HER2- Advanced breast cancer: what are the latest developments in CDK4/6 inhibition?

Professor Sibylle Loibl
Associate Professor at the University of Frankfurt and
Chief Executive Officer and Chair of the German Breast Group

Webinar recorded May 2019

This activity is supported by an educational grant from Eli Lilly and Company.

Disclosures

	Applicability	Company
(1) Advisory role	Yes	To institution: Pfizer, Roche, Puma, SeaGen, Lilly, AstraZeneca, Merck KG/Serono, Daiichi
(2) Stock ownership/profit	No	
(3) Patent royalties/licensing fees	No	
(4) Lecture fees	Yes	To institution: Roche, Novartis, Pfizer,
(5) Manuscript fees	No	
(6) Scholarship/research fund	Yes	To institution: AstraZeneca, Amgen, Celgene, Roche, Pfizer, Novartis, NSABP, ABCSG, BIG, Myriad, Cepheid,
(7) Other remuneration	No	

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Webinar overview

HR+/HER2- advanced breast cancer

- Part 1: ESMO Breast Cancer Congress 2019 – Latest findings on the role of CDK4/6i
- Part 2: ESMO Breast Cancer Congress 2019 – What does the future hold for patient identification and selection?
- Part 3: ESMO Breast Cancer Congress 2019 – What does the future hold for treatment management in the advanced setting?

CDK, cyclin-dependent kinase.

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Part 1.
ESMO Breast Cancer Congress 2019 – Latest findings on the role of CDK4/6i

Focus on CDK4/6 inhibitors for HR+/HER2- advanced breast cancer

CDK, cyclin-dependent kinase; HER2-, human epidermal growth factor receptor 2 negative; HR+, hormone receptor positive.

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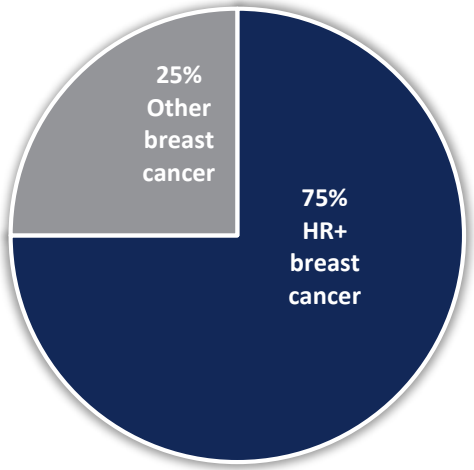
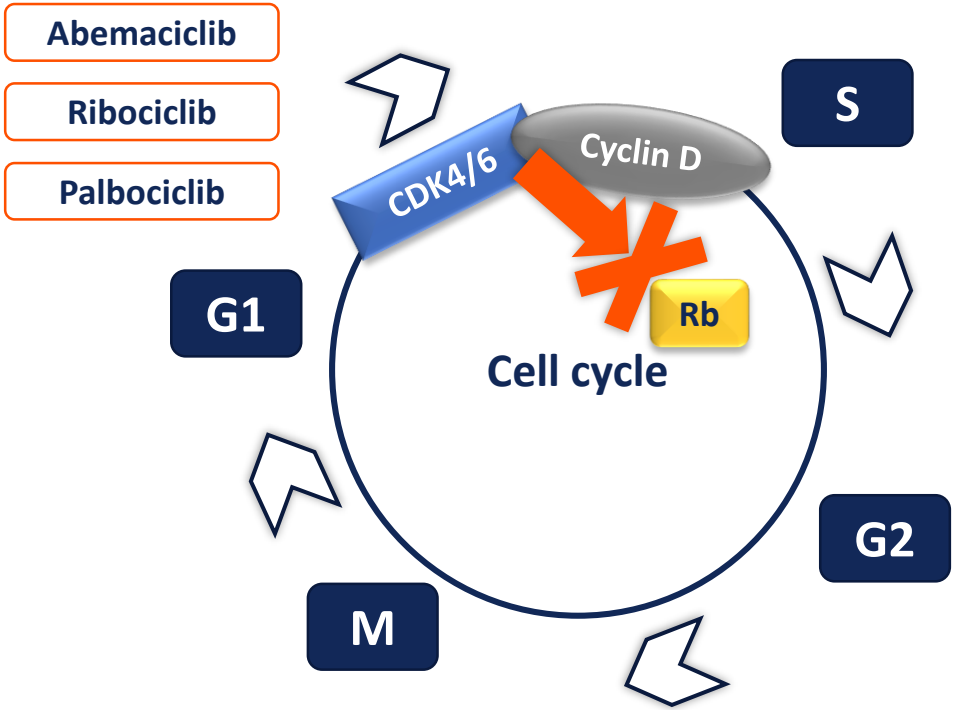
Breast cancer and CDK4/6 inhibitors





CDK4/6, cyclin-dependent kinase 4/6.

Perou CM, Sørlie T, Eisen MB, et al. *Nature* 2000;406:747–752; Vidula N and Rugo HS. *Clin Breast Cancer* 2016;16:8–17.

