

**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): November 30, 2021**

**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.)

**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**

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))

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

<b>Title of each class</b>	<b>Trading Symbol</b>	<b>Name of each exchange on which registered</b>
<b>Common stock, \$0.0000002 par value</b>	<b>MEIP</b>	<b>The Nasdaq Stock Market LLC</b>

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 November 30, 2021, MEI Pharma, Inc. (the “Company”) and Kyowa Kirin Co., Ltd issued a press release announcing the results of the pivotal Phase 2 TIDAL study evaluating zandelisib as a single agent for follicular lymphoma (FL) patients.

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.

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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release dated November 30, 2021</a>
104	Cover Page Interactive Data File (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.

MEI PHARMA, INC.

Date: November 30, 2021

By: /s/ Daniel P. Gold  
Daniel P. Gold  
Chief Executive Officer



**MEI Pharma and Kyowa Kirin Announce Data From the Ongoing Global Phase 2 TIDAL Study Evaluating Zandelisib as a Single Agent in Patients with Relapsed or Refractory Follicular Lymphoma**

*– Zandelisib Demonstrated 70.3% Objective Response Rate; 35.2% Achieved Complete Response –*

*–9.9% of Patients Discontinued Therapy Due to a Drug Related Adverse Event –*

*– MEI to Host Webcast Today at 8:00am Eastern Time –*

SAN DIEGO and TOKYO, November 30, 2021 – MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, and Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151), a global specialty pharmaceutical company that utilizes the latest biotechnology to discover and deliver novel medicines, today announced that the pivotal Phase 2 TIDAL study evaluating zandelisib as a single agent for follicular lymphoma (FL) patients who received at least two prior systemic therapies demonstrated a 70.3% objective response rate (ORR) as determined by Independent Review Committee (IRC) assessment in the primary efficacy population (n=91). In addition, 35.2% of patients achieved a complete response. The data are currently insufficiently mature to accurately estimate duration of response (DOR). In line with previously reported data from the Phase 1B study, zandelisib was generally well tolerated. With 9.4 months (range: 0.8-24) median duration of follow-up in the total study population (n=121), interim data demonstrated a discontinuation rate due to any drug related adverse event of 9.9%. Patients enrolled in the study will continue to be followed for safety and DOR. Zandelisib is an investigational selective phosphatidylinositol 3-kinase delta (“PI3Kδ”) inhibitor in clinical development for the treatment of B-cell malignancies.

**Overview of Preliminary TIDAL Data in Relapsed or Refractory (r/r) FL**

The ongoing TIDAL study (NCT03768505) is a global, open-label Phase 2 trial evaluating zandelisib as a single agent across two disease cohorts: the first cohort for the treatment of adults with r/r FL and the second cohort for r/r marginal zone lymphoma (MZL), in both cases after failure of at least two prior systemic therapies, including chemotherapy and an anti-CD20 antibody. Enrollment in the FL cohort is complete; enrollment in the MZL cohort is ongoing. Subject to the results and discussion with the U.S. Food and Drug Administration (FDA), TIDAL study data from each study cohort are intended to be submitted to the FDA to support accelerated approval marketing applications.

The r/r FL cohort enrolled a total of 121 patients, 91 of which were enrolled in the primary efficacy population for the evaluation of ORR and DOR. The median age of patients with FL was 64 years old. Patients enrolled in both the FL primary efficacy and total patient populations received a median of 3 prior lines of treatment (range: 2-8). Patients were administered zandelisib once daily for two 28-day cycles as response induction therapy, followed thereafter by once daily dosing for the first seven days of each subsequent 28-day cycle, a schedule called Intermittent Dosing Therapy (IDT).

---

## **Efficacy**

The ORR in the 91 patients with r/r FL enrolled in the primary efficacy population was 70.3% (n=64), 95% CI=59.8, 79.5, as assessed by IRC after a minimum follow-up of 6 months; the complete response rate was 35.2%, 95% CI=25.4, 45.9. The ORR represents the primary endpoint of the TIDAL study.

As of the data cutoff date, the data are not sufficiently mature to accurately estimate the final DOR in the FL primary efficacy population, a secondary outcome measure of the TIDAL study. However, with a median follow-up time for response of 8.4 months, the median DOR had not been reached. The data cutoff date is approximately 6 months after the last patient in the primary efficacy population received their first dose of zandelisib.

## **Safety and Tolerability**

Zandelisib appeared generally well-tolerated in the total TIDAL study population through the data cutoff date. The safety observed in TIDAL was consistent with data previously reported from the Phase 1B study (NCT02914938) evaluating zandelisib in patients with B-cell malignancies as a single agent or in combination with rituximab (Rituxan®).

