BLA 761060: Mylotarg (gemtuzumab ozogamicin)

INTRODUCTORY COMMENTS

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Proposed Indication

For combination therapy with daunorubicin (DNR) and cytarabine (AraC) for the treatment of adult patients with previously untreated, de novo CD33 positive acute myeloid leukemia (AML)

Standard of Care - 7 days of cytarabine + 3 days of anthracycline (7+3)

DA - 7+3 using daunorubicin as the anthracycline

Key Regulatory Events

2000	GO granted accelerated approval as a single-agent for treatment of patients ≥60 with relapsed CD33-positive AML
2009	SWOG S0106 confirmatory trial of GO + DA terminated early due to increased induction mortality and lack of improvement in efficacy
2010	Mylotarg withdrawn from the market
2015	BLA submitted based on ALFA-0701 using a lower GO dose in the combination with DA

GO Doses

GO Dose in Induction	Monotherapy (R/R AML)	Combination with DA* (AML 1st Line)
9 mg/m^2	Original approval	-
6 mg/m^2	Other studies	S0106
3 mg/m^2 D 1, 4, 7	Other studies	ALFA-0701

Key Safety Outcomes

	Odds Ratio (95% CI)*	
Induction	**Day 30-Mortality**	**VOD**
S0106 (DA +/- GO 6 mg/m^2 D 4)	3.58 (1.16, 11.03)	7.62 (0.75, 76.89)
ALFA-0701 (DA +/- GO 3 mg/m^2 D 1, 4, 7)	1.99 (0.36, 7.36)	2.42 (0.54, 10.83)

*From Individual Patient Data (IPD) meta-analysis

Issues

1. Do the data for the GO 3 mg/m^2/dose fractionated regimen in combination with DA show an acceptable safety profile and address previous safety concerns about the use of GO in combination with DA?

2. EFS does not have a strong correlation with OS due in part to active treatments for induction failure or relapse, but can EFS represent a benefit in itself for patients with newly-diagnosed AML?

ALFA-0701: Efficacy Analysis

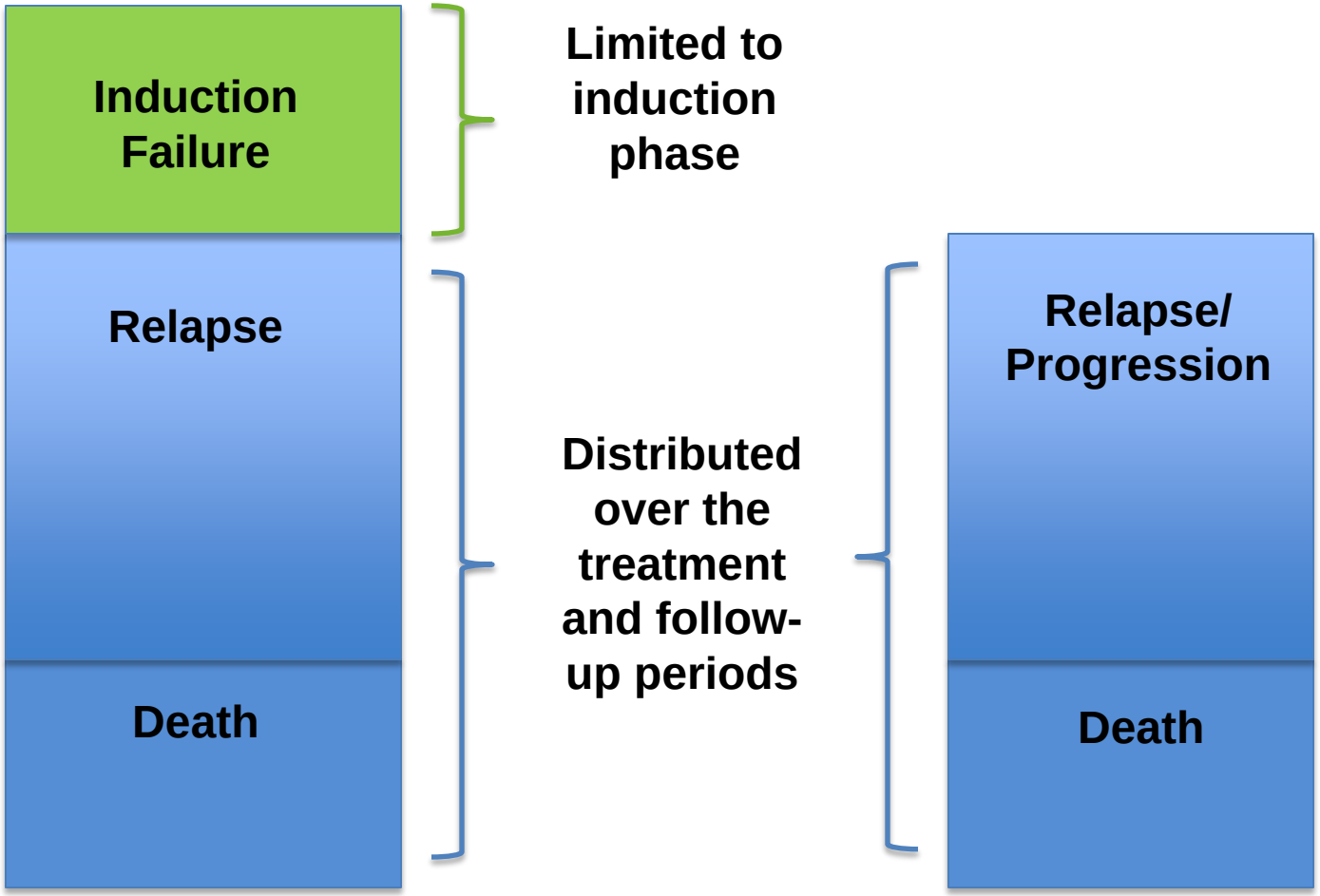
Primary Efficacy Endpoint: Event-free survival (EFS)

- EFS Results: HR 0.56 (0.42, 0.76), $p < 0.001$
- The study met the prespecified primary objective.

FDA usually uses overall survival (OS) for the assessment of clinical benefit for treatments of patients with newly-diagnosed AML with curative intent.

