

# Clinical Updates From San Antonio

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## HER2- Advanced Breast Cancer: Heavily Pretreated Patients

This activity is provided by Integrity Continuing Education, Inc.

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# GS4-08 10-year Results of a Phase 3 Trial of Low-Dose Tamoxifen in Noninvasive Breast Cancer

## Patients (N=500)

- Females aged <75 years with IEN (ADH, LCIS, ER+, or unknown DCIS)

## Randomization

1:1

## Primary Endpoint

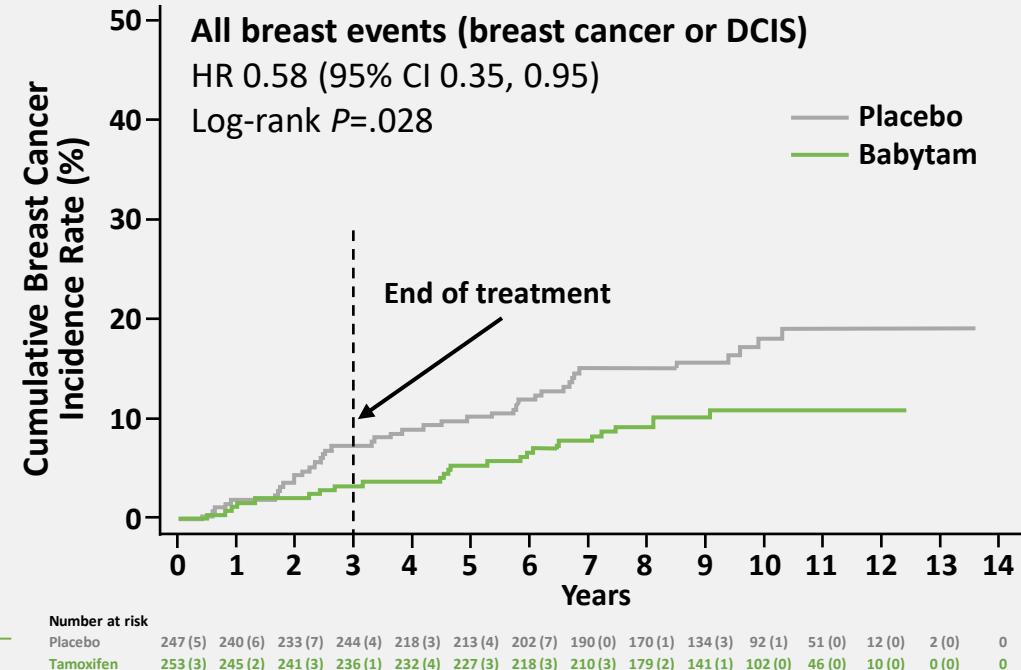
- Incidence of invasive BC or DCIS

Tamoxifen  
5 mg/day

Placebo

3-year treatment  
≥7 years follow-up

De Censi A, Lazzeroni M, Puntoni M, Boni L, Guerrieri Gonzaga A, Buttiron Webber T, Fava M, Briata IM, Giordano L, Digennaro M, Cortesi L, Falcini F, Avino F, Millo F, Cagossi K, Gallerani E, De Simone A, Cariello A, Aprile G, Renne M, Bonanni B



ADH, atypical ductal hyperplasia; BC, breast cancer;  
CI, confidence interval; DCIS, ductal carcinoma in situ;  
ER+, estrogen receptor positive; HR, hazard ratio;  
IEN, intraepithelial neoplasia; LCIS, lobular carcinoma in situ.

De Censi A, et al. SABCS 2022. Abstract GS4-08.

# GS3-01, Overall Survival Results From EMERALD: A Phase 3 Trial Evaluating Elacestrant, an Oral Selective Estrogen Receptor Degrader (SERD), vs Investigator's Choice of Endocrine Monotherapy for ER+/HER2- Advanced Breast Cancer

