1033IL/0027/0030 ISE

TABLE T4.3.1 BEST OBJECTIVE RESPONSE - 1033IL/0027

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027)

OVERALL OBJECTIVE RESPONSE RATE	BEST OBJECTIVE RESPONSE	ANASTROZOLE N = 340		TAMOXIFEN N = 328		TOTAL N = 668	
		N	%	N	%	N	%
RESPONSE	COMPLETE RESPONSE	19	5.6	16	4.9	35	5.2
	PARTIAL RESPONSE	93	27.4	91	27.7	184	27.5
	TOTAL	112	32.9	107	32.6	219	32.8
NON RESPONSE	STABLE DISEASE >=24 WEEKS	79	23.2	75	22.9	154	23.1
	STABLE DISEASE < 24 WEEKS	9	2.6	8	2.4	17	2.5
	PROGRESSION	140	41.2	138	42.1	278	41.6
	TOTAL	228	67.1	221	67.4	449	67.2

ST20

TABLE T4.3.3 BEST OBJECTIVE RESPONSE : MEASURABLE DISEASE - 1033IL/0027

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027 WITH MEASURABLE DISEASE AT ENTRY)

OVERALL OBJECTIVE RESPONSE RATE	BEST OBJECTIVE RESPONSE	ANASTROZOLE N = 301		TAMOXIFEN N = 286		TOTAL N = 587	
		N	%	N	%	N	%
RESPONSE	COMPLETE RESPONSE	34	11.3	31	10.8	65	11.1
	PARTIAL RESPONSE	81	26.9	80	28.0	161	27.4
	TOTAL	115	38.2	111	38.8	226	38.5
NON RESPONSE	STABLE DISEASE >=24 WEEKS	58	19.3	48	16.8	106	18.1
	STABLE DISEASE < 24 WEEKS	12	4.0	11	3.8	23	3.9
	PROGRESSION	116	38.5	116	40.6	232	39.5
	TOTAL	186	61.8	175	61.2	361	61.5

RESPONSE BASED ON MEASURABLE DISEASE ASSESSMENTS ONLY

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TABLE T4.3.4 BEST OBJECTIVE RESPONSE BY EXTENT OF DISEASE - 1033IL/0027

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027)

EXTENT OF DISEASE = SOFT TISSUE AND/OR LUNG DISEASE ONLY

OVERALL OBJECTIVE RESPONSE RATE	BEST OBJECTIVE RESPONSE	ANASTROZOLE N = 155		TAMOXIFEN N = 132		TOTAL N = 287	
		N	%	N	%	N	%
RESPONSE	COMPLETE RESPONSE	19	12.3	8	6.1	27	9.4
	PARTIAL RESPONSE	54	34.8	47	35.6	101	35.2
	TOTAL	73	47.1	55	41.7	128	44.6
NON RESPONSE	STABLE DISEASE >=24 WEEKS	25	16.1	30	22.7	55	19.2
	STABLE DISEASE < 24 WEEKS	4	2.6	4	3.0	8	2.8
	PROGRESSION	53	34.2	43	32.6	96	33.4
	TOTAL	82	52.9	77	58.3	159	55.4

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TABLE T4.3.4 BEST OBJECTIVE RESPONSE BY EXTENT OF DISEASE - 1033IL/0027

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027)

EXTENT OF DISEASE = ALL OTHER DISEASE COMBINATIONS

OVERALL OBJECTIVE RESPONSE RATE	BEST OBJECTIVE RESPONSE	ANASTROZOLE N = 185		TAMOXIFEN N = 196		TOTAL N = 381	
		N	%	N	%	N	%
RESPONSE	COMPLETE RESPONSE	0	0	8	4.1	8	2.1
	PARTIAL RESPONSE	39	21.1	44	22.4	83	21.8
	TOTAL	39	21.1	52	26.5	91	23.9
NON RESPONSE	STABLE DISEASE >=24 WEEKS	54	29.2	45	23.0	99	26.0
	STABLE DISEASE < 24 WEEKS	5	2.7	4	2.0	9	2.4
	PROGRESSION	87	47.0	95	48.5	182	47.8
	TOTAL	146	78.9	144	73.5	290	76.1

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TABLE T4.3.5 CLINICAL BENEFIT - 1033IL/0027

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027)

CLINICAL BENEFIT	BEST OBJECTIVE RESPONSE	ANASTROZOLE N = 340		TAMOXIFEN N = 328		TOTAL N = 668	
		N	%	N	%	N	%
BENEFIT	COMPLETE RESPONSE	19	5.6	16	4.9	35	5.2
	PARTIAL RESPONSE	93	27.4	91	27.7	184	27.5
	STABLE DISEASE >=24 WEEKS	79	23.2	75	22.9	154	23.1
	TOTAL	191	56.2	182	55.5	373	55.8
NO BENEFIT	STABLE DISEASE < 24 WEEKS	9	2.6	8	2.4	17	2.5
	PROGRESSION	140	41.2	138	42.1	278	41.6
	TOTAL	149	43.8	146	44.5	295	44.2

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TABLE T4.3.6 OBJECTIVE RESPONSE RATE : ANALYSIS RESULTS - 1033IL/0027

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027)

ANASTROZOLE:TAMOXIFEN	ODDS RATIO	LOWER 95% CONFIDENCE LIMIT
ADJUSTED ANALYSIS	0.95	0.72
UNADJUSTED ANALYSIS	1.01	0.77

ANASTROZOLE-TAMOXIFEN	ESTIMATED DIFFERENCE IN RESPONSE RATES	LOWER 95% CONFIDENCE LIMIT
ADJUSTED ANALYSIS	-1.01	-6.74
UNADJUSTED ANALYSIS	0.32	-5.37

THE ADJUSTED ANALYSIS WAS PERFORMED USING A LOGISTIC REGRESSION MODEL INCLUDING FACTORS FOR TREATMENT, AGE, PREVIOUS HORMONAL THERAPY, ER/PR STATUS AND EXTENT OF DISEASE AT ENTRY

THE UNADJUSTED ANALYSIS WAS PERFORMED USING A LOGISTIC REGRESSION MODEL INCLUDING TREATMENT FACTOR ONLY

RESPONDERS ARE SUBJECTS WITH A BEST OBJECTIVE RESPONSE OF COMPLETE RESPONSE (CR) OR PARTIAL RESPONSE (PR)

AN ODDS RATIO >1 FAVOURS ANASTROZOLE WHEREAS <1 FAVOURS TAMOXIFEN

A DIFFERENCE IN RESPONSE RATES >0 FAVOURS ANASTROZOLE WHEREAS <0 FAVOURS TAMOXIFEN

TABLE T4.4.1 REASONS FOR TREATMENT FAILURE - 1033IL/0027

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027)