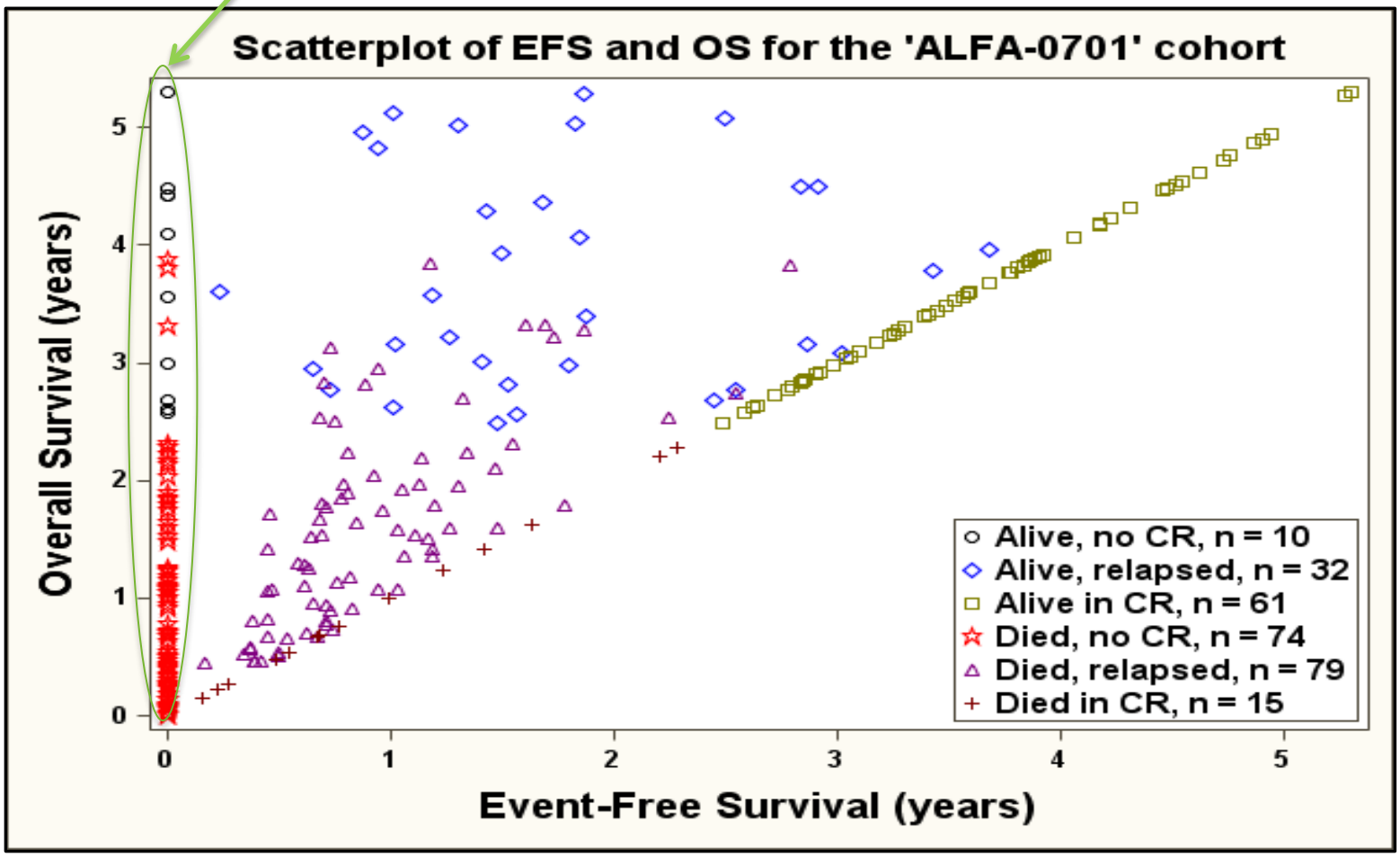
Is EFS a surrogate for OS in AML?

EFS vs PFS


Induction Failure
Relapse
Death
Limited to induction phase
Distributed over the treatment and follow-up periods
Relapse/ Progression
Death
EFS
PFS

Assessment of Patient-Level Correlation Between EFS and OS

Patients with no CR (induction failures).



Issues

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2. EFS does not have a strong correlation with OS due in part to active treatments for induction failure or relapse, but can EFS represent a benefit in itself for patients with newly-diagnosed AML?

Voting Question

Do the results of ALFA-0701 demonstrate a favorable risk:benefit for GO 3 mg/m^2 days 1, 4 and 7 added to DA for patients with newly-diagnosed CD33-positive AML?

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FDA Presentation

July 11, 2017

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Issues

- Gemtuzumab ozogamicin (GO) dose
  - Previously approved dose: GO 9 mg/m^2 x 2
  - Removed from the US market in 2010 due to increased deaths in induction when used at 6 mg/m^2 + daunorubicin and cytarabine (DA)
  - A fractionated schedule using a 3 mg/m^2/dose is proposed in combination with DA

- EFS as an endpoint for AML?
  - Overall survival is the accepted endpoint for regular approval in AML.

Outline

- GO dose selection
  - Pharmacology of GO monotherapy
  - Clinical outcomes of GO monotherapy
- Efficacy issues
  - ALFA-0701
  - Surrogacy of EFS for OS
- Safety issues
- Summary

Rationale for the Fractionated GO Dosing Regimen

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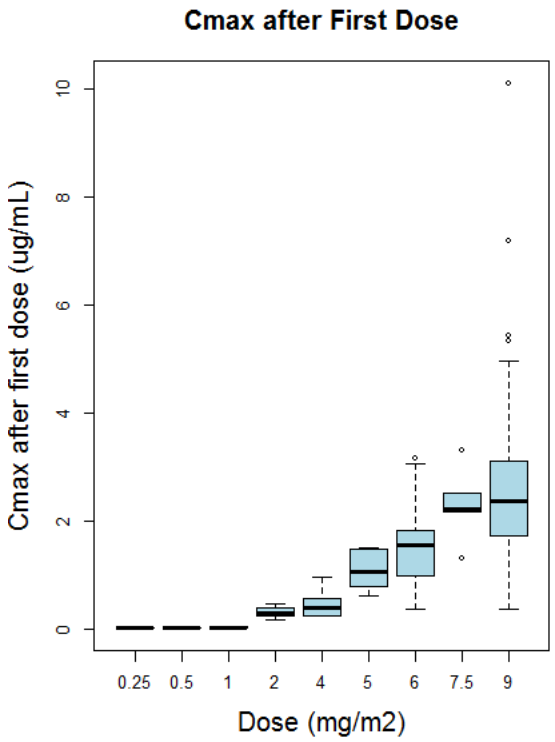
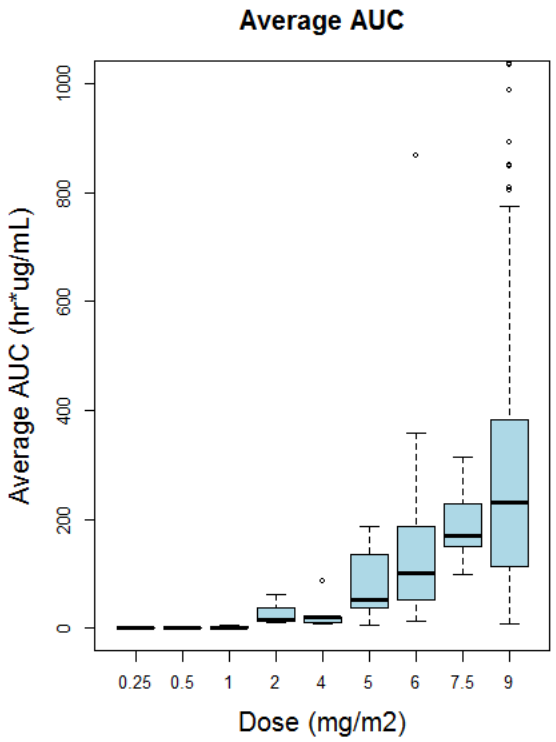
What data support the proposed fractionated GO dose?

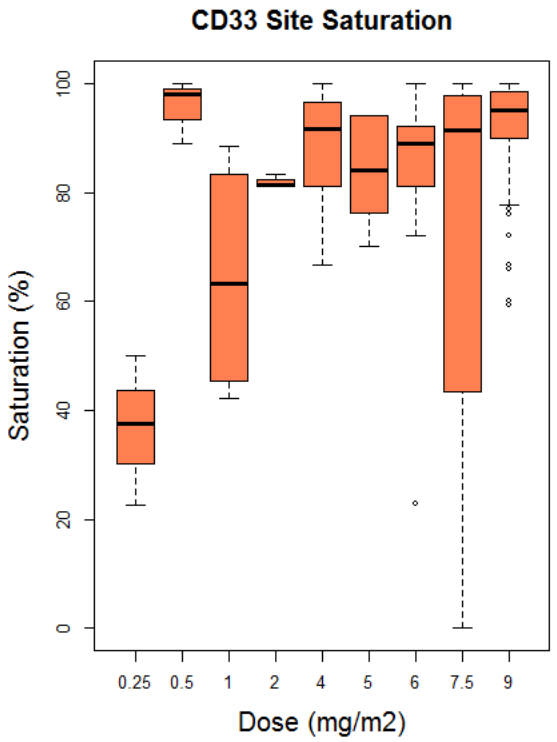
- Original GO dose approved – 9 mg/m^2 x 2 doses 14 days apart
- Fractionated GO schedule – 3 mg/m^2/dose
  - Days 1, 4, and 7 of induction
  - Day 1 of 1st consolidation and 2nd consolidation
- FDA looked first at exposure-response analyses and clinical outcomes of GO monotherapy to assess the impact of GO dose fractionation on safety and activity.

