visit. Data from the Global Quality of Life collected for the first nine months of study has been analyzed. The baseline scores for all three treatment arms are similar (within two percentage points of each other). For completers (patients on study for more than six months) the baseline quality of life score is higher than for the dropouts on each treatment arm (about eight points in the letrozole 0.5 mg arm, about 11 points in the letrozole 2.5 mg arm, and about 7 points in the megestrol arm). If the quality of life is examined in completers who had objective response to therapy (CR,PR) and in completers who did not have an objective response (SD, PD), on the letrozole 0.5 mg arm no difference in quality of life scores is detected over time. In the megestrol arm no decrease in quality of life is observed in either subgroup of completers. On the letrozole 2.5 mg arm for completers who are nonresponders no change in quality of life is observed. For responders a slight decline in the quality of life scores is observed over the study period. The reason for the unexpected finding of a slight decrease in global quality of life over time in this group is not clear. For the dropout on all three treatment arms the most decline in global quality of life is observed on the megestrol arm, the least on the letrozole 2.5 mg arm, with letrozole 0.5 mg in between in decline of quality of life. (See Statistical Review for further detail.)

Pharmacokinetic Data

Plasma levels of letrozole were to be measured at each visit. Evaluation of the plasma trough levels on both letrozole arms indicates marked intersubject variability. For the letrozole 0.5 mg arm the mean plasma trough level of letrozole was 0.45 nmol/lL with a coefficient of variation of 52.1 - 90.3% for visits with more than ten patient samples available for analysis. For the letrozole 2.5 gm arm the mean plasma trough level of letrozole was 360 nmol/L with a coefficient of variation of 33.0 - 52.5% for visits with more than ten patient samples available for analysis. Marked intrasubject variability was also noted with a coefficient of variation of 32%. The plasma concentration is more than dose proportional for the two different dose levels indicating that pharmacokinetics are non-linear at letrozole 2.5 mg dose level. Plasma steady state was reach on the letrozole 0.5 mg arm at one month on study and between one and two months on the letrozole 2.5 mg arm. No increase in mean plasma trough levels for letrozole was observed after month two on study at either dose level. The increase in the intrapatient variability in the trough plasma level as compared to previous studies in healthy male volunteers and the lower trough level observed on this study as compared to previous studies in patients with advanced breast cancer raise questions as to a possible differences in clearance and /or compliance in the study populations.

Letrozole is metabolized by enzymes in the P450 cytochrome system. Comedications such as cimetidine (inhibitor of hepatic microsomal system), barbiturates (inducers of the hepatic microsomal system), benzodiazepines, or omeprazole did not affect letrozole concentrations. Likewise impaired hepatic function did not result in a significant increase in letrozole blood levels.

Estrone and Estradiol Data

Estrone (E_1) and estradiol (E_2) levels were measured on all three study arms. At baseline mean estrone (E_1) values were similar (letrozole 0.5 mg - 22.0±11.1 pg/ml, letrozole 2.5 mg - 22.5± 11.7 pg/ml, and megestrol 24.0±14.7 pg/ml). Mean estrone levels were suppressed about 80% from baseline in the both letrozole arms and about 60-65% on the megestrol arm. On the letrozole arms the estrone (E_1) levels were not detectable by the assay used for estrone measurement after the first visit in about 40% of the patients. Mean estradiol (E_2) levels were 5.6±4.2 pg/ml on the letrozole 0.5 mg arm, 5.6±3.4 pg/ml on the letrozole 2.5 mg arm, and 6.2±5.7 pg/ml on the megestrol arm at baseline. On the letrozole arms E2 suppression was 60 - 65% of baseline while on the megestrol arm estradiol suppression was 10 - 15% of baseline. After the baseline visit estradiol levels could not be quantitated in about 15% of the patients.

Statistical analysis was performed to determine if correlation between the letrozole plasma concentration and the estrone (E_1) and/or estradiol (E_2) levels exists. No difference in the level of estrogen suppression was detected at varying serum concentrations of letrozole even when a more sensitive assay to measure estrone and estradial levels was utilized. The plasma letrozole concentration can not be correlated with the degree of E_1 and E_2 suppression.

Increases in letrozole concentration did not significantly affect the time to progression with concnetrations up to 300 nmol/l. At letrozole plasma concentrations > 300 nmol/l the TTP is rly increased with borderline statistical significance. Information about the actual number of days by concentration are not provided. Analysis of time to progression utilizes the hormone information and letrozole plasma concentrations from 297 patients who remain on study for > 2 months (achieved steady state letrozole concentration). The actual time to progression for each plasma concentration range is not provided. Table SR-16 provides the risk ratios, 95% confidence intervals, and the P-value for comparison of the four groups: letrozole 0 - 50 nmol/L, 50 -150 nmol/L, 150 - 300 nmol/L, and > 300 nmol/L (as taken from Exhibit 4.4.2.-1, Vol. 1.95, pg. 022)

SR- 18: Risk Ratios for TTP by Concentration Groups with 95% Confidence Intervals (Ciba)

Concentration Group Comparisons (nmol/L)	Risk Ratio	95% Confidence Interval	P-value
	1.12	(0.74, 1.70)	0.60
	1.00	(0.69, 1.46)	0.99
	0.90	(0.57, 1.41)	0.63
	0.71	(0.48, 1.04)	0.08
	0.63	(0.40, 1.00)	0.05
	0.71	(0.46, 1.07)	0.10

Letrozole Blood Concentrations and Adverse Events

Increasing severity of adverse events could not be correlated with increasing letrozole plasma concentrations.

SAFETY REVIEW - AR/BC2

DEATHS

As expected, for the majority of the deaths reported on AR/BC2, the cause is disease progression. One death on the megestrol arm is related to drug therapy. (PAT died for an acute pulmonary embolus within one week of initiation of megestrol therapy.) No deaths due to drug related complications were observed on either letrozole arm. Table SF - 1 lists the cause of death for patients who died on study, within six weeks of study removal, or after completion of study by therapy.

SF-1: Number and Cause of Death by Treatment Arm

Timing, Cause of Death	Letrozole 0.5 mg (N = 188)	Letrozole 2.5 mg (N = 174)	Megestrol (N = 190)
Total Number of Deaths	89 (43.7%)	72 (29.8%)	94 (48.5%)
Deaths on Study	5 (5.6%)	7 (9.1%)	7 (7.4%)
Disease Related	4	6	2
Not Related to Disease/Drug	1	1	4
Drug Related			1
Deaths within Six Weeks of Study	2 (2.2%)	0	2 (2.1%)
Disease Related	1		1
Not Related to Disease/Drug	1		1
Deaths After Study Removal	82 (92.1%)	65 (90.3%)	75 (79.8%)
Disease Related	71	60	75
Cause Unknown	6	3	7
Not Related to Disease/Drug	5	2	2

As would be expected with a study population ≥ age 50, deaths on study which were not related to disease or drug included: two sudden deaths due to MI on the megestrol arm; one CVA on the megestrol arm; one episode considered trauma by the reviewer (Pat on the megestrol arm; one episode of ? intestinal perforation on the megestrol arm; one death on the letrozole 2.5 mg arm due to respiratory failure, and one sudden death on the letrozole 0.5 mg arm.

SERIOUS ADVERSE EXPERIENCES

Trial Discontinuations due to Adverse Experiences

According to Ciba, trial discontinuations due to serious adverse experiences occurred in 8/188 (4.3%) of patients treated with letrozole 0.5 mg, in 4/172 (2.3%) of patients treated with letrozole 2.5 mg, and in 15/190 (14.9%) of patients treated with megestrol. One of the eight trial discontinuations on the letrozole 0.5 mg arm was treatment related. On the letrozole 2.5 mg arm none of trial discontinuations were treatment related. On the megestrol arm according to the applicant twelve of fifteen drug related adverse experiences lead to discontinuation.

FDA review of study discontinuations for adverse experiences, whether drug related or not, is shown by study arm in Table SF - 2. In the appendix after this study, a listing of study participants who discontinued due entirely or in part to an adverse event, whether related to study drug or not, is included for review. On the letrozole 0.5 arm eleven discontinuations due to adverse events occurred. Three were definitely related to study drug (Pat. and two possibly related to study drug (Pat. . On the letrozole 2.5 mg arm eleven study drug discontinuations occurred secondary to adverse events. Two were considered related to study drug therapy (Pat. and two possibly related to study drug therapy (Pat. On the megestrol arm twenty-six study discontinuations occurred of which six (Pat. were definitely considered to be related to drug therapy and five (Pat. were possibly related to drug therapy. A significant difference is noted in the number of study discontinuations due to adverse events in favor of the letrozole ($p = 0.015$, two-sided). No significant difference in the number of patient discontinuations due to adverse events definitely or possibly associated with study drug is detected ($p = 0.17$, two-sided).

SF - 2: Study Discontinuation due to Adverse Events

Treatment Arm	L 0.5 (N = 188)	L 2.5 , (N = 174)	Megestrol (N = 190)	Significance (Fisher's Exact)
No. Patients Discontinued	11 (5.8%)	11 (6.3%)	22 (11.6%)	P = 0.01
No.Discontinuations due to Death as AE Drug Related	0 0	2 0	7 1	N.D.
No. Drug Related Discontinuations	3	2	6	P = 0.17
No. Discontinuations Possibly Related to Drug	3	1	5	
No. Unlikely to be Drug Related	1	3	4	N.D.
No. Discontinuation Not Related to Study Drug	6	3	11	N.D.

Types of Serious Adverse Events Reported on Study or Within Six Weeks of Study Discontinuation

Sixty-one serious adverse events were reported in 60 patients on the megestrol arm, thirty-seven seroius adverse events were reported in thirty-three patients on the letrozole 0.5 arm, and twenty-six serious adverse events were reported in twenty-two patients on the letrozole 2.5 mg arm. The serious adverse events which are summarized in the following table were either reported in the NDA as short summaries and /or may have been among the twenty-nine cases associated with study drug discontinuation and / or death where the submitted Case Report Forms were reviewed. Table SF- 3 includes a listing of those serious adverse experiences (whether due to drug, to disease progression, or to other disease processes) the number of times that the adverse reaction has been reported, the number of serious adverse experiences which the FDA considers related to the study drug is shown in parenthesis, and the percentage of serious adverse experiences by category. A question mark in the parenthesis indicates that, based on the available information, the possibility of a relationship between the event and the study drug exists in the FDA reviewer's judgement.

The majority of the serious adverse events on any treatment arm were not related to study drug but to the underlying disease process. Between 15-20% of the"serious adverse events" were due to other intercurrent disease processes of differing severity. A significant difference in the number of thromboembolic events (Fisher's Exact, p = 0.045) and significant increase in the incidence of vaginal bleeding is noted in the megestrol arm as compared to the letrozole arms (Fisher's Exact, p = 0.03). Grade III/IV nausea and vomiting due to study drug are seen on the letrozole arm but are not significantly increased over the megestrol arm (ie. Fisher's Exact, p= 0.14). One case of hypercalcemia on the letrozole 2.5 mg arm was thought to be secondary to drug use (? tumor flare).

