
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 7, 2015

MEI Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

000-50484
(Commission File Number)

51-0407811
(I.R.S. Employer Identification No.)

11975 El Camino Real, Suite 101, San Diego, California 92130
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (858) 792-6300

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events

On December 7, 2015, MEI Pharma, Inc. (the "Company"), presented the attached final results from an open-label Phase II clinical study of the Company's lead investigational drug candidate Pracinostat in combination with azacitidine in elderly patients with newly diagnosed acute myeloid leukemia ("AML") in an abstract entitled "Final Results from a Phase 2 Study of Pracinostat in Combination with Azacitidine in Elderly Patients with Acute Myeloid Leukemia (AML)," at the 57th American Society of Hematology (ASH) Annual Meeting and Exposition (the "ASH Conference").

A copy of the above referenced abstract is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The Company also presented the attached results from a randomized, double-blind, Phase II clinical study of the Company's lead investigational drug candidate Pracinostat in combination with azacitidine in patients with previously untreated myelodysplastic syndrome ("MDS") in an abstract entitled "A Randomized, Placebo-Controlled, Phase II Study of Pracinostat in Combination with Azacitidine (AZA) in Patients with Previously Untreated Myelodysplastic Syndrome (MDS)," at the ASH Conference.

A copy of the above referenced abstract is filed as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

On December 7, 2015, the Company issued a press release reporting the final results from the aforementioned open-label Phase II clinical study of the Company's lead investigational drug candidate Pracinostat in combination with azacitidine in elderly patients with newly diagnosed AML and announced its intent to initiate a Phase III registration study of Pracinostat and azacitidine in elderly patients with newly diagnosed AML in the second half of 2016.

A copy of the above referenced press release is filed as Exhibit 99.3 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Final Results from a Phase 2 Study of Pracinostat in Combination with Azacitidine in Elderly Patients with Acute Myeloid Leukemia (AML)
99.2	A Randomized, Placebo-Controlled, Phase II Study of Pracinostat in Combination with Azacitidine (AZA) in Patients with Previously Untreated Myelodysplastic Syndrome (MDS)
99.3	Press Release dated December 7, 2015

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MEI PHARMA, INC.

By: /s/ Daniel P. Gold

Daniel P. Gold

Chief Executive Officer

Dated: December 8, 2015

Index to Exhibits

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99.2	A Randomized, Placebo-Controlled, Phase II Study of Pracinostat in Combination with Azacitidine (AZA) in Patients with Previously Untreated Myelodysplastic Syndrome (MDS)
99.3	Press Release dated December 7, 2015

Final Results from a Phase 2 Study of Pracinostat in Combination with Azacitidine in Elderly Patients with Acute Myeloid Leukemia (AML)

G Garcia-Manero¹, E Atallah², B Medeiros³, M Arellano⁴, SK Khaled⁵, M Patnaik MD⁶, O Odenike⁷, SH Sayar⁸, MK Tummala⁹, P Patel¹⁰, L Maness-Harris¹¹, R Stuart¹², E Traer¹³, K Karamlou¹⁴ and A Yacoub¹⁵

¹ University of Texas MD Anderson Cancer Center, Houston, TX; ²Medical College of Wisconsin, Milwaukee, WI; ³Stanford Cancer Center, Stanford University, Stanford, CA; ⁴Winship Cancer Institute, Emory University, Atlanta, GA; ⁵City of Hope Comprehensive Cancer Center, Duarte, CA; ⁶Mayo Clinic, Rochester, MN; ⁷University of Chicago, Chicago, IL; ⁸Simon Cancer Center, Indiana University, Indianapolis, IN; ⁹Mercy Medical Research Institute, Springfield, MO; ¹⁰UT Southwestern Medical Center, Dallas, TX; ¹¹University of Nebraska Medical Center, Omaha, NE; ¹²Medical University of South Carolina, Charleston, SC; ¹³Oregon Health & Science University Center for Hematologic Malignancies, Portland OR; ¹⁴Bay Area Cancer Research Group, Pleasant Hill, CA; ¹⁵University of Kansas Cancer Center, Westwood, KS

Abstract #453

Aza + Pracinostat in AML: Introduction

- **Elderly AML patients, deemed unsuitable for intensive therapy, have limited treatment options**
- **Pracinostat is a potent hydroxamic acid based oral HDAC inhibitor selective for class I, II and IV isoforms**
- **The combination of azacitidine and pracinostat synergistic in vitro**
- **Pilot study of Aza + Pracinostat very high rate of complete and cytogenetic response**

Quintas-Cardama. ASH 2012; abstract #3821

Aza + Pracinostat in AML: Study Design

Elderly (Age \geq 65 years) Patients with Newly Diagnosed AML



Pracinostat + Azacitidine

- 50 patients enrolled at 15 sites in the U.S.
 - Last patient in on November 24, 2014
- Primary endpoint: CR + CRi + MLFS*
 - Secondary endpoints: ORR, CCyR, duration of response, EFS, OS, safety & tolerability
- Response assessments end of cycle 1 and 2, then every other cycle until CR is achieved or as clinically indicated

* Morphologic leukemia-free state (i.e., marrow CR)

Aza + Pracinostat in AML: Eligibility Criteria

- **Key Inclusion**
 - Age ≥ 65 years
 - Newly diagnosed de novo, secondary, or treatment-related AML
 - Intermediate or unfavorable-risk cytogenetics (SWOG classification: Slovak et al, 2000)
 - $\geq 20\%$ bone marrow blasts
 - Adequate renal, cardiac and liver function
 - QTcF ≤ 450 ms for males or ≤ 470 ms for females
- **Key Exclusion**
 - Acute promyelocytic leukemia (FAB M3); t(15;17), t(8;21), t(16;16), del(16q), or inv(16) karyotype
 - Candidate for intensive chemotherapy within the next 4 months
 - Active CNS disease

Aza + Pracinostat in AML: Treatment Regimen

- Azacitidine 7 days (days 1-7) 75 mg/m² IV/sq 28-day cycle
- Pracinostat 60 mg orally 3 days a week for 21 days on 28 day cycle
- Dose Modifications:
 - Reductions
 - Azacitidine for myelosuppression
 - Pracinostat: non-Heme toxicity
 - Delays (between or within cycles)
 - ≥Grade 3 hematologic toxicity in the absence of disease
 - ≥Grade 3 non-hematologic toxicity following maximal medical treatment

Aza + Pracinostat in AML: Patient Characteristics

	Pracinostat + Azacitidine n=50 %
Age, Years	
Median	76
Min-max	67-84
≥75	50
Male gender	58
AML classification (by WHO)	
Not otherwise specified	44
With myelodysplasia-related changes	40
With therapy-related myeloid neoplasms	10
With recurrent genetic abnormalities*	6
Prior MDS	
Yes	24
Secondary	10
No	66

* Excluding the provisional entities of AML with NPM1 and AML with CEBPA mutation (molecular data not available)

Aza + Pracinostat in AML: Patient Characteristics

	Pracinostat + Azacitidine (n=50) %
BM blasts	
Median	40
Min-max	20 – 89
ECOG PS	
0 - 1	84
2	16
Cytogenetic risk group	
Intermediate	54
Intermediate, cytogenetically normal	42
Poor*	42

*The poor risk category for MEI-004 was defined using Southwest Oncology Group (SWOG) and Medical Research Council Cytogenetic Risk Definitions.

