



KLINIKUM
DER UNIVERSITÄT MÜNCHEN

CAMPUS GROSSHADERN
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KLINIK UND POLIKLINIK FÜR FRAUENHEILKUNDE UND GEBURTSHILFE
DIREKTOR: PROF. DR. MED. SVEN MAHNER



SABCS

SAN ANTONIO BREAST CANCER SYMPOSIUM
December 10-14, 2019
Henry B. Gonzalez Convention Center
San Antonio, Texas, USA



SABCS 2019: Meine persönlichen Highlights

Nadia Harbeck

Brustzentrum, Klinik für Frauenheilkunde und Geburtshilfe
Klinikum der Universität München



KLINIK UND POLIKLINIK FÜR FRAUENHEILKUNDE
in Zusammenarbeit mit dem St. Elisabeth Krankenhaus
Leipzig und dem Klinikum St. Georg

3. Leipziger Post-SABCS

Neues zur Behandlung des Mammakarzinoms

Mittwoch, 22. Januar 2020
16.30 – 20.00 Uhr



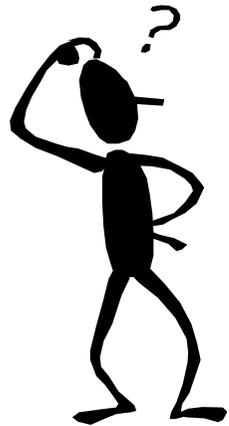
**Brustzentrum der
Universität München**

Leitung:
Prof. Nadia Harbeck

Was war wichtig für die Klinik morgen ?



SAN ANTONIO BREAST CANCER SYMPOSIUM
December 10-14, 2019
Henry B. Gonzalez Convention Center
San Antonio, Texas, USA



Frühes Mammakarzinom

- Prognose verbessert sich mit moderner Therapie
 - HR+: EBCTCG Metaanalyse
 - HER2+: APHINITY; ATEMPT
- Immuntherapie: Viel Hoffnung, noch mehr Fragezeichen
TNBC: Keynote 522; NeoTRIPaPDL1

Fortgeschrittene Erkrankung: Neue Hoffnung

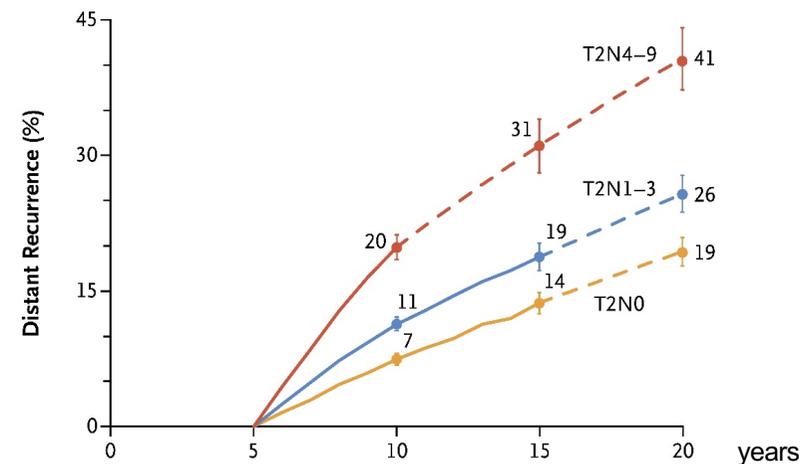
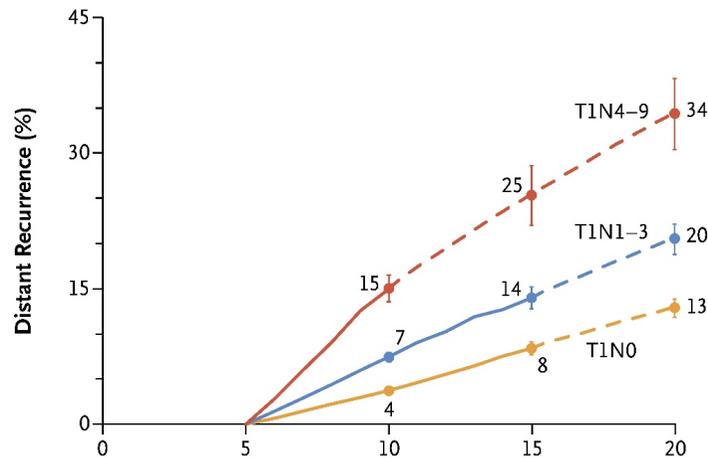
- HER2+: HERCLIMB; Destiny-Breast 01
- HR+: PEARL

Ausblick 2020

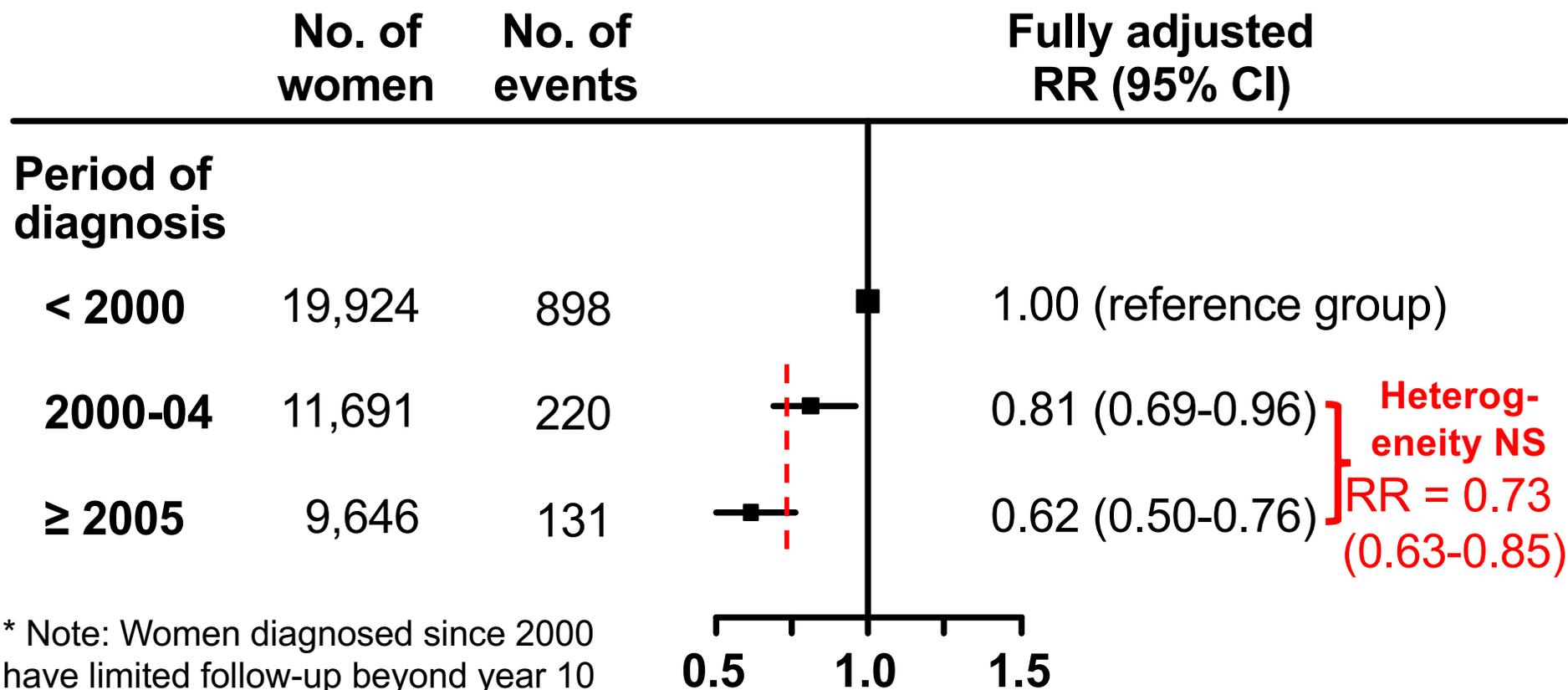


Adjuvant endocrine therapy (ET) in ER+ disease

- In women given 5 years adjuvant ET, appreciable risks continue during years 5-20, even for T1N0
- After 5 years of ET for N0 disease, the risks of distant recurrence during years 5-20 were reported to be T1N0: 13% & T2N0: 19%



EBCTCG analyses (n=86,000; 110 trials) - ER+ **NO** disease: Distant recurrence during years 5-9,* by period of diagnosis



Genexpressionstestung in der Regelversorgung

Neu
2019

Pressemitteilung



Gemeinsamer Bundesausschuss gemäß § 91 SGB V

Nr. 17 / 2019

Methodenbewertung

Unterstützung der Therapieentscheidung bei Brustkrebs im Frühstadium: Biomarker-Test künftig Kassenleistung

Berlin, 20. Juni 2019 – Der Gemeinsame Bundesausschuss (G-BA) hat am Donnerstag in Berlin einen ersten Beschluss zum Einsatz von biomarkerbasierten Tests gefasst. Patientinnen mit Brustkrebs im frühen Stadium, bei denen das Rückfallrisiko nicht sicher bestimmt werden kann, können künftig einen Biomarker-Test als Leistung der gesetzlichen Krankenversicherung (GKV) in Anspruch nehmen. Die Ergebnisse sollen bei bestehender Unsicherheit hinsichtlich des zu erwartenden individuellen Nutzens einer Chemotherapie die gemeinsame Entscheidungsfindung von Patientinnen und Ärztinnen und Ärzten unterstützen. Für die ärztliche Aufklärung vor der Durchführung des Tests legt der G-BA die verpflichtende Verwendung einer [Patientinneninformation](#) fest, die auf den Internetseiten des G-BA als ausdrückbare Datei bereitgestellt wird.

Seite 1 von 3

Stabsabteilung Öffentlichkeitsarbeit und Kommunikation

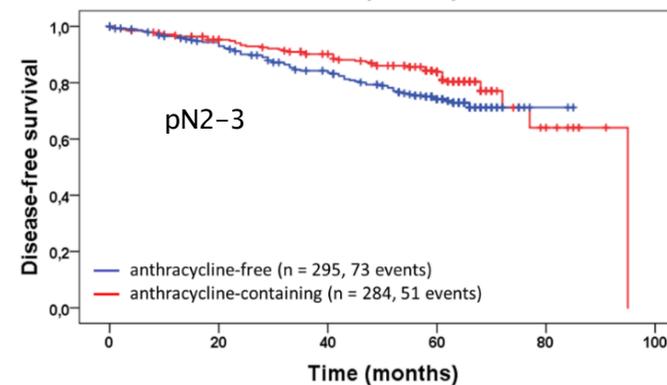
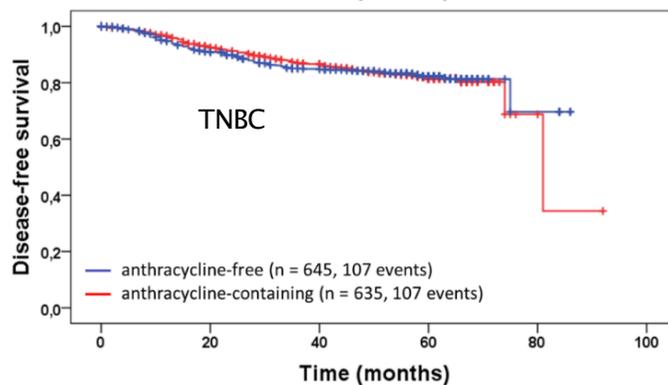
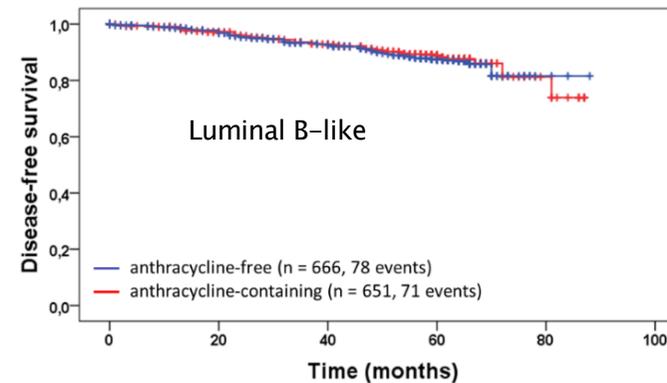
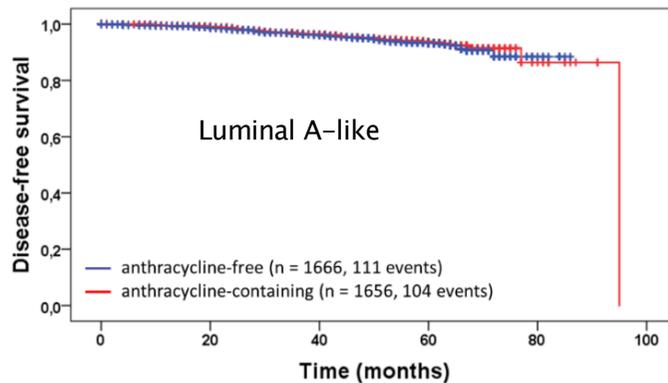
Gutenbergstraße 13, 10587 Berlin
Postfach 120606, 10596 Berlin

Telefon: 030 275838-811
Fax: 030 275838-805
E-Mail: presse@g-ba.de

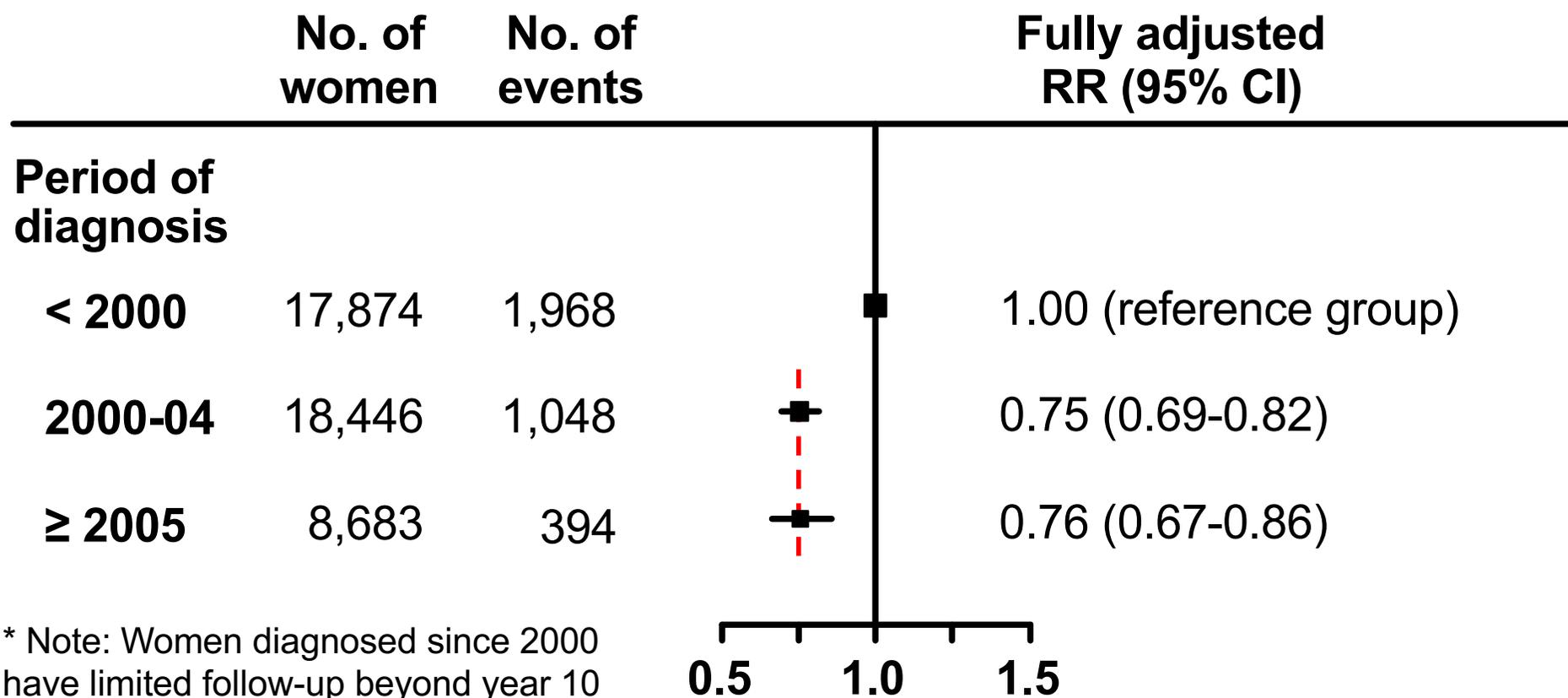
www.g-ba.de
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Ansprechpartnerinnen
für die Presse:
Kristine Reis (Ltg.)
Gudrun Köster
Annette Steger

