

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

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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 6, 2014

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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))

**Item 8.01. Other Events**

On December 6, 2014, MEI Pharma, Inc. (the “Company”), presented the attached interim data 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 a poster entitled “Pracinostat in Combination with Azacitidine Produces a High Rate and Rapid Onset of Disease Remission in Patients with Previously Untreated Acute Myeloid Leukemia (AML),” at the 56th American Society of Hematology (ASH) Annual Meeting and Exposition.

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

On December 8, 2014, the Company issued a press release reporting clinical activity in its Phase II study of Pracinostat in front line AML, preparations for a Phase III registration study based on such clinical data and recent discussions with the U.S. Food and Drug Administration and plans for unblinding its randomized, placebo-controlled Phase II study and reporting top line data in March 2015.

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

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

<b>Exhibit No.</b>	<b>Description</b>
99.1	Poster Presented at ASH 2014 Annual Meeting and Exposition
99.2	Press Release dated December 8, 2014

## 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, 2014

**Index to Exhibits**

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99.1	Poster Presented at ASH 2014 Annual Meeting and Exposition
99.2	Press Release dated December 8, 2014

# Pracinostat in Combination With Azacitidine Produces a High Rate and Rapid Onset of Disease Remission in Patients With Previously Untreated Acute Myeloid Leukemia

Guillermo Garcia-Manero, MD<sup>1</sup>; Ehab Atallah, MD<sup>2</sup>; Olatoyosi Odenike, MD<sup>3</sup>; Bruno C. Medeiros, MD<sup>4</sup>; Jorge Cortes, MD<sup>1</sup>; Vanessa Esquibel<sup>5</sup>; Steven Cha, MD<sup>5</sup>; Samer K. Khaled, MD<sup>6</sup>

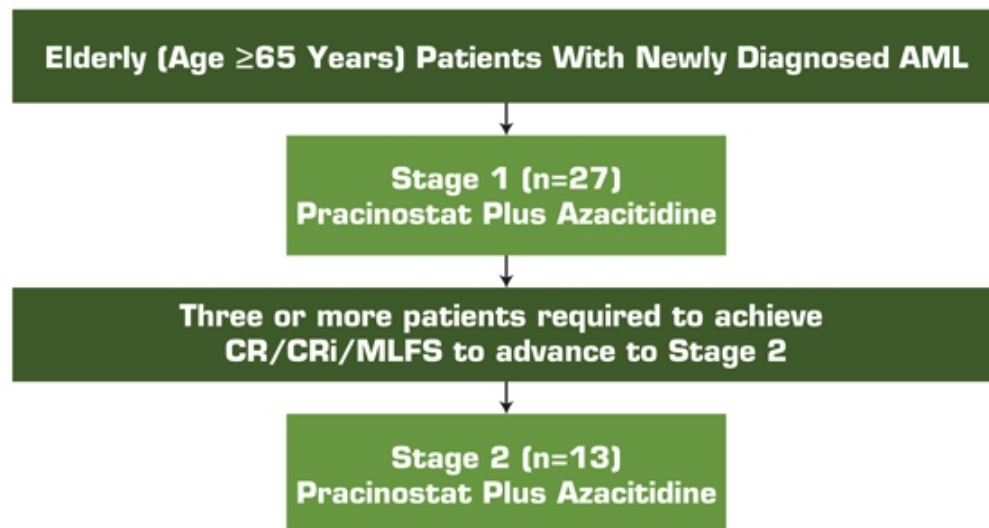
<sup>1</sup>Department of Leukemia, University of Texas MD Anderson Cancer Center, Houston, TX; <sup>2</sup>Department of Hematology/Oncology, Medical College of Wisconsin, Milwaukee, WI; <sup>3</sup>Section of Hematology/Oncology, University of Chicago, Chicago, IL; <sup>4</sup>Division of Hematology/Oncology, Stanford Cancer Center, Stanford, CA; <sup>5</sup>MEI Pharma Inc, San Diego, CA; <sup>6</sup>Department of Hematology/Hematopoietic Cell Transplantation, City of Hope, Duarte, CA

