ASCO 2019 Breast Cancer - CDK4/6

REF	Study	Study details	Line	Drug	Biomarker/Subgroup	N	Primary endpoint	Secondary endpoints
1	I3Y-MC-JPBO NCT02308020 (N=58)	Phase II cohort study HmR+/HER2- MBC ≥1 new/not previously irradiated measurable BM ≥10mm *or* A progressive previously irradiated BM	≥1st	abemaciclib		52	OIRR: 6%	6-mo CBR-rate: 25% mPFS: 4.4 mo
2	MONALEESA-7 NCT02278120 (N=672)	Phase III double-blind randomised Pre- and peri-menopausal women HmR+/HER2- ABC	≥1st	ribociclib + ET + GOS placebo + ET + GOS	ET with NSAI	672 495	**mPFS** 23.8 mo 13.0 mo	**mOS / 42-mo OS-rate** NR / 70.2% 40.9 mo / 46.0% mOS HR: 0.699
3	MONALEESA-7 NCT02278120 (N=672)	Biomarker-analysis Phase III double-blind randomised Pre- and peri-menopausal women HmR+/HER2- ABC	≥1st	ribociclib + ET + GOS placebo + ET + GOS	CCND1 IGF1R ERBB3 CCNE1 MYCx FGFR1 ESR1 MKI67	185 175		**HR for PFS** **(high vs low)** HR 0.38 vs 0.67 HR 0.33 vs 0.77 HR 0.33 vs 0.76 HR 0.38 vs 0.65 HR 0.37 vs 0.69 HR 0.45 vs 0.61 (NS) HR 0.57 vs 0.57 (NS) HR 0.50 vs 0.51 (NS)
4	TRINITI-1 NCT02732119 (N=95)	Phase I/II Men and postmenopausal women Progression on prior CDK4/6i ≥ 1 prior ET and ≤ 1 prior CTx	≥1st	ribociclib + EVE mg + EXE mg	ESR1 mut vs wt	95	24-wk CBR: 41.1%	ORR: 8% mPFS: 5.7mo 1-year PFS: 33% mPFS: 3.5 vs 6.9 mo
5	KCSG-BR 15-10 NCT02592746 (N=189)	Phase II open label randomised Premenopausal women HmR+/HER2- MBC	2nd	capecitabine vs palbociclib + EXE + GNRHa		 92 92	**mPFS** 11.3 mo 19.0 mo	

Abbreviations and citations on final slide
Data based on public abstracts and clinicaltrials.gov information

ASCO 2019 Breast Cancer - HmR+

REF	Study	Study details	Line	Drug	Biomarker/Subgroup	N	Primary endpoint	Secondary endpoints
6	GIM4 LEAD NCT01064635 (N=2056)	Phase III, multicentre, randomised Postmenopausal women HmR+ early breast cancer Recurrence-free after 2-3 ys tamoxifen	Adj	 letrozole 2-3 yr letrozole 5 yr		 1030 1026	**8-yr DFS** 80% 85%	**Osteoporosis** 4.8% 8.3%
7	FAKTION NCT01992952 (N=140)	Phase II, double-blind, randomised HmR+, HER2- Relapse or progression on AI	≥1st	 capivasertib + fulvestrant placebo + fulvestrant		 69 71	**mPFS / mOS** 10.3 mo / 26.0 mo 4.8. mo / 20.0 mo	

Abbreviations and citations on final slide
Data based on public abstracts and clinicaltrials.gov information

ASCO 2019 Breast Cancer - Chemotherapy

REF	Study	Study details	Line	Drug	Biomarker/Subgroup	N	Primary endpoint	Secondary endpoints
8	TBCRC030 NCT01982448 (N=140)	Phase II randomised BRCA1/2-proficient/unknown Stage I-III TNBC	Neo	cisplatin	All HRD+ (score >33) HRD- (score <33) HRD+ (score >33) HRD- (score <33)	72	pCR: 15% RCB0-1: 38.0% RCB0-1: 21.1% RCB0-1: 4.2% RCB2-3: 54.3% RCB2-3: 32.0% RCB2-3: 18.3%	
				paclitaxel	All HRD+ (score >33) HRD- (score <33) HRD+ (score >33) HRD- (score <33)	68	pCR: 13% RCB0-1: 43.3% RCB0-1: 19.4% RCB0-1: 7.5% RCB2-3: 46.3% RCB2-3: 23.9% RCB2-3: 9.0%	
9	NeoSTOP NCT02413320 (N=100)	Phase II, open-label Stage I-IIII TNBC	Neo	carboplatin+paclitaxel—>doxorubicin+cyclophosphamide carboplatin+docetaxel		48 52	pCR: 55% pCR: 52%	RCB 0+1: 67% RCB 0+1: 67%
10	ETNA NCT01822314 (N=695)	Phase III, multicentre, open-label Stage T2, T3, T4 breast cancer TNBC or HmR+ with grade II-III	Neo	nab-paclitaxel Paclitaxel	All Luminal B TNBC All Luminal B TNBC	346 349	pCR: 68.1% NS pCR: 72.1% NS pCR: 61.0% NS pCR: 75.6% NS pCR: 80.3% NS pCR: 63.5% NS	
11	GeparOLA NCT02789332 (N=102)	Phase II open-label, multicentre Tumour (palpable) >2 cm *or* Tumour (sonographical) >1 cm tBRCA-positive/mut and/or HRD-high	Neo	paclitaxel + olaparib —> epirubicin + cyclophosphamide paclitaxel + carboplatin —> epirubicin + cyclophosphamide	All HmR+ HmR- Age <40 yr old Age ≥40 yr old All HmR+ HmR- Age <40 yr old Age ≥40 yr old	65 37	**pCR-rates** 52.6% 56.0% NS 76.2% 45.8% NS 20.0% 59.3% NS 45.5% 50.0% NS	