Pharmacokinetics/Pharmacodynamics

- **Exposures of both antibody and calicheamicin decrease more than proportionally as GO dose decreases from 9 mg/m^2 to 3 mg/m^2**
- **CD33 saturated at GO doses >2 mg/m^2**



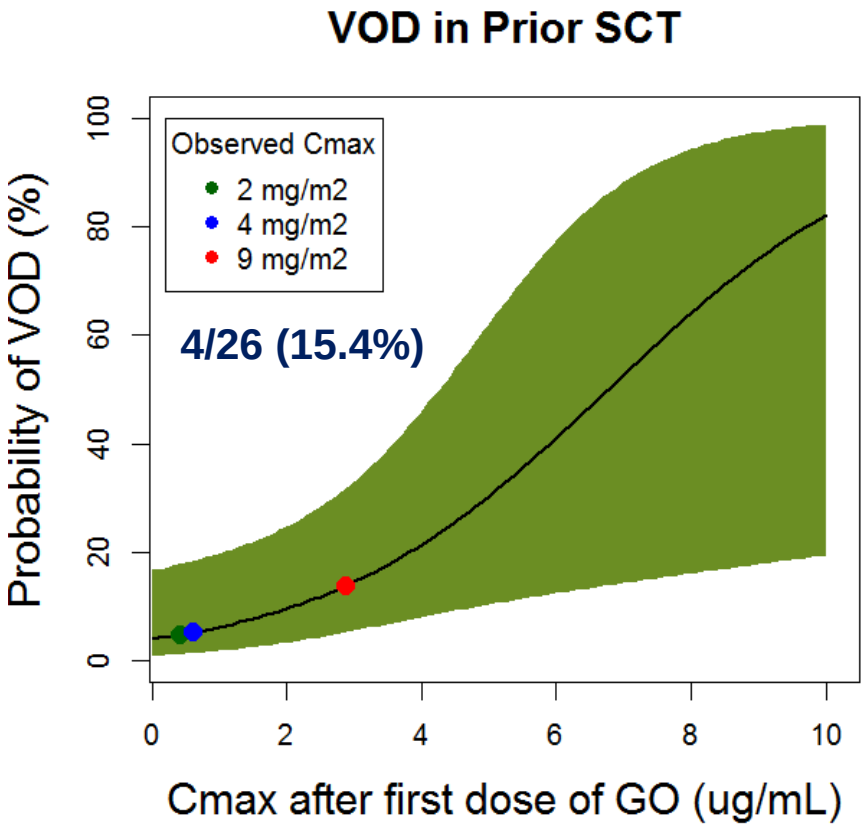


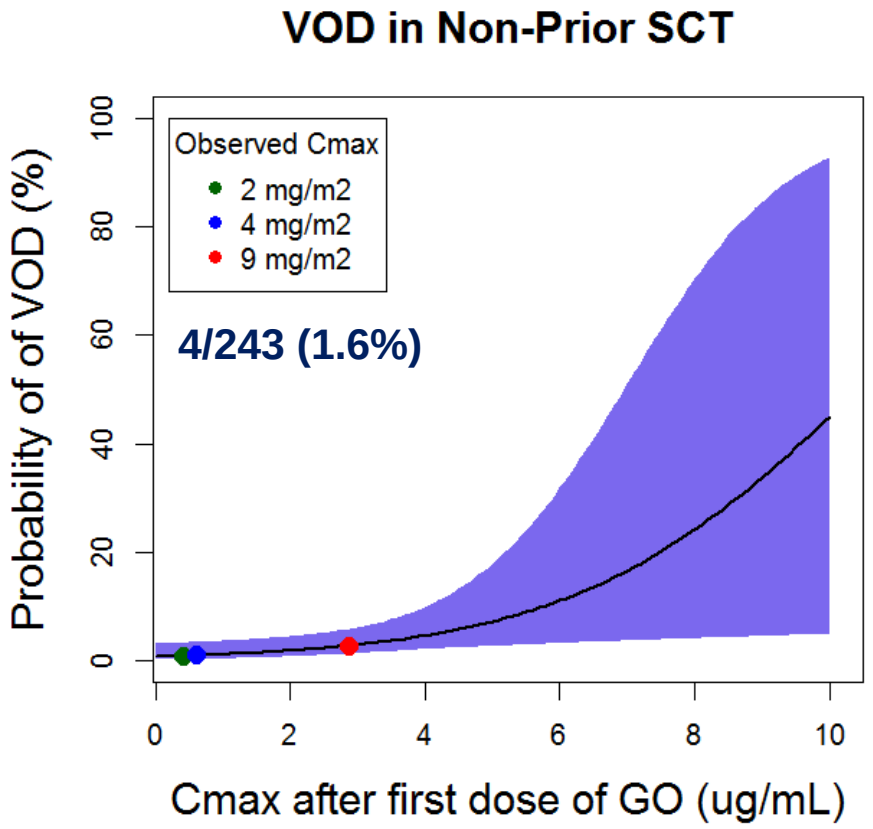


- **No PK data were collected in ALFA-0701**

Exposure-Safety for Veno-Occlusive Disease with Monotherapy

Significant relationship → Significant reduction of VOD risk is expected with a fractionated low-dose GO regimen

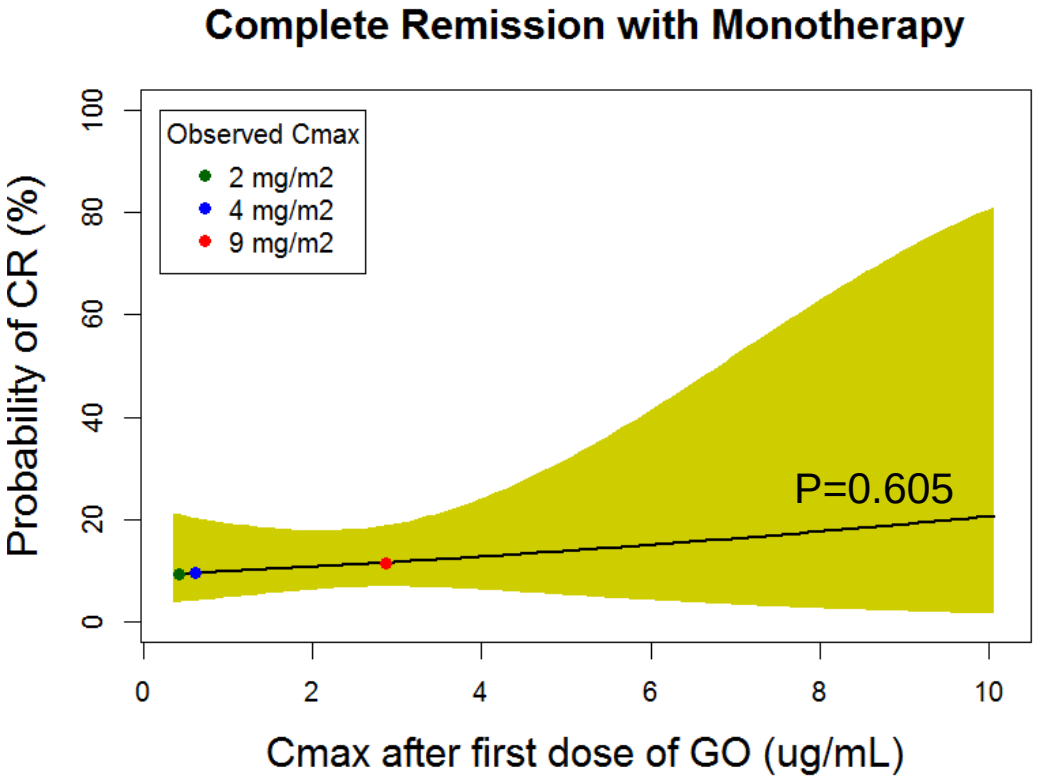




- N=269 from pivotal studies (Studies 201, 202, and 203)
- P=0.03369 after adjusted with Prior Stem Cell Transplant (SCT)