PRIMARY REASON FOR TREATMENT FAILURE	ANASTROZOLE N = 340		TAMOXIFEN N = 328		TOTAL N = 668	
	N	%	N	%	N	%
DEATH	5	1.5	3	0.9	8	1.2
DISEASE PROGRESSION (OBJECTIVE)	216	63.5	208	63.4	424	63.5
DISEASE PROGRESSION (INVESTIGATOR'S OPINION)	15	4.4	16	4.9	31	4.6
PATIENT LOST TO FOLLOW UP	2	0.6	1	0.3	3	0.4
ADVERSE EVENT	13	3.8	15	4.6	28	4.2
PROTOCOL NON-COMPLIANCE	3	0.9	6	1.8	9	1.3
PATIENT UNWILLING TO CONTINUE	5	1.5	10	3.0	15	2.2
NEVER STARTED RANDOMIZED TREATMENT	2	0.6	1	0.3	3	0.4
OTHER REASON	6	1.8	6	1.8	12	1.8
TOTAL	267	78.5	266	81.1	533	79.8

DISEASE PROGRESSION (INVESTIGATOR'S OPINION) REFERS TO PROGRESSION NOT CONFIRMED BY THE CRITERIA SET IN THE PROTOCOL

TABLE T4.4.2 MEDIAN TIME TO TREATMENT FAILURE - 1033IL/0027

(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027)

	ANASTROZOLE	TAMOXIFEN
	N = 340	N = 328
TIME TO TREATMENT FAILURE (DAYS)	189	182

MEDIAN TIMES TO EVENT WERE ESTIMATED USING KAPLAN-MEIER METHOD

TABLE T4.4.3 TIME TO TREATMENT FAILURE : ANALYSIS RESULTS - 1033IL/0027

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027)

TAMOXIFEN:ANASTROZOLE	HAZARD RATIO	LOWER 95% CONFIDENCE LIMIT
ADJUSTED ANALYSIS	1.03	0.89
UNADJUSTED ANALYSIS	1.04	0.90

A HAZARD RATIO >1 INDICATES THAT ANASTROZOLE IS ASSOCIATED WITH A LONGER TIME TO PROGRESSION(TREATMENT FAILURE) THAN IS TAMOXIFEN

THE ADJUSTED ANALYSIS WAS PERFORMED USING A COX REGRESSION MODEL INCLUDING FACTORS FOR TREATMENT, AGE, PREVIOUS HORMONAL THERAPY, ER/PR STATUS AND EXTENT OF DISEASE AT ENTRY

THE UNADJUSTED ANALYSIS WAS PERFORMED USING A COX REGRESSION MODEL INCLUDING TREATMENT FACTOR ONLY

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TABLE T4.5.1 DURATION OF RESPONSE FROM RANDOMIZATION - 1033IL/0027

(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0027 WITH A COMPLETE OR PARTIAL RESPONSE)

DURATION OF RESPONSE (DAYS)	ANASTROZOLE	TAMOXIFEN
	N = 112	N = 107
MEDIAN	498	518
MIN	111	83
MAX	1194	1124

MEDIAN TIMES TO EVENT WERE ESTIMATED USING KAPLAN-MEIER METHOD

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TABLE T4.5.2 DURATION OF RESPONSE FROM FIRST DOCUMENTATION OF OBJECTIVE RESPONSE - 1033IL/0027
(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0027 WITH A COMPLETE OR PARTIAL RESPONSE)

DURATION OF RESPONSE (DAYS)	ANASTROZOLE	TAMOXIFEN
	N = 112	N = 107
MEDIAN	378	421
MIN	35	56
MAX	1027	1037

MEDIAN TIMES TO EVENT WERE ESTIMATED USING KAPLAN-MEIER METHOD

TABLE T4.5.3 DURATION OF CLINICAL BENEFIT - 1033IL/0027

(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0027 WITH A COMPLETE RESPONSE, PARTIAL RESPONSE, OR STABLE DISEASE >= 24 WEEKS)

DURATION OF CLINICAL BENEFIT (DAYS)	ANASTROZOLE	TAMOXIFEN
	N = 191	N = 182
MEDIAN	462	448
MIN	111	83
MAX	1194	1260

MEDIAN TIMES TO EVENT WERE ESTIMATED USING KAPLAN-MEIER METHOD

1033IL/0027/0030 ISE

TABLE T4.6.1 SURVIVAL STATUS - 1033IL/0027

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027)

SURVIVAL STATUS	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N = 340		N = 328		N = 668	
	N	%	N	%	N	%
ALIVE	249	73.2	254	77.4	503	75.3
DEAD	91	26.8	74	22.6	165	24.7

TABLE T4.6.3 SURVIVAL AT TWO YEARS - 1033IL/0027

(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027)

	ANASTROZOLE	TAMOXIFEN
	N = 340	N = 328
PROPORTION ALIVE AT TWO YEARS (%)	67.9	73.3

SURVIVAL WAS ESTIMATED USING KAPLAN-MEIER METHOD

TABLE T6.1 THE PROPORTION OF SUBJECTS WHO RECEIVED FURTHER BREAST CANCER THERAPY - 1033IL/0027
(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0027 WITHDRAWN FROM TRIAL TREATMENT)

THERAPY		ANASTROZOLE N = 235		TAMOXIFEN N = 241		TOTAL N = 476	
		N	%	N	%	N	%
RADIOTHERAPY	YES	73	31.1	77	32.0	150	31.5
	NO	162	68.9	164	68.0	326	68.5
CHEMOTHERAPY	YES	106	45.1	105	43.6	211	44.3
	NO	129	54.9	136	56.4	265	55.7
HORMONAL THERAPY	YES	117	49.8	142	58.9	259	54.4
	NO	118	50.2	99	41.1	217	45.6
OTHER THERAPIES	YES	52	22.1	49	20.3	101	21.2
	NO	183	77.9	192	79.7	375	78.8

TABLE T6.2 DURATION OF FURTHER BREAST CANCER THERAPY - 1033IL/0027
(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0027 WITHDRAWN FROM TRIAL TREATMENT)

THERAPY	DURATION (DAYS)	ANASTROZOLE N = 235	TAMOXIFEN N = 241
RADIOTHERAPY (SESSIONS PER PATIENT)	TOTAL TREATED	73	77
	N	72	69
	MEAN	17	16
	MEDIAN	11	10
	SD	15.6	12.6
	MIN	1	1
	MAX	77	66
CHEMOTHERAPY (CYCLES PER PATIENT)	TOTAL TREATED	69	58
	N	68	57
	MEAN	8	7
	MEDIAN	6	6
	SD	6.5	5.7
	MIN	1	1
	MAX	40	31
TAMOXIFEN	TOTAL TREATED	66	18
	N	31	9
	MEAN	211	173
	MEDIAN	148	97
	SD	157.3	205.0

(CONTINUED)