The following cytogenetic abnormalities were included in this definition for this study: Del(5q)/-5, -7/del(7q), abnormal 3q, 9q, 20q, 17p, t(6;9), t(9;22) and complex karyotypes (≥ 3 unrelated abnormalities)

Aza + Pracinostat in AML: Patient Characteristics

	Pracinostat + Azacitidine (n=50)
WBC (x 10⁹/L)	
Median	2.6
Min-max	0.8 – 29.6
Hemoglobin (g/dL)	
Median	9.2
Min-max	6.5 – 14.9
Platelets (x 10⁹/L)	
Median	47
Min-max	11-643
Peripheral Blasts (x 10⁹/L)	
Median	0.2
Min-max	0 – 8.5
Serum Creatinine (mg/dL)	
Median	0.6
Min-max	0.2 – 1.5
Total Bilirubin (mg/dL)	
Median	0.9
Min-max	0.5 – 1.7

Aza+Pracinostat in AML: Patient Disposition

50 patients have been enrolled at 15 centers

FPI: December 24, 2013 LPI: November 24, 2014

	n=50 (%)
Number of Patients Alive	28 (56)
Number of Patients Active	11 (22)
Median Observation Time: 14.3 months	
Number of Patients Discontinued	39 (50)
<i>Reasons for discontinuation:</i>	
Progressive Disease	15 (30)
Adverse Event	11 (22)
Other*	13 (26)

* Includes patient and/or physician decision

Aza+ Pracinostat in AML: TEAE's in $\geq 25\%$ of Patients (all causality)

	All Grades (%), n=50	Grades 3-4 (%), n=50
Hematologic		
Febrile Neutropenia	24 (48.0)	20 (40.0)
Thrombocytopenia	22 (44.0)	22 (44.0)
Anemia	18 (36.0)	15 (30.0)
Neutropenia	17 (34.0)	17 (34.0)
Non-Hematologic		
Nausea	38 (76.0)	3 (6.0)
Constipation	35 (70.0)	0
Fatigue	30 (60.0)	15 (30.0)
Decreased Appetite	26 (52.0)	4 (8.0)
Diarrhea	23 (46.0)	2 (4.0)
Vomiting	18 (36.0)	2 (4.0)
Cough	17 (34.0)	0
Dyspnea	17 (34.0)	1 (2.0)
Dizziness	16 (32.0)	0
Hypokalemia	16 (32.0)	0
Edema Peripheral	15 (30.0)	0
Pyrexia	14 (28.0)	0
Back Pain	14 (28.0)	3 (6.0)
Insomnia	13 (26.0)	0

TEAE = treatment-emergent adverse events

Treatment Emergent Adverse Events Leading to Drug Discontinuation (n=11)

AE Term	Grade	Discontinuation (Cycle/Day)	Outcome
Intermittent Fatigue	1	4/28	Resolved
Acute Kidney Injury	1	3/7	Not Resolved
Peripheral Motor Neuropathy	3	3/15	Resolved
Intermittent Fatigue	3	4/28	Not Resolved
Parainfluenza	3	3/15	Resolved w Sequelae
Diverticulitis	3	7/15	Not Resolved
Prolonged QTc/AF	3	2/4	Resolved
Supraglottic Ulcer	3	7/15	Resolved w Sequelae
Sepsis	5	1/22	Fatal
Sepsis	5	1/22	Fatal
Sepsis	5	2/15	Fatal

AE, adverse event; AF, atrial fibrillation; QTc, Corrected QT interval

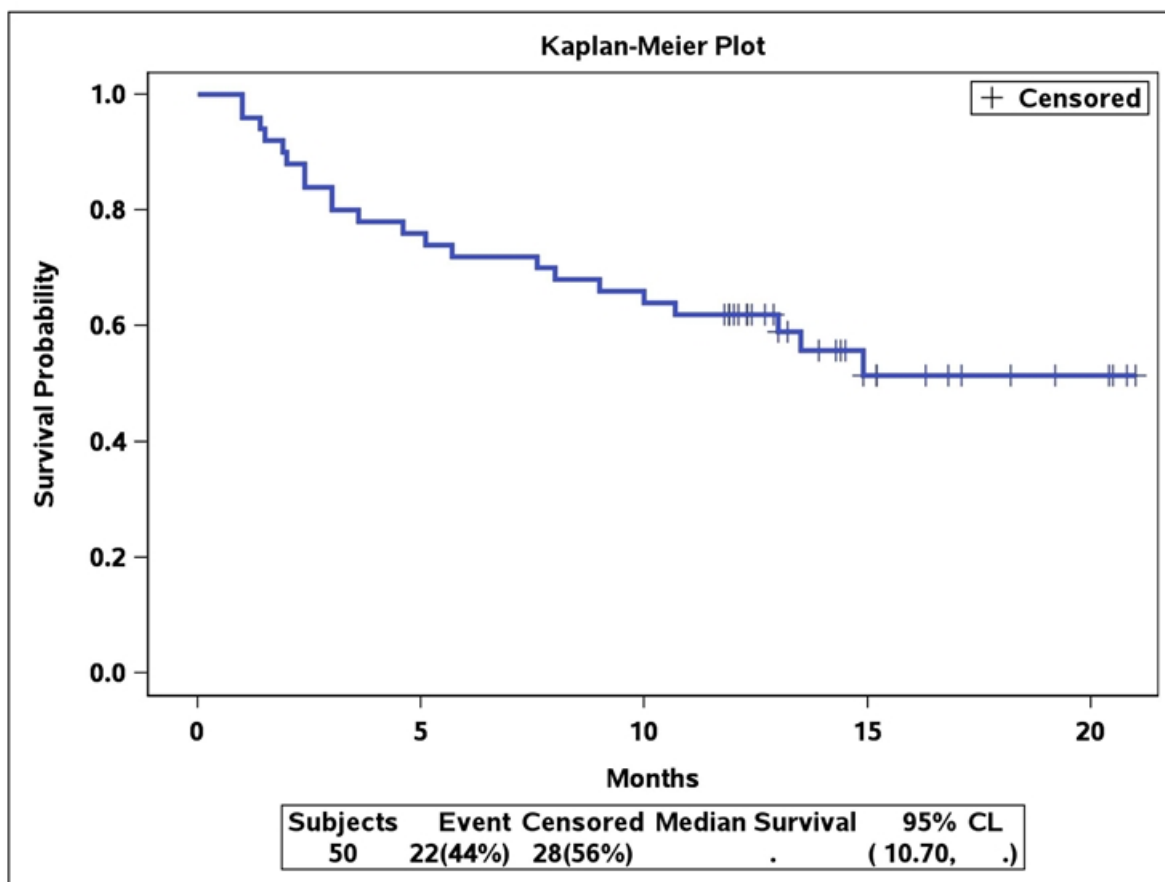
Aza + Pracinostat in AML: Response

Response Assessment			
	Cytogenetic Risk*		
	All n=50(%)	Intermediate n=27(%)	High n=21(%)
CR/Cri/MLFS (Primary endpoint)	28 (56)	17 (81)	11 (52)
CR	21 (42)	15 (56)	6 (29)
Cri	2 (4)	0 (0)	2 (10)
MLFS	5 (10)	2 (7)	3 (14)