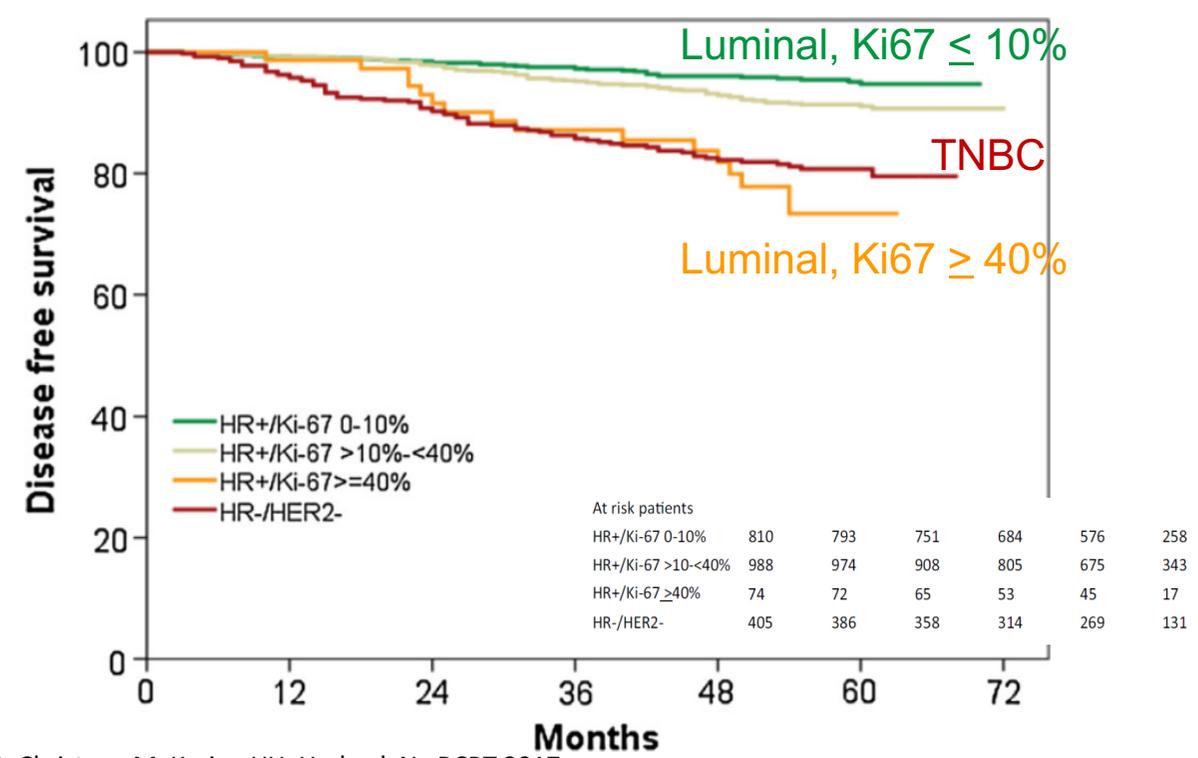
Pooled analysis PlanB und SUCCESS C: DFS nach 6x TC vs. Anthrazyklin-Taxan Sequenz (62 Monate medianes Follow-up; n=5923)



EBCTCG analyses (n=86,000; 110 trials) - ER+ **N+** disease: Distant recurrence during years 5-9,* by period of diagnosis



PlanB: 5-Jahres DFS in molekularen Subgruppen

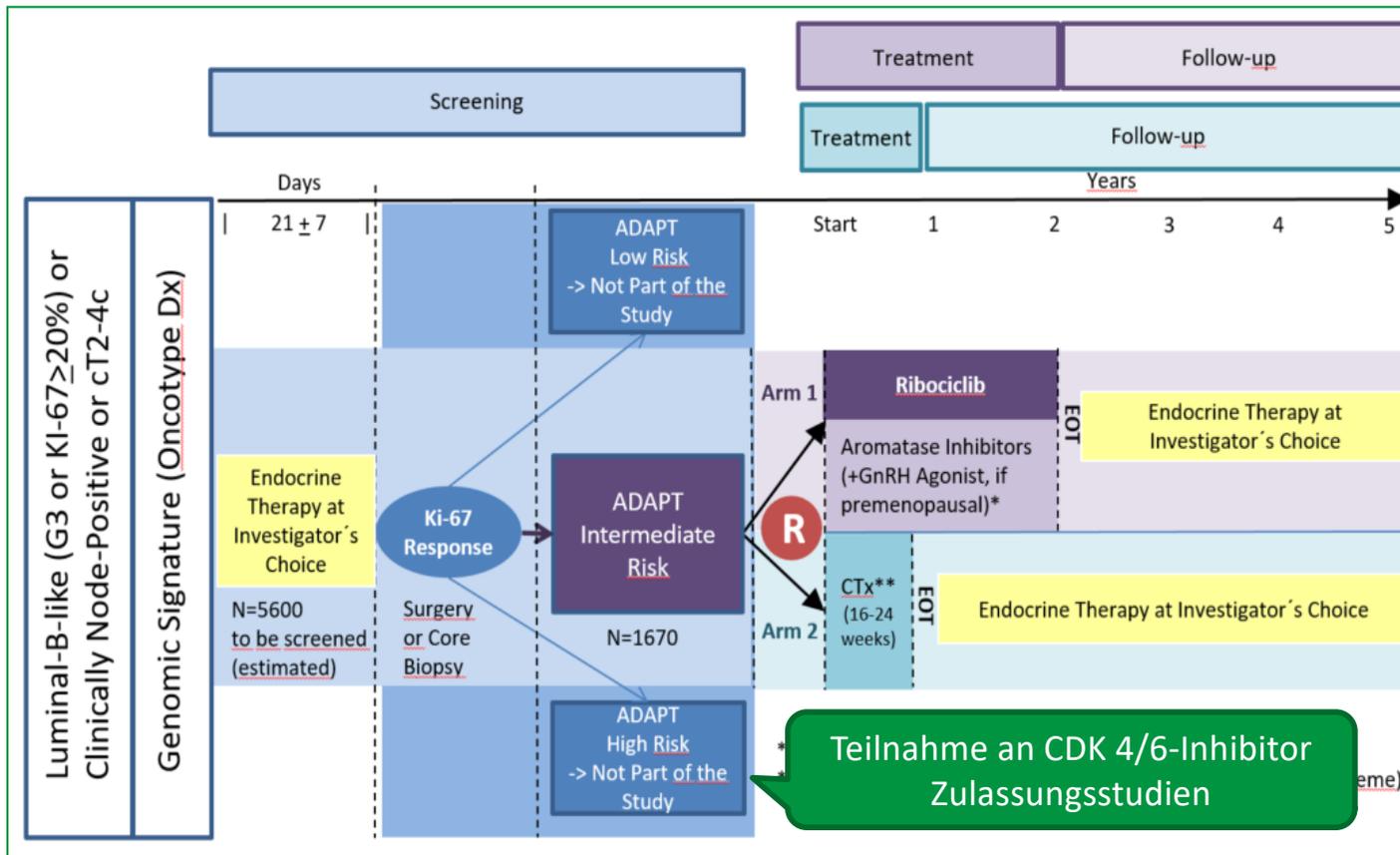


Gluz et al, ESMO 2017; Nitz U, Gluz O, Christgen M, Kreipe HH, Harbeck N; BCRT 2017

Adjuvante Studien mit CDK 4/6i

PALLAS NCT02513394	PENELOPE B NCT01864746	MONARCH E NCT03155997	NATALEE NCT03701334	ADAPTcycle EudraCT 2018-003749-40)
5792 (M, W)	1250 (W)	4580 (M, W)	4000 (M, W)	1670 (W) – 5600 screened
Palbociclib ₁₂₅	Palbociclib ₁₂₅	Abemaciclib ₁₂₅	Ribociclib ₄₀₀	Ribociclib ₆₀₀
2 years	1 year (after non-pCR)	2 years	3 years	2 years (vs.chemo)
iDFS	iDFS	iDFS	iDFS	DFS; 5y DDFS > 92%
completed	completed	completed	started 2019	started 2019
ABCSG, BIG GBG, NSABP, PrECOG	GBG, AGO-B, BIG, NSABP	Lilly	TRIO	WSG

ADAPTcycle



Teilnahme an CDK 4/6-Inhibitor Zulassungsstudien

N0*-1: Low or Intermediate risk RS (≤ 25) ohne bzw. high risk RS (> 25) mit endokrinem Ansprechen

N2-3: RS ≤ 25 mit endokrinem Ansprechen

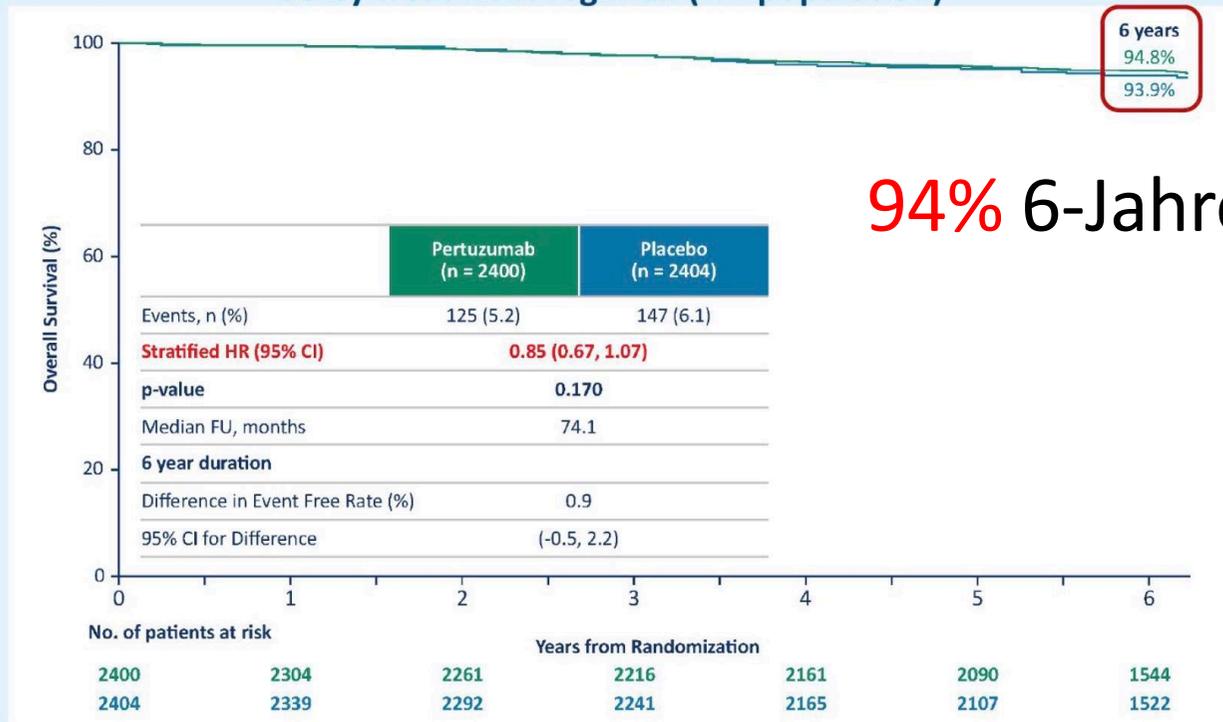
APHINITY: Interim OS



SAN ANTONIO BREAST CANCER SYMPOSIUM
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San Antonio Breast Cancer Symposium®, December 10-14, 2019 APHINITY Interim Overall Survival Analysis 74.1 months median FU, OS by treatment regimen (ITT population)



