

Aktuelle Daten aus San Antonio zum HER2+ mBC



Seagen Satellitensymposium, GBG Jahrestreffen 2021, 24.02.2021

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	Company
(1) Advisory role	Amgen, AstraZeneca, Biom'Up, Clovis, Celgene, Daiichi Sankyo, Eisai, Exact Sciences, GSK, Lilly, MSD, Norgine, Neodynamics, Novartis, Pfizer, pfm medical, Roche, RTI Surgical, Sysmex, Tesaro
(2) Lecture/speaker engagement fees	Amgen, art tempi, AstraZeneca, Celgene, Clovis, Connect Medica, Daiichi Sankyo, Eisai, Exact Sciences, Hexal, I-Med-Institute, Lilly, MCI, Medtronic, MSD, Novartis, Omniamed, Pfizer, pfm medical, Roche, RTI Surgical, Seagen, Sysmex, Vifor
(3) Manuscript fees	Amgen, Celgene, Clearcut, pfm medical, Roche
(4) Trial Funding	Endomagnetics, Exact Sciences

Neue Entwicklungen HER2-gerichteter Therapien haben zu **signifikanten Überlebensvorteilen** geführt

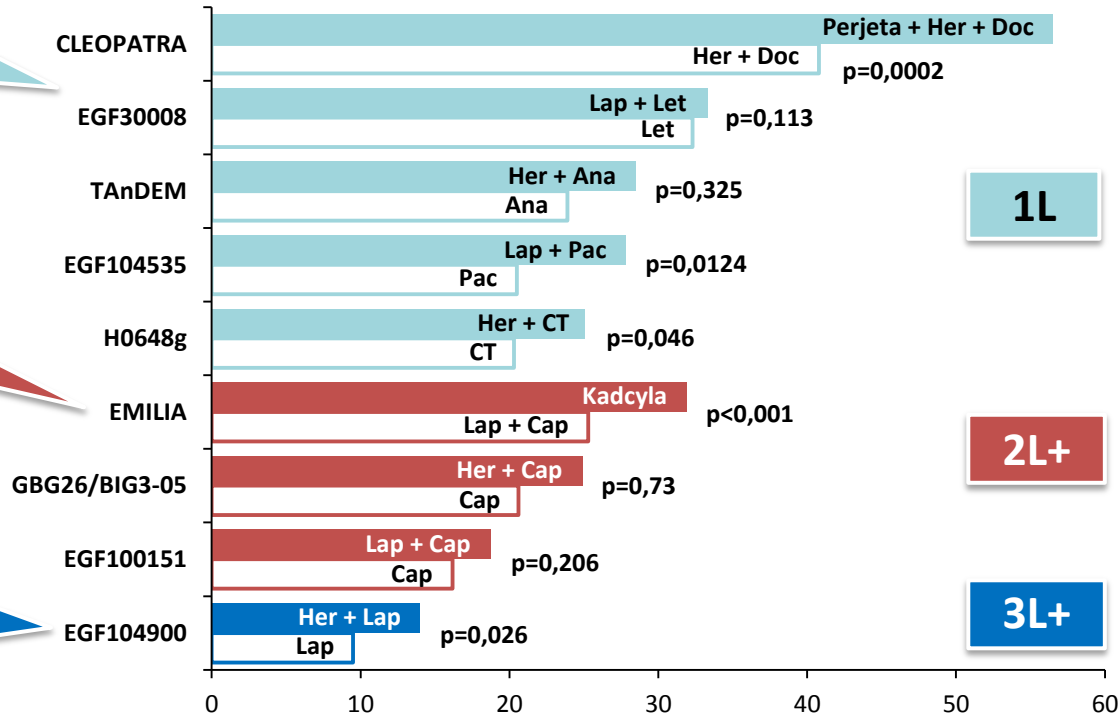
**Pertuzumab + Trastuzumab
+ Docetaxel**
OS ~ 5 Jahre



T-DM1
OS ~ 2,5 Jahre



**Kombinationen mit
Trastuzumab**
OS ~ 14 Monate



Reicht uns das? Ist das genug?

Wo liegen die Probleme?

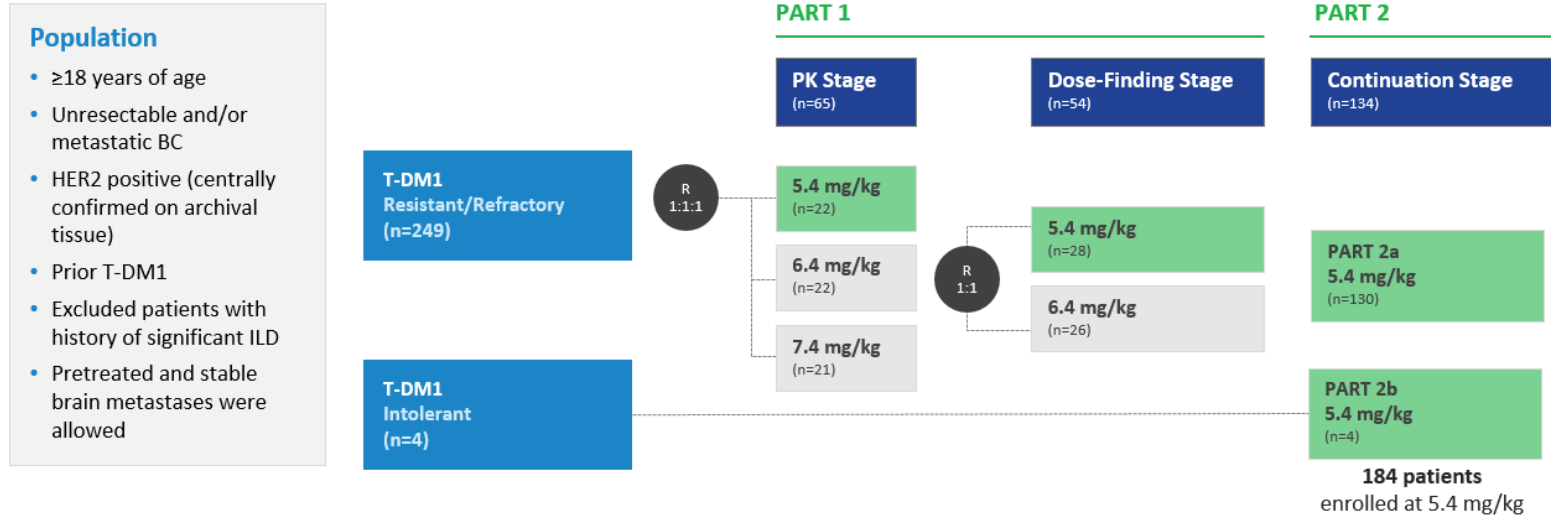
- In frühen Therapielinien ist das Ansprechen gut
- In späteren Therapielinien ist jedoch ein schlechteres Ansprechen zu erwarten
 - Akquirierte Mutationen, sekundäre Resistenzen, bei der triple-positiven Erkrankung auch endokrine Resistenzen
- Chemotherapie als Kombinationspartner einer HER2-gerichteten Therapie aufgrund von Toxizität keine Dauertherapie

Was sind die Medical Needs?

- Kann in späteren Therapielinien auch effektiv behandelt werden?
- Können Hirnmetastasen effektiver therapiert werden?
- Kann durch Bindung von Chemotherapiemolekülen an einen HER2-gerichteten Antikörper die Chemotherapie direkt in die Zelle gebracht, die Effektivität gesteigert und die Toxizität reduziert werden?

Trastuzumab Deruxtecan: DESTINY-Breast01, Phase II

Prior treatment: 100% Trast./ 100% T-DM1/ 65% Pertuz.



Endpoints

- **Primary:** confirmed ORR by independent central imaging facility review per RECIST v1.1
- **Secondary:** investigator-assessed ORR, DCR, DOR, CBR, PFS, OS, PK and safety

Median Duration of Follow-Up

- **August 1, 2019 data cutoff:** 11.1 months (range, 0.7-19.9 months)
- **June 8, 2020 data cutoff:** 20.5 months (range, 0.7-31.4 months)

Modi S, et al. *N Engl J Med.* 2020; 382(7):610-621; Modi S, et al. SABCS 2020. Poster PD3-06.