CDK 4/6 inhibitors + hormonal therapy for HR+/HER2- advanced breast cancer

	Trial	n	Treatment	PFS CDK4/6i	PFS placebo	HR (95%CI)
First-line, AI-sensitive	**PALOMA-2**	666	Letrozole+palbociclib Letrozole+placebo	27.6	14.5	0.56 (0.46–0.69)
	MONALEESA-2	668	Letrozole+ribociclib Letrozole+placebo	25.3	16.0	0.57 (0.46–0.70)
	MONARCH-3	493	AI+abemaciclib AI+placebo	28.8	14.8	0.54 (0.42–0.70)
	MONALEESA-3	367	Fulvestrant+ribociclib Fulvestrant+placebo	NR	18.3	0.58 (0.42–0.80)
Second-line/ endocrine resistant	**PALOMA-3**	521	Fulvestrant+palbociclib Fulvestrant+placebo	11.2	4.6	0·50 (0·40–0·62)
	MONARCH-2	669	Fulvestrant+abemaciclib Fulvestrant+placebo	16.4	9.3	0.55 (0.45–0.68)
	MONALEESA-3	345	Fulvestrant+ribociclib Fulvestrant+placebo	14.6	9.1	0.57 (0.43–10.74)

CDK, cyclin-dependent kinase; CI, confidence interval; HER2-, human epidermal growth factor receptor 2 negative; HR, hazard ratio; HR+, hormone receptor positive; PFS, progression-free survival.

Finn, *N Engl J Med.* 2016; Rugo H, SABCS 2017; Hortobagyi G, *N Engl J Med.* 2016 & *Ann Oncol* 2018; Goezt M, *J Clin Oncol.* 2017 & AACR 2018; Turner N, *N Engl J Med.* 2015, updated SABCS 2016; Cristofanilli M, *Lancet Oncol.* 2016; Sledge, *J Clin Oncol.* 2017; Slamon DJ, ASCO 2018.

CDK4/6 inhibitors in the advanced setting: adverse event profiles

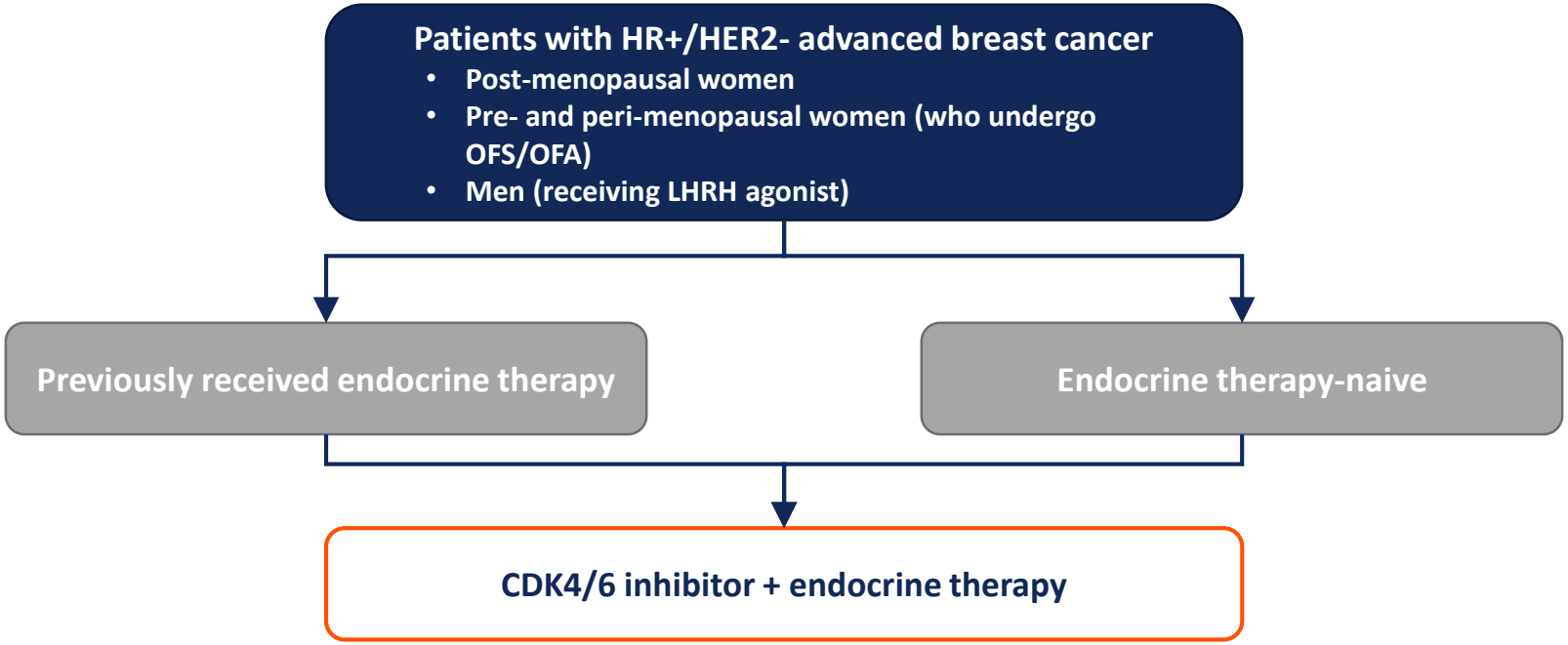
Most common grade 3/4 adverse events

Abemaciclib (MONARCH-3)[1]	Palbociclib (PALOMA-2)[2]	Ribociclib (MONALEESA-2)[3]
• Neutropenia 21.1% vs. 1.2% • Diarrhoea 9.5% vs. 1.2% • Leukopenia 7.6% vs. 0.6% • Anaemia 5.8% vs. 1.2%	• Neutropenia 66.4% vs. 1.4% • Leukopenia 24.8% vs. 0% • Anaemia 5.4% vs. 1.8% • Asthenia 2.3% vs. 0%	• Neutropenia, 62% vs. 7% • Leukopenia 21.3% vs. 0.9% • Abnormal LFTs 10.2% vs. 2.4% • Vomiting 3.6% vs. 0.9%

CDK, cyclin-dependent kinase; LFT, liver function test.