Exposure-Efficacy for CR with Monotherapy

Lack of relationship → Significant loss of efficacy is NOT projected with a fractionated low-dose GO regimen



- Only 9 mg/m^2 was evaluated
- Covariates:
  - ✓ Baseline platelet counts
  - ✓ Baseline bone marrow blasts
  - ✓ Baseline P-gp

- N=269 from pivotal studies for monotherapy (Studies 201, 202, 203)

Clinical Pharmacology
Conclusions on Fractionated Dose

- Fractionated dosing of 3 mg/m^2 on Days 1, 4, and 7
  - Is likely to reduce the risk of VOD in patients with or without prior SCT
  - Appears to be sufficient to saturate CD33
  - Is unlikely to lose efficacy substantially

Meta-Analysis: VOD Rate by GO Monotherapy Dose in Patients with Relapsed/Refractory AML

GO dose	N	VOD incidence (95% CI)
9 mg/m^2 x 2 (10 studies combined)	378	5.6% (3.5, 8.1)
6 mg/m^2 x 2 (7 studies combined)	48	15.0% (6.4, 26.4)
3 mg/m^2 d1, 4, 7 (3 studies combined)	87	0% (0.0, 1.1)

Meta-Analysis: CR Rate by GO Monotherapy Dose in Patients with Relapsed/Refractory AML

GO dose	N	CR (95% CI)
9 mg/m^2 x 2 (11 studies combined)	436	13.7% (10.7, 17.1)
6 mg/m^2 x 2 (6 studies combined)	57	1.2% (0.0, 5.7)
3 mg/m^2 d1, 4, 7 (2 studies combined)	63	25.3% (15.5, 36.7)

Conclusions

- The GO 3 mg/m^2/dose fractionated schedule would be expected to have less VOD and no apparent loss of activity compared with the unfractionated GO dose.

- FDA concluded that the GO 3 mg/m^2/dose fractionated schedule chosen for ALFA-0701 is reasonable to study.

ALFA-0701 Pivotal Trial – Design

- Multi-center, open-label, 1:1 randomized Phase 3 trial of GO plus DA vs DA alone for induction and consolidation therapy
- Patients 50-70 years old with untreated de novo AML
- CD33-positivity was not required for eligibility for the trial.
- Primary endpoint – Event-free survival (EFS)
- Overall survival (OS) is one of the key secondary endpoints
- 271 patients enrolled: 135 GO+DA, 136 DA

U.S. FOOD & DRUG ADMINISTRATION

Efficacy Evaluation in First Line AML

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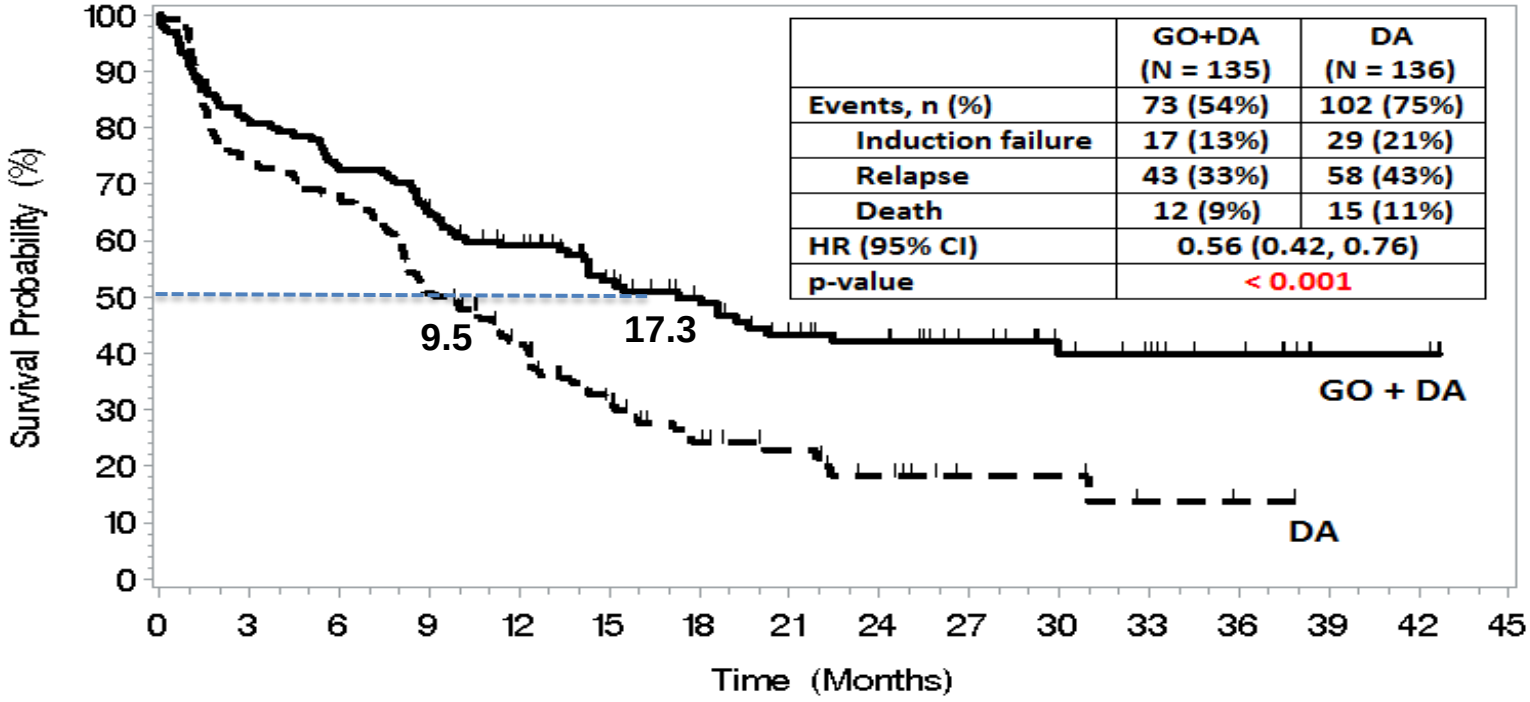
Basis of the Efficacy Evaluation

1. Pivotal trial results: primary endpoint event-free survival (EFS) and key secondary endpoint overall survival (OS)
2. Applicant individual patient data meta-analysis of 5 trials for GO treatment benefit on OS
3. Applicant patient data and literature data meta-analyses of EFS and OS correlation

1. **Pivotal trial results**
2. OS meta-analysis
3. EFS and OS correlation meta-analyses

ALFA-0701 Primary Endpoint: EFS

EFS = the time from randomization to occurrence of an event
Events included: induction failure (IF=no CR/CRp), relapse, death
IF date = date of post-induction assessment
EFS was not censored for the occurrence of transplantation

