
**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 8, 2014

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 8, 2014, MEI Pharma, Inc. (the “Company”), conducted an Analyst and Investor Event at which Dr. Robert D. Mass presented a clinical update along with a presentation by Dr. Guillermo Garcia-Manero of the MD Anderson Cancer Center. A webcast of the presentation is available at www.meipharma.com.

A copy of the slides which accompanied the presentation is filed as Exhibit 99.1 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 | Slides Presented at Analyst and Investor Event |

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

| <u>Exhibit No.</u> | <u>Description</u> |
|-------------------------------|--|
| 99.1 | Slides Presented at Analyst and Investor Event |



Pioneering new therapies for cancer

Analyst & Investor Event
December 8, 2014

Forward-Looking Statements

These slides and the accompanying oral presentation contain forward-looking statements. Actual events or results may differ materially from those projected in any of such statements.

Additional information concerning factors that may cause actual events or results to differ from those projected is contained in MEI Pharma's most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other subsequent filings with the SEC.

Agenda

| Time | Presentation | Speaker |
|---------|--|-----------------------------|
| 6:00 pm | Welcome & Introduction | Daniel P. Gold, PhD |
| 6:05 pm | Pracinostat: A Differentiated HDAC Inhibitor | Guillermo Garcia-Manero, MD |
| | Update on MDS Pilot Study | Guillermo Garcia-Manero, MD |
| | Review of Front Line AML Data | Guillermo Garcia-Manero, MD |
| 6:25 pm | Next Steps for Pracinostat in AML | Robert D. Mass, MD |
| | Preview of Front Line MDS Data | Robert D. Mass, MD |
| 6:30 pm | Q & A | All |
| 7:00 pm | Conclusion | |