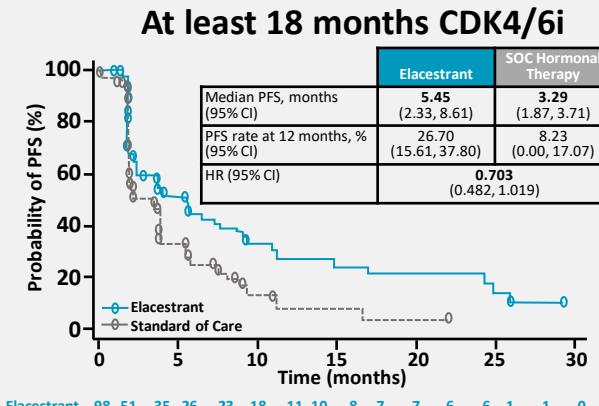
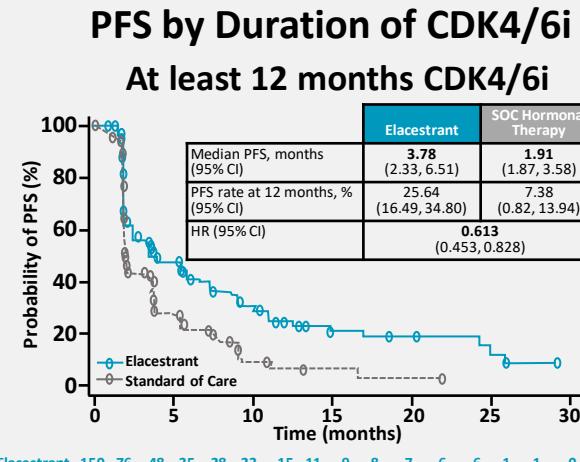
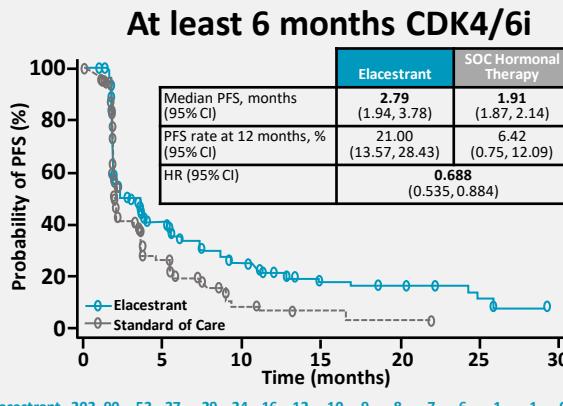
**Patients (N=477)**

- ER+/HER2- BC
- 1-2 prior lines of ET (1 with a CDK4/6i)
- ≤1 of chemotherapy for a/mBC

**Randomization**  
1:1

Elacestrant  
SOC monotherapy\*

Bardia A, Bidard F-C, Neven P, Streich G, Montero AJ, Forget F, Mouret-Reynier M-A, Sohn JH, Taylor D, Harnden KK, Khong H, Kocsis J, Dalenc F, Dillon P, Babu S, Waters S, Deleu I, García-Sáenz JA, Bria E, Cazzaniga ME, Aftimos P, Cortés J, Tonini G, Sahmoud T, Habboubi N, Grzegorzewski K, Kaklamani V



\*Fulvestrant, anastrozole, letrozole, or exemestane.

a/m, advanced/metastatic; CDK4/6i, cyclin dependent kinase 4/6 inhibitor; ET, endocrine therapy; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PFS, progression-free survival; SOC, standard of care.

Bardia A, et al. SABCS 2022. Abstract GS3-01; Bidard FC, et al. *J Clin Oncol*. 2022;40(28):3246-3256.

# GS3-04, Capivasertib and Fulvestrant for Patients With Aromatase Inhibitor-Resistant Hormone Receptor-Positive/Human Epidermal Growth Factor Receptor 2-Negative Advanced Breast Cancer: Results From The Phase III CAPtello-291 Trial

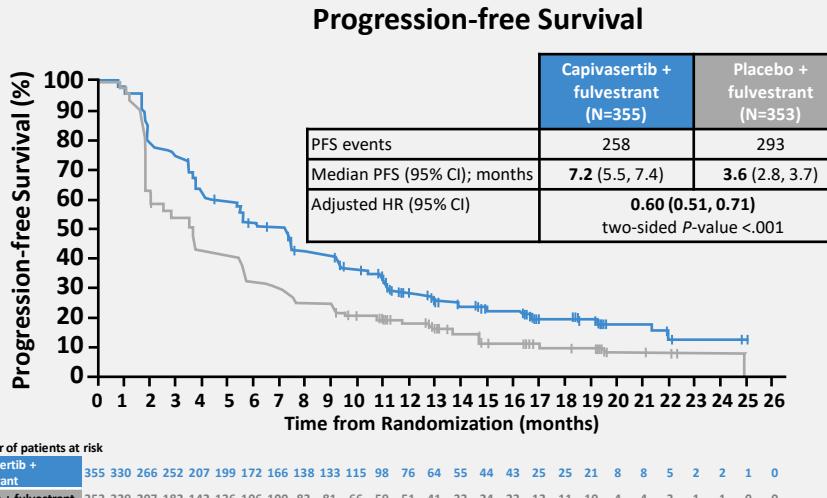
## Patients (N=220)