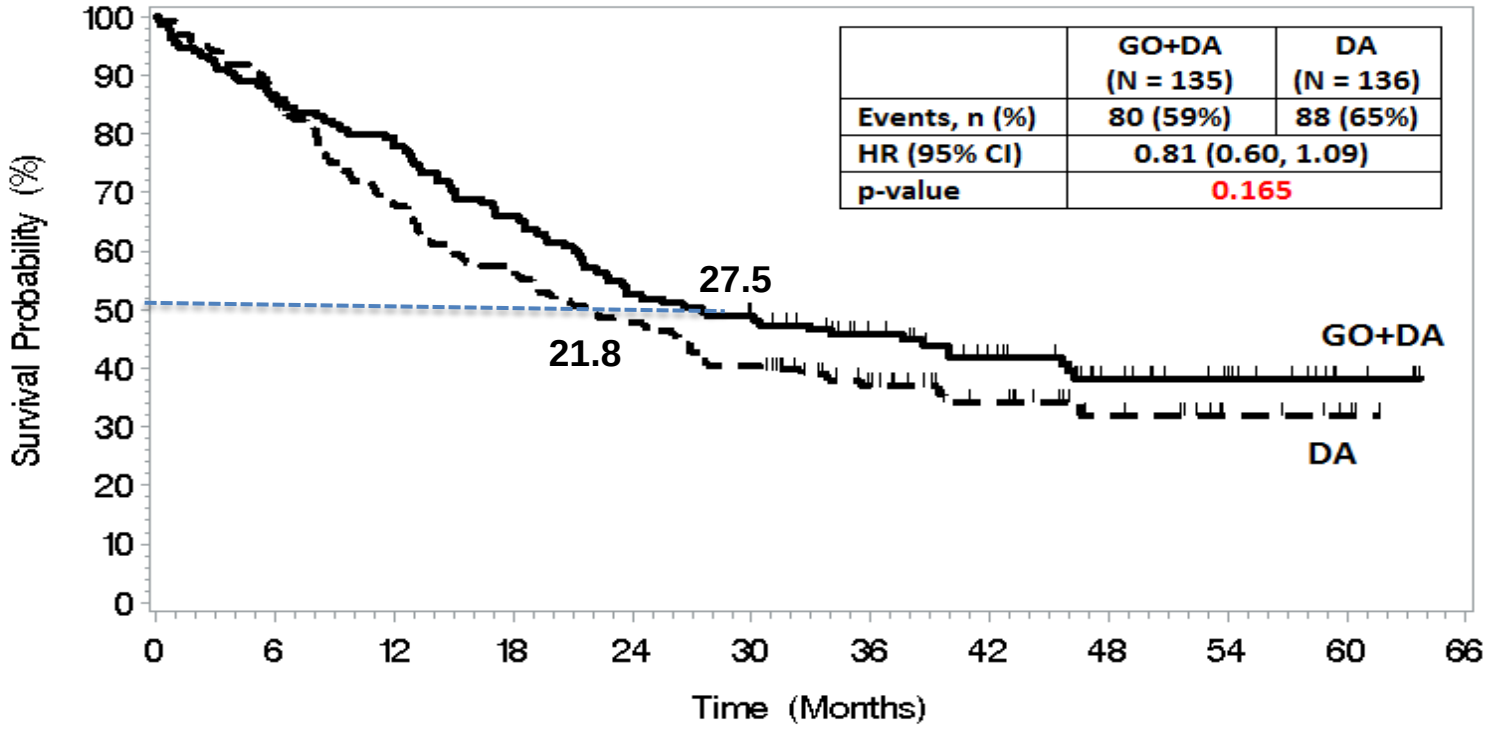


	GO+DA (N = 135)	DA (N = 136)
Events, n (%)	73 (54%)	102 (75%)
Induction failure	17 (13%)	29 (21%)
Relapse	43 (33%)	58 (43%)
Death	12 (9%)	15 (11%)
HR (95% CI)	0.56 (0.42, 0.76)	
p-value	< 0.001	

ALFA-0701 Secondary Endpoint: OS

OS = the time from randomization to death

OS was not censored for the occurrence of transplantation



	GO+DA (N = 135)	DA (N = 136)
Events, n (%)	80 (59%)	88 (65%)
HR (95% CI)	0.81 (0.60, 1.09)	
p-value	0.165	

Points to consider

- OS has been the accepted endpoint that demonstrates the clinical benefit needed for regular approval in AML
  - Progression-free survival (PFS) has been accepted in other settings
- Impact of stem cell transplantation on OS
- Definition of EFS – events and censored observations

Effect of HSCT on Survival

- Hematopoietic stem cell transplant (HSCT) could have impacted survival in patients with no CR or relapse irrespective of treatment arm

Pivotal Trial	ALFA-0701 (N = 271)	
No CR or Relapsed	195	72.0%
Received HSCT	59	21.8%
Survival in months	n	median
No CR	84	12.0
Received HSCT	18	20.1
No HSCT	66	8.6
Relapsed	111	23.4
Received HSCT	41	30.4
No HSCT	70	20.1

Alternative Definitions of EFS

- As sensitivity analyses in the pivotal trial for EFS
- Alternated the primary definition in: induction failure date, censoring status for HSCT, or events

Definitions of EFS	
Primary	Events: induction failure (IF), relapse, death IF date=date of post-induction assessment Not censored for HSCT
Alt 1	IF date=date of randomization
Alt 2	HSCT censored
Alt 3	IF date=randomization, HSCT censored
Alt 4	Salvage therapy, including HSCT, classified as an IF event
Alt 5	Events of relapse and death only (death instead of IF as the event in patients with IF)

EFS Sensitivity Analyses by Alternative Definitions

Pivotal Trial ALFA-0701		GO + DA versus DA	
EFS Definitions		Hazard ratio	[95% CI]
Primary	Events: IF, relapse, death IF date=date of post-induction assessment Not censored for HSCT	0.56	[0.42, 0.76]
Alt 1	IF date=date of randomization	0.56	[0.41, 0.75]
Alt 2	HSCT censored	0.59	[0.43, 0.81]
Alt 3	IF date=randomization, HSCT censored	0.58	[0.43, 0.80]
Alt 4	Salvage therapy classified as an IF event	0.60	[0.45, 0.81]
Alt 5	Events of relapse and death only	0.60	[0.44, 0.81]

1. Pivotal trial results
2. **OS meta-analysis**
3. EFS and OS correlation meta-analyses

Patient Data Meta-Analysis of OS

- A marginal effect was suggested; however, important differences exist between studies in age and dosing

Trial (enrollment)	Pt. N	Pt. Age	GO dose	Overall Survival				HR	(95% CI)
				Death rate (%)		Median (months)			
				GO	No-GO	GO	No-GO		
Meta-analysis	3,331	18-70	various	66.2	69.1	23.6	21.5	0.91	(0.84, 0.99)
AML 15 (2002-2006)	1,099	< 60	3 mg/m^2 D1	61.9	64.8	34.4	27.5	0.93	(0.80, 1.08)
AML 16 (2006-2010)	1,115	> 60	3 mg/m^2 D1	84.4	88.8	14.0	12.0	0.87	(0.77, 0.99)
ALFA-0701 (2008-2010)	271	50-70	3 mg/m^2 D 1, 4, 7	59.3	64.7	27.5	21.8	0.81	(0.60, 1.09)
AML2006IR (2007-2010)	251	18-60	6 mg/m^2 D 4	44.4	50.4	NR	67.4	0.86	(0.60, 1.23)
S0106 (2004-2009)	595	< 56	6 mg/m^2 D 4	52.2	30.3	43.6	61.0	1.09	(0.87, 1.36)

