

MEI Pharma and Kyowa Kirin Announce Publication in The Lancet Oncology of Data from Phase 1b Clinical Study of Zandelisib in Patients with Relapsed or Refractory B-cell Malignancy

SAN DIEGO & TOKYO -- (BUSINESS WIRE) -- 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 creating innovative medical solutions utilizing the latest biotechnology, today announced publication of data from the Phase 1B clinical study of zandelisib, an orally administered investigational phosphatidylinositol 3-kinase delta ("PI3K δ ") inhibitor, in patients with relapsed or refractory (R/R) B-cell malignancy in The Lancet Oncology. The published data demonstrate that an intermittent dosing regimen of zandelisib resulted in lower cumulative risk of Grade 3 or worse adverse events of special interest compared to a continuous daily dosing regimen without loss of efficacy. The publication, entitled "Zandelisib with continuous or intermittent dosing as monotherapy or in combination with rituximab in patients with relapsed or refractory B-cell malignancy: a multicentre, first-in-patient, dose-escalation and dose-expansion, phase 1b trial," is available on the journal [website](#).

"The results observed in our Phase 1b study reinforce the potential of zandelisib, an investigational clinical candidate, to provide a well-tolerated clinical profile either as a single-agent or in combination with other therapies without a loss of efficacy via a unique intermittent schedule compared to continuous daily dosing," said Richard Ghalie, M.D., chief medical officer of MEI Pharma. "We remain encouraged by zandelisib's potential as we continue its development using the intermittent schedule as an oral, chemotherapy-free, time-limited, therapeutic option to meet the needs of patients."

"Based on the results of the Phase 1b study, zandelisib could establish a potential alternative to chemotherapy with a unique dosing schedule for this class, both as a single agent and in combination with other drugs." said Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin. "We will continue to work with MEI to develop new treatment options for patients with B-cell malignancies."

The Phase 1b study ([NCT02914938](#)) is an open-label, dose escalation and expansion study evaluating zandelisib in patients with B-cell malignancies. The manuscript reported on a total of 97 patients, including 31 patients in the dose escalation stage that established 60 mg once daily as the recommended Phase 2 dose. The study evaluated zandelisib in 56 patients as a monotherapy and 41 patients in combination with rituximab. Zandelisib was administered either on a continuous schedule of 60 mg once daily (n=38) or an intermittent dosing schedule of 60 mg once daily for the initial two 28-day cycles followed by the intermittent dosing (ID) schedule of 60 mg once daily on days 1-7 in cycles ≥ 3 (n=59).

In the initial monotherapy dose-finding part of the study, no dose-limiting toxicities were observed across the evaluated doses of 60 mg, 120 mg and 180 mg given daily continuously, and anti-tumor activity was similar across doses. With a median duration of treatment of 10.4 months and 15.2 months, in the continuous and intermittent dosing group respectively, Grade 3 or worse adverse events of special interest occurred less frequently in the intermittent dosing group than in the continuous dosing group. For example, Grade 3 diarrhea or colitis in 8% vs 24%, and Grade 3 lung infection or pneumonia in 2% vs 16%, of patients in the intermittent dosing group vs the continuous dosing group, respectively. Grade 3 or worse AST or ALT elevation (5%) and rash (5%) were uncommon with each dosing schedules. There was a continued increased risk of Grade 3 diarrhea or colitis in the continuous dosing group, compared with a decreased risk over time in the intermittent dosing group after switching to the intermittent dosing. At a median follow-up of 24.9 months in the continuous dosing group and 15.7 months (95% CI 6.5-33.9) in the intermittent dosing group the cumulative incidence of Grade 3 or worse adverse events of special interest was 45% in the continuous dosing group and 20% in the intermittent dosing group.

Intermittent dosing showed comparable efficacy to continuous dosing. Patients with indolent B-cell malignancies (follicular lymphoma, chronic lymphocytic leukemia or small lymphocytic lymphoma, and marginal zone lymphoma) demonstrated an objective overall response rate of 87%.

The published Phase 1b safety and efficacy results for zandelisib 60 mg once daily on an intermittent dosing schedule warranted initiating the ongoing global Phase 2 TIDAL and Phase 3 COASTAL studies evaluating zandelisib alone or in combination with rituximab, respectively.

About Zandelisib

Zandelisib, a selective PI3K δ inhibitor, is an investigational cancer treatment being developed as an oral, once-daily, potential therapeutic option for patients with B-cell malignancies. Clinical trials are investigating the efficacy and safety of zandelisib as a single agent and in combination with other modalities while administered on an Intermittent Dosing Regimen (ID) and in a time-limited manner when dosed in combination. The ID leverages molecular and biologic properties specific to zandelisib.

Ongoing zandelisib studies include the cohort in TIDAL evaluating patients with r/r marginal zone lymphoma (MZL) and continuing evaluation of the cohort of patients in the study with r/r FL. 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 FL or MZL who received more than one prior line of therapy, which must have included an anti-CD20 antibody in combination with chemotherapy or lenalidomide. COASTAL, which is also evaluating time-limited intermittent administration of zandelisib, is intended to support marketing applications in the U.S. and globally.

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

In March 2020, the FDA granted zandelisib Fast Track designation for the treatment of adult patients with r/r follicular lymphoma who have received at least two 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.

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. 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 heritage of more than 70 years, the company applies cutting-edge science, including expertise in antibody research and engineering, to address the needs of patients across multiple therapeutic areas such as nephrology, oncology, immunology/allergy and neurology. Across its four regions – Japan, Asia Pacific, North America and EMEA/International – Kyowa Kirin focuses on its purpose, to make people smile, and is united by its shared values of commitment to life, teamwork, innovation and integrity. Learn more about the Company at www.kyowakirin.com.

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, including statements regarding the results of our clinical trials of zandelisib, the anticipated timing of our submission of an FDA marketing application for zandelisib, the anticipated timing of the disclosure of the final study data for our Phase 2 TIDAL trial, the timing and success of enrollment for our Phase 3 COASTAL trial, our projected financial position and our expected cash runway, the overall advancement of our product candidates in clinical trials and our plans to continue development of our product candidates. We may in some cases use terms such as “predicts,” “believes,” “potential,” “continue,” “anticipates,” “estimates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “likely,” “will,” “should” or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. 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 of our product candidates, or the failure to obtain such approval, of our product candidates; uncertainties or differences in interpretation in clinical trial results; the risk that our clinical trials are discontinued or delayed for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; 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. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.