BOLERO-1 Trial

SUMMARIZED BY:

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Phase III BOLERO-1/TRIO 019 Trial (Results at SABCS 2014)

Enrollment: 2009 - 2011

n = 719
Her2 +ve Advanced
Breast Cancer
Patients (Excluding
Brain Mets)

R A N D O M I

D

Front-line Treatment

n = 239
Paclitaxel (80 mg/m²
weekly) + Trastuzumab (4
mg/kg → 2 mg/kg weekly)
+ Placebo

n = 480Paclitaxel + Trastuzumab +Evirolimus (10 mg PO daily)

Till
Disease
Progressi
on or
unaccep
table
Toxicity

- Primary endpoint was PFS
- Secondary endpoints were OS, ORR, CBR, & toxicity.

BOLERO-1 Trial

► Results	Results		Toxicity		
	PFS: Overall (months)	PFS: HR-ve (months)	Severe Neutropenia	Severe Stomatitis	Severe Diarrhea
Control Arm	14.49	13.08	25%	1%	4%
Evirolimus Arm	14.95	20.27	15%	13%	9%
p-value	0.1166	0.0049			

Overall: Despite the positive frontline data in HR-negative patients, the safety profile of Evirolimus combined with the emergence of new treatment options (e.g. Trastuzumab + Pertuzumab + Paclitaxel) might make it difficult to establish the drug in this setting.