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): June 1, 2019

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

Delaware	**000-50484**	**51-0407811**
(State of other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

3611 Valley Centre Drive	
Suite 500	
San Diego, California	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 369-7100

(Former name or former address, if changed since last report)

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 240.13c-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common stock, $0.00000002 par value	**MEIP**	**The NASDAQ Stock Market LLC**

Item 8.01. Other Events

On June 1, 2019, MEI Pharma, Inc. (the "Company") issued a press release reporting interim data from the results of an investigator-initiated study of ME-344 in combination with bevacizumab (marketed as Avastin®) in patients with HER2-negative breast cancer.

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

On June 3, 2019, the Company issued a press release reporting interim data from the results of its Phase 1b study of ME-401, a selective oral inhibitor of PI3K delta, administered both as a single-agent and in combination with rituximab.

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.

Exhibit No.	Description
99.1	Press Release dated June 1, 2019
99.2	Press Release dated June 3, 2019

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.

Date: June 3, 2019

By: /s/ Brian G. Drazba
Name: Brian G. Drazba
Title Chief Financial Officer and Secretary

Exhibit 99.1

MEI Pharma Presents Clinical Results for ME-344 in Combination with Bevacizumab in Early HER2 Negative Breast Cancer Patients at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

– Statistically significant biologic anti-tumor activity demonstrated as measured by a reduction in Ki67 in patients treated with ME-344 compared to an increase in patients receiving placebo –

SAN DIEGO, June 1, 2019 – MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing potential new therapies for cancer, today announced data presented at ASCO 2019 from an investigator-initiated study of investigational ME-344 in combination with bevacizumab (marketed as Avastin®) in patients with early HER2-negative breast cancer. This study demonstrated proof of biologic anti-tumor activity as measured by a statistically significant reduction in Ki67, a measure of cell proliferation that is highly correlated with tumor response, in the group of patients treated with ME-344 compared to an increase in the group receiving saline.

“Data from this clinical study of ME-344 in combination with bevacizumab represents a potential novel approach to disrupting tumor metabolism and limiting tumor proliferation by inhibiting the heightened energy production necessary for cell division and cancer growth,” stated the study principal investigator, Miguel Quintela-Fandino, M.D., Ph.D., Director of the Clinical Research Program, Centro Nacional De Investigaciones Oncologicas, Madrid, Spain. “These results offer evidence for the biologic antitumor activity of ME-344 in certain metabolic contexts and support further exploration of the mitochondrial inhibitor ME-344 in a therapeutic role, providing a potential novel mechanism that may improve patient outcomes in combination with antiangiogenic therapeutics such as bevacizumab.”

The ME-344 ASCO 2018 poster can be accessed on the MEI Pharma website.

ME-344 Clinical Data

The clinical study was a multicenter, investigator-initiated, randomized, open-label trial evaluating ME-344 in a total of 42 patients with early HER2-negative breast cancer in combination with the vascular endothelial growth factor inhibitor bevacizumab. Patients were randomized one-to-one to either ME-344 plus bevacizumab or saline plus bevacizumab.

The primary objective of the study was to show proof of ME-344 biologic activity as measured by Ki67 reductions from day 0 to 28 compared to placebo. Secondary objectives included determining whether ME-344 biologic activity correlates with vascular normalization. The data demonstrate significant biologic activity in the ME-344 treatment group:

- In ME-344 treated patients, mean absolute Ki67 decreases were 13.3 compared to an increase of 1.1 in the bevacizumab monotherapy group (P=0.01).
- In ME-344 treated patients, mean relative Ki67 decreases were 23% compared to an increase of 186% in the bevacizumab monotherapy group ($P < 0.01$).
- The mean relative Ki67 reduction in patients experiencing vascular normalization in the ME-344 treated patients was 33%, compared to an increase of 11.8% in normalized patients from the bevacizumab monotherapy group (P=0.09). Approximately one-third of patients in each arm had vascular normalization.

Treatment was generally well tolerated; two Grade 3 adverse events of high blood pressure were reported, 1 in each arm, and deemed related to bevacizumab.