N = NUMBER OF SUBJECTS FOR WHICH DURATION COULD BE CALCULATED

TABLE T6.2 DURATION OF FURTHER BREAST CANCER THERAPY - 1033IL/0027

(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0027 WITHDRAWN FROM TRIAL TREATMENT)

THERAPY	DURATION (DAYS)	ANASTROZOLE	TAMOXIFEN
		N = 235	N = 241
TAMOXIFEN	MIN	46	10
	MAX	735	574
ANASTROZOLE	TOTAL TREATED	9	56
	N	3	17
	MEAN	237	164
	MEDIAN	253	119
	SD	147.2	126.3
	MIN	82	10
	MAX	375	462
MEGESTROL	TOTAL TREATED	28	26
	N	13	14
	MEAN	88	182
	MEDIAN	74	123
	SD	67.1	204.0
	MIN	6	-1
	MAX	279	819
MEDROXYPROGESTERONE	TOTAL TREATED	16	20
	N	10	13
	MEAN	182	183

(CONTINUED)

N = NUMBER OF SUBJECTS FOR WHICH DURATION COULD BE CALCULATED

TABLE T6.2 DURATION OF FURTHER BREAST CANCER THERAPY - 1033IL/0027

(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0027 WITHDRAWN FROM TRIAL TREATMENT)

THERAPY	DURATION (DAYS)	ANASTROZOLE N = 235	TAMOXIFEN N = 241
MEDROXYPROGESTERONE	MEDIAN	205	135
	SD	134.0	138.6
	MIN	10	18
	MAX	420	410
PAMIDRONIC ACID	TOTAL TREATED	21	15
	N	5	10
	MEAN	78	116
	MEDIAN	50	90
	SD	75.2	105.0
	MIN	28	0
	MAX	210	323
HORMONE THERAPY, NOT OTHERWISE SPECIFIED	TOTAL TREATED	12	13
	N	8	11
	MEAN	159	178
	MEDIAN	110	118
	SD	192.0	179.6
	MIN	16	56
	MAX	605	678
CLODRONIC ACID	TOTAL TREATED	13	10

(CONTINUED)

N = NUMBER OF SUBJECTS FOR WHICH DURATION COULD BE CALCULATED

TABLE T6.2 DURATION OF FURTHER BREAST CANCER THERAPY - 1033IL/0027

(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0027 WITHDRAWN FROM TRIAL TREATMENT)

THERAPY	DURATION (DAYS)	ANASTROZOLE	TAMOXIFEN
		N = 235	N = 241
CLODRONIC ACID	N	8	3
	MEAN	114	204
	MEDIAN	88	221
	SD	88.2	84.8
	MIN	2	112
	MAX	257	279
FORMESTANE	TOTAL TREATED	6	14
	N	4	7
	MEAN	70	139
	MEDIAN	80	136
	SD	59.0	62.7
	MIN	0	40
	MAX	119	249
AMINOGLUTETHIMIDE	TOTAL TREATED	6	13
	N	3	11
	MEAN	119	426
	MEDIAN	70	462
	SD	106.0	213.8
	MIN	47	51

(CONTINUED)

N = NUMBER OF SUBJECTS FOR WHICH DURATION COULD BE CALCULATED

TABLE T6.2 DURATION OF FURTHER BREAST CANCER THERAPY - 1033IL/0027
(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0027 WITHDRAWN FROM TRIAL TREATMENT)

THERAPY	DURATION (DAYS)	ANASTROZOLE	TAMOXIFEN
		N = 235	N = 241
AMINOGLUTETHIMIDE	MAX	241	725
LETROZOLE	TOTAL TREATED	5	11
	N	2	6
	MEAN	79	171
	MEDIAN	79	139
	SD	67.2	163.1
	MIN	31	28
	MAX	126	474
MASTECTOMY	TOTAL TREATED	5	8
	N	5	8
	MEAN	0	0
	MEDIAN	0	0
	SD	0.0	0.0
	MIN	0	0
	MAX	0	0

N = NUMBER OF SUBJECTS FOR WHICH DURATION COULD BE CALCULATED

TABLE T12.1 RANDOMIZATION AND SUBJECT STATUS - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

TREATMENT GIVEN	RANDOMISED TREATMENT					
	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N = 171		N = 182		N = 353	
	N	%	N	%	N	%
ANASTROZOLE	169	98.8	1	0.5	170	48.2
TAMOXIFEN	1	0.6	181	99.5	182	51.6
OTHER	0	0.0	0	0.0	0	0.0
NONE	1	0.6	0	0.0	1	0.3
TOTAL	171	100.0	182	100.0	353	100.0

SUBJECT STATUS AT DATA CUT-OFF	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N	%	N	%	N	%
STARTED TRIAL TREATMENT	170	99.4	182	100.0	352	99.7
ON TREATMENT	48	28.1	40	22.0	88	24.9
WITHDRAWN FROM TREATMENT (ALIVE)	74	43.3	90	49.5	164	46.5
DEAD	48	28.0	52	28.6	100	28.3

PERCENTAGE CALCULATED USING NUMBER OF SUBJECTS RANDOMIZED AS DENOMINATOR

TABLE T12.2 AGE, HEIGHT, WEIGHT AND BODY MASS INDEX AT ENTRY - 1033IL/0030
(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

		ANASTROZOLE	TAMOXIFEN	TOTAL
		N = 171	N = 182	N = 353
AGE (YEARS)	N	171	182	353
	MEAN	67	67	67
	MEDIAN	68	67	68
	SD	11.8	11.2	11.5
	MAX	88	92	92
	MIN	30	40	30
HEIGHT (CM)	N	165	173	338
	MEAN	160	160	160
	MEDIAN	160	160	160
	SD	7.8	7.2	7.5
	MAX	180	183	183
	MIN	133	142	133
WEIGHT (KG)	N	168	178	346
	MEAN	73	71	72
	MEDIAN	72	69	70
	SD	15.2	17.6	16.5
	MAX	121	140	140
	MIN	43	36	36
BMI (KG/M2)	N	163	172	335
	MEAN	28	28	28

(CONTINUED)

TABLE T12.2 AGE, HEIGHT, WEIGHT AND BODY MASS INDEX AT ENTRY - 1033IL/0030
(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

		ANASTROZOLE	TAMOXIFEN	TOTAL
		N = 171	N = 182	N = 353
BMI (KG/M2)	MEDIAN	28	27	27
	SD	6.1	6.6	6.4
	MAX	48	53	53
	MIN	16	14	14