1. Goetz MP, et al. *J Clin Oncol.* 2017;35:3638–3646; 2. Finn RS, et al. *N Engl J Med.* 2016;375:1925–1936; 3. Hortobagyi GN, et al. *Ann Oncol.* 2018;29:1541–1547.

Treatment strategy for advanced breast cancer

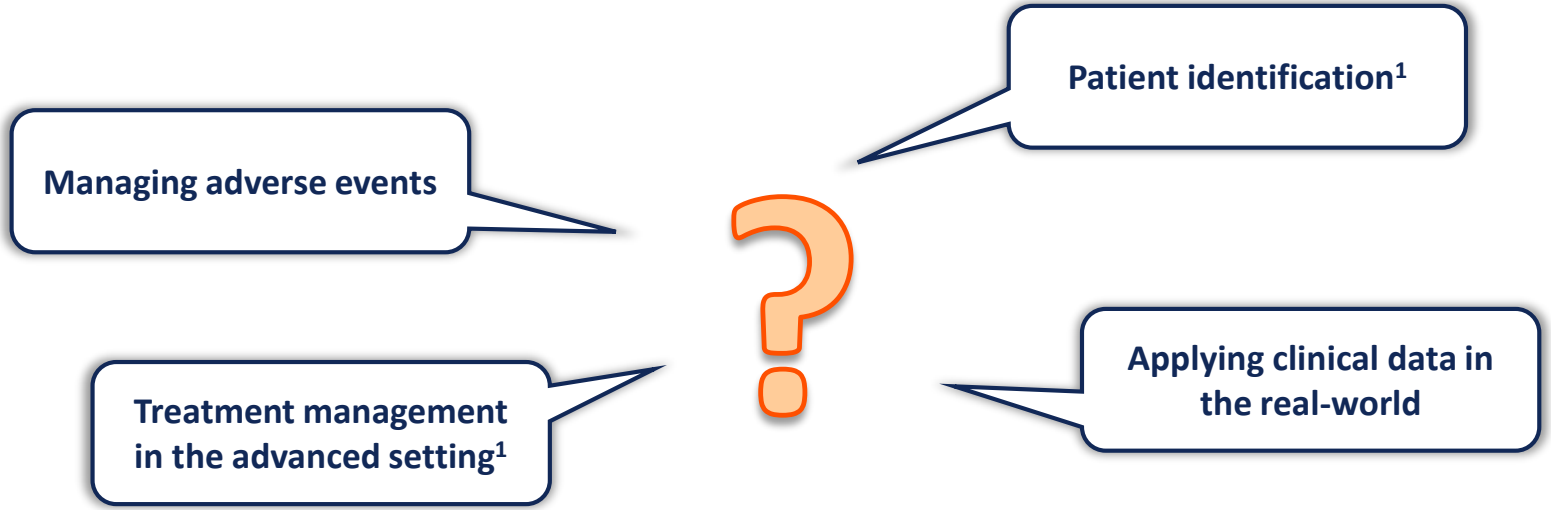


Endocrine therapy should be different from any prior treatments

CDK, cyclin-dependent kinase; HER2-, human epidermal growth factor receptor 2 negative; HR+, hormone receptor positive; LHRH, luteinizing hormone-releasing hormone; OFA, ovarian function ablation; OFS ovarian function suppression.

Cardoso F, et al. *Ann Oncol*. 2018;29:1634–1657; NCCN Clinical Practice Guidelines Breast Cancer. Version 1.2019. Available at NCCN.org.

Key challenges in the management of advanced breast cancer



Clinicians face important challenges in providing optimal care for patients with advanced breast cancer[1]

1. Hart CD, et al. *Nat Rev Clin Oncol.* 2015;12:541–552.

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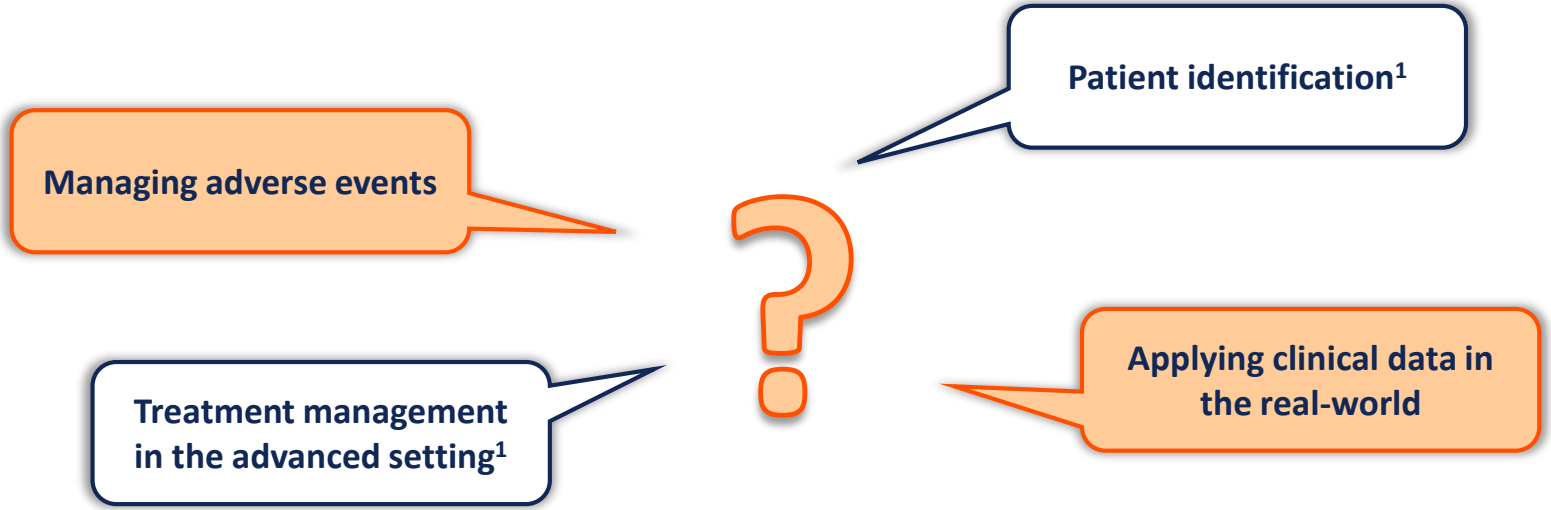

