資料 2-1

S0106 Phase III

Coordinating Group: SWOG

A Phase III Study of the Addition of Gemtuzumab Ozogamicin (Mylotarg®) Induction Therapy Versus Standard Induction with Daunomycin and Cytosine Arabinoside Followed by Consolidation and Subsequent Randomization to Post-Consolidation Therapy with Gemtuzumab Ozogamicin (Mylotarg®) or No Additional Therapy for Patients under Age 61 with Previously Untreated de novo Acute Myeloid Leukemia (AML)

Participants:
SWOG, CTSU (endorsed by NCIC CTG and the Leukemia Group of Middle Sweden)

Study Coordinators:
S Petersdorf, M Slovak, C Willman

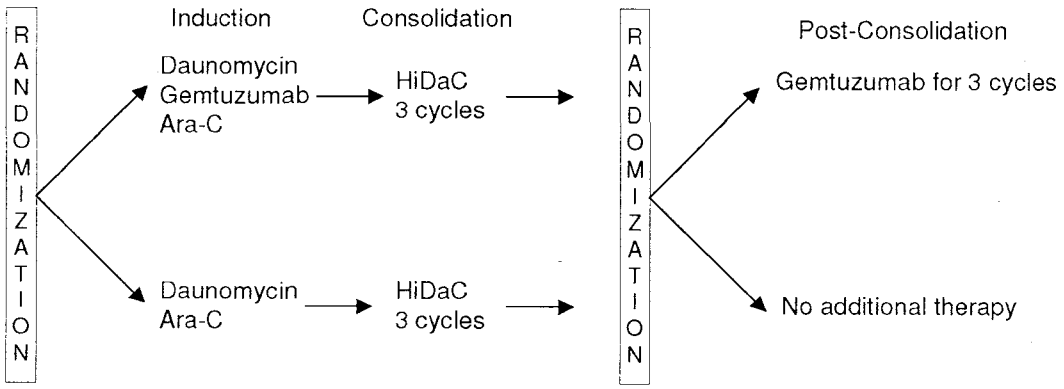
Statisticians:
K Kopecky, H Gundacker

Data Coordinators:
T Maher, C White

Date Activated:
5/15/2004

Date Closed:
8/20/2009

Schema



Objectives

To compare disease-free survival (DFS) of patients under age 61 with previously untreated, de novo, non-M3, AML who receive gemtuzumab ozogamicin as post-consolidation therapy versus patients who receive no post-consolidation therapy.

To compare the complete remission (CR) rate achieved by the addition of gemtuzumab ozogamicin to standard induction chemotherapy to that achieved with standard induction chemotherapy in patients under the age of 61 with previously untreated, de novo, non-M3 AML. The durability of complete responses will also be measured.

To estimate the frequency and severity of toxicities of the addition of gemtuzumab ozogamicin to induction therapy and post-consolidation therapy.

To evaluate the prognostic significance of CD33 expression on the response rate of patients who receive gemtuzumab ozogamicin.

To evaluate the prognostic significance of FLT3 mutations prior to therapy, and of minimal residual disease in remission specimens collected be-

fore and after consolidation therapy and after post-consolidation therapy with gemtuzumab ozogamicin.

To evaluate the prognostic significance of the flow cytometric detection of minimal residual disease in specimens collected before and after consolidation therapy and after post-consolidation therapy with gemtuzumab ozogamicin

Patient Population

Patients must have a morphologically confirmed diagnosis of acute myeloid leukemia (AML) with FAB classification other than M3, based on bone marrow aspiration and biopsy performed within 14 days prior to registration. Patients with M3 AML or blastic transformation of chronic myelogenous leukemia are not eligible. Patients with a preexisting hematologic disorder evolving to AML such as myelodysplasia or secondary leukemia are not eligible.

Patients must not have received systemic chemotherapy or more than one dose of intrathecal chemotherapy for acute leukemia. Administration of hydroxyurea to control high cell counts prior to registration is permitted.

Patients must have reached their 18th birthday but not reached their 61st birthday and must have a Zubrod performance status of 0, 1, 2, or 3. Patients must have normal hepatic and left ventricular function. Patients with unstable cardiac arrhythmias or unstable angina are not eligible.

Stratification/Descriptive Factors

At first (induction) randomization, patients will be stratified by age at enrollment: less than 35 years vs 35 years or older.