SF-3 :Types of Serious Adverse Experiences by Treatment Arm

Type of Adverse Event	Letrozole 0.5 mg (No. AE = 37)	Letrozole 2.5 mg (No. AE = 26)	Megestrol 160 mg (No. AE = 63)
Thromboembolic	2.7%	3.8%	14.2%
PTE			3 (3)
DVT	1 (?)		4 (3)
Superficial Phlebitis		1 (1)	1 (1)
Axillary V. Thrombosis			1 (?)
Dermatologic	5.4%		
Cutaneous Eruption	2 (1)		
Reproductive / GU	2.7%	3.8%	11.1%
Vaginal Bleeding	1 (?)		6 (6)
Endometrial Cancer			1 (?)
Uterine Prolapse	1 (0)		
Urinary Retention		1 (0)	

SF-3 :Types of Serious Adverse Experiences by Treatment Arm

Type of Adverse Event	Letrozole 0.5 mg (No. AE = 37)	Letrozole 2.5 mg (No. AE = 26)	Megestrol 160 mg (No. AE = 63)
Cardiovascular	10.8%	15.4%	20.6%
Hypertension		1 (1)	1 (1)
Acute MI	2 (0)		3 (0)
CHF	1 (0)	2 (0)	1 (?)
CVA / TIA			3 (0)
Pericarditis/ Effusion			1 (0)
Sudden Death	1 (0)	1 (1)	4 (0)
Endocrine	2.7%		6.3%
New Onset Diabetes Mellitus	1 (?)		2 (?2)
Hyperparathyroidism			1 (0)
Adreno-cortical Insufficiency			1 (1)
Metabolic	16.2%	15.4%	14.3%
Hypercalcemia	2 (?1)	1 (1)	4 (?1)
Fluid Retention	1 (?)		1 (1)
Abnormal LFTs	1 (?1)	2 (1)	3 (2)
Hyponatremia	1 (0)		
Cachexia		1 (0)	1 (0)
Pulmonary		7.7%	7.9%
Pneumonia			3 (0)
Pleural Effusion		1 (0)	2 (0)
Respiratory Failure		1 (0)	
Gastrointestinal	24.3%	26.9%	31.7%
Nausea and Vomiting	6 (4)	2 (2)	1 (0)
Abdominal Pain		1 (0)	1 (0)
Diverticulosis / Diverticulitis	1 (0)		
Acute Pancreatitis	1 (0)		
Esophagitis	1 (0)	1 (0)	
Gastroenteritis		1 (0)	
Dysphagia		1 (0)	
Constipation		1 (0)	
Hematologic	5.4%	3.8%	
Anemia	1 (0)		1 (0)
Thrombocytopenia	1 (0)	1 (?)	
Neurologic	10.8%	3.8%	1.6%
Mental Confusion	1 (0)		
Increased Bone Pain	3 (?1)	1 (1)	1 (0)

SF-3 :Types of Serious Adverse Experiences by Treatment Arm

Type of Adver Event	Letrozole 0.5 mg (No. AE = 37)	Letrozole 2.5 mg (No. AE = 26)	Megestrol 160 mg (No. AE = 63)
Miscellaneous	16.2%	19.2%	19.0%
Fractures	2 (0)	1 (0)	3 (0)
Hip Replacements	2 (0)		1 (0)
Cataract Surgery		1 (0)	4 (0)
Edipermal Cyst Removal			1 (0)
Cholecydectomy			1 (0)
Sepsis w Cholecystitis	1 (0)		1 (0)
Lymphoma, New Onset			
Rectal Cancer		1 (0)	
Cellulitis		1 (0)	
Nasal Polypectomy	1 (0)	1 (0)	
Peritonitis due to Perforation			1 (0)

Adverse Experiences

Table SR - 4 is excerpted from the NDA submission and indicates the nature of adverse events related to study drug seen in greater than 3% of the patients (NDA Vol 1.71, pg. 77) . The nature of the most common adverse experiences are different for megestrol (weight increase, fatigue, dyspnea) than for letrozole (nausea, headache, fatigue).

SF-4: Adverse Experience Related to Treatment Reported by > 3% of Study Participants

	Letrozole 0.5 mg (N = 188)		Letrozole 2.5 mg (N = 174)		Megestrol 160 mg (N = 189)	
Nature of Adverse Experience	No.	%	No.	%	No.	%
Nausea	21	11.2	11	6.3	8	4.2
Weight Increase	4	2.1	4	2.1	15	7.9
Headache	12	6.4	11	6.3	9	4.8
Peripheral Edema*	5	2.7	11	6.3	7	3.7
Fatigue	6	3.2	9	5.2	12	6.3
Hot Flushes	8	4.3	9	5.2	7	3.7
Dyspnea	3	1.6	1	0.6	7	3.7
Dizziness	4	2.1	2	1.1	7	3.7
Increase Appetite	0	0	2	1.1	7	3.7
Alopecia	4	2.1	6	3.4	2	1.1
Vomiting	6	3.2	5	2.9	3	1.6
Constipation	6	3.2	3	1.7	4	2.1
Hypertension	6	3.2	0	0	5	2.6

*Edema may include peripheral edema, unilateral edema of any extremity, dependent edema, leg edema.

The nature of adverse events in the megestrol arm is consistent with the progestational nature of the drug and are similar to those reported for megestrol in the literature. No dose-response relationship is observed in the incidence of adverse events in the letrozole arms. Most adverse experiences associated with letrozole use are not serious in nature.

Age and Adverse Experiences

With regard to age ($\leq$ 55, 56-69, $\geq$ 70) no difference in the type of adverse events (whether related to trial treatment or not) was observed on any treatment arm. With regard to adverse events related to trial treatment, on the letrozole 0.5 mg arm the incidence of nausea, vomiting, rash, and headaches were similar in each age group, while hot flushes and alopecia were more common in those < age 70. On the letrozole 2.5 mg arm no nausea, hot flushes, or alopecia were reported in the $\geq$ age 70 group. Rash and headache were reported in one patient $\geq$ age 70. Vomiting occurred with equal frequency in all age groups. In patients treated with megestrol fatigue and weight gain were reported with equal frequency in all age groups, while dyspnea and dizziness were increased in patients $\geq$ age 70. No headaches were reported in patients $\geq$ age 70.

Impaired Organ Function and Adverse Experiences

No difference in the nature or the severity of adverse experiences in any treatment arm (letrozole 0.5 mg, letrozole 2.5 mg, or megestrol) could be linked with renal function impairment. More adverse experiences related to trial drug exposure were reported in patients with hepatic dysfunction treated with megestrol than with either dose of letrozole, (6/12 in the megestrol arm, 2/15 in the letrozole 2.5 mg arm, and 3/9 in the letrozole 0.5 mg arm). Likewise the number of adverse reactions related to study drug in patients with normal hepatic function is similarly increased on the megestrol arm. No difference in the pattern of severity of adverse events in patients with hepatic impairment was observed between the treatment arms.

Duration of Exposure and Adverse Events

With regard to adverse experiences by duration of exposure to trial medication the majority of adverse experiences on each treatment arm occurred in the first month of treatment. As the duration of exposure to study drug increased, the number of adverse events reported decreased. The nature of adverse experiences during the first nine months of treatment on any trial arm did not vary except for the increase in alopecia (reported in three patients on the letrozole 2.5 mg arm after six months of therapy) and weight gain (reported in six patients on megestrol arm after six months of therapy). No evidence of cumulative toxicity is seen with letrozole.

Laboratory Abnormalities Associated with Therapy

No Grade III/IV hematological toxicities due to drug therapy were observed. With regard to liver function abnormalities NCI grade 3/4 changes were reported in all arms for bilirubin, SGOT.

SGPT, and gamma-GT. More liver function abnormalities occurred in the megestrol group than in either letrozole arm as shown in the following table. The number in parentheses indicates the number of patients with known hepatic metastases. (Taken from Volume 1.71, pg 171, Exhibit 9.6-1)

SF-5: NCI CTC Grade 3/4 Liver Function Abnormalities by Treatment Arm

Laboratory Parameter	Letrozole 0.5 mg	Letrozole 2.5 mg	Megestrol
Bilirubin	4 (1)	9 (5)	10 (4)
SGOT	3 (2)	4 (3)	4 (3)
SGPT	1 (1)	4 (3)	1 (0)
Gamma-GT	8 (7)	8 (6)	22 (12)

The number of patients with grade 3/4 liver function abnormalities is increased on the megestrol acetate arm as compared to the other arms. Abnormalities of liver function are known to occur with megestrol although the incidence (5.2%) is increased as compared to the incidence reported in the PDR. No abnormalities of renal function clearly related to the study drug were identified. Likewise no abnormalities in electrolytes attributable to study drug were reported.

Summary of AR/BC2

In AR/BC2 with regard to response letrozole 2.5 mg (23.6%) had a significantly better response rate than letrozole 0.5 mg (11.7%) with an odds ratio of 0.43 (p = 0. 004). No significant differance was demonstated in a comparison of the response rates for megestrol and letrozole although the trend is in favor of letrozole 2.5 mg (OR = 1.57, p = 0.09). The median duration of response for the letrozole 2.5 mg arm has not been reached, for the letrozole 0.5 mg arm the median duration of response is 552 days and for the megestrol arm is 561 days. With regard to time to progression the median progression time on the letrozole 2.5 mg arm is 170 days, for letrozole 0.5 mg 154 days, and for megestrol 168 days. The risk of progression is significantly better for letrozole 2.5 mg than for megestrol ($RR_{L2.5M}$ = 0.77, p = 0.03) and a comparison of the risk of progression for letrozole 2.5 mg with letrozole 0.5 mg approaches significance ($RR_{L2.5:L0.5}$ = 1.24, p = 0.085). No differeance in survival is noted between the treatment arms.

No deaths attributable to letrozole occurred on study. One death directly related to study drug treatment occurred on the megestrol arm. Adverse experiences which required removal from study were varied. The most common adverse event associated with study removal with either dose of letrozole is grade 3/4 nausea and vomiting. With megestrol a significant increase in the number of thromboembolic events is observed on the megestrol arm as compared to the letrozole arms. A significant increase in vaginal bleeding on the megestrol arm as compared to the letrozole arms is also observed. Other common side effects of letrozole include headache, hot flushes, fatigue, alopecia, and rash. Fatigue and weight gain were reported with megestrol. No dose response relationship was detected in a comparison of the incidence and severity of adverse events on the two letrozole arms with more serious adverse events and more study discontinuations on the letrozole 0.5 mg arm. While other cardiovascular events (excluding thromboembolic events) occurred with increased frequency on the megestrol arm, these events do not appear related to study drug usage. Overall the safety profile of letrozole is very reassuring and a five fold difference in dose does not adversely affect the safety profile.

Appendix I: Summary of Protocol AR/BC2:

Title: Double-Blind, Randomized, Multicenter, Comparative, Between Patient Phase II Trial Comparing Daily Doses of 0.5 mg CSG 20267 Versus 2.5 mg CGS 20267 Versus 160 mg Megestrol Acetate as Second Line Endocrine Therapy in Postmenopausal Patients with Advanced Breast Cancer (TIP-NO. 920237)

1.1 Summary:

AR/BC2 is a double-blind, randomized, multicenter Phase II trial which proposes to determine the efficacy and tolerability of letrozole (CGS 20267) 0.5 mg, letrozole (CGS 20267) 2.5 mg, and megestrol acetate 160 mg/day. The primary endpoints for efficacy were defined as tumor response, time to progression, and time to treatment failure. Random allocation to one of three treatment arms for five hundred forty postmenopausal patients with advanced breast cancer with positive or unknown receptor status with disease progression on previous anti-estrogen therapy given as adjuvant therpay and /or first line therapy for advanced disease (~180 patients/arm).

1.2 Rationale for Trial:

In postmenopausal women peripheral conversion of androgens, mainly androstenedione into estrone is the major pathway of estrogen synthesis. Aromatase enzymes catalyze this reaction. Aromatase inhibitors block the enzyme action which results in decreased systemic estrogen levels. The use of aromatase inhibitors may provide significant palliation. Other agents used in palliative endocrine treatment include tamoxifen, gestagens such as megestrol, and other aromatase inhibitors such as aminogluthemide. This trial proposes a comparative trial of two doses of an aromatase inhibitor to megestrol, a known active agent , as second line therapy in advanced postmenopausal breast cancer with positive or unknown receptor status. The trial is designed to draw conclusions as to whether (1) CGS 20267 is active in advanced breast cancer or not, and (2) the dose levels of CGS 20267 are different or not in terms of efficacy.

2. Trial Objectives:

Primary objective:

to assess the anti-tumor efficacy, as evaluated by objective tumor response, duration of tumor response, time to treatment failure, and time to progression in the three treatment arms: letrozole 0.5 mg/day, letrozole 2.5 mg/ day, and megestrol acetate 160 mg/day and to compare the treatment arms to each other.

Secondary objectives are:

(1) to assess the tolerability and toxicity of letrozole 0.5 mg/day, letrozole 2.5 mg/ day, and megestrol acetate 160 mg/day and compare them;

(2) to evaluate the effect of daily doses of letrozole 0.5 or 2.5 mg on the serum estrogen

levels (estrone, E1; estradiol, E2) throughout the trial; and,
(3) to assess the trough plasma drug concentration levels during daily therapy with either letrozole 0.5 or 2.5 mg.

3. Trial Design and Treatments:

The trial is a double-blind, randomized, multicenter, comparative Phase II study in postmenopausal women with advanced breast cancer who previously progressed under antiestrogens (e.g. tamoxifen) given as adjuvant therapy and/or as treatment for advanced disease. Treatments were randomly allocated such that approximately equal numbers of patients should receive daily doses of 0.5 mg CGS 20267 or 2.5 mg CGS 20267 or 160 mg. megestrol acetate. Patients who have a complete or partial response or have stable disease will continue therapy until disease progression or until any reason necessitates discontinuation. Five hundred forty patients will be enrolled in the trial within 18 months, 180 patients on each treatment arm. The trial will be performed in nine countries in approximately 50 centers.

To ensure blinding a double-dummy technique has been used using film coated tablets and placebos of the same appearance for letrozole 0.5 and 2.5 mg manufactured by Ciba-Geigy. Megestrol acetate film coated tablets and matching placebos were manufactured by

All patients were required to take three tablets daily in the morning with a glass of water. No washout period for previous antiestrogen therapy was required, but all anticancer drugs had to be discontinued prior to initiation of study treatment.