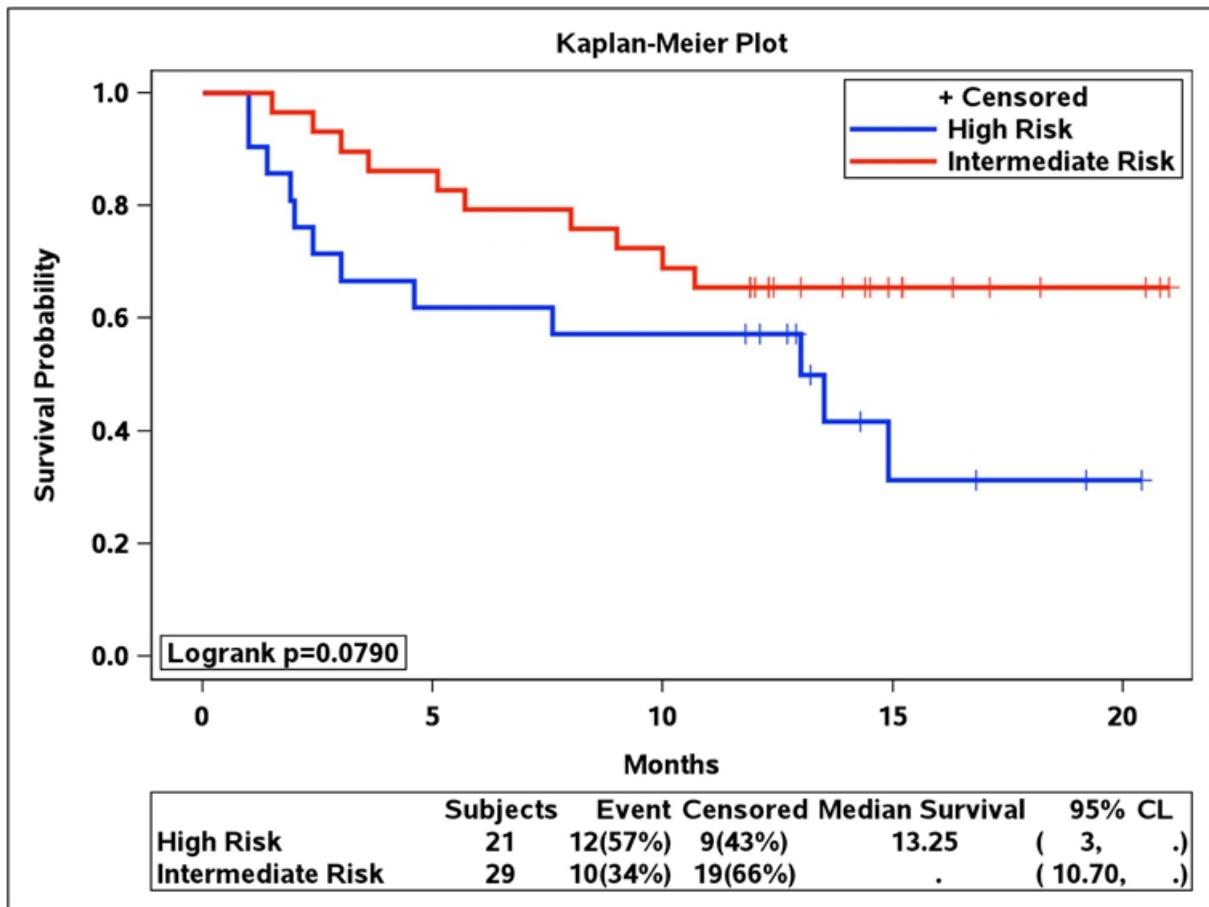
**2 not evaluable for cytogenetic risk assessment*

CR, complete response; Cri, complete response with incomplete blood count recovery; MLFS, morphologic leukemia free state;

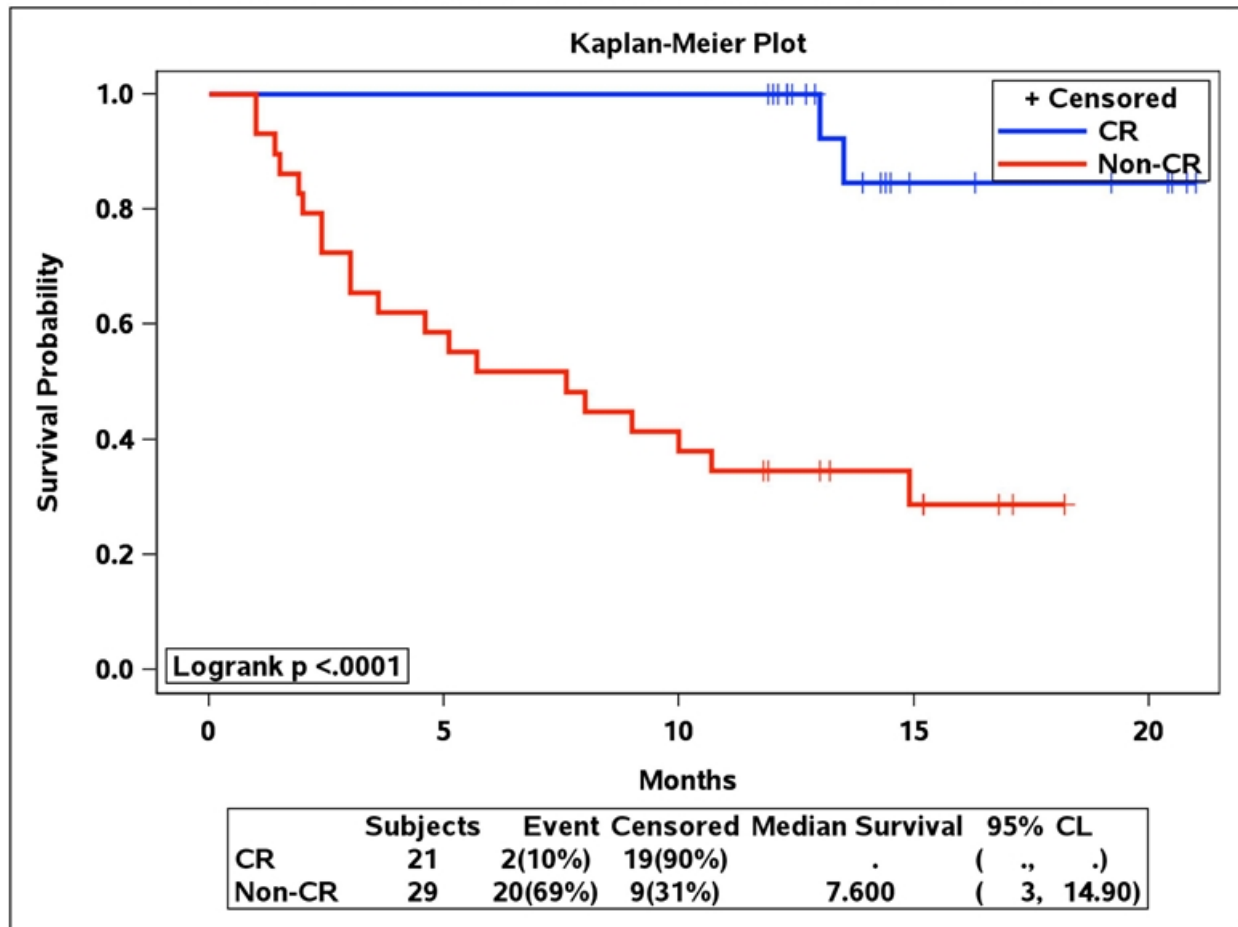
Aza + Pracinostat in AML: Overall Survival



Aza+ Pracinostat in AML OS by Cytogenetic Risk



Aza + Pracinostat in AML: Association of Survival with CR



MEI-004 vs. AZA-001: Baseline Characteristics

	MEI-004	AZA-001 ¹
	Pracinostat + Azacitidine (n=50)	Azacitidine (n=241)
Age, Years		
Median	76	75
Min-max	67-84	64-91
≥75	50	57
Male gender		
	58	57.7
AML classification (by WHO)		
Not otherwise specified	44	63.5
With myelodysplasia-related changes	40	31.
With therapy-related myeloid neoplasms	10	3.3
With recurrent genetic abnormalities*	6	2.1
Prior MDS		
Yes	24	20.3
Secondary	10	1.2
No	66	79.7