At the second (post-consolidation) randomization, patients will be stratified by (1) gemtuzumab ozogamicin therapy in step 1: Yes vs. No, and (2) pre-induction cytogenetic risk group: favorable vs intermediate vs unfavorable vs indeterminate.

Accrual Goals

The accrual goal for this study is to randomize 342 eligible patients (171 per arm) to the second (post-consolidation) randomization. It is estimated that approximately 50% of the patients enrolled will proceed to the second randomization. Therefore, approximately 684 patients will be enrolled and randomized to the first (induction) randomization.

Three interim analyses will be conducted during the course of the study; they will be done when approximately 25%, 50% and 75% of the anticipated relapse events have occurred.

Summary Statement

The study was closed on August 20, 2009 with a total of 637 patients accrued. Currently 33 patients are ineligible and are excluded from the analysis: 17 with preexisting hematologic disorders or secondary leukemia, ten without documented AML, five with M3 AML, and one who was older than 60 at randomization. Three other patients who withdrew consent after registration and received no protocol therapy are excluded from this analysis.

Induction Therapy:

Thirteen major protocol deviations were reported. Three patients received no protocol treatment for various reasons. Three patients assigned to the gemtuzumab arm did not receive gemtuzumab due to refusal, high LFTs, and lung hemorrhage. Two patients did not receive the second induction course for residual disease, two received a higher dose of Ara-C than prescribed in the protocol, one received gemtuzumab in error, one was given a second induction cycle after achieving CR, and one did not receive daunomycin during the first induction cycle.

Eight patients on the gemtuzumab arm were taken off protocol treatment due to toxicity: three due to VOD and other liver toxicity, two due to renal failure, and one each due to skin/neurologic toxicities, lung hemorrhage, and infusion reaction to gemtuzumab. No patients were taken off standard therapy due to toxicity. Eleven patients on the gemtuzumab arm and 23 patients on the standard treatment arm came off protocol treatment early for various other reasons primarily to pursue therapy off protocol.

The three patients who received no protocol treatment are excluded from the analysis of induction toxicities, along with four treated patients whose toxicities were not assessed. Of 283 patients on the gemtuzumab arm who have been evaluated for induction toxicities, sixteen (5.7%) suffered fatal toxicities: five due to hemorrhage, five due to infection, two due to ARDS, one due to liver failure, one due to ARDS with dyspnea, one due to hemorrhage, infection, ARDS and acidosis, and one due to multi-organ failure. Various Grade 4 non-hematologic toxicities have been reported for 45 additional patients, including 26 with infection and one with VOD.

Of 281 patients on the standard arm who have been evaluated for induction toxicities, four (1.4%) suffered fatal toxicities: two due to infection and one each due to hemorrhage and gastrointestinal colitis. Grade 4 non-hematologic toxicities have been reported for 30 patients, including 15 with infection.

The fatal induction toxicity rate is significantly higher in the gemtuzumab arm compared to the standard arm (5.7% vs 1.4%, two-sided p = 0.01 by Fisher's exact test). Notably, the fatal toxicity rate on the gemtuzumab arm is similar to the rates in earlier SWOG studies using induction regimens similar to the standard arm of S0106, while the rate on the standard arm is significantly lower than in the earlier studies.

One patient who received no treatment due to insurance refusal and another whose diagnosis was revised to ALL are excluded from the analysis of response. Of the 287 patients who have been evaluated for response to induction on the gemtuzumab arm, 214 (75%) achieved CR or CRi (95% CI: 70% - 80%) and 47 (16%) had resistant disease. Of the 285 patients evaluated for response on the standard arm, 207 (73%) achieved CR or CRi and 60 (21%) had resistant disease.

One hundred seven of the 297 evaluable patients with follow-up on the gemtuzumab arm have died and the median overall survival is 31 months (95% CI: 25 - 39 months). One hundred four of the 299 evaluable patients with follow-up on the standard arm have died, with median overall survival 34 months (95% CI: 24 - 41 months). Of the 214 patients who achieved CR on the gemtuzumab arm, 60 have reports of relapse and 20 died without a report of relapse, and the estimated probability of relapse-free survival (RFS) at two years is 50% (95% CI: 42% - 59%). Of the 207 patients who achieved CR on the standard arm, 61 have reports of relapse and 19 died without a report of relapse, and the estimated two-year RFS is 49% (95% CI: 41% - 58%).