Randomization was performed using a computer-generated list produced by Ciba-Geigy, LTD in Basle. Each country had a separate list which employed a fixed block size for randomization. Blinding could only be broken with the permission of the Ciba-Geigy monitor or, in the case of emergency situations, notification of trial monitor within twenty-four hours is required. The reason for the code break and the date of code break had to be reported and the patient removed from trial. To ensure random allocation each patient is to be given the pack with the lowest available number. The blinding of the trial will be broken at the time that the statistical analysis in performed. However, in cases of disease progression where the patient could benefit from further hormonal therapy the code could be broken after notification of the trial monitor for that site.

Examinations were scheduled at baseline, at one month, at two months, at three months, and then every three months until withdrawal from trial. Follow-up data for survival analysis will be collected at three month intervals.

Trial medications were supplied in weekly blister packs (7 day supply) and patients were given 15 blister packs every three months to ensure continuous supply of medication. All unused medication for the treatment interval was returned at the next follow-up appointment. The patients were advised not to take the study medication on the morning of the examination day. A medication dispensing system to allowed for accountability for study drug at each site was used.

4. Patient Selection:

A. Inclusion Criteria:

Compliant postmenopausal women
(Postmenopausal defined as: (1) no spontaneous menses for five years; (2) if spontaneous menses within the past five years, amenorrhea for the past twelve months with LH and FSH levels > 40 IU/L; (3) bilateral oophorectomy; or (4) radiation castration and amenorrhea for at least three months
Histologic or cytologic proof of breast cancer
Estrogen and / or progesterone receptor positivity or unknown receptor status
Documented measurable and/or evaluable disease and objective evidence of progression of disease either as new lesions or a > 25% increase in the size of existing lesions;
[For bone disease-enlargement of existing lytic lesions, presence of new lesions, bone pain which correlated with a lytic lesion on xray in an area previously not evaluated; positive bone scan or bone pain only is not acceptable for diagnosis of progression in bone]
Progression within six months of completion of adjuvant antiestrogen therapy or progression while on antiestrogen therapy given for more than six months and / or progression under first-line antiestrogens (e.g. tamoxifen) for advanced disease
May have received previous chemotherapy, corticosteroids, immunotherapy, biological response modifiers in combination with antiestrogens (One regimen of chemotherapy for advanced disease is allowed prior to antiestrogen therapy; primary (neo-adjuvant) treatment with endocrine or chemotherapy is allowed).
Performance status: 0, 1, or 2[6]
Written informed consent

Exclusion Criteria:

Rapid progressive metastases: CNS involvement; pulmonary lymphangitic carcinomatoses; inflammatory breast cancer, liver involvement > 1/3 with metastatic disease on CT or sonogram
Concurrent or previous malignancy except: (1) contralateral breast cancer; (2) cone-biopsied in

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[6]WHO Performance Status:

Grade 0: Able to carry out all normal activity without restriction (Karnofsky 90 -100)
Grade 1: Restricted in physically strenuous activity but ambulatory and able to do light work (Karnofsky 70-80)
Grade 2: Ambulatory and capable of all self-care but unable to carry out any work. Up and about more than 50% of waking hours (Karnofsky 50-60)
Grade 3: Capable of only limited self care, confined to the bed or /chair more than 50% of waking hours (Karnofsky 30 -40)
Grade 4: Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair (Karnofsky 10 -20)

situ carcinoma of the cervix; or, (3) treated basal cell or squamous cell carcinoma of the skin

Sole manifestation of disease: (1) hilar enlargement not measurable by CT; (2) pleural effusion; or, (3) ascites

Blastic or mixed lytic-blastic lesions with no other sites of measurable or evaluable disease

Uncontrolled cardiac disease or diabetes mellitus

Hx. of DVT or pulmonary embolism

Laboratory based exclusions:

Renal dysfunction (creatinine $\geq$ 1.5x upper limit of normal)

Hepatic dysfunction (total bilirubin $\geq$ 1.5x ULN, transaminases $\geq$ 2.6x ULN)

Hematologic abnormalities: WBC $< 3.0 \times 10^9$/Ll; AGN $\leq 1.5 \times 10^9$/L; Plts. $< 75 \times 10^9$/L; Hgb < 10 g/dl

Hx. of > one cytotoxic chemotherapy regimen for metastatic disease

Hx. of adjuvant endocrine therapy other than ovariectomy, antiestrogens, or radiation castration

Hx. of endocrine therapy other than antiestrogens for first line therapy of metastatic disease

Failure of recovery from toxicities of previous therapies

History of investigational systemic therapy (except investigational antiestrogens) within thirty days or topical investigational agents within seven days of planned enrollment on this trial or concurrent use of the above

Previous bisphosphonate therapy within six months of study entry

Use of antiestrogens or other anticancer medications concurrent with start of trial medication

Concomitant use of systemic steroids

Concurrent bisphosphonate therapy if bony metastases sole manifestation of advanced disease

5. Assessments Prior To, During, and After Trial:

Prestudy Evaluations:

History including concomitant medication, physical exam and baseline subjective measurements

Hematology, blood chemistry[7] w/in two weeks of enrollment

Chest xray, skeletal survey, and liver ultrasound / abdominal CT scan w/in 4 weeks of enrollment

FSH, LH levels if indicated

ECG at baseline

Informed consent signature

OnStudy Evaluations:
(at one month. two months, three months, and every three months thereafter)

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[7]Blood chemistry includes: sodium, potassium, total calcium and/or ionized calcium, phosphate; cholesterol, urea, creatinine, total protein and/or albumin, total bilirubin, SGOT (AST) and/or SGPT (ALT), gamma GT, alkaline phosphatase

Chest xray- if positive for involvement every 3 months, if negative every 6 months
Liver ultrasound / abdominal CT scan if positive or at six months for restaging
Skeletal survey every six months or bone scan if negative skeletal survey at baseline
X-rays of suspicious areas on skeletal surveys every 3 months or on appearance of signs and/or symptoms; xrays of any suspicious areas on bone scan
Superficial or palpable lesions measured every 3 months along the long two perpendicular axes
Color photographs every three months
Scans of involved areas
Subjective response assessed at every examination including performance status, pain measurement including pain score and analgesic consumption, and quality of life questionnaires
Hematology and chemistry every three months
Adverse experience[8] reporting every examination
ECG at 3 months and a 12 months and at discontinuation
Weight, blood pressure, pulse rate at each examination
Quality of Life Assessment (EORTC questionaire) at every visit
Estrone, estradiol measurement monthly
CGS 20267 drug concentrations monthly
Concomitant medications

6. Criteria for Safety and Efficacy Evaluations:

Serious Adverse Event (SAE): any event which results in (1) death, (2) hospitalization, (3) persistence of significant disability or incapacity, (4) a life threatening condition, (5) cancer, (6) drug overdose, (7) any event which suggests a significant hazard, drug interaction, dependence, contraindication, or need for a new precautionary statement, or (8) any abnormal laboratory findings indicating serious vital organ dysfunction whether or not clinical symptomatology is evident. Adverse events will be graded using the NIH Common Toxicity Criteria.

Efficacy will be assessed using the UICC criteria. Patients receiving bisphosphonate therapy objective tumor response (CR, PR, SD) in bone will not be included in the overall assessment of tumor response. Likewise blastic (sclerotic) and mixed bone lesions will be monitored by xray and/ or scan but will not be evaluated for response. Confirmed corrected hypercalcemia occurring during trial which requires intravenous bisphosphonate therapy will be considered as progression in bone.

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[8] Adverse reaction is defined as any undesirable experience occurring to a patient during a clinical trial whether or not it is considered related to the trial drug. Trial drug relationships for each adverse experience will be graded as: Not related, Unlikely, Possible, Probable, or Highly Probably.

Evaluation of Tumor Response-UICC Criteria (Addendum I):

Definitions of Measurable/Evaluable Disease

Measurable Bidimensional / Evaluable Disease includes palpable lesions for which two perpendicular diameters may be measured or lesions for which two perpendicular diameters can be measured from x-ray, CT scan, ultrasound, or NMR.

Measurable Unidimensional Disease includes palpable lesions for which only one diameter may be measured (i.e. supraclavicular node partially under the clavicle) or lesions for which any one diameter may be measured from x-ray, CT scan, ultrasound or NMR (i.e. mediastinal enlargement, enlarged hilar nodes, lung metastases not completely surrounded by lung tissue).

Evaluable disease includes malignant disease evident on clinical (physical or radiographic) examination, but not measurable by ruler or calipers (i.e. lytic bone metastases, pelvic and abdominal masses, confluent skin or lung metastases).

Evaluation of Measurable and Non-Measurable Lesions

Complete response (CR): disappearance of all known disease determined by two observations not less than four weeks apart

Partial Response (PR):

MEASURABLE LESIONS:

Ideally all lesions should be measured at each assessment. When multiple lesions are present, this may not be possible and under such circumstances a representative number may be selected for measurement.)

In the case of bidimensional lesions (i.e. pulmonary nodules surrounded by lung tissue on X-ray, cutaneous / subcutaneous metastases or peripheral lymph nodes metastases): decrease by 50% or more in the sum of the products of the two largest diameters of each individual lesion determined by two observations not less than four weeks apart.

In the case of unidimensional lesions (i.e. mediastinal enlargement, lung metastases not surrounded by lung tissue, intra-abdominal mass) decrease by 50% or more in the largest linear tumor measurement determined by two observations of the lesions not less than four weeks apart. In situations such as infiltration of the breast, liver involvement and mediastinal enlargement, objective regression is a 50% or greater decrease in that measurement which is regarded as being in excess of that usual for the site under consideration.

There should be no appearance of new lesions or progression on any lesion.

Liver metastases (Not UICC) may be acceptable as a measurable lesion, if the liver ultrasound or CT scan contains at least one clearly defined measurable defect > 3 cm. in diameter, clearly attributable to metastases.

EVALUABLE BUT NOT MEASURABLE LESIONS

Serial evidence of appreciable change documented by radiography or photography must be obtained and be available for subsequent review.

Estimated decrease in tumor size of 50% or more for at least four weeks.

It is not necessary for every lesion to have regressed to qualify as a partial response, but in all cases no lesions should have increased in size and no new lesions should appear.

No Change (NC or SD): Stable disease or a reduction of the measurable or evaluable lesions by less than 50%, or increase by less than 25% in the size of one or more lesions without new lesions appearing for at least four weeks. If non-measurable but evaluable lesions represent the bulk of disease and these clearly do not respond, even though measurable lesions have improved the response must be considered as "no change" and not as "partial response".

Progressive Disease (PD): increase of 25% or more of one or more measurable lesions, or estimated increase of 25% or more in existent non-measurable disease or appearance of new lesions.

EVALUATION OF BONE METASTASES:

Objective response:

Complete Response (CR): complete disappearance of lesions on X-ray

Partial Response (PR): partial decrease in size of lytic lesions or recalcification of lytic lesions.

No Change (NC or SD): Because of the slow response of bone lesions, the designation "no change" should not be applied until at least eight weeks have passed from the start of therapy.

Progressive Disease (PD): Increase in the size of existing lesions or appearance of new lesions. Occurrence of bone compression or fracture and its healing should not be used as the sole indicator for evaluation of therapy.

OVERALL RESPONSE

If both measurable and non-measurable disease are present in a given patient, the results of each should be recorded separately. Overall assessment of response involves all parameters: measurable and nonmeasurable disease, bone metastases.

Progression in any site, or the appearance of a new lesion, indicates disease progression despite objective responses in other sites.

In the case of measurable lesions, the poorest response designation shall prevail in the overall assessment of response

"No Change" in non-measurable lesions will not detract from a partial response in measurable lesions

but will reduce a complete response in measurable lesions to partial response overall.

If, in the responses by organ site there are equal or greater numbers of complete plus partial responses than of "No Change" designation , then the overall response will be partial.

DURATION OF RESPONSE:

Complete Response (CR): The period of CR should last from the date the CR is first recorded until the date when progressive disease is first noted.

Partial Response (PR): In patients who only achieve partial response, only the period of overall response should be recorded.

Overall Response (OR): The period of overall response lasts from the first day of treatment until the date of the first observation of progressive disease.

Premature discontinuation from trial may occur for the following reasons: (1) adverse experience; (2) abnormal laboratory value(s); (3) abnormal test procedure(s) results; (4) unsatisfactory therapeutic effects; (5) patient's condition no longer requires trial treatment; (6) failure to meet protocol criteria; (7) non-compliance; (8) withdrawal of consent; (9) lost to follow-up; (10) administrative problems; and, (11) death.