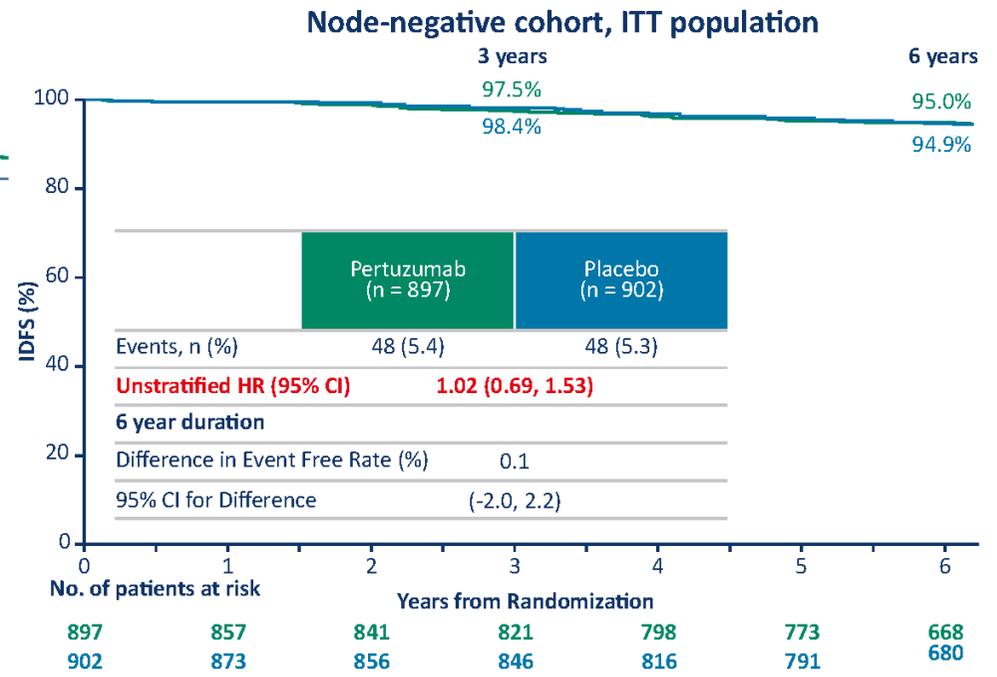
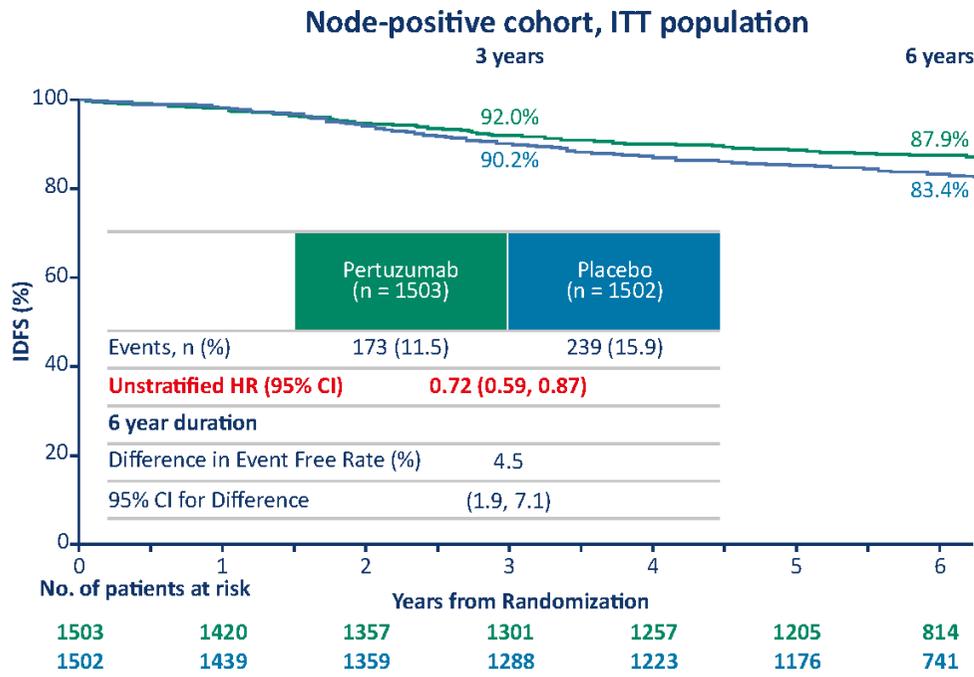
94% 6-Jahresüberleben

P-value of 0.0012 is required for statistical significance for OS. Survival data remain immature at this time.

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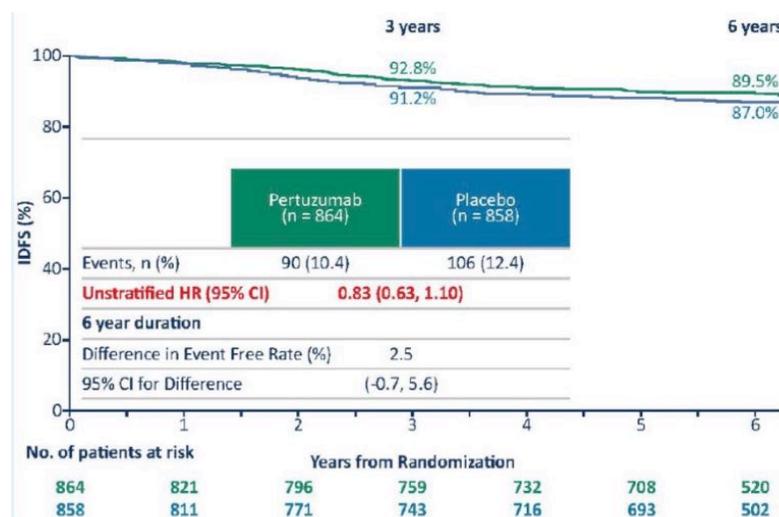
APHINITY Updated descriptive analysis 74.1 months median FU Time to first IDFS event by treatment regimen and nodal status

The node positive cohort continues to derive clear benefit from addition of pertuzumab.



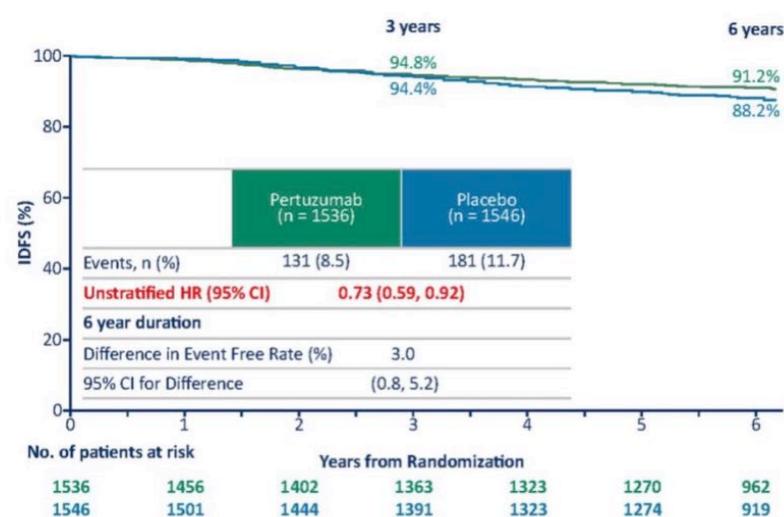
APHINITY: updated iDFS – HR status

HR positive cohort ITT population



6y Δ: 2.5%

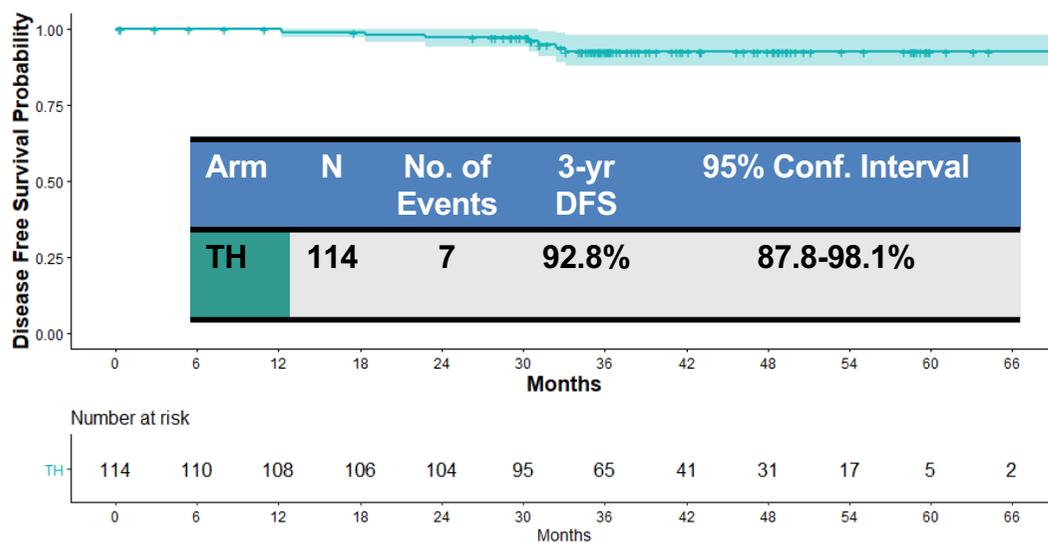
HR negative cohort ITT population



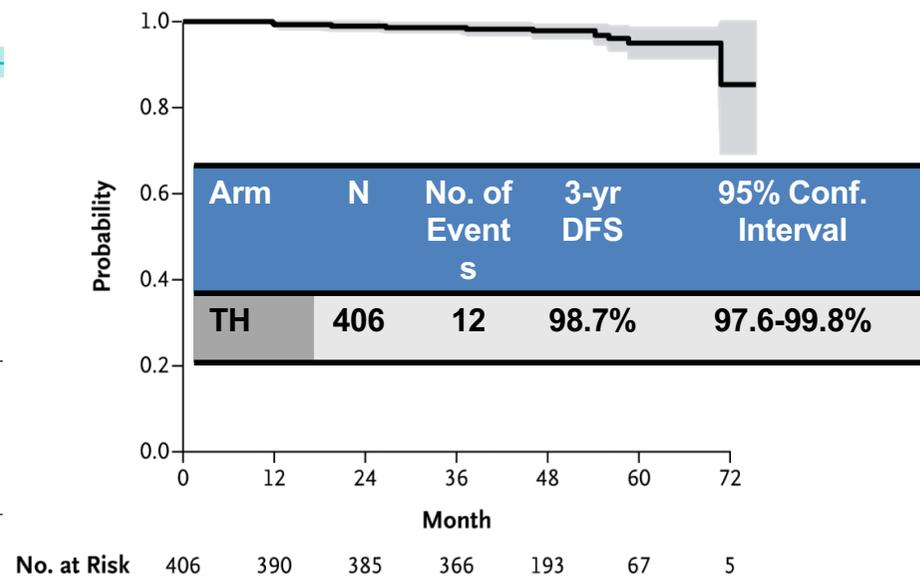
6y Δ: 3.0%

Disease-Free Survival: TH

TH (ATEMPT Trial): n=114



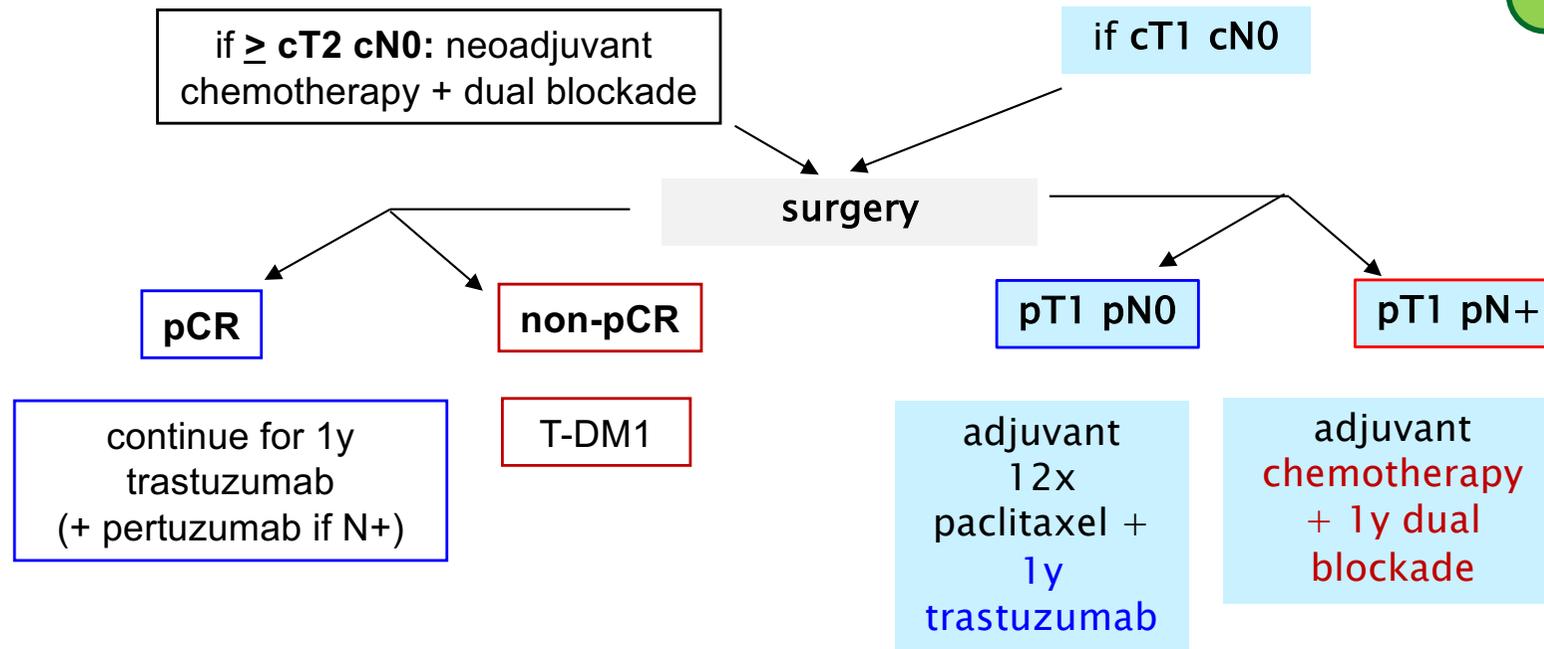
TH (APT Trial): n=406



Tolaney S et al, NEJM 2015

HER2+ EBC: Therapiealgorithmus

Neu
2019

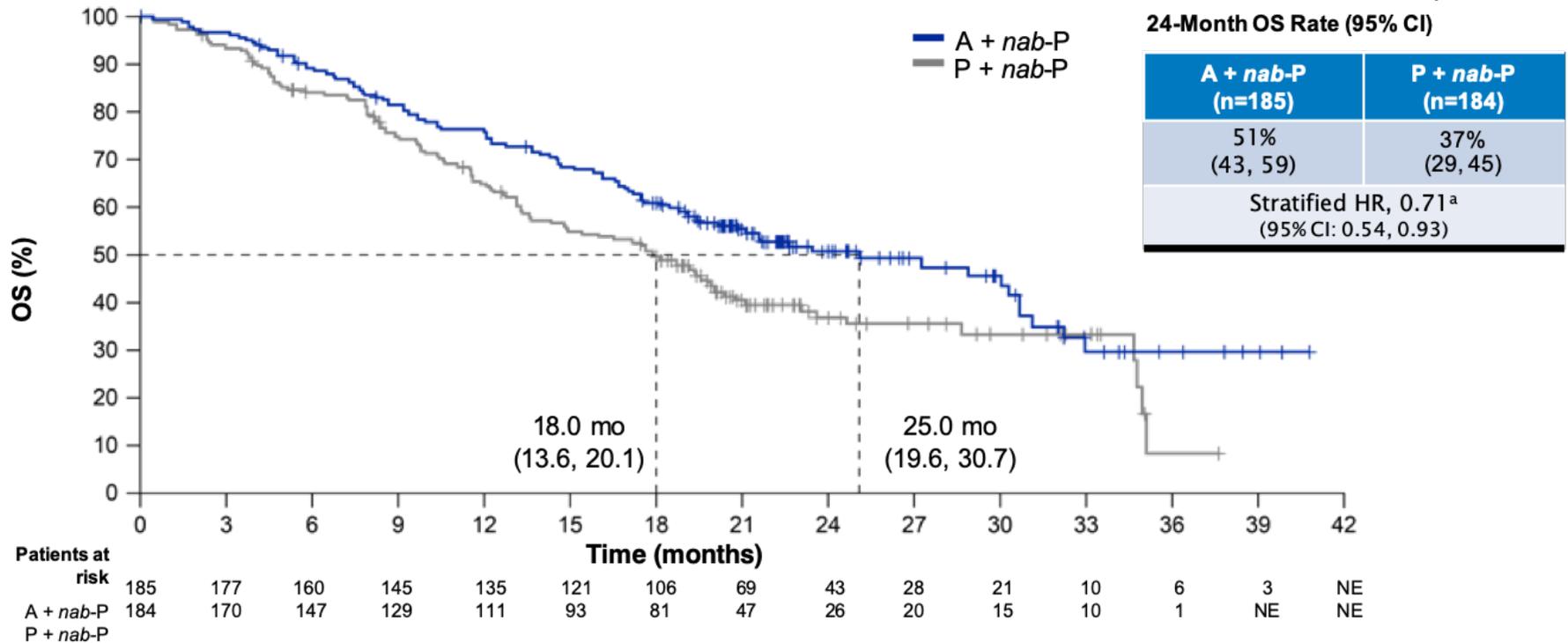


If indicated: Radiotherapy; Adjuvant endocrine therapy if HR+*

*DXA, offer adjuvant bisphosphonates (if postmenopausal / or with ovarian suppression)

Immuntherapie jetzt auch bei Brustkrebs: IMPASSION 130 – Erstlinie TNBC (PD-L1_{ic} +)

**Neu
2019**



^aNot formally tested due to pre-specified hierarchical analysis plan. Clinical cutoff date: January 2, 2019. Median PFS (95% CI) is indicated on the plot. Median FU (ITT): 18.0 months..