1. Pivotal trial results
2. OS meta-analysis
3. **EFS and OS correlation meta-analyses**

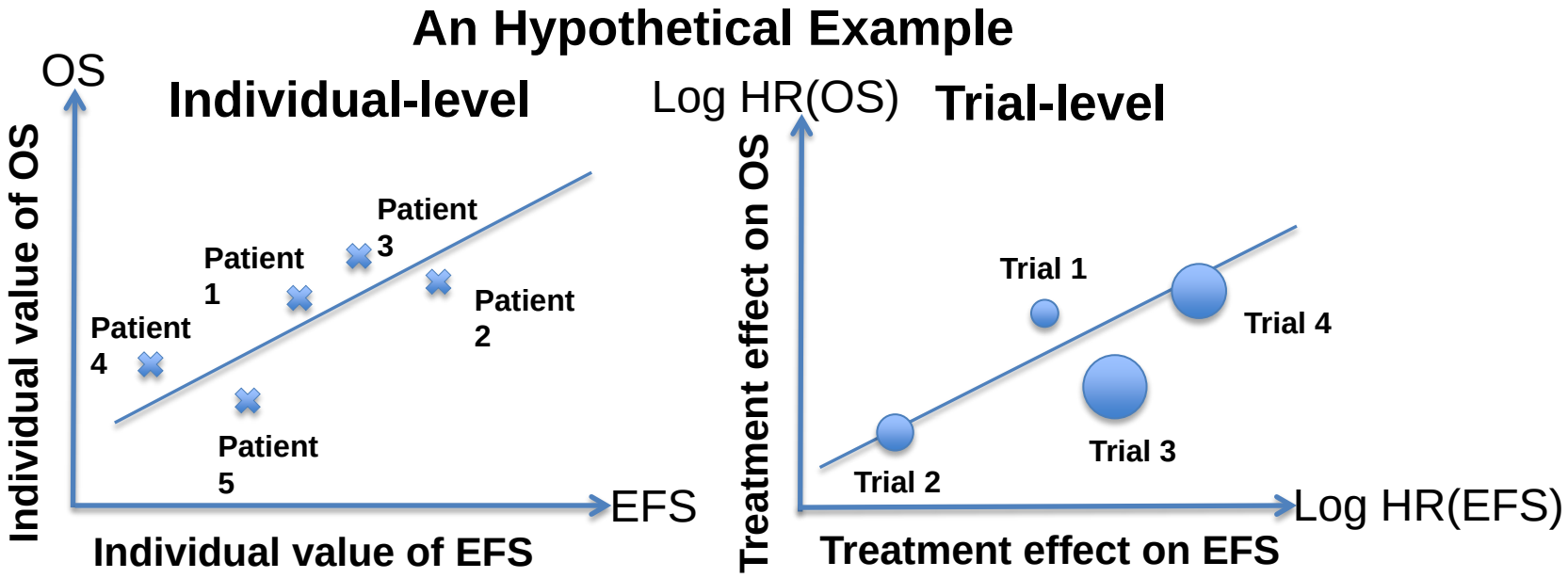
Correlation between EFS and OS

- OS was not the primary endpoint in the pivotal trial. Applicant conducted EFS/OS correlation analyses on
  - Individual patient data from 5 GO trials in 3,331 patients
  - Summary data from 33 published trials in AML

- Correlation was assessed at individual and trial levels
  - Individual level by Kendall's tau as degree of concordance
  - Trial level by R^2 from linear regression of treatment effects
  - For analysis in the GO trials, copula models were applied

EFS/OS Correlation – points to consider

- Correlation between EFS and OS at both the individual and the trial levels should be evaluated



- Correlation of 1 implies perfect correlation.

Applicant EFS/OS Correlation Analyses

- Individual-level (based on individual values)
  - Kendall's tau ranged from 0.48 to 0.52 by various models

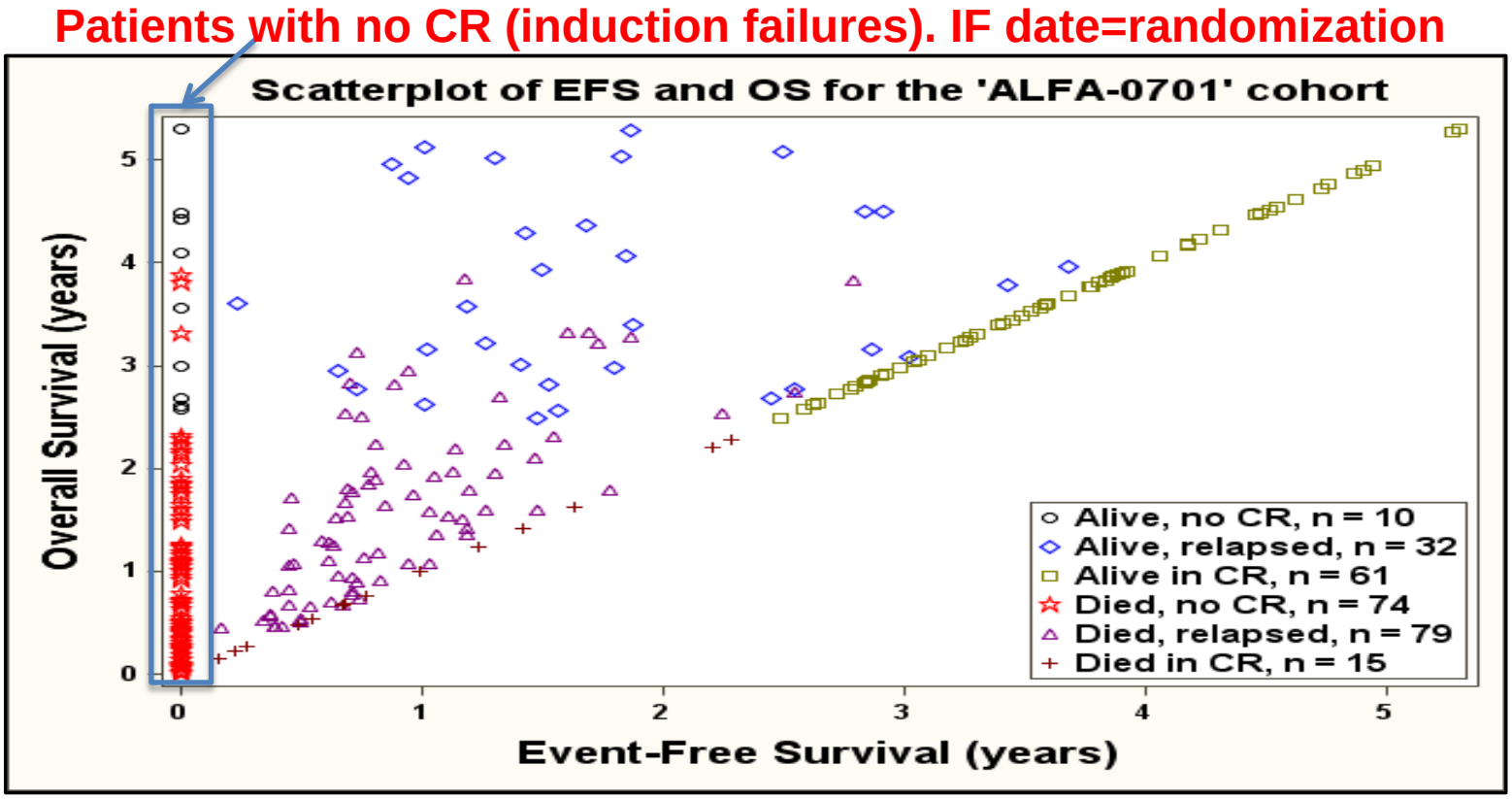
- Trial-level (based on estimated treatment effects)

  Using trial results from only the 5 GO trials
  - R-square ranged from 0.45 to 0.62 by various models. Wide confidence intervals indicate low precision.