TABLE T12.3 AGE GROUP, ETHNIC ORIGIN AND GENDER - 1033IL/0030

(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

		ANASTROZOLE N = 171		TAMOXIFEN N = 182		TOTAL N = 353	
		N	%	N	%	N	%
AGE GROUP	<= 65	74	43.3	76	41.8	150	42.5
	> 65	97	56.7	106	58.2	203	57.5
ORIGIN	CAUCASIAN	152	88.9	160	87.9	312	88.4
	AFRO-CARIBBEAN	8	4.7	11	6.0	19	5.4
	ASIAN/ORIENTAL	1	0.6	1	0.5	2	0.6
	HISPANIC	5	2.9	8	4.4	13	3.7
	MIXED	0	0.0	0	0.0	0	0.0
	OTHER	5	2.9	2	1.1	7	2.0
GENDER	FEMALE	171	100.0	182	100.0	353	100.0
	MALE	0	0.0	0	0.0	0	0.0

TABLE T12.4 BREAST CANCER DISEASE STATUS AT FIRST DIAGNOSIS - 1033IL/0030

(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

DISEASE STATUS AT FIRST DIAGNOSIS	ANASTROZOLE N = 171		TAMOXIFEN N = 182		TOTAL N = 353	
	N	%	N	%	N	%
ADVANCED	52	30.4	60	33.0	112	31.7
EARLY	118	69.0	122	67.0	240	68.0
UNKNOWN	1	0.6	0	0	1	0.3
TOTAL	171	100.0	182	100.0	353	100.0

TABLE T12.5.1 PRIOR ADJUVANT THERAPY (HORMONAL OR CYTOTOXIC) FOR BREAST CANCER - 1033IL/0030
(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

PRIOR ADJUVANT THERAPY	ANASTROZOLE N = 171		TAMOXIFEN N = 182		TOTAL N = 353	
	N	%	N	%	N	%
YES	68	39.8	70	38.5	138	39.1
NO	102	59.6	111	61.0	213	60.3
UNKNOWN	1	0.6	1	0.5	2	0.6

TYPE OF ADJUVANT THERAPY	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N	%	N	%	N	%
HORMONAL ONLY	21	12.3	20	11.0	41	11.6
CYTOTOXIC ONLY	32	18.7	37	20.3	69	19.5
BOTH	15	8.8	13	7.1	28	7.9

TABLE T12.5.2 DURATION OF ADJUVANT HORMONAL TREATMENT - 1033IL/0030

(SUBJECTS INCLUDED: ALL SUBJECTS IN TRIAL 1033IL/0030 WHO WERE GIVEN PREVIOUS ADJUVANT HORMONAL TREATMENT)

DURATION OF ADJUVANT TREATMENT (WEEKS)	ANASTROZOLE	TAMOXIFEN	TOTAL
	N =36	N =33	N =69
MEDIAN	257	104	209
MIN	0	1	0
MAX	708	565	708

TABLE T12.6.1 MOST RECENT HORMONAL RECEPTOR STATUS: ER AND PR GROUPED - 1033IL/0030
(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

GROUPED ER AND PR STATUS	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N =171		N =182		N =353	
	N	%	N	%	N	%
ER AND/OR PR POSITIVE	151	88.3	162	89.0	313	88.7
ALL OTHER COMBINATIONS	20	11.7	20	11.0	40	11.3

ER AND/OR PR POSITIVE IS ONE OF THE FOLLOWING: ER+
PR+
ER+ AND PR+

ALL OTHER COMBINATIONS INCLUDE UNKNOWN RECEPTOR STATUS

TABLE T12.6.2 MOST RECENT HORMONAL RECEPTOR STATUS: ER AND PR SEPARATELY - 1033IL/0030
(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

ER	PR	ANASTROZOLE N =171		TAMOXIFEN N =182		TOTAL N =353	
		N	%	N	%	N	%
+	+	109	63.7	121	66.5	230	65.2
	−	32	18.7	31	17.0	63	17.8
	UNKNOWN	4	2.3	4	2.2	8	2.3
−	+	6	3.5	5	2.7	11	3.1
	−	1	0.6	0	0.0	1	0.3
	UNKNOWN	0	0.0	0	0.0	0	0.0
UNKNOWN	+	0	0.0	1	0.5	1	0.3
	−	0	0.0	0	0.0	0	0.0
	UNKNOWN	19	11.1	20	11.0	39	11.0

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TABLE T12.7 SUBJECTS WITH MEASURABLE AND NO MEASURABLE DISEASE AT ENTRY - 1033IL/0030
(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N =171		N =182		N =353	
	N	%	N	%	N	%
MEASURABLE DISEASE	117	68.4	140	76.9	257	72.8
NO MEASURABLE DISEASE	54	31.6	42	23.1	96	27.2

MEASURABLE DISEASE INCLUDES SUBJECTS WITH ANY BIDIMENSIONALLY OR UNIDIMENSIONALLY MEASURABLE LESIONS

NO MEASURABLE DISEASE INCLUDES SUBJECTS WITH EITHER NO LESIONS OR NON-MEASURABLE DISEASE ONLY

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TABLE T12.8.1 SITE OF METASTATIC DISEASE AT ENTRY - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

SITE OF DISEASE	ANASTROZOLE N = 171		TAMOXIFEN N = 182		TOTAL N = 353	
	N	%	N	%	N	%
SKIN	52	30.4	50	27.5	102	28.9
LYMPH	63	36.8	64	35.2	127	36.0
BONE	112	65.5	98	53.8	210	59.5
VISCERAL	83	48.5	87	47.8	170	48.2
LUNG	76	44.4	68	37.4	144	40.8
LIVER	13	7.6	30	16.5	43	12.2
ABDOMEN	7	4.1	8	4.4	15	4.2
OTHER	0	0.0	1	0.5	1	0.3
NO EVALUABLE DISEASE	2	1.2	2	1.1	4	1.1

SUBJECTS WITH METASTATIC DISEASE MAY APPEAR IN MORE THAN ONE ROW

PLEURAL EFFUSIONS ARE CONSIDERED VISCERAL LUNG DISEASE

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TABLE T12.8.2 EXTENT OF METASTATIC DISEASE AT ENTRY - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

EXTENT OF DISEASE		ANASTROZOLE N = 171		TAMOXIFEN N = 182		TOTAL N = 353	
		N	%	N	%	N	%
EXTENT COVARIATE	SOFT TISSUE AND/OR LUNG DISEASE ONLY	39	22.8	49	26.9	88	24.9
	ALL OTHER DISEASE COMBINATIONS	132	77.2	133	73.1	265	75.1
NO VISCERAL DISEASE	SOFT TISSUE ONLY	18	10.5	33	18.1	51	14.4
	BONE ONLY	46	26.9	42	23.1	88	24.9
	BONE AND SOFT TISSUE ONLY	22	12.9	18	9.9	40	11.3
VISCERAL DISEASE	NO EVIDENCE OF LIVER INVOLVEMENT	70	40.9	57	31.3	127	36.0
	LIVER INVOLVEMENT	13	7.6	30	16.5	43	12.2
NO EVALUABLE DISEASE	NO EVALUABLE DISEASE	2	1.2	2	1.1	4	1.1