## BACKGROUND

- Pracinostat is a potential best-in-class histone deacetylase inhibitor (HDACi)
- Potent inhibitor of Class I, II, and IV isoenzymes
  - SB991, the major *in vivo* metabolite of pracinostat, demonstrates higher activity than pracinostat
  - Combined pharmacokinetics of pracinostat and SB991 predicts on-target IC<sub>50</sub> activity for HDAC1 >24 hours
- A Phase I study of single-agent pracinostat demonstrated clinical activity in patients with acute myeloid leukemia (AML)
- A pilot Phase II study of pracinostat in combination with azacitidine in higher-risk myelodysplastic syndrome (MDS) demonstrated a complete response (CR) + complete response with incomplete blood count recovery (CRi) rate of 89% (Proc ASH, 2012:3821)
- We report interim data from the ongoing MEI-004 Phase 2 clinical trial testing the safety and efficacy of pracinostat in combination with azacitidine in elderly patients with previously untreated AML

## METHODS

Figure 1. Study Design



AML, acute myeloid leukemia; CR, complete response; CRi, complete response with incomplete blood count recovery; MLFS, morphologic leukemia-free state.

### Treatment Regimen

- Pracinostat 60 mg is administered orally 3 days a week (days 1, 3, and 5 of each week) for 21 days of each 28-day cycle
- Azacitidine is administered subcutaneously or intravenously on days 1-7 or days 1-5 and 8-9 (per site preference) of each 28-day cycle
- Dose Modifications
  - Reductions
    - Begin with azacitidine which may be reduced to 75% of the starting dose
    - Subsequent reduction to 45 mg of pracinostat is allowed
  - Delays (between or within cycles)
    - Indicated for treatment-related <sup>3</sup>Grade 3 hematologic toxicity in the absence of disease
    - Indicated for treatment-related <sup>3</sup>Grade 3 non-hematologic toxicity following maximal medical treatment

### Eligibility Criteria

- Key Inclusion
  - Age <sup>3</sup>65 years
  - Newly diagnosed de novo, secondary, or treatment-related AML with intermediate or unfavorable-risk cytogenetics based on the Southwest Oncology Group (SWOG) classifications (Slovak et al, 2000)
  - <sup>3</sup>20% bone marrow blasts
  - Adequate renal, cardiac, and liver function
  - QTcF £450 ms for males or QTcF £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 (induction chemotherapy, bone marrow, or stem cell transplant) within the next 4 months
- | Active central nervous system (CNS) disease

### **Study Evaluations**

- Primary endpoint: complete response (CR) + complete response with incomplete blood count recovery (CRI) + morphologic leukemia-free state (MLFS)
- Secondary Endpoints
  - | Overall response rate (CR + CRi + partial response [PR] + PR with incomplete blood count recovery [PRi] + MLFS)
  - | Complete cytogenetic response (CRc) + molecular complete remission (CRm)
  - | Duration of response
  - | Event-free survival (EFS)
  - | Overall survival (OS)
  - | Assess the tolerability and adverse event profile
- Response assessments end of cycle 1 or 2, and then every other cycle until CR is achieved or as clinically indicated

**Presented at the 56th American Society of Hematology Annual Meeting, December 6-9, 2014, San Francisco, California**

# Pracinostat in Combination With Azacitidine Produces a High Rate and Rapid Onset of Disease Remission in Patients With Previously Untreated Acute Myeloid Leukemia

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## RESULTS

— At time of evaluation 41 patients have been enrolled at 15 centers

⌋ Enrollment ongoing since December 25, 2013

**Table 1. Patient Disposition**

	N=41
Number of Patients Active	25
Number of Patients Discontinued	16
Reasons for Discontinuation	
Progressive disease	6
Adverse event	6
Other	4

Other – includes patient or physician decision.

**Table 2. Baseline Characteristics**

	N=41
Age (years)	
Median	76
Range	69-84
Gender, n (%)	
Male	24 (59)
Female	17 (41)
AML Disease Status, n (%)	
Newly diagnosed de novo	29 (71)
Secondary (AHD and treatment related)	12 (29)
ECOG Status, n (%)	
0-1	33 (80)
2	8 (20)
Bone Marrow Blasts at Baseline	
Median	38
20-29% Range, n (%)	13 (32)
30-50% Range, n (%)	15 (36)
>50% Range, n (%)	13 (32)
Cytogenetic Risk Category, n (%)	
Intermediate	23 (56)
High	17 (41)
Not Evaluable	1 (3)

AHD, antecedent hematologic disorder; AML, acute myeloid leukemia; ECOG, Eastern Cooperative Oncology Group.