DESTINY-Breast01

Trastuzumab Deruxtecan (T-DXd, DS-8201) ist ein neues ADC, das einen optimalen anti-Tumor-Effekt erzielen soll

Trastuzumab Deruxtecan ist ein ADC, das aus drei Komponenten besteht:

- Ein humanisierter monoklonaler anti-HER2-IgG1-Antikörper mit der gleichen Aminosäuresequenz wie Trastuzumab
- Die Topoisomerase-I-Inhibitor-“Ladung“ (Payload), ein Exatecan-Derivat (DXd)
- Ein tetrapeptidbasierter spaltbarer Linker

Wirkprinzip Payload: Topoisomerase-I-Inhibitor

Hohe Potenz des Payloads

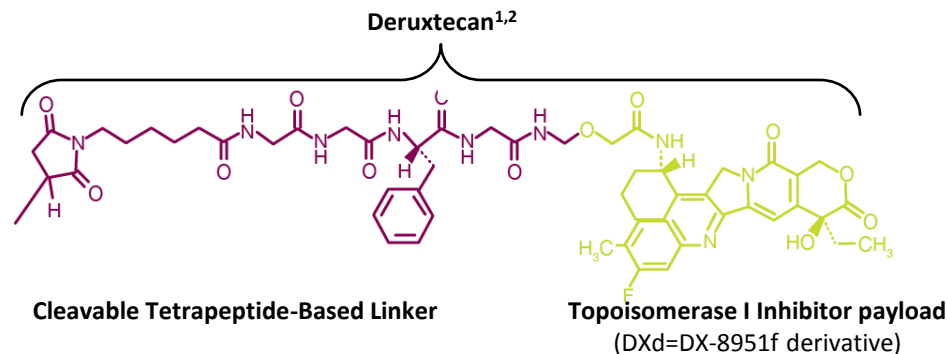
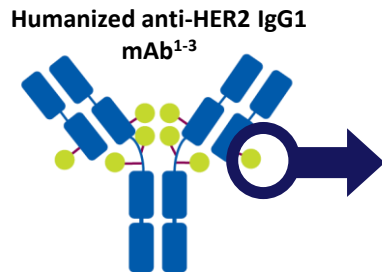
Hohes Verhältnis von Wirkstoff zu Antikörper: ~ 8

Payload mit kurzer systemischer Halbwertszeit

Stabile Verbindung Linker - Payload

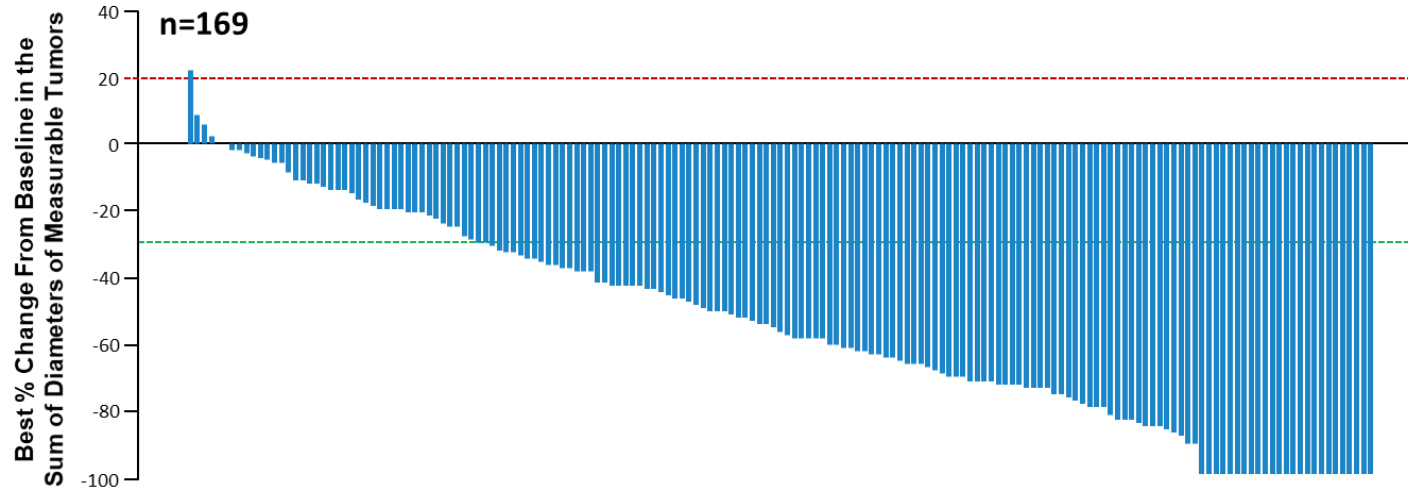
Tumor-selektiver spaltbarer Linker

Membranpermeabler Payload



SABCS 2020: Update DESTINY-Breast01 ¹

- Primary EP: ORR
- confirmed ORR by ICR: 61.4 %



By independent central review. A total of 169 patients from the enrolled analysis set (N=184) had both baseline and postbaseline target lesion assessments by independent central review and are included in this analysis.

Modi S, et al. SABCS 2020. Poster PD3-06.

SABCS 2020: Update DESTINY-Breast01

Drug-related ILD/Pneumonitis^a

Interstitial lung disease, n (%)	T-DXd 5.4 mg/kg (N=184)					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any grade/ Total
Aug 2019 data cutoff	5 (2.7)	15 (8.2)	1 (0.5)	0	4 (2.2)	25 (13.6)
June 2020 data cutoff	6 (3.3)	16 (8.7)	1 (0.5)	0	5 (2.7)	28 (15.2)

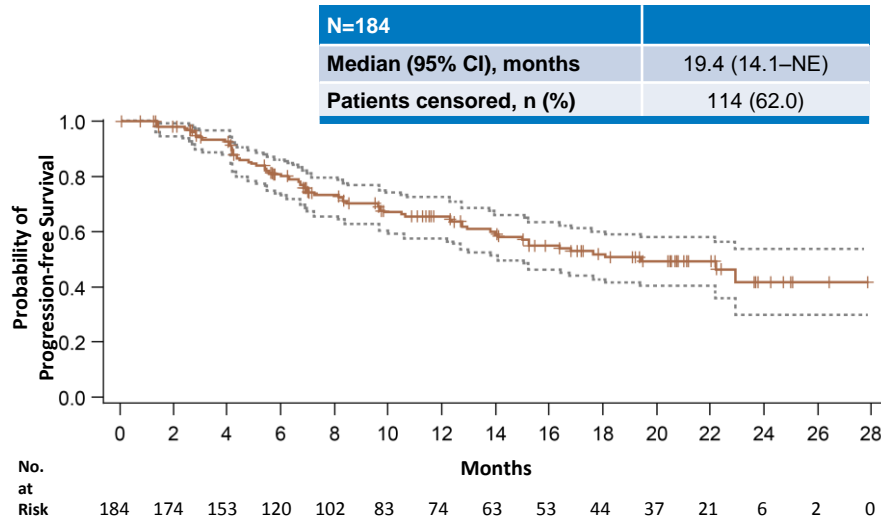
^aAs determined by an independent interstitial lung disease adjudication committee. At data cutoff, 1 grade 1 event and 1 grade 3 event were pending adjudication