PLEURAL EFFUSIONS ARE CONSIDERED VISCERAL LUNG DISEASE

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TABLE T13 REASON FOR WITHDRAWAL OF TRIAL TREATMENT - 1033IL/0030
(SUBJECTS INCLUDED : ALL TREATED SUBJECTS IN TRIAL 1033IL/0030)

PRIMARY REASON FOR WITHDRAWAL	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N = 170		N = 182		N = 352	
	N	%	N	%	N	%
DEATH	6	3.5	2	1.1	8	2.3
DISEASE PROGRESSION (INVESTIGATOR'S OPINION)	94	55.3	122	67.0	216	61.4
ADVERSE EVENT	8	4.7	7	3.8	15	4.3
PROTOCOL NON-COMPLIANCE	5	2.9	3	1.6	8	2.3
PATIENT UNWILLING TO CONTINUE	2	1.2	5	2.7	7	2.0
OTHER REASON	7	4.1	3	1.6	10	2.8
TOTAL	122	71.8	142	78.0	264	75.0

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TABLE T15.1.1 DURATION OF TREATMENT - 1033IL/0030

(SUBJECTS INCLUDED : ALL TREATED SUBJECTS IN TRIAL 1033IL/0030)

DURATION OF TREATMENT (DAYS)	ANASTROZOLE	TAMOXIFEN
	N = 170	N = 182
MEDIAN	263	182
MIN	18	12
MAX	932	933

1033IL/0027/0030 ISE

TABLE T15.1.2 DURATION OF TREATMENT IN WEEKS - 1033IL/0030

(SUBJECTS INCLUDED : ALL TREATED SUBJECTS IN TRIAL 1033IL/0030)

DURATION OF TREATMENT (WEEKS)	ANASTROZOLE		TAMOXIFEN	
	N = 170		N = 182	
	N	%	N	%
<0 TO 12	25	14.7	35	19.2
<12 TO 24	28	16.5	48	26.4
<24 TO 48	41	24.1	45	24.7
<48 TO 96	61	35.9	43	23.6
>96	15	8.8	11	6.0

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TABLE T15.1.3 DURATION OF FOLLOW-UP TO DATE LAST SEEN ALIVE - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030 WHO WERE ALIVE AT DATA CUTOFF)

DURATION OF FOLLOW-UP (DAYS)	ANASTROZOLE	TAMOXIFEN	TOTAL
	N = 124	N = 129	N = 253
MEDIAN	533	538	538
MIN	1	35	1
MAX	931	1097	1097

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TABLE T15.2.1 PROGRESSION STATUS - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

SUBJECT STATUS		ANASTROZOLE N = 171		TAMOXIFEN N = 182		TOTAL N = 353	
		N	%	N	%	N	%
NOT PROGRESSED	ALIVE NO PROGRESSION	57	33.3	44	24.2	101	28.6
PROGRESSED	TOTAL PROGRESSED	114	66.7	138	75.8	252	71.4
	PROGRESSION DURING TREATMENT	100	58.5	121	66.5	221	62.6
	PROGRESSION AFTER TREATMENT WITHDRAWAL	2	1.2	3	1.6	5	1.4
	DEATH BEFORE PROGRESSION	12	7.0	14	7.7	26	7.4

1033IL/0027/0030 ISE

TABLE T15.2.3 MEDIAN TIME TO PROGRESSION - 1033IL/0030

(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

	ANASTROZOLE	TAMOXIFEN
	N = 171	N = 182
TIME TO PROGRESSION (DAYS)	338	170

MEDIAN TIMES TO EVENT WERE ESTIMATED USING KAPLAN-MEIER METHOD

1033IL/0027/0030 ISE

TABLE T15.2.5 TIME TO PROGRESSION : ANALYSIS RESULTS - 1033IL/0030
(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

TAMOXIFEN:ANASTROZOLE	HAZARD RATIO	LOWER 95% CONFIDENCE LIMIT
ADJUSTED ANALYSIS	1.44	1.16
UNADJUSTED ANALYSIS	1.42	1.15

A HAZARD RATIO >1 INDICATES THAT ANASTROZOLE IS ASSOCIATED WITH A LONGER TIME TO PROGRESSION(TREATMENT FAILURE) THAN IS TAMOXIFEN

THE ADJUSTED ANALYSIS WAS PERFORMED USING A COX REGRESSION MODEL INCLUDING FACTORS FOR TREATMENT, AGE, PREVIOUS HORMONAL THERAPY, ER/PR STATUS AND EXTENT OF DISEASE AT ENTRY

THE UNADJUSTED ANALYSIS WAS PERFORMED USING A COX REGRESSION MODEL INCLUDING TREATMENT FACTOR ONLY

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TABLE T15.3.1 BEST OBJECTIVE RESPONSE - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

OVERALL OBJECTIVE RESPONSE RATE	BEST OBJECTIVE RESPONSE	ANASTROZOLE N = 171		TAMOXIFEN N = 182		TOTAL N = 353	
		N	%	N	%	N	%
RESPONSE	COMPLETE RESPONSE	5	2.9	5	2.7	10	2.8
	PARTIAL RESPONSE	31	18.1	26	14.3	57	16.1
	TOTAL	36	21.1	31	17.0	67	19.0
NON RESPONSE	STABLE DISEASE >=24 WEEKS	65	38.0	52	28.6	117	33.1
	STABLE DISEASE < 24 WEEKS	7	4.1	4	2.2	11	3.1
	PROGRESSION	63	36.8	95	52.2	158	44.8
	TOTAL	135	78.9	151	83.0	286	81.0

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TABLE T15.3.3 BEST OBJECTIVE RESPONSE : MEASURABLE DISEASE - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030 WITH MEASURABLE DISEASE AT ENTRY)

OVERALL OBJECTIVE RESPONSE RATE	BEST OBJECTIVE RESPONSE	ANASTROZOLE		TAMOXIFEN		TOTAL	
		N = 117		N = 140		N = 257	
		N	%	N	%	N	%
RESPONSE	COMPLETE RESPONSE	11	9.4	12	8.6	23	8.9
	PARTIAL RESPONSE	27	23.1	19	13.6	46	17.9
	TOTAL	38	32.5	31	22.1	69	26.8
NON RESPONSE	STABLE DISEASE >=24 WEEKS	30	25.6	26	18.6	56	21.8
	STABLE DISEASE < 24 WEEKS	7	6.0	5	3.6	12	4.7
	PROGRESSION	42	35.9	78	55.7	120	46.7
	TOTAL	79	67.5	109	77.9	188	73.2

RESPONSE BASED ON MEASURABLE DISEASE ASSESSMENTS ONLY

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TABLE T15.3.4 BEST OBJECTIVE RESPONSE BY EXTENT OF DISEASE - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