Introductions

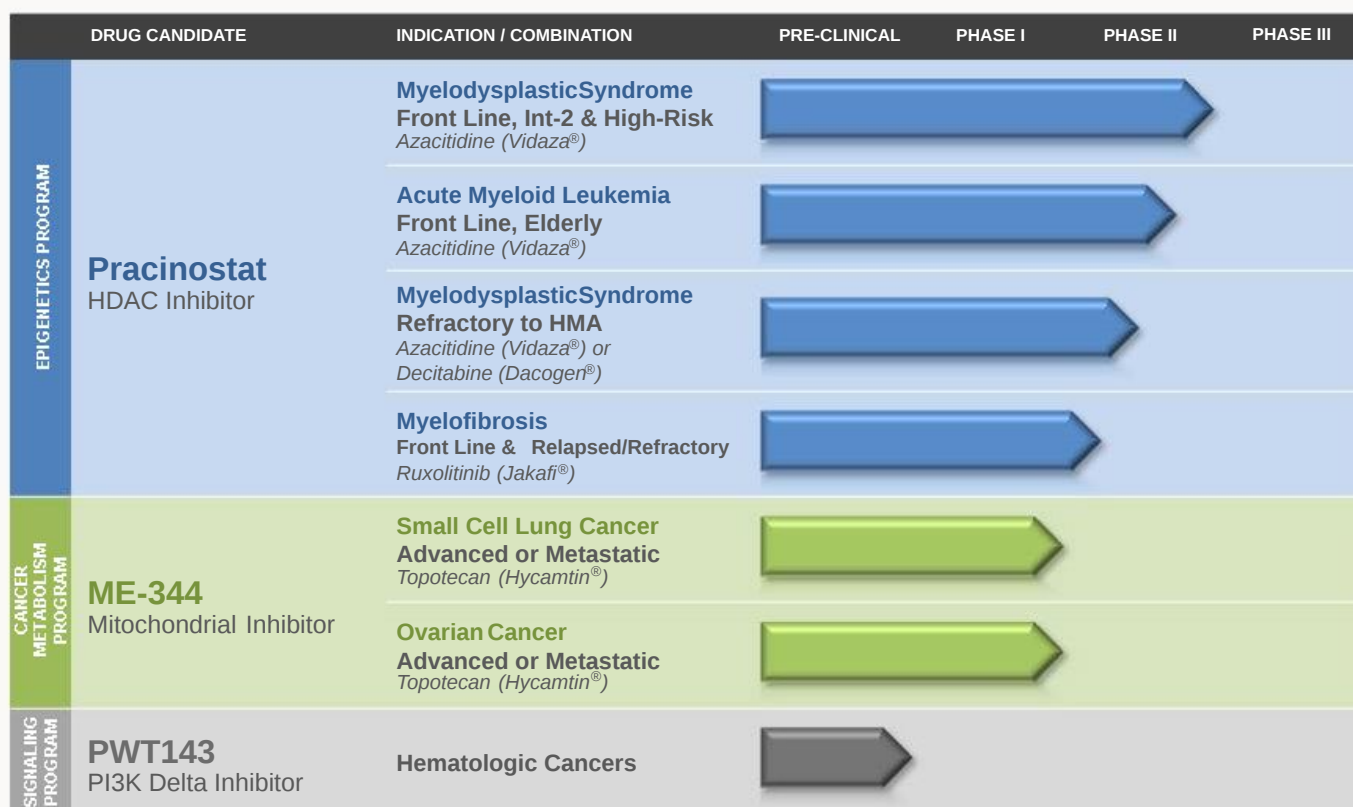
Guillermo Garcia-Manero, MD

- Professor, Department of Leukemia, MD Anderson Cancer Center
- Chief, Section of Myelodysplastic Syndromes, MD Anderson Cancer Center
- Deputy Chair, Translational Research, MD Anderson Cancer Center
- Co-Chair, MDS Clinical Research Consortium
 - Principal Investigator of Pracinostat studies

Robert D. Mass, MD

- Chief Medical Officer, MEI Pharma
 - Former Head of Medical Affairs, BioOncology, Genentech

Clinical Development Pipeline



Pracinostat: A Clinical Perspective

**Guillermo Garcia-Manero, MD
MD Anderson Cancer Center**

Pracinostat: A Differentiated HDAC Inhibitor

- Potent inhibitor of Class I, II and IV HDAC isoenzymes
- Tested in 300+ patients in multiple Phase I and Phase II clinic trials
 - Hematologic and solid tumor indications, adult and pediatric patients
 - Well tolerated
 - Manageable side effects consistent with drugs of this class
- Best-in-class pharmacokinetic profile, broadly active
 - SB991, the major *in vivo* metabolite of Pracinostat, demonstrates higher activity than Pracinostat
 - Combined on target IC₅₀ activity for HDAC1 predicted to be >24 hours

Evidence of Clinical Activity in MDS and AML

- Evidence of single-agent activity in elderly AML¹
 - 14% (2/14) CR rate in Phase I dose-escalation study
- Evidence of activity in combination with azacitidine in MDS²
 - 80% (8/10) CR/CRi rate in pilot Phase II study
 - Rapid complete bone marrow responses observed
 - 50% (5/10) achieved complete cytogenetic bone marrow response
 - 50% (5/10) went on to bone marrow transplantation