7. Statistical Considerations;

Sample Size Calculation:

Sample size was calculated based on both tumor response and time to progression. For tumor response an overall objective response rate (CR and PR) of 20% was assumed with a minimum response rate of 10% to be of interest. Setting $a = 0.05$, two-sided level of significance, and a power $(1-B) = 0.90$ of detecting a difference of 15% (absolute difference) between any two treatments, a sample size of 146 patients per treatment arm is calculated. Adjustments were made for the three arms to be simultaneously compared, and for possible loss to follow-up or non -evaluability of response were made yielding a sample size of 180 patients / arm. For time to progression (or time to treatment failure) a 50% difference in the median time (i.e. detection of a 1.5 ratio of hazards) between any two of the three treatments was defined as relevant assuming $a = 0.05$,, and $1-B = 0.9$. Sample size, comparing three arms simultaneously, was calculated to be n=154 per arm, all followed to the end-point (progression or failure). Adjusting for loss-to-follow-up and for approximately 15% patients not reaching the endpoint, the estimate was revised to a total of 544 patients.

[redacted]

Considerations in Analysis:

Primary analysis which will be performed will be intent to treat. The database will be frozen nine months after the end of the enrollment period for the first (main) statistical analysis which will take place one year after the enrollment of the last patient. The median time to progression in postmenopausal patients with advanced breast cancer being treated with second line hormonal therapy is six months, therefore a nine month between enrollment of the last patient and database freezing will allow for adequate data collection.

If the observed number of deaths exceed 100 at the time of analysis, time to death will constitute a primary endpoint. If the number of deaths is less than 100, time to death will be analyzed as a secondary endpoint and a formal survival analysis will be conducted approximately three years after the end of enrollment. At the time of the second analysis tumor response data including time to progression and time to treatment failure and tolerability will be updated but will be designated as secondary endpoints.

The assessment of tumor response given by the peer review committee will be definitive with discrepancies between the investigator and the peer review committee documented. The following subsets of patients will be identified (all patients enrolled or intent to treat, evaluable patients, and eligible and evaluable patients) and analyzed with respect to the primary endpoints. Time to event analyses will utilize the Kaplan-Meier product-limit method.

Time to progression will be dated from the first day of treatment until documented progression. Time to progression will be right censored for patients withdrawing from the trial without progressive disease or for patients still on treatment at the time of analysis and who have no evidence of progressive disease. Time to treatment failure is defined as the interval from the first day of treatment to diagnosis of progression, withdrawal from the trial for any reason, or death due to any cause, whichever is the earliest event. Time to treatment failure will be right-censored only for patients remaining on trial treatment at the time of analysis and who have no evidence of progressive disease. Treatments will be compared using the log rank test. If the overall logrank statistically significant, the two degrees of freedom will be partitioned orthogonally to make the following comparisons: CGS 20267 (i.e. average effect) vs megestrol acetate and 0.5 mg/day CGS 20267 vs 2.5 mg/day CGS 20267. As the trial is mainly a phase II trial for which the analysis is essentially exploratory, no adjustment of the p-value is planned to accommodate for multiple endpoints. For the variables TTP and TTF, the stratified logrank test (Mantel-Haenszel) will be applied to selective baseline characteristic to determine their prognostic influence. In particular, performance status, age class ($\leq$ 55 years, 56-69 years, $\geq$ 70 years), disease free interval (Stage IV disease, <2 years, $\geq$ 2 years) dominant site of disease (soft tissue, bone, visceral), previous chemotherapy, previous response to hormone therapy, previous / concomitant use of bisphosphonates, and receptor status (unknown, positive ER & PR, positive ER or PR) will be examined.

Overall tumor response (CR and PR) will be analyzed using a non-parametric method for ordered

categorical data and the 95% intervals around the difference in response rates (CR and PR) will be determined. Prognostic influence of selected baseline characteristics (performance status, age class, disease-free interval, previous chemotherapy, previous response to hormone therapy, and previous or concomitant bisphosphonates) will be examined by logistic regression procedure. Baseline characteristics will be summarized for each group but not significance testing will be performed as the treatments are randomly allocated.

Hormone measurements and drug levels will be log-transformed. Descriptive summary statistics for each hormone will be provided. Dependent on the available measurements, a repeated measures type of analysis will be performed. The minimal planned points are: baseline, 1 month, 3 months, and on progression of disease. Missing values will not be replaced. Values below the limit of detection of the assay will be considered as = [limit of detection - 0.01]. Baseline drug levels greater than zero will result in exclusion of all data for the individual patient from the analysis of both drug levels and of hormone levels.

The analysis of the quality of life measurements using the EORTC QLQ-C30 questionnaire in the validated, local language version will be defined outside of this protocol. The weights for the subscales proposed by Aaronson et al will be used. Performance status will be tabulated and summarized in the form of frequency tables. Individual changes in performance status will be documented but no formal analysis is planned. Adverse reactions will be tabulated according to patient and will be summarized for each treatment group according to COSTART body system and, if appropriated, for individual symptoms. No formal analysis is planned. Laboratory data will be listed and flagged according to the NIH. Key laboratory variables will be summarized in tabular (descriptive statistics) and graphical form (box and whisker plots).

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	L0.5	11/2/93	PD		0	03JAN94	1/4/94	64		DEAD	1/1/95		CANCER
	L0.5	2/3/94	PD		0	15MAY94	5/16/94	103		DEAD	11/10/95		CANCER
	L2.5	6/13/94	PD		0	03AUG94	8/31/94	80		DEAD	8/31/94		CANCER
	MA	6/29/94	NE		0	01JUL94		3	7/1/94	DEAD	7/5/94		AE -PTE
	L2.5	4/16/93	PD		0	29MAR95	10/27/93			ALIVE		12/22/95	
	MA	4/21/93	NE		0	15MAY93			5/15/93	DEAD	11/17/93		CANCER
	L2.5	4/23/93	PD		0	20SEP93	7/27/93	96		DEAD	2/1/95		CANCER
	MA	11/19/93	NE		0	20DEC93			12/20/93	DEAD	10/16/95		CANCER
	L0.5	2/23/94	SD		0	11JAN95	1/11/95	323		DEAD	11/17/95		CANCER
	MA	3/8/94	PD		0	06SEP94	5/17/94	71		DEAD	2/13/95		CANCER
	L2.5	3/31/94	PD		0	24MAY94	5/31/94	62		ALIVE		9/30/95	
	L2.5	4/13/94	PD		0	13OCT94	7/7/94	86		ALIVE		10/12/95	
	L0.5	5/4/94	PD		0	19JUN94	6/20/94	47		DEAD	7/14/95		CANCER
	MA	5/11/94	NE		0	11MAY94		0	5/11/94	ALIVE		5/11/94	
	L0.5	6/29/94	SD		0	19OCT94		167	12/12/94	ALIVE		12/12/94	
	MA	3/8/94	PD		0	17MAY94	6/23/94	108		DEAD	7/16/94		CANCER
	L0.5	8/19/94	PD		0	14NOV94	11/14/94	93		ALIVE		11/19/95	
	MA	9/3/93	PD		0	05OCT93	10/5/94	33		DEAD	6/1/95		CANCER
	L0.5	7/13/94	PD		0	24NOV94	10/6/94	86		ALIVE		11/13/95	
	MA	7/20/94	SD		0		4/4/95	259		ALIVE		10/16/95	
	MA	7/30/94	PD		0	30MAY95	10/28/94	91		ALIVE		11/29/95	
	L0.5	3/25/93	PD		0	01AUG93	6/28/93	96		DEAD		4/30/94	CANCER
	L2.5	5/14/93	SD		0	22NOV93	11/23/93	194		ALIVE		11/13/95	
	MA	5/28/93	NE		0	23OCT93	10/26/93	152		DEAD	9/28/95		
	L0.5	6/4/93	SD		0	27NOV94	11/29/94	544		ALIVE		12/4/95	
	MA	7/5/93	PR	10/11/93	99	16JAN95	1/17/95	561		ALIVE		10/17/95	
	L2.5	8/3/93	SD		0	05DEC95	2/7/95	544		ALIVE		12/5/95	
	L0.5	3/30/94	PD		0	22JUN94	6/22/94	85		DEAD	11/1/94		CANCER
	L2.5	3/30/94	PD		0	14JUL94	6/22/94	85		DEAD	7/26/94		CANCER
	L2.5	3/30/94	PD		0	21JUN94	6/22/94	85		DEAD	7/1/94		CANCER
	MA	5/25/94	PR	8/16/94	84	30SEP95	10/4/94			ALIVE		9/30/95	
	L0.5	6/22/94	NE		0	15JUL94			7/15/94	ALIVE		10/15/95	
	MA	8/18/94	PD		0	26NOV94	11/26/94	101		DEAD	5/24/95		CANCER
	L0.5	6/15/93	NE		0	21JUN93		7	6/21/93	ALIVE		4/12/95	
	L0.5	7/12/93	NE		0	24JUL93		13	7/25/93	DEAD	7/25/93		CANCER
	MA	5/11/94	PD		0	30JAN95	8/31/94	113		ALIVE		1/30/95	
	L2.5	7/15/94	PD		0	05JAN95	10/10/94	87		ALIVE		1/6/95	
	L2.5	5/3/93	PD		0	05AUG93	8/6/93	95		DEAD	6/8/95		CANCER
	L0.5	5/28/93	NE		0	28JUN93		32	7/25/93	DEAD	7/25/93		NOT CANCER RE
	MA	6/1/93	CR	12/27/93	84					ALIVE		12/7/95	
	MA	10/6/93	PD		0		1/5/94			ALIVE		10/9/95	
	L2.5	10/26/93	SD		0	20OCT95	10/11/95	716		ALIVE		10/20/95	
	MA	9/29/93	PD		0	27APR94	3/22/94	175		DEAD	2/6/95		CANCER
	MA	10/28/93	PD		0	28JUN94	1/25/94	90		ALIVE		6/26/95	

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	L0.5	8/30/93	SD		0	18JAN94		142	1/19/94	ALIVE		11/28/95	
	L2.5	4/13/94	PD		0	21SEP94	7/7/94	86		ALIVE		12/28/95	
	MA	5/20/94	SD		0	09NOV94	11/10/94	175		ALIVE		12/8/95	
	L2.5	10/13/93	PD		0	06DEC93	12/7/93	56		DEAD	2/12/95		CANCER
	L0.5	11/3/93	NE		0	02JAN94			2/2/94	DEAD	12/2/94		UNKNOWN
	MA	1/31/94	PR	10/19/94	262	04JUL95	4/5/95	430		ALIVE		10/25/95	
	MA	6/3/94	PD		0	08JAN95	1/9/95	220		ALIVE		11/28/95	
	L0.5	8/12/94	NE		0	14OCT94			10/14/93	DEAD		10/18/94	UNKNOWN
	L2.5	11/24/93	NE		0	24NOV93		1	11/24/93	ALIVE		11/24/95	
	MA	10/24/93	PD		0	02FEB94	2/2/94	102		DEAD	3/22/95		CANCER
	MA	12/13/93	PD		0	06MAR94	3/7/94	85		DEAD	12/26/94		CANCER
	L0.5	12/20/93	PD		0	13MAR94	3/14/94	85		DEAD	9/12/95		CANCER
	L2.5	1/22/94	CR	4/18/94	87	30AUG95	8/22/95	578		ALIVE		11/14/95	
	MA	3/3/94	PD		0	24MAY94	5/25/94	84		DEAD	8/13/95		CANCER
	L0.5	3/8/94	SD		0					ALIVE		12/6/95	
	L2.5	7/12/94	PD		0	20OCT94	10/5/94	86		ALIVE		10/25/95	
	MA	10/6/94	PD		0	06FEB95	12/29/94	85		ALIVE		11/15/95	
	MA	9/7/94	PD		0	15DEC94	12/21/94	107		DEAD	4/1/95		
	L0.5	9/15/94	NE		0	15NOV94		62	11/15/94	ALIVE		12/22/95	
	L0.5	6/8/93	PD		0	26JUL93	8/5/93	49		DEAD	11/12/93		CANCER
	L2.5	6/25/93	PD		0	16SEP93	9/17/93	84		DEAD	2/3/95		CANCER
	L2.5	8/12/93	PD		0	04NOV93	11/5/93	85		DEAD	8/12/95		CANCER
	MA	9/24/93	SD		0	26JUL94	6/3/94	253		ALIVE		12/28/95	
	MA	10/1/93	SD		0	30NOV94	8/24/94	331		ALIVE		12/14/95	
	L0.5	10/11/93	PD		0	02JAN94	1/3/94	84		ALIVE		12/28/95	
	L2.5	5/20/93	CR	11/7/93	179					ALIVE		12/21/95	
	L0.5	6/11/93	CR	12/2/93	166					ALIVE		9/22/95	
	L2.5	7/16/93	SD		0	31MAY94	6/1/94	320		ALIVE		12/14/95	
	L0.5	4/19/94	SD		0					ALIVE		10/11/95	
	MA	4/29/94	SD		0	09OCT95	7/10/95			ALIVE		12/14/95	
	MA	5/3/94	SD		0	25OCT94	10/26/94	176		ALIVE		12/28/95	
	L2.5	12/23/93	PD		0	07MAR94	3/8/94	75		ALIVE		12/21/95	
	MA	1/14/94	SD		0	11MAY94	4/8/95	118		ALIVE		11/14/95	
	L2.5	3/31/94	PD		0	26JUN94	6/27/94	88		DEAD		11/11/95	CANCER
	L0.5	5/3/94	SD		0	25JAN95	11/10/94	268		DEAD	6/8/95		CANCER
	MA	6/29/93	PD		0	02AUG93	8/2/93	35		DEAD	1/16/94		CANCER
	L0.5	11/10/93	PD		0	24MAY94	2/8/94	91		ALIVE		12/7/95	
	L2.5	11/10/93	PR	2/7/95	455			736		ALIVE		11/15/95	
	L0.5	11/12/93	PD		0	07FEB94	2/8/94	88		DEAD	11/16/95		CANCER
	MA	11/24/93	PD		0	28FEB94	2/22/94	91		DEAD	12/17/95		CANCER
	L2.5	2/16/94	NE					638		ALIVE		11/15/95	
	L0.5	8/26/93	PD		0	16NOV93	11/17/93	84		ALIVE		11/16/95	
	MA	9/9/93	PD		0	13JAN94	12/1/93	84		ALIVE		12/28/95	
	L2.5	12/27/93	PD		0	22MAR94	3/23/94	87		DEAD	1/13/95		CANCER