  Using trial results from 33 published trials in AML
  - R-square, weighted by trial size: 0.46 [0.23, 0.70]

EFS/OS Correlation in Individual Patients

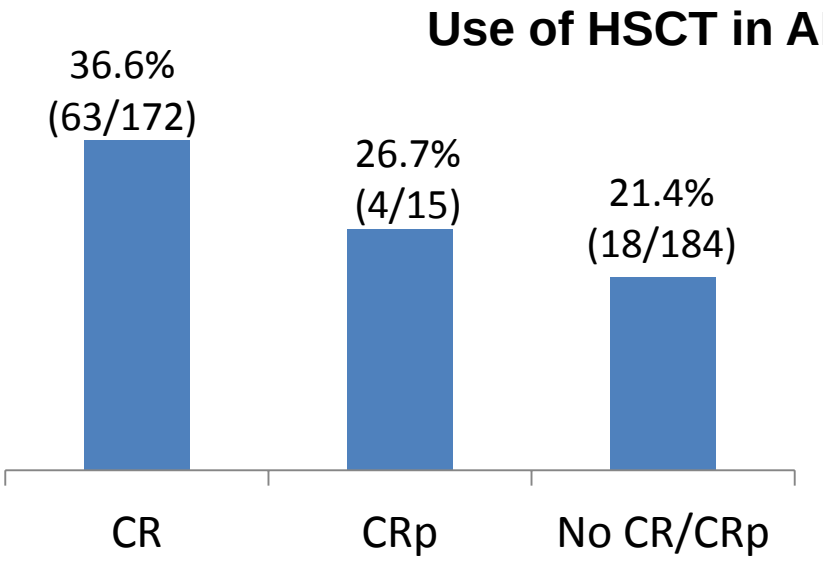
- Correlation of EFS and OS was low in patients who relapsed, and was un-evaluable in patients with no CR



Similar pattern was also observed in the other 4 historical trials of GO

Use of HSCT

- HSCT could have impacted survival
- It is difficult to assess EFS/OS correlation, when there is no criteria for whom and when to receive a HSCT



Status of HSCT in responders (CR/CRp)	
Before Relapse	35
After Relapse	32

EFS/OS Correlation by Various EFS Definitions Estimated by 5 GO Trials

EFS	Definition	Individual Patients	Treatment Effects
1	Events: induction failure (IF), relapse, or death; IF = did not achieve a CR by Day 60 IF date=date of randomization	0.49	0.63
2	Events: induction failure (IF), relapse, or death; IF = did not achieve a CR during induction IF date=date of end of induction	0.72	0.73
3	Events: induction failure (IF), relapse, or death; IF = did not achieve a CR during induction IF date=date of randomization	0.55	0.70
4	Events: induction failure (IF), relapse, or death; IF = did not achieve a CR during induction IF date=date of randomization; HSCT censored	0.52	0.82
5	Events: induction failure (IF), relapse, or death; IF = did not achieve a CR during induction IF date=date of randomization; True CR only	0.52	0.90
6	Events: relapse or death only	0.84	0.78

Correlation in individual patients estimated using Kendall's tau, with copula
Correlation in treatment effects estimated using R-square, weighted by trial size
Limited data (5 studies) with wide confidence intervals

Summary

1. The pivotal trial demonstrated statistically significant effect of GO on primary endpoint EFS
   - Analysis using alternative definitions of EFS with or without considering induction failures as events and HSCT provided consistent results

2. Confirmatory benefit on OS has not been established
   - The pivotal trial did not demonstrate statistically significant effect of GO on OS
   - Retrospective meta-analysis based on patient data from 5 GO trials suggested a marginal effect (HR=0.91), but the analysis was limited by number of studies and different dosing across studies

Summary

3. EFS was not strongly correlated with OS
   - Applicant's analyses did not suggest a strong correlation
     - Agency's evaluation suggested EFS and OS were not strongly correlated, but correlations improved under alternative definitions.
     - Transplantation complicated interpretation of EFS/OS correlation
   - Endpoints in the same family of EFS (PFS, for example) have been accepted as clinically meaningful in other disease settings

Clinical Perspective on EFS

- OS is clearly a benefit.
- Durable CR is also beneficial for the patient.
- EFS reflects durable CR and survival.
- The surrogacy of EFS for OS may be influenced in part by active salvage therapies (HSCT); therefore the lack of correlation between EFS and OS is not unexpected.
- FDA has accepted PFS for drug approvals in other diseases with similar circumstances.

Issue for Discussion

- Could EFS itself represent a benefit for patients with newly-diagnosed AML?

Safety Analysis

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Safety Overview

Sources of data:

– ALFA-0701

– Individual Patient Data Meta-analysis

– Literature review

Potential limitations of the data:

– ALFA-0701 – safety data used for these analyses were collected retrospectively by the applicant

– IPD Meta-analysis – safety data available only for limited pre-specified Grade 3-4 events

Review Strategy

- Early mortality
- Treatment-emergent adverse events
- VOD
- Hepatotoxicity
- Hemorrhage
- Prolonged thrombocytopenia

ALFA-0701 Safety Population

- Some patients randomized to the GO arm did not receive GO in each phase of treatment.

ALFA-0701 – Randomized vs As-Treated Patients

	Phase of Regimen		
	Induction	**Consolidation 1**	**Consolidation 2**
Randomized			
GO + DA	135	97	82
DA	136	97	89
As-Treated			
GO + DA	131	91	64
DA	137	103	107

ALFA-0701 Early Mortality

- 4% of patients in the GO+DA arm vs 2% in the DA arm died within the first 30 days of treatment
- GO + DA: 5 deaths
  - 4 treatment-related: 2 CNS hemorrhage, 1 hemorrhagic shock, 1 VOD
- DA: 3 deaths
  - 1 treatment-related: sepsis in the setting of bone marrow aplasia after reinduction