- HR+, HER2- locally advanced (inoperable) or metastatic BC
- ≤2 prior lines of ET and/or ≤1 line of chemotherapy

**Randomization**  
1:1

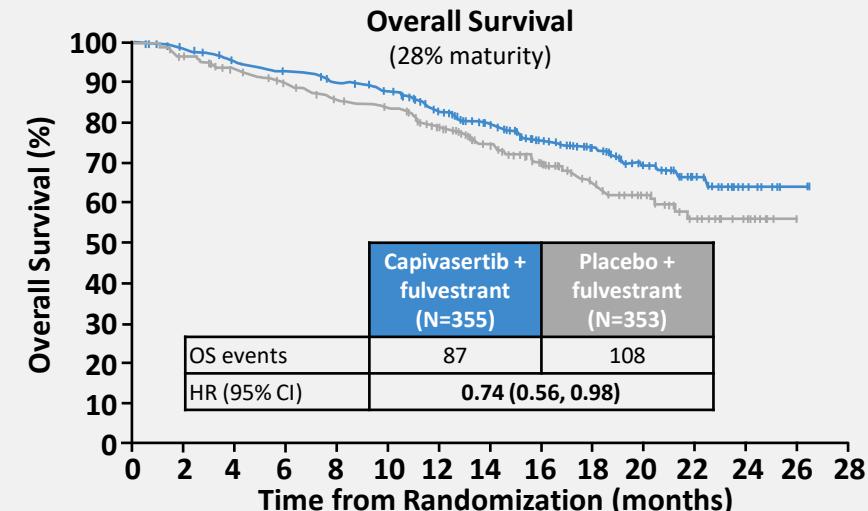
Capivasertib + fulvestrant

Placebo + fulvestrant



HR+, hormone receptor positive.

Turner NC, Oliveira M, Howell S, Dalenc F, Cortés J, Gomez H, Hu X, Jhaveri K, Loibl S, Morales Murillo S, Nowecki Z, Okera M, Park YH, Toi M, Zhukova L, Yan C, Schiavon G, Foxley A, Rugo HS



Turner N, et al. Ann Oncol. 2020;31:S388-S389; Turner NC, et al. SABCS 2022. Abstract GS3-04.

# Phase 3 Outcomes With Sacituzumab Govitecan in Heavily Pretreated Patients With HR+/HER2- Metastatic Breast Cancer

Trial	TROPiCS-02 (N=543)	
Intervention	Sacituzumab govitecan (n=272)	Chemotherapy* (n=271)
Population	Endocrine-resistant HR+/HER2- mBC At least 1 ET, taxane, and CDK4/6i 2–4 prior lines of chemotherapy in the metastatic setting	
Median follow-up, months	PFS: 10.2; OS: 12.5	
mPFS <sup>†</sup> , months (95% CI)	5.5 (4.2, 7.0)	4.0 (3.1, 4.4)
HR (95% CI); P	HR 0.66 (0.53, 0.83); P=.0003	
mOS, months (95% CI)	14.4 (13.0, 15.7)	11.2 (10.1, 12.7)
HR (95% CI); P	HR 0.79 (0.65, 0.96); P=.02	
ORR <sup>‡</sup> , %	21	14
CBR, %	34	22
mDOR, months (95% CI)	8.1 (6.7, 9.1)	5.6 (3.8, 7.9)
AEs grade ≥3 (≥5%), %		
Neutropenia	51	38
Diarrhea	9	1
Leukopenia	9	5
Anemia	6	3
Fatigue	6	2
Febrile Neutropenia	5	4

