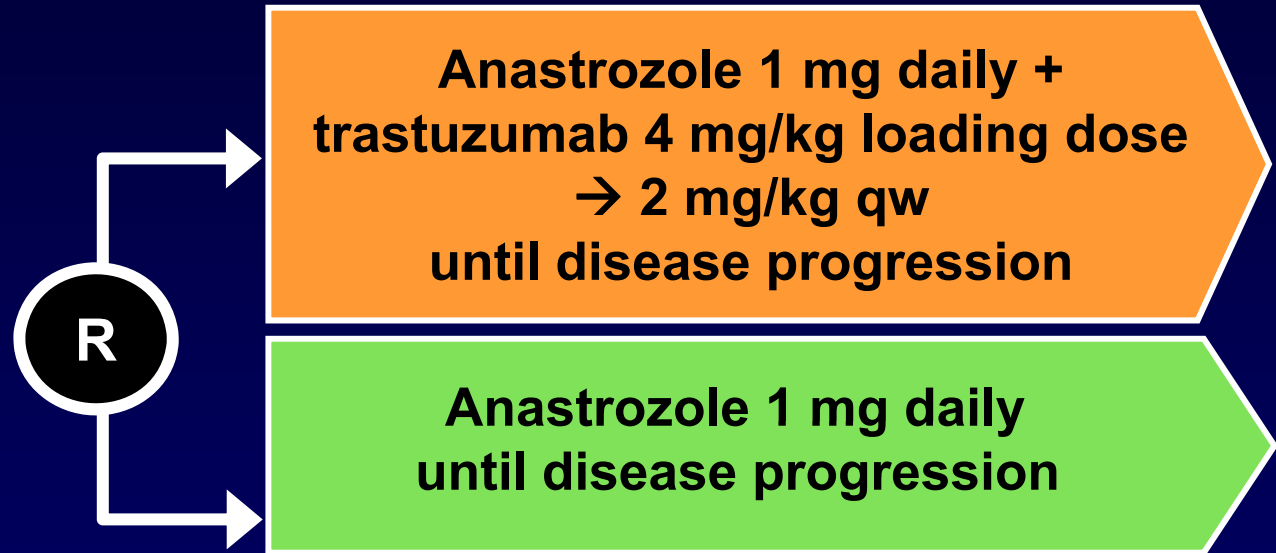


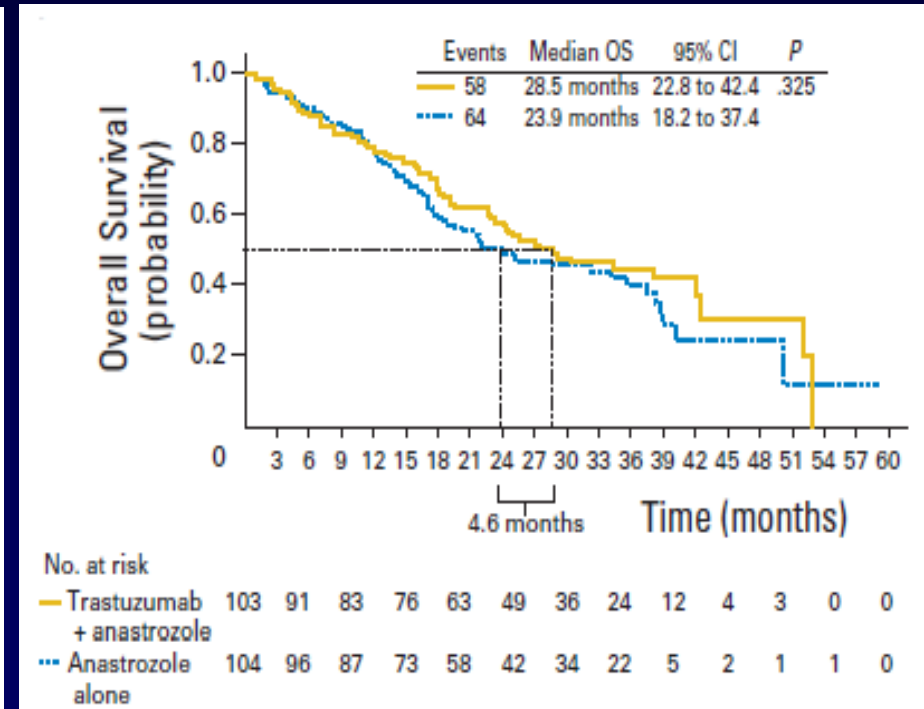
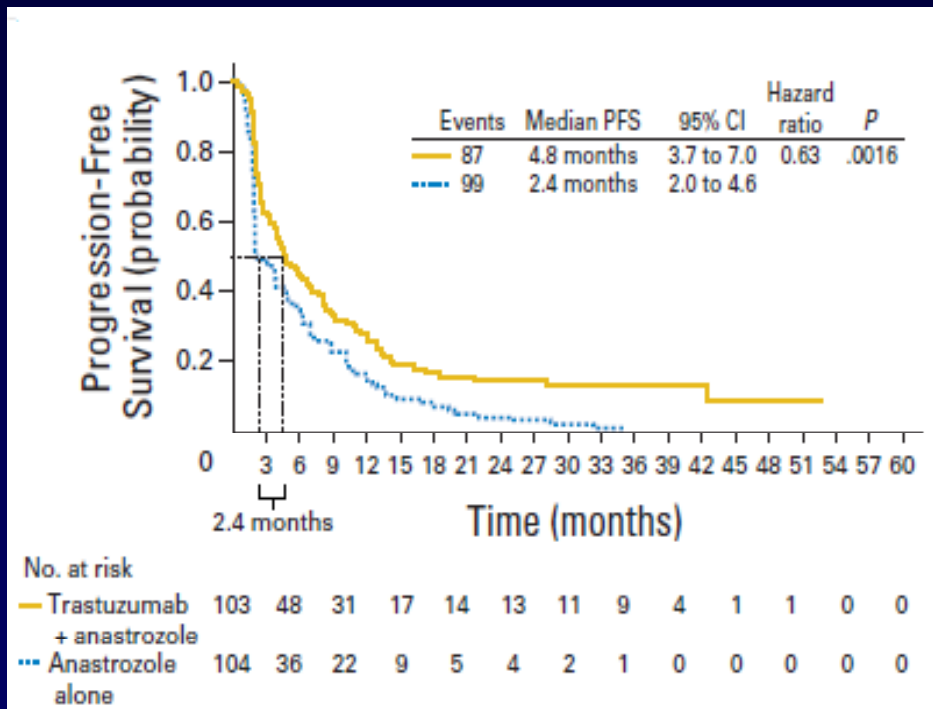
# TAnDEM Study: Anastrozole ± Trastuzumab

HER2-positive,  
hormone receptor-  
positive metastatic  
breast cancer  
(n = 208)



- Crossover to receive trastuzumab was actively offered to all patients who progressed on anastrozole alone

# TAnDEM Study: Progression-Free and Overall Survival



# EGF30008: Phase III, Randomized, Double-Blind Controlled Trial: Study Design

## Patient Population:

- ER+ and/or PgR+