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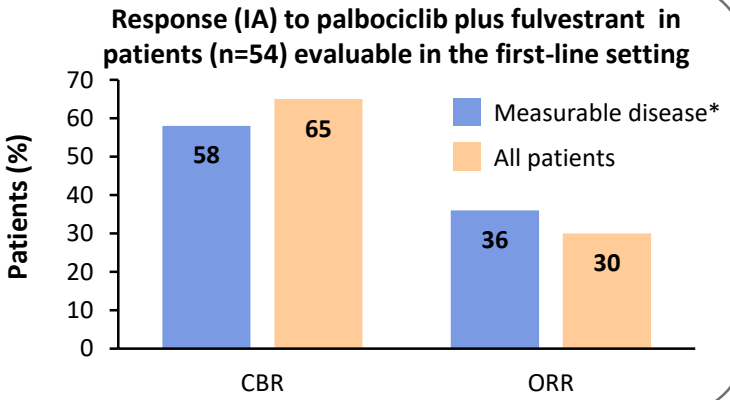
Efficacy of CDK4/6 inhibitors: further analyses support clinical trial results

A phase 2 study and a systematic literature review examined the efficacy of CDK4/6 inhibitors plus endocrine therapy in patients with HR+/HER2- advanced breast cancer

Interim analysis from a phase 2 study of the efficacy and safety of palbociclib plus fulvestrant in the first-, second- or later-line setting in patients with HR+/HER2- advanced breast cancer[1]



Systematic literature review[2]

- Cross-trial review of CDK4/6 inhibitors, including 7 clinical trials
- CDK4/6 inhibitors + ET were consistently associated with a 50% reduction in the rate of disease progression
- PFS did not change with subgroups

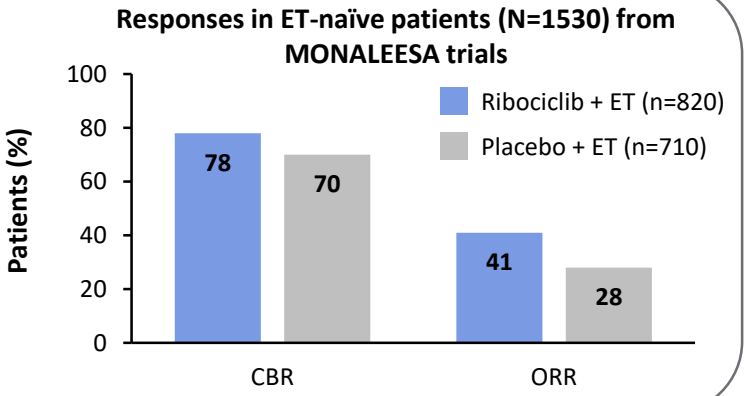
Results from a systematic literature review and a phase 2 study both supported the clinical benefit of CDK4/6 inhibitors in patients with HR+/HER2- advanced breast cancer

*Measurable disease by RECIST V1.1 in 36 patients.
CBR, clinical benefit rate; CDK, cyclin-dependent kinase; ET, endocrine therapy; HER2- human epidermal receptor 2-negative; HR+ hormone receptor-positive; IA, investigator-assessed; RECIST, Response Evaluation Criteria in Solid Tumours; ORR, overall response rate.
1. Welt A, et al. Poster 156P Presented at ESMO Breast Cancer Congress 2019; 2. D'Avanozo F, et al. Poster 160P Presented at ESMO Breast Cancer Congress.

Efficacy of CDK4/6 inhibitors: selecting patients for treatment

Analyses of pooled efficacy results and from a compassionate use programme assessed the response to CDK4/6 inhibitors in subgroups of patients with HR+/HER2- advanced breast cancer

Pooled analysis of ET-naïve patients with HR+/HER2- advanced breast cancer from the MONALEESA-2 (all patients), MONALEESA-3 (ET-naïve only) and MONALEESA-7 (NSAI only) phase 3 trials[1]



Retrospective observational analysis[2]

- CUP of palbociclib in patients with HR+/HER2- MBC who have received ≥4L of prior therapy
- Palbociclib plus ET showed encouraging activity in this patient population

In a variety of subgroups of patients, including those who were ET-naïve and those who had received multiple lines of therapy, CDK4/6 inhibitors have shown activity

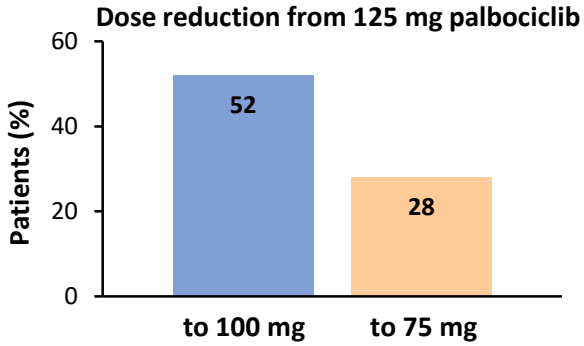
CBR, clinical benefit rate; CDK, cyclin-dependent kinase; CUP, compassionate use programme; ET, endocrine therapy; HER2- human epidermal receptor 2-negative; HR+ hormone receptor-positive; MBC, metastatic breast cancer; ORR, overall response rate; PFS, progression-free survival.