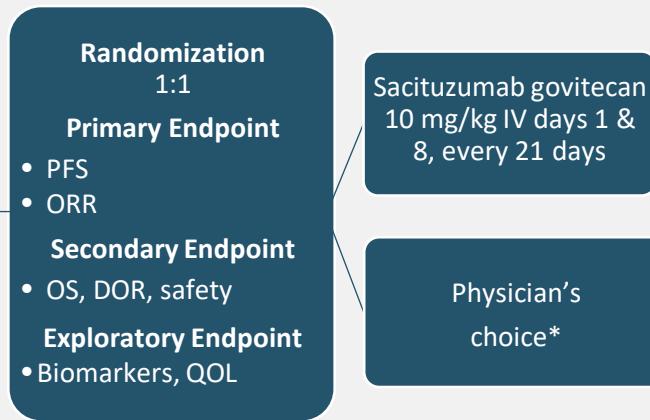
\*Physician's choice: eribulin, vinorelbine, capecitabine, or gemcitabine. <sup>†</sup>Primary endpoint. <sup>‡</sup>Not formally tested at first planned interim analysis. AE, adverse event; CBR, clinical benefit rate; mDOR, median duration of response; mOS, median overall survival; mPFS, median progression-free survival; ORR, objective response rate.

Rugo HS, et al. *Ann Oncol*. 2022;33:S1386; Rugo HS, et al. *J Clin Oncol*. 2022;40(29):3365-3376; Rugo HS, et al. SABCS 2022. Abstract GS5-11.

# GS1-11, Second Interim Analysis of Overall Survival From the Tropics-02 Phase 3 Study Of Sacituzumab Govitecan (SG) vs Treatment of Physician's Choice (TPC) in Patients With HR+/HER2- Advanced Breast Cancer

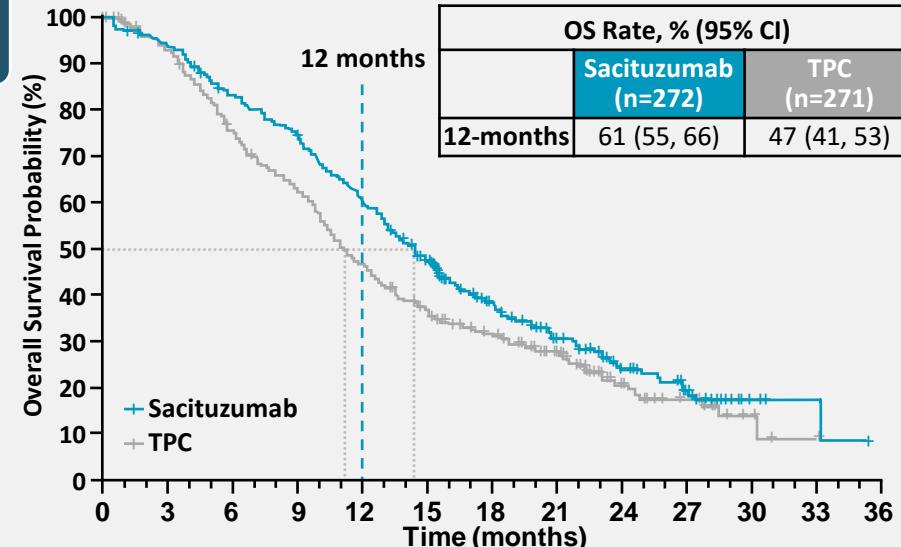
**Patients (N=400)**

- HR+/HER2- mBC
- At least 1 ET, taxane, and CDK4/6i
- 2–4 prior lines of chemotherapy in the metastatic setting
- Measurable disease



Rugo HS, Bardia A, Marmé F, Cortés J, Schmid P, Loirat D, Trédan O, Ciruelos E, Dalenc F, Gómez Pardo P, Jhaveri K, Delaney R, Fu O, Wang H, Verret W, Tolaney SM

	Sacituzumab (n=272)	TPC (n=271)
Median OS, months (95% CI)	14.1 (13.0, 15.7)	11.2 (10.1, 12.7)
Stratified HR (95% CI)	<b>0.79</b> (0.65, 0.96)	
Stratified Log Rank P value		<i>P=.020</i>



\*Eribulin, vinorelbine, capecitabine, or gemcitabine.

IV, intravenous; QOL, quality of life; TPC, treatment of physician's choice.

Rugo HS, et al. *Future Oncol.* 2020;16(12):705-715; Hugo HS, et al. *Ann Oncol.* 2022;33:S1386; Hugo HS, et al. SABCS 2022. Abstract GS1-11.