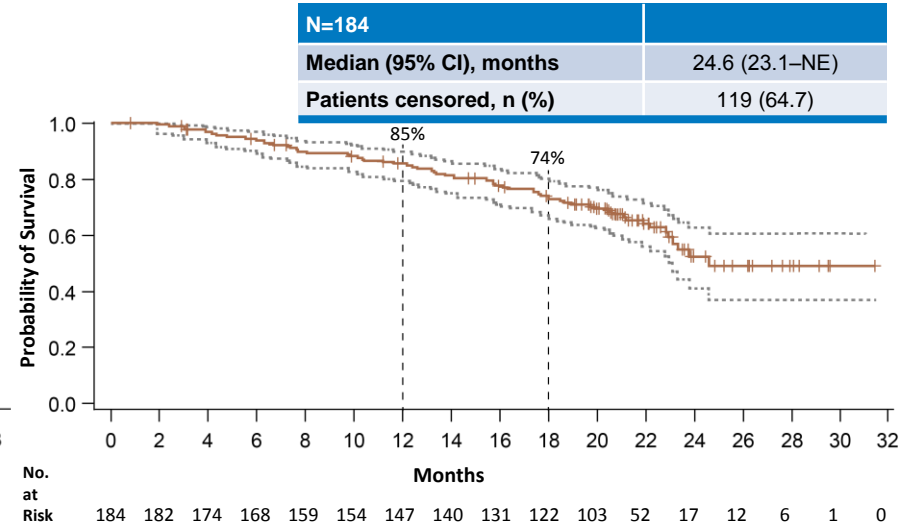
SABCS 2020: Update DESTINY-Breast01

Progression-Free Survival & Overall Survival

Kaplan-Meier Analysis of Progression-Free Survival



Kaplan-Meier Analysis of Overall Survival



Light gray dashed lines indicate 95% CI



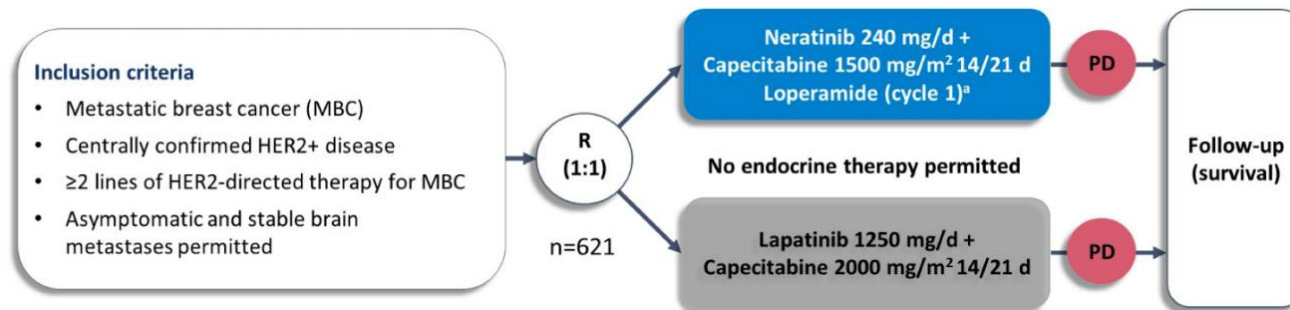
DESTINY-Breast01 - Fazit

- Das konsistente Nutzen-Risiko-Profil bedeutet Sicherheit und die Bestätigung der Therapieeffektivität für den Therapeuten
- Extensives Studienprogramm ongoing
 - DESTINY-Breast02 – vs. SOC after T-DM1 (HER2+)
 - DESTINY-Breast03 – vs. T-DM1 (HER2+)
 - DESTINY-Breast04 – vs. CTX (HER2 low)
- Substanz zwar von der EMA zugelassen aber da in der DESTINY-Breast01 Studie kein Vergleichsarm existierte, aktuell in Deutschland nicht verfügbar



NALA-Studie, Phase III, HER2+ mBC, Neratinib + Capecitabin vs. Lapatinib + Capecitabin, N=621

- Neratinib: second-generation (irreversible) TKI of EGFR, HER2 and HER4
- NEfERT-T: Activity of neratinib plus paclitaxel comparable to trastuzumab plus paclitaxel (1st-line)², N=479
- NALA: Randomized phase III trial, neratinib plus cap vs. lapatinib plus cap in pretreated pts. (significant PFS benefit of 2.2 months)



Stratification variables

- Number of prior HER2 therapies for MBC
- Disease location
- HR status
- Geographic location

Endpoints

- Co-primary: PFS (centrally confirmed) and OS
- Secondary: PFS (local), ORR, DoR, CBR, intervention for CNS metastases, safety, health outcomes

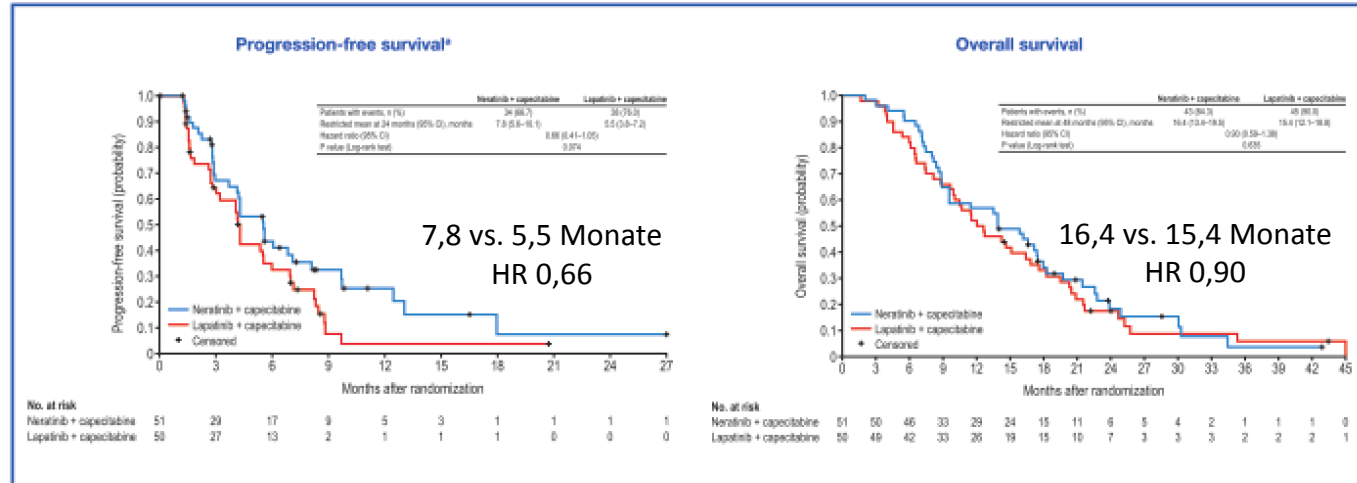
^aLoperamide 4 mg with first dose of neratinib, followed by 2 mg every 4 h for first 3 d, then loperamide 2 mg every 6–8 h until end of Cycle 1. Thereafter as needed



SABCS 2020: activity depending on BM ¹

- NALA: 101/621 pt BM (16.3%), 82% with local prior treatment
- no mandatory CNS screening at baseline
- pt with progredient, symptomatic or instabile BM excluded
- LMC allowed
- Screening via cMRT or cCT at baseline

Figure 2. Progression-free survival and overall survival in patients with CNS metastases at baseline



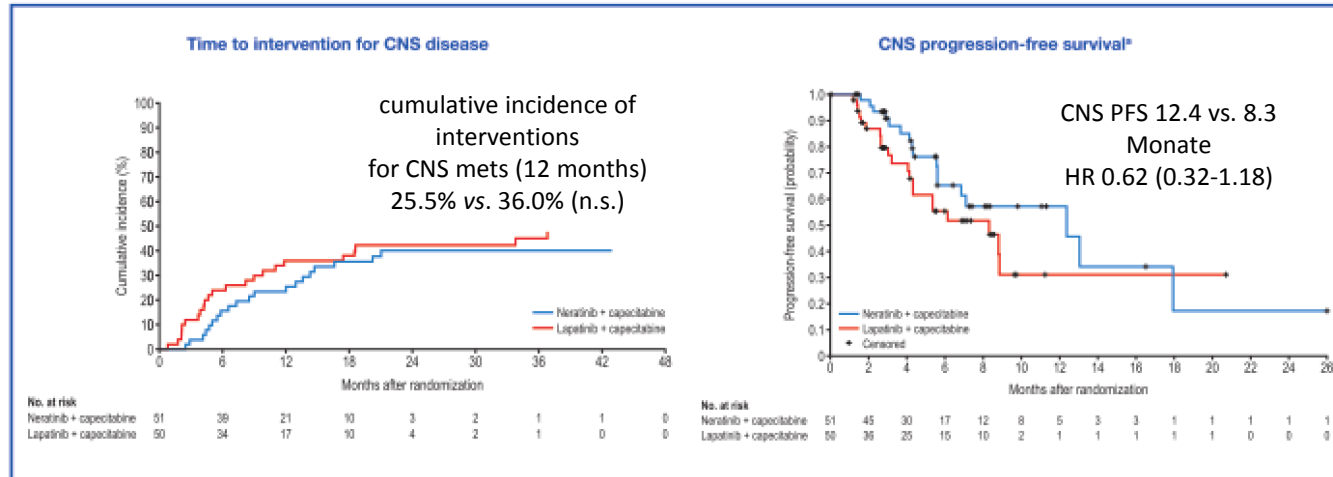
*Independently adjudicated.



SABCS 2020: activity depending on BM ₁

- NALA: 101/621 pt BM (16.3%), 82% with local prior treatment
- no mandatory CNS screening at baseline
- pt with progredient, symptomatic or instabile BM excluded
- LMC allowed
- Screening via cMRT or cCT at baseline