IPD Meta-analysis – 30-Day Mortality

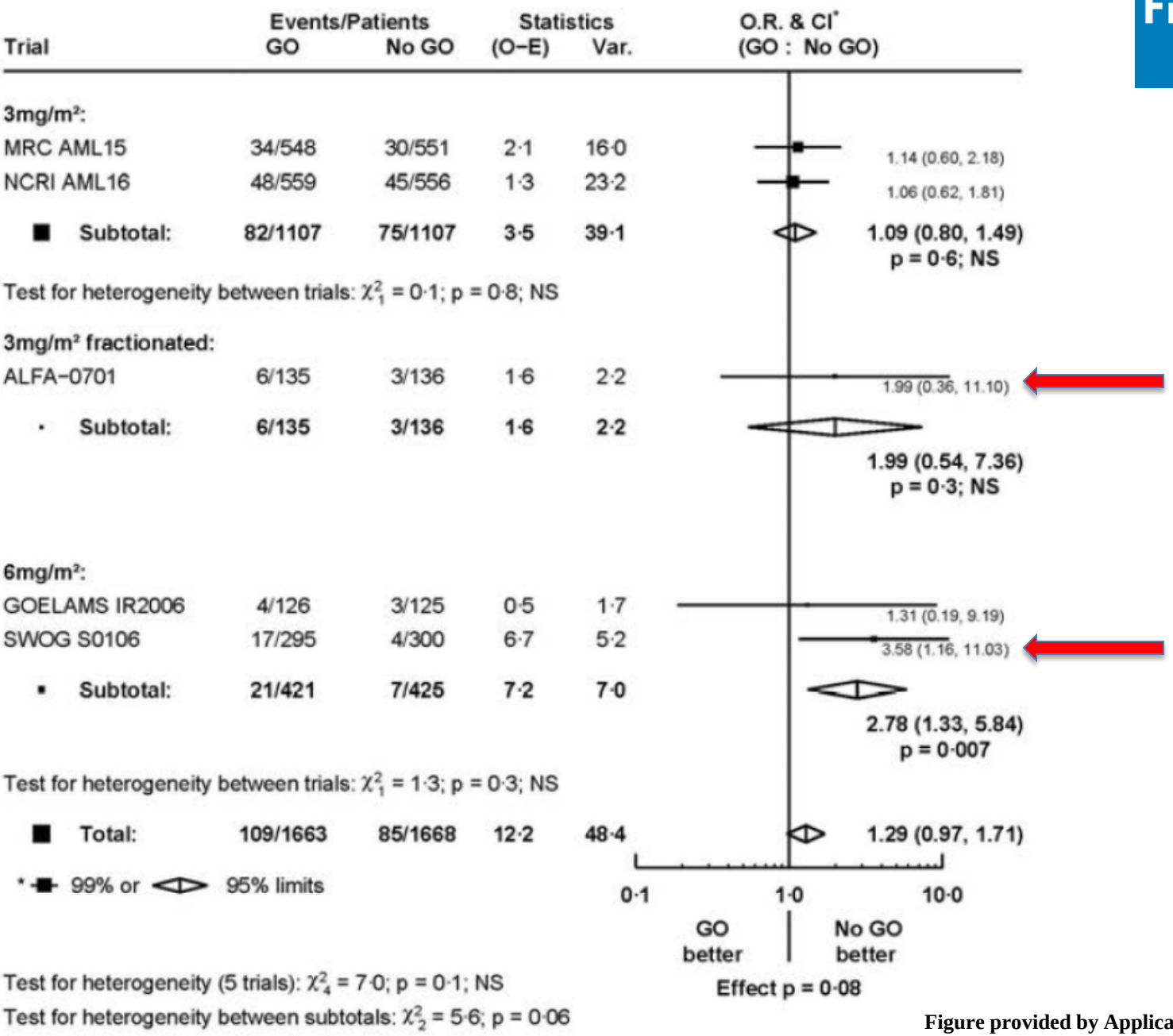

Figure provided by Applicant

Common Adverse Events

ALFA-0701 TEAE Ordered by Risk Difference - Induction

	GO + DA (N = 131)		DA (N = 137)		
Preferred Term	**Number of patients**	**Proportion (%)**	**Number of patients**	**Proportion (%)**	**Risk Difference**
Epistaxis	62	47	43	31	16
Purpura	29	22	17	12	10
Blood blister	18	14	7	5	9
Mouth hemorrhage	16	12	5	4	9
Petechiae	25	19	16	12	7
Hemoptysis	16	12	7	5	7
Device related infection	24	18	16	12	7
Gingival bleeding	19	15	12	9	6
Thrombocytopenia	7	5	0	0	5
Hematuria	19	15	13	9	5
Catheter site hematoma	10	8	4	3	5
Melena	5	4	0	0	4
Post procedural hemorrhage	8	6	4	3	3
Conjunctival hemorrhage	6	5	2	1	3
Veno-occlusive liver disease	4	3	0	0	3

ALFA-0701 Treatment Discontinuations

Treatment discontinuation due to TEAEs:

- 31% in the GO arm vs 7% in the control arm
- Thrombocytopenia (15% vs 0%)
- Hepatobiliary disorders (6% vs <1%)

Veno-Occlusive Disease

- ALFA-0701
  - GO+DA vs DA risk difference: 4.6%
  - 6 patients treated with GO+DA, 3 fatal cases
  - 2 patients randomized to DA developed VOD after receiving GO for relapsed disease

- Meta-analysis and literature – there was a trend towards decreased imbalance of VOD vs the control arm with a decrease in dose of GO.

Hepatotoxicity

- ALFA-0701 –
  - Grade 3-4 bilirubin and AST elevations were more common with GO+DA
- 8 patients met criteria for potential Hy's Law cases
  - GO + DA: 5 cases, DA: 3 cases
  - GO: 1 death due to VOD, 1 death due to disease progression
  - DA: 1 patient recovered after discontinuing DA
- Meta-analysis – there was a trend for decreased imbalance in Grade 3-4 bilirubin and AST elevations vs the control arm with a decrease in dose of GO

Hemorrhage

ALFA-0701: Any Grade Hemorrhage Events[a]

	DA + GO		DA	
Phase of Regimen	**Number of patients**	**Proportion (%)**	**Number of patients**	**Proportion (%)**
Induction	114 / 131	87	97 / 137	71
Consolidation 1	55 / 91	60	35 / 103	26
Consolidation 2	40 / 64	63	46 / 107	43
Any Phases	119 / 131	91	107 / 137	78

[a] Based on SMQ Hemorrhages (excluding laboratory terms)

ALFA-0701: Grade ≥3 Hemorrhage Events[a]

	DA + GO Proportion (%)	DA Proportion (%)
Induction 1	18	9
Consolidation 1	5	0
Consolidation 2	6	0
Any Phase*	23	9

***Risk difference 13.4% (95% CI: 4.7, 22.1)**

[a] Based on SMQ Hemorrhages (excluding laboratory terms)

Note: ALFA-0701 had a higher overall risk difference of Grade ≥3 hemorrhage vs the control arm than any of the other protocols in the meta-analysis or literature review.

Prolonged Thrombocytopenia

ALFA-0701 - Time to Platelet Recovery and Incidence of Prolonged Thrombocytopenia by Treatment Phase

	Median time to Plt > 100,000 cells/mm^3 Days (25-75 percentile)		Prolonged thrombocytopenia* n (%)	
	GO+DA	DA	GO+DA	DA
Induction	34 (27-41)	29 (26-35)	24 (18%)	12 (9%)
Consolidation 1	34 (27-44)	27 (23-35)	22 (24%)	6 (6%)
Consolidation 2	42 (30-59)	34 (27-47)	24 (38%)	28 (26%)

*Prolonged thrombocytopenia = time to platelet recovery (>100,000 cells/mm^3) greater than 45 days

ALFA-0701 Safety Summary

- The safety analysis is limited by the retrospective nature of the collection of adverse events.
- 30-day mortality is not significantly different between the GO + DA arm vs the DA arm (4% vs 2%).
- Adverse events occurring more frequently with GO + DA vs DA were due to bleeding or infection, and differences in rates occurred during each phase of treatment.
- VOD occurred in 5% of patients randomized to GO vs 0% in the control arm.
- Hemorrhage events occurred more frequently with GO + DA than with DA during all phases of treatment.
- Platelet recovery appeared to be delayed in patients treated with GO + DA vs DA alone.

Issue for Discussion

- Do the available safety data allay the concerns about the safety of GO when added to DA for treatment of patients with newly-diagnosed AML?

ALFA-0701
Summary of Efficacy and Safety

- Fractionated GO in combination with DA showed a clinically meaningful EFS benefit without a corresponding OS benefit.
  - EFS: HR 0.56 (0.42, 0.76), $p < 0.001$
  - Median EFS: GO+DA 17.3 mos vs 9.5 mos DA alone
  - Overall survival: HR 0.81 (0.60, 1.09), p = NS
- EFS does not strongly correlate with OS in AML.
- Safety findings:
  - VOD 5% with GO
  - Prolonged platelet recovery time and higher Grade ≥3 hemorrhage with GO
  - Small difference in early mortality

Issues

- The GO 3 mg/m^2/dose fractionated schedule appears to be safer for use with DA than the previously studied 6 mg/m^2 dose.

- Could EFS be a reasonable endpoint for new therapies for treatment of patients with newly-diagnosed AML?

Voting Question

- Do the results of ALFA-0701 demonstrate a favorable risk:benefit for gemtuzumab ozogamicin 3 mg/m^2 days 1, 4 and 7 added to DA for patients with newly-diagnosed CD33-positive AML?


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