About ME-344

ME-344 is a novel, tumor selective, isoflavone-derived mitochondrial inhibitor drug candidate. It directly targets the OXPHOS complex 1, a pathway involved in the production of adenosine triphosphate, or ATP, in the mitochondria. Treatment of tumor cells with ME-344 results in a rapid loss of ATP and cancer cell death. ME-344 demonstrated evidence of single-agent activity against refractory solid tumors in a Phase I study, and in preclinical studies, tumor cells treated with ME-344 resulted in a rapid loss of ATP and cancer cell death.

In addition to single-agent activity, ME-344 may also have potential in combination with antiangiogenic therapeutics. While antiangiogenics reduce the rate of glycolysis in tumors as a mechanism to block growth, tumor metabolism often shifts to mitochondrial metabolism to continue energy production to support continued tumor proliferation. In such cases of tumor plasticity in the presence of treatment with antiangiogenics, targeting the alternative metabolic source with ME-344 may open an important therapeutic opportunity.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a late-stage pharmaceutical company focused on developing potential new therapies for cancer. Our portfolio of drug candidates contains four clinical-stage assets, including one candidate in an ongoing global registration trial and another candidate in a Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. Each of our pipeline candidates leverages a different mechanism of action with the objective of developing therapeutic options that are: (1) differentiated, (2) address unmet medical needs and (3) deliver improved benefit to patients either as standalone treatments or in combination with other therapeutic options. 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 studies 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.

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MEI Pharma Presents Updated Clinical Data from the ME-401 Monotherapy and in Combination with Rituximab Phase 1b study in Patients with Follicular Lymphoma at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

– 80% overall response rate in patients with relapsed or refractory follicular lymphoma –

– Intermittent dosing schedule demonstrates comparable overall response rates with lower rate of delayed Grade 3 adverse events compared to continuous dosing schedule –

SAN DIEGO, June 3, 2019 – MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing potential new therapies for cancer, today announced that updated data presented at ASCO 2019 from a Phase 1b study of investigational ME-401, a selective oral inhibitor of PI3K delta, demonstrate an 80% overall response rate in patients with relapsed or refractory (r/r) follicular lymphoma (FL) (n= 50). Additionally, the data demonstrate:

- Comparable overall response rates, ranging from 75% to 83%, across patient groups receiving ME-401 as a monotherapy or in combination with rituximab, and in patient groups dosed with ME-401 once daily on a continuous schedule (CS) or on an intermittent schedule (IS) of once daily for the first 7 days of a 28-day cycle after 2 months of continuous dosing.
- A lower rate of delayed, grade 3 adverse events (e.g. 8.7% diarrhea/colitis for IS dosing) observed in patients in the IS group.
- Durable responses in both CS and IS groups with no median yet reached.

The ME-401 ASCO 2019 poster can be accessed on the MEI Pharma website.

Andrew D. Zelenetz, M.D., Ph.D., Principal Investigator of the Phase 1b study and Professor of Medicine at Weill Cornell Medical College, Medical Director of Quality Informatics at Memorial Sloan Kettering Cancer Center, and Chair of the National Comprehensive Cancer Network's Non-Hodgkin Lymphoma Guideline Panel, commented: "ME401 is a second generation PI3K inhibitor specific for the delta isoform that has excellent activity in CLL and FL. This class of drugs has been associated with immune related toxicities which are also seen with ME401 dosed continuously. However, we explored a novel dosing strategy with intermittent drug exposure (one week on, 3 weeks off) that appears to markedly reduce toxicity and maintain efficacy. If validated, this could expand the role of PI3K in B-cell malignancies. A prospective randomized phase 2 trial is underway comparing intermittent to continuous dosing aiming to confirm these preliminary findings."

"The Phase 1b data remain very encouraging and support the further investigation of ME-401 for patients with relapsed or refractory follicular lymphoma," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "ME-401 further represents a unique opportunity to more broadly leverage the utility of PI3K as a central component of B-cell signaling and potentially offer a treatment option across multiple B-cell malignancies either as a monotherapy or in combination with other therapies."

MEI has initiated a global Phase 2 study to evaluate the efficacy, safety, and tolerability of ME-401 as a single agent in patients with follicular lymphoma after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. The Phase 2 study, now labeled the TIDAL study '(**T**rials of P**I**3K **D**elt**A** in Non-Hodgkin's **L**ymphoma), is intended to support an accelerated approval marketing application with the U.S. Food and Drug Administration.