1. Tripathy D, et al. Poster 155P Presented at ESMO Breast Cancer Congress 2019; 2. Manso L, et al. Poster 193P Presented at ESMO Breast Cancer Congress 2019.

Using CDK4/6 inhibitors in the real world: recent safety findings

Several studies examined the management of adverse events associated with CDK4/6 inhibitors in patients with HR+/HER2- advanced breast cancer, in a real-world setting

Retrospective and ongoing analysis of palbociclib in daily clinical use in patients (n=75) with HR+ MBC[1]



Analysis of women with HR+/HER2- MBC included in the MARIA registry to determine the prevalence of GI symptoms[2]

Mean differences (SEM) in FACT-G scores between the 'any' and 'no symptoms' groups

	Baseline	3 months	6 months
Diarrhoea	-5.0 (2.4)*	-8.5 (3.7)*	-6.5 (2.9)*
Vomiting	-13.4 (2.3)***	-17.6 (4.3)***	-15.6 (2.6)***

*p <0.05, *** p<0.001

The safety findings presented supported the results from clinical trials, highlighted the need for monitoring and individualized decision-making and demonstrated the role of dose reduction in managing AEs

AEs, adverse events; CDK, cyclin-dependent kinase; FACT-G, Functional Assessment of Cancer Therapy-General; HER2- human epidermal receptor 2-negative; HR+ hormone receptor-positive; MBC, metastatic breast cancer; SEM, standard error of the mean.

1. Hester A, et al. Poster 180P Presented at ESMO Breast Cancer Congress 2019; 2. Brucker S, et al. Poser 171P Presented at ESMO Breast Cancer Congress 2019.

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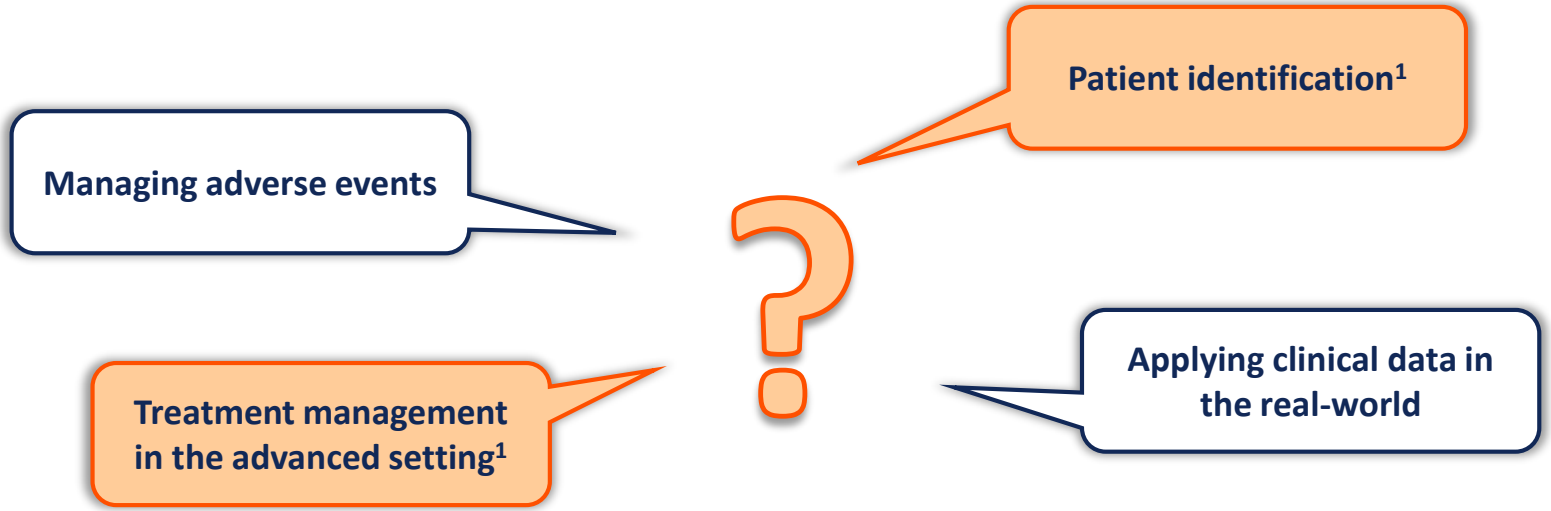
What does the future hold?



Clinicians face important challenges in providing optimal care for patients with advanced breast cancer[1]

1. Hart CD, et al. *Nat Rev Clin Oncol.* 2015;12:541–552.

Part 2.
ESMO Breast Cancer Congress 2019 – What does the future hold for patient identification and selection?

Focus on HR+/HER2- advanced breast cancer

HER2-, human epidermal growth factor receptor 2 negative; HR+, hormone receptor positive.

First report of AURORA, the Breast International Group (BIG) molecular screening initiative for metastatic breast cancer (MBC) patients

Aftimos PG, et al.

AURORA is a European multi-centre study that performs TGS on DNA extracted from primary tumour, biopsy of a metastasis, whole blood and ctDNA samples from patients with MBC, at diagnosis or after first-line therapy

- Molecular results are available for 381 patients, enrolled up to November 2017, including 232 HR+/HER2-, 69 HER2+, 77 TNBC, 3 N/A
- Clinical factors analyzed: *de novo* and bone-only MBC, endocrine resistance; patients treated with targeted agents; chemotherapy-resistant TNBC and BC with late relapse
- Molecular factors analyzed are: mechanisms of resistance; activating drivers; somatic and germline alterations in DNA-damage repair genes

The findings from the AURORA study contribute to the understanding of the molecular profiles of patients with MBC and in the future may inform patient identification and clinical decision-making

BC, breast cancer; ctDNA, circulating tumour DNA; HER2- human epidermal receptor 2-negative; HR+ hormone receptor-positive; MBC, metastatic breast cancer; N/A, not available; TGS, targeted gene sequencing; TNBC, triple-negative breast cancer.