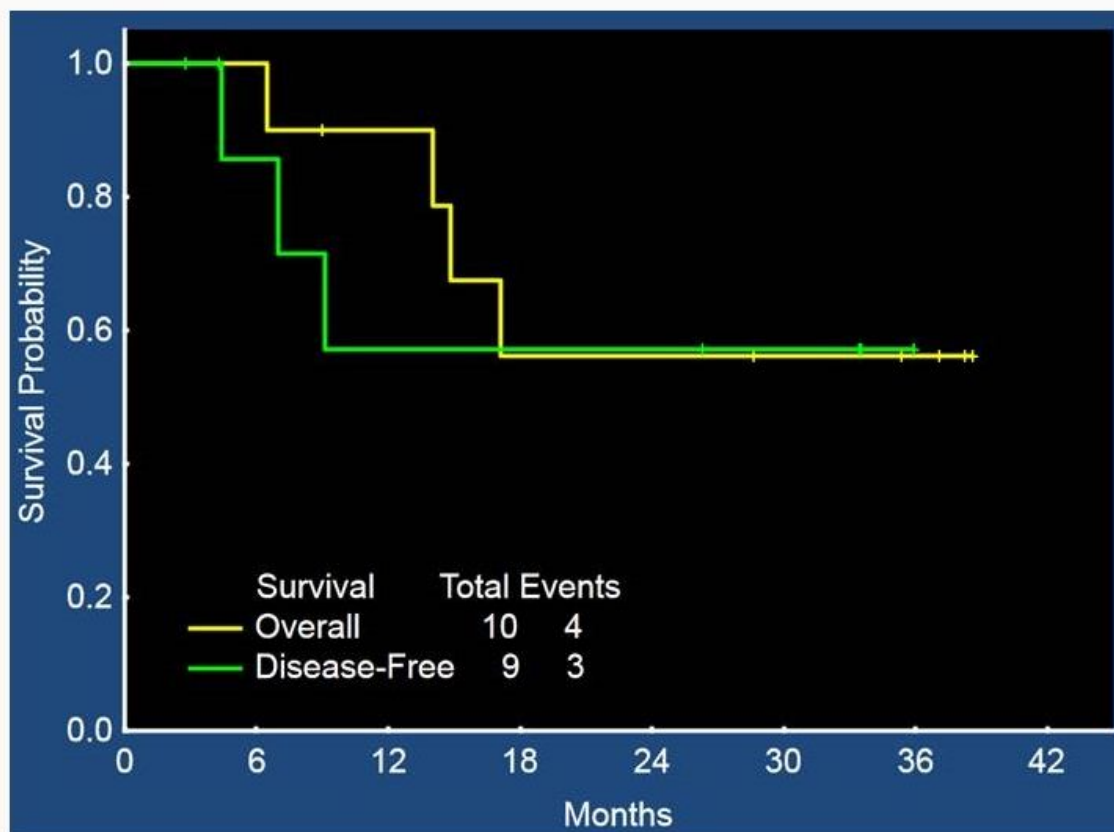
¹ G. Garcia-Manero, et al. Phase 1 Study of the Oral Deacetylase Inhibitor, SB939, in Patients with Advanced Hematologic Malignancies. 2010 ASH Annual Meeting, Abstract 3292

² Quintás-Cardama et al. Very high rates of clinical and cytogenetic response with the combination of the histone deacetylase inhibitor Pracinostat (sb939) and 5-azacitidine in high-risk myelodysplastic syndrome. 2012 ASH Annual Meeting, Abstract 3821

MDS Pilot Study – Patient Characteristics

| Patient | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Median (range) |
|------------------|------|------|------|------|------|-----|--------|------|------|------|------------------|
| Age (years) | 71 | 71 | 63 | 57 | 22 | 70 | 18 | 71 | 52 | 66 | 64.5 (18-71) |
| Sex | F | M | F | F | F | M | M | F | F | F | |
| % BM blasts | 18 | 8 | 2 | 9 | 3 | 3 | 6 | 1 | 12 | 9 | 7 (1-18) |
| Hemoglobin g/dL | 11 | 9.3 | 10.9 | 9.5 | 10.2 | 9.2 | 8.2 | 10.7 | 11.1 | 9.9 | 10.05 (8.2-11.1) |
| WBC K/uL | 3.2 | 1.5 | 2.3 | 2.5 | 0.7 | 2.6 | 9.3 | 4.5 | 1.2 | 1.5 | 2.4 (0.7-9.3) |
| ANC K/uL | 1.44 | 0.2 | 1.3 | 1.55 | 0.9 | 1.7 | 4.7 | 2.8 | 0.4 | 0.25 | 1.37 (0.2-4.7) |
| Platelets k/uL | 29 | 56 | 130 | 14 | 27 | 32 | 269 | 13 | 92 | 52 | 42 (13-269) |
| Creatinine mg/dL | 1.03 | 0.99 | 0.72 | 0.7 | 0.5 | 1 | 0.8 | 0.67 | 0.78 | 0.6 | 0.75 (0.5-1.03) |
| Bilirubin mg/dL | 1.1 | 0.7 | 0.6 | 1.3 | 0.4 | 1 | 1.1 | 0.6 | 0.8 | 0.5 | 0.75 (0.4-1.3) |
| Cytogenetics | C | C | C | -7 | -7 | C | t(6;9) | -7 | C | C | |
| t-MDS | Y | Y | Y | Y | N | Y | Y | Y | Y | N | |
| Response | CR | CRp | CR | CRp | CR | NR | CRp | CR | CR | CR | |