Mod. Schmid P et al. ASCO 2019, Oral Abstract Session – Breast Cancer – Metastatic, Abstract No. 1003

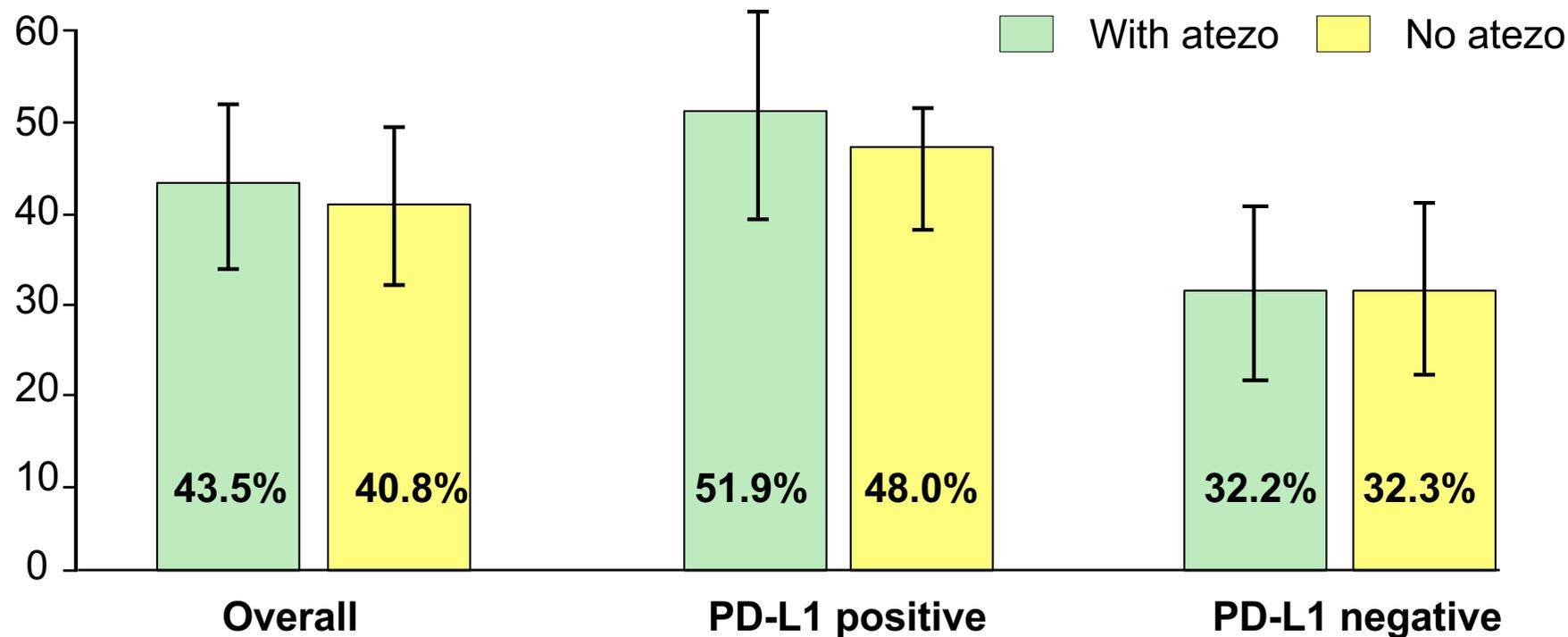
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NeoTRIP: ITT analysis - pCR rate

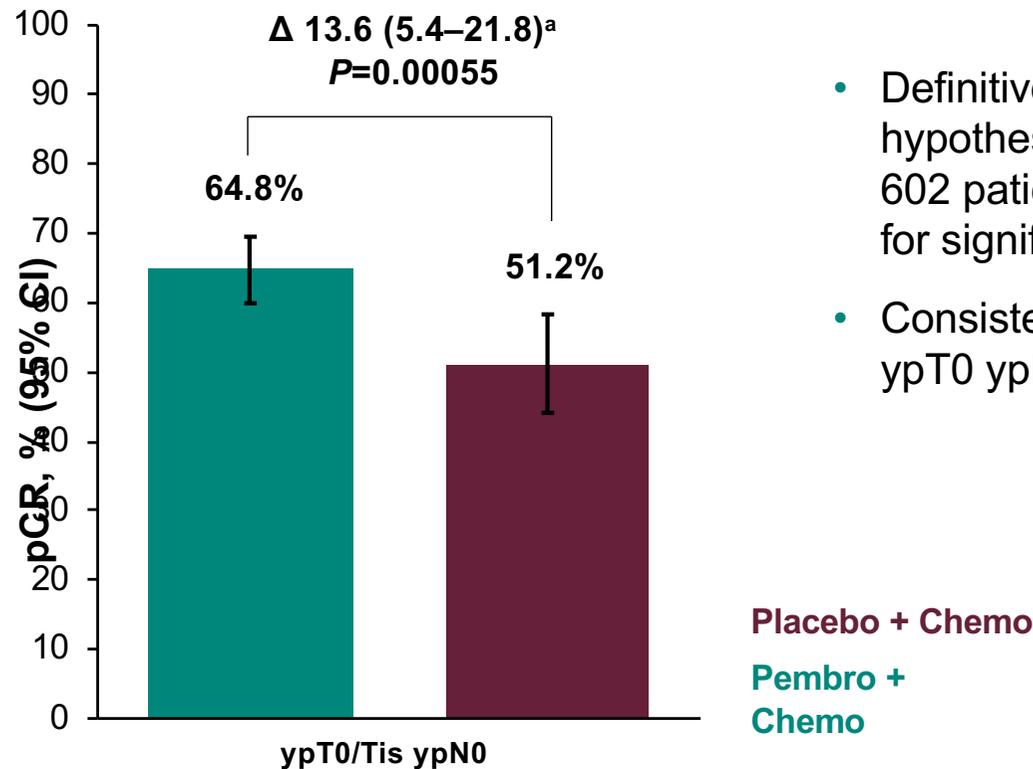
	ITT population	
	With atezo (138)	No atezo (142)
% pCR rate	43.5	40.8
95% CI	35.1-52.2	32.7-49.4
Difference: atezo vs no atezo (95% CI)	2.63 (14.0-8.8)	
*Odds ratio (95% CI)	1.11 (0.69-1.79)	
*p-value	0.66	

*Cochran-Mantel-Haenszel test, controlling for PD-L1 expression and disease stage and quantified by OR and rate difference

pCR rate and *PD-L1* expression



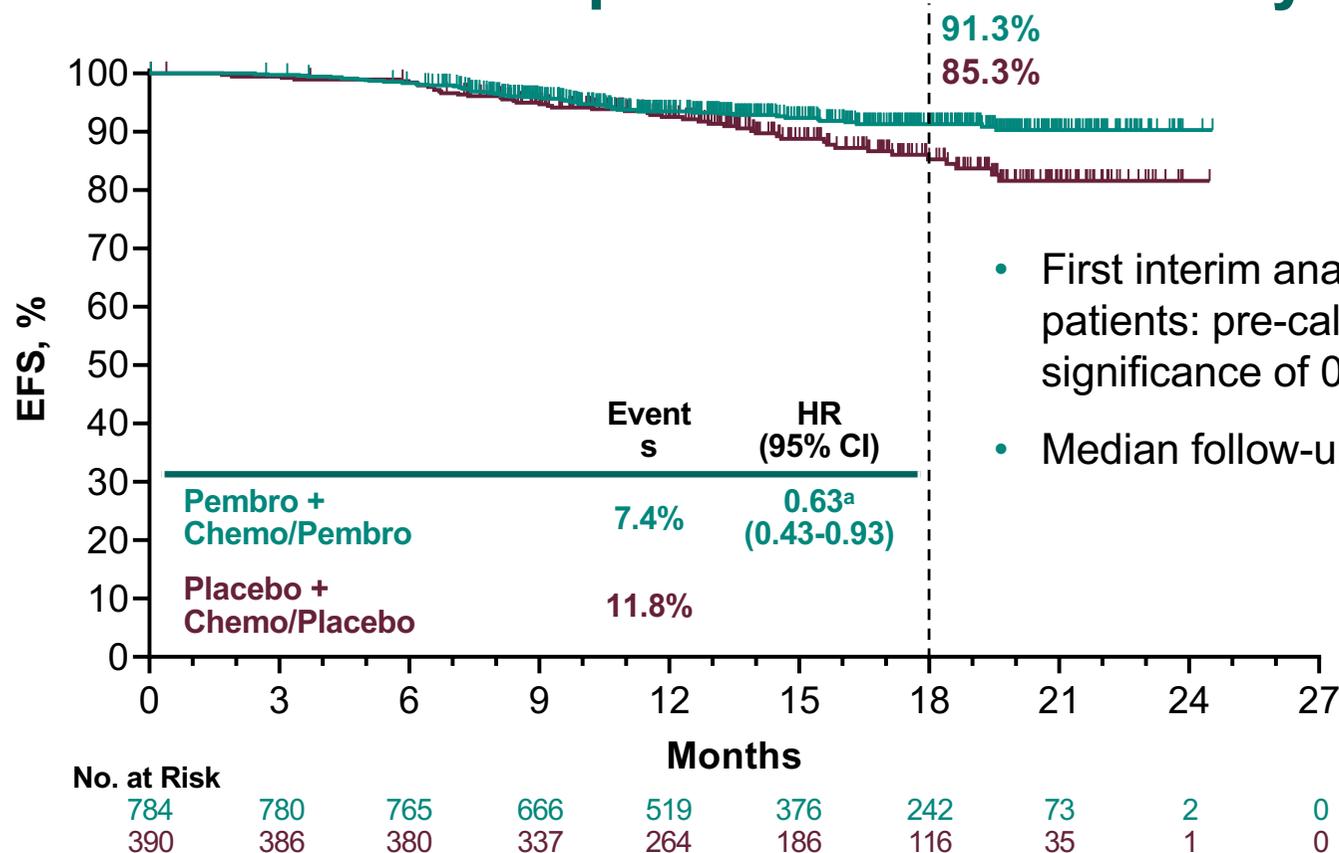
KEYNOTE 522: Definitive pCR Analysis



- Definitive pCR analysis to test primary hypothesis of pCR based on prespecified first 602 patients (pre-calculated P value boundary for significance of 0.003)
- Consistent benefit seen with pCR defined as ypT0 ypN0 and ypT0/Tis

^aEstimated treatment difference based on Miettinen & Nurminen method stratified by randomization stratification factors. Data cutoff date: September 24, 2018.

KN 522: First Pre-planned Interim Analysis for EFS

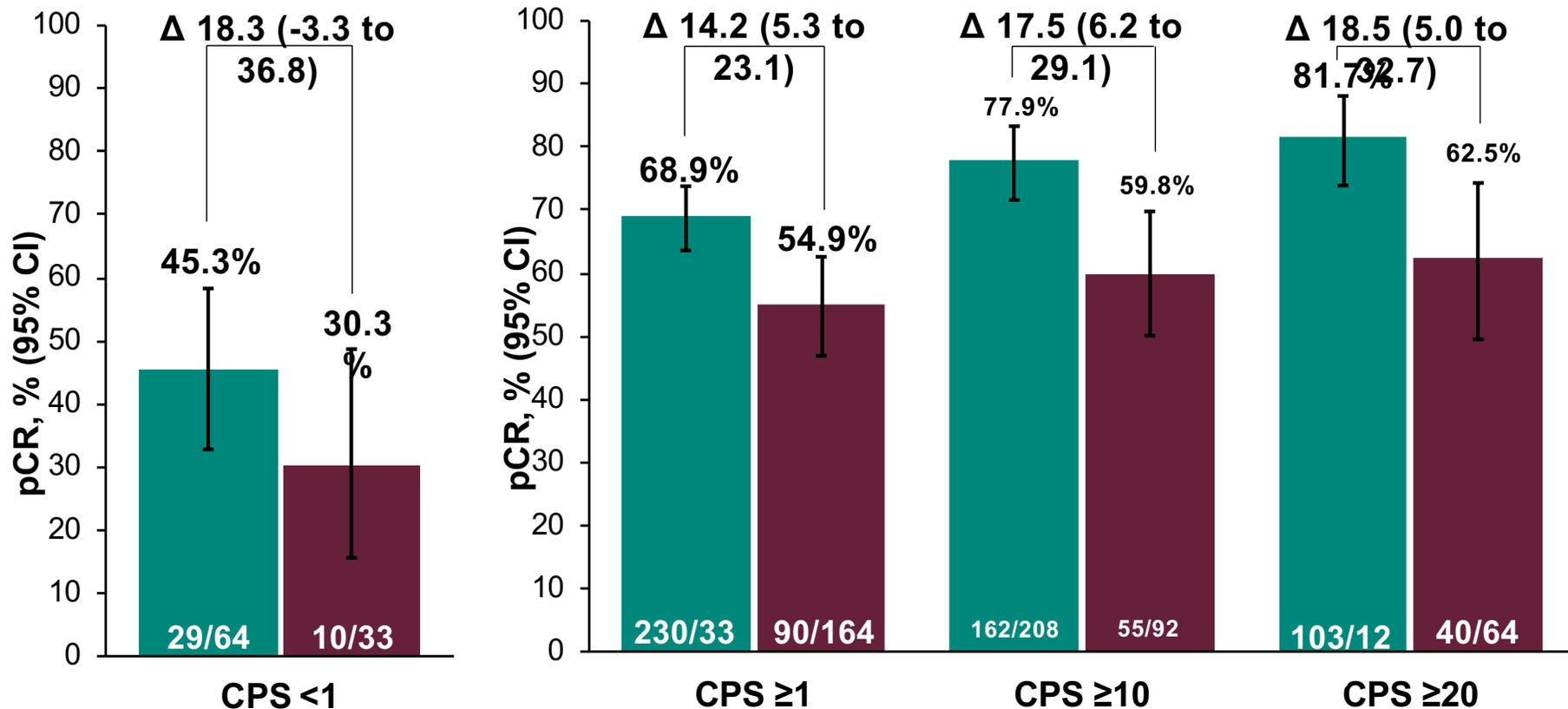


- First interim analysis of EFS based on 1174 patients: pre-calculated P value boundary for significance of 0.000051 (HR <0.4)
- Median follow-up, 15.5 months

^aPre-specified P value boundary of 0.000051 not reached at this analysis (the first interim analysis of EFS). Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. Data cutoff April 24, 2019.

pCR by PD-L1 Expression Level

Pembro + Chemo
Placebo + Chemo

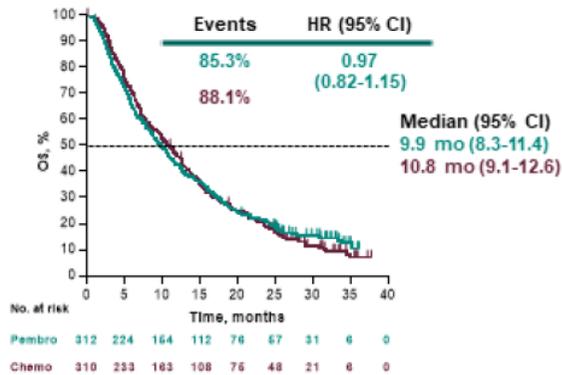


Pre-specified analysis. PD-L1 assessed at a central laboratory using the PD-L1 IHC 22C3 pharmDx assay and measured using CPS; number of PD-L1-positive tumor cells, lymphocytes, and macrophages divided by total number of tumor cells x 100; PD-L1-positive = CPS ≥1. Estimated treatment difference based on Miettinen & Nurminen method stratified by nodal status (positive vs negative), tumor size (T1/T2 vs T3/T4) and choice of carboplatin (Q3W vs QW). Data cutoff date: September 24, 2018.