Afitimos PG, et al. Oral 152O Presented at ESMO Breast Cancer Congress 2019.

Double PIK3CA mutations in *cis* enhance PI3Kα oncogene activation and sensitivity to PI3Kα inhibitors in breast cancer

Vasan N, et al.

Comprehensive analysis of double PIK3CA mutations to assess the biological relevance and correlation with sensitivity to PI3Kα

Double PIK3CA mutations

Located in *cis*

PIK3CA

- Present in 12–15% of breast cancers and other tumours
- Composed of a single hotspot mutation plus a recurrent second-site mutation

Altered biological mechanisms

- Increased disruption of p110α binding to the inhibitory subunit p85α
- Increased membrane lipid binding

Increased oncogenicity

- Increased PI3K activity and downstream signalling
- Enhanced cell proliferation and tumour growth

Double PIK3CA mutations predict for increased sensitivity to PI3Kα inhibitors compared with single hotspot mutations

Double PIK3CA mutations in *cis* is a hypermorphic oncogene compared with single hotspot mutations and therefore are an important therapeutic target

PI3K, Phosphoinositide 3-kinase; PIK3CA, phosphatidylinositol 4,5-bisphosphate 3-kinase catalytic subunit alpha isoform.

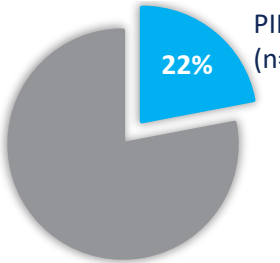
Vasan N, et al. Oral 1O Presented at ESMO Breast Cancer Congress 2019.

Outcome and mutational landscape of patients with PIK3CA-mutated metastatic breast cancer (MBC)

Mosele FF, et al.

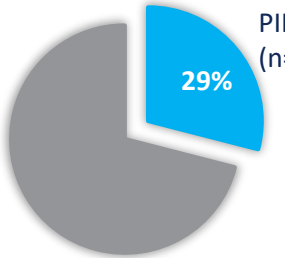
Patients (n=649) with MBC from the SAFIR02 trial with available mutational profile and clinical data were selected to assess the natural history of PIK3CA mutation-positive breast cancer

Study population



PIK3CA mutations (n=143)

Patients with HR+/HER2- MBC



PIK3CA mutations (n=104)

Patients with HR+/HER2- MBC

Less sensitive to chemotherapy with PIK3CA mutation than WT

mOS was 19.6 months with PIK3CA mutation vs. 23.5 months for WT (p=0.048)

Tumours with PIK3CA mutations were enriched with MAP3K1 mutations vs. WT (17% vs. 5%; p=0.0002)

Patients with PIK3CA mutation-positive HR+/HER2- MBC were less sensitive to chemotherapy and experience a shorter survival

HER2- human epidermal receptor 2-negative; HR+ hormone receptor-positive; MAP3K1, mitogen-activated protein kinase kinase kinase 1; MBC, metastatic breast cancer; mOS, median overall survival; PI3K, Phosphoinositide 3-kinase; PIK3CA, phosphatidylinositol 4,5-bisphosphate 3-kinase catalytic subunit alpha isoform; WT, wild-type.

Mosele FF, et al. Oral 149O Presented at ESMO Breast Cancer Congress 2019.

Summary

- PIK3CA mutation is clinically currently one of the most relevant somatic mutations
- About 30–40% of breast cancer patients with HR+/HER2- disease harbour a mutation
- Patients with a PIK3CA mutation being HR+/HER2- have an inferior outcome, but this seems different in TNBC
- Double mutations of PIK3CA are less frequent, about 10%, but seem to respond better

HER2- human epidermal receptor 2-negative; HR+ hormone receptor-positive; PIK3CA, phosphoinositide-3-kinase, catalytic, alpha polypeptide; TNBC, triple-negative breast cancer.

Part 3.
ESMO Breast Cancer Congress 2019 – What does the future hold for treatment management in the advanced setting?

Focus on HR+/HER2- advanced breast cancer

HER2-, human epidermal growth factor receptor 2 negative; HR+, hormone receptor positive.

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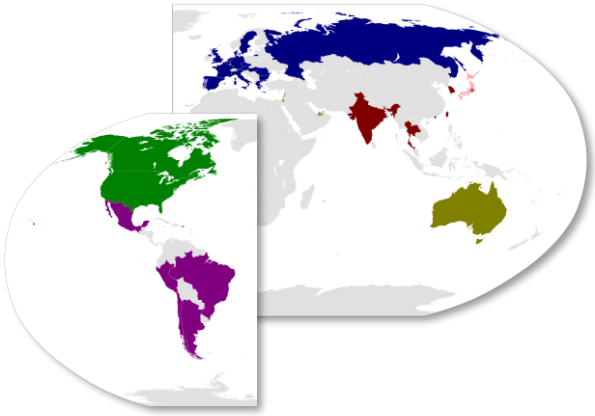
Response rate by geographic region in patients with hormone receptor-positive, human epidermal growth factor receptor-2–negative advanced breast cancer from the SOLAR-1 trial

Loibl S, et al.