Figure 3. CNS-specific outcomes in patients with CNS metastases at baseline



*Scans centrally read

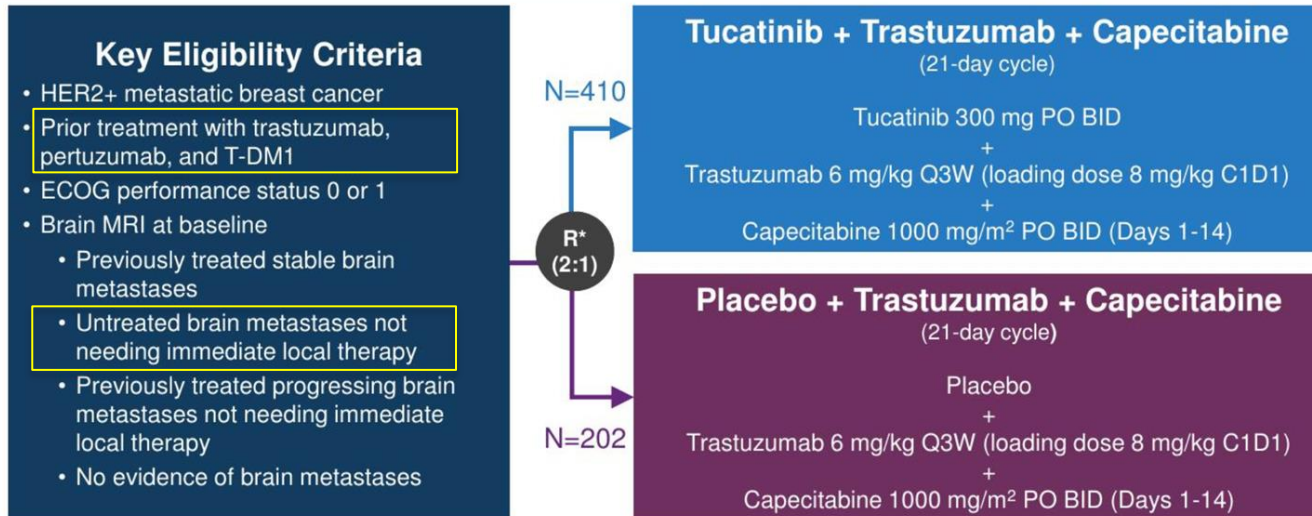


- Die Daten der NALA-Studie zeigen beim HER2+ mBC durch die Kombination aus Neratinib und Capecitabin vs. Lapatinib und Capecitabin ein verbessertes PFS bei Pats. mit ZNS-Metastasen
- Die Ergebnisse sind konsistent zu den Ergebnissen der anderen 3 prospektiven Studien: NEfERT-T, TBCRC-022 und ExteNET, in welchen die Pats. mit ZNS-Mets. ein verbessertes Outcome durch die Neratinib-basierte Therapie hatten
- Besonders war der Einschluss von Pats. mit Leptomeningeosis carcinomatosa (LMD)

HER2CLIMB Studie – Tucatinib + Trastuz. + Capecitabin, N=612, vorherige Therapie mit Trastuzumab, Pertuzumab und T-DM1

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

HER2CLIMB Trial Design



*Stratification factors: presence of brain metastases (yes/no), ECOG status (0 or 1), and region (US or Canada or rest of world)

<https://clinicaltrials.gov/ct2/show/NCT02614794>

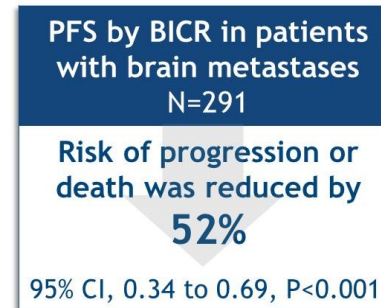
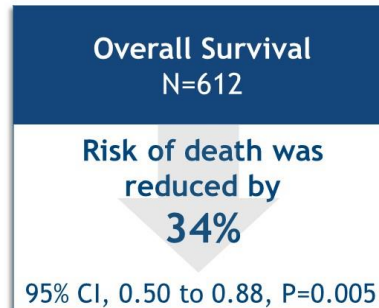
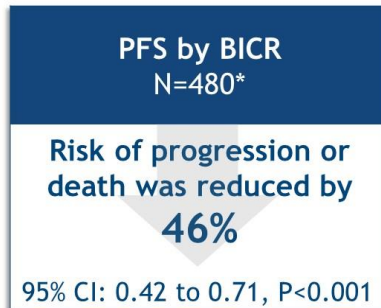
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HER2CLIMB Studie – Tucatinib + Trastuz. + Capecitabin, N=612, nach Trastuzumab, Pertuzumab und T-DM1 - Update ASCO 2020

HER2CLIMB Primary Analysis Results

- The HER2CLIMB trial met all primary and alpha-controlled secondary endpoints at the first interim analysis.
- Importantly, the secondary endpoint of PFS in patients with brain metastases was met.



PFS: progression-free survival; BICR: blinded independent central review
*The primary endpoint of PFS was assessed in the first 480 patients enrolled.

Murthy RK, et al. *N Engl J Med* 2020;382:597-609.



TUCATINIB VS PLACEBO IN COMBINATION WITH TRASTUZUMAB AND CAPECITABINE FOR PATIENTS WITH LOCALLY ADVANCED UNRESECTABLE OR HER2-POSITIVE METASTATIC BREAST CANCER (HER2CLIMB): OUTCOMES BY HORMONE RECEPTOR STATUS

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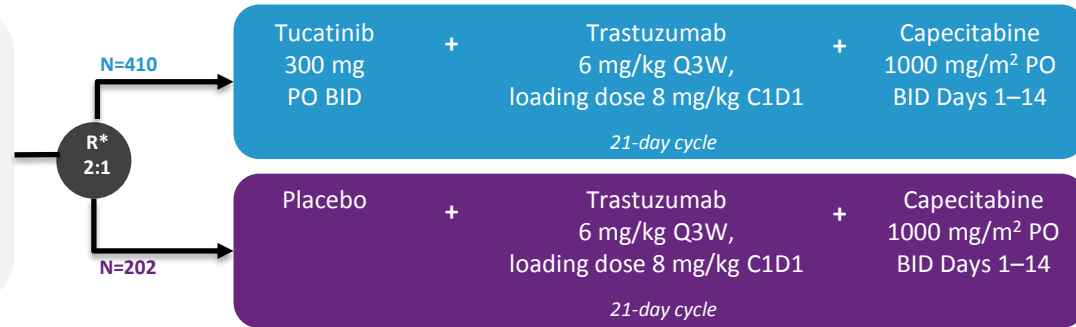
San Antonio Breast Cancer Symposium*, December 8–11, 2020; Poster No. PD3-08



HER2CLIMB Studie – Tucatinib + Trastuz. + Capecitabin, Pats. mit Hirnmetastasen, N=612 - Update SABCS 2020

Key Eligibility Criteria

- HER2+ MBC
- Prior treatment with trastuzumab, pertuzumab, and T-DM1
- ECOG performance status 0 or 1
- Brain MRI at baseline



*Stratification factors: presence of brain metastases (yes/no), ECOG performance status (0 or 1), Region (US or Canada or rest of world)
<https://clinicaltrials.gov/ct2/show/NCT02614794>

- The primary endpoint was PFS (Response Evaluation Criteria in Solid Tumors [RECIST] v1.1 by blinded independent central review [BICR]) analyzed in the first 480 patients enrolled.
- Multiplicity-adjusted secondary efficacy endpoints were analyzed in the total population:
 - OS (n=612)
 - PFS in patients with brain metastases (RECIST v1.1 by BICR; n=291)
 - Confirmed ORR in patients with measurable disease (RECIST v1.1 by BICR; n=511)



HER2CLIMB-Studie, Trast. + Cape + Tucatinib, N=612

Update SABCS 2020 - Patientencharakteristika

- Baseline demographics and disease characteristics in HR+/HR- subgroups were generally balanced between treatment arms.

		HR+		HR-	
		TUC+Tras+Cape (N=243)	Pbo+Tras+Cape (N=127)	TUC+Tras+Cape (N=167)	Pbo+Tras+Cape (N=75)
Age in years, median (range)		55.0 (22, 80)	54.0 (31, 82)	53.0 (32, 78)	53.0 (25, 78)
Female, n (%)		240 (98.8)	125 (98.4)	167 (100)	75 (100)
ECOG performance status, n (%)	0	121 (49.8)	64 (50.4)	83 (49.7)	30 (40.0)
	1	122 (50.2)	63 (49.6)	84 (50.3)	45 (60.0)
Stage IV at initial diagnosis, n (%)		95 (39.1)	51 (40.2)	48 (28.7)	26 (34.7)
Prior lines of therapy, median (range)	Overall	4.0 (2, 14)	4.0 (2, 9)	4.0 (2, 10)	3.0 (2, 17)
	Metastatic setting	3.0 (1, 14)	3.0 (1, 8)	2.0 (1, 8)	3.0 (1, 13)
Presence/history of brain metastases, n (%)		107 (44.0)	59 (46.5)	91 (54.5)	34 (45.3)

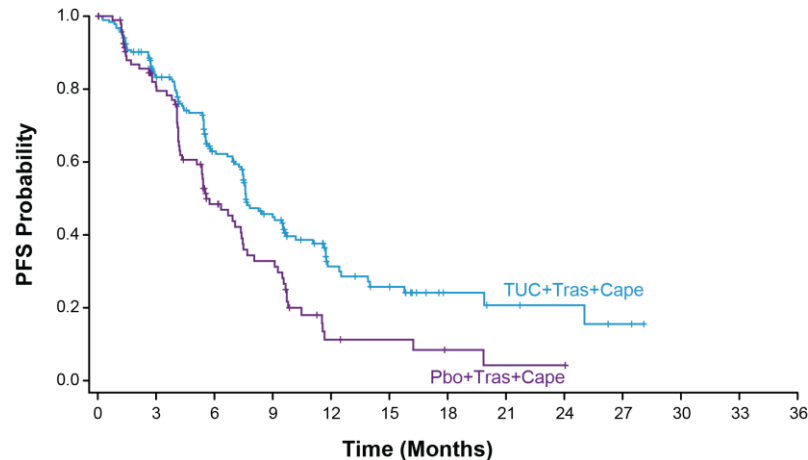


HER2CLIMB-Studie, Trast. + Cape + Tucatinib, N=612

Update SABCS 2020 - PFS nach HR-Status, primärer Endpunkt PFS

- PFS benefit was observed in patients in the tucatinib arm of the primary endpoint population regardless of hormone receptor status.