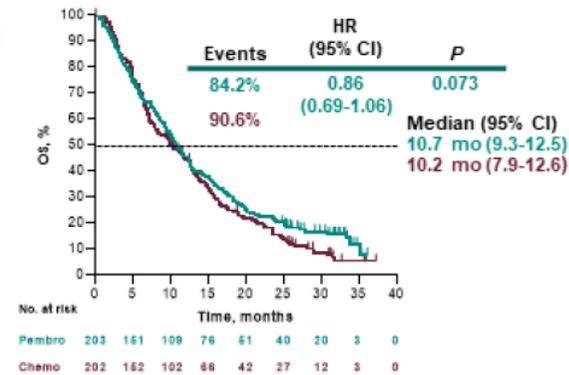
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KEYNOTE-119 (Pembrolizumab vs. Monochemotherapie): Gesamtüberleben ITT und nach PD-L1 Status

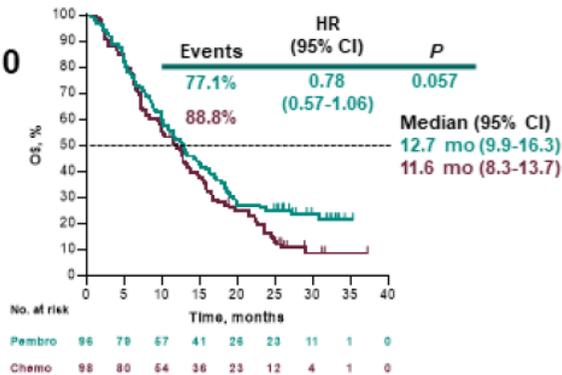
ITT



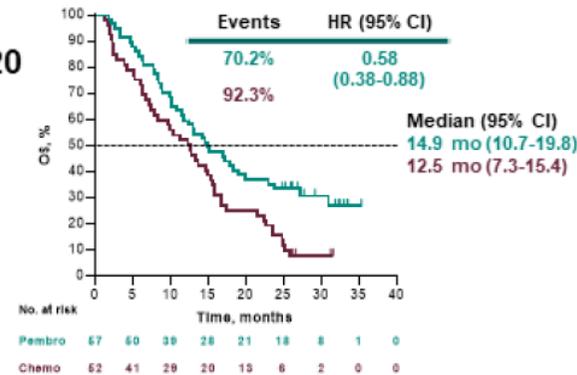
CPS ≥1



CPS ≥10

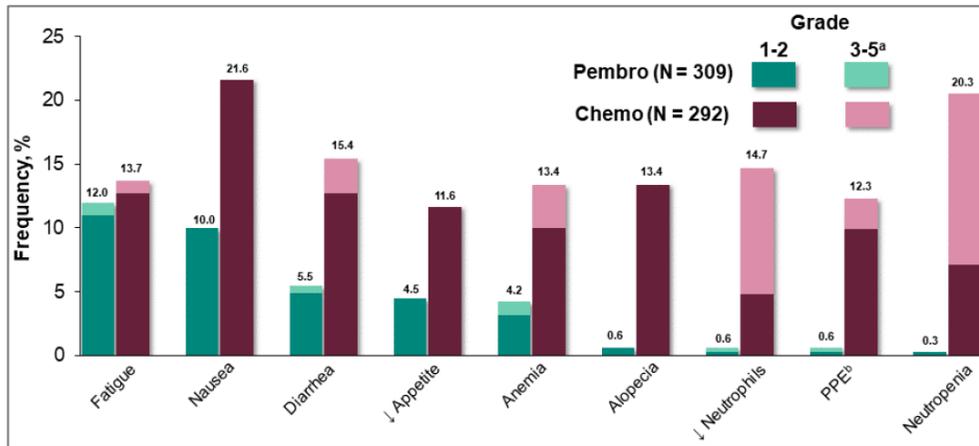


CPS ≥20



KEYNOTE-119: Nebenwirkungen (Pembrolizumab vs. Monochemotherapie)

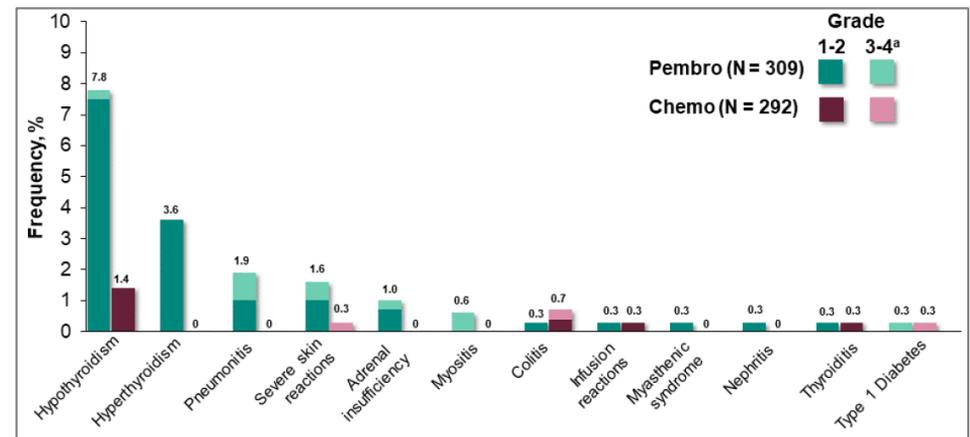
Behandlungsbedingte Nebenwirkungen $\geq 10\%$



^a Grad 5 Nebenwirkungen: Panzytopenie und Sepsis (n=1), Hämothorax (n=1); Chemotherapie; Kreislaufkollaps (n=1); Pembrolizumab

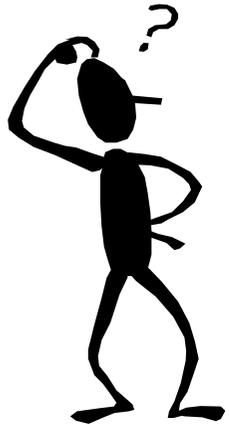
^b Hand-Fuss-Syndrom
Data cut-off 11.April 2019

Immunvermittelte Nebenwirkungen und Infusionsreaktionen



^a Keine Grad 5 Nebenwirkungen; Data cut-off 11.April 2019

Immuntherapie jetzt auch bei Brustkrebs – viele offene klinische Fragen und noch (viel zu) wenig Antworten

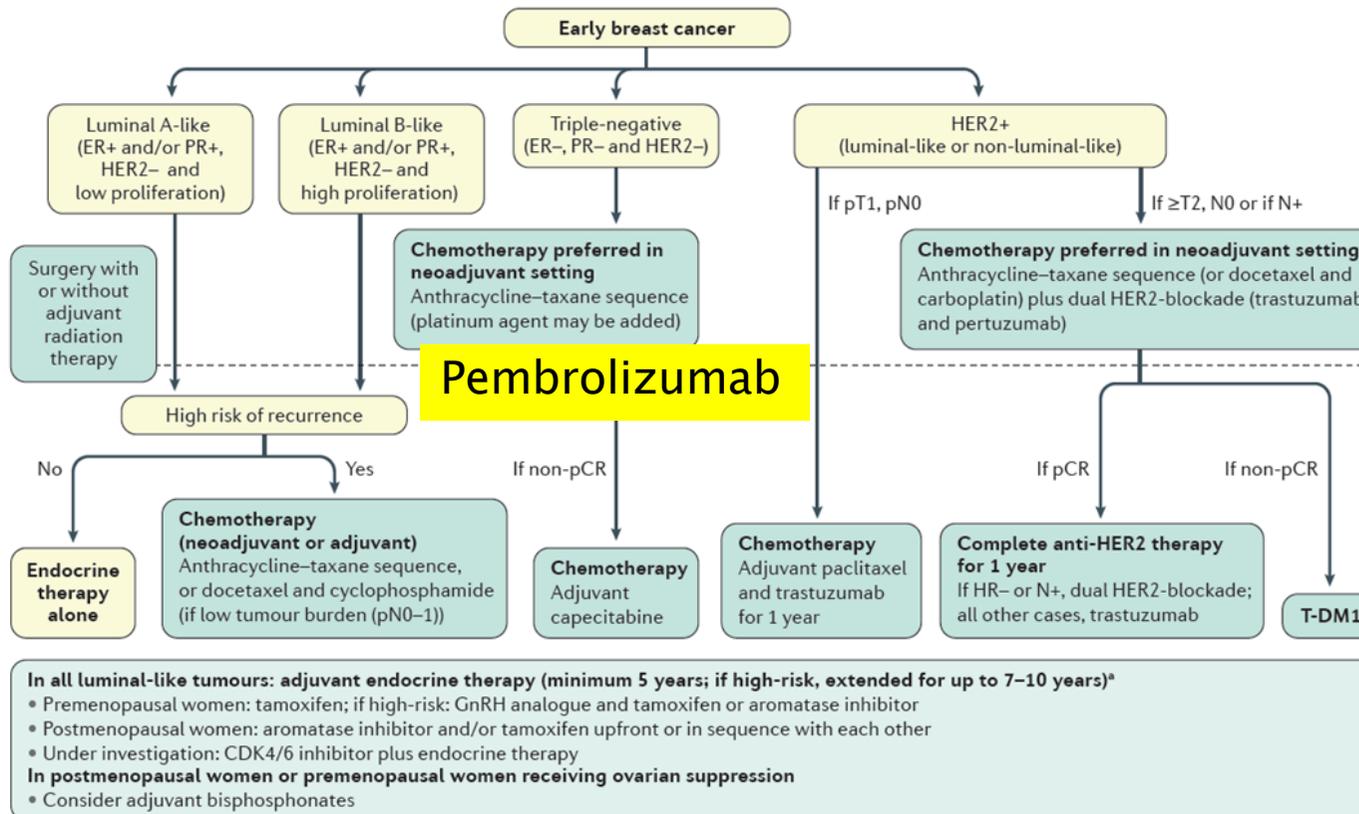


- Optimale IO Medikamente
- Optimale Biomarker
- Optimales Anwendungsgebiet
- Optimales Therapieregime
- Optimale Kombinationspartner
- Optimale Dauer
- ...



**“Before I came here, I was confused about this subject. Having listened to your lecture, I am still confused -- but on a higher level.”
Enrico Fermi**

Early breast cancer: Treatment strategies



Nature Reviews | Disease Primers

Advanced or Metastatic Breast Cancer:
Will we do something different on Monday morning?



Metastasiertes HER2+ Mammakarzinom: Klinische Herausforderungen bei immer besserer (neo-) adjuvanter Therapie

San Antonio Breast Cancer Symposium®, December 10-14, 2019

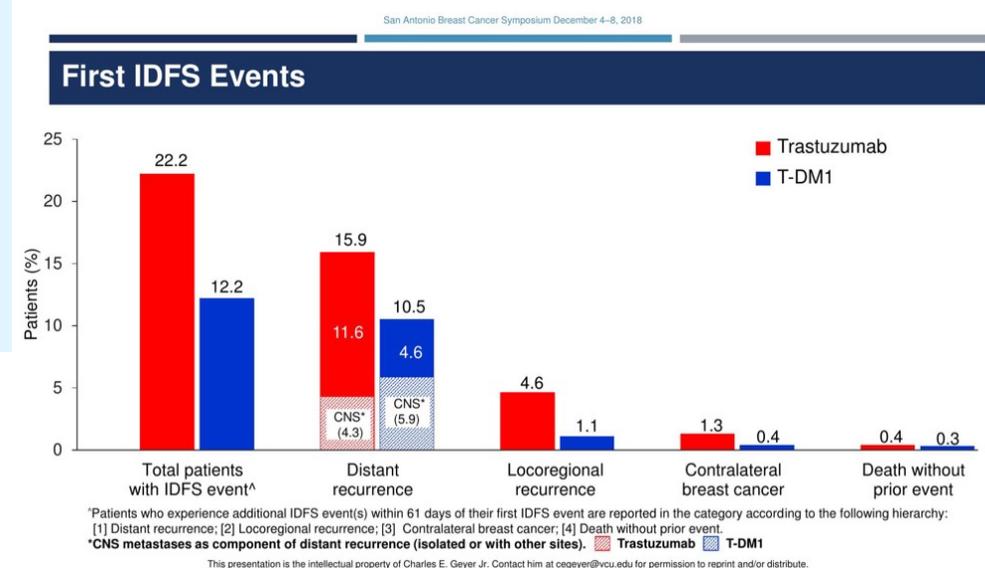
APHINITY Updated descriptive analysis 74.1 months median FU, Site of First Occurrence of an IDFS event

	Pertuzumab n=2400	Placebo n=2404
Total patients with IDFS event: n (%)	221 (9.2%)	287 (11.9%)
Category of IDFS event: n (%)		
• Distant recurrence	141 (5.9%)	184 (7.7%)
• CNS metastases	49 (2.0%)	49 (2.0%)
• Locoregional BC recurrence	28 (1.2%)	49 (2.0%)
• Contralateral invasive BC recurrence	13 (0.5%)	15 (0.6%)
• Death without prior event	39 (1.6%)	39 (1.6%)

Hierarchy applied if a patient experiences additional IDFS event(s) within 61 days of their 1st IDFS event