**Table 3. Treatment Emergent Adverse Events All Causality in <sup>3</sup>10% of Patients**

	All Grades (%) N=41	Grades 3-4 (%) N=41
<b>Hematologic</b>		
Febrile Neutropenia	12 (29)	10 (24)
Thrombocytopenia	11 (27)	10 (24)
Anemia	9 (22)	4 (10)
Neutropenia	4 (10)	4 (10)
Leukopenia	4 (10)	1 (2)
<b>Non-Hematologic</b>		
Nausea	18 (44)	2 (5)
Constipation	17 (41)	0
Fatigue	17 (41)	4 (10)
Peripheral Edema	6 (15)	0
Vomiting	6 (15)	0
Diarrhea	5 (12)	1 (2)
Dizziness	5 (12)	0
Headache	5 (12)	1 (2)
Hypokalemia	5 (12)	0
Pyrexia	4 (10)	0
Cellulitis	4 (10)	4 (10)
Rash	4 (10)	0
Hypotension	4 (10)	0
Cough	4 (10)	0
Dyspnea	4 (10)	0
QTc Prolongation*	2 (5)	1 (2)

\*QTc events were seen in <10% of patients, however are noted here.

# Pracinostat in Combination With Azacitidine Produces a High Rate and Rapid Onset of Disease Remission in Patients With Previously Untreated Acute Myeloid Leukemia

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**Table 4. Treatment-Emergent Adverse Events Leading to Drug Discontinuation**

AE Term	Grade	Discontinuation (Cycle/Day)	Outcome
Peripheral Motor Neuropathy	3	3/1	Resolved
Parainfluenza	3	3/22	Resolved
Prolonged QTc/AF	3	2/15	Resolved
Subdural Hematoma	5	3/22	Fatal
Sepsis	5	2/3	Fatal
Sepsis	5	2/14	Fatal

AE, adverse event; AF, atrial fibrillation.

**Table 5. Response**

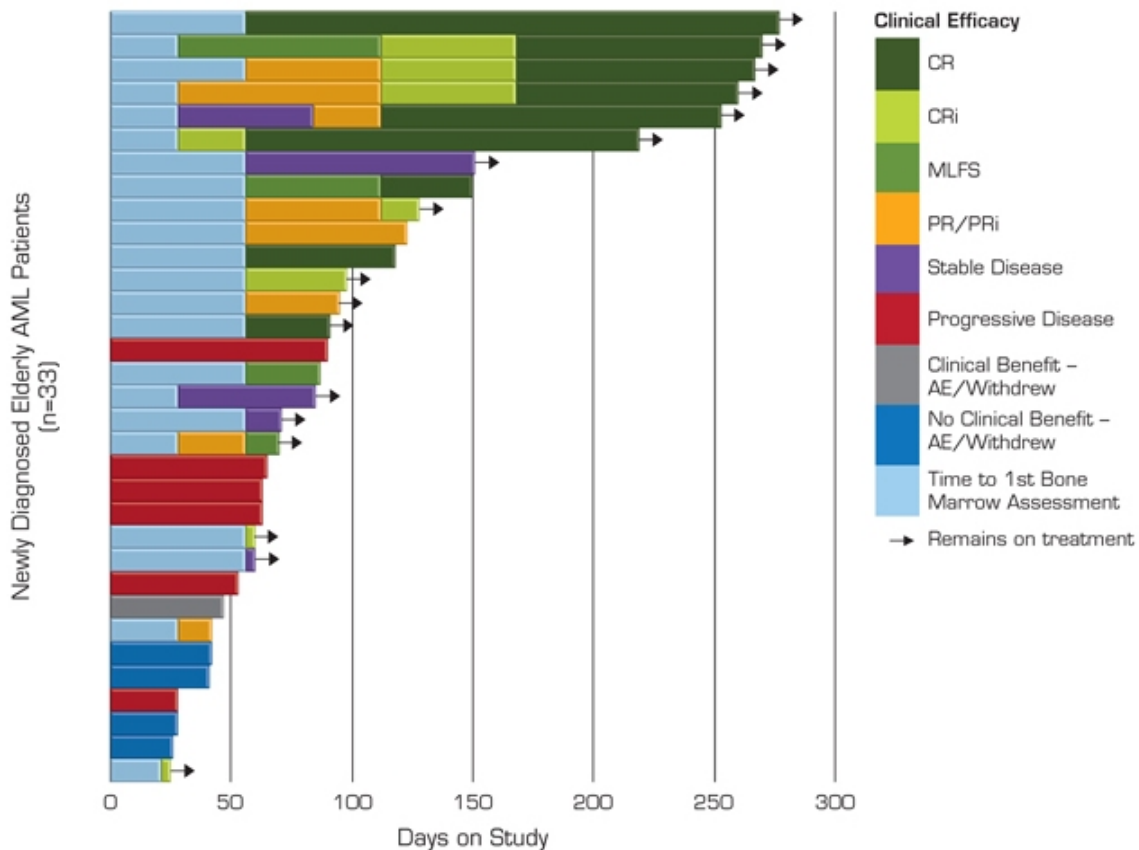
Interim Response Assessment n=33* (%)	
CR/CRi/MLFS (Primary endpoint)	15 (45)
CR	9 (27)
CRi	4 (12)
MLFS	2 (6)
PR/PRI	3 (10)
Stable Disease	4 (12)
Progressive Disease	6 (18)
Clinical Benefit**	1 (3)
No Clinical Benefit	4 (12)

