

Real-World Outcomes of Elacestrant in ER+/HER2-, ESR1-Mutant Metastatic Breast Cancer

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OBJECTIVES

Real-world insights are valuable for affirming the efficacy benefit of elacestrant in ER+/HER2- ESR1-mutant mBC in current clinical practice. The primary objective of this clinical and genomic analysis was to describe TTNT as a surrogate for PFS in clinically relevant patient subgroups, offering insights that complement the findings from the EMERALD trial.

Key Patient Characteristics (n=306)

Prior therapy



93.8%

had prior
ET ± CDK4/6i
for ≥12 months



50%

had prior ChT



72.2%

had prior
fulvestrant

Genomic alterations



100%

had an
ESR1-mut



43.5%

had a
PIK3CA-mut



42.5%

had coexisting
ESR1/PI3K mut

Study Design

Data Sources



U.S. healthcare insurance claims data from **KRD**, Komodo Health data schema designed for RWE/ HEOR studies, linked with **FIMCG** data

Patients



Patients were selected for inclusion if they had been treated for **ER+/HER2- ESR1-mut mBC**

Treatment



Real-world **TTNT** was defined as the time from index date until initiation of a new line of treatment

Outcomes*



Patients were selected for inclusion in the analysis if they had received **elacestrant** between Jan 2023-Feb 2025

*Real-world differences with routine clinical care vs prospective trials may be due to multiple factors impacting patient selection, including: Treatment heterogeneity, Tumor burden genomic profile, Clinical interpretation of surrogate outcomes, incomplete or missing data, imprecise or inconsistent definitions of lines of therapy, and issues related to censoring and follow-up duration

Results: Median efficacy outcomes of elacestrant in three analyses in clinically relevant subgroups

Median efficacy outcomes across patient subgroups	Real-World Data Rugo et al. Komodo/Foundation Medicine ¹		Real-World Data Lloyd et al. Guardant Health ²		Phase 3 EMERALD Bardia et al. Subgroup Analysis ³	
	N	mTTNT	N	mTTNT	N	mPFS
1-2 prior lines of ET ± CDK4/6i	128	8.2	-	-	-	-
1-2 prior lines of ET ± CDK4/6i ≥12 months	116	8.4	-	-	78	8.6
1 prior line of ET ± CDK4/6i	56	10.8	104	8.8	-	-
2 prior lines of ET ± CDK4/6i	72	7.7	144	5.9	-	-
≥3 prior lines of ET ± CDK4/6i	172	7.5	492	6.4	-	-
Visceral metastasis	266	7.9	-	-	-	-
Liver metastases	138	7.2	-	-	-	-
Liver and/or lung metastases	-	-	-	-	56	7.3
Coexisting ESR1 and PI3K pathway mutations	130	6.3	234	5.2	27	5.5
All patients with no prior chemotherapy	153	8.4	-	-	-	-
All patients with no prior fulvestrant	85	12.9	347	7.7	-	-



KEY TAKEAWAYS



Elacestrant demonstrated a **durable benefit** in realworld clinical practice, particularly in earlier lines and in patients with prolonged prior ET exposure



Despite coexisting **ESR1** and **PI3K** pathway mutations, **TTNT remained clinically meaningful**, reinforcing the role of elacestrant in personalized ET sequencing strategies prior to ChT, ADC, or targeted combinations



Magnitude of benefit seems to be **greater in patients with no prior exposure to fulvestrant**, and in those with no prior exposure to chemotherapy



The results of this real-world study are **consistent with those of the EMERALD trial subgroup analysis in patients with prolonged prior exposure to ET + CDK4/6i**

Observational retrospective analyses are not intended for direct comparisons with clinical trials.