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	MA	1/5/94	NE		0	13JAN94		9	2/9/94	ALIVE		5/2/95	
	L0.5	4/21/94	PR	7/14/94	85	24NOV94	11/25/94	218		ALIVE		11/24/95	
	L2.5	7/26/94	PD		0	19SEP94	9/20/94	56		ALIVE		12/28/95	
	L2.5	1/19/94	NE		0	13JUN94		146		DEAD	7/7/94		CANCER
	L2.5	11/16/93	PD		0	22DEC93	12/29/93	37		ALIVE		5/31/95	
	MA	1/19/94	SD		0	09OCT94		264	11/3/94	ALIVE		11/29/95	
	MA	3/4/94	PD		0	30MAY94	5/31/94	88		DEAD	6/10/94		CANCER
	L2.5	3/5/94	PD		0	06JUN94	6/2/94	90		DEAD	3/1/95		CANCER
	L0.5	4/12/94	PR	1/19/95	283	18OCT95	8/18/95	555		ALIVE		10/18/95	
	L0.5	6/1/94	PD		0	30AUG94	8/31/94	92		ALIVE		11/29/95	
	L0.5	5/20/93	PD		0	17NOV93	8/17/93	90		DEAD	11/12/94		CANCER
	L2.5	7/6/93	PD		0	28SEP93	9/29/93	85		DEAD	3/10/94		CANCER
	L0.5	9/28/93	PD		0	12DEC93	12/13/93	77		DEAD	10/14/95		CANCER
	MA	1/25/94	PD		0	08FEB94	3/8/94	15		DEAD	6/7/94		CANCER
	MA	2/18/94	PD		0	21FEB95	8/31/94	195		DEAD	5/5/95		CANCER
	L2.5	8/11/94	PR	2/22/95	196					ALIVE		11/28/95	
	L2.5	12/18/93	PR	3/16/94	89				11/13/95	DEAD	11/19/95		NOT RELATED
	L0.5	1/22/94	PR	7/25/94	185		1/26/95	474		ALIVE		11/17/95	
	L0.5	4/8/94	PD		0	19AUG94	7/20/94	104		DEAD	8/14/95		
	L2.5	4/20/94	PR	10/27/94	191					ALIVE		10/28/95	
	MA	6/3/94	PD		0	06AUG94	8/8/94	65		DEAD	1/21/95		CANCER
	MA	6/2/94	SD		0	10DEC94	12/6/94	188		DEAD	8/13/95		CANCER
	L2.5	1/24/94	NE							ALIVE		10/2/95	
	L0.5	10/12/93	SD		0	11SEP94	9/12/94	336		DEAD	3/15/95		CANCER
	L0.5	2/21/94	PD		0	22MAY94	5/23/94	91		DEAD	1/10/95		CANCER
	MA	2/21/94	CR	5/30/94	99					ALIVE		11/27/95	
	MA	10/25/93	SD	1/17/94	0	05NOV95	10/16/95	722		ALIVE		11/5/95	
	L2.5	3/14/94	PR	6/6/94	85	03DEC95	9/4/95	540		ALIVE		12/3/95	
	MA	2/4/94	PD		0	04APR94	4/5/94	60		DEAD	8/13/94		CANCER
	L2.5	4/23/94	SD		0	06JUN95	6/15/95	419		ALIVE		12/28/95	
	L0.5	7/6/94	PD		0	20APR95	10/3/94			ALIVE		12/28/95	
	L0.5	6/25/94	PR	1/19/95	179			516		ALIVE		12/22/95	
	MA	10/8/93	NE		0	16DEC93		70	12/24/93	DEAD	3/7/95		CANCER
	L0.5	11/13/93	PD		0	05MAY94	2/14/94	94		ALIVE		11/7/95	
	L0.5	12/3/93	PD		0	05MAY94	5/6/94	154		DEAD	10/15/94		CANCER
	L2.5	12/16/93	PD		0	18JAN94	1/19/94	34		DEAD	4/14/94		CANCER
	MA	12/23/93	SD		0	29MAY94	5/30/94	158		ALIVE		11/3/95	
	L2.5	1/10/94	SD		0	28JUN94	6/29/94	170		ALIVE		11/16/95	
	MA	9/8/93	SD		0	23MAY94	5/25/94	258		ALIVE		12/21/95	
	L0.5	1/21/94	SD		363	04APR95	4/5/95	439		DEAD	5/8/95		CANCER
	L0.5	10/7/94	SD		0					ALIVE		11/30/95	
	MA	5/26/93	PR	8/18/93	85	10JAN95	1/11/95	595		ALIVE		12/21/95	
	MA	6/23/93	PD		0	14SEP93	9/15/93	84		DEAD	4/12/94		CANCER
	L2.5	7/23/93	PR	1/17/94	169					ALIVE		12/1/95	

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	L2.5	5/17/94	PR	8/9/94	85			539		ALIVE		11/6/95	
	MA	7/6/93	SD		0	02FEB94	2/4/94	169		ALIVE		11/8/95	
	L2.5	10/26/93	PR	4/26/94	183					ALIVE		10/25/95	
	L0.5	1/27/94	PD		0	27APR94	4/28/94	91		DEAD	4/8/95		CANCER
	MA	2/18/94	PD		0	18MAY94	5/19/94	90		ALIVE		11/22/95	
	L0.5	2/21/94	NE		0					ALIVE		11/21/95	
	L2.5	2/25/94	CR	8/30/94	97			635		ALIVE		11/21/95	
	L2.5	11/10/93	NE		0					DEAD	11/20/95		
	MA	11/17/93	PR	2/17/94	0	28APR94		163	4/28/94	DEAD	4/28/94		SUDDEN DEATH ?
	L0.5	11/20/93	PD		0	01FEB94	2/7/94	74		DEAD	6/28/94		CANCER
	L0.5	2/28/94	NE		0	29APR94		61	4/30/94	DEAD	7/2/95		CANCER
	L2.5	3/18/94	CR	6/21/94	96	20MAR95	3/21/95	368		ALIVE		12/28/95	
	MA	3/24/94	CR	6/29/94	98	11APR95	4/12/95	384		ALIVE		12/28/95	
	L0.5	11/3/93	PD		0	01MAR94	1/26/94	85		ALIVE		6/30/95	
	MA	11/19/93	SD		0	14AUG94	8/9/94	264		DEAD	8/3/95		CANCER
	L0.5	11/24/93	CR	2/23/94	92					ALIVE		12/20/95	
	L2.5	12/1/93	SD		0	30NOV94	12/1/94	365		ALIVE		12/15/95	
	MA	12/8/93	PR	3/7/94	90	28AUG94		212	8/28/94	DEAD	9/3/95		CANCER
	L2.5	12/21/93	NE		0	02FEB94		44	2/3/94	DEAD	2/3/94		RESPIRATORY FA
	L0.5	5/27/93	PD		0	02SEP93	9/3/93	99		DEAD	10/2/94		CANCER
	L2.5	7/9/93	SD		0	18APR94	1/25/94	201		ALIVE		12/28/95	
	MA	8/5/93	PD		0	29SEP93	9/30/93	56		ALIVE		12/28/95	
	MA	1/11/94	PD		0	04APR94	4/5/94	84		ALIVE		12/28/95	
	L0.5	12/28/93	PD		0	06APR94	4/7/94	100		ALIVE		12/28/95	
	L2.5	1/17/94	PD		0	18APR94	4/19/94	92		ALIVE		12/28/95	
	L2.5	4/14/94	PD		0	18JUL94	7/19/94	96		DEAD	7/30/94		CANCER
	MA	6/8/94	PD		0	06SEP94	9/7/94	91		DEAD	8/19/95		CANCER
	MA	9/7/94	SD		0	15SEP95	9/16/95			ALIVE		12/28/95	
	L0.5	2/10/94	PD		0	09MAR94	3/10/94	28		DEAD	11/6/94		CANCER
	L2.5	3/8/94	CR	6/2/94	87					ALIVE		12/12/95	
	L0.5	3/11/94	PR	12/5/94	179					ALIVE		12/12/95	
	MA	4/19/94	SD		0	19DEC95	8/30/95			ALIVE		12/19/95	
	L2.5	7/28/94	CR	10/26/94	91					ALIVE		11/2/95	
	MA	9/13/94	PD		0	17MAY95	5/18/95	247		DEAD	11/8/95		CANCER
	L2.5	10/27/93	PD		0	18JAN94	1/19/94	84		DEAD	9/6/95		CANCER
	L2.5	11/4/93	SD		0	26JAN94		84	1/27/94	ALIVE		10/26/95	
	MA	3/8/94	NE		0	04APR94		28	4/5/94	DEAD	10/12/94		UNKNOWN
	MA	4/15/94	SD		0	22DEC94	12/23/94	252		ALIVE		12/28/95	
	L0.5	5/6/94	PD		0	02JUN94	6/3/94	28		ALIVE		12/28/95	
	L0.5	1/4/94	SD		0					ALIVE		12/4/95	
	MA	1/28/94	SD		0	11JUL94	7/12/94	165		DEAD	5/23/95		CANCER
	L0.5	2/12/94	PD		0	03MAY94	5/4/94	81		ALIVE		11/17/95	
	L2.5	3/4/94	PR	5/31/94	181					ALIVE		12/5/95	
	MA	3/12/94	NE		0	24MAY94		74	5/24/94	DEAD	5/24/94		PERITONITIS WIT