CR, complete response; CRi, complete response with incomplete blood count recovery; MLFS, morphologic leukemia-free state; PR, partial response; PRI, partial response with incomplete blood count recovery.

\*All patients who have had at least 1 on-study disease assessment OR discontinued study therapy prior to an on-study disease assessment due to adverse event or other reasons.

\*\*Patients did not meet strict International Working Group (IWG) response criteria, but were determined to have clinical benefit by Investigator.

**Figure 2. Interim Efficacy and Duration on Study**



AE, adverse event; AML, acute myeloid leukemia; CR, complete response; CRi, complete response with incomplete blood count recovery; MLFS, morphologic leukemia-free state; PR, partial response; PRI, partial response with incomplete blood count recovery.



# Pracinostat in Combination With Azacitidine Produces a High Rate and Rapid Onset of Disease Remission in Patients With Previously Untreated Acute Myeloid Leukemia

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Figure 3. Event-Free Survival

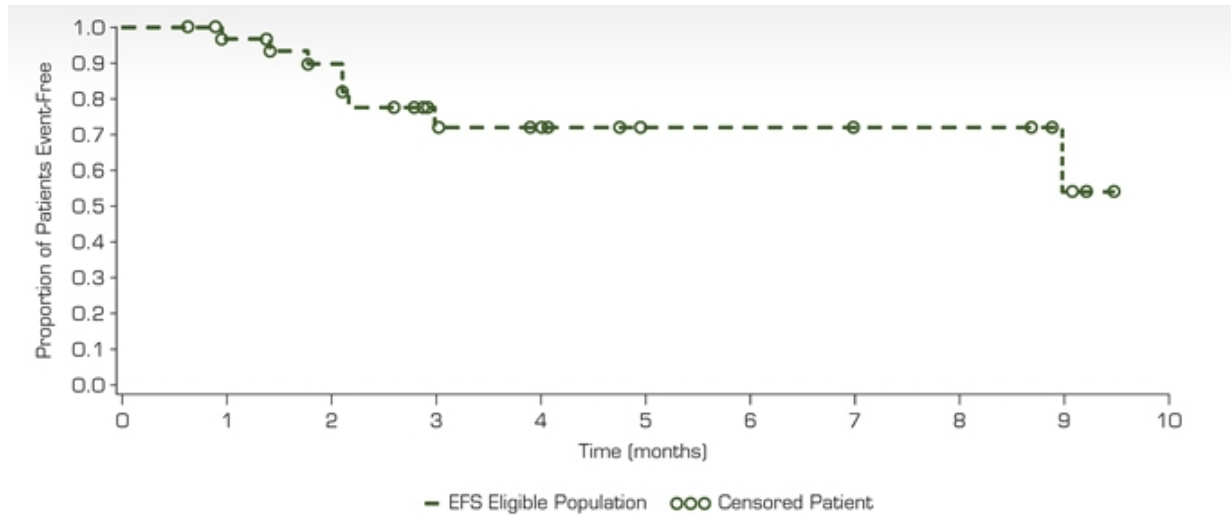
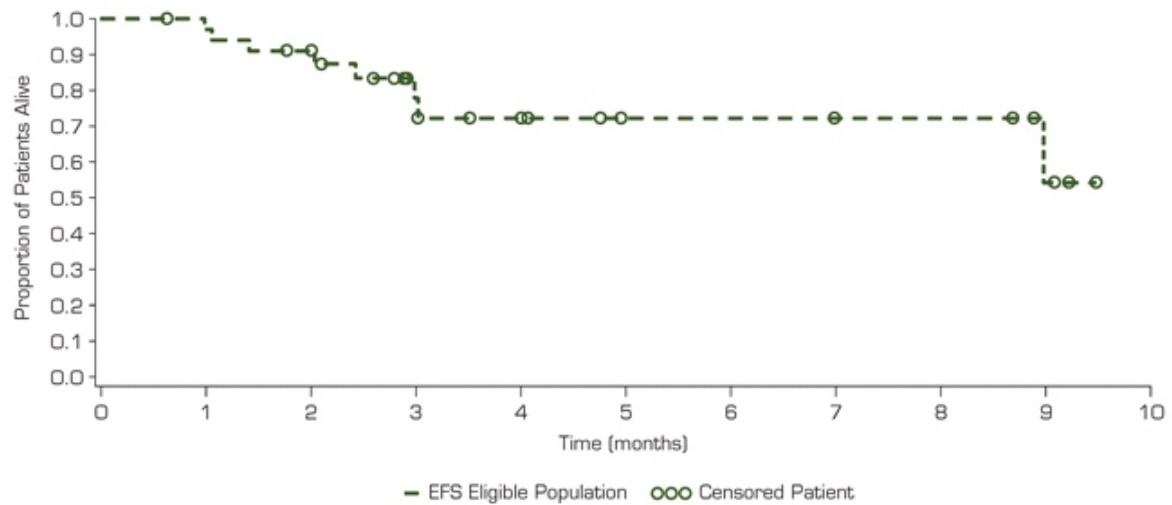