Consolidation Therapy:

Of 402 patients registered for consolidation, 24 were not eligible because they were not shown to have a complete response to induction therapy, had inadequate liver function, or were ineligible for the initial registration. Major deviations were recorded for two patients who did not receive consolidation due to detection of peripheral blood blasts on the day of registration and late induction toxicities. Ten patients were removed from protocol consolidation therapy due to consolidation toxicities: five due to slow platelet recovery, two due to neurotoxicities and one each due to late induction toxicities, febrile neutropenia, and unspecified toxicity. Forty-six additional patients were taken off therapy early for other reasons, primarily to pursue transplant. Of 353 patients evaluated for consolidation toxicities, one fatal consolidation toxicity (infection) has been reported. Grade 4 non-hematologic toxicities have been reported for 52 patients during consolidation therapy, including 38 with infection.

Post-consolidation Therapy:

Of 182 patients registered for post-consolidation randomization, twelve are ineligible: eight because they were ineligible for a previous registration on this study, two without neutrophil recovery when registered, one due to progression, and one due to relapse. Major protocol deviations were reported for six patients who refused to receive gemtuzumab before starting treatment. Five other patients refused to complete post-consolidation gemtuzumab therapy. Eleven patients were taken off post-consolidation therapy due to toxicity, most frequently prolonged hematologic recovery.

Among the 73 patients evaluated for toxicity of post-consolidation gemtuzumab, no fatal toxicities have been reported. Forty-eight have Grade 4 toxicities, primarily hematologic. Five patients had Grade 4 non-hematologic toxicities, four with infection.

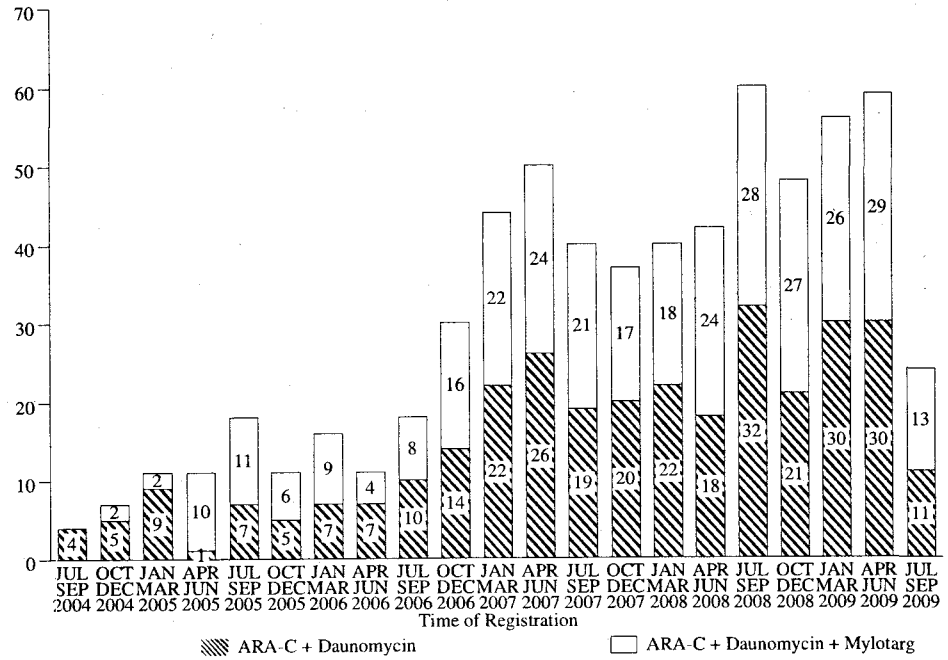
Of the 84 evaluable patients with follow-up on the post-consolidation gemtuzumab arm, 41 have relapsed and two have died without a report of relapse, and the estimated disease-free survival (DFS) two years after the post-consolidation randomization is 39% (95% CI: 27% - 51%) for the gemtuzumab arm. Of the 84 evaluable patients on the post-consolidation observation arm, 34 have reports of relapse and two have died without a report of relapse, and the estimated two-year DFS is 50% (95% CI: 38% - 62%).