PFS by BICR in HR+ Subgroup

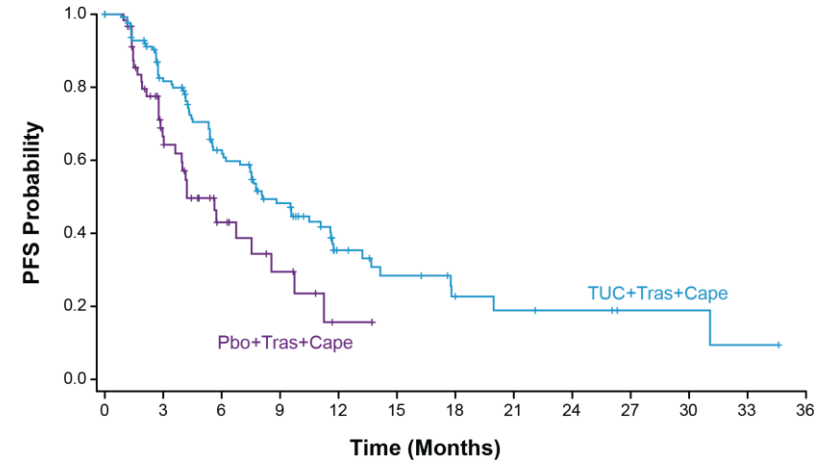


Subjects at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TUC+Tras+Cape 190	141	89	55	23	17	7	5	4	2	1	0	0	0
Pbo+Tras+Cape 99	65	33	21	5	4	2	1	1	0	0	0	0	0

Risk of progression or death was reduced 42% in all HR+ patients in the TUC arm

	Events/Total	HR (95% CI)	P-value	One-year PFS (95% CI)	Median (95% CI)
TUC+Tras+Cape	106/190			31.3% (23.1, 39.9)	7.6 mo (7.4, 9.5)
Pbo+Tras+Cape	66/99	0.58 (0.42, 0.80)	0.0008	11.3% (4.6, 21.2)	5.6 mo (4.3, 7.4)

PFS by BICR in HR- Subgroup



Subjects at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TUC+Tras+Cape 130	94	63	43	17	12	8	5	4	2	2	1	0	0
Pbo+Tras+Cape 61	29	12	6	1	0	0	0	0	0	0	0	0	0

Risk of progression or death was reduced 46% in all HR- patients in the TUC arm

	Events/Total	HR (95% CI)	P-value	One-year PFS (95% CI)	Median (95% CI)
TUC+Tras+Cape	72/130			35.4% (25.5, 45.6)	8.1 mo (7.0, 11.6)
Pbo+Tras+Cape	31/61	0.54 (0.34, 0.86)	0.008	15.8% (3.7, 35.5)	4.2 mo (3.1, 8.6)

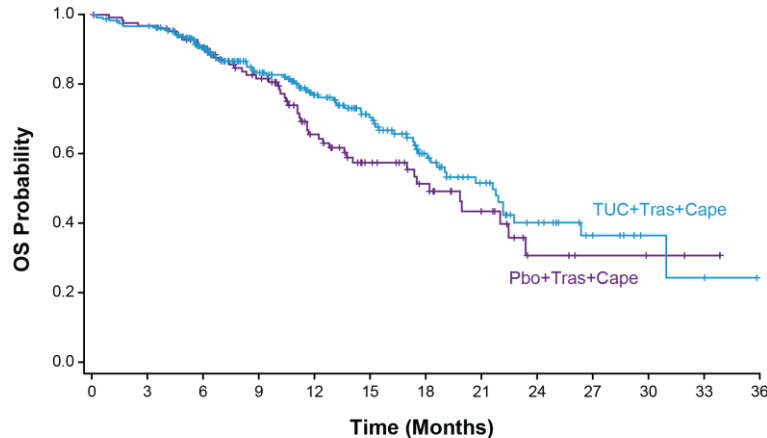


HER2CLIMB-Studie, Trast. + Cape + Tucatinib, N=612

Update SABCS 2020 - OS nach HR-Status, gesamte Studienpopulation

- Clinically meaningful improvement of OS was observed in patients on the tucatinib arm regardless of hormone receptor status.
- Of the HR+ patients who discontinued or never received tucatinib or placebo, 16% (n=23/172) in the tucatinib arm and 15% (n=16/108) in the placebo arm received one or more subsequent new hormonal therapies.

OS in HR+ Subgroup

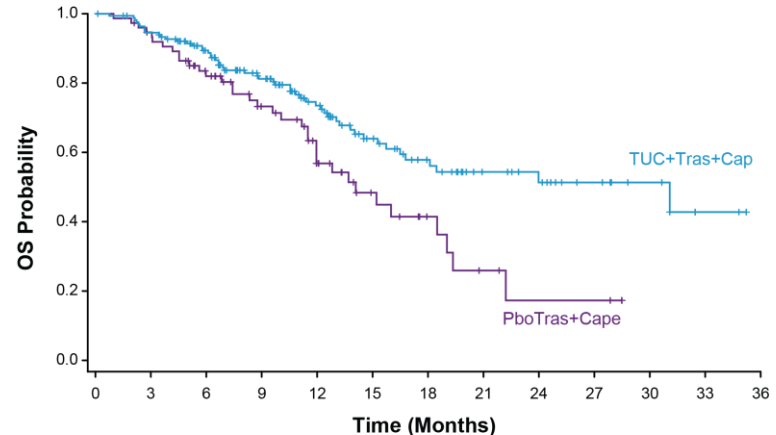


Subjects at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TUC+Tras+Cape	243	233	192	147	109	78	47	30	17	9	3	2	0
Pbo+Tras+Cape	127	122	106	80	52	34	24	15	5	3	2	1	0

Risk of death was reduced 15% in all HR+ patients in the TUC arm

	Events/Total	HR (95% CI)	P-value	Two-year OS (95% CI)	Median (95% CI)
TUC+Tras+Cape	78/243	0.85 (0.59, 1.23)	0.4	40.2% (29.1, 50.9)	21.7 mo (18.1, 26.4)
Pbo+Tras+Cape	51/127			30.7% (16.5, 46.1)	18.2 mo (13.6, 22.5)

OS in HR- Subgroup



Subjects at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TUC+Tras+Cape167	167	155	130	98	69	45	33	21	17	11	7	2	0
Pbo+Tras+Cape 75	75	69	54	39	25	14	8	4	2	2	0	0	0

Risk of death was reduced 50% in all HR- patients in the TUC arm

	Events/Total	HR (95% CI)	P-value	Two-year OS (95% CI)	Median (95% CI)
TUC+Tras+Cape	52/167	0.50 (0.31, 0.80)	0.003	51.3% (39.3, 62.1)	31.1 mo (16.5, -)
Pbo+Tras+Cape	35/75			17.3% (4.3, 37.6)	14.1 mo (11.5, 19.0) mo=months

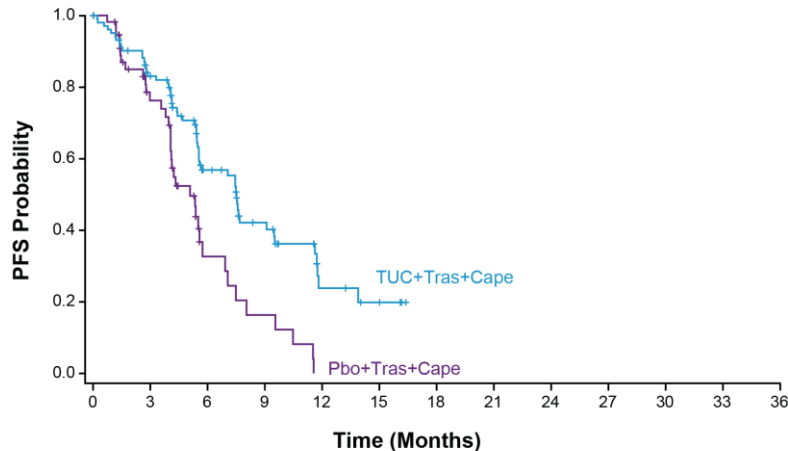


HER2CLIMB-Studie, Trast. + Cape + Tucatinib, N=612

Update SABCS 2020 - PFS nach HR-Status bei Pats. mit Hirnmetas.