* Excluding the provisional entities of AML with NPM1 and AML with CEBPA mutation (molecular data not available)

¹ Dombret et al. *Blood*. 2015 Jul 16;126(3):291-9

MEI-004 vs. AZA-001: Baseline Characteristics

	MEI-004	AZA-001 ¹
	Pracinostat + Azacitidine (n=50)	Azacitidine (n=241)
BM blasts		
Median	40	70
Min-max	20 – 89	2 - 100
ECOG PS		
0 - 1	84	77.2
2	16	22.8
Cytogenetic risk group		
Intermediate	54	64.3
Intermediate, cytogenetically normal	42	46.9
Poor	42	35.3

¹ Dombret et al. *Blood*. 2015 Jul 16;126(3):291-9

MEI-004 vs. International Phase III Study of Azacitidine in Newly Diagnosed AML (AZA-001)

	AZA-001		MEI-004
	Conventional Care Regimens	Azacitidine	Pracinostat + Azacitidine
High-Risk Population¹	n=85	n=85	n=21
1-year survival estimate	14	30.9	57
Median overall survival	3.2 months	6.4 months	13.3 months
Overall Population²	n=247	n=241	n=50
CR rate	21.9	19.5	42
60-day mortality rate	18.2	16.2	10
1-year survival rate	34.2	46.5	62
Event-free survival	4.8 months (3.8-6.0)	6.7 months (5.0-8.8)	7.7 months (0.9 – 21.2+)
Duration of response	12.3 months (9.0-17.0)	10.4 months (7.2-15.2)	11.2 months (2.1-19.7+)
Median overall survival	6.5 months (95%CI: 5.0-8.6)	10.4 months (95%CI: 8.0-12.7)	>14 months (95%CI: 10.7-NR)

¹ Döhner et al. ASH 2014. Abstract 621

² Dombret et al. Blood. 2015 Jul 16;126(3):291-9

Aza+ Pracinostat in AML: Conclusions

- **Combination of Aza+ Pracinostat is safe in elderly AML**
- **High response rate compared to single agent Azacitidine**
- **Potential for prolongation of survival**
- **Apparent correlation of CR and survival in this low intensity therapy**

- **Future plans:**
- **Additional analysis genomic annotation**
- **Confirmation in planned phase III trial**

Acknowledgements

This work was supported by MEI Pharma, Inc.

A Randomized, Placebo-Controlled, Phase II Study of Pracinostat in Combination with Azacitidine (AZA) in Patients with Previously Untreated Myelodysplastic Syndrome (MDS)

Guillermo Garcia-Manero, MD¹, Jesus G. Berdeja, MD², Rami S. Komrokji, MD³, James Essell, MD⁴, Roger M. Lyons, MD⁵, Michael Maris, MD⁶, Amy E. DeZern, MD, MHS⁷, Mikkael A. Sekeres, MD, MS⁸ and Gail J Roboz, MD⁹

¹Department of Leukemia, The University of Texas M.D. Anderson Cancer Center, Houston, TX, Houston, TX; ²Sarah Cannon Research Institute, Nashville, TN; ³H. Lee Moffitt Cancer Center, Tampa, FL; ⁴Oncology/Hematology Care, Cincinnati, OH; ⁵Cancer Care Center of South Texas, San Antonio, TX; ⁶Colorado Blood Cancer Institute, Denver, CO; ⁷Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, Baltimore, MD; ⁸Leukemia Program, Cleveland Clinic, Cleveland, OH; ⁹Joan and Sanford I. Weill Department of Medicine, Weill Cornell Medical College, New York, NY

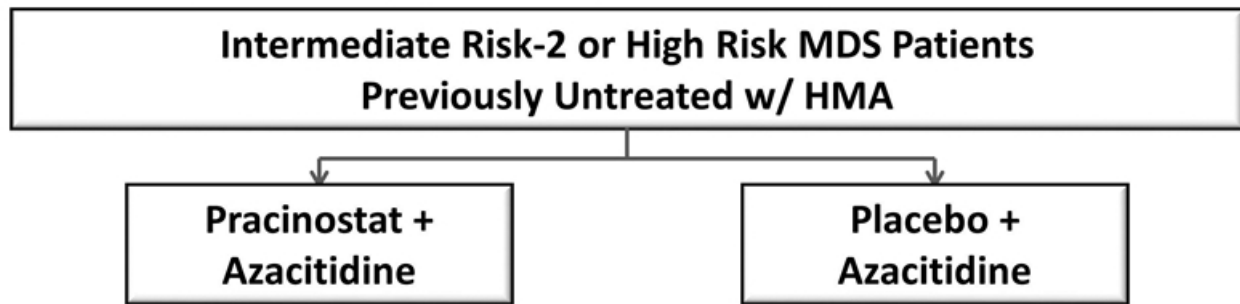
Abstract #911

Aza + Pracinostat in MDS: Introduction

- **Combination studies with HDAC inhibitors plus HMA has the potential to improve outcomes in MDS**
- **Pracinostat is a potent hydroxamic acid based oral HDAC inhibitor selective for class I, II and IV isoforms**
- **A pilot study of Pracinostat in combination with azacitidine (AZA) in higher risk MDS showed a CR/CRi rate of 89%¹**
- **This study was designed to assess clinical activity of this combination in multi-center environment**

¹ *Quintás-Cardama et al. ASH 2012: Abstract 3821*

Aza + Pracinostat in MDS: Study Design



- **102 evaluable patients: one-to-one randomization**
 - **Primary analysis population defined as all randomized and treated patients**
 - **Randomization stratified by IPSS risk group with a planned sample size of 100**
- **24 sites in the U.S. activated, 19 sites enrolled patients**
- **FPI: June 17, 2013; LPI: Aug 29, 2014**

Aza + Pracinostat in MDS: Study Design

- **Primary endpoint: Confirmed CR within 6 cycles, based on IWG criteria (Cheson 2006)**
 - CR rates calculated for each group with 95% CI's and compared using Chi-square testing
 - BMBx and aspirate as well as a CBC with differential were required at the end of Cycles 2 and 6
 - CBC with differential was required for confirmation of CR or PR Cycle Day 1, 8 weeks following the initial report of response
- **Secondary endpoints: ORR, HI, clinical benefit rate, duration of response, PFS, rate of leukemic transformation, OS, safety & tolerability**
 - Time-to-event secondary endpoints (PFS, EFS, OS) analyzed by Kaplan-Meier and hazard ratios calculated

Aza + Pracinostat in MDS: Inclusion Criteria

- **Age ≥ 18 years**
- **Morphological diagnosis of MDS (any FAB subtype that is classified as intermediate 2 (1.5 to 2.0 points) or high risk (≥ 2.5 points) according to IPSS**
- **Previously untreated with hypomethylating agents**
- **Peripheral WBC count of $< 20,000 /\mu\text{L}$**
- **ECOG Performance status ≤ 2**
- **Adequate organ function**

Aza + Pracinostat in MDS: Exclusion Criteria

- **Received the following prior to administration of study treatment**
 - Investigational agent within 14 days or 5 half-lives
 - Hydroxyurea within 48 hours prior to first study treatment
 - Hematopoietic growth factors at least 7 days prior
- **Treatment with the HDAC inhibitors**
- **Cardiopulmonary function abnormalities**
 - Current unstable arrhythmia requiring treatment
 - History of symptomatic congestive heart failure
 - History of myocardial infarction within 6 months of enrollment
 - Current unstable angina
- **Evidence of central nervous system involvement**
- **GI tract disease, causing the inability to take oral medication**
- **Active infection with human immunodeficiency virus or hep B or C**
- **Presence of a malignant disease within the last 12 months**