MDS Pilot Study... Three Years Later



Phase II Study in Front Line AML (MEI-004)

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

Stage 1 (n = 27)
Pracinostat plus Azacitidine

Three or more patients required to achieve CR/CRi/MLFS to advance to Stage 2

Stage 2 (n = 13)
Pracinostat plus Azacitidine

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 & 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 \geq Grade 3 hematologic toxicity in the absence of disease
 - Indicated for treatment related \geq Grade 3 non-hematologic toxicity following maximal medical treatment

Eligibility Criteria

- Key Inclusion:
 - Age ≥ 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).
 - $\geq 20\%$ 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 (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) + Marrow CR (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

Baseline Characteristics

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

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

Treatment Emergent Adverse Events in $\geq 10\%$ of Patients (all causality)

| | All Grades (%), n=41 | Grades 3-4 (%), n=41 |
|------------------------|----------------------|----------------------|
| Hematologic | | |
| 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) |
| Non-Hematologic | | |
| 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

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.

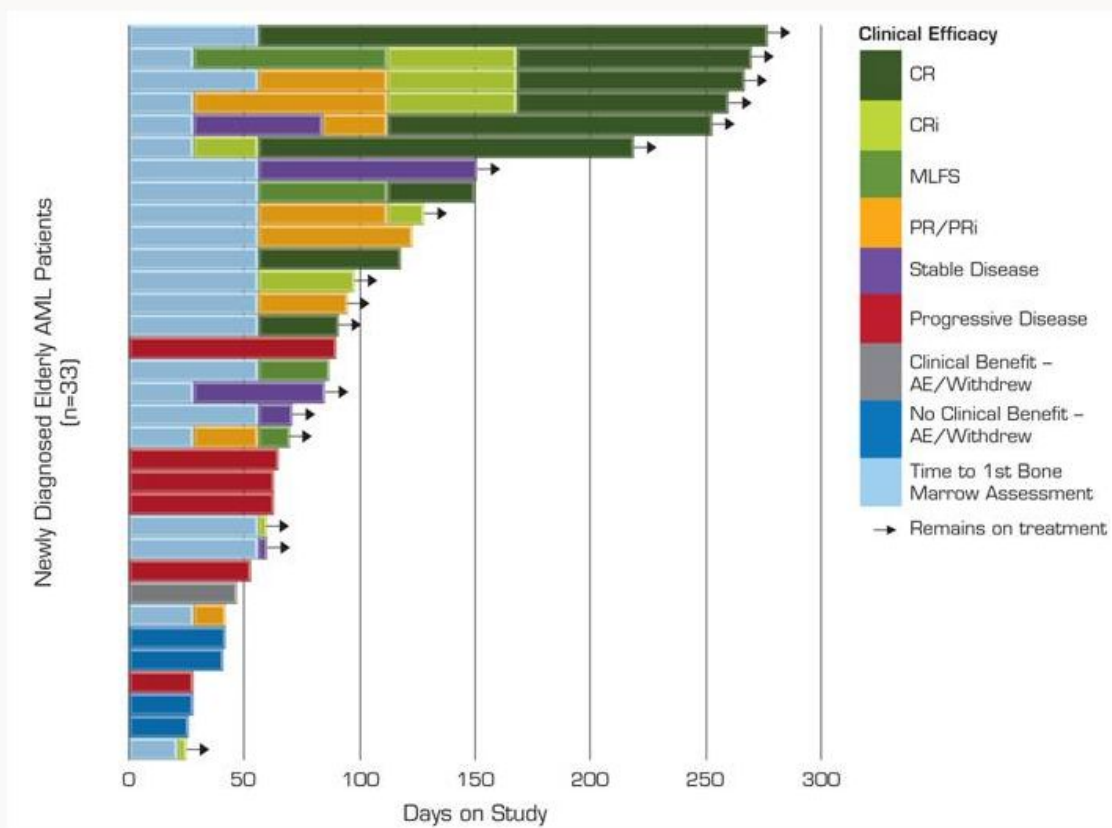
Response

| 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) |

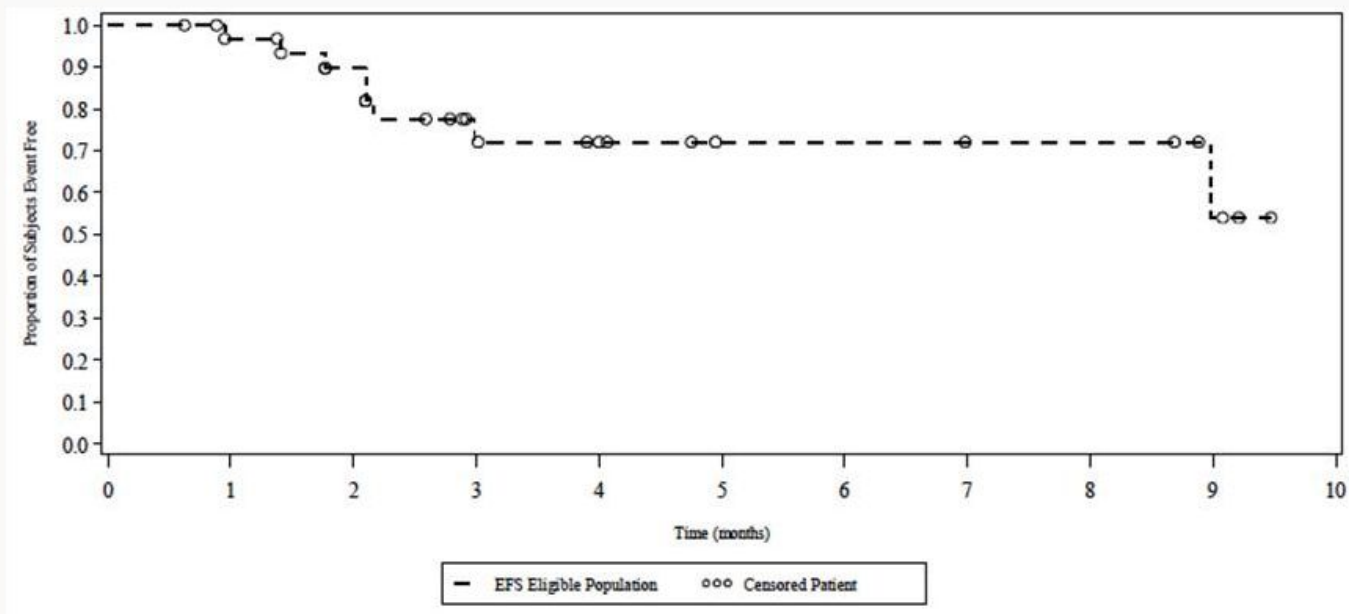
*All patients who have had at least 1 on-study disease assessment OR discontinued study therapy prior to an on study disease assessment due to adverse event or other reasons

