# 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): September 2, 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))

# Item 8.01 Other Events.

On September 2, 2014, MEI Pharma, Inc. issued a press release announcing the completion of enrollment in its randomized Phase II clinical trial of its lead investigational drug candidate Pracinostat in combination with azacitidine in patients with previously untreated intermediate-2 or high-risk myelodysplastic syndrome (MDS). A copy of the press release is attached 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

Exhibit No.	Description
99.1	Press release, dated September 2, 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: September 2, 2014

# Exhibit Index

Exhibit No.	Description
99.1	Press release, dated September 2, 2014.



Contact: Pete De Spain Vice President, Investor Relations & Corporate Communications (858) 792-3729 pdespain@meipharma.com

# MEI PHARMA COMPLETES ENROLLMENT IN RANDOMIZED PHASE II CLINICAL TRIAL OF PRACINOSTAT IN FRONT LINE MYELODYSPLASTIC SYNDROME

### Data from Multi-Center, Placebo-Controlled Study Anticipated in Q1 2015

San Diego – September 2, 2014 – MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, announced today that it has completed enrollment in a randomized Phase II clinical trial of its lead investigational drug candidate Pracinostat in combination with azacitidine in patients with previously untreated intermediate-2 or high-risk myelodysplastic syndrome (MDS). The multi-center, placebo-controlled, double-blind study enrolled a total of 108 patients with a one-to-one randomization. The Company plans to unblind the study approximately six months after the last patient was enrolled and report topline data in Q1 2015.

"The achievement of this important milestone is the culmination of months of diligence and collaboration," said Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "Following the very high response rate reported in our MDS pilot study, we set out to execute a comprehensive development program in order to better elucidate the clinical benefit of Pracinostat plus azacitidine in this patient population. Now we look forward to unblinding this study early next year and determining the most efficient registration path forward for Pracinostat."

The randomized Phase II study is designed to evaluate the safety and efficacy of Pracinostat compared to placebo when combined with azacitidine<sup>1</sup>, a drug approved by the U.S. Food and Drug Administration for the treatment of MDS. The primary endpoint of the study is rate of complete remission (CR). Secondary endpoints include overall response rate, hematologic improvement, duration of response, progression-free survival, rate of leukemic transformation, overall survival and safety. Additional information regarding the study is available at www.clinicaltrials.gov.

Results from an earlier pilot study of Pracinostat in combination with azacitidine in patients with intermediate-2 or high-risk MDS presented at the American Society of Hematology Annual Meeting in December 2012 reported an overall response rate of 89% (eight out of nine), including seven patients who achieved either a CR or a complete remission with incomplete blood count recovery (CRi). Combined with the results from an additional patient treated at the University of Wisconsin-Madison who also achieved a CR, the trial's overall response rate was 90% (nine out of 10). The combination of Pracinostat and azacitidine was well tolerated in the study; the most frequent side effects were nausea and fatigue.

<sup>&</sup>lt;sup>1</sup> Azacitidine, or 5-azacitidine, is marketed as Vidaza<sup>®</sup>.

In June 2014, MEI Pharma announced preliminary data from its ongoing Phase II study of Pracinostat plus azacitidine in elderly patients with newly diagnosed AML. Of the first nine patients enrolled in the multicenter study, three achieved a CR or CRi, each following one or two treatment cycles. In addition, three patients achieved a partial response (PR) or a partial response with incomplete blood count recovery (PRi) after their initial or second treatment evaluation, for an overall response rate of 67%. The combination of Pracinostat and azacitidine has been generally well tolerated in the study, with no new or more severe adverse events than previously reported. The Company expects to report additional data from this open-label study at a scientific conference later this year.

### **About Pracinostat**

Pracinostat is an oral histone deacetylase (HDAC) inhibitor that has been tested in multiple Phase I and Phase II clinical trials in advanced hematologic disorders and solid tumor indications in adult and pediatric patients. Pracinostat has been generally well tolerated in more than 250 patients to date, with readily manageable side effects that are often associated with drugs of this class, including fatigue, myelosuppresion and gastrointestinal toxicity (nausea, vomiting and diarrhea). 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.

MEI Pharma owns exclusive worldwide rights to Pracinostat.

#### **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 in development for MDS and AML. MEI Pharma is also developing ME-344, a mitochondrial inhibitor that has shown preliminary evidence of single-agent activity in a first-in-human clinical study in patients with refractory solid tumors, including eight of 21 evaluable patients (38%) who achieved stable disease or better. In September 2013, the Company further expanded its pipeline of drug candidates with the acquisition of PWT143, a highly selective PI3-kinase delta inhibitor. For more information, 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 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.