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ASCO 2019 Breast Cancer - HER2+

REF	Study	Study details	Line	Drug	Biomarker/Subgroup	N	Primary endpoint	Secondary endpoints
12	KRISTINE NCT02131064 (N=444)	Phase III open-label, multicentre Stage II-III HER2+ breast cancer	Neo	docetaxel + carboplatin + trastuzumab + pertuzumab T-DM1 + pertuzumab	All pCR No pCR All pCR No pCR	221 223	EFS: 5.9% 3-yr IDFS: 97.5% 3-yr IDFS: 84.2% ESF: 13.9% 3-yr IDFS: 96.7% 3-yr IDFS: 89.4%	
13	PREDIX HER2 NCT02568839 (N=164)	Phase II single arm Operable HER2+ breast cancer Tumour size >20mm	Neo	T-DM1 + pertuzumab	All HmR- HmR+ ITH-HER2 HER2+ (IHC 3+) HER2+ (IHC 2+)	162 111 51 16	RCB-0: 49% (pCR) RCB-1: 14% RCB-2: 26% RCB-3: 11% RCB-0: 65% (pCR) RCB-0: 42% (pCR) RCB-1: 25% RCB-2: 25% RCB-3: 50% RCB-0: 56% (pCR) RCB-0: 27% (pCR)	
14	14-409 NCT02326974 (N=202)	Phase II randomised Stage II/III HER2+ breast cancer Size >20mm or confirmed LNM	Neo	 docetaxel + trastuzumab + pertuzumab T-DM1	All All HmR+ HmR- All HmR+ HmR-	190	**pCR-rates** 46.4% NS 35.9% NS 66.7% NS 44.1% NS 34,6% NS 57.9% NS	

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ASCO 2019 Breast Cancer - HER2+

REF	Study	Study details	Line	Drug	Biomarker/Subgroup	N	Primary endpoint	Secondary endpoints
15	CLEOPATRA NCT00567190 (N=808)	Phase III double-blind randomised Placebo-controlled HER2+ MBC	1st	 pertuzumab + trastuzumab + docetaxel placebo + trastuzumab + docetaxel		 402 406	**mOS / 8-yr OS-rate** 57.1 mo / 37% 40.8 mo / 23%	
16	HERITAGE NCT02472964 (N=500)	Phase III double-blind randomised Placebo-controlled HER2+ locally recurrent or MBC Not amenable to curative therapy	1st	 trastuzumab-dkst vs trastuzumab		 179 164	**DoR** 9.9 mo 9.8 mo	**mPFS / mOS** 11.1 mo / 35.0 mo 11.1 mo / 30.2 mo
17	SOPHIA NCT02492711 (N=536)	Phase III, open-label, randomised HER2+ MBC Prior pertuzumab Prior 1-3 lines of Tx for MBC	≥2nd	 margetuximab + CTx* Trastuzumab + CTx* **CTx, capecitabine, eribulin, gemcitabine, or vinolrebine*	 ITT CD16A/158F Measurable disease ITT CD16A/158F Measurable disease	 266 262 270 262	**mPFS** 5.8 mo 6.9 mo 4.9 mo 5.1 mo	**ORR** 22% 16%
18	HR-BLTN-III-MBC-A NCT02973737 (N=279)	Phase III, double-blind, randomised HER2+ MBC Prior trastuzumab and taxane	1st	 pyrotinib + capecitabine placebo + capecitabine (arm B) arm B (N=94) —> PD —> pyrotinib		 185 94 77	**mPFS / ORR** 11.1 mo / 68.6% 4.1 mo / 16.0% 5.5 mo / 38%	**inv-mPFS / inv-ORR** 10.9 mo / 71.9% 4.1 mo / 16.0%
19	NALA NCT01808573 (N=621)	Phase III, open-label, randomised HER2+ MBC ≥2 lines of prior anti-HER2 therapies	≥3rd	 neratinib + capecitabine lapatinib + capecitabine		 307 314	**PFS / OS-rates** 6 mo: 47.2% / 90.2% 12 mo: 28.8% / 72.5% NS 6 mo: 37.8% / 87.5% 12 mo: 14.8% / 66.7% NS	**ORR / CBR** 32.8% NS / 44.5% 26.7% NS / 35.6%