***Post-hoc* analysis of the consistency of treatment effects by geographic region in patients with PIK3CA-mutation positive HR+/HER2- ABC in the phase 3 SOLAR-1 trial**

- Improved PFS consistent with the overall patient population particularly in Europe, North America, and Asia
- In Asia, Latin America, and Other, limited conclusions can be drawn, as the 95% confidence intervals are large
- Higher ORR across regions with similar trends observed in Europe, North America, and Latin America, consistent with overall population



In Asia, not including Japan*, a higher ORR was observed, and no difference in ORR was observed in Other, in patients treated with alpelisib plus fulvestrant

Analysis of efficacy by geographic region showed similar findings to the overall efficacy outcomes from SOLAR-1 for alpelisib when used in combination with fulvestrant in patients with HR+, HER2– ABC

*Per SOLAR-1 protocol.

ABC, advanced breast cancer; HER2- human epidermal receptor 2-negative; HR+ hormone receptor-positive; PFS, progression-free survival; PIK3CA, phosphatidylinositol 4,5-bisphosphate 3-kinase catalytic subunit alpha isoform; ORR, overall response rate.

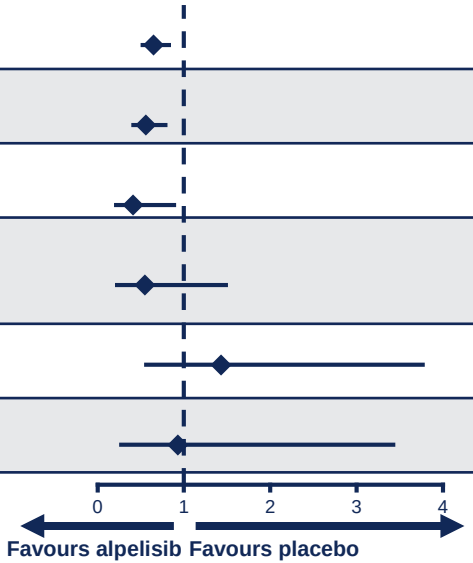
Loibl S, et al. Oral 149O Presented at ESMO Breast Cancer Congress 2019.

Response rate by geographic region in patients with hormone receptor-positive, human epidermal growth factor receptor-2–negative advanced breast cancer from the SOLAR-1 trial

Loibl S, et al.

Patients in the PIK3CA mutation-positive cohort

Region	Total, n	Alpelisib plus fulvestrant		Placebo plus fulvestrant		HR (95% CI)
		Events/N (%)	PFS, months (95% CI)	Events/N (%)	PFS, months (95% CI)	
Overall[1]	**341**	**103/169 (60.9)**	**11.0 (7.5, 14.5)**	**129/172 (75.0)**	**5.7 (3.7, 7.4)**	**0.65 (0.50, 0.85)**
Europe	173	50/86 (58.1)	11.0 (7.36, 19.12)	67/87 (77.0)	3.6 (2.07, 7.23)	0.56 (0.39, 0.81)
North America	43	11/19 (57.9)	15.2 (5.45, NE)	21/24 (87.5)	3.6 (1.61, 8.38)	0.41 (0.19, 0.91)
Asia, not including Japan[a]	34	9/15 (60.0)	14.5 (4.07, 16.76)	14/19 (73.7)	9.0 (3.75, 14.06)	0.55 (0.20, 1.51)
Latin America	31	9/14 (64.3)	9.4 (3.75, NE)	9/17 (52.9)	12.9 (3.65, NE)	1.43 (0.54, 3.79)
Other	24	13/18 (72.2)	6.5 (3.84, 12.94)	3/6 (50.0)	NE (1.81, NE)	0.93 (0.25, 3.45)



[a] Per SOLAR-1 protocol, Asia subgroup included Japan; a separate, dedicated analysis was conducted including only patients from the Japanese sites (n=68), and is not included in the current analysis.

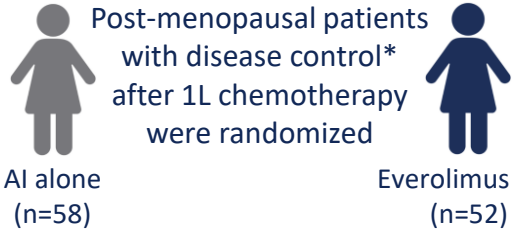
CI, confidence interval; HR, hazard ratio; NE, not evaluable; PFS, progression-free survival; PIK3CA, phosphatidylinositol 4,5-bisphosphate 3-kinase catalytic subunit alpha isoform.

Loibl S, et al. Oral 149O Presented at ESMO Breast Cancer Congress 2019. 1. Andre F, et al. ESMO 2018. Abstract LBA3 [oral].

Everolimus plus aromatase inhibitors vs. aromatase inhibitors as maintenance therapy after first-line chemotherapy in HR+/HER2- metastatic breast cancer: Final results of the phase 3 randomized MAIN-A trial

Guarneri V, et al.

Phase 3 trial to assess whether maintenance everolimus plus AI can prolong PFS compared with AI alone in patients who had received 1L chemotherapy for HR+/HER2- MBC



	PFS events	mPFS, months (95% CI)	
Everolimus + AI	40	9.9	7.4–13.8
AI alone	48	7.2	4.7–10.9
mPFS HR (95% CI)		0.764 (0.501–1.164)	

- Treatment-related AEs were reported for 87% of patients in the everolimus + AI arm and 26% in the AI alone arm
- Most common AEs ≥Grade 2 in the everolimus + AI arm were stomatitis (19.2%), neutropenia (9.6%), interstitial pneumonia (7.7%) and skin toxicity (7.7%)

In this first study of maintenance therapy in patients with HR+/HER2- MBC, addition of everolimus to an AI extended PFS, but the increase was not significant

*Disease control = stable disease, partial response or complete response.