ME-401 Phase 1b Clinical Study

The ongoing Phase 1b clinical study is evaluating ME-401 as a monotherapy and in combination with rituximab or with zanubrutinib in patients with r/r B-cell malignancies. Over 85 patients have been enrolled to date, including 54 patients with r/r FL reported on in the ASCO 2019 poster. Sixty-five percent (35/54) of r/r FL patients had 2 or more prior lines of therapy. Of the 50 evaluable r/r FL patients, 52% (26/50) were a group of FL patients with progression of disease within 24 months (POD24) of initial immunochemotherapy, which typically have a poor prognosis compared to other r/r FL patients.

ME-401 was administered once daily at 60 mg for 2 28-day cycles and then on an intermittent schedule of once daily dosing for the first 7 days of each subsequent 28-day cycle (i.e. the intermittent schedule or IS). A previous cohort of monotherapy patients in the study was treated with ME-401 administered continuously once daily or were switched to the intermittent schedule in later cycles.

The overall response rate in patients with r/r FL was 80% (40/50), with 20% (10/50) achieving a complete response. Patients receiving monotherapy achieved a 79% (30/38) overall response rate and patients receiving ME-401 in combination with rituximab achieved an 83% (10/12) overall response rate. The group of patients receiving IS dosing achieved a 75% (15/20) overall response rate and patients receiving the CS dosing achieved an 83% (25/30) overall response rate. The response rate among POD24 patients was 92% (24/26).

Evaluable R/R FL Patients	Overall Response
All groups (N = 50)	40 (80%)
CR	10 (20%)
By treatment arm	
ME-401 monotherapy (N = 38)	30 (79%)
ME-401 + rituximab (N = 12)	10 (83%)
By schedule	
IS Group (N = 20)	15 (75%)
CS Group (N = 30)	25 (83%)

The majority of responses, 88% (35/40), had an objective response by the first two treatment cycles and the achieved responses, to date, are durable; neither median duration of response nor median progression-free survival has been reached. Median follow-up for duration of response in the IS group is 8.8 months (range: 1.9-15.5) and 8.3 months in the CS group (range: 3.0-25.8). Median follow-up for progression free survival is 5.5 months in the IS group (range: 0.9-15.5) and 6.5 months in the CS group (range: 0.9-25.8). Four patients in the IS group and 2 patients in the CS group that were switched to IS dosing experienced progressive disease and reverted to CS dosing to continue treatment.

ME-401 was generally well-tolerated and no grade 4 or grade 5 adverse events have been observed in the Phase 1b study. Among drug related grade 3 adverse events of special interest, the most common are diarrhea/colitis at 8.7% (2/23) on IS dosing and 16.1% (5/31) on CS dosing, and rash with none on IS dosing and 12.9% (4/31) on CS dosing. Four patients, each on the continuous schedule, discontinued due to an adverse event.

The rate of the development of delayed, grade 3 adverse events was improved in patients on the intermittent dosing schedule. There were no isolated grade 3 elevations in ALT and AST; such elevations were transient and in each case were associated with grade 3 diarrhea or rash.

	Grade 3	
Adverse Events of Special Interest	**CS Group (N = 31)**	**IS Group (N = 23)**
Diarrhea/colitis	5 (16.1%)	2 (8.7%)
Rash, all types	4 (12.9%)	0
ALT increased	2 (6.5%)	1 (4.3%)
AST increased	2 (6.5%)	0
Pneumonia	2 (6.5%)	0
Mucositis	1 (1.9%)	0

About ME-401

ME-401 is an investigational oral phosphatidylinositol 3-kinase (“PI3K”) delta inhibitor; PI3K delta is often overexpressed in cancer cells and plays a key role in the proliferation and survival of hematologic cancers. ME-401 displays high selectivity for the PI3K delta isoform and has distinct pharmaceutical properties from other PI3K delta inhibitors. It is being clinically evaluated in patients with various B-cell malignancies. An ongoing, global, Phase 2 study is evaluating the efficacy, safety, and tolerability of ME-401 as a single agent in patients with follicular lymphoma after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. The Phase 2 study is intended to support an accelerated approval new drug application with the U.S Food and Drug Administration.

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