Early Closure of the Study:

On August 11, 2009 the SWOG Data and Safety Monitoring Committee (DSMC) reviewed the second scheduled interim analysis of CR rates, which was based, as planned, on the first 456 evaluable patients. The CR rates in that analysis were similar to those for all patients in the present analysis, 66% in 227 patients on the gemtuzumab arm, and 69% in 229 patients on the standard arm. With these data the hypothesis that the gemtuzumab arm increases the CR rate by 12% was rejected at the predefined significance level ($p<0.0025$). In addition, as shown above, RFS was not significantly better on the gemtuzumab arm. The DSMC also reviewed the first planned interim analysis of post-consolidation DFS, the results of which were similar to those described above. That analysis rejected the hypothesis that gemtuzumab improves DFS with a hazard ratio (observation : gemtuzumab) of 1.5 at the prespecified significance level ($p<0.001$). Based on these results, as well as the higher incidence of fatal toxicities in the gemtuzumab induction arm similar to that described above, the DSMC recommended closure of both the induction and

post-consolidation randomizations. This recommendation was reviewed and accepted by the study team, Leukemia Committee, and SWOG leadership, and the study was closed to accrual on August 20, 2009.

Initial Registrations By 3 Month Intervals



Registration by Institution

Initial Registration / Randomization

Institutions	Total Reg
CTSU	250
Michigan, U of	36
MUSC, Hollings CC	30
Loyola University	29
Puget Sound	28
Rochester, Univ of	23
Stanford University	21
New Mexico MBCCOP	19
Wichita CCOP	19
Wayne State Univ	18
Karolinska Univ Hosp	13
LSU-Shreveport	11
Utah, U of	11
Kentucky, U of	10
LSU-Shreveport CCOP	10
Cleveland Clinic OH	9
Southeast CCC CCOP	9
Grand Rapids CCOP	7
Columbus CCOP	6
Dayton CCOP	6
San Antonio, U of TX	6
Akademiska Hospital/Karolinska Univ Hosp	5

Institutions	Total Reg
Boston Univ Med Ctr	5
Providence Hosp	5
Upstate Carolina	5
Sutter Hlth Western/Davis, U of CA	4
Akron Gen Med Ctr/Cleveland Clinic OH	3
Arkansas, U of	3
Central IL CCOP	3
Kansas City CCOP	3
LSU-New Orleans CCOP	3
BAMC/WHMC	2
Madigan Army Med Ctr/BAMC/WHMC	2
Michigan CRC CCOP	2
Montana CCOP	2
Sahlgrenska U Hosp/Karolinska Univ Hosp	2
So Calif, U of	2
St Edward Mercy MC/Arkansas, U of	2
St Louis CCOP	2
Stormont-Vail Health/Kansas, U of	2
Watson Clinic Center/H Lee Moffitt CC	2
All Other Institutions	7
Total (48 Institutions)	637

Registration, Eligibility, and Evaluability

Initial Registration / Randomization

Data as of February 15, 2010

	TOTAL	ARA-C + Daunomycin + Mylotarg	ARA-C + Daunomycin
NUMBER REGISTERED	637	317	320
INELIGIBLE	33	16	17
ELIGIBLE	604	301	303
Not Analyzable	3	2	1
RESPONSE ASSESSMENT			
Determinable	534	263	271
Not Determinable	38	24	14
Too Early	27	12	15
Not Applicable	2	0	2
ADVERSE EVENT ASSESSMENT			
Evaluable	564	283	281
Not Evaluable	7	2	5
Too Early	30	14	16

Patient Characteristics

Initial Registration / Randomization

Data as of February 15, 2010

	ARA-C + Daunomycin + Mylotarg (n=299)		ARA-C + Daunomycin (n=302)	
AGE				
Median	47.2		48.5	
Minimum	18.7		18.5	
Maximum	60.7		60.9	
< 35 years	63	21%	63	21%
≥ 35 years	236	79%	239	79%
SEX				
Males	164	55%	153	51%
Females	135	45%	149	49%
HISPANIC				
Yes	10	3%	18	6%
No	226	76%	240	79%
Unknown	63	21%	44	15%
RACE				
White	240	80%	262	87%
Black	27	9%	11	4%
Asian	9	3%	18	6%
Pacific Islander	3	1%	1	0%
Native American	3	1%	3	1%
Unknown	17	6%	7	2%

Treatment Summary

Initial Registration / Randomization

Data as of February 15, 2010

	TOTAL	ARA-C + Daunomycin + Mylotarg	ARA-C + Daunomycin
NUMBER ON PROTOCOL TREATMENT	10	8	2
NUMBER OFF PROTOCOL TREATMENT	591	291	300
REASON OFF TREATMENT			
Treatment completed as planned	513	256	257
Adverse Events or side effects	8	8	0
Refusal unrelated to adverse events	3	1	2
Progression/relapse	7	3	4
Death	10	7	3
Other - not protocol specified	34	11	23
Reason under review	16	5	11
MAJOR PROTOCOL DEVIATIONS	13	7	6