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

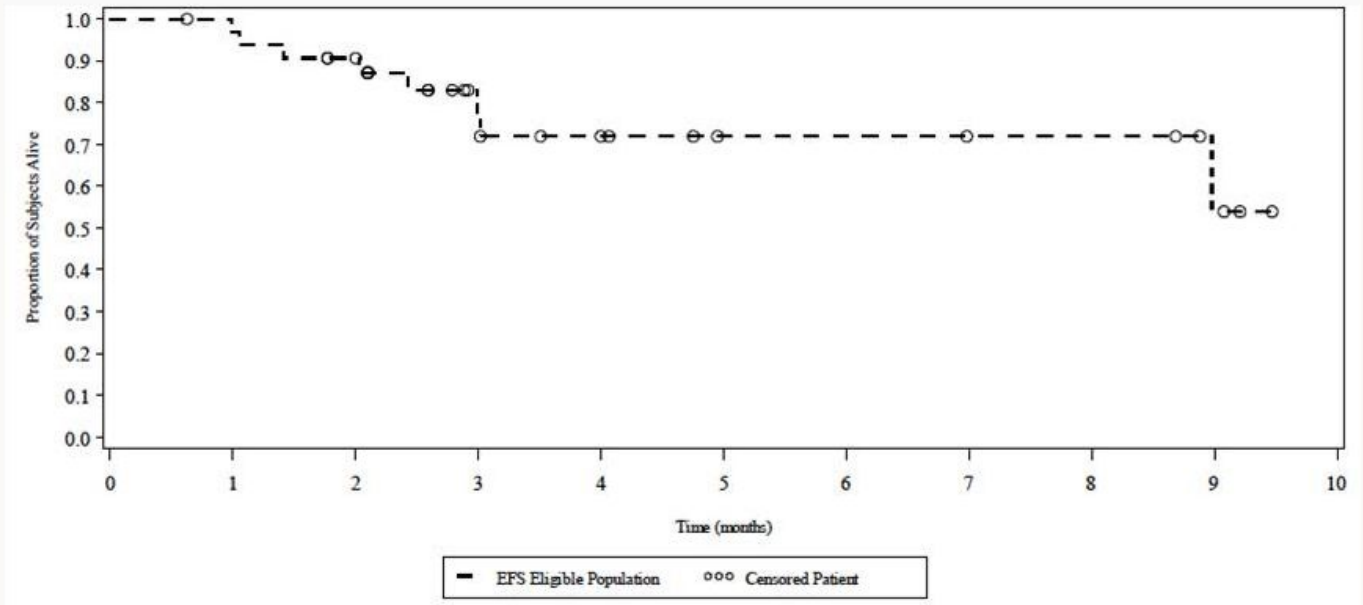
Evolution of Clinical Responses: Interim Efficacy and Duration on Study