35% ZNS bei Fernmetastasen nach T-P

56 % ZNS bei Fernmetastasen nach T-DM1



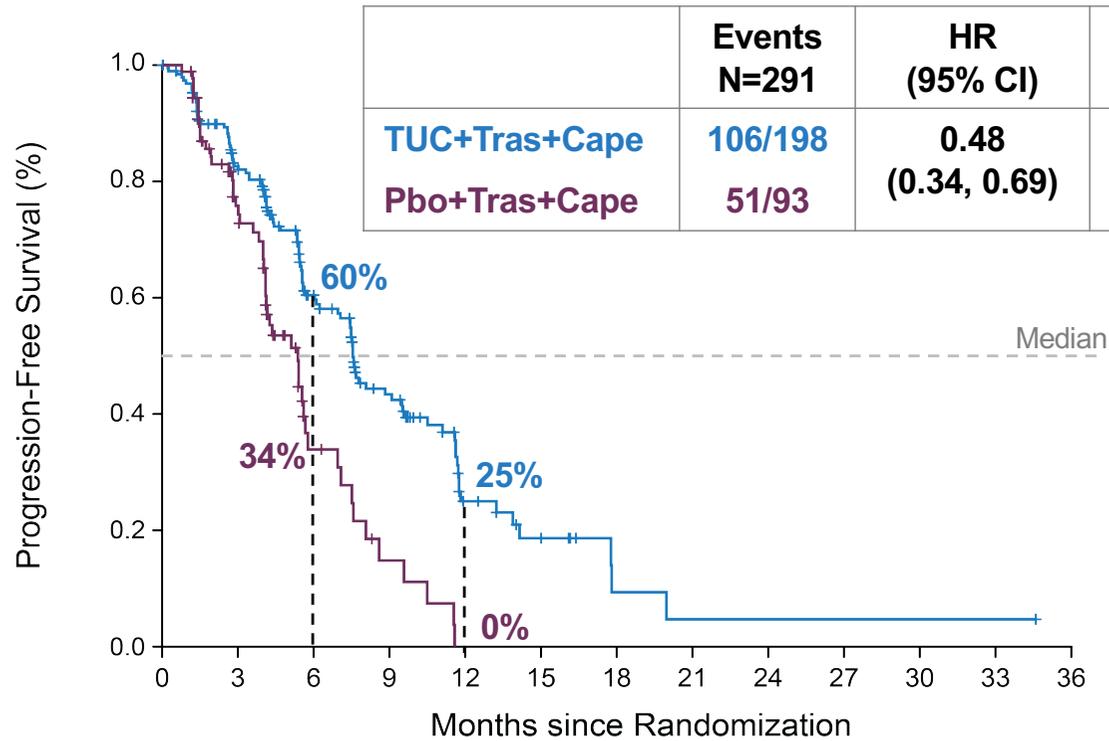
HER2CLIMB: Key Baseline Demographics and Disease Characteristics

Characteristic, n (%)		Total Population, N=612	
		TUC+Tras+Cape n=410	Pbo+Tras+Cape n=202
Female		407 (99)	200 (99)
Age (years), median (range)		55.0 (22, 80)	54.0 (25, 82)
ECOG performance status	0	204 (50)	94 (47)
	1	206 (50)	108 (54)
Stage IV at initial diagnosis		143 (35)	77 (39)
Hormone receptor status	ER and/or PR-positive	243 (60)	127 (63)
	ER and PR-negative	161 (40)	75 (37)
Prior lines of therapy, median (range)	Overall	4.0 (2, 14)	4.0 (2, 17)
	Metastatic setting	3.0 (1, 14)	3.0 (1, 13)
Presence/history of brain metastases		198 (48)	93 (46)
Treated, stable		118 (59.6)	55 (59.1)
Untreated		44 (22.2)	22 (23.7)
Treated, progressing		36 (18.2)	16 (17.2)

Baseline characteristics were balanced between endpoint populations and treatment arms

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Progression-Free Survival for Patients with Brain Metastases



	Events N=291	HR (95% CI)	P Value
TUC+Tras+Cape	106/198	0.48 (0.34, 0.69)	<0.00001
Pbo+Tras+Cape	51/93		

No. at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TUC+Tras+Cape 198	144	78	45	14	8	2	1	1	1	1	1	1	0
Pbo+Tras+Cape 93	49	12	4	0	0	0	0	0	0	0	0	0	0

Risk of progression or death in patients with brain metastases was reduced by 52% in the total population

One-year PFS (95% CI):

TUC+Tras+Cape	Pbo+Tras+Cape
25% (17, 34)	0%

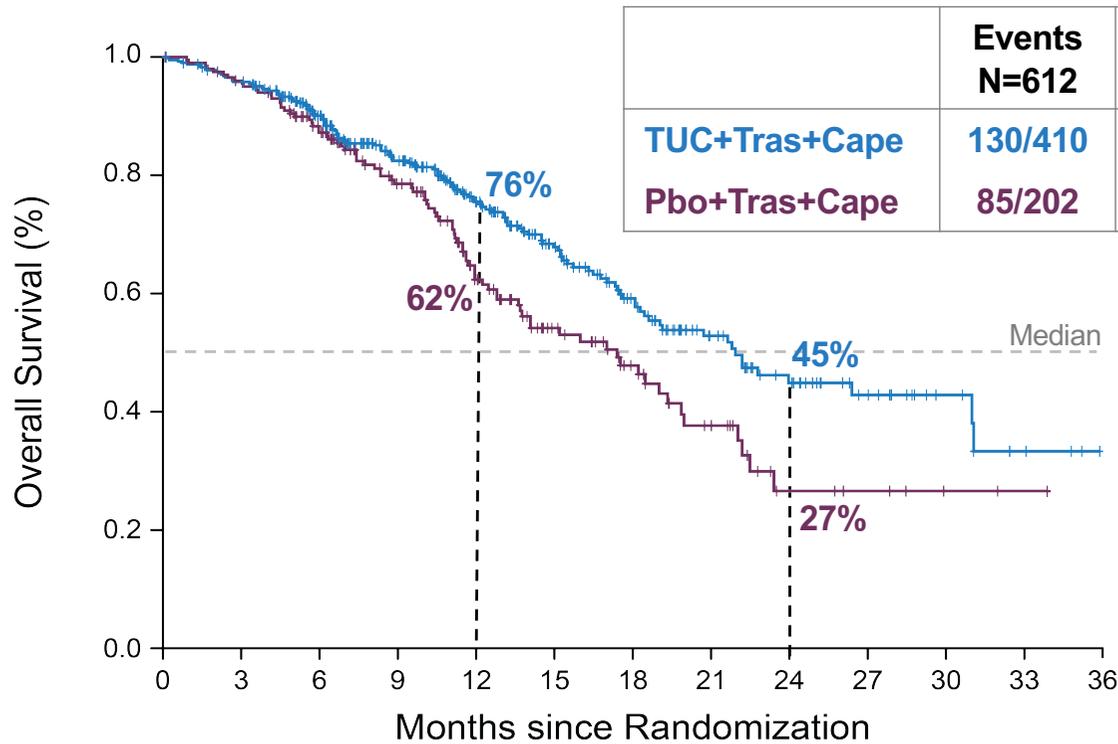
Median PFS (95% CI):

TUC+Tras+Cape	Pbo+Tras+Cape
7.6 months (6.2, 9.5)	5.4 months (4.1, 5.7)

Prespecified efficacy boundary for PFS_{BrainMets} (P=0.0080) was met at the first interim analysis.
Data cut off: Sep 4, 2019

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Overall Survival in the Total Study Population



	Events N=612	HR (95% CI)	P Value
TUC+Tras+Cape	130/410	0.66 (0.50, 0.88)	0.00480
Pbo+Tras+Cape	85/202		

Risk of death was reduced by 34% in the total population

Two-year OS (95% CI):

TUC+Tras+Cape	Pbo+Tras+Cape
45% (37, 53)	27% (16, 39)

Median OS (95% CI):

TUC+Tras+Cape	Pbo+Tras+Cape
21.9 months (18.3, 31.0)	17.4 months (13.6, 19.9)

No. at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TUC+Tras+Cape	410	388	322	245	178	123	80	51	34	20	10	4	0
Pbo+Tras+Cape	202	191	160	119	77	48	32	19	7	5	2	1	0

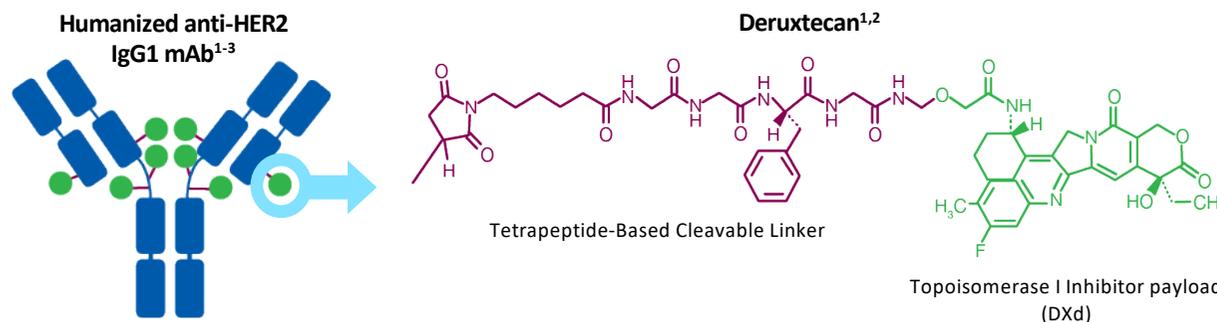
Prespecified efficacy boundary for OS (P=0.0074) was met at the first interim analysis.
Data cut off: Sep 4, 2019



Trastuzumab Deruxtecan (DS-8201) is a Novel ADC Designed to Deliver an Optimal Antitumor Effect

Trastuzumab deruxtecan is an ADC composed of 3 components:

- A humanized anti-HER2 IgG1 mAb with the same amino acid sequence as trastuzumab
- A topoisomerase I inhibitor payload, an exatecan derivative
- A tetrapeptide-based cleavable linker



Payload MOA:
topoisomerase I inhibitor

High potency of payload

High drug to antibody ratio ≈ 8

Payload with short systemic half-life

Stable linker-payload

Tumor-selective cleavable linker

Membrane-permeable payload

The clinical relevance of these features is under investigation.

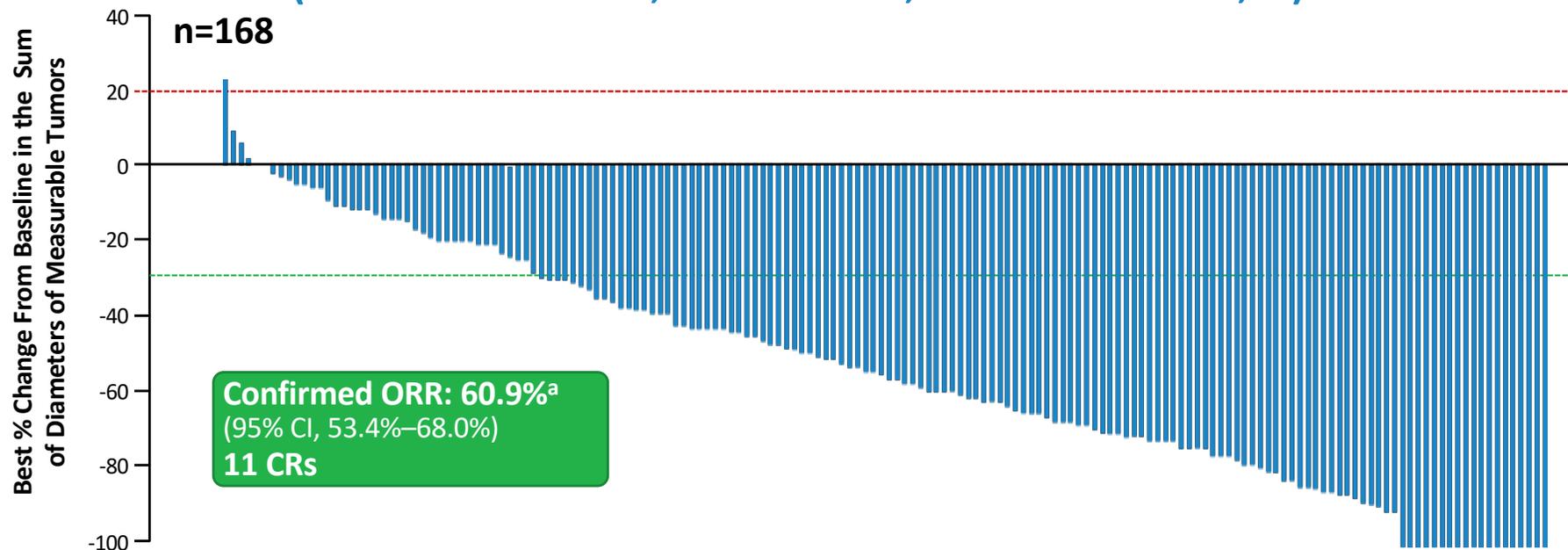
ADC, antibody-drug conjugate; MOA, mechanism of action.

1. Nakada T, et al. Chem Pharm Bull (Tokyo). 2019;67(3):173-185. 2. Ogitani Y, et al. Clin Cancer Res. 2016;22(20):5097-5108. 3. Trail PA, et al. Pharmacol Ther. 2018;181:126-142. 4. Ogitani Y, et al. Cancer Sci. 2016;107(7):1039-1046.



Best Change in Tumor Size

Median prior lines of cancer therapy: 6 (range 2-27)
(100% Trastuzumab; 100% T-DM1; 66% Pertuzumab; ...)



By independent central review.

The line at 20% indicates progressive disease; the line at -30% indicates partial response.

^a Includes all patients who received T-DXd 5.4 mg/kg (intent-to-treat analysis; N=184).



Adverse Events of Special Interest: Interstitial Lung Disease

Patients who received T-DXd 5.4 mg/kg (N=184)						
Preferred Term, n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade/ Total
Interstitial lung disease	5 (2.7)	15 (8.2)	1 (0.5)	0	4 (2.2)	25 (13.6)

Drug related; ILD was determined by the Independent ILD Adjudication Committee based on 44 preferred terms.