Number of Patients with a Given Type and Grade of Adverse Event

Initial Registration / Randomization
Non-Hematologic Toxicities Only
Adverse Events Unlikely or Not Related to Treatment Excluded
Adverse Events with No Entries for Grades 3 to 5 Have Been Suppressed
Data as of February 15, 2010

	ARA-C + Daunomycin + Mylotarg (n=283)					ARA-C + Daunomycin (n=281)				
	Grade					Grade				
ADVERSE EVENT	Unk	≤2	3	4	5	Unk	≤2	3	4	5
Allergy/immunology	0	277	4	2	0	0	281	0	0	0
Cardiac General	0	273	6	4	0	0	276	3	2	0
Cardiovascular Infect., Gr. 3-4 ANC	0	282	0	1	0	0	280	1	0	0
Clotting	0	281	1	1	0	0	280	0	1	0
Death	0	282	0	0	1	0	281	0	0	0
Dermatologic/Skin	0	277	6	0	0	1	272	8	0	0
Endocrine	0	282	1	0	0	0	281	0	0	0
Eye	0	283	0	0	0	0	278	2	1	0
Flu-Like Symptoms	0	253	27	3	0	0	251	29	1	0
GI Fistula	0	282	0	1	0	0	281	0	0	0
GI Hemorrhage	0	280	3	0	0	0	279	2	0	0
GI Infection, Gr. 0-2 ANC	0	282	1	0	0	0	281	0	0	0
GI Infection, Gr. 3-4 ANC	1	274	7	0	1	0	270	11	0	0
GI Infection, Unk ANC	0	283	0	0	0	0	280	1	0	0
GI Pain	0	275	8	0	0	0	277	4	0	0
GI Perforation	0	283	0	0	0	0	280	0	1	0
GU	0	275	6	2	0	0	275	6	0	0
GU Fistula	0	282	0	1	0	0	281	0	0	0
GU Hemorrhage	0	278	5	0	0	0	278	3	0	0
GU Infection, Gr. 0-2 ANC	0	283	0	0	0	0	280	1	0	0
GU Infection, Gr. 3-4 ANC	0	277	6	0	0	0	274	7	0	0
GU Infection, Unk ANC	0	281	2	0	0	0	280	1	0	0
Gastrointestinal	0	253	30	0	0	0	243	36	1	1
Hemorrhage	0	265	13	1	4	0	273	7	0	1
Hepatobiliary Infect., Gr. 0-2 ANC	0	282	1	0	0	0	281	0	0	0
Hepatobiliary/Pancreas	0	278	2	2	1	0	280	1	0	0
Infection	0	111	146	22	4	0	92	176	13	0
Infection, Gr. 3-4 ANC	0	248	30	3	2	0	253	24	3	1
Infection, Unk ANC	0	280	3	0	0	0	276	5	0	0
Lung	0	261	11	7	4	0	273	6	2	0
Lung Hemorrhage	0	275	4	2	2	0	280	1	0	0
Lung Infection, Gr. 0-2 ANC	0	277	5	1	0	0	281	0	0	0
Lung Infection, Gr. 3-4 ANC	0	260	19	4	0	0	250	26	4	1
Lung Infection, Unk ANC	0	282	1	0	0	0	278	3	0	0
Lung Pain	0	281	2	0	0	0	279	1	1	0
Lymphatics	0	281	2	0	0	0	281	0	0	0
Metabolic/Laboratory	0	185	82	15	1	0	217	54	10	0
Mood Alteration	0	282	1	0	0	0	280	1	0	0
Mucositis, Clinical	0	277	6	0	0	0	267	14	0	0
Mucositis, Functional	0	278	5	0	0	0	272	8	1	0
Muscle Weakness	0	283	0	0	0	0	280	1	0	0
Musculoskel. Infect., Gr. 0-2 ANC	0	282	1	0	0	0	281	0	0	0
Musculoskeletal Pain	0	282	1	0	0	1	278	2	0	0
Musculoskeletal/Soft Tissue	0	282	1	0	0	0	281	0	0	0
Neurologic	0	275	7	1	0	0	276	4	1	0
Neurologic Infection, Gr. 3-4 ANC	0	282	1	0	0	0	280	0	1	0
Neurologic Pain	0	275	8	0	0	0	280	1	0	0
Pain	0	282	1	0	0	0	281	0	0	0
Sexual/Repro. Infect., Gr. 3-4 ANC	0	282	0	1	0	0	281	0	0	0
Skin Infection, Gr. 0-2 ANC	0	281	2	0	0	0	281	0	0	0
Skin Infection, Gr. 3-4 ANC	0	278	5	0	0	0	277	4	0	0
Skin Infection, Unk ANC	0	279	4	0	0	0	278	3	0	0
Skin Pain	0	283	0	0	0	0	280	1	0	0
Supraventricular Arrhythmia	0	282	0	1	0	0	280	1	0	0
Syndromes	0	281	2	0	0	0	279	2	0	0
Vascular	0	278	3	2	0	0	277	3	1	0
Ventricular Arrhythmia	0	282	0	1	0	0	281	0	0	0
MAXIMUM GRADE ANY ADVERSE EVENT										
Number	0	58	164	45	16	0	48	199	30	4