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	L2.5	6/30/94	SD		0	19AUG94		51	8/20/94	DEAD	10/15/94		CANCER
	L0.5	1/28/94	SD		0	30OCT94	10/31/94	276		DEAD	10/8/95		CANCER
	L2.5	2/1/94	SD		0	07AUG94	8/8/94	188		DEAD	11/6/95		CANCER
	MA	3/4/94	SD		0					ALIVE		10/25/95	
	L0.5	4/11/94	PD		0	11OCT94	7/8/94	89		ALIVE		11/22/95	
	L2.5	5/21/94	PR	12/5/94	199	30NOV95	12/1/95			ALIVE		12/1/95	
	MA	7/7/94	PD		0	31AUG94	9/1/94	56		DEAD	6/3/95		CANCER
	MA	2/23/94	PR	5/24/94	175	12JUL95	7/13/95	505		ALIVE		12/28/95	
	MA	4/13/94	PD		0	07JUL94	7/8/94	86		DEAD	7/21/95		CANCER
	L2.5	7/20/94	PD		0	24OCT94	10/25/94	97		ALIVE		10/11/95	
	L0.5	10/1/94	PD		0	29NOV94	11/29/94	60		ALIVE		11/30/95	
	MA	3/8/94	PR	3/28/95	386	26JUN95	6/27/95	476		DEAD	8/8/95		
	L0.5	6/7/94	NE		0	06JUL94		30	7/7/94	ALIVE		12/28/95	
	MA	6/7/94	PD		0	25JUL94	7/26/94	49		DEAD	8/14/94		CANCER
	L0.5	6/24/94	CR	12/21/94	91					ALIVE		12/21/95	
	L2.5	6/24/94	PD		0	10NOV94	9/26/94			DEAD	8/27/95		CANCER
	L2.5	9/29/94	SD		0	27JUN95	6/28/95	272		ALIVE		12/27/95	
	L0.5	8/3/94	SD		0	20NOV95			11/20/95	ALIVE		11/20/95	
	L0.5	3/21/94	PD		0	19JUN94	6/20/94	91		ALIVE		11/30/95	
	L2.5	5/23/94	PD		0	31AUG94	8/25/94	95		DEAD	1/22/95		CANCER
	MA	5/30/94	NE		0	26FEB95		273	2/26/95	DEAD	3/18/95		NOT RELATED
	L0.5	6/15/94	SD		0	01SEP94		79	9/2/94	DEAD	1/24/95		NOT RELATED
	MA	7/11/94	PD		0	18SEP94	9/19/94	70		ALIVE		9/7/95	
	L0.5	8/4/94	NE		0					ALIVE		10/5/95	
	L2.5	9/13/94	NE		0	14OCT94		32	10/25/94	ALIVE		4/14/95	
	L0.5	6/30/94	NE		0	06MAY95		104	10/11/94	DEAD	7/7/95		CANCER
	MA	7/16/94	PD		0	20OCT94	10/21/94	97		ALIVE		7/12/95	
	L2.5	8/1/94	PD		0	01NOV94	11/2/94	93		ALIVE		11/14/95	
	MA	7/18/94	PD		0	26OCT94	10/27/94	101		ALIVE		11/10/95	
	L0.5	7/28/94	SD		0	07AUG95	8/8/95	376		ALIVE		11/22/95	
	L2.5	8/31/94	PD		0	22FEB95	2/23/95	176		ALIVE		12/5/95	
	L0.5	9/30/94	PD		0	22DEC94	12/23/94	84		DEAD	8/28/95		CANCER
	L2.5	4/5/93	NE		0	04JUN93		61	6/5/93	DEAD	6/5/93		CANCER
	L0.5	11/2/93	SD		0	06NOV95	7/31/95			ALIVE		11/6/95	
	MA	9/9/94	SD		0	06NOV95	3/10/95	274		ALIVE		12/28/95	
	MA	3/16/94	PD		0	20JUN94	6/15/94	92		DEAD	8/9/95		CANCER
	L0.5	5/25/94	PR	11/24/94	184					ALIVE		10/19/95	
	L0.5	1/6/94	SD	3/29/94	0	11DEC95	12/7/95			ALIVE		12/11/95	
	L2.5	8/1/94	PD		0	28AUG94	8/29/94	28		DEAD	9/18/94		CANCER
	MA	4/23/93	NE		0	26MAY93		34	5/27/93	DEAD	7/25/93		CANCER
	MA	5/25/93	NE		0	28JUN93		35	6/29/93	DEAD	9/3/95		CANCER
	L2.5	10/19/93	SD		0	27JAN94		101	1/27/94	DEAD	4/15/95		CANCER
	L0.5	10/28/93	SD		0	06MAY94	5/2/94	187		DEAD	8/17/95		
	L0.5	3/28/94	NE		0	30APR94		34	4/30/94	ALIVE		12/28/95	

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	L2.5	4/8/94	PR	7/4/94	190					ALIVE		11/13/95	
	MA	3/28/94	SD		0	24APR95	4/24/95	393		ALIVE		4/24/95	
	L2.5	4/11/94	PD		0	11JUL94	7/11/94	92		ALIVE		4/11/95	
	MA	3/23/94	SD		0	27SEP94	9/21/94	183		DEAD	6/28/95		
	MA	10/21/93	CR	1/13/94	85	27JUL94	7/27/94	280		ALIVE		12/28/95	
	L2.5	5/11/94	PD		0	13JUN94	6/13/94			DEAD	6/28/94		CANCER
	L0.5	7/6/94	PD		0	12OCT94	10/12/94	99		DEAD	1/12/95		CANCER
	MA	7/29/94	PD		0	22FEB95	11/22/94	117		DEAD	12/19/95		CANCER
	L0.5	10/4/94	PD		0	25OCT94		22	11/2/94	DEAD	11/2/94		CANCER
	L2.5	5/23/93	PD		0	10JUN93	6/11/93	17		DEAD	2/8/94		CANCER
	L0.5	9/7/93	SD		0	10OCT93	10/10/93			DEAD	10/14/93		CANCER
	MA	12/7/93	PD		0	03JAN94	1/4/94	28		DEAD	4/20/94		CANCER
	L0.5	1/21/94	PD		0	13APR94	4/15/94	83		ALIVE		9/8/95	
	L2.5	3/29/94	PD		0	26MAY94	6/7/94	59		DEAD	8/15/94		CANCER
	MA	5/3/94	PR	7/29/94	88	08DEC94	12/9/94	221		DEAD	4/16/95		CANCER
	L0.5	5/24/94	PD		0	12SEP94	8/16/94	85		DEAD	8/5/95		CANCER
	L2.5	7/19/94	PD		0	10OCT94	10/11/94	84		DEAD	11/26/94		CANCER
	L2.5	8/5/94	CR	10/28/94	85					ALIVE		10/6/95	
	MA	8/9/94	PD		0	05JAN95	11/1/94	85		ALIVE		10/17/95	
	L0.5	8/30/94	SD		0	10FEB95	2/10/95	165		ALIVE		12/8/95	
	MA	8/30/94	CR	8/30/94	88					ALIVE		10/27/95	
	L2.5	9/16/94	PR	12/13/94	89	21AUG95	8/22/95			ALIVE		11/7/95	
	L0.5	7/25/94	PD		0	01SEP94	9/1/94	39		DEAD	1/5/95		CANCER
	MA	8/2/94	SD	10/27/94	0	01JUN95	1/17/95			ALIVE		12/22/95	
	L2.5	9/28/94	PR	12/20/94	84	05NOV95	8/28/95			ALIVE		11/5/95	
	MA	9/30/94	SD		0	24FEB95		148	3/1/95	DEAD	3/1/95		CANCER
	L2.5	5/21/93	PD		0	01JUL93	7/1/93	42		DEAD	9/26/93		CANCER
	MA	6/21/93	PD		0	16SEP93	9/17/93	88		DEAD	10/28/94		CANCER
	L0.5	7/13/93	PD		0	27OCT93	10/11/93	91		DEAD	6/27/94		CANCER
	L0.5	8/12/93	PR	11/11/93	92	17JAN94		159	1/18/94	DEAD	10/28/94		CANCER
	MA	10/4/93	PD		0	02NOV93	11/2/93	30		DEAD	11/4/93		CANCER
	L2.5	11/22/93	PD		0	22DEC93	12/22/93	31		DEAD	10/15/94		CANCER
	L0.5	1/17/94	SD		0	03JUL94	7/12/94	168		DEAD	11/14/94		CANCER
	L2.5	2/11/94	SD		0					ALIVE		11/24/95	
	MA	4/19/94	PR	10/14/94	179					ALIVE		11/7/95	
	L0.5	5/3/94	PD		0	17MAY94	5/17/94	17		DEAD	10/5/94		CANCER
	L2.5	6/21/94	CR	9/20/94	92					ALIVE		9/26/95	
	MA	7/8/94	SD		0	05JAN95	1/6/95	182		ALIVE		12/14/95	
	L2.5	7/22/94	PD		0	20SEP94	9/20/94	61		ALIVE		12/14/95	
	L0.5	7/27/94	PD		0	20SEP94	8/23/94	28		ALIVE		12/14/95	
	MA	7/29/94	PD		0	22SEP94	9/23/94	56		DEAD	5/20/95		CANCER
	L2.5	8/4/94	PR	1/31/95	181			447		ALIVE		10/24/95	
	MA	8/29/94	PD		0	23SEP94	9/23/94	26		DEAD	2/4/95		CANCER
	L0.5	9/21/94	PD		0	22NOV94	11/18/94	59		ALIVE		12/14/95	

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	L0.5	8/18/94	SD		0	10MAY95	2/9/95			ALIVE		11/9/95	
	L0.5	6/23/94	PD		0	13SEP94	9/14/94	83		DEAD	12/13/94		CANCER
	L0.5	8/10/93	PD		0	01NOV93	11/2/93	84		ALIVE		10/24/95	
	L2.5	9/15/93	SD		0	23MAY94	3/1/94	168		ALIVE		9/4/95	
	L2.5	12/15/93	SD		0	21AUG94	8/22/94	250		ALIVE		11/27/95	
	MA	2/26/94	PD		0	15MAY94	5/16/94	79		DEAD	2/4/95		CANCER
	MA	5/6/94	PD		0	18OCT94	7/27/94	83		ALIVE		12/11/95	
	L0.5	5/6/94	PR	8/1/94	88	08NOV95	11/9/95			ALIVE		11/9/95	
	L0.5	5/10/94	NE		0	01JUL94		86	8/3/94	ALIVE		11/21/95	
	L0.5	6/7/94	PD		0	13FEB95	8/29/94	84		ALIVE		12/4/95	
	MA	6/17/94	SD		0	22FEB95	12/1/94	168		ALIVE		10/31/95	
	L2.5	6/27/94	PD		0	13SEP94	9/14/94	79		ALIVE		10/2/95	
	L2.5	7/19/94	PD		0	10OCT94	10/11/94	84		DEAD	6/18/95		CANCER
	MA	7/26/94	PD		0	04JAN95	1/5/95	164		DEAD	4/7/95		CANCER
	MA	7/27/94	PD		0	21NOV94	12/13/94	140		ALIVE		12/11/95	
	L0.5	8/29/94	SD		0	15FEB95	2/16/95	171		DEAD	11/5/95		CANCER
	L0.5	9/14/94	SD		0	03JUL95			7/4/95	DEAD	7/4/95		NOT RELATED
	L0.5	7/15/93	PD		0	12APR94	10/6/93	84		ALIVE		4/29/94	
	L0.5	8/11/93	PD		0	28SEP93	9/29/93	49		ALIVE		5/5/94	
	MA	8/17/93	PD		0	09NOV93	11/10/93	85		DEAD	9/17/95		CANCER
	L2.5	10/30/93	PR	4/15/93	168					ALIVE		9/27/95	
	MA	12/20/93	NE		0	06FEB94		49	2/6/94	DEAD	5/5/94		CANCER
	L2.5	1/20/94	SD		0	12JUL94	4/13/94	84		DEAD	12/14/94		CANCER
	MA	2/1/94	PD		0	25APR94	4/26/94	84		DEAD	7/5/95		CANCER
	L2.5	3/31/94	PD		0	15JUN94	6/22/94	77		DEAD	4/29/95		CANCER
	L0.5	4/21/94	PD		0	19JUN94	6/20/94	60		DEAD	4/10/95		CANCER
	MA	4/21/94	PD		0	16JUN94	6/14/94	55		DEAD	11/6/94		CANCER
	L0.5	4/28/94	SD		0	30JUN94		64	7/1/94	DEAD	10/20/95		CANCER
	L2.5	5/26/94	PR	2/15/95	266					ALIVE		10/4/95	
	L0.5	6/4/93	SD	8/24/93	0	15SEP93			9/16/93	DEAD	4/16/95		CANCER
	MA	6/18/93	PD		0	06SEP93	9/7/93	81		DEAD	9/25/95		CANCER
	L0.5	6/24/93	SD		0	24MAY95	12/14/93	174		ALIVE		5/24/95	
	L2.5	8/27/93	PD		0	16NOV93	11/16/93	82		DEAD	5/6/95		CANCER
	L2.5	10/12/93	SD		0	13JUN95	7/5/94	267		ALIVE		12/18/95	
	MA	2/22/94	PD		0	31MAR94	3/31/94	38		DEAD	6/11/94		
	L2.5	3/8/94	PD		0	06JUN94	6/7/94	91		DEAD	3/20/95		CANCER
	MA	3/15/94	SD		0	09MAY94		56	5/10/94	DEAD	9/18/95		CANCER
	L0.5	4/19/94	SD		0	03MAY94		15	5/3/94	DEAD	5/25/94		CANCER
	MA	5/31/94	PD		0	29AUG94	8/30/94	91		DEAD	8/30/95		CANCER
	L2.5	8/17/94	PD		0	13FEB95	2/14/95	181		ALIVE		11/15/95	
	L2.5	9/22/93	PD		0	04JAN94	12/15/93	85		DEAD	8/12/94		CANCER
	L2.5	10/27/93	PR	4/12/95	0	20SEP95	9/20/95			ALIVE		12/11/95	
	L0.5	6/27/94	PD		0	26JUL94	7/27/94	30		DEAD	10/6/94		CANCER
	L0.5	8/9/94	SD		0	04JUL95			7/4/95	ALIVE		11/14/95	