EXTENT OF DISEASE = SOFT TISSUE AND/OR LUNG DISEASE ONLY

OVERALL OBJECTIVE RESPONSE RATE	BEST OBJECTIVE RESPONSE	ANASTROZOLE N = 39		TAMOXIFEN N = 49		TOTAL N = 88	
		N	%	N	%	N	%
RESPONSE	COMPLETE RESPONSE	1	2.6	5	10.2	6	6.8
	PARTIAL RESPONSE	12	30.8	11	22.4	23	26.1
	TOTAL	13	33.3	16	32.7	29	33.0
NON RESPONSE	STABLE DISEASE >=24 WEEKS	12	30.8	8	16.3	20	22.7
	STABLE DISEASE < 24 WEEKS	2	5.1	1	2.0	3	3.4
	PROGRESSION	12	30.8	24	49.0	36	40.9
	TOTAL	26	66.7	33	67.3	59	67.0

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TABLE T15.3.4 BEST OBJECTIVE RESPONSE BY EXTENT OF DISEASE - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

EXTENT OF DISEASE = ALL OTHER DISEASE COMBINATIONS

OVERALL OBJECTIVE RESPONSE RATE	BEST OBJECTIVE RESPONSE	ANASTROZOLE N = 132		TAMOXIFEN N = 133		TOTAL N = 265	
		N	%	N	%	N	%
RESPONSE	COMPLETE RESPONSE	4	3.0	0	0	4	1.5
	PARTIAL RESPONSE	19	14.4	15	11.3	34	12.8
	TOTAL	23	17.4	15	11.3	38	14.3
NON RESPONSE	STABLE DISEASE >=24 WEEKS	53	40.2	44	33.1	97	36.6
	STABLE DISEASE < 24 WEEKS	5	3.8	3	2.3	8	3.0
	PROGRESSION	51	38.6	71	53.4	122	46.0
	TOTAL	109	82.6	118	88.7	227	85.7

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TABLE T15.3.5 CLINICAL BENEFIT - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

CLINICAL BENEFIT	BEST OBJECTIVE RESPONSE	ANASTROZOLE		TAMOXIFEN		TOTAL	
		N = 171		N = 182		N = 353	
		N	%	N	%	N	%
BENEFIT	COMPLETE RESPONSE	5	2.9	5	2.7	10	2.8
	PARTIAL RESPONSE	31	18.1	26	14.3	57	16.1
	STABLE DISEASE >=24 WEEKS	65	38.0	52	28.6	117	33.1
	TOTAL	101	59.1	83	45.6	184	52.1
NO BENEFIT	STABLE DISEASE < 24 WEEKS	7	4.1	4	2.2	11	3.1
	PROGRESSION	63	36.8	95	52.2	158	44.8
	TOTAL	70	40.9	99	54.4	169	47.9

TABLE T15.3.6 OBJECTIVE RESPONSE RATE : ANALYSIS RESULTS - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

ANASTROZOLE:TAMOXIFEN	ODDS RATIO	LOWER 95% CONFIDENCE LIMIT
ADJUSTED ANALYSIS	1.38	0.87
UNADJUSTED ANALYSIS	1.30	0.83

ANASTROZOLE-TAMOXIFEN	ESTIMATED DIFFERENCE IN RESPONSE RATES	LOWER 95% CONFIDENCE LIMIT
ADJUSTED ANALYSIS	5.01	-1.90
UNADJUSTED ANALYSIS	4.02	-2.47

THE ADJUSTED ANALYSIS WAS PERFORMED USING A LOGISTIC REGRESSION MODEL INCLUDING FACTORS FOR TREATMENT, AGE, PREVIOUS HORMONAL THERAPY, ER/PR STATUS AND EXTENT OF DISEASE AT ENTRY

THE UNADJUSTED ANALYSIS WAS PERFORMED USING A LOGISTIC REGRESSION MODEL INCLUDING TREATMENT FACTOR ONLY

RESPONDERS ARE SUBJECTS WITH A BEST OBJECTIVE RESPONSE OF COMPLETE RESPONSE (CR) OR PARTIAL RESPONSE (PR)

AN ODDS RATIO >1 FAVOURS ANASTROZOLE WHEREAS <1 FAVOURS TAMOXIFEN

A DIFFERENCE IN RESPONSE RATES >0 FAVOURS ANASTROZOLE WHEREAS <0 FAVOURS TAMOXIFEN

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TABLE T15.4.1 REASONS FOR TREATMENT FAILURE - 1033IL/0030
(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

PRIMARY REASON FOR TREATMENT FAILURE	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N = 171		N = 182		N = 353	
	N	%	N	%	N	%
DEATH	3	1.8	3	1.6	6	1.7
DISEASE PROGRESSION (OBJECTIVE)	100	58.5	121	66.5	221	62.6
DISEASE PROGRESSION (INVESTIGATOR'S OPINION)	13	7.6	13	7.1	26	7.4
ADVERSE EVENT	8	4.7	6	3.3	14	4.0
PROTOCOL NON-COMPLIANCE	2	1.2	2	1.1	4	1.1
PATIENT UNWILLING TO CONTINUE	2	1.2	4	2.2	6	1.7
NEVER STARTED RANDOMIZED TREATMENT	1	0.6	0	0	1	0.3
OTHER REASON	6	3.5	3	1.6	9	2.5
TOTAL	135	78.9	152	83.5	287	81.3

DISEASE PROGRESSION (INVESTIGATOR'S OPINION) REFERS TO PROGRESSION NOT CONFIRMED BY THE CRITERIA SET IN THE PROTOCOL

TABLE T15.4.2 MEDIAN TIME TO TREATMENT FAILURE - 1033IL/0030

(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

	ANASTROZOLE	TAMOXIFEN
	N = 171	N = 182
TIME TO TREATMENT FAILURE (DAYS)	231	163

MEDIAN TIMES TO EVENT WERE ESTIMATED USING KAPLAN-MEIER METHOD

TABLE T15.4.3 TIME TO TREATMENT FAILURE : ANALYSIS RESULTS - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

TAMOXIFEN:ANASTROZOLE	HAZARD RATIO	LOWER 95% CONFIDENCE LIMIT
ADJUSTED ANALYSIS	1.35	1.11
UNADJUSTED ANALYSIS	1.33	1.10

A HAZARD RATIO >1 INDICATES THAT ANASTROZOLE IS ASSOCIATED WITH A LONGER TIME TO PROGRESSION(TREATMENT FAILURE) THAN IS TAMOXIFEN

THE ADJUSTED ANALYSIS WAS PERFORMED USING A COX REGRESSION MODEL INCLUDING FACTORS FOR TREATMENT, AGE, PREVIOUS HORMONAL THERAPY, ER/PR STATUS AND EXTENT OF DISEASE AT ENTRY

