

Kyowa Kirin and MEI Pharma Announce Topline Data from the Phase 2 MIRAGE Study Evaluating Zandelisib in Patients with Indolent B-cell non-Hodgkin's Lymphoma in Japan

- Interim data from Phase II Study of Zandelisib shows 75.4% ORR in Japanese patients with Indolent B-cell NHL -

- Publication of results from additional Phase 1 study now available in International Journal of Hematology -

TOKYO and SAN DIEGO, November 18 and 17, 2022 — Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151), a global specialty pharmaceutical company creating innovative medical solutions utilizing the latest biotechnology and MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, today announced topline data from the Phase 2 MIRAGE study evaluating zandelisib, an orally administered investigational phosphatidylinositol 3-kinase delta ("PI3K δ ") inhibitor, 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) in Japan.

The data demonstrated a 75.4% objective response rate (ORR) and 24.6% of patients achieved a complete response (CR) as determined by Independent Review Committee (IRRC) assessment (n=61). The data is currently insufficiently mature to accurately estimate duration of response (DOR). With 9.5 months median duration of follow-up, a discontinuation rate due to any treatment emergent adverse event was 14.8%.

"We are very pleased to announce the data from Phase 2 MIRAGE study," said Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin. "We continue to see a favorable profile of zandelisib with intermittent dosing that aims to balance efficacy and safety in Japanese patients who have been heavily pre-treated. These results are consistent with the data of the similarly designed TIDAL study already announced in November 2021. We remain committed to maximizing the value of zandelisib in B-cell malignancies with our partner MEI Pharma and bringing hope to lymphoma patients around the world."

"The results from the MIRAGE study announced today are not only consistent with the data from the Phase 2 TIDAL study, but support the potential of zandelisib on the intermittent schedule to also provide a high rate of response and low rate of Grade 3 or greater adverse

events in Japanese patients with indolent B-cell non-Hodgkin lymphoma,” said Richard Ghalie, M.D., chief medical officer of MEI Pharma.

[MIRAGE Study Details]

The MIRAGE study is a multicenter, open-label, single-arm Phase 2 trial evaluating zandelisib as monotherapy for Japanese patients with relapsed or refractory (r/r) iB-NHL who received at least two prior systemic therapies ([NCT04533581](#)).

A total of 61 patients were enrolled and the median age of patients was 70 years old. Enrolled patients were generally heavily pretreated; the median number of prior therapies was 3 (range 2-9). The primary efficacy endpoint is ORR as assessed by IRRC using a modified Lugano criteria. Patients were administered zandelisib 60 mg once daily for two 28-day cycles as response induction therapy, followed thereafter by 60 mg once daily dosing for the first seven days of each subsequent 28-day cycle, a schedule called Intermittent Dosing Therapy.

Efficacy

The primary endpoint of ORR of zandelisib as a single agent was 75.4% (95% CI [62.7, 85.5]), as assessed by IRRC; the complete response rate was 24.6% (95% CI [14.5, 37.3]). As of the data cutoff date, the data are not sufficiently mature to accurately estimate the final DOR.

Safety and Tolerability

With a median follow-up of 9.5 months (95%CI [8.0, 11.1]), 14.8% of patients discontinued therapy due to any treatment emergent adverse event. Grade 3 adverse events of special interest (AESI) were AST and ALT elevation in 8.2% of patients, rash in 3.3%, and 1.6% each for diarrhea, colitis and lung infection.

[Phase 1 Study]

We also recently announced the publication of data from the Phase 1 study of zandelisib in Japanese patients with r/r iB-NHL in the International Journal of Hematology ([NCT03985189](#)). The publication, entitled "Zandelisib (ME-401) in Japanese patients with relapsed or refractory indolent non-Hodgkin's lymphoma: an open-label, multicenter, dose-escalation phase 1 study" is available on the journal [website](#).

The publication reported a 100% (N=9) ORR and that 22.2% (N=2) of patients achieved CR starting on a continuous daily schedule (45 or 60 mg); patients could be switched to intermittent dosing for an adverse event. No dose-limiting toxicities were observed in the first

cycle of therapy, and the maximum tolerated dose was not reached. With 17.5 months median duration of follow-up, zandelisib was generally well tolerated at 60 mg resulting in the recommended phase 2 dose in Japanese patients.

About Zandelisib

Zandelisib, a selective PI3K δ 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 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.

In November 2021, MEI Pharma and Kyowa Kirin announced topline data from ongoing Phase 2 TIDAL study ([NCT03768505](https://clinicaltrials.gov/ct2/show/study/NCT03768505)) evaluating zandelisib as a single agent for follicular lymphoma (FL) patients who received at least two prior systemic therapies. Zandelisib demonstrated a 70.3% objective response rate (ORR) as determined by an Independent Review Committee (IRRC) assessment in the primary efficacy population (n=91). In addition, 35.2% of patients achieved a complete response. At the time of the data cutoff, the data were 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.

Other ongoing studies include the Phase 3 COASTAL study ([NCT04745832](https://clinicaltrials.gov/ct2/show/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.

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 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.

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).

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. to these forward-looking statements.