As of the data cutoff date, with a median follow up of 9.4 months (range: 0.8-24) in the total FL study population, the incidence of Grade 3/4 Adverse Events of Special Interest were: 1.7% ALT/AST elevation, 1.7% colitis, 5% diarrhea, 2.5% mucositis, 0.8% pneumonitis, and 3.3% rash. The discontinuation rate due to any drug related adverse event in the group was 9.9%, also as of the data cutoff date.

A more complete report of the TIDAL data as of the data cutoff date will be submitted for presentation at upcoming scientific congresses in 2022.

“The emerging zandelisib data are very promising and indicate the potential to positively impact the standard-of-care for patients with relapsed or refractory follicular lymphoma,” said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. “The response data and interim safety data reported today support our plans to continue discussions with the FDA on timing of an accelerated approval submission, and we look forward to reporting a more comprehensive review of the data at upcoming medical conferences while continuing this trial and continuing to advance the zandelisib clinical development program in indications beyond follicular and marginal zone lymphomas with our partner, Kyowa Kirin.”

“We are encouraged by the zandelisib data reported today from the TIDAL study,” said Yoshifumi Torii, PhD, Executive Officer, vice president, Head of R&D Division of Kyowa Kirin. “Our team is continuing to study this investigational medicine with our partner MEI Pharma in the hopes of understanding zandelisib’s value and bringing more hope to lymphoma patients around the world.”

## **MEI Pharma Conference Call and Webcast**

MEI will host an investor and analyst webcast event today, November 30, 2021, at 8:00 AM Eastern Time to review the TIDAL phase 2 study data reported today and to provide a corporate overview.

You can access the live webcast with slides under the investor relations section of MEI's website on the "Events and Presentation" page at: [www.meipharma.com](http://www.meipharma.com). A replay of the webcast will be archived for at least 30 days after the conclusion of the live event.

To view additional media and investor resources from MEI Pharma [click here](#).

### **About Zandelisib**

Zandelisib, a selective PI3K $\delta$  inhibitor, is an investigational cancer treatment being developed as an oral, once-daily, treatment for patients with B-cell malignancies. Clinical trials are investigating the efficacy and safety of zandelisib utilizing an Intermittent Dosing Regimen (IDT), as a single agent and in combination with other modalities for the treatment of patients with B-cell malignancies. The IDT leverages molecular and biologic properties specific to zandelisib.

In March 2020 the FDA granted zandelisib Fast Track designation for treatment of adult patients with relapsed or refractory follicular lymphoma who have received at least 2 prior systemic therapies. In November 2021 the FDA granted zandelisib Orphan Drug designation for the treatment of patients with follicular lymphoma.

In April 2020, MEI and Kyowa Kirin entered a global license, development, and commercialization agreement to further develop and commercialize zandelisib. MEI and Kyowa Kirin will co-develop and co-promote zandelisib in the U.S., with MEI booking all revenue from the U.S. sales. Kyowa Kirin has exclusive commercialization rights outside of the U.S.

Ongoing zandelisib studies include the cohort in TIDAL evaluating patients with r/r marginal zone lymphoma and continuing follow up in the cohort of the study evaluating patients with r/r follicular lymphoma. Also ongoing is the Phase 3 COASTAL study (NCT04745832) comparing zandelisib plus rituximab to standard of care chemotherapy plus rituximab, in patients with r/r follicular or marginal zone lymphomas who received <sup>3</sup> 1 prior line of therapy, which must have included an anti-CD20 antibody in combination with chemotherapy or lenalidomide. COASTAL is intended to support marketing applications in the U.S. and globally. Pending FDA agreement, COASTAL is also intended to act as the required confirmatory study for potential U.S. accelerated approvals of zandelisib based on the TIDAL study.

Other ongoing studies include a Phase 2 pivotal study in Japan (NCT04533581) in patients with indolent B-cell non-Hodgkin's lymphoma (iNHL) without small lymphocytic lymphoma (SLL), lymphoplasmacytic lymphoma (LPL), and Waldenström's macroglobulinemia (WM) conducted by Kyowa Kirin.

### **About the TIDAL Phase 2 Study**

The TIDAL study (Trials of PI3K $\delta$  DeltA in Non-Hodgkin's Lymphoma) is a global Phase 2 trial evaluating zandelisib as a single agent across two study cohorts: the first cohort for the treatment of adults with r/r FL and the second cohort for r/r MZL, in both cases after failure of at least two prior systemic therapies including chemotherapy with an alkylating agent and an anti-CD20 antibody. Subject to the results and discussions with the FDA, data from each study cohort are intended to be submitted to the FDA to support separate accelerated approval marketing applications under 21 CFR Part 314.500, Subpart H.