- PFS benefit favoring the tucatinib arm was observed in patients with brain metastases regardless of hormone receptor status.

PFS in Patients with Brain Metastases by BICR in HR+ Subgroup



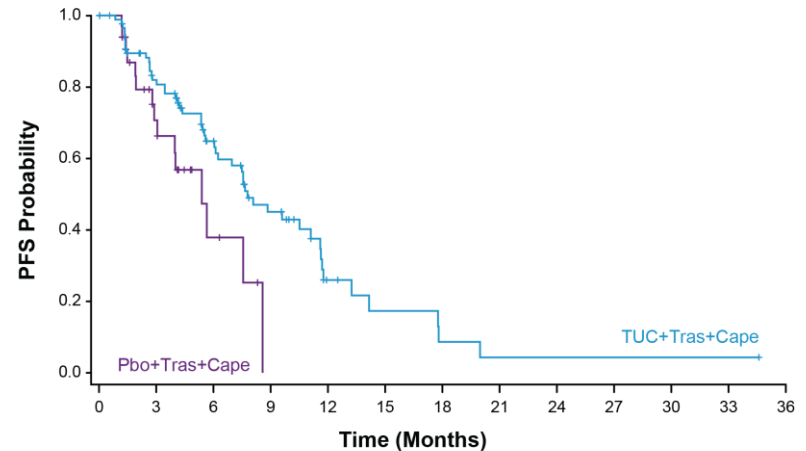
Subjects at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TUC+Tras+Cape	107	79	39	22	7	4							
Pbo+Tras+Cape	59	33	8	4	0	0							

Risk of progression or death was reduced 52% in all HR+ patients with brain metastases in the TUC arm

	Events/Total	HR (95% CI)	P-value	One-year PFS (95% CI)	Median (95% CI)
TUC+Tras+Cape	56/107			23.8% (12.6, 37.0)	7.5 mo (5.6, 9.5)
Pbo+Tras+Cape	36/59	0.48 (0.31, 0.75)	0.0008	0%	5.1 mo (4.1, 5.7)

mo=months

PFS in Patients with Brain Metastases by BICR in HR- Subgroup



Subjects at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TUC+Tras+Cape	91	65	39	23	7	4	2	1	1	1	1	1	0
Pbo+Tras+Cape	34	16	4	0	0	0	0	0	0	0	0	0	0

Risk of progression or death was reduced 50% in all HR- patients with brain metastases in the TUC arm

	Events/Total	HR (95% CI)	P-value	One-year PFS (95% CI)	Median (95% CI)
TUC+Tras+Cape	50/91			26.0% (14.2, 39.5)	7.8 mo (6.1, 11.6)
Pbo+Tras+Cape	15/34	0.50 (0.27, 0.95)	0.03	0%	5.4 mo (2.9, 8.6)

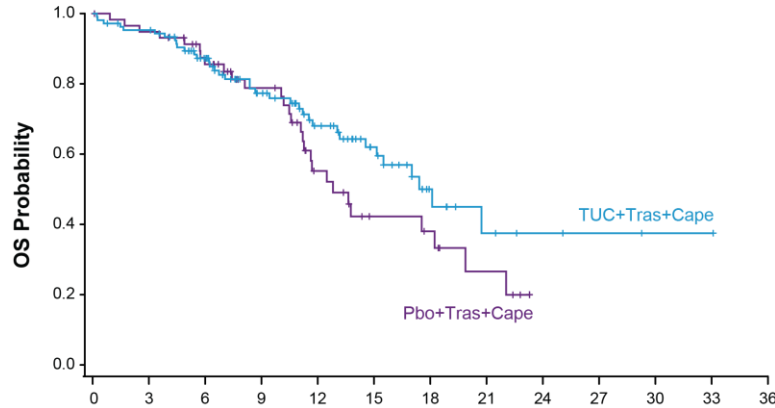


HER2CLIMB-Studie, Trast. + Cape + Tucatinib, N=612

Update SABCS 2020 - OS nach HR-Status bei Pats. mit Hirnmetas.

- OS was numerically improved in patients with brain metastases in the tucatinib arm in both hormone receptor subgroups.

OS in Patients with Brain Metastases in HR+ Subgroup



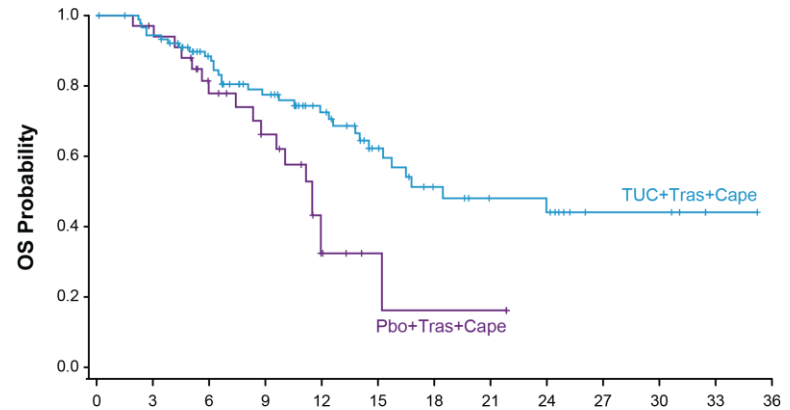
Subjects at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TUC+Tras+Cape	107	100	79	56	40	25	10	5	3	2	1	1	1
Pbo+Tras+Cape	59	55	45	33	18	10	8	4	0	0	0	0	0

Risk of death was reduced 24% in all HR+ patients with brain metastases in the TUC arm

	Events/Total	HR (95% CI)	P-value	Two-year OS (95% CI)	Median (95% CI)
TUC+Tras+Cape	36/107	0.76 (0.46, 1.26)	0.3	37.5% (19.5, 55.5)	18.1 mo (14.6, -)
Pbo+Tras+Cape	28/59				

mo=months

OS in Patients with Brain Metastases in HR- Subgroup



Subjects at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TUC+Tras+Cape	91	84	67	52	39	24	16	12	11	5	5	1	0
Pbo+Tras+Cape	34	32	22	16	5	2	1	1	0	0	0	0	0

Risk of death was reduced 63% in all HR- patients with brain metastases in the TUC arm

	Events/Total	HR (95% CI)	P-value	Two-year OS (95% CI)	Median (95% CI)
TUC+Tras+Cape	32/91	0.37 (0.19, 0.70)	0.001	44.1% (28.7, 58.4)	18.5 mo (14.5, -)
Pbo+Tras+Cape	18/34				

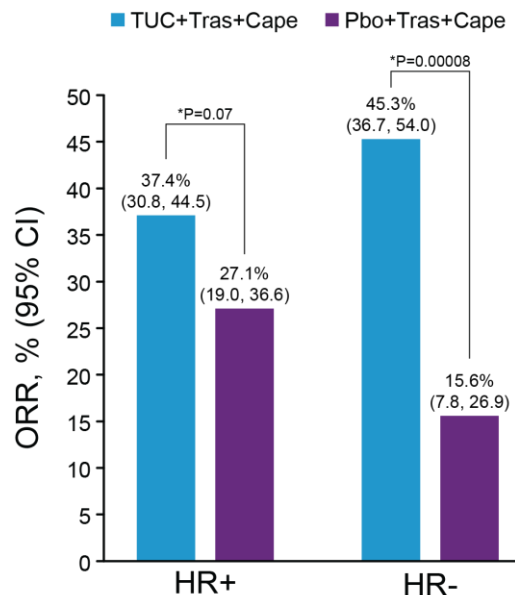


HER2CLIMB-Studie, Trast. + Cape + Tucatinib, N=612

Update SABCS 2020 – ORR mit messbarer Erkrankung per BICR

- ORR was numerically higher in the tucatinib arm compared to the placebo arm regardless of hormone receptor status.

Confirmed Objective Response Rate (RECIST v1.1, BICR)



*Stratified Cochran-Mantel-Haenszel p-value for ORR

Response, n (%)	Patients with Measurable Disease N=511			
	HR+		HR-	
	TUC+Tras+Cape (n=203)	Pbo+Tras+Cape (n=107)	TUC+Tras+Cape (n=137)	Pbo+Tras+Cape (n=64)
Best overall Response^a				
Complete response	1 (0.5)	2 (1.9)	2 (1.5)	0
Partial response	75 (36.9)	27 (25.2)	60 (43.8)	10 (15.6)
Stable disease	99 (48.8)	60 (56.1)	56 (40.9)	40 (62.5)
Progressive disease	16 (7.9)	13 (12.1)	11 (8.0)	11 (17.2)
Not evaluable	0	0	0	1 (1.6)
Not available ^b	12 (5.9)	5 (4.7)	8 (5.8)	2 (3.1)

a Confirmed Best overall response assessed per RECIST v1.1.

b Subjects with no post-baseline response assessments.