Figure 4. Overall Survival



## CONCLUSIONS

- Pracinostat in combination with azacitidine demonstrates significant clinical activity in elderly patients with newly diagnosed AML
  - ┆ To date, 15 of 33 patients (45%) achieved the primary endpoint of CR + CRi + MLFS
  - ┆ No patient who achieved a clinical response has progressed
  - ┆ Most clinical responses occur within the first 2 cycles and continue to improve with ongoing therapy
  - ┆ The observed response rate may increase with longer follow-up of patients achieving PR or SD (stable disease)
- Pracinostat in combination with azacitidine was well tolerated in this population of elderly AML patients
  - The most common treatment-emergent AEs included neutropenia, febrile neutropenia, thrombocytopenia, nausea, fatigue, and anemia
  - ┆ Adverse events resulting in dose reductions were uncommon, and frequently due to disease under study
  - ┆ The 60-day mortality rate is approximately 10% (3/33)
  - ┆ 6 patients to date have received study drug beyond 230 days, reflecting long-term tolerability
- These data support definitive development of pracinostat in combination with azacitidine in elderly AML patients

**Presented at the 56th American Society of Hematology Annual Meeting, December 6-9, 2014, San Francisco, California**

# Pracinostat in Combination With Azacitidine Produces a High Rate and Rapid Onset of Disease Remission in Patients With Previously Untreated Acute Myeloid Leukemia

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## DISCLOSURES

G. Garcia-Manero receives consultancy fees from MEI Pharma; E. Atallah reports no relevant conflicts of interest to disclose; O. Odenike receives honoraria and advisory fees from Sunesis Pharmaceuticals, Incyte, Sanofi-Aventis, Algeta Pharmaceuticals, and Spectrum Pharmaceuticals; B.C. Medeiros receives research funding from MEI Pharma; J. Cortes receives research funding from Celgene; V. Esquibel is an employee of MEI Pharma; S. Cha was employed by MEI Pharma at the time of abstract submission; S.K. Khaled receives research funding from Sequenom.



<http://go.gf/PAHEDA>

Presented at the 56th American Society of Hematology Annual Meeting, December 6-9, 2014, San Francisco, California



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 Vice President, Investor Relations &  
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## **MEI PHARMA REPORTS SIGNIFICANT CLINICAL ACTIVITY IN PHASE II STUDY OF PRACINOSTAT IN FRONT LINE ACUTE MYELOID LEUKEMIA**

### **Company Outlines Plans for Phase III Registration Study**

San Diego – December 8, 2014 – MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, reported significant clinical activity 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). Interim data from 33 evaluable patients treated at 15 centers were presented at the American Society of Hematology (ASH) Annual Meeting in San Francisco on Saturday.

