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 11, 2023

MEI Pharma, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41827**	**51-0407811**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11455 El Camino Real, Suite 250 **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:

☐ 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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00000002 par value	MEIP	The Nasdaq Stock Market LLC

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. ☐

Item 8.01 Other Events.

On December 11, 2023, MEI Pharma, Inc. issued a press release reporting clinical data results on oral CDK9 Inhibitor Voruciclib at ASH2023. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

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

Exhibit No.	Description
99.1	Press Release, dated December 11, 2023
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

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.

Date: December 11, 2023

By: /s/ Justin J. File

Justin J. File
Chief Financial Officer and Secretary.

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MEI Pharma Reports Clinical Data on Oral CDK9 Inhibitor Voruciclib at ASH2023

– Safety Profile Observed to Date as Monotherapy and in Combination with Venetoclax Suggests no Overlapping Toxicity –

– Initial Results from Correlative Studies Demonstrate On-target Reductions in Mcl-1 and RNA Pol II p-S2 –

SAN DIEGO – December 11, 2023 – MEI Pharma, Inc. (Nasdaq: MEIP), a clinical-stage pharmaceutical company evaluating novel drug candidates to address known resistance mechanisms to standard-of-care cancer therapies, today announced clinical data from the monotherapy dose escalation stage of the ongoing Phase 1 study evaluating voruciclib, a selective oral cyclin-dependent kinase 9 (“CDK9”) inhibitor, alone and in combination with venetoclax (Venclexta®), a B-cell lymphoma 2 ("BCL2") inhibitor, in patients with acute myeloid leukemia (“AML”) or B-cell malignancies, is highlighted in a poster session at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition.

The poster can be viewed on the MEI Pharma website here: https://meipharma.com/ash2023.html.

“The potential to use an oral CDK9 inhibitor such as voruciclib to reduce Mcl-1 protein, an established resistance factor for the BCL-2 inhibitor venetoclax, is a promising approach to improve therapeutic options for patients with hematologic malignancies,” said Matthew S. Davids, MD, MMSc., Director, Clinical Research, Division of Lymphoma, Dana-Farber Cancer Institute, and study chair of the monotherapy stage of the Phase 1 study. “The data reported today, along with the experience with voruciclib in combination with venetoclax to date, provides encouraging support for the approach of this combination to address a common resistance mechanism to venetoclax therapy and improve clinical response without overlapping toxicity.”

“I’d like to recognize the support and high level of engagement by our investigators, and the participation of the patients enrolling in this study, as we advance the evaluation of voruciclib in combination with venetoclax in patients with AML,” said David M. Urso, president and chief executive officer of MEI Pharma. “We look forward to disclosing additional data in early 2024 from the dose escalation portion of the ongoing Phase 1 clinical trial evaluating voruciclib in combination with venetoclax in patients with AML.”

Clinical Data from the Monotherapy Dose Escalation Stage of the Ongoing Phase 1 Study Evaluating Voruciclib in Combination with Venetoclax

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- Presentation Title: A Phase 1 Study of the Oral CDK9 Inhibitor Voruciclib in Relapsed/Refractory (R/R) B-Cell Lymphoma (NHL) or Acute Myeloid Leukemia (AML)
- Session Title: Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster III (616)
- Presenter: Matthew S. Davids, MD, MMSc., Associate Professor, Harvard Medical School, Director, Clinical Research, Division of Lymphoma, Dana-Farber Cancer Institute
- Date: Monday, December 11, 2023, 6:00-8:00 PM (Pacific Time)
- Publication Number: 4286

Phase 1 Study Details

The Phase 1 study is a two stage, open-label, 3+3 dose escalation and expansion study evaluating voruciclib, a CDK9 inhibitor, as a monotherapy and in combination with venetoclax (marketed as Venclexta®), a BCL2 inhibitor. The first stage of the study, evaluating the dose and schedule of voruciclib as a single-agent in patients with relapsed and refractory ("R/R") acute myeloid leukemia ("AML") or B-cell malignances after failure of standard therapies, is complete. The second stage of the study is ongoing and is evaluating voruciclib in combination with venetoclax in patients with R/R AML.

