

# BOLERO-1 Trial

SUMMARIZED BY:

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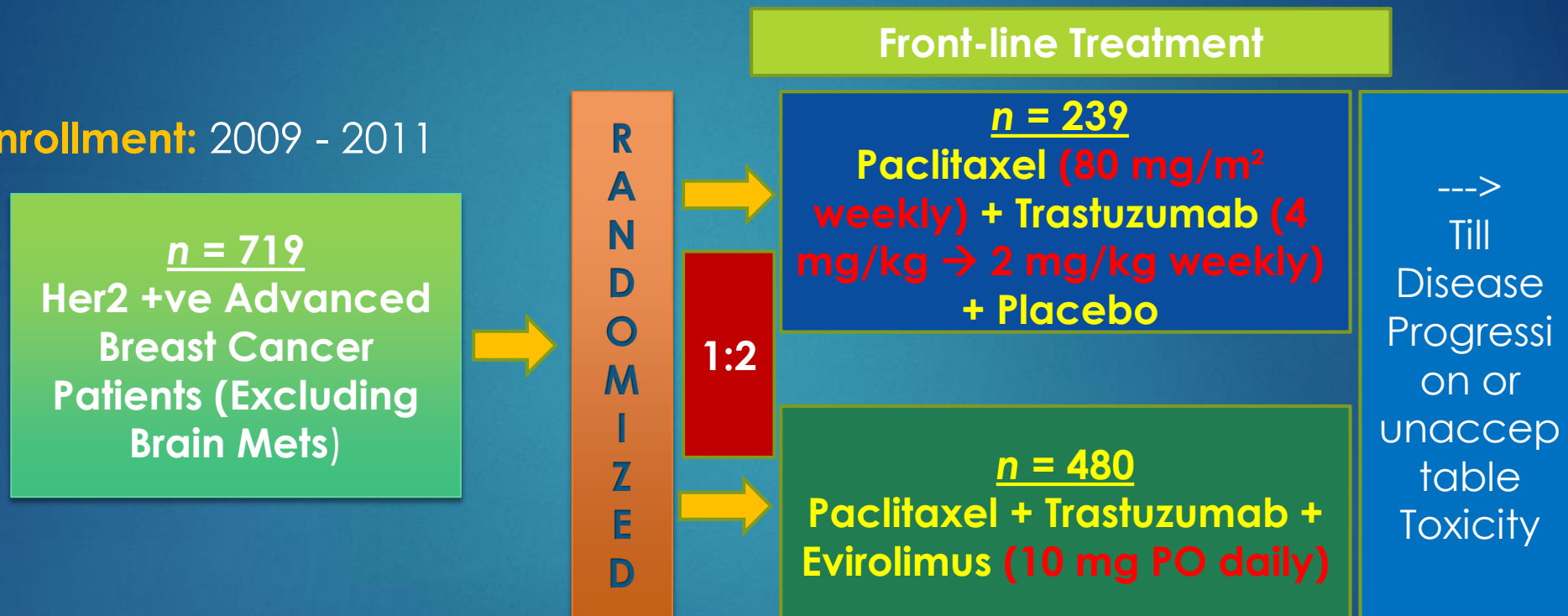
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# Phase III BOLERO-1/TRIO 019 Trial (Results at SABCS 2014)

- **Enrollment:** 2009 - 2011



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

# BOLERO-1 Trial

## ► Results

	PFS		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.