

Tumor Biomarker Changes After Presurgical Treatment of Patients with Breast Cancer with High-Dose Fulvestrant and Anastrozole

Presentation discussed in this issue:

Robertson JFR et al. **Tumor biomarker changes following pre-surgical treatment with 500 mg fulvestrant plus anastrozole versus 500 mg fulvestrant alone and 1 mg anastrozole alone.** SABCS 2009; [Abstract 24](#).

Slides from a presentation at SABCS 2009

Tumor Biomarker Changes Following Pre-Surgical Treatment with 500 mg Fulvestrant plus 1 mg Anastrozole versus 500 mg Fulvestrant Alone and 1 mg Anastrozole Alone

Robertson JFR et al.
SABCS 2009;Abstract 24.

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Introduction

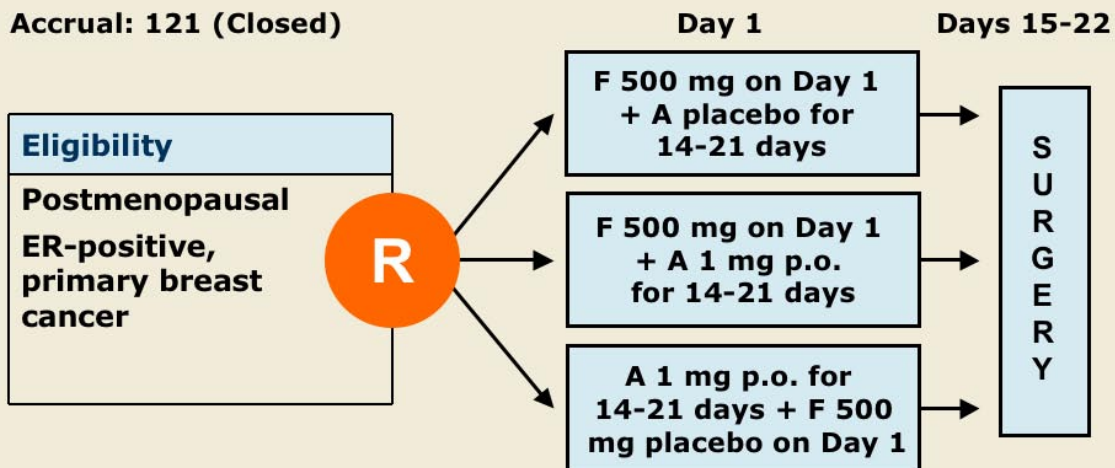
- FIRST trial indicated that a high dose of fulvestrant (500 mg) had significantly greater biological activity than the approved dose of 250 mg in the first-line setting (*JCO* 2009;27:4530).
- IMPACT trial demonstrated that the aromatase inhibitor anastrozole is as effective as tamoxifen in postmenopausal women with estrogen receptor-positive (ER+) breast cancer (*JCO* 2005;23:5108).
- FACT trial was underway to assess the efficacy of fulvestrant 250 mg plus anastrozole (SABCS 2009;Abstract 23).
- **Current study objectives:**
 - Compare the biological activity of high dose 500 mg fulvestrant (F) plus anastrozole (A) with 500 mg F alone and A alone in postmenopausal women with ER+ primary breast cancer.

Source: Robertson JFR et al. SABCS 2009;Abstract 24.

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Phase II, Double-blind, Multicenter Trial of Higher Dose Fulvestrant plus Anastrozole

Accrual: 121 (Closed)



Tumor biopsies to measure ER, progesterone receptor (PgR), and Ki67 were taken pre- and post-treatment and analyzed in a blind manner.

Source: Robertson JFR et al. SABCS 2009;Abstract 24.

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ER H-score*

	F 500 mg	F 500 mg + A	A
No. of patients	35	31	37
Pre-treatment mean H-score	187.7	184.2	192.2
Post-treatment mean H-score	111.9	115.8	164.2
% change (post-treatment)	-41%	-39%	-13%
Comparison vs baseline	p=0.0001	p=0.0001	p=0.0034

*Changes in ER index were evaluated by non-automated H-score assessment on a scale ranging from 0 to 300.

Source: Robertson JFR et al. SABCS 2009;Abstract 24.

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PgR H-score

	F 500 mg	F 500 mg + A	A
No. of patients*	33	28	33
Pre-treatment mean H-score	145.7	141.7	157.6
Post-treatment mean H-score	97.9	81.1	93.8
% change (post-treatment)	-34%	-45%	-37%
Comparison vs baseline	p=0.0001	p=0.0001	p=0.0001

*Nine patients with a PR H-score of zero at baseline were omitted (F 500 mg n=2; F 500 mg + A n=3; A n=4).

Source: Robertson JFR et al. SABCS 2009;Abstract 24.

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Ki67 Index

	F 500 mg	F 500 mg + A	A
No. of patients	35	31	37
Pre-treatment mean H-score	17.1	17.8	16.2
Post-treatment mean H-score	4.2	3.3	2.6
% change (post-treatment)	-75%	-81%	-85%
Comparison vs baseline	p=0.0001	p=0.0001	p=0.0001

Source: Robertson JFR et al. SABCS 2009;Abstract 24.

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Conclusions

- Addition of anastrozole to fulvestrant 500 mg caused no significant additional decrease in:
 - ER H-score, PgR H-score, Ki67 levels
- Overall incidence of adverse events was similar between study arms (data not shown):
 - F arm (69.2%); F+A arm (66.7%); A arm (71.4%)
- These data extend the FACT study results (SABCS 2009;Abstract 23) at the biological level and suggest the fulvestrant 500 mg + anastrozole combination is unlikely to provide a clinical benefit over fulvestrant 500 mg alone.

Source: Robertson JFR et al. SABCS 2009;Abstract 24.

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