- Postmenopausal
- HER2+, HER-ve/Unknown
- Stage IIIb/IIIc/IV
- No prior treatment for metastatic breast cancer (MBC)

## Stratification:

- Disease sites
  - Bone only/visceral or soft tissue
- Interval since adjuvant tamoxifen therapy
  - <6 mo / ≥6 mo or none

R  
A  
N  
D  
O  
M  
I  
Z  
E

Letrozole 2.5 mg daily +  
placebo

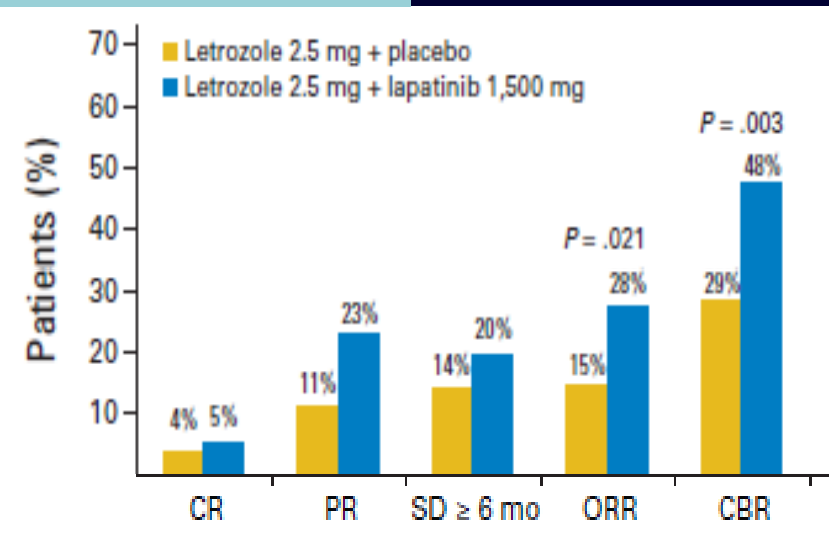
Letrozole 2.5 mg daily +  
lapatinib 1500 mg daily