1L, first-line; AEs, adverse events; AI, aromatase inhibitor; CI, confidence interval; HER2- human epidermal receptor 2-negative; HR, hazard ratio; HR+ hormone receptor-positive; MBC, metastatic breast cancer; mPFS, median progression-free survival; PFS, progression-free survival.

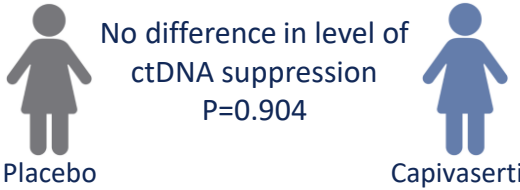
Guarneri V, et al. Oral LBA2 Presented at ESMO Breast Cancer Congress 2019.

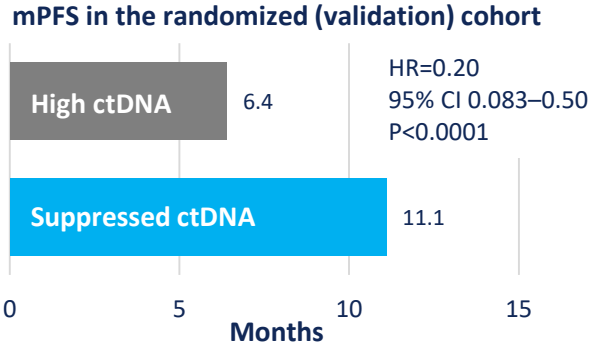
Utility of early circulating tumour DNA dynamics as a surrogate for progression-free survival in the BEECH phase 1/2 trial in metastatic breast cancer

Hrebien S, et al.

Plasma samples were collected from patients with HR+ MBC in the phase 1/2 BEECH study randomized to capivasertib or placebo plus paclitaxel to assess ctDNA as a surrogate for PFS

- ctDNA suppression was evident after 8 days of treatment, in the safety run-in (development) cohort
- Day 1, cycle 2 was identified as the optimal time point to predict PFS from early ctDNA





Early on-treatment ctDNA dynamics can be used as a surrogate for PFS in patients with HR+ MBC

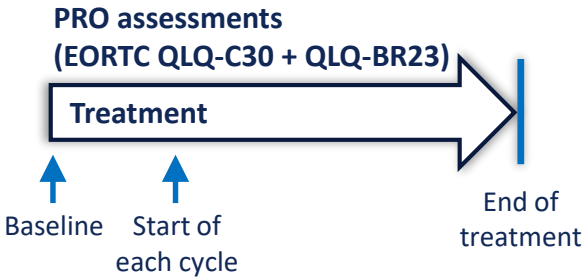
CI, confidence interval; ctDNA, circulating tumour DNA; HER2- human epidermal receptor 2-negative; HR, hazard ratio; HR+ hormone receptor-positive; MBC, metastatic breast cancer; mPFS, median progression-free survival.

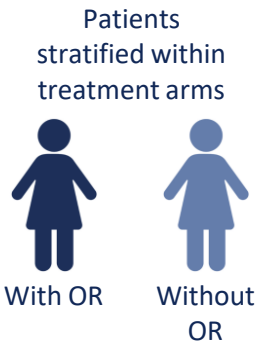
Hrebien S, et al. Oral 6O Presented at ESMO Breast Cancer Congress 2019.

Impact of objective response (OR) on patient-reported outcomes (PRO) in patients (pts) with advanced breast cancer (ABC) and a germline BRCA1/2 (gBRCA) mutation in the phase 3 EMBRACA trial

Fasching PA, et al.

Post-hoc **analysis to evaluate the effects of OR on PRO in patients with ABC included in the phase 3 EMBRACA trial comparing talazoparib with physician's choice of chemotherapy**





Delay in TTD of GHS/QoL: with OR vs. without OR

Arm	HR, 95% CI
Combined	0.67 (0.46–0.98)
Talazoparib	0.78 (0.49–1.24)
Chemotherapy	0.85 (0.43–1.71)

Change from baseline in QoL scores and the delay in time to clinically meaningful deterioration in QoL favoured patients who experienced OR, suggesting higher OR rates may lead to improved QoL in patients with MBC and a gBRCA mutation

ABC, advanced breast cancer; CI, confidence interval; GHS, global health status; HER2- human epidermal receptor 2-negative; HR, hazard ratio; HR+ hormone receptor-positive; OR, objective response; PRO, patient-reported outcomes; QoL, quality of life; TTD, time to definitive clinically meaningful deterioration.

Fasching PA, et al. Oral 154O Presented at ESMO Breast Cancer Congress 2019.

Summary

- Alpelisib is an alpha-specific PI3 kinase inhibitor which increases PFS and ORR when given to women with HR+/HER2- MBC and a PIK3CA mutation
- Differences between regions (if any) appear to mainly be in the toxicity profile; PFS was consistent between Europe and the US and differed in other regions
- Talazoparib is a PARP inhibitor that improved PFS in gBRCA carriers either with TNBC or HR+/HER2- tumour
- Change from baseline in QoL scores and the delay in time to clinically meaningful deterioration in QoL, favoured patients who experienced OR, suggesting higher OR rates may lead to improved QoL in patients with MBC and a gBRCA mutation

HER2- human epidermal receptor 2-negative; HR, hazard ratio; HR+ hormone receptor-positive; MBC, metastatic breast cancer; OR, objective response; ORR, objective response rate; PARP, poly ADP ribose polymerase PFS, progression-free survival; PI3K, Phosphoinositide 3-kinase; PIK3CA, phosphatidylinositol 4,5-bisphosphate 3-kinase catalytic subunit alpha isoform; QoL, quality of life; TNBC, triple-negative breast cancer.

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