

ERG addendum: Fulvestrant for the treatment of locally advanced or metastatic breast cancer
Baseline patient characteristics in the trials included in the network meta-analysis
15 July 2011

Baseline characteristics in trials included in the network meta-analysis^a (all figures are presented as percentages) -

Trial	Intervention/ comparator(s)	WHO performance status	Visceral involvement ^b	Known to be ER+	Previous chemotherapy	Previous endocrine therapy with an AO ^c
CONFIRM [di Leo 2010] (n=736)	FUL 500mg (n=362)	██████████	66.0	100.0	EBC: 51.1 ABC: 22.4	58.0 ^c EBC: 55.8 ^c ABC: 19.9 ^c
	FUL 250mg (n=374)	██████████	62.0	100.0	EBC: 53.5 ABC: 18.4	57.0 ^c EBC: 55.3 ^c ABC: 20.0 ^c
FINDER-1 [Ohno 2010] (n=143)	FUL 500mg (n=47)	0=85.1;1=14.9;2=0	57.4	100.0	70.2	48.9 ^c
	FUL 250mg (n=45)	0=86.7;1=13.3;2=0	57.8	100.0	55.6	42.2 ^c
	FUL 250mg LD (n=51)	0=86.3;1=11.8;2=2.0	54.9	100.0	72.5	37.3 ^c
FINDER-2 [Pritchard 2010] (n=144)	FUL 500mg (n=46)	0=67.4;1=30.4;2=2.2	80.4	100.0	56.5	58.7 ^c
	FUL 250mg (n=47)	0=55.3;1=42.6;2=0	72.3	100.0	59.6	59.6 ^c
	FUL 250mg LD (n=51)	0=60.8;1=31.4;2=7.8	80.4	100.0	49.0	70.6 ^c
020 [Howell 2002] (n=451)	FUL 250mg (n=222)	Not reported but all should be ≤2 if eligibility criteria fully adhered to	13.5 ^b	Not reported ^f	42.3	100.0 EBC: 54.5 ABC: 56.8
	ANA 1mg (n=229)		17.9 ^b	Not reported ^f	42.8	100.0 EBC: 52.0 ABC: 56.3
021 [Osborne 2002] (n=400)	FUL 250mg(n=206)	Not reported but all should be ≤2 if eligibility criteria fully adhered to	18.9 ^b	Not reported ^f	62.6	100.0 EBC: 59.2 ABC: 53.4
	ANA 1mg (n=194)		23.2 ^b	Not reported ^f	62.9	100.0 EBC: 59.8 ABC: 50.0
Buzdar 1996/1998 (n=764)	ANA 1mg (n=263)	0=52.5;1=34.6;2=12.9;>2=0	47.1	73.4 ^e	37.3	100.0
	ANA 10mg (n=248)	0=44.0;1=40.7;2=13.7;>2=1.6	41.1	66.9 ^e	37.1	100.0
	Megace (n=253)	0=45.8;1=40.7;2=12.6;>24=0	44.7	68.4 ^e	35.1	100.0

Trial	Intervention/ comparator(s)	WHO performance status	Visceral involvement ^b	Known to be ER+	Previous chemotherapy	Previous endocrine therapy with an AO ^c
Buzdar 2001 (n=602)	LET 0.5mg (n=202)	KPS 100=33; KPS <100=67	50.0	83.1	35.6	100.0 EBC: 41.1 ABC: 50.9
	LET 2.5mg (n=199)	KPS 100=29; KPS <100=70	47.7	80.4	41.2	100.0 EBC: 35.1 ABC: 56.2
	Megace (n=201)	KPS 100=25; KPS <100=75	48.2	80.1	42.8	100.0 EBC: 38.8 ABC: 51.7

^a No data reported in the above table on Lundgren 1989 as this was not used in the network analysis for TTP or OS; ^b the manner in which data on visceral involvement was reported differed across trials and so comparisons across trials should be treated with extreme caution – specifically, 020 and 021 stipulated the extent of metastatic disease was visceral *only*; ^c CONFIRM, FINDER-1 and FINDER-2 included patients treated previously with AIs as well as AOs; ^d these 1.6% of patients with PS>2 were in breach of the eligibility criteria (which stipulated PS≤2) ^e in 020 and 021, 70.2% of all patients were ER+ ^f the number of patients with ER+ was not reported, only ER+ and/or PgR+, ER/PgR unknown or ER/PgR-

Key baseline characteristics of trials included only in the scenario analysis (i.e. those relating to eligibility criteria)

Trial	comparators	Known to be ER+	Previous endocrine therapy with an AO
Dombernowsky 1998 (n=551)	LET 0.5 (n=188)	<70	100
	LET 2.5 (n=174)	<70	100
	Megace (n=189)	<70	100
Gershanovich 1998 (n=555)	LET 0.5 (n=192)	<70	100
	LET 2.5 (n=185)	<70	99.5
	Aminoglutethimide (n=178)	<70	100
Kaufmann 2000 (n=769)	EXE (n=366)	<70	100
	Megace (n=403)	<70	100
EFECT [Chia 2008] (n=693)	FUL 250mg LD (n=351)	98.3	0 ^a
	EXE (n=342)	98.2	0 ^a

^a all patients were previously treated with an AI