According to the presentation, 15 of 33 patients (45%) to date have achieved the primary endpoint of complete response (CR) plus complete response with incomplete blood count recovery (CRi) plus morphologic leukemia-free state (MLFS). No patient who achieved a clinical response has progressed. The combination of Pracinostat and azacitidine has been generally well-tolerated in the study, with no unexpected toxicities, with six subjects discontinued due to treatment-emergent adverse events. The study recently completed enrollment with a total of 50 patients, 17 of which are still too early for their initial clinical response assessment. The 60-day mortality rate, often used as an important benchmark in AML clinical studies, is approximately 10% (three of 33 patients). Currently, 14 patients have exceeded 90 days on study of which nine (64%) have achieved a CR, many evolving from a lesser earlier response.

“These data support definitive development of Pracinostat in combination with azacitidine in elderly AML patients,” concluded Dr. Guillermo Garcia-Manero, MD Anderson Cancer Center, lead author and principal investigator of the study. “Most responses are occurring rapidly, often within the first two cycles, and continue to improve with ongoing therapy. Therefore, the observed response rate, which is already higher than we would expect from azacitidine alone, is likely to increase with longer follow-up of patients.”

Pracinostat in combination with azacitidine was well tolerated in this population of elderly AML patients. The most common treatment-emergent adverse events included neutropenia, febrile neutropenia, thrombocytopenia, nausea, fatigue and anemia. Adverse events resulting in dose reductions were uncommon and frequently due to disease under study. Six patients to date have received study drug beyond 230 days, reflecting long-term tolerability.

“Based on these encouraging data and recent discussions with the U.S. Food and Drug Administration, we are now actively preparing for a Phase III registration study using CR as the primary endpoint to support accelerated approval for this indication and overall survival as the endpoint for full approval,” said Robert D. Mass, MD, Chief Medical Officer of MEI Pharma. “Meanwhile, we look forward to unblinding our randomized, placebo-controlled Phase II study of Pracinostat and azacitidine in front line myelodysplastic syndrome and reporting top line data in March 2015.”

A copy of Saturday's poster presentation, entitled "Pracinostat in Combination with Azacitidine Produces a High Rate and Rapid Onset of Disease Remission in Patients with Previously Untreated Acute Myeloid Leukemia (AML)," is available at [www.meipharma.com](http://www.meipharma.com).

### **About Pracinostat**

Pracinostat is an oral histone deacetylase (HDAC) inhibitor that has been tested in a number of Phase I and Phase II clinical trials in advanced hematologic disorders and solid tumor indications in both adult and pediatric patients. Pracinostat has been generally well tolerated in more than 300 patients to date, with manageable side effects often associated with drugs of this class, including fatigue, myelosuppression and gastrointestinal toxicity. In a Phase I dose-escalation trial, Pracinostat demonstrated evidence of single-agent activity in elderly AML patients, including two out of 14 (14%) who achieved a CR, with durable responses persisting 206+ and 362 days, respectively. In addition, results from a pilot study of Pracinostat in combination with Vidaza in patients with advanced myelodysplastic syndrome (MDS) showed an overall response rate of 90% (nine out of 10), including eight patients who achieved either a CR or a CRi.

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 increase as the population ages. The American Cancer Society estimates about 14,590 new cases of AML per year in the U.S., with an average age of about 66. 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 lead drug candidate is Pracinostat, a potential best-in-class, oral HDAC inhibitor currently being developed for MDS and AML. In August 2014, the Company completed enrollment in a randomized, placebo-controlled Phase II study of Pracinostat in combination with azacitidine in patients with previously untreated intermediate-2 or high-risk MDS. The Company plans to unblind the study and report topline data in Q1 2015. MEI Pharma is also developing ME-344, a mitochondrial inhibitor currently in a Phase Ib study in combination with topotecan (marketed as Hycamtin®) in patients with small cell lung or ovarian cancer who failed initial therapy. In September 2013, the Company further expanded its pipeline of drug candidates with the acquisition of PWT143, a highly selective PI3K delta inhibitor. For more information, go to [www.meipharma.com](http://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.