A total of 40 patients, median age 75 years (range 63-80), were enrolled in the first stage of the study evaluating voruciclib as a monotherapy. The majority of patients (n=21) had AML and the remaining patients (n=19) had B-cell malignancies. Enrolled patients were generally heavily pretreated; the median number of prior therapies was 3 (range 1-9) and 5 patients had prior hematopoietic stem cell transplant.

Patients enrolled in Cohort 1 (n= 16) of the monotherapy stage of the study were administered voruciclib once daily continuously at doses of 50 mg and 100 mg. Patients enrolled in Cohort 2 (n=24) were administered voruciclib on an intermittent schedule (IS) on days 1-14 in a 28-day cycle implemented after 2 dose limiting toxicities (DLT) were observed at 100 mg daily continuously. Dose escalation in Cohort 2 was stopped at 200 mg before reaching the maximum tolerated dose (MTD) at this schedule to focus on evaluation of venetoclax in combination with voruciclib.

The primary objectives of the study are to determine the safety and biologic effective dose of voruciclib monotherapy or voruciclib in combination with venetoclax. Secondary objectives of the study include assessing the preliminary efficacy, pharmacokinetics, pharmacodynamics, and biomarkers of voruciclib monotherapy or voruciclib in combination with venetoclax.

Monotherapy Safety and Tolerability

Voruciclib at doses up to 200 mg administered on 14 consecutive days in a 28-day cycle (Cohort 2) was well tolerated with no DLT reported. The most common adverse events (≥20% of patients) were diarrhea, nausea, anemia and fatigue. The large majority of adverse events were

Grade 1-2; of note, the only Grade 3-4 adverse events in Cohort 2 were diarrhea (n=1) and anemia (n=5).

AEs in ≥15% of Patients in Overall Population

	Cohort I (n=16)			Cohort II (n=24)			Total (N=40)
Event, n (%)	Grade 1-2	Grade 3-4	All Grades	Grade 1-2	Grade 3-4	All Grades	All Grades
Diarrhea	3 (19)	0	3 (19)	8 (33)	1 (4)	9 (38)	12 (30)
Nausea	3 (19)	0	3 (19)	7 (29)	0	7 (29)	10 (25)
Anemia	0	2 (13)	2 (13)	2 (8)	5 (21)	7 (29)	9 (23)
Fatigue	2 (13)	0	2 (13)	7 (29)	0	7 (29)	9 (23)
Constipation	2 (13)	0	2 (13)	5 (21)	0	5 (21)	7 (18)
Decreased appetite	0	0	0	7 (29)	0	7 (29)	7 (18)
Dizziness	2 (13)	0	2 (13)	4 (17)	0	4 (17)	6 (15)
Dyspnea	1 (6)	1 (6)	2 (13)	4 (17)	0	4 (17)	6 (15)

Pharmacokinetics were dose proportional and mean half-life of approximately 24 hours supports once daily dosing.

Monotherapy Efficacy

In the 21 patients enrolled with AML, 1 patient at 100 mg achieved a morphologic leukemia-free state and 9 patients had disease stabilization, which lasted at least 3 months in 2 patients. In the 19 patients enrolled with B-cell malignancies, 4 patients had stable disease with a decrease in tumor size.

Change in SPD in 4 Patients with B-cell Malignancies with SD

Diagnosis	No. of Prior Therapies	Therapy Duration (weeks)	Baseline SPD (cm^2)	Change SPD (%)
FL	2	18	49.8	-49%
DLBCL	3	16	14.5	-28%
CLL	5	22	74.5	-7%
MZL	4	22	28.4	-4%

FL=Follicular lymphoma; DLBCL=Diffuse large B-cell lymphoma; CLL=Chronic lymphocytic leukemia; MZL=Marginal zone lymphoma

Initial results from correlative studies assessing myeloid leukemia cell differentiation protein (“Mcl-1”) and RNA Pol II phosphorylation on Ser2 (“RNA Pol II p-S2”) demonstrated reduction in expression consistent with the anticipated on-target pharmacodynamic effect of voruciclib on Mcl-1 and RNA Pol II p-S2 (Figures A and B, respectively, below).