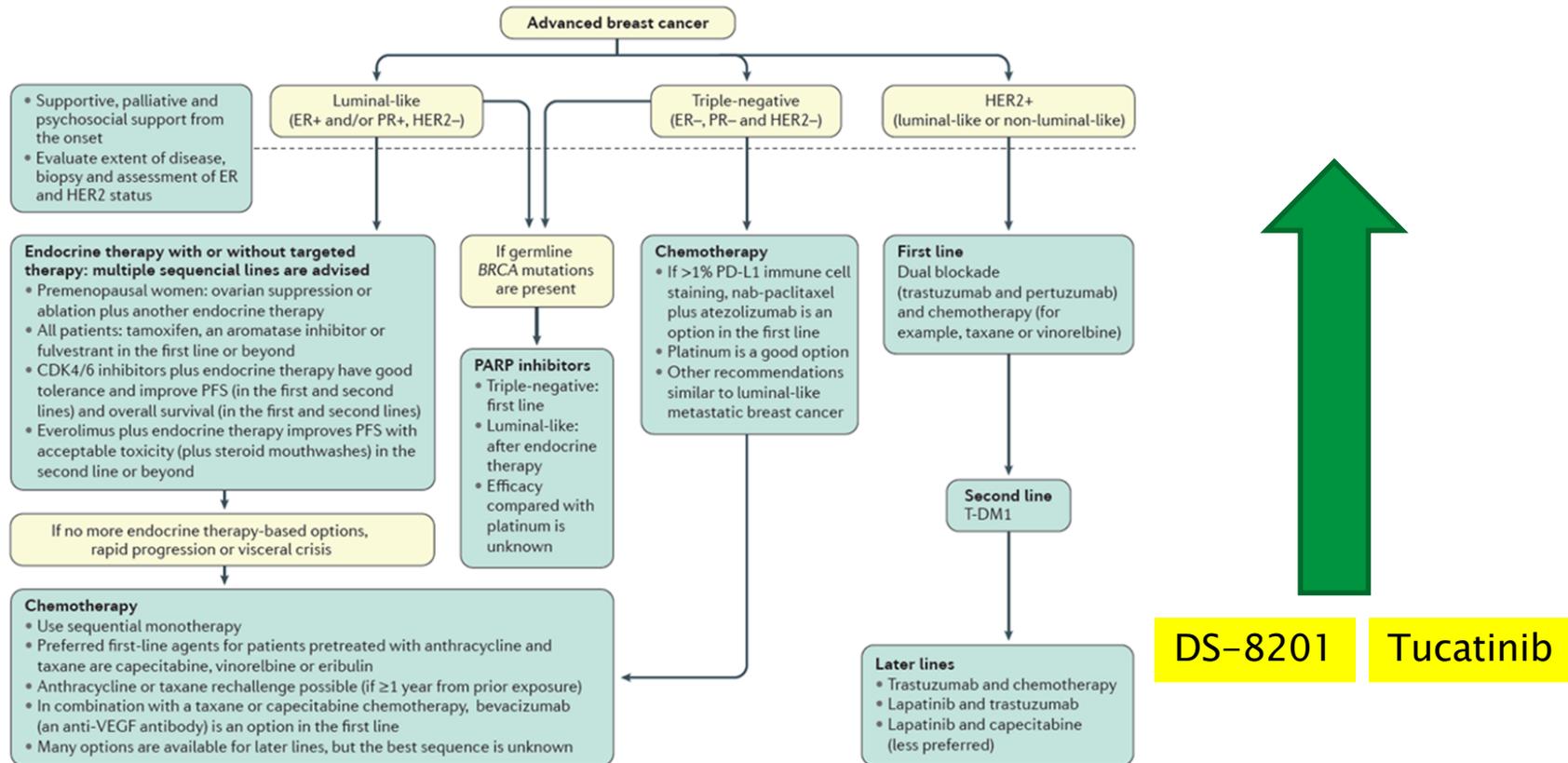
Among the 25 total events:

- **Median time to investigator-reported onset was 193 days (range, 42-535 days)**
- 13 of 20 patients with grade ≥ 2 ILD received corticosteroids
- 7 patients recovered, 2 were recovering, 12 were either outcome unknown or not followed until resolution, and 4 died
- Of the 4 fatal cases, onset was from 63-148 days, 3 received steroids as part of treatment, and death occurred 9-60 days after ILD diagnosis

Recommendations: Monitor for symptoms. Hold T-DXd and start steroids as soon as ILD is suspected

ILD, interstitial lung disease.

Metastatic breast cancer: Treatment strategies



DS-8201 **Tucatinib**

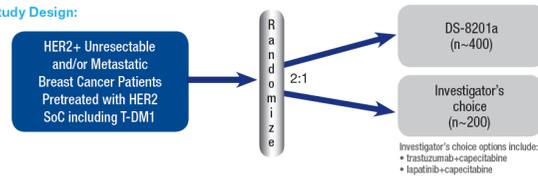
Nature Reviews | Disease Primers

DS-8201a (Trastuzumab Deruxtecan) → DESTINY Breast Phase 3 Programm

DESTINY-Breast02

DS-8201a in Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer

Study Design:



A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Trial of DS-8201a, an Anti-HER2-Antibody Drug Conjugate (ADC), Versus Treatment of Investigator's Choice for HER2-Positive, Unresectable and/or Metastatic Breast Cancer Patients Pretreated with Prior Standard of Care (SoC) HER2 Therapies, Including Ado-Trastuzumab Emtansine (T-DM1)

Primary Endpoint: Progression Free Survival (PFS)

Secondary Endpoints:

- Overall Survival (OS)
- Objective Response Rate (ORR)
- Duration of Response (DoR)
- Pharmacokinetics (PK)
- Safety
- Clinical Benefit Rate (CBR)

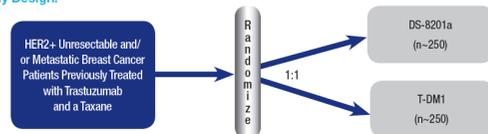
ClinicalTrials.gov Identifier: NCT03523585

HER2
positiv

DESTINY-Breast03

DS-8201a in Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer

Study Design:



Primary Endpoint: Progression Free Survival (PFS)

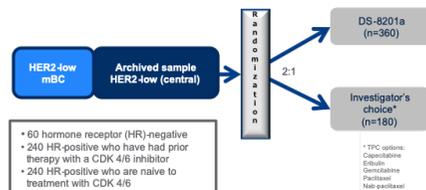
Secondary Endpoints:

- Overall Survival (OS)
- Objective Response Rate (ORR)
- Duration of Response (DoR)
- Pharmacokinetics (PK)
- Safety
- Clinical Benefit Rate (CBR)

ClinicalTrials.gov Identifier: NCT03529110

DESTINY-Breast 04

A Phase 3, multicenter, randomized, open-label, active-controlled trial of DS-8201a, an anti-HER2-antibody drug conjugate (ADC), versus treatment of physician's choice for HER2-low, unresectable and/or metastatic breast cancer subjects



Primary Outcome Measures:

- (PFS) based on Blinded Independent Central Review (BICR)

Secondary Outcome Measures:

- PFS based on Investigator Assessment
- Overall Survival (OS)
- Objective Response Rate (ORR)
- Duration of Response (DoR)

ClinicalTrials.gov Identifier: NCT03734029

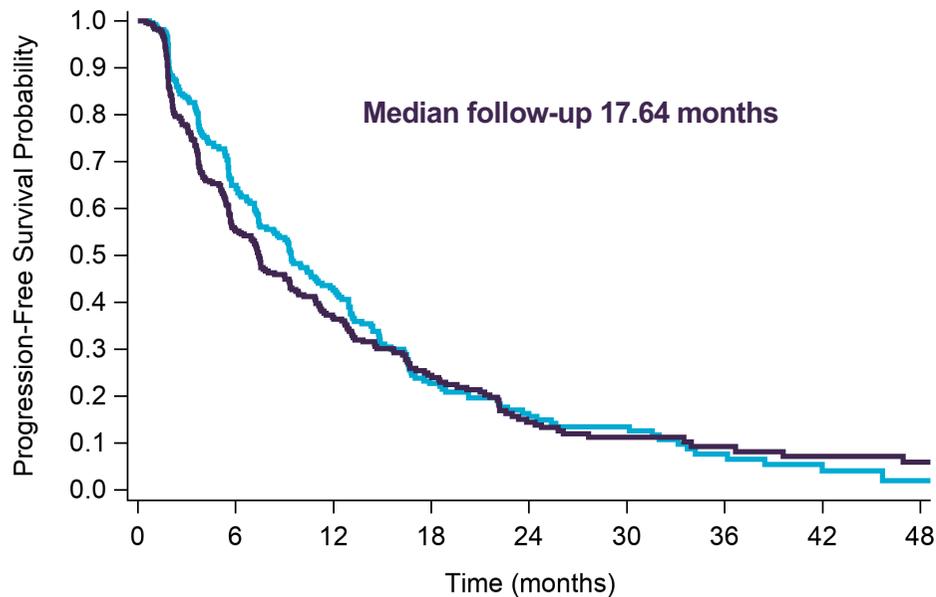
Stratified By:

- HER2 IHC status
- Hormone receptor status (+, -)/CDK 1 status
- Number of prior lines of chemotherapy

On-study treatment period: Until subject withdrawal, PD, unacceptable toxicity, treatment delay>28d, etc.

HER2
low

PEARL: Secondary Objective: PFS Cohort 1 + Cohort 2 (N=601)

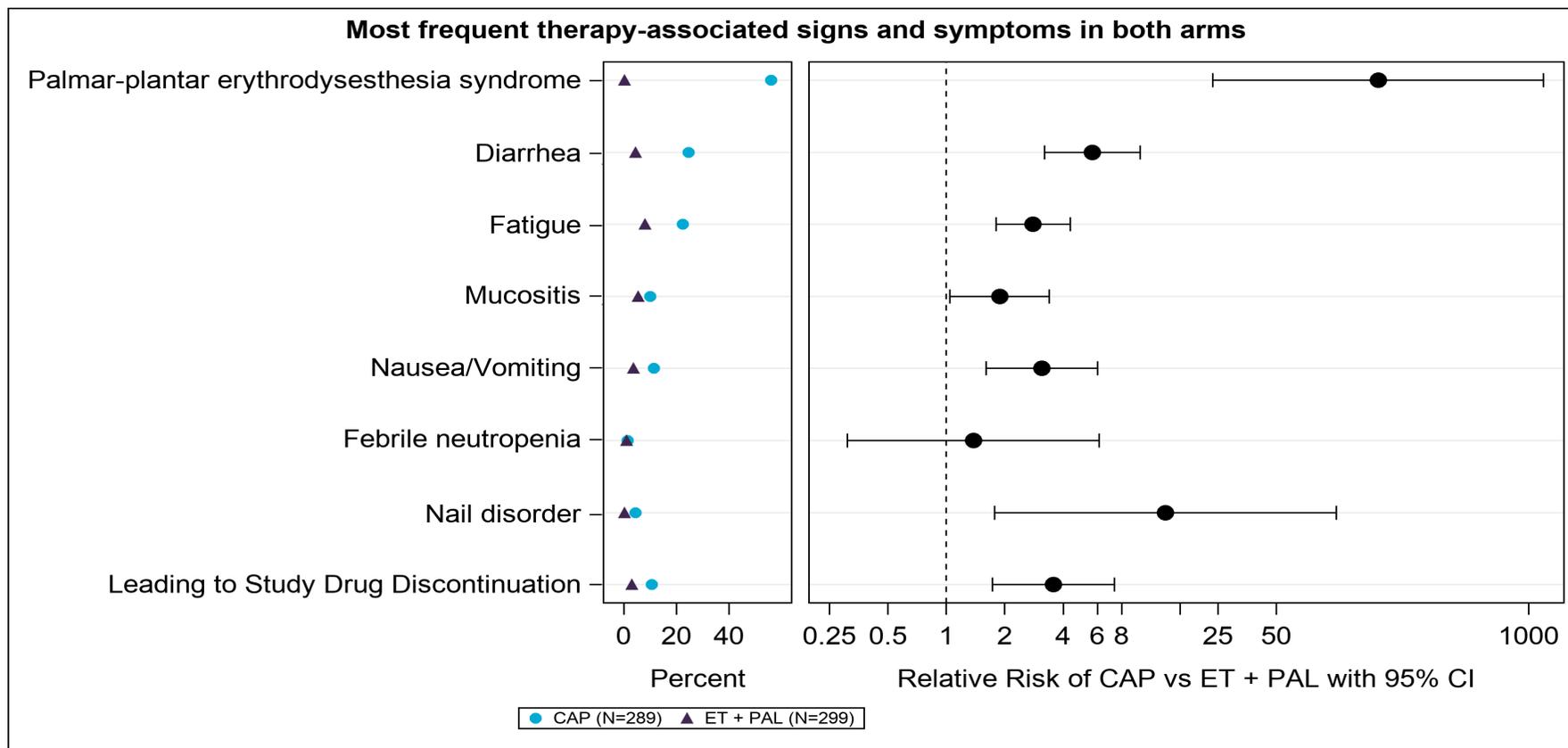


	ET + PAL N=302	CAP N=299
Events, n (%)	236 (78.1)	203 (67.9)
Censored, n (%)	66 (21.9)	96 (32.1)
Median PFS, months (95% CI)	7.4 (5.9, 9.3)	9.4 (7.5, 11.3)
Adjusted Hazard Ratio (95% CI)	1.09 (0.90, 1.31)	
Adjusted p-value (Cox)	0.380	

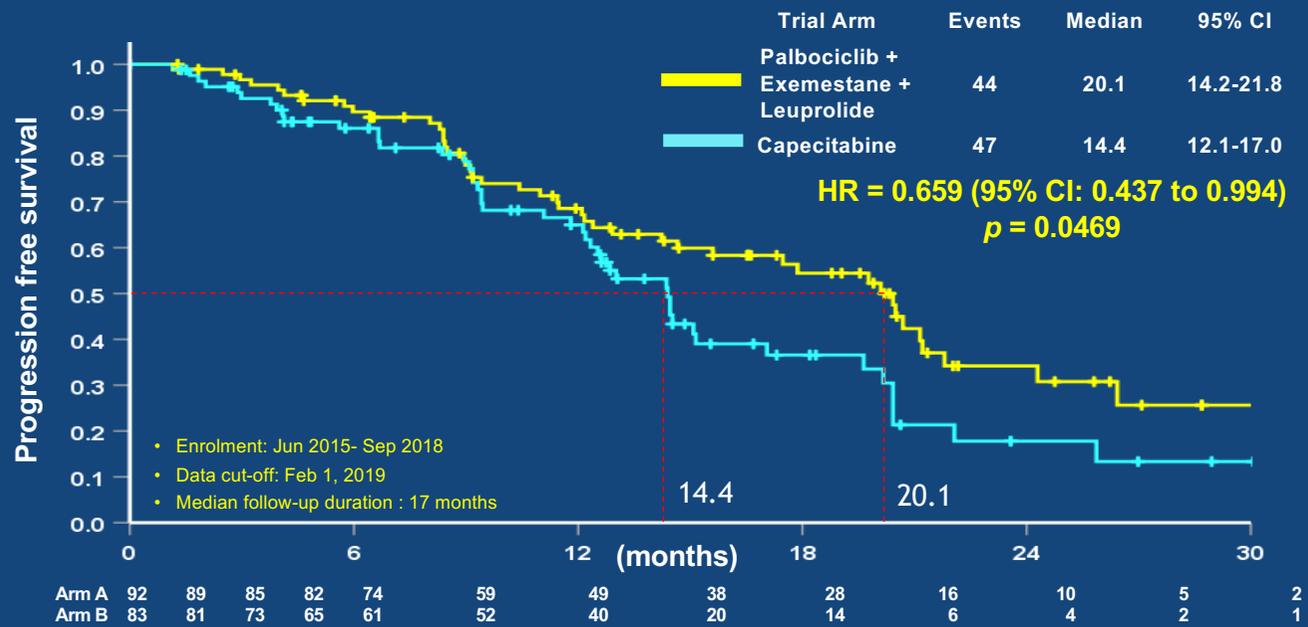
	0-6	6-12	12-18	18-24	24-30	30-36	36-42	42-48
CAP 299	154	86	39	23	15	7	3	1
ET + PAL 302	159	87	50	24	15	9	7	5

The adjusted hazard ratio was obtained using a stratified Cox proportional hazard model with treatment arm and the stratification factors as covariates

PEARL: Safety (Grade ≥ 2 per patient)