Response

Initial Registration

Data as of February 15, 2010

	ARA-C + Daunomycin + Mylotarg		ARA-C + Daunomycin	
Complete Response	194	68%	192	67%
CR w/Incomplete Hem. Recovery	20	7%	15	5%
Partial Response	2	1%	4	1%
Assessment Inadequate	13	5%	9	3%
Resistant Disease	47	16%	60	21%
Died During Aplasia	1	0%	0	0%
Died <7 Days After 1st Course	4	1%	0	0%
Died Without Bone Marrow Exam	6	2%	5	2%
Total	287	100%	285	100%

Registration, Eligibility, and Evaluability

Consolidation

Data as of February 15, 2010

	ARA-C Consolidation		ARA-C Consolidation
NUMBER REGISTERED	402	ADVERSE EVENT ASSESSMENT	
INELIGIBLE	24	Evaluable	353
ELIGIBLE	378	Not Evaluable	2
Analyzable, Pend. Elig.	1	Too Early	23

Treatment Summary

Consolidation

Data as of February 15, 2010

	ARA-C Consolidation
NUMBER ON PROTOCOL TREATMENT	22
NUMBER OFF PROTOCOL TREATMENT	356
REASON OFF TREATMENT	
Treatment completed as planned	245
Adverse Events or side effects	10
Refusal unrelated to adverse events	10
Progression/relapse	8
Death	2
Other - not protocol specified	46
Reason under review	35
MAJOR PROTOCOL DEVIATIONS	2

Number of Patients with a Given Type and Grade of Adverse Event

Consolidation
Non-Hematologic Toxicities Only
Adverse Events Unlikely or Not Related to Treatment Excluded
Adverse Events with No Entries for Grades 3 to 5 Have Been Suppressed
Data as of February 15, 2010

ARA-C Consolidation
(n=353)

ADVERSE EVENT	Grade Unk	≤2	3	4	5
Airway Obstruction	0	352	0	1	0
Cardiac Arrhythmia	0	351	1	1	0
Cardiac General	0	341	8	4	0
Cardiovascular Infect., Gr. 0-2 ANC	0	352	1	0	0
Clotting	0	352	1	0	0
Dermatologic/Skin	0	352	1	0	0
Eye Pain	0	352	1	0	0
Flu-Like Symptoms	0	317	35	1	0
GI Hemorrhage	0	351	2	0	0
GI Infection, Gr. 3-4 ANC	0	344	8	1	0
GI Necrosis	0	352	1	0	0
GI Pain	1	348	4	0	0
GU Hemorrhage	0	352	1	0	0
GU Infection, Gr. 3-4 ANC	0	344	8	1	0
Gastrointestinal	0	340	12	1	0
Hematologic	0	352	1	0	0
Hemorrhage	0	338	14	1	0
Hepatobiliary Infect., Gr. 3-4 ANC	0	352	1	0	0
Hepatobiliary Infection, Unk ANC	0	352	1	0	0
Infection	0	182	141	30	0
Infection, Gr. 0-2 ANC	0	344	9	0	0
Infection, Gr. 3-4 ANC	0	297	43	13	0
Infection, Unk ANC	0	346	7	0	0
Lung	0	333	16	4	0
Lung Hemorrhage	0	349	4	0	0
Lung Infection, Gr. 0-2 ANC	0	346	6	1	0