Aza + Pracinostat in MDS: Treatment Regimen

- **Azacitidine: 75 mg/m² 7 days I.V./sq every 28 days**
- **Pracinostat or placebo P.O., 60 mg 3 days/week for 3 weeks**
- **Cycles repeated every 28 days until disease progression, lack of benefit, or intolerance**

Aza + Pracinostat in MDS: Study Status

Study Status	
Number of Sites	19
Number of Patients Enrolled	102
FPI	17-Jun-2013
LPI	29-Aug-2014
Last Patient Completed	11-May-2015

Aza + Pracinostat in MDS: Patient Characteristics

	Azacitidine + Pracinostat n=(51)	Azacitidine + Placebo (n=51)
Age	70 (26-90)	69 (43-83)
Gender (male/female)	32/19	38/13
ECOG		
0	16	18
1	31	28
IPSS @ baseline		
Int-2	34	34
High Risk	17	17
FAB		
RAEB (-1/-2)	36 (12/21)	36(8/28)
RAEB-T	6	2
CMML	3	5

Aza + Pracinostat in MDS: Patient Characteristics

	Pracinostat + Azacitidine (n=51)	Pracinostat + Placebo (n=51)
WBC (x 10⁹/L)		
Median	2.3	2.5
Min-max	1 – 15	1 – 47
Hemoglobin (g/dL)		
Median	9.2	9.2
Min-max	7 – 13	7 – 13
Platelets (x 10⁹/L)		
Median	39.0	53.5
Min-max	2 – 1370	15 – 701
Peripheral Blasts (%)		
Median	0.0	0.0
Min-max	0 – 12	0 – 33
Serum Creatinine (mg/dL)		
Median	1.0	0.9
Min-max	0 – 2	1 – 2
Total Bilirubin (mg/dL)		
Median	0.7	0.7
Min-max	0 – 2	0 – 1

Aza + Pracinostat in MDS: Adverse Events (>10%)

	All Grades		≥ Grade 3	
	Pracinostat	Placebo	Pracinostat	Placebo
Hematologic	77%	63%	77%	59%
Anemia	31%	39%	20%	33%
Febrile Neutropenia	33%	18%	33%	18%
Neutropenia	45%	33%	45%	33%
Thrombocytopenia	49%	29%	47%	26%
Non-Hematologic				
Nausea	69%	57%	4%	2%
Fatigue	55%	51%	24%	0%
Constipation	53%	53%	2%	2%
Vomiting	47%	33%	4%	2%
Dyspnoea	43%	29%	8%	0%
Diarrhoea	39%	33%	4%	2%
Peripheral Oedema	43%	24%	4%	0%
Dizziness	37%	29%	4%	2%
Pyrexia	26%	28%	4%	0%
Cough	22%	31%	0%	0%
Decreased Appetite	33%	22%	0%	0%
Myalgia	20%	14%	2%	2%
Dehydration	24%	12%	8%	0%
Pneumonia	18%	14%	16%	10%
Headache	20%	18%	0%	0%
QTc Prolongation	2%	2%	0%	0%

Aza + Pracinostat in MDS: Summary of Dose Modifications by Treatment Arm

	PRACINOSTAT / PLACEBO		AZACITIDINE	
	Pracinostat	Placebo	Pracinostat	Placebo
Drug Withdrawn	18%	8%	2%	2%
Dose Reduced	10%	6%	18%	6%
Dose Interrupted	63%	69%	69%	69%

Aza + Pracinostat in MDS: Summary of Response

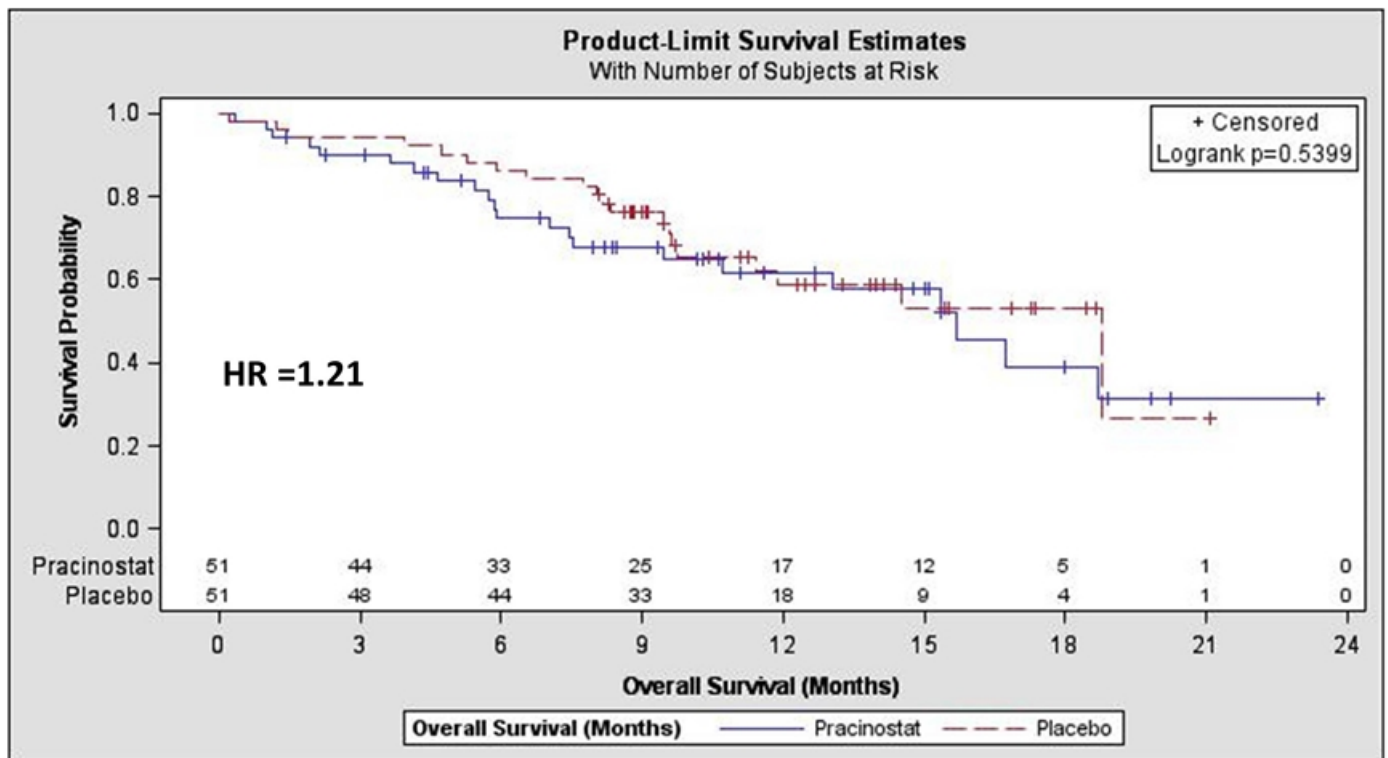
Azacitidine

	Pracinostat	Placebo
CR, within 180 days	18%	33%
Best Response		
Complete Remission	20%	33%
Partial Remission	0%	0%
Marrow CR	28%	22%
Stable Disease	26%	29%
Progressive Disease	6%	6%
Not evaluable	22%	10%