Young-PEARL : Investigator-assessed Progression free survival



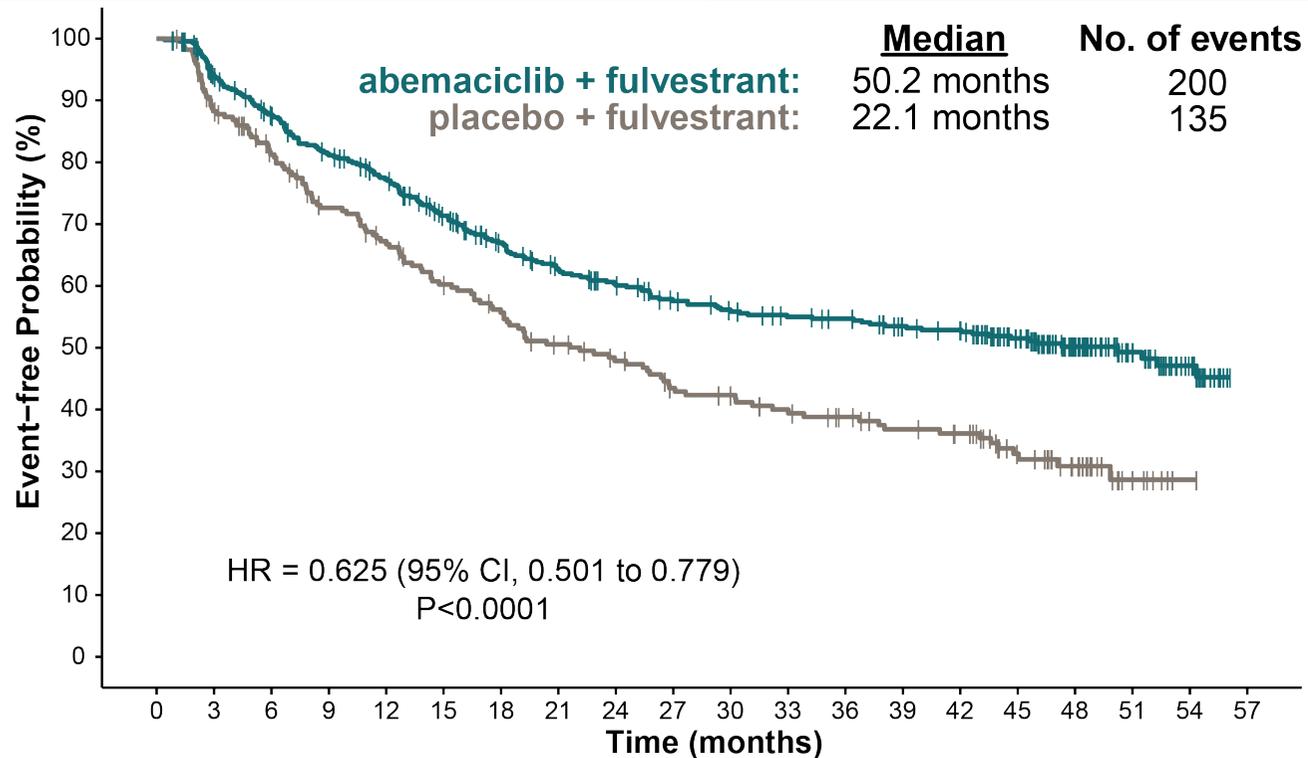
HR+ HER2- MBC: Phase III Studien nach Progression unter ET

Phase III trial	PALOMA 3 (n=521)	MONALEESA 3 (n=345)	MONARCH 2 (n=669)	BOLERO 2 (n=724)
CDK 4/6i	Palbociclib	Ribociclib	Abemaciclib	Everolimus
Endocrine agent	Fulvestrant	Fulvestrant	Fulvestrant	Exemestane
PFS (months)	11.2 vs. 4.6	14.6 vs. 9.1	16.4 vs. 9.3	10.6 vs. 4.1
HR (PFS)	0.50	0.57	0.553	0.43
HR (OS)	0.81 (0.64–1.03) Endocrine sensitive: HR=0.72 (0.55–0.94); median Δ 10 months	0.72 (0.57-0.92) p=0.0046 Δ alive at 42 months 11.9% (median OS n.r.)	0.76 (0.61-0.95) p=0.014 median Δ 9.4 months	0.89 (0.73-1.10) median Δ 4.4 months
Most frequent G3/4 side effects	neutropenia, leukopenia, anaemia	neutropenia, leukopenia, anaemia	diarrhoea, neutropenia, leukopenia, anaemia, nausea, fatigue	stomatitis, anaemia, dyspnea, hyperglycemia, fatigue, pneumonitis

Turner et al. SABCs 2016; Christofanilli et al. 2016; Turner et al, NEJM 2018; Slamon et al, ASCO 2018 and ESMO 2019; Sledge et al. 2017 and ESMO 2019; Baselga et al. 2012; Piccart et al, 2014

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MONARCH 2: Exploratory Analysis - Time to Chemotherapy^a

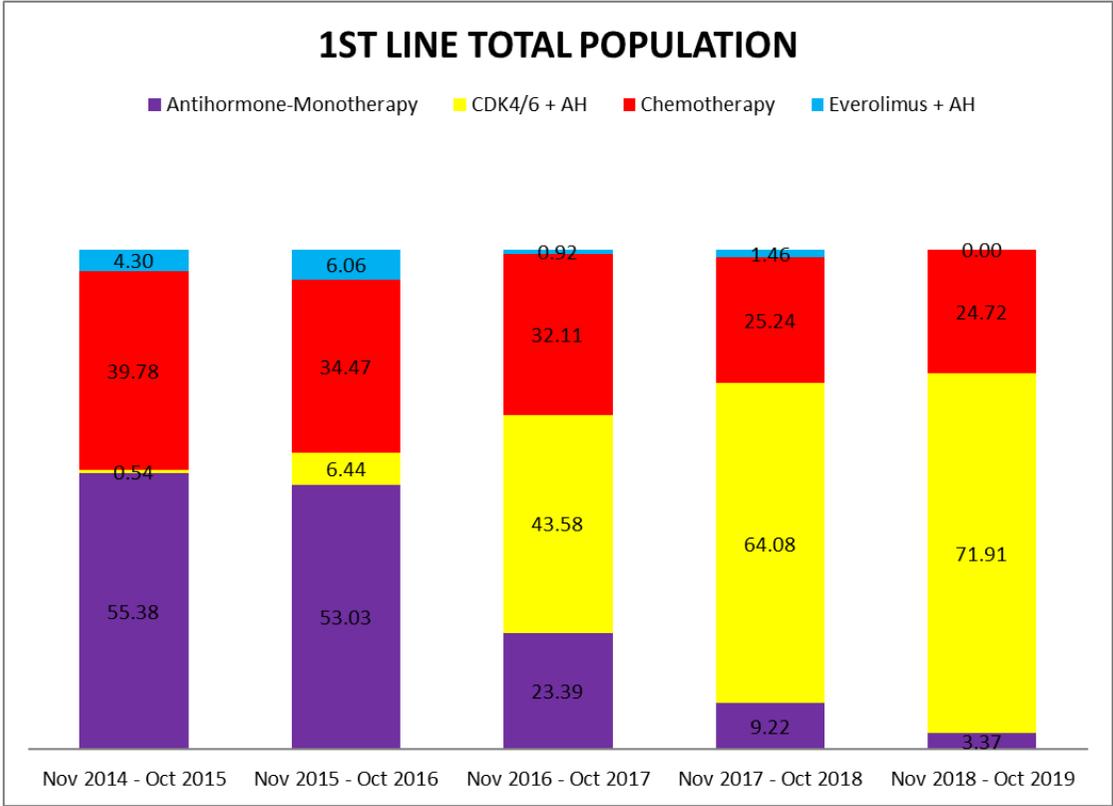


No. at risk

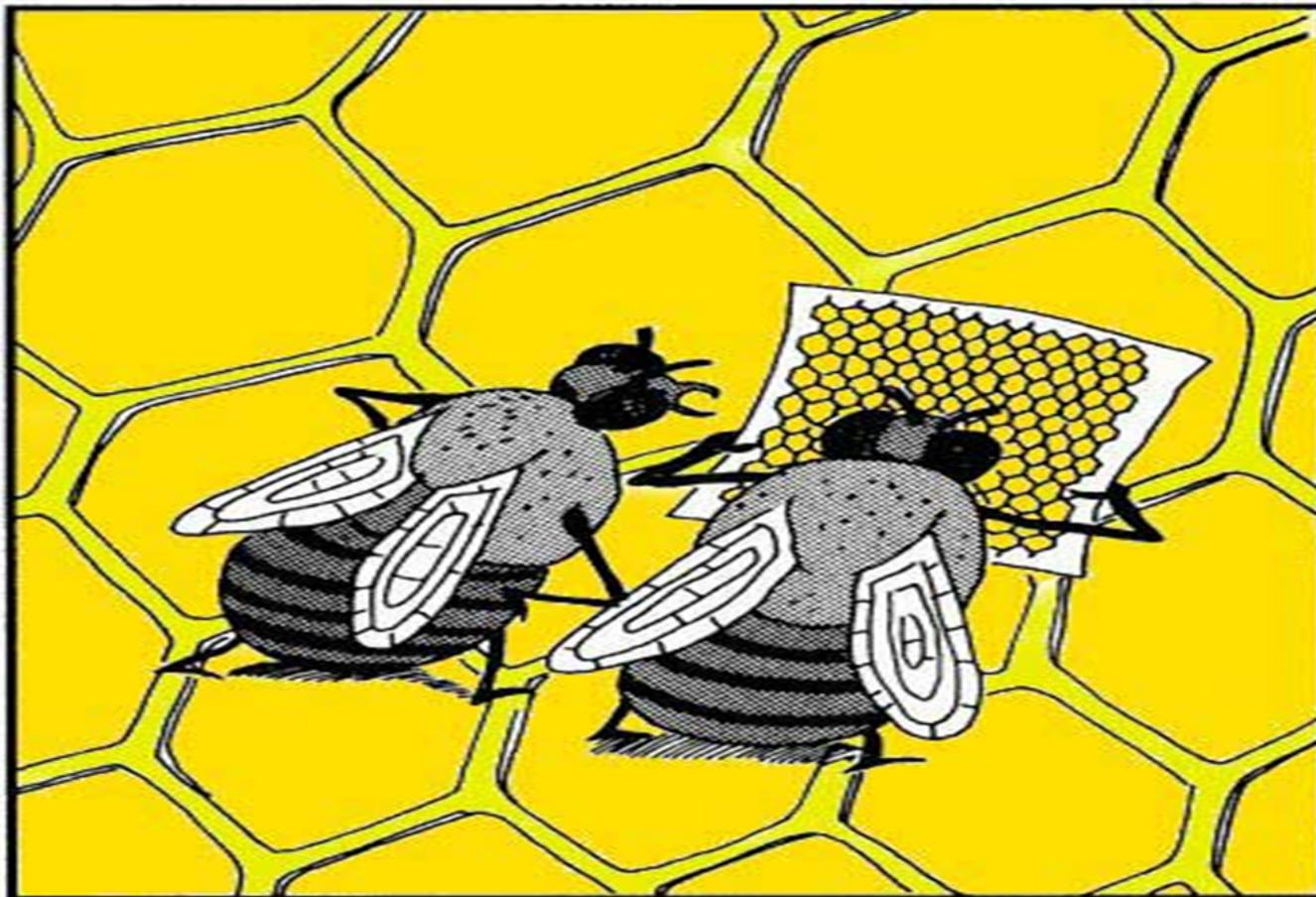
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57
abemaciclib + fulvestrant	446	406	372	342	319	284	255	234	220	204	195	188	184	172	167	134	84	49	28	0
placebo + fulvestrant	223	194	171	149	136	120	109	97	88	77	73	67	61	55	51	36	24	7	1	0

^aTime to chemotherapy was analyzed from randomization to initiation of first post discontinuation chemotherapy (censoring patients who died prior to initiation of chemotherapy)

Erstlinientherapie HR+ HER2- MBC in Deutschland (PRAEGNANT Netzwerk 2014-2019)



© Peter Fasching, personal communication



So, Where are we exactly?





Mammakarzinom–Therapie nach SABCS 2019

- ✓ **Luminales Mammakarzinom (HR+ HER2–):**
 - ✓ EBC: Prognoseverbesserung; *high-risk* luminal nach wie vor problematisch: CDK 4/6i vielversprechend – Studien als aktuelle Chance
 - ✓ MBC: CDK 4/6i haben Therapierealität verändert; Chemotherapie nur bei viszeraler Krise oder nach ausgeschöpfter endokriner Sequenz –
- ✓ **HER2+:** Prognoseverbesserung durch neo–adjuvante Therapie mit dualer Blockade und ggf. T–DM1; Änderung Metastasierungsmuster
- ✓ **MBC:** Vielversprechend: Tucatinib und DS8201 (FDA Zulassung seit 12/19); Zugang in klinischen Studien (HER2CLIMB 02; DESTINY Programm)
- ✓ **TNBC:** Immuntherapie: Standard MBC Erstlinie; Zulassung EBC erwartet. Bei vielen offenen Fragen und ggf. permanenter Toxizität nur evidenzbasierter Einsatz sinnvoll

Mammakarzinom 2019: Was haben wir erreicht ?

- Vermeidung von Übertherapie HR+ HER2- (GBA Beschluss GEA)
- Eskalation nach non-pCR HER2+ (Zulassung T-DM1)
- Erste Immuntherapie: TN-MBC (Zulassungserweiterung Atezolizumab)
- Zielgerichtet statt Chemo bei gBRCA Mutation (Zulassung PARPi)
- Erste tumor-unabhängige Zulassung in EU bei NTRK Genfusion (Larotrectinib: Vitrakvi®)



■ ...

Mammakarzinom 2020: Wie geht es weiter ?

- Weitere Daten zur Immuntherapie: Atezolizumab neoadjuvant (IMP031); Pembrolizumab Erstlinie MBC (KN355); ...
- PIK3CA Mutation (HR+): zielgerichtete Therapie MBC (Alpelisib)
- Zulassungen (Einreichung) erwartet: Pembrolizumab (TNBC neoadjuvant); Tucatinib (MBC HER2+); DS8201 (MBC HER2+ für EMA)
- ...





**Vorstellung der aktualisierten
Empfehlungen zur Diagnostik
und Therapie des frühen und fort-
geschrittenen Mammakarzinoms
2020 durch die Mitglieder der
AGO Kommission Mamma**

InterContinental Hotel Frankfurt
Wilhelm-Leuschner-Strasse 43, 60329 Frankfurt am Main

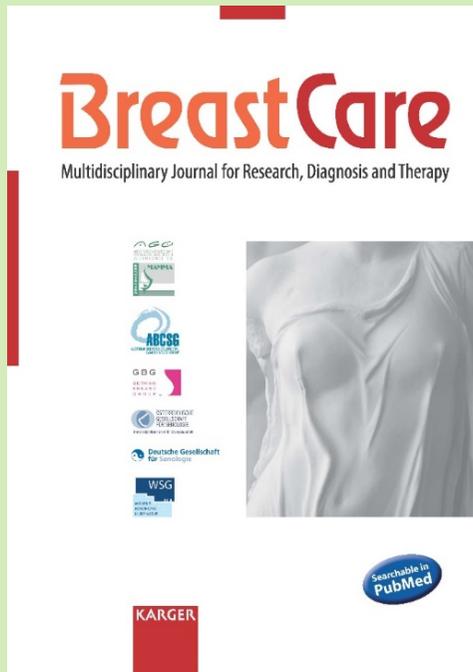
Für die Veranstaltung werden Fortbildungspunkte beantragt.
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