Clinical trials of Selective estrogen receptor downregulators (SERDs) for advanced breast cancer (metastatic) in patients recurring or progressing after prior endocrine therapy

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1 fulvestrant + anastrozole

Trial	Treatments	Patients	Trials design and methods
fulvestrant + anastrozole vs exemestane			
SoFEa (Johnston) combination , 2012 [NCT00253422] n=NA follow-up:	Fulvestrant With Concomitant Anastrozole versus Exemestane	Postmenopausal Women With ER+ve Locally Advanced/Metastatic Breast Cancer Following Progression on Non-Steroidal Aromatase Inhibitors	
9238UK/0005 (combination) *unpublished* [NCT00944918] n=NA follow-up:	-	postmenopausal locally advanced / metastatic breast cancer patients who have progressed on NSAIs	double-blind Korea

References

SoFEa (Johnston) combination, 2012:

Johnston S et al. Fulvestrant alone or with concomitant anastrozole vs exemestane following progression on non-steroidal aromatase inhibitor first results of the SoFEa trial (CRUKE/03/021 & CRUK/09/007) Abstract LBA2, presented at EBCC-8, 2012.

Johnston SR, Kilburn LS, Ellis P, Dodwell D, Cameron D, Hayward L, Im YH, Braybrooke JP, Brunt AM, Cheung KL, Jyothirmayi R, Robinson A, Wardley AM, Wheatley D, Howell A, Coombes G, Sergenson N, Sin HJ, Folkerd E, Dowsett M, Bliss JM Fulvestrant plus anastrozole or placebo versus exemestane alone after progression on non-steroidal aromatase inhibitors in postmenopausal patients with hormone-receptor-positive locally advanced or metastatic breast cancer (SoFEA): a composite, multicentre, phase 3 randomised trial. Lancet Oncol 2013;14:989-98 [23902874]

9238UK/0005 (combination), 0:

2 fulvestrant alone

Trial	Treatments	Patients	Trials design and methods
fluvestrant 250mg vs exemestane			

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Trial	Treatments	Patients	Trials design and methods
9238UK/0005 (fluvestrant alone) *unpublished* [NCT00944918] n=NA follow-up:	fulvestrant Intramuscular injection on days 1, 15, and 29 and then once monthly until disease progression versus exemestane oral, once daily until disease progression.	postmenopausal locally advanced / metastatic breast cancer patients who have progressed on NSAIs	double-blind Korea
SoFEa (Johnston) fluvestrant alone , 2012 [NCT00253422] n=NA follow-up:	fulvestrant intramuscularly (IM) on days 1, 15, and 29 and then once monthly versus exemestane once daily	Postmenopausal Women With ER+ve Locally Advanced/Metastatic Breast Cancer Following Progression on Non-Steroidal Aromatase Inhibitors	Parallel groups UK

References

9238UK/0005 (fluvestrant alone), 0:

SoFEa (Johnston) fluvestrant alone, 2012:

Johnston S et al. Fulvestrant alone or with concomitant anastrozole vs exemestane following progression on non-steroidal aromatase inhibitor first results of the SoFEa trial (CRUKE/03/021 & CRUK/09/007) Abstract LBA2, presented at EBCC-8, 2012.

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3 fulvestrant high dose alone

Trial	Treatments	Patients	Trials design and methods
fulvestrant 500mg vs fulvestrant 250mg			
FINDER 2 , 2010 [NCT00313170] n=NA follow-up:	500 mg (high dose [HD]; 500 mg/month plus 500 mg on day 14 of Month 1). versus fulvestrant: 250 mg/month (approved dose [AD]);	Western postmenopausal women recurring or progressing after prior endocrine therapy	

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Trial	Treatments	Patients	Trials design and methods
D6997L00021 , 3000 *unpublished* [NCT01300351] n=NA follow-up:	Fulvestrant 500mg (2 syringes of Fulvestrant 250mg), Fulvestrant 500 mg i.m. every 28 (+/- 3) days plus an additional 500 mg on day 14 (+/-3) of first month only versus Fulvestrant 250mg (1 syringe of fulvestrant 250mg + 1 syringe matching placebo), Fulvestrant 250 mg and matching placebo i.m. every 28 (+/- 3) days plus an additional 2 placebo syringes on day 14 (+/-3) of first month only	Chinese postmenopausal women with oestrogen receptor positive advanced breast cancer who have failed a prior endocrine treatment	double-blind China
CONFIRM (Di Leo) , 2010 [NCT00099437] n=NA follow-up:	fulvestrant 500 mg (500 mg intramuscularly [IM] on day 0, then 500 mg IM on days 14 and 28 and every 28 days thereafter) versus fulvestrant 250 mg every 28 days	women with oestrogen receptor positive advanced breast cancer who have failed on a previous endocrine treatment	double-blind US

References

FINDER 2, 2010:

Pritchard KI, Rolski J, Papai Z, Mauriac L, Cardoso F, Chang J, Panasci L, Ianuli C, Kahan Z, Fukase K, Lindemann JP, Macpherson MP, Neven P Results of a phase II study comparing three dosing regimens of fulvestrant in postmenopausal women with advanced breast cancer (FINDER2). Breast Cancer Res Treat 2010 Sep;123:453-61 [20632084] 10.1007/s10549-010-1022-9

D6997L00021, 3000:

CONFIRM (Di Leo), 2010:

Di Leo A, Jerusalem G, Petruzelka L, Torres R, Bondarenko IN, Khasanov R, Verhoeven D, Pedrini JL, Smirnova I, Lichinitser MR, Pendergrass K, Garnett S, Lindemann JP, Sapunar F, Martin M Results of the CONFIRM phase III trial comparing fulvestrant 250 mg with fulvestrant 500 mg in postmenopausal women with estrogen receptor-positive advanced breast cancer. J Clin Oncol 2010;28:4594-600 [20855825] 10.1200/JCO.2010.28.8415

4 About TrialResults-center.org

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The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.