N = 1286

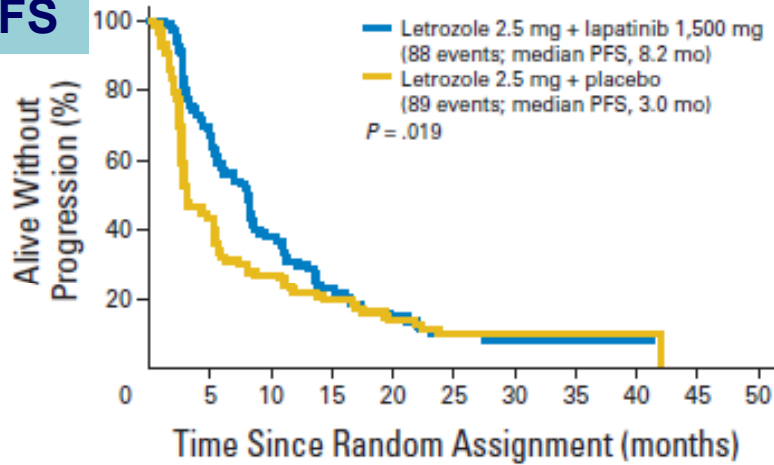
(including n = 219 HER2+)

# EGF30008: Clinical Efficacy of Lapatinib + Letrozole in HER2-Positive Population

## Response Rate

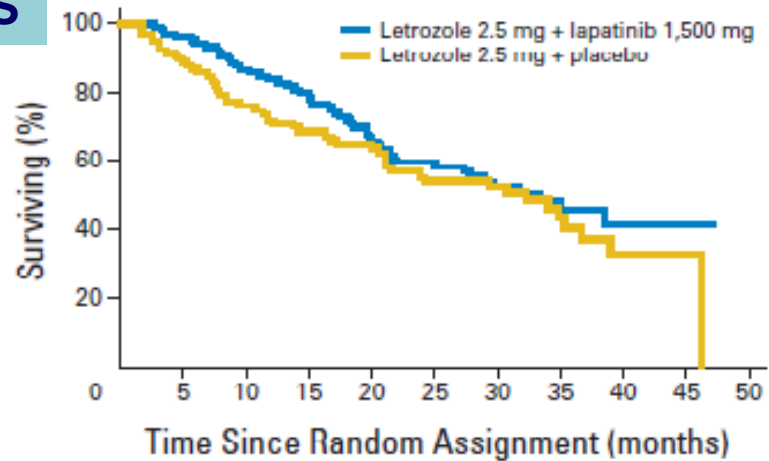


## PFS



Patients at risk	0	5	10	15	20	25	30	35	40	45	50
Letrozole + lapatinib	111	69	33	20	12	8	4	1	1		
Letrozole	108	43	26	18	12	7	5	2	2		

## OS



Patients at risk	0	5	10	15	20	25	30	35	40	45	50
Letrozole + lapatinib	111	104	89	80	64	48	32	19	9	4	
Letrozole	108	93	76	69	59	38	31	15	8	2	

Johnston S, et al. *J Clin Oncol.* 2009;27(33):5538-5546.

# EMA Approvals of Anti-HER2 Therapy for Hormone Receptor-Positive MBC

## **May 2007: a new indication for trastuzumab:**

*Herceptin® is indicated for the treatment of patients with HER2-positive metastatic breast cancer in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone receptor-positive metastatic breast cancer, not previously treated with trastuzumab.*

## **February 2010: a new indication for lapatinib:**

*Tyverb® is indicated for the treatment of patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with an aromatase inhibitor for postmenopausal women with hormone receptor-positive metastatic disease, not currently intended for chemotherapy. The patients in the registration study were not previously treated with trastuzumab or an aromatase inhibitor.*