- Tucatinib ist der erste Tyrosinkinase-Inhibitor, der bei Patienten mit einem HER2-positiven Mammakarzinom (mit und ohne ZNS-Metastasen) das Gesamtüberleben signifikant verlängert
- Konsistente Ergebnisse für die beiden Hormonrezeptor-Subgruppen unabhängig vom Hormonrezeptorstatus. Die Patientinnen erhielten parallel keine endokrine Therapie (!)
- Tucatinib in Kombination mit Capecitabin + Trastuzumab zeigt eine bedeutende Verbesserung des PFS unabhängig vom HR-Status
- Die Daten sind konsistent mit den vorherigen Analysen

IMPACT OF TUCATINIB ON HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH HER2+ METASTATIC BREAST CANCER WITH BRAIN METASTASES

Andrew Wardley¹, Volkmar Mueller², Elisavet Paplomata³, Laurence Crouzet⁴, Nayyer Iqbal⁵, Sramila Aithal⁶, Margaret Block⁷, Soren Cold⁸, Marie-Agnes By⁹, Olwen Hahn¹⁰, Teja Poosarla¹¹, Erica Stringer-Reasor¹², Marco Colleoni¹³, David Cameron¹⁴, Giuseppe Curigliano¹⁵, Kendra DeBusk¹⁶, Muriel Siadak¹⁶, Jorge Ramos¹⁶, Wentao Feng¹⁶, Karen Gelmon¹⁷

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San Antonio Breast Cancer Symposium[®]; December 8–11, 2020; Poster No. PD13-04

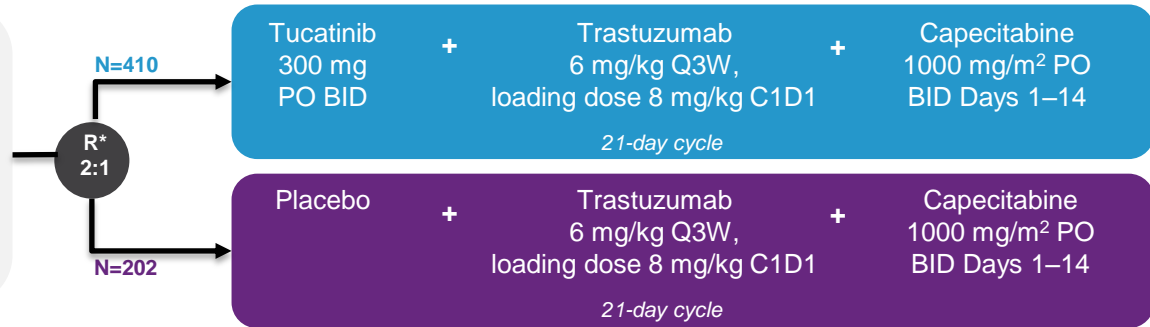


HER2CLIMB-Studie, Trast. + Cape + Tucatinib, N=612

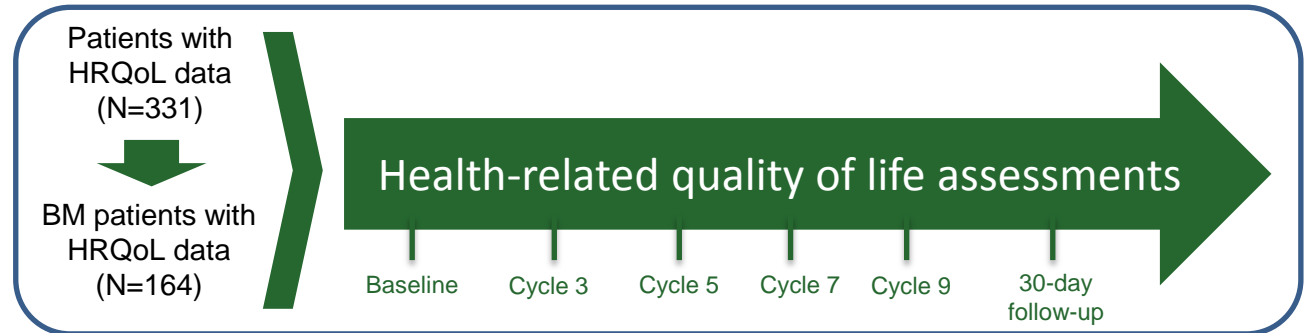
Update SABCS 2020 – Quality of life analysis

Key Eligibility Criteria

- HER2+ MBC
- Prior treatment with trastuzumab, pertuzumab, and T-DM1
- ECOG performance status 0 or 1
- Brain MRI at baseline



*Stratification factors: presence of brain metastases (yes/no), ECOG performance status (0 or 1), Region (US or Canada or rest of world)
<https://clinicaltrials.gov/ct2/show/NCT02614794>¹⁰



Total Study Population

- 612 patients randomized 2:1 February 2016 to May 2019

HRQoL with Brain Metastases Study Population

- Assessments initiated in August 2017
- HRQoL data were available from 331 of 612 patients, including 164 patients with brain metastases:
 - 107 patients in the tucatinib arm
 - 57 patients in the placebo arm

HRQoL Assessments

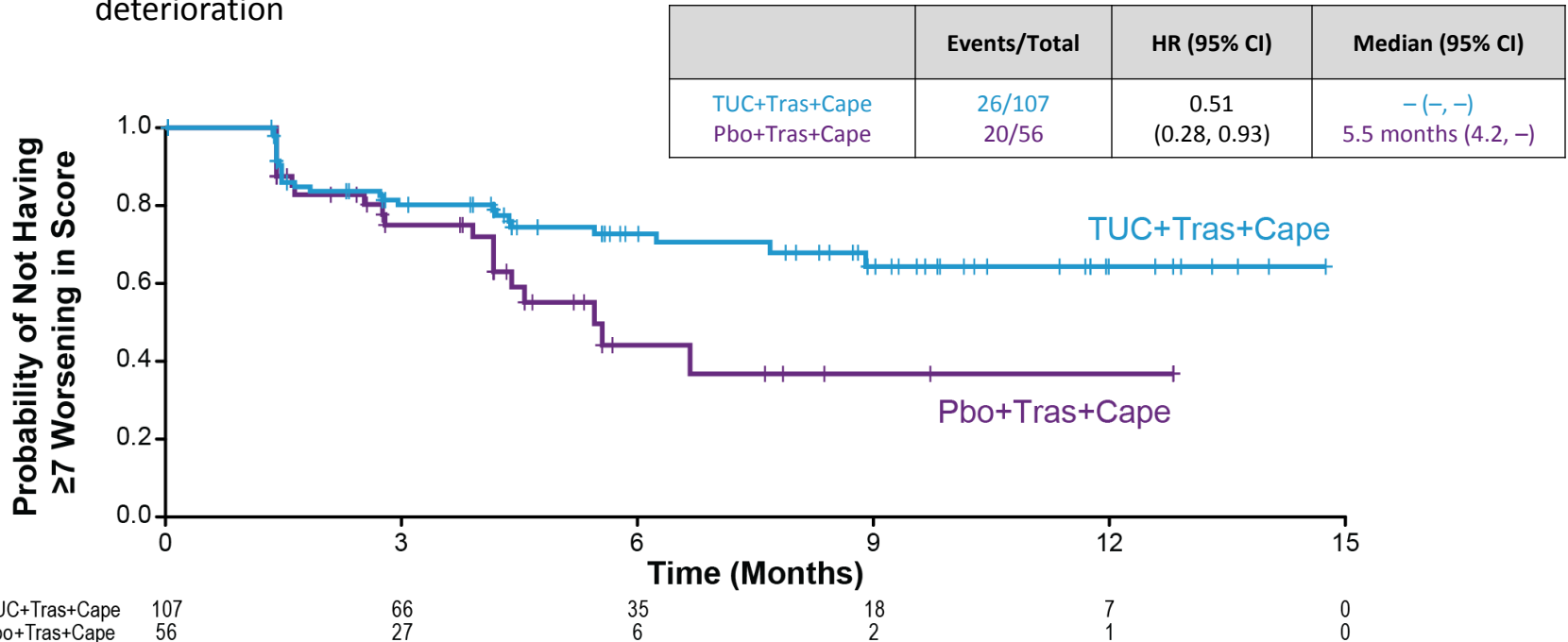
- **Overall health status:** visual analog scale (VAS)
- **Time to deterioration of QoL:** defined as decrease of 7 points on VAS¹¹
- **Change from baseline on individual patient-reported items**
 - Mobility, self-care, usual activities, pain/discomfort, and anxiety/depression
 - Each dimension has 5 levels: no, slight, moderate, severe, or extreme problems



HER2CLIMB-Studie, Trast. + Cape + Tucatinib, N=612

Quality of life analysis – Zeit bis zur Verschlechterung (≥ 7 Punkte) in EQ-5D-5L Health Score in HRQoL Population mit Hirnmets.

