





















ITT population	Placebo + T + D (n = 406)		Pertuzumab + T + D (n = 402)	
Median age, years (range)	54.0	(27-89)	54.0	(22-82)
Region, n (%) Asia Europe North America South America	128 152 68 58	(31.5) (37.4) (16.7) (14.3)	125 154 67 56	(31.1) (38.3) (16.7) (13.9)
Hormone receptor status, n (%) ER- and/or PgR-positive ER- and PgR-negative Unknown	199 196 11	(<mark>49.0</mark>) (48.3) (2.7)	189 212 1	(47.0) (52.7) (0.2)
Disease type at screening, n (%) Nonvisceral Visceral	90 316	(22.2) (77.8)	88 314	(21.9) (78.1)
再発症例が約半数 アジア30%、ホル MBCに対する前ホ トラスツズマブ伸目	数 ・モン陽性が ・ルモン療法(日歴あるのは	半分、内蔵転利 よ1レジメまで 10%だけ	多あるかた多い	<i>л</i>





























*臨床試験などで例外あり



- TP53とPIK3CA変異が最も頻度が多い*(30%程度)
- ERBB2, FGFR1, CCND1の増幅がその次*(10-20%)
- 頻度は低いが、PTEN変異・欠失、AKT1, RB1, BRCA1/2 変異は臨床的に重要
- PI3K/AKT/mTOR, p53, CCND1(cyclin D1)/CDK4/Rb 経路の活性化が頻度多い*

*全サブタイブあわせての頻度 Stephens PJ, Nature 2012. Arnedos M, Nat Rev Clin Oncol 2015.





	BOLER	O (Breas	t can	cer trials of OraL Evel	ROlimus)
		mTOF	R阻害薬:	エベロリスムの臨床試験	
	name	phase/type	MBC line	drug	Hazard ratio
	BOLERO 1	III HER2+	1st	wPAC+Tras+EVE vs. wPAC+Tras+placebo	0.89 (0.66* in HR-)
	BOLERO 2	III ER+HER2-	res to ns-AI	EXE + EVE vs. EXE + placebo	0.43*
	BOLERO 3	III HER2+	res to Tras	VNR + Tras + EVE 5mg vs. VNR + Tras + placebo	0.78 (0.65* in HR-)
	BOLERO 4	II ER+HER2-	1st	LET + EVE -> EXE + EVE	
	BOLERO 6	rII ER+HER2-	res to ns-AI	EVE vs. Cape vs. EXE + EVE	
P/ ns *9	AC: paclitaxel, Tras: AI: non steroidal a Statistically significa Hurvitz SA, SABCS	Trastuzumab, EVE: aromatase inhibitor nt 2014, 2: Baselga J	everolimus, , NEJM 2011	EXE: exemestane, VNR: vinorelbine, LET: letrozo , 3: O'regan M, Lancet Oncology 2014	le, Cape: capecitabine
31 注:本	邦での未承認薬、承証	8外適応使用を含む情	報です	佐治重衡 エベロリムスによる羽	.癌治療の新展開 2014.





















モン	療法+分子	そ標的治療薬の)第II	I相試験 1 st	ラインデータは	これか
inhibitor		Trial (n)	phase	endocrine	patient group	PFS (m)
HDAC	entinostat	ECOG-ACRIN (n=600)	ш	exemestane	postmeno 2nd line	-
	palbociclib	PALOMA-2 (n=650)	ш	letrozole	postmeno 1st line	-
		PALOMA-3 (n=417)	ш	fulvestrant	post and premeno with LHRHa, 2nd line	9.2 vs. 3.8
CDK4/6 ribc (LEI abern (LY28	(PD-0332991)	PALOMA-4 (n=330)	ш	letrozole	Asian postmeno 1st line	-
		PEARL (n=348)	ш	exemestane vs. capecitabine	postmeno 2nd line	-
	ribociclib (LEE011)	MONALEESA-2 (n=650)	ш	letrozole	postmeno 1st line	-
		MONALEESA-3 (n=660)	ш	fulvestrant	Postmeno 1st, 2nd line	-
		MONALEESA-7 (n=660)	ш	tamoxifen/ns-Al +LHRHa	premeno 1st line	-
	abemaciclib	MONARCH 2 (n=550)	ш	fulvestrant	post and premeno with LHRHa, 2nd line	-
	(LY2835219)	MONARCH 3 (n=450)	ш	ns-Al	postmeno 1st line	-
mTOR	everolimus	BOLERO-2 (n=724)	ш	exemestane	postmeno 2nd line	6.9 vs. 2.8
		SWOG 1222 (n=825)	ш	fulvestrant +anastrozole	postmeno, stage-IV 1st line	-
Pan- PI3K	buparlisib (BKM120)	BELLE-2 (n=842)	ш	fulvestrant	postmeno 2nd line	6.9 vs. 5.0
の未承認薬、承認外適応使用を含む情報です 改変:Saji S, Breast Cano						