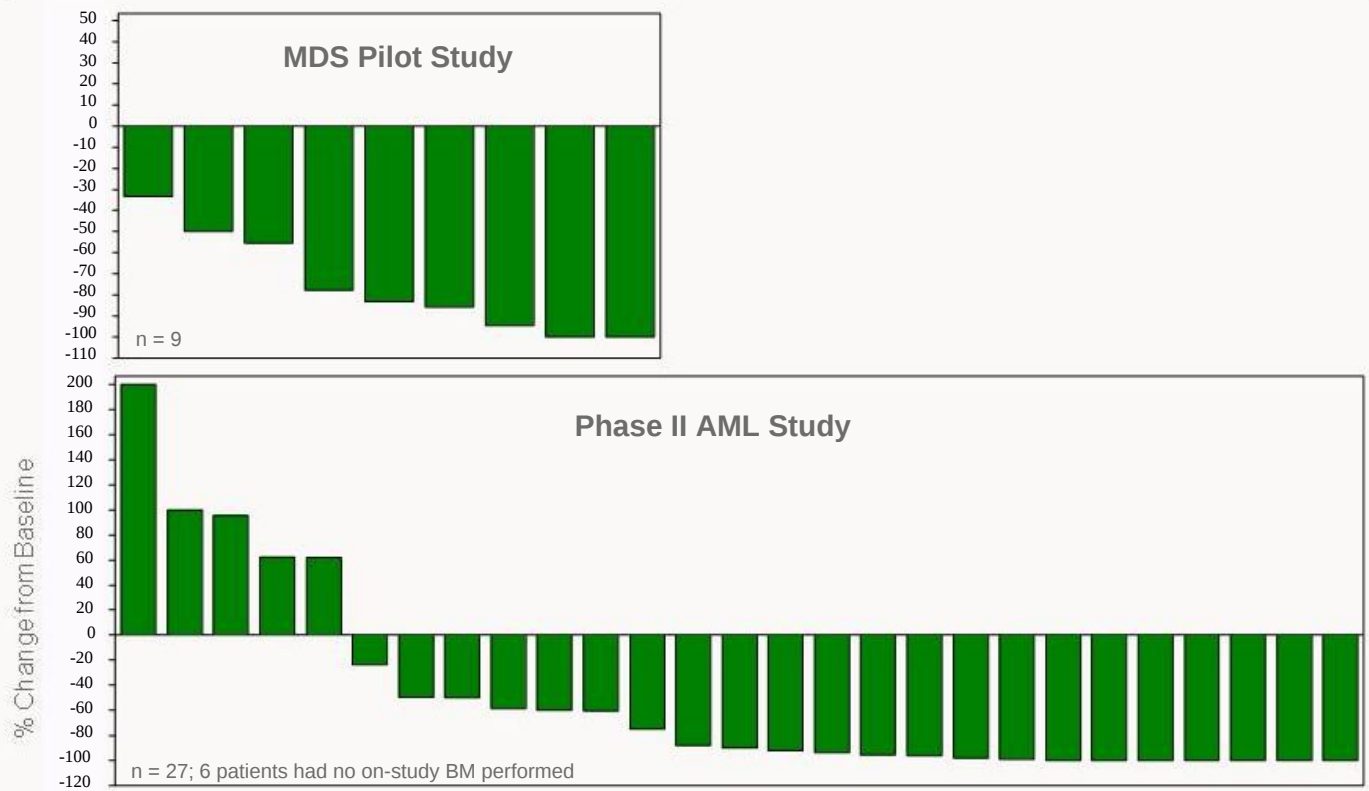
Event Free Survival



Overall Survival



Bone Marrow Response in MDS and AML



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
 - The 60 day mortality rate is approximately 10% (3/33)

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Conclusions (cont'd)

- 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
 - Six 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

Pracinostat: Looking Ahead

Robert D. Mass, MD
Chief Medical Officer

Proposed Phase III AML Study Designs

Elderly (Age \geq 60 years) Patients with Newly Diagnosed AML
Unsuitable for Intensive Therapy



- Primary endpoint: CR
 - Secondary endpoints: OS, ORR, transfusion independency rate, duration of response, PFS, tolerability and AE rate, PK
- ~450 patients, one-to-one randomization
- Estimated initiation: June 2015

Phase II Front Line MDS Study (MEI-003)



- Primary Endpoint: CR
 - Secondary endpoints: overall response rate, hematologic improvement, clinical benefit rate, duration of response, progression-free survival, rate of leukemic transformation, overall survival, safety & tolerability
- 102 evaluable patients enrolled, one-to-one randomization
- 24 sites in the U.S.
- Expect to unblind study and report topline data in March 2015

Phase II Front Line MDS Study (MEI-003)

Patient Demographics

| | Study MEI-003 ¹ (N=102) | Pub ² (N=99) | Pub ³ (N=179) |
|--------|---------------------------------------|----------------------------|-----------------------------|
| Age | | | |
| Median | 70 yrs | 69 yrs | 69 yrs |
| <65 | 29% | NR | 32% |
| ≥65 | 71% | NR | 68% |
| Gender | | | |
| Male | 69% | 72% | 74% |
| Female | 31% | 27% | 26% |
| PS | | | |
| 0 | 34% | NR | 44% |
| 1 | 57% | NR | 48% |
| 2 | 9% | NR | 7% |
| IPSS | | | |
| INT-2 | 65% | 11% | 43% |
| High | 35% | 9% | 46% |

¹ Based on unclean data; study closed to enrollment on August 29, 2014

² Vidaza® package insert, table 1 (Silverman, JCO 2002 study)

³ Vidaza® package insert, table 2 (Fenaux, Lancet Oncology 2009 study)



2015 Clinical Milestones

Pracinostat

- Top line data from Phase II study in front line MDS (March)
- Full data set from Phase II study in front line MDS (June)
- Initiation of Phase III study in front line elderly AML (June)

ME-344

- Data from Phase Ib trial in small cell lung & ovarian cancers

PWT143

- Initiation of first-in-human study



Q & A

**Analyst & Investor Event
December 8, 2014**