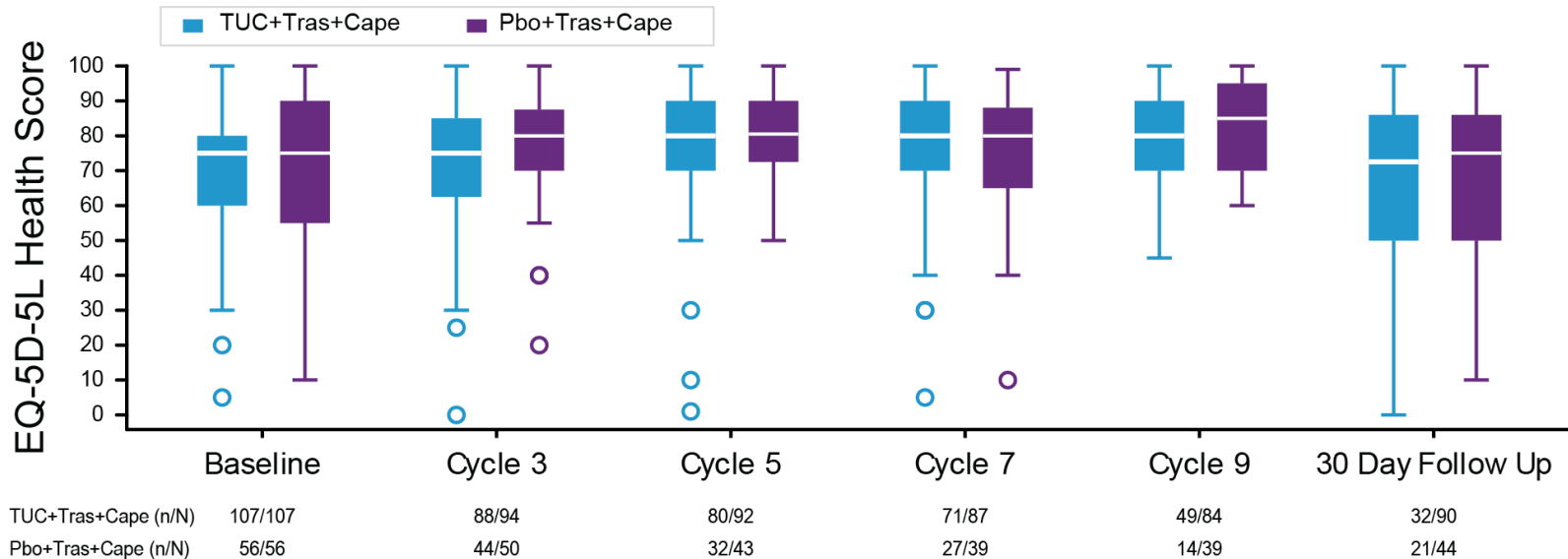
- Addition of tucatinib significantly delayed time to worsening of EQ-5D-5L Health Score.
 - Compared to the placebo arm, patients on the tucatinib arm had a 49% reduction in the risk of deterioration



HER2CLIMB-Studie, Trast. + Cape + Tucatinib, N=612

Quality of life analysis – Overall HRQoL Population mit Hirnmets.

- HRQoL was maintained throughout treatment and was not noticeably different between treatment arms.



Fazit – HER2CLIMB QoL

- Tucatinib zeigt in Kombination mit Trastuzumab und Capecitabin eine signifikant längere und klinisch bedeutsame Zeit bis zur Verschlechterung der HRQoL bei Pats. mit HER2+ mBC



Fazit Tucatinib

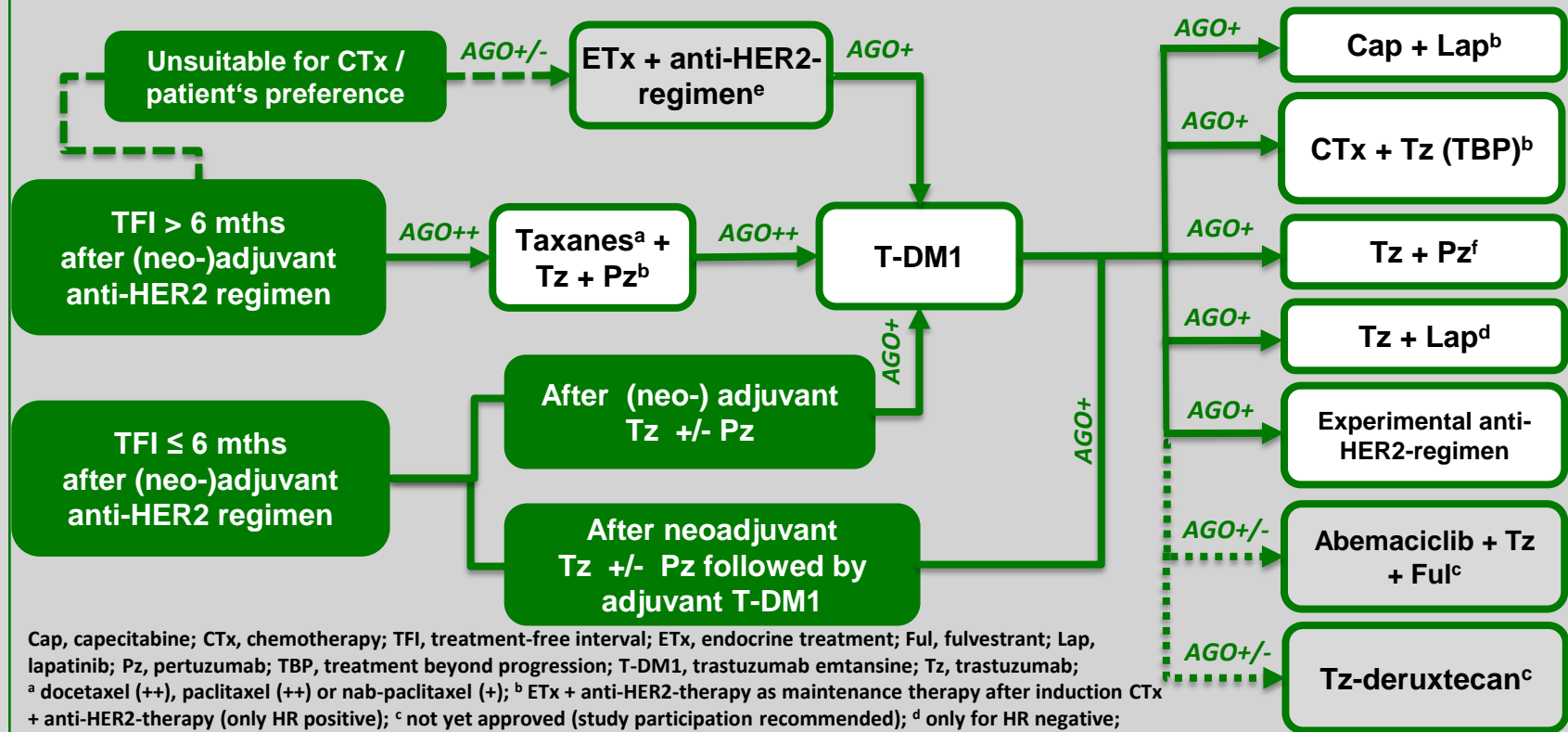
- Tucatinib in Kombination mit Trastuzumab und Capecitabin hat das Potential zu einem neuem Therapiestandard bei HER2+ MBC mit / ohne Hirnmetastasen zu werden
- Über ein Expanded Access Programm verfügbar



HER2-positive Metastatic Breast Cancer: 1st-3rd-line

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Guidelines Breast
Version 2020.1D



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Cap, capecitabine; CTx, chemotherapy; TFI, treatment-free interval; ETx, endocrine treatment; Ful, fulvestrant; Lap, lapatinib; Pz, pertuzumab; TBP, treatment beyond progression; T-DM1, trastuzumab emtansine; Tz, trastuzumab;
^a docetaxel (++) , paclitaxel (++) or nab-paclitaxel (+); ^b ETx + anti-HER2-therapy as maintenance therapy after induction CTx + anti-HER2-therapy (only HR positive); ^c not yet approved (study participation recommended); ^d only for HR negative;
^e no OS benefit, consider induction chemotherapy + anti-HER2-therapy (followed by ETx + anti-HER2-therapy as maintenance therapy); ^f only data available for pts. after trastuzumab treatment

Save the Date:

Update virtuell am 27. Februar 2021

<https://www.ago2021.de>



Vielen Dank!