The study is evaluating zandelisib administered once daily at 60 mg for two 28-day cycles as response induction therapy, followed thereafter by Intermittent Dosing Therapy, or “IDT.” The zandelisib IDT consists of once daily dosing for the first seven days of each subsequent 28-day cycle and was developed based on zandelisib-specific preclinical and clinical supporting evidence. The primary efficacy endpoint is the rate of objective responses to therapy and other endpoints will include duration of response and tolerability of zandelisib. The primary efficacy population sample size for r/r FL is 91 patients and the primary efficacy population sample size for r/r MZL is 64 patients. Complete enrollment of the FL primary efficacy population was announced in April 2021. The total study population in the FL cohort is 121 patients to provide additional safety data for the registration application.

More information about this trial is available at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03768505) (NCT03768505).

### **About PI3K Delta**

Phosphatidylinositol 3-kinase delta (PI3Kd) is often overexpressed in cancer cells and plays a key role in the proliferation and survival of hematologic cancers. Targeting the inhibition PI3Kd is a validated strategy in various B cell malignancies, including follicular and marginal zone lymphomas. However, PI3Kd inhibition can lead to immune dysregulation, including inhibition of regulatory T-cell (T-reg) activity, which is understood to contribute to immune-mediated treatment-limiting toxicities.

Strategies to minimize immune dysregulation, while maintaining tumor control with PI3K inhibitors, are required. Subject to suitable pharmacodynamic characteristics, intermittent dosing of PI3Kd inhibitors is a promising approach to decouple the inhibitory activity on malignant B-cells from T-reg inhibition, potentially allowing T-reg recovery, improving tolerability and optimizing the therapeutic potential of this class of therapy.

### **About Follicular Lymphoma**

Follicular lymphoma (FL) is the most common indolent lymphoma, comprising about 20-30% of all non-Hodgkin lymphomas (NHL). The disease also forms on B-cells, is chronic in most cases and tends to progress slowly. Follicular lymphoma is most common in the elderly, having a median age at diagnosis of approximately 65 years old. Sometimes follicular lymphomas can transform into a more aggressive form of large B-cell lymphoma, a fast-growing type of NHL.

### **About MEI Pharma**

MEI Pharma, Inc. (NASDAQ: MEIP) is a late-stage pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma’s portfolio of drug candidates contains multiple clinical-stage assets, including zandelisib, currently in ongoing clinical trials which may support marketing approvals with the U.S. Food and Drug Administration and other regulatory authorities globally. Each of MEI Pharma’s 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](http://www.meipharma.com). Follow us on Twitter [@MEI\\_Pharma](https://twitter.com/MEI_Pharma) and on [LinkedIn](https://www.linkedin.com/company/meipharma).

## About Kyowa Kirin

Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company with a more than 70-year heritage, the company applies cutting-edge science including an expertise in antibody research and engineering, to address the needs of patients and society across multiple therapeutic areas including Nephrology, Oncology, Immunology/Allergy and Neurology. Across our four regions – Japan, Asia Pacific, North America and EMEA/International – we focus on our purpose, to make people smile, and are united by our shared values of commitment to life, teamwork/Wa, innovation, and integrity. You can learn more about the business of Kyowa Kirin at: <https://www.kyowakirin.com>. Follow us on Twitter [@KyowaKirin\\_US](#) and on [LinkedIn](#).

## 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. 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, the availability or appropriateness of utilizing the FDA’s accelerated approval pathway for our product candidates, or the failure to obtain such approval, of our product candidates; uncertainties or differences in interpretation in clinical trial results; the impact of the COVID-19 pandemic on our industry and individual companies, including on our counterparties, the supply chain, the execution of our clinical development programs, our access to financing and the allocation of government resources; 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. You should further be aware that with exception of the ORR data reported in the primary follicular lymphoma efficacy population of 91 patients, the data reported today provides an initial look at the data as of the data cutoff date and is interim and subject to change as more patient data become available with longer follow up. Because the data reported today is from an ongoing study, the final data may differ materially from the data reported in this press release. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.*



---

**Contacts:****MEI Pharma, Inc.**

David A. Walsey

Tel: 858-369-7104

[investor@meipharma.com](mailto:investor@meipharma.com)

Jason I. Spark

Canale Communications for MEI

Tel: 619-849-6005

[jason.spark@canalecomm.com](mailto:jason.spark@canalecomm.com)

**Kyowa Kirin Co., Ltd.:**

Hiroki Nakamura

Corporate Communications Department

[media@kyowakirin.com](mailto:media@kyowakirin.com)

Lauren Walrath

VP, Public Affairs - Kyowa Kirin North America

[publicaffairs.na@kyowakirin.com](mailto:publicaffairs.na@kyowakirin.com)