Aza + Pracinostat in MDS: Summary of Response

RESPONSE	Pracinostat	Placebo
Hematological improvement	35%	55%
Erythroid response (HI – E)	28%	45%
Platelet response (HI – P)	31%	53%
Neutrophil response (HI – N)	26%	39%
Clinical benefit rate (CR + PR + HI + mCR)	53%	63%
Cytogenetic response	42%	55%
Cytogenetic CR	24%	29%
Cytogenetic PR	18%	26%

Aza + Pracinostat in MDS: Overall Survival

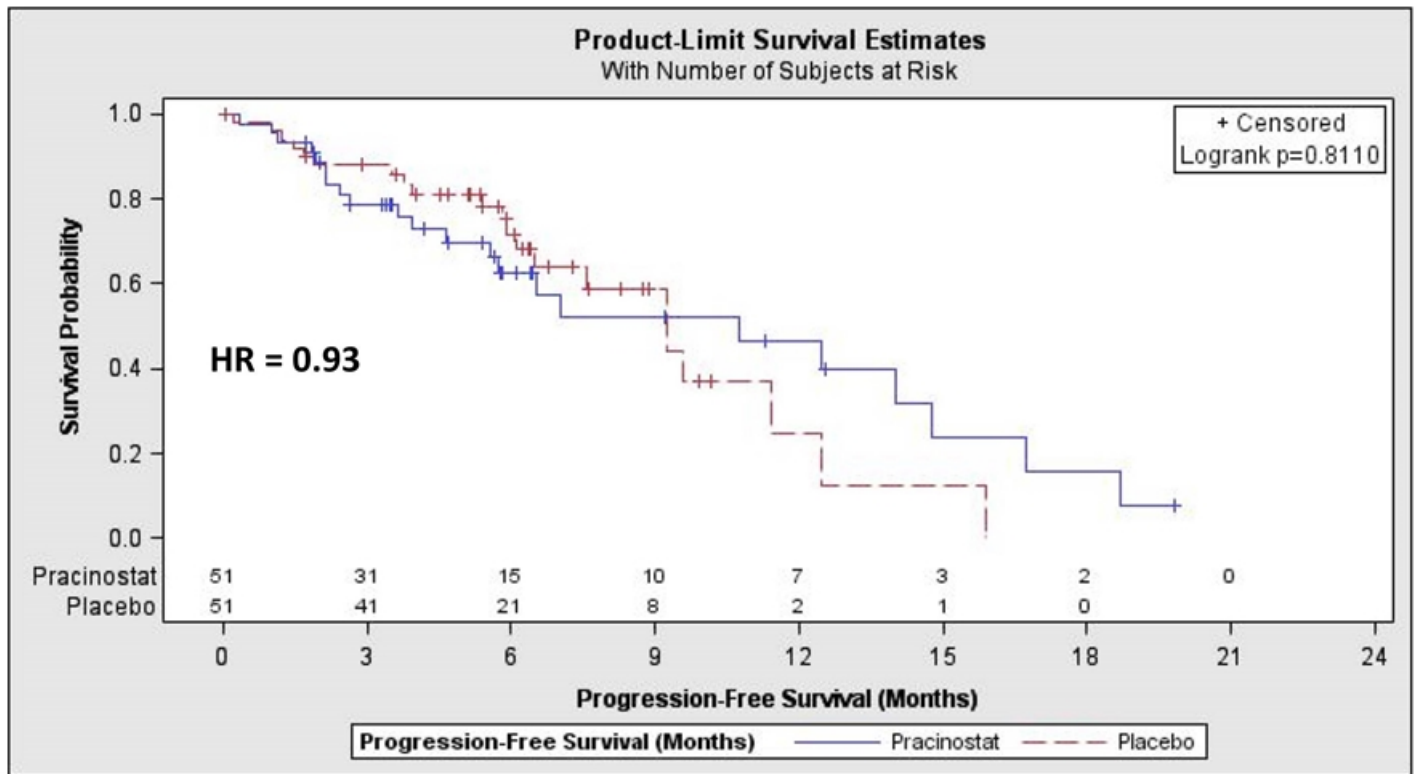


Median Follow Up = 15.4 months

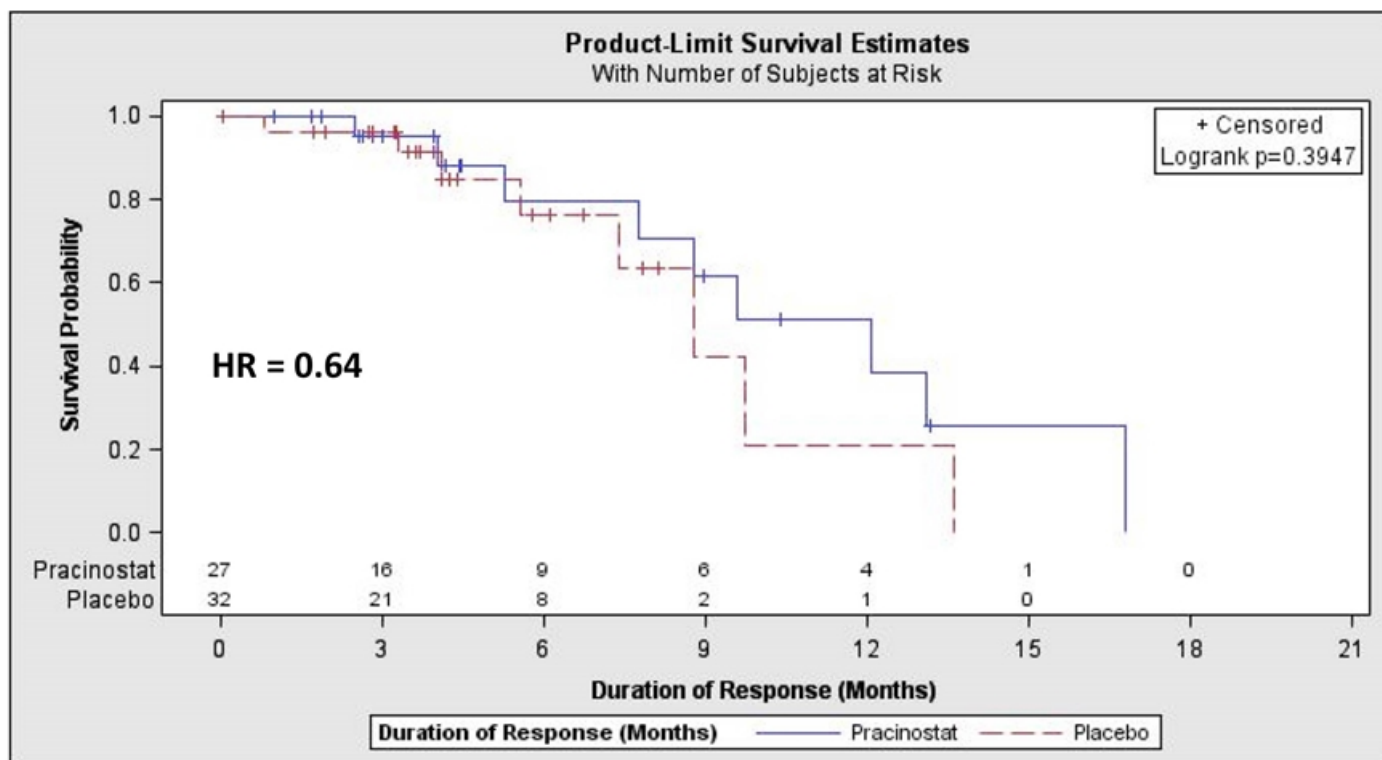