THE UNADJUSTED ANALYSIS WAS PERFORMED USING A COX REGRESSION MODEL INCLUDING TREATMENT FACTOR ONLY

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TABLE T15.5.1 DURATION OF RESPONSE FROM RANDOMIZATION - 1033IL/0030

(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0030 WITH A COMPLETE OR PARTIAL RESPONSE)

DURATION OF RESPONSE (DAYS)	ANASTROZOLE	TAMOXIFEN
	N = 36	N = 31
MEDIAN	490	546
MIN	63	84
MAX	917	924

MEDIAN TIMES TO EVENT WERE ESTIMATED USING KAPLAN-MEIER METHOD

TABLE T15.5.2 DURATION OF RESPONSE FROM FIRST DOCUMENTATION OF OBJECTIVE RESPONSE - 1033IL/0030
(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0030 WITH A COMPLETE OR PARTIAL RESPONSE)

DURATION OF RESPONSE (DAYS)	ANASTROZOLE	TAMOXIFEN
	N = 36	N = 31
MEDIAN	376	332
MIN	34	54
MAX	833	784

MEDIAN TIMES TO EVENT WERE ESTIMATED USING KAPLAN-MEIER METHOD

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TABLE T15.5.3 DURATION OF CLINICAL BENEFIT - 1033IL/0030

(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0030 WITH A COMPLETE RESPONSE, PARTIAL RESPONSE, OR STABLE DISEASE >= 24 WEEKS)

DURATION OF CLINICAL BENEFIT (DAYS)	ANASTROZOLE	TAMOXIFEN
	N = 101	N = 83
MEDIAN	503	442
MIN	63	77
MAX	917	924

MEDIAN TIMES TO EVENT WERE ESTIMATED USING KAPLAN-MEIER METHOD

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TABLE T15.6.1 SURVIVAL STATUS - 1033IL/0030

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

SURVIVAL STATUS	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N = 171		N = 182		N = 353	
	N	%	N	%	N	%
ALIVE	124	72.5	129	70.9	253	71.7
DEAD	47	27.5	53	29.1	100	28.3

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TABLE T15.6.3 SURVIVAL AT TWO YEARS - 1033IL/0030

(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0030)

	ANASTROZOLE	TAMOXIFEN
	N = 171	N = 182
PROPORTION ALIVE AT TWO YEARS (%)	57.7	61.2

SURVIVAL WAS ESTIMATED USING KAPLAN-MEIER METHOD

TABLE T17.1 THE PROPORTION OF SUBJECTS WHO RECEIVED FURTHER BREAST CANCER THERAPY - 1033IL/0030
(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0030 WITHDRAWN FROM TRIAL TREATMENT)

THERAPY		ANASTROZOLE N = 122		TAMOXIFEN N = 142		TOTAL N = 264	
		N	%	N	%	N	%
RADIOTHERAPY	YES	34	27.9	28	19.7	62	23.5
	NO	88	72.1	114	80.3	202	76.5
CHEMOTHERAPY	YES	36	29.5	53	37.3	89	33.7
	NO	86	70.5	89	62.7	175	66.3
HORMONAL THERAPY	YES	55	45.1	80	56.3	135	51.1
	NO	67	54.9	62	43.7	129	48.9
OTHER THERAPIES	YES	31	25.4	29	20.4	60	22.7
	NO	91	74.6	113	79.6	204	77.3

TABLE T17.2 DURATION OF FURTHER BREAST CANCER THERAPY - 1033IL/0030
(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0030 WITHDRAWN FROM TRIAL TREATMENT)

THERAPY	DURATION (DAYS)	ANASTROZOLE	TAMOXIFEN
		N = 122	N = 142
RADIOTHERAPY (SESSIONS PER PATIENT)	TOTAL TREATED	34	28
	N	34	28
	MEAN	11	15
	MEDIAN	10	11
	SD	10.7	12.3
	MIN	0	0
	MAX	42	48
ANASTROZOLE	TOTAL TREATED	8	54
	N	3	25
	MEAN	297	150
	MEDIAN	186	112
	SD	210.4	143.7
	MIN	166	9
	MAX	540	608
CHEMOTHERAPY (CYCLES PER PATIENT)	TOTAL TREATED	20	39
	N	20	39
	MEAN	9	8
	MEDIAN	7	6
	SD	5.7	7.1

(CONTINUED)

N = NUMBER OF SUBJECTS FOR WHICH DURATION COULD BE CALCULATED

TABLE T17.2 DURATION OF FURTHER BREAST CANCER THERAPY - 1033IL/0030
(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0030 WITHDRAWN FROM TRIAL TREATMENT)

THERAPY	DURATION (DAYS)	ANASTROZOLE	TAMOXIFEN
		N = 122	N = 142
CHEMOTHERAPY (CYCLES PER PATIENT)	MIN	0	0
	MAX	20	31
TAMOXIFEN	TOTAL TREATED	50	9
	N	27	4
	MEAN	126	63
	MEDIAN	119	64
	SD	80.5	38.9
	MIN	0	24
	MAX	302	98
PAMIDRONIC ACID	TOTAL TREATED	17	23
	N	6	8
	MEAN	166	120
	MEDIAN	89	124
	SD	252.0	120.0
	MIN	0	0
	MAX	664	338
MEGESTROL	TOTAL TREATED	14	16
	N	10	8
	MEAN	104	124

(CONTINUED)

N = NUMBER OF SUBJECTS FOR WHICH DURATION COULD BE CALCULATED

TABLE T17.2 DURATION OF FURTHER BREAST CANCER THERAPY - 1033IL/0030
(SUBJECTS INCLUDED : ALL SUBJECTS IN TRIAL 1033IL/0030 WITHDRAWN FROM TRIAL TREATMENT)

THERAPY	DURATION (DAYS)	ANASTROZOLE	TAMOXIFEN
		N = 122	N = 142
MEGESTROL	MEDIAN	104	84
	SD	59.7	104.5
	MIN	17	42
	MAX	230	369
CLODRONIC ACID	TOTAL TREATED	8	4
	N	3	1
	MEAN	81	263
	MEDIAN	100	263
	SD	60.2	0
	MIN	14	263
	MAX	130	263

N = NUMBER OF SUBJECTS FOR WHICH DURATION COULD BE CALCULATED

TABLE T23.1 RANDOMIZATION AND SUBJECT STATUS - COMBINED

(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIALS 1033IL/0027 AND 1033IL/0030)

TREATMENT GIVEN	RANDOMISED TREATMENT					
	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N = 511		N = 510		N = 1021	
	N	%	N	%	N	%
ANASTROZOLE	503	98.4	3	0.6	506	49.6
TAMOXIFEN	5	1.0	506	99.2	511	50.0
OTHER	1	0.2	1	0.2	2	0.2
NONE	2	0.4	0	0.0	2	0.2
TOTAL	511	100.0	510	100.0	1021	100.0