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	MA	8/23/94	PR	2/14/95	176					ALIVE		11/14/95	
	MA	9/5/94	SD		0	20AUG95	8/21/95	350		ALIVE		12/8/95	
	_2.5	10/19/93	PD		0	17JAN94	1/18/94	91		ALIVE		12/15/95	
	_0.5	11/3/93	SD		0	21JUL94	5/4/94	183		DEAD	4/16/95		CANCER
	MA	1/26/94	PD		0	09NOV94	4/20/94	85		ALIVE		11/30/95	
	MA	3/1/94	PD		0	24MAY94	5/24/94	85		DEAD	10/3/94		CANCER
	_0.5	3/10/94	PR	9/22/94	0	16AUG95	8/17/95			ALIVE		11/1/95	
	_2.5	4/28/94	NE		0	24MAY94		27	5/25/94	DEAD	6/26/95		CANCER
	MA	8/18/93	PD		0	09NOV93	11/10/93	84		DEAD	11/6/94		CANCER
	_2.5	9/1/93	SD		0	15FEB94		168	2/16/94	DEAD	2/24/95		CANCER
	_0.5	10/20/93	CR	1/12/95	85	11JAN95	11/9/94			ALIVE		12/7/95	
	MA	12/10/93	PD		0	03FEB94	2/3/94	56		DEAD	3/5/94		CANCER
	_0.5	12/15/93	PR	3/16/94	92	28MAR95	3/29/95			ALIVE		7/13/95	
	_2.5	1/5/94	PR	4/6/94	92	23AUG94	8/24/94	231		ALIVE		12/13/95	
	_2.5	4/20/94	PR	10/19/94	183					ALIVE		11/8/95	
	L0.5	1/19/94	PD		0	14JUN94	4/13/94	85		DEAD	11/7/94		CANCER
	MA	1/26/94	PR	4/20/94	85	4/12/95		441		ALIVE		11/30/95	
	_2.5	4/29/94	PR	7/20/94	83	11APR95	4/12/95	348		DEAD	5/27/95		CANCER
	_0.5	8/7/94	SD		0	14FEB95	2/15/95	92		ALIVE		11/16/95	
	MA	10/10/94	PR	1/4/95	87					ALIVE		12/6/95	
	MA	8/3/93	PD		0	24OCT93	10/25/93	83		DEAD	9/17/95		CANCER
	L2.5	12/17/93	PD		0	29APR94	3/16/94	90		DEAD	4/29/94		CANCER
	L0.5	12/23/93	SD		0	15MAR94		83	3/16/94	DEAD	6/4/94		CANCER
	L0.5	4/26/94	SD		0	05JUN95	10/31/94	189		ALIVE		10/30/95	
	L2.5	7/27/93	CR	11/2/94	99					ALIVE		11/6/95	
	L0.5	7/27/93	SD	10/19/93	0	17OCT94	1/18/94	176		ALIVE		12/20/95	
	L0.5	8/10/93	NE		0	07SEP93		29	9/7/93	DEAD	7/8/95		CANCER
	L2.5	10/14/93	PD		0	16DEC93	12/17/93	64		DEAD	2/19/94		CANCER
	MA	11/2/93	SD		0	24APR94	4/25/94	174		DEAD	5/16/94		CANCER
	MA	11/30/93	SD		0	04APR94		126	4/4/94	DEAD	4/4/94		NOT RELATED
	L0.5	12/3/93	SD		0	15JUN94	5/23/94	172		DEAD	8/28/95		CANCER
	MA	1/25/94	SD		0	09APR95	4/10/95	440		ALIVE		12/20/95	
	L2.5	2/4/94	PD		0	08MAY94	5/9/94	94		DEAD	12/19/94		CANCER
	L0.5	2/25/94	SD		0	15AUG94	8/15/94	172		ALIVE		12/20/95	
	MA	3/9/94	PD		0	04SEP94	6/6/94	90		ALIVE		12/20/95	
	L2.5	3/17/94	PD		0	26JUN94	6/27/94	102		DEAD	6/19/95		CANCER
	MA	10/22/93	CR	4/14/94	175					ALIVE		10/19/95	
	L2.5	11/5/93	CR	1/27/94	84					ALIVE		10/26/95	
	L2.5	3/11/94	SD		0	28SEP94	9/1/94	202		ALIVE		10/26/95	
	MA	3/30/94	SD		0	11JUN95	3/13/95	349		DEAD	7/19/95		CANCER
	L0.5	5/12/94	SD		0	29JUN94			6/29/94	ALIVE		12/18/95	
	L0.5	3/14/94	SD		0	28JUL94		137	7/28/94	DEAD	12/30/94		CANCER
	L2.5	6/10/94	PR	9/6/94	89					ALIVE		12/8/95	
	MA	6/13/94	PD		0	15JUL94	8/19/94	33		DEAD	1/14/95		CANCER

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	MA	6/14/94	SD	9/6/94	0	28NOV94	11/29/94	168		ALIVE		11/17/95	
	L0.5	6/20/94	PR	9/12/94	85					ALIVE		12/4/95	
	L2.5	4/22/94	PD		0	07SEP94	7/25/94	95		DEAD	3/19/95		CANCER
	L0.5	4/27/94	PD		0	26JUN94	6/27/94	61		DEAD	2/2/95		CANCER
	MA	6/22/94	SD		0	13MAR95	3/13/95	265		DEAD	3/30/95		CANCER
	MA	6/29/94	PD		0	18JAN95	1/19/95	204		ALIVE		10/23/95	
	L0.5	7/13/94	PD		0	07AUG94	8/8/94	26		ALIVE		12/20/95	
	L2.5	7/25/94	PR	4/25/95	274					ALIVE		10/23/95	
	MA	6/3/94	SD		0	20MAR9[illegible]	11/30/94	181		DEAD	5/29/95		CANCER
	L2.5	6/29/94	PD		0	14SEP94	9/14/94	78		DEAD	10/5/94		CANCER
	L2.5	5/7/94	PD		0	13JUL94	7/13/94	68		DEAD	8/12/94		CANCER
	L0.5	5/18/94	PD		0	23AUG94	8/24/94	98		DEAD	8/21/95		CANCER
	MA	7/4/94	PR	9/21/94	80	21MAR95	3/22/95	261		DEAD		12/27/95	
	MA	7/27/94	SD		0	19SEP95	4/27/95	275		ALIVE		9/19/95	
	L0.5	8/9/94	PD		0	03JAN95	11/1/94	85		DEAD	7/18/95		CANCER
	L2.5	8/23/94	SD		0	24JAN95	1/24/95	155		ALIVE		11/2/95	
	MA	5/3/94	SD		0	23FEB95	2/23/95	297		ALIVE		11/3/95	
	L2.5	6/22/94	SD		0	09NOV94	9/16/94	87	11/9/94	DEAD	11/30/95		CANCER
	L0.5	6/23/94	PR	3/24/95	275	21SEP95		456	9/22/95	ALIVE		12/8/95	
	L2.5	6/30/94	SD		0					ALIVE		9/27/95	
	MA	7/7/94	PD		0	23MAY95	10/5/94	91		ALIVE		12/4/95	
	L0.5	7/14/94	PR	1/4/95	175					ALIVE		10/4/95	
	MA	6/30/94	PD		0	28JUL94	7/29/94	29		DEAD	8/3/94		NOT RELATED
	L2.5	9/22/94	PD		0	21DEC94	12/22/94	91		ALIVE		12/21/95	
	L0.5	9/21/94	PR	12/13/94	84					ALIVE		11/7/95	
	MA	10/10/94	PD		0	20JAN95	1/5/95	88		ALIVE		12/7/95	
	L0.5	9/27/94	SD		0					ALIVE		12/19/95	
	L2.5	8/25/94	SD		0	26OCT95	12/7/94	105		DEAD	11/13/95		CANCER
	L0.5	9/2/94	NE		0	08NOV94		68	11/9/94	DEAD	11/18/94		CANCER
	MA	10/5/94	SD		0	03OCT95	4/5/95	183		ALIVE		10/3/95	
	L0.5	8/11/94	PR	11/2/94	84					ALIVE		11/15/95	
	L2.5	9/15/94	PR	12/7/94	84					ALIVE		11/29/95	
	MA	9/21/94	PD		0	16NOV94	11/16/94	57		ALIVE		9/8/95	
	MA	6/4/93	PD		0	30AUG93	8/31/94	88		DEAD	10/2/95		CANCER
	L0.5	6/8/93	PD		0	02SEP93	9/3/93	87		DEAD	12/4/93		CANCER
	L2.5	7/9/93	NE		0	30MAR95	3/30/95			ALIVE		11/14/95	
	L2.5	7/13/93	PD		0	10OCT93	10/11/93	90		DEAD	2/1/95		CANCER
	L0.5	8/5/93	PD		0	17OCT93	10/28/93	74		DEAD	11/15/93		CANCER
	MA	8/12/93	PD		0	29NOV94	11/11/93	92		ALIVE		12/21/95	
	L2.5	8/19/93	SD		0	07JUN94	3/2/94	196		DEAD	10/16/95		
	MA	10/4/93	PR	12/27/93	85	25AUG94	8/25/94	326		DEAD	9/10/95		CANCER
	L2.5	10/7/93	PD		0	10JAN94	1/17/94	96		DEAD	2/24/94		UNKNOWN
	L0.5	10/12/93	SD		0	05JUL94	7/6/94	267		ALIVE		11/14/95	
	L0.5	10/29/93	PD		0	26JAN94	1/26/94	90		DEAD	7/1/94		CANCER

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	MA	11/8/93	SD		0	09NOV94			11/10/94	ALIVE		10/25/95	
	L2.5	11/11/93	SD		0	04MAY94	5/5/94	175		ALIVE		12/21/95	
	L0.5	11/17/93	SD		0	15AUG95	12/19/94	463		ALIVE		8/16/95	
	MA	1/6/94	PR	1/25/95	385	10OCT95	7/5/95			ALIVE		12/21/95	
	L2.5	2/24/94	PR	5/27/94	176	24MAR95	2/21/95	363		ALIVE		11/1/95	
	MA	3/12/94	SD		0	07DEC94	12/8/94	271		ALIVE		11/14/95	
	L0.5	3/19/94	PD		0	22SEP94	6/24/94	98		ALIVE		11/8/95	
	L2.5	7/20/93	PR	10/19/93	92	16AUG94	8/17/94	393		DEAD	4/15/95		CANCER
	L2.5	10/14/93	PD		0	10JAN94	1/11/94	89		ALIVE		12/27/95	
	MA	12/15/93	NE		0	21DEC93		7	12/21/93	ALIVE		12/27/95	
	L0.5	12/20/93	SD		0	30MAR94	4/12/94	101		DEAD	6/30/94		NOT RELATED
	MA	9/29/94	PR	1/3/95	97					ALIVE		12/21/95	
	L2.5	7/4/94	PR	12/29/92	179	27JUN95	7/25/95	359		DEAD	12/25/95		CANCER
	L0.5	7/6/94	NE		0	08SEP94		65	9/8/94	DEAD	12/27/94		NOT RELATED
	L2.5	3/21/94	PR	9/23/94	187					ALIVE		12/20/95	
	L0.5	3/26/94	PD		0	22SEP94	9/23/94	181		ALIVE		11/24/95	
	MA	5/10/94	PD		0	22JUL94	7/22/94	74		DEAD	2/7/95		CANCER
	L2.5	5/25/94	SD		0					ALIVE		11/24/95	
	L0.5	8/5/94	PR	1/23/95	172	30JUL95	7/31/95			DEAD	9/29/95		CANCER
	MA	8/5/94	PR	10/26/93	83	18APR95	4/18/95	257		DEAD	5/30/95		CANCER
	L0.5	9/20/94	PD		0	02DEC94	12/2/94	74		DEAD	12/29/94		CANCER
	MA	10/1/94	PD		0	22DEC94	12/23/94	83		ALIVE		11/8/95	
	MA	7/13/94	SD		0					ALIVE		10/3/95	
	L2.5	8/3/94	SD		0					ALIVE		11/1/95	
	L0.5	9/1/94	PD		0	29NOV94	11/25/94	86		DEAD	3/28/95		CANCER
	MA	9/6/94	PD		0	05DEC94	11/29/94	85		DEAD	9/27/95		cancer
	L0.5	10/17/94	NE		0	05DEC94		50	12/16/94	DEAD	12/31/94		CANCER
	L2.5	7/7/93	PD		0	11NOV93	9/29/93	85		DEAD	7/17/94		CANCER
	L0.5	9/10/93	SD		0	07MAR94	3/8/94	179		DEAD	3/8/95		CANCER
	L0.5	9/29/93	PD		0	12JAN94	12/21/93	84		ALIVE		12/22/95	
	L2.5	11/26/93	PD		0	24JAN94	1/18/94	54	1/24/94	DEAD	3/26/94		CANCER
	MA	12/20/93	PD		0	17FEB94	2/18/94	60		DEAD	2/21/94		CANCER
	MA	4/1/94	PD		0	04JUL94	7/5/94	95		DEAD	2/25/95		CANCER
	L0.5	10/13/94	PD		0	15FEB95	1/10/95	90		ALIVE		12/18/95	
	L0.5	1/11/94	PD		0	05JUN95	4/5/94	85		ALIVE		9/6/95	
	L2.5	2/4/94	CR	5/5/94	91	19DEC95				ALIVE		12/19/95	
	MA	10/11/94	PD		0	12FEB95	1/9/95	91		ALIVE		11/9/95	
	L0.5	9/24/93	SD		0	16DEC93	12/17/93	84		DEAD	3/21/94		CANCER
	L2.5	6/16/94	SD		0	05MAR95	12/14/94	182		ALIVE		11/30/95	
	L2.5	7/30/94	PD		0	26OCT94	10/27/94	89		ALIVE		10/12/95	
	L0.5	10/13/94	PD		0	07DEC94	12/8/94	56		DEAD	8/26/95		
	L2.5	6/4/93	SD		0	14JUN95	3/2/94	727		ALIVE		11/29/95	
	L2.5	6/22/93	NE		0	04JAN94	9/24/93	95		DEAD	11/16/94		CANCER
	MA	11/12/93	PR	11/9/94	363	14AUG95	8/9/95			ALIVE		11/29/95	