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ASCO 2019 Breast Cancer - Immunotherapy

REF	Study	Study details	Line	Drug	Biomarker/Subgroup	N	Primary endpoint	Secondary endpoints
20	16-001 NCT02734290 (N=28)	Phase Ib laTNBC or mTNBC	1st/2nd	 pembrolizumab + paclitaxel pembrolizumab + capecitabine any any	 PD<12 mo since prior Tx PD>12 mo since prior Tx	 14 14	 	**12-wk ORR** 25% (1 CR, 1 PR) 43% (1 CR, 5 PR) 27% (1 CR, 2 PR) 45% (1 CR, 4 PR)
21	COLET NCT02322814 (N=63)	Phase II cohort randomised laTNBC or mTNBC	1st	 cobimetinib + atezolizumab + paclitaxel cobimetinib + atezolizumab + nab-paclitaxel	 All PD-L1 + PD-L1- All PD-L1 + PD-L1-	 32 16 9 31 15 11	**ORR** 34% (2 CR, 9 PR) 44% (1 CR, 6 PR) 11% (11 PR) 29% (9 PR) 33% (5 PR) 27% (35 PR)	**6-mo PFS / OS rate** 40.5% / 84.1% 55.6% / 85.6% 20.0% / 75.0% 50.1% / 90.0% 55.3% / 86.7% 46.0% / 90.1 %
22	IMpassion130 NCT02425891 (N=902)	Phase III randomised laTNBC or mTNBC	1st	 atezolizumab + nab-paclitaxel placebo + nab-paclitaxel	 All PD-L1+ All PD-L1+	 451 185 451 184	**mOS / 2-yr OS rate** 21.0 mo / 42% 25.0 mo / 51% 18.7 mo / 39% 18.0 mo / 37%	
23	TAPUR NCT02693535 (N=28)	Phase II basket, single arm MBC TMB-high (≥9 mut/megabase)	≥2nd	pembrolizumab	All	28	DCR: 37% ORR: 21%	mPFS: 10.6 wk mOS: 31.6 wk
24	16-577 NCT03051659 (N=88)	Phase II randomised HmR+/HER2- MBC ≥2 lines hormonal Tx 0-2 lines of prior CTx	≥1st	All pembrolizumab + eribulin mesylate eribulin mesylate	 PD-L1+ TIL > 10% NLR > 4 TMB > 6 PD-L1+ TIL > 10% NLR > 4 TMB > 6	88	**mPFS** 4.1 mo (NS) 3.2 mo (NS) 5.2 mo (NS) 4.1 mo (NS) 4.2 mo (NS) 4.1 mo (NS) 4.1 mo (NS) 3.9 mo (NS)	

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Abbreviations: ABC, advanced breast cancer; Adj, adjuvant; AI, aromatase inhibitor; BM, brain metastasis; CBR, clinical benefit rate; CDK4/6i, cyclin-dependent kinases 4 & 6 inhibitor; CR, complete response; CTx, chemotherapy; DCR, disease control rate; DFS, disease-free survival; DoR, duration of response; EFS, event-free survival; ET, endocrine treatment; EVE, everolimus; EXE, exemestane; GNRHa, gonadotropin-releasing hormone agonist; GOS, goserelin; HER2-, human epidermal growth factor receptor-negative; HER2+, human epidermal growth factor receptor-positive; HmR+, hormone receptor-positive; HmR-, hormone receptor-negative; HR, hazard ratio; HRD, homologous recombinant deficiency; IDFS, invasive disease-free survival; ITH-HER2, intratumor HER2 heterogeneity; ITT, intention-to-treat population; inv; investigator-assessed; laTNBC, locally advanced triple negative breast cancer; MBC, metastatic breast cancer; mo, month(s); mOS, median overall survival; mPFS, median progression-free survival; mTNBC, metastatic triple negative breast cancer; mut, mutation; Neo, neoadjuvant; NLR, neutrophil to lymphocyte ratio; NS, non-significant; NSAI, non-steroidal aromatase inhibitor; OIRR, objective intracranial response rate; ORR, overall response rate; pCR, pathological complete response; PD, progression disease; PD-L1-, programmed death 1 ligand negative; PD-L1+, programmed death 1 ligand positive; PR, partial response; RCB, residual cancer burden; tBRCA, germline and somatic BRCA mutations; T-DM1, trastuzumab emtansine; TIL, tumour infiltrating lymphocyte; TMB, tumour mutational burden; Tx, treatment; wk, week(s); wt, wildtype; yr, year(s).