SUBJECT STATUS AT DATA CUT-OFF	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N	%	N	%	N	%
STARTED TRIAL TREATMENT	506	99.0	511	100.2	1017	99.6
ON TREATMENT	149	29.2	128	25.1	277	27.1
WITHDRAWN FROM TREATMENT (ALIVE)	218	42.7	257	50.4	475	46.5
DEAD	139	27.2	126	24.7	265	26.0

PERCENTAGE CALCULATED USING NUMBER OF SUBJECTS RANDOMIZED AS DENOMINATOR

TABLE T23.2 AGE, HEIGHT, WEIGHT AND BODY MASS INDEX AT ENTRY - COMBINED
(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIALS 1033IL/0027 AND 1033IL/0030)

		ANASTROZOLE	TAMOXIFEN	TOTAL
		N = 511	N = 510	N = 1021
AGE (YEARS)	N	511	510	1021
	MEAN	67	66	66
	MEDIAN	67	67	67
	SD	11.2	10.8	11.0
	MAX	91	92	92
	MIN	30	40	30
HEIGHT (CM)	N	485	483	968
	MEAN	160	160	160
	MEDIAN	160	160	160
	SD	7.3	7.2	7.3
	MAX	180	183	183
	MIN	133	125	125
WEIGHT (KG)	N	501	496	997
	MEAN	69	69	69
	MEDIAN	68	67	68
	SD	14.1	14.8	14.4
	MAX	121	140	140
	MIN	40	36	36
BMI (KG/M2)	N	480	480	960
	MEAN	27	27	27

(CONTINUED)

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TABLE T23.2 AGE, HEIGHT, WEIGHT AND BODY MASS INDEX AT ENTRY - COMBINED
(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIALS 1033IL/0027 AND 1033IL/0030)

		ANASTROZOLE	TAMOXIFEN	TOTAL
		N = 511	N = 510	N = 1021
BMI (KG/M2)	MEDIAN	27	26	26
	SD	5.4	5.6	5.5
	MAX	48	53	53
	MIN	16	14	14

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TABLE T23.3 AGE GROUP, ETHNIC ORIGIN AND GENDER - COMBINED

(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIALS 1033IL/0027 AND 1033IL/0030)

		ANASTROZOLE N = 511		TAMOXIFEN N = 510		TOTAL N = 1021	
		N	%	N	%	N	%
AGE GROUP	<= 65	234	45.8	236	46.3	470	46.0
	> 65	277	54.2	274	53.7	551	54.0
ORIGIN	CAUCASIAN	465	91.0	457	89.6	922	90.3
	AFRO-CARIBBEAN	11	2.2	12	2.4	23	2.3
	ASIAN/ORIENTAL	1	0.2	3	0.6	4	0.4
	HISPANIC	14	2.7	17	3.3	31	3.0
	MIXED	13	2.5	16	3.1	29	2.8
	OTHER	7	1.4	5	1.0	12	1.2
GENDER	FEMALE	511	100.0	510	100.0	1021	100.0
	MALE	0	0.0	0	0.0	0	0.0

TABLE T23.4 BREAST CANCER DISEASE STATUS AT FIRST DIAGNOSIS - COMBINED
(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIALS 1033IL/0027 AND 1033IL/0030)

DISEASE STATUS AT FIRST DIAGNOSIS	ANASTROZOLE N = 511		TAMOXIFEN N = 510		TOTAL N = 1021	
	N	%	N	%	N	%
ADVANCED	215	42.1	229	44.9	444	43.5
EARLY	294	57.5	280	54.9	574	56.2
UNKNOWN	2	0.4	1	0.2	3	0.3
TOTAL	511	100.0	510	100.0	1021	100.0

TABLE T23.5.1 PRIOR ADJUVANT THERAPY (HORMONAL OR CYTOTOXIC) FOR BREAST CANCER - COMBINED
(SUBJECTS INCLUDED: ALL RANDOMIZED SUBJECTS IN TRIAL 1033IL/0027 AND 1033IL/0030)

PRIOR ADJUVANT THERAPY	ANASTROZOLE N = 511		TAMOXIFEN N = 510		TOTAL N = 1021	
	N	%	N	%	N	%
YES	173	33.9	167	32.7	340	33.3
NO	336	65.8	342	67.1	678	66.4
UNKNOWN	2	0.4	1	0.2	3	0.3

TYPE OF ADJUVANT THERAPY	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N	%	N	%	N	%
HORMONAL ONLY	52	10.2	40	7.8	92	9.0
CYTOTOXIC ONLY	96	18.8	99	19.4	195	19.1
BOTH	25	4.9	28	5.5	53	5.2

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TABLE T23.5.2 DURATION OF ADJUVANT HORMONAL TREATMENT - COMBINED

(SUBJECTS INCLUDED: ALL SUBJECTS IN TRIALS 1033IL/0027 AND 1033IL/0030 WHO WERE GIVEN PREVIOUS ADJUVANT HORMONAL TREATMENT)

DURATION OF ADJUVANT TREATMENT (WEEKS)	ANASTROZOLE	TAMOXIFEN	TOTAL
	N =77	N =68	N =145
MEDIAN	146	117	139
MIN	0	1	0
MAX	708	565	708

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TABLE T23.6.1 MOST RECENT HORMONAL RECEPTOR STATUS: ER AND PR GROUPED - COMBINED
(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIALS 1033IL/0027 AND 1033IL/0030)

GROUPED ER AND PR STATUS	ANASTROZOLE		TAMOXIFEN		TOTAL	
	N =511		N =510		N =1021	
	N	%	N	%	N	%
ER AND/OR PR POSITIVE	305	59.7	306	60.0	611	59.8
ALL OTHER COMBINATIONS	206	40.3	204	40.0	410	40.2

ER AND/OR PR POSITIVE IS ONE OF THE FOLLOWING: ER+
PR+
ER+ AND PR+

ALL OTHER COMBINATIONS INCLUDE UNKNOWN RECEPTOR STATUS

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TABLE T23.6.2 MOST RECENT HORMONAL RECEPTOR STATUS: ER AND PR SEPARATELY - COMBINED
(SUBJECTS INCLUDED : ALL RANDOMIZED SUBJECTS IN TRIALS 1033IL/0027 AND 1033IL/0030)

ER	PR	ANASTROZOLE N =511		TAMOXIFEN N =510		TOTAL N =1021	
		N	%	N	%	N	%
+	+	189	37.0	206	40.4	395	38.7
	−	62	12.1	58	11.4	120	11.8
	UNKNOWN	40	7.8	34	6.7	74	7.2
−	+	14	2.7	6	1.2	20	2.0
	−	2	0.4	1	0.2	3	0.3
	UNKNOWN	0	0.0	0	0.0	0	0.0
UNKNOWN	+	0	0.0	2	0.4	2	0.2
	−	0	0.0	0	0.0	0	0.0
	UNKNOWN	204	39.9	203	39.8	407	39.9