ARA-C Consolidation
(n=353)

ADVERSE EVENT	Grade Unk	≤2	3	4	5
Lung Infection, Gr. 3-4 ANC	1	332	19	0	1
Lung Infection, Unk ANC	0	350	3	0	0
Lung Pain	0	351	2	0	0
Lymphatics	0	352	1	0	0
Metabolic/Laboratory	0	290	54	9	0
Mood Alteration	0	352	1	0	0
Mucositis, Clinical	0	352	1	0	0
Mucositis, Functional	0	351	1	1	0
Muscle Weakness	0	351	2	0	0
Musculoskel. Infect., Gr. 3-4 ANC	0	352	1	0	0
Musculoskeletal Infection, Unk ANC	0	351	2	0	0
Musculoskeletal Pain	0	348	5	0	0
Neurologic	0	342	11	0	0
Neurologic Infection, Gr. 3-4 ANC	0	352	1	0	0
Neurologic Pain	0	348	5	0	0
Sexual/Repro. Infect., Gr. 0-2 ANC	0	352	1	0	0
Sexual/Repro. Infect., Gr. 3-4 ANC	0	352	1	0	0
Skin Infection, Gr. 3-4 ANC	1	344	8	0	0
Skin Infection, Unk ANC	1	349	3	0	0
Syndromes	0	351	2	0	0
Vascular	0	350	1	2	0
MAXIMUM GRADE ANY ADVERSE EVENT					
Number	0	117	183	52	1

Registration, Eligibility, and Evaluability

Post-Consolidation

Data as of February 15, 2010

	TOTAL	Mylotarg	Observation
NUMBER REGISTERED	182	91	91
INELIGIBLE	12	5	7
ELIGIBLE	170	86	84
Analyzable, Pend. Elig.	16	12	4
ADVERSE EVENT ASSESSMENT			
Evaluable	73	73	0
Not Evaluable	6	6	0
Too Early	7	7	0
Not Applicable	84	0	84

Treatment Summary

Post-Consolidation

Data as of February 15, 2010

	Mylotarg
NUMBER ON PROTOCOL TREATMENT	4
NUMBER OFF PROTOCOL TREATMENT	82
REASON OFF TREATMENT	
Treatment completed as planned	36
Adverse Events or side effects	11
Refusal unrelated to adverse events	11
Progression/relapse	4
Death	0
Other - not protocol specified	3
Reason under review	17
MAJOR PROTOCOL DEVIATIONS	6

Number of Patients with a Given Type and Grade of Adverse Event

Post-Consolidation

Includes Hematologic Toxicities

Adverse Events Unlikely or Not Related to Treatment Excluded

Adverse Events with No Entries for Grades 3 to 5 Have Been Suppressed

Data as of February 15, 2010

	Mylotarg (n=73)			
	Grade			
ADVERSE EVENT	≤2	3	4	5
ALT	71	1	1	0
AST	71	1	1	0
Dehydration	72	1	0	0
Fatigue	69	4	0	0
Febrile neutropenia	51	19	3	0
Fever	72	0	1	0
GI Pain: anus	72	1	0	0
GI Pain: rectum	72	1	0	0
Hemoglobin	71	2	0	0
Hyperglycemia	71	1	1	0
Hypokalemia	70	3	0	0
Hypophosphatemia	72	1	0	0
Hypotension	72	1	0	0
Inf, 3-4 ANC: blood	69	3	1	0
Inf, 3-4 ANC: cath-related	71	2	0	0
Leukocytes	35	7	31	0

	Mylotarg (n=73)			
	Grade			
ADVERSE EVENT	≤2	3	4	5
Lung Inf, 3-4 ANC: pharynx	72	1	0	0
Lymphopenia	69	3	1	0
Musculo. Pain: back	72	1	0	0
Musculo. Pain: limb	72	1	0	0
Nausea	72	1	0	0
Neuro Pain: head/headache	72	1	0	0
Neutrophils	34	3	36	0
Opportunistic infection	72	1	0	0
Petechiae	72	1	0	0
Platelets	36	21	16	0
Serum sickness	72	1	0	0
Skin Inf, 3-4 ANC: skin	72	1	0	0
Vomiting	72	1	0	0
MAXIMUM GRADE ANY ADVERSE EVENT				
Number	9	16	48	0