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	L0.5	6/29/94	SD		0	14JUN95	6/15/95	351		ALIVE		10/6/95	
	MA	8/26/94	SD		0					AL;IVE		11/17/95	
	L0.5	5/12/94	SD							ALIVE		11/9/95	
	L2.5	2/9/94	NE		0			658	8/25/94	ALIVE		11/28/95	
	L0.5	2/11/94	NE		0	19MAY94		98	5/19/94	DEAD	3/8/95		CANCER
	L2.5	3/12/94	PD		0	05JUN94	6/6/94	86		DEAD	9/25/95		CANCER
	MA	4/13/94	PD		0	10JUL94	9/1/94	89		ALIVE		11/15/95	
	L0.5	4/29/94	NE		0	05MAY94		7	5/9/94	ALIVE		3/6/95	
	L0.5	9/22/93	PD		0	19OCT93	10/15/93	24		DEAD	8/29/94		CANCER
	L0.5	8/30/93	SD		0					ALIVE		11/27/95	
	L2.5	9/1/93	PD		0	02DEC93	12/3/93	93		DEAD	2/2/94		CANCER
	MA	9/8/93	SD		0	12JUN94	6/13/94			ALIVE		12/28/95	
	L0.5	9/22/93	SD		0	18DEC94	6/20/94	272		ALIVE		10/18/95	
	L2.5	9/23/93	NE		0	02DEC93		71	12/2/93	DEAD	10/18/94		CANCER
	MA	9/27/93	NE		0	31OCT93		35	11/1/93	DEAD	11/12/93		CANCER
	MA	10/6/93	PD		0	07APR94	4/8/94	184		ALIVE		10/18/95	
	L2.5	9/29/93	NE		0	06NOV95		769		ALIVE		11/6/95	
	L0.5	10/8/93	SD		0	30MAR95	3/31/95	539		DEAD	9/21/95		NOT RELATED
	L0.5	10/8/93	PR	4/25/94	200	11DEC94		430	11/9/94	DEAD	6/3/95		CANCER
	L2.5	12/10/93	SD		0	01MAY95		508		DEAD	5/8/95		CANCER
	MA	12/13/93	CR	3/14/94	92	21MAR95	12/16/94	369		ALIVE		11/22/95	
	L0.5	1/3/94	PD		0	04FEB94	2/4/94	33		DEAD	6/2/94		CANCER
	L2.5	1/19/94	NE		0	31JUL94			9/12/94	ALIVE		10/9/95	
	MA	1/26/94	PD		0	31JUL94	4/11/94			DEAD	11/17/94		CANCER
	MA	6/8/94	PR	9/12/94	97					ALIVE		12/11/95	
	L2.5	7/1/94	PR	12/21/94	174	20JUN95	6/21/95	355		DEAD	11/7/95		CANCER
	L0.5	7/18/94	PR	1/11/95	178					ALIVE		10/18/95	
	MA	8/3/94	SD		0	04SEP94		33	9/5/94	DEAD	11/27/94		CANCER
	L2.5	8/12/94	PD		0	09OCT94	10/10/94	59		ALIVE		10/10/94	
	L0.5	8/8/94	NE		0	21AUG94	9/7/94	14		DEAD	9/7/94		CANCER
	L2.5	9/14/94	PD		0	22NOV94	11/23/94	70		DEAD	2/7/95		CANCER
	L0.5	9/21/94	NE		0	19OCT94		29	10/19/94	DEAD	12/14/94		CANCER
	MA	9/23/94	NE		0	20NOV94		59	11/21/94	DEAD	11/21/94		SUDDEN DEATH
	MA	11/4/93	PD		0	23FEB94	2/24/94	112		DEAD	8/25/95		CANCER
	MA	2/3/94	PD		0	08JUN94	6/9/94	126		DEAD	2/7/95		CANCER
	L0.5	4/7/94	SD		0	05APR95	9/29/94	176		ALIVE		12/28/95	
	L0.5	9/3/93	SD		0	17FEB94	2/18/94	168		ALIVE		11/14/95	
	MA	9/30/93	SD		0	31JAN94		63	2/1/94	ALIVE		11/14/95	
	MA	3/8/94	PD		0	07APR94	4/8/94	31		DEAD	12/6/94		CANCER
	L2.5	4/19/94	PD		0	11JUL94	7/12/94	84		DEAD	7/10/95		CANCER
	L0.5	7/12/94	PD		0	24AUG94	8/24/94	44		DEAD	11/4/94		CANCER
	MA	9/1/93	SD		0	25NOV93		86	11/25/93	DEAD	12/7/94		CANCER
	L2.5	9/13/93	PD		0	07DEC93	12/8/93	86		DEAD	6/17/95		CANCER
	L0.5	9/23/93	PD		0	16NOV93	11/16/93	55		DEAD	12/10/93		CANCER

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	MA	9/27/93	SD		0	09MAY94	3/21/94	176		DEAD	1/18/95		CANCER
	L2.5	10/7/93	SD		0	22SEP94	3/24/94	169		ALIVE		12/1/95	
	L0.5	11/26/93	PD		0	20JAN94	1/20/94	56		DEAD	4/16/94		CANCER
	MA	12/22/93	PR	6/7/94	168	22JUN95	6/26/95			ALIVE		10/23/95	
	L0.5	4/23/94	SD		0	14JUL94		83	7/14/94	ALIVE		10/23/95	
	L2.5	5/16/94	PD		0	05AUG94	8/5/94	82		ALIVE		10/11/95	
	MA	6/29/94	PD		0	21SEP94	9/22/94	85		ALIVE		12/28/95	
	L0.5	9/28/94	SD		0	08MAR95	3/9/95	162		ALIVE		12/21/95	
	L0.5	6/1/94	SD		0	02MAR95	11/29/94			ALIVE		12/19/95	
	MA	7/6/94	PD		0	29SEP94	9/29/94	86		ALIVE		11/23/95	
	L2.5	10/7/94	PD		0	24FEB95	1/23/95	109		ALIVE		12/5/95	
	L0.5	2/18/94	PD		0	03AUG95	5/19/94	378		ALIVE		11/6/95	
	L0.5	1/5/94	SD		0	22JUN94	6/23/94	169		DEAD	8/17/94		CANCER
	MA	5/17/94	PD		0	07JUL94	7/7/94	52		DEAD	11/10/94		CANCER
	MA	1/20/94	SD		0	22MAR95	3/29/95	427		ALIVE		12/13/95	
	L0.5	2/24/94	SD			06APR95				ALIVE		12/14/95	
	L2.5	3/22/94	NE		0	05SEP95				ALIVE		12/6/95	
	L0.5	4/4/94	PD		0	08MAR95	6/30/94	88		ALIVE		11/23/95	
	MA	4/21/94	SD		250	19AUG95			8/19/95	ALIVE		12/28/95	
	L2.5	5/5/94	PD		0	03AUG94	8/4/94	91		ALIVE		11/16/95	
	L0.5	3/26/94	PD		0	28JUN94	6/22/94	89		DEAD	7/15/94		CANCER
	L2.5	4/1/94	PR	9/13/94	156	13MAR95	9/12/95			ALIVE		12/5/95	
	MA	7/25/94	PD		0	18OCT94	10/19/94	86		DEAD	5/3/95		CANCER
	MA	1/26/94	PD		0	08JUL94	4/26/94	91		DEAD	5/14/95		CANCER
	L2.5	4/14/94	SD		0	20MAY95				ALIVE		11/22/95	
	L2.5	7/5/94	NE		0	03OCT94		91	10/3/94	DEAD	2/10/95		CANCER
	L2.5	7/1/94	SD		0	04APR95	3/27/95	270		ALIVE		11/27/95	
	L0.5	6/3/94	NE		0	29NOV94		168	11/17/94	ALIVE		11/29/95	
	L2.5	9/2/94	PD		0	13OCT94	10/27/94	42		ALIVE		10/3/95	
	L0.5	10/7/94	NE		0	06APR95				ALIVE		10/5/95	
	L0.5	5/26/94	PD		0	01AUG94	7/28/94	64		ALIVE		11/30/95	
	MA	6/15/94	SD		0	14DEC94	12/15/94	183		ALIVE		12/13/95	
	L2.5	7/14/94	PD		0	01NOV94	9/29/94	78		ALIVE		12/7/95	
	MA	5/31/94	CR	11/16/94	170	11MAY95				ALIVE		11/30/95	
	L2.5	8/31/94	PD		0	30NOV94	12/1/94	92		DEAD	12/22/95		CANCER
	L0.5	8/24/94	PD		0	19SEP94	10/18/94	27		DEAD	10/18/94		CANCER
	MA	9/8/94	SD	8/24/95		18MAY95				ALIVE		11/16/95	
	L2.5	9/22/94	PD		0	19DEC94	12/19/94	89		ALIVE		12/28/95	
	L0.5	10/6/94	PD		0	10NOV94	11/10/94	36		DEAD	1/22/95		?CAUSE
	MA	3/7/94	SD		0	11AUG95	12/21/94			DEAD	8/30/95		CANCER
	L0.5	3/7/94	SD		0	08JUN95	5/23/95	443		DEAD	9/20/95		CANCER
	L2.5	3/9/94	PD		0	25MAY94	5/25/94	78		DEAD	7/8/94		CANCER
	L0.5	6/9/94	PD		0	27JUL94	7/27/94	49		ALIVE		12/22/95	
	L2.5	2/5/94	SD		0	26APR94		81	4/27/94	ALIVE		12/22/95	

PATNO	TDRSDO	ONSTUDY	RESPONS	RESP DAT	TTR	PDLSTDT	PROG DATE	TTT	TF DATE	STATUS	DEATH DATE	CENSOR D	PDCAUS
	MA	6/11/94	PR	9/15/94	78	25APR95		319	4/25/95	ALIVE		12/22/95	
	L0.5	12/28/93	PD		0	30MAR94	4/30/94	93		ALIVE		10/3/95	
	L2.5	4/8/94	PD		0	19SEP94	7/5/94	89		DEAD	3/9/95		CANCER
	MA	4/8/94	NE		0	11MAY94		34		DEAD	5/11/94		NOT RELATED
	L0.5	4/19/94	SD		0	05DEC94	10/11/94	176		DEAD	1/1/95		CANCER
	MA	4/27/94	NE		0	28JUL94		93	7/28/94	DEAD	10/31/94		CANCER
	L2.5	5/31/94	PD		0	06MAR95	11/29/94	280		ALIVE		12/19/95	
	MA	9/2/94	PD		0	27OCT94	10/27/94	56		DEAD	1/10/95		CANCER
	L2.5	5/31/94	SD		0	06FEB95	12/12/94	196		DEAD	8/15/95		
	MA	10/5/94	SD		0	02APR95	4/3/95	180		ALIVE		12/22/95	
	L0.5	3/19/94	PD		0	13SEP94	6/8/94	82		DEAD	4/4/95		
	L2.5	7/14/94	PR	1/19/95	190					ALIVE		11/30/95	
	L0.5	4/27/94	PD		0	08JUL94	7/29/94	73		DEAD	7/9/95		
	MA	5/26/94	PD		0	29NOV94	9/9/94	107		ALIVE		11/1/95	
	L2.5	6/2/94	PD		0	19SEP94	8/30/94	90		DEAD	4/9/95		CANCER
	MA	6/28/94	NE		0	26JUL94		29	7/26/94	DEAD	3/1/95		CANCER
	L2.5	7/26/94	NE		0					ALIVE		10/27/95	
	L0.5	7/1/94	NE		0	31JUL94		31	8/26/94	DEAD	5/1/95		CANCER
	L0.5	6/30/94	NE		0	29JUL94		30	7/29/94	DEAD	3/17/95		CANCER
	MA	7/11/94	PR	10/11/94	93	05JUL95			7/5/95	ALIVE		11/1/95	
	MA	8/30/94	PD		0	26JAN95	11/29/94	92		DEAD	9/3/95		
	L0.5	9/2/94	SD		0	04DEC95	6/2/95			ALIVE		12/4/95	
	L2.5	9/13/94	PD		0	21DEC94	12/6/94	85		DEAD	9/6/95		CANCER
	L0.5	9/27/94	PD		0	31OCT94	11/1/94	35		DEAD	2/3/95		CANCER