One Year Survival: Pracinostat = 57.1%

Placebo = 57.4%

Aza + Pracinostat in MDS: Progression Free Survival



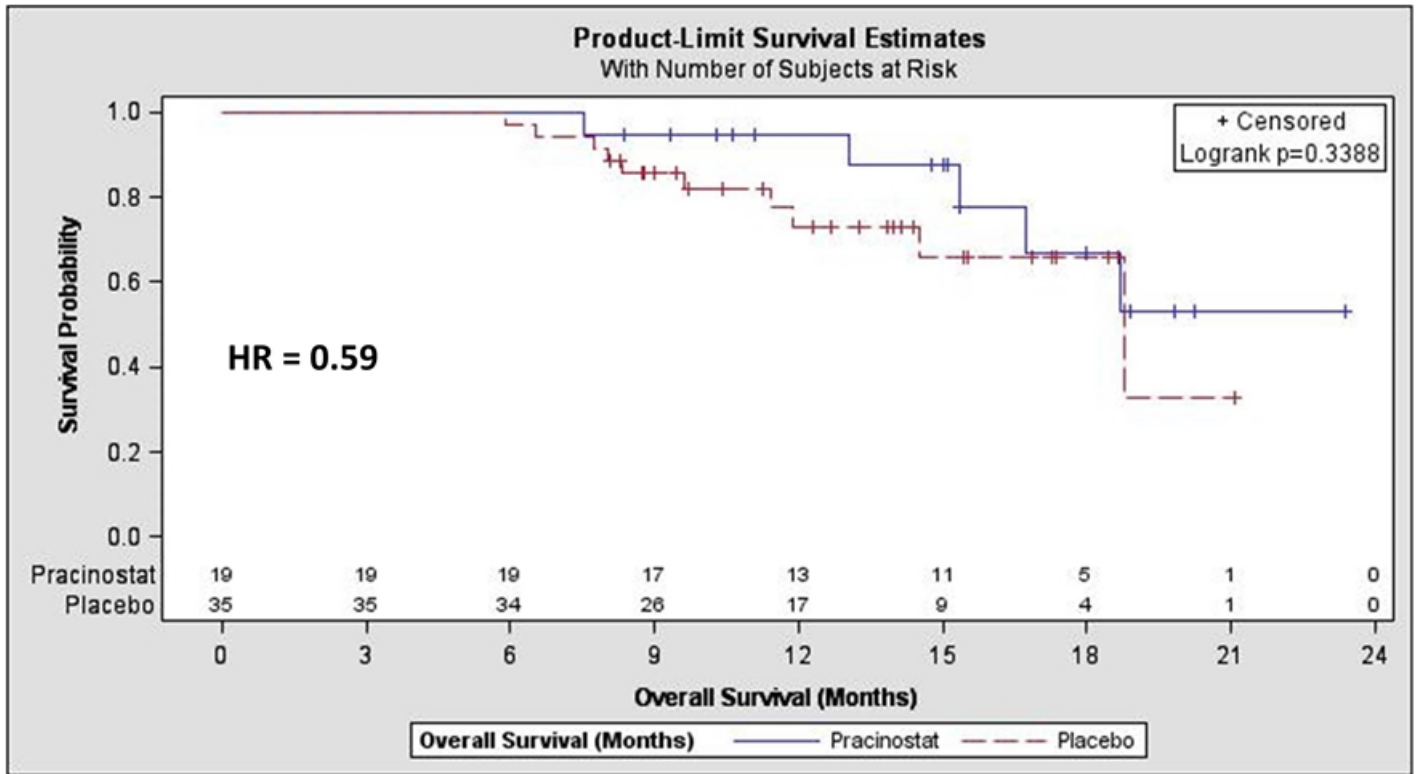
Aza + Pracinostat in MDS: Duration of Response



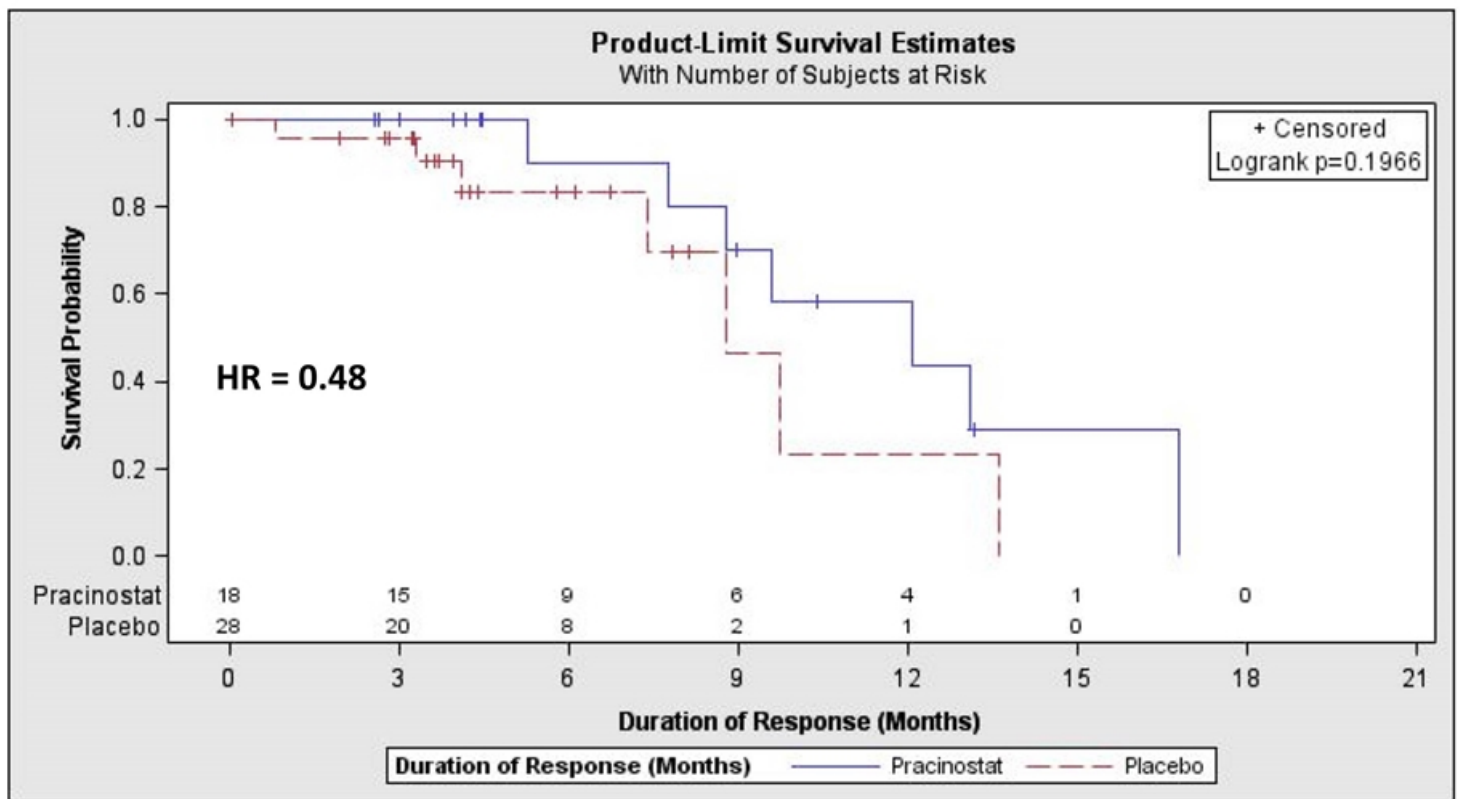
Aza + Pracinostat in MDS: Exploratory Sensitivity Analyses

Sensitivity analyses suggest that patients that tolerate treatment with Pracinostat plus azacitidine for > 4 cycles appear to derive benefit compared to azacitidine alone