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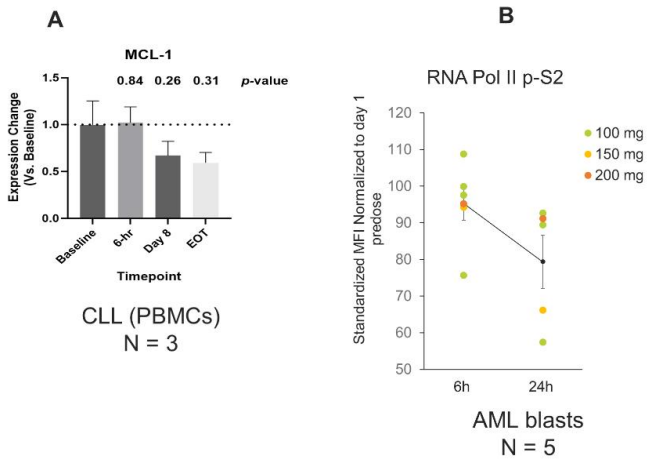

Voruciclib Plus Venetoclax Combination: Initial Data
Voruciclib at doses up to 200 mg on the intermittent schedule have been administered in combination with venetoclax in patients with relapsed or refractory AML. Dose escalation is continuing.

No DLTs have been reported and no evidence of overlapping toxicity has been observed to date. Anti-tumor activity has been demonstrated by objective responses and reductions in transfusions, with multiple patients continuing on therapy for ≥ 4 months.

About Voruciclib
Voruciclib is an orally administered cyclin-dependent kinase 9 (“CDK9”) inhibitor with potential to treat both hematological malignancies and solid tumors. It is in clinical development for acute myeloid leukemia and B-cell malignancies. Applications in solid tumors are also being considered.

The CDK family of proteins are important cell cycle regulators responsible for the control of cell proliferation, differentiation, apoptosis, and DNA repair. CDK9, one of several members of the CDK family of proteins, functions as a gene transcription controller and is also involved in regulating protein degradation. Specifically, CDK9 is a promising target to treat a range of cancers because of its role in controlling two other proteins often dysregulated in cancerous cells: Mcl-1 and the MYC proto-oncogene protein ("MYC")

Mcl-1 is a member of the family of anti-apoptotic proteins which, when elevated, may prevent the cell from undergoing cell death. Inhibition of CDK9 blocks the production of Mcl-1, which is an established resistance mechanism to the B-cell lymphoma 2 ("BCL2") inhibitor venetoclax (marketed as Venclexta®).

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MYC regulates cell proliferation and growth. Upregulation of MYC is implicated in many human cancers and is frequently associated with poor prognosis and unfavorable patient survival. CDK9, in addition to being a transcription factor for MYC, also decreases phosphorylation of MYC protein that is implicated in stabilizing MYC in KRAS mutant cancers. Targeting MYC directly has historically been difficult, but CDK9 is a promising approach to target this oncogene.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical-stage pharmaceutical company committed to developing novel and differentiated cancer therapies. We build our pipeline by acquiring promising cancer agents and creating value in programs through development, strategic partnerships, out-licensing and commercialization, as appropriate. Our approach to oncology drug development is to evaluate our drug candidates in combinations with standard-of-care therapies to overcome known resistance mechanisms and address clear medical needs to provide improved patient benefit. The drug candidate pipeline includes voruciclib, an oral cyclin-dependent kinase 9 ("CDK9") inhibitor, and ME-344, an intravenous small molecule mitochondrial inhibitor targeting the oxidative phosphorylation pathway. For more information, please visit www.meipharma.com. Follow us on X (formerly Twitter) @MEI_Pharma and on LinkedIn.

Forward-Looking Statements

Certain information contained 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 including, without limitation, statements regarding: the potential, safety, efficacy, and regulatory and clinical progress of our product candidates, including the anticipated timing for initiation of clinical trials and release of clinical trial data and our expectations surrounding potential regulatory submissions, approvals and timing thereof, our business strategy and plans; the sufficiency of our cash, cash equivalents and short-term investments to fund our operations; and our ability to fund future capital returns. 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; the availability or appropriateness of utilizing the FDA's accelerated approval pathway for our product candidates; final data from our pre-clinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; 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; uncertainty regarding the impact of rising inflation and the increase in interest rates as a result; potential economic downturn; activist investors; 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. 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.

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