Aza+ Pracinostat in MDS: OS For Patients On Study For 4 or More Cycles



Aza+Pracinostat in MDS: DR For Patients On Study For 4 or More Cycles



MEI-003 vs. North American Intergroup Randomized Phase 2 MDS Study (SWOG S1117)¹

SWOG S1117	Azacitidine (n=92)	Vorinostat + Azacitidine (n=91)
CR rate	24%	15%
Off Tx due to adverse events	9%	24%
On Tx > 6 months (median)	Relapse-free survival: 7 months	Relapse-free survival: 13 months (P = .11)

MEI-003	Azacitidine (n=51)	Pracinostat + Azacitidine (n=51)
CR rate	33%	20%
Off Tx due to adverse events	10%	26%
On Tx > 4 cycles (n=54)	HRs: OS=0.59, DR=0.48, PFS=0.37	

¹ Sekeres et al. ASH 2014: LBA - 5

Aza + Pracinostat in MDS: Conclusions

- **Pracinostat failed to improve the clinical effectiveness of AZA in this population of higher risk MDS**
- **Pracinostat resulted in more toxicity when added to AZA**
 - **Grade 3 Fatigue, 24% vs. 0%**
 - **Febrile Neutropenia, 33% vs.18%**
 - **Thrombocytopenia, 47% vs. 26%**
- **This toxicity led to more, and earlier, drug discontinuation in the Pracinostat group**
 - **Drug discontinuations for adverse events, 26% vs 10%**
 - **Not evaluable for response, 22% vs 10%**
- **Exploratory analyses suggest that patients able to tolerate Pracinostat for at least 4 cycles may derive benefit**
- **Need consider alternative doses/schedules**

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MEI Pharma Announces Positive Results from Phase II Study of Pracinostat in Acute Myeloid Leukemia, Plans to Initiate Phase III Registration Study

San Diego – December 7, 2015 – MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, today announced positive results from a Phase II study of its investigational drug candidate Pracinostat in combination with azacitidine (marketed as Vidaza®) in elderly patients with newly diagnosed acute myeloid leukemia (AML). The results were presented earlier today at the American Society of Hematology (ASH) Annual Meeting in Orlando. A copy of the presentation is now available at www.meipharma.com.

According to the oral presentation by principal investigator Dr. Guillermo Garcia-Manero, MD Anderson Cancer Center, 28 of the 50 patients in the study (56%) achieved the primary endpoint of complete response (CR) plus complete response with incomplete blood count recovery (CRi) plus morphologic leukemia-free state (MLFS), including 21 patients (42%) who achieved a CR. Notably, 19 of the 21 patients who achieved a CR are still alive with a 100% one-year survival rate among all CR patients, indicating a correlation between CR and survival with this low intensity therapy.

Median overall survival for all 50 patients in the study has not been reached, with 28 patients still living and a median observation time of 14.3 months. These data compare favorably to a recent international Phase III study of azacitidine (AZA-001)¹, which showed a median overall survival of 10.4 months with azacitidine alone and a CR rate of 19.5% in a similar patient population. Median survival among patients with high-risk cytogenetics in this study (n=21) was 13.3 months, more than double the median survival of the high-risk population in the AZA-001 study (6.4 months).

“These are impressive results by virtually any measure for a group of patients in dire need of effective new treatment options,” said Dr. Garcia-Manero. “Not only did we observe a high rate of responses, but many occurred rapidly and continued to improve with ongoing therapy. Most importantly, we are seeing an encouraging trend in overall survival, particularly among patients who achieved a complete response. These data clearly support further development of Pracinostat in combination with azacitidine for the treatment of elderly patients with AML.”

The open-label study enrolled a total of 50 patients at 15 centers across the U.S. Median age in the study was 76 years. Patients received 60 mg of Pracinostat orally three times a week for three weeks followed by one week of rest and 75 mg/m² of azacitidine via subcutaneous

¹ Dombret H et al. International phase 3 study of azacitidine vs conventional care regimens in older patients with newly diagnosed AML with >30% blasts. Blood. 2015 May 18.

injection or intravenous infusion for the first seven days of each 28-day cycle. The combination of Pracinostat and azacitidine was generally well tolerated in the study, with no unexpected toxicities. The most common grade 3/4 treatment-emergent adverse events reported in >10% of all patients included febrile neutropenia, thrombocytopenia, anemia and fatigue.

“We are very excited about our growing body of AML data, which continues to exceed expectations and guide us forward with the development of this program,” said Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. “Over the past several months we have learned that our randomized study of Pracinostat and azacitidine in myelodysplastic syndrome (MDS) was hindered by a high rate of discontinuations due to adverse events, but appeared to show a benefit for patients who were able to tolerate treatment for at least four cycles compared to azacitidine alone. The results from our AML study demonstrate that many patients are achieving responses within the first two cycles, with fewer discontinuations overall due to adverse events compared to our MDS study, suggesting a prudent development path forward for the combination.

“Based on these findings,” continued Dr. Gold, “we will now begin to prepare for a Phase III registration study of Pracinostat and azacitidine in elderly patients with newly diagnosed AML, which we plan to initiate in the second half of 2016. We look forward to sharing more information regarding the design of this study in the months ahead.”

About Pracinostat

Pracinostat is a potent oral inhibitor of a group of enzymes called histone deacetylases, or HDACs. HDACs belong to a larger set of proteins collectively known as epigenetic regulators that can alter gene expression by chemically modifying DNA or its associated chromosomal proteins. Abnormal activity of these regulators is believed to play an important role in cancer and other diseases. Pracinostat has been tested in multiple Phase I and Phase II clinical studies in advanced hematologic diseases and solid tumor indications. The results of these studies suggest that Pracinostat has potential best-in-class pharmacokinetic properties when compared to other oral HDAC inhibitors, with side effects often associated with drugs of this class, including fatigue and myelofibrosis. Pracinostat has not been approved for commercial distribution in the U.S.

MEI Pharma owns exclusive worldwide rights to Pracinostat.

About AML

Acute myeloid leukemia (also known as acute myelogenous leukemia) is the most common acute leukemia affecting adults, and its incidence is expected to continue to increase as the population ages. The American Cancer Society estimates about 20,830 new cases of AML per year in the U.S., with an average age of about 67 years. Treatment options for AML remain virtually unchanged over the past 30 years. Front line treatment consists primarily of chemotherapy, while the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology recommend azacitidine or decitabine (marketed as Dacogen®) as low intensity treatment options for AML patients over the age of 60 who are unsuitable for induction chemotherapy.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based oncology company focused on the clinical development of novel therapies for cancer. The Company's portfolio of drug candidates includes Pracinostat, a potential best-in-class, oral HDAC inhibitor that is expected to enter a Phase III registration study in combination with azacitidine for the treatment of elderly patients with newly diagnosed AML in the second half of 2016. The Company is also developing ME-344, a novel mitochondrial inhibitor that has shown evidence of clinical activity in refractory solid tumors, and ME-401 (formerly PWT143), a highly selective, oral PI3K delta inhibitor that is expected to enter a Phase Ib study for the treatment of B-cell malignancies in the first half of 2016. For more information, please visit www.meipharma.com.

Under U.S. law, a new drug cannot be marketed until it has been investigated in clinical trials and approved by the FDA as being safe and effective for the intended use. Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our failure to successfully commercialize our product candidates; costs and delays in the development and/or FDA approval, or the failure to obtain such approval, of our product candidates; uncertainties or differences in interpretation in clinical trial results; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products; competitive factors; our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business; our inability to operate our business without infringing the patents and proprietary rights of others; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.