

MEI Pharma and Kyowa Kirin Announce First Patient Dosed in the Phase 3 COASTAL Study Evaluating Zandelisib Plus Rituximab in Relapsed or Refractory Indolent Non Hodgkin's B-cell Lymphoma

-COASTAL is intended to support FDA and global marketing approvals in patients with relapsed or refractory follicular or marginal zone lymphomas who have received at least one prior line of treatment -

SAN DIEGO and TOKYO, August 17, 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 strives to create new value through the pursuit of advances in life sciences and technologies, today announced the dosing of the first patient in a Phase 3 study of zandelisib known as COASTAL. COASTAL is evaluating zandelisib, a selective phosphatidylinositol 3-kinase delta ("PI3Kδ") inhibitor, in combination with rituximab in patients with relapsed or refractory (r/r) follicular lymphoma (FL) or marginal zone lymphoma (MZL) who have received at least one prior line of therapy.

"Zandelisib has the potential to provide a best-in-class therapeutic profile that delivers a meaningful and improved clinical benefit to patients with relapsed or refractory follicular or marginal zone lymphomas," said Professor Wojciech Jurczak, *M.D., Ph.D., COASTAL principal investigator*, Department of Clinical *Oncology*, Maria Skłodowska-Curie National Research Institute of Oncology in Kraków, Poland. "Because most patients diagnosed with follicular and marginal zone lymphomas will experience disease relapse or some may not respond well to initial treatments, additional chemotherapy-free therapeutic options are invaluable after first line chemoimmunotherapy."

About the Phase 3 COASTAL Study

The global, randomized, two-arm Phase 3 COASTAL study will compare zandelisib plus rituximab to standard of care chemotherapy plus rituximab, in patients with r/r FL or MZL who received ≥ 1 prior line of therapy, which must have included an anti-CD20 antibody in combination with chemotherapy or lenalidomide. COASTAL is expected to enroll 534 patients. Zandelisib will be administered once daily for two 28-day cycles followed by an intermittent schedule of once daily dosing for 7 days of each subsequent 28-day cycle for a total of 24 months, in combination with rituximab (R) in the first 6 months only. The control arm will consist of 6 cycles of the standard chemoimmunotherapy regimens R-CHOP or R-bendamustine. The primary efficacy endpoint is progression-free survival; secondary endpoints include overall response rate, overall survival, patient reported outcomes assessments, and safety and tolerability.

COASTAL is intended to support marketing applications in the U.S. and globally in r/r FL and MZL patients who have received at least one prior line of treatment. COASTAL is also intended to act as the required confirmatory study for the potential U.S. accelerated approval of zandelisib based on the ongoing Phase 2 TIDAL study evaluating patients with r/r FL and MZL patients who have received two or more prior lines of treatment.

"Phase 1b zandelisib data reported at the ASCO annual meeting earlier this year, including the 95% overall response rate achieved in combination with rituximab in relapsed or refractory follicular lymphoma patients and a low incidence of Grade 3 adverse events, are encouraging and supports our

expanding clinical development efforts as we initiate the Phase 3 COASTAL study,” said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. “In close collaboration with our global partner Kyowa Kirin, we are excited to advance the zandelisib development program into patients with follicular or marginal zone lymphomas that have received at least one prior line of treatment, building on our efforts to realize zandelisib’s potential as a novel treatment for patients with B-cell malignancies.”

"The Phase 3 COASTAL study occupies an important position in evaluating the potential efficacy of zandelisib in patients with relapsed or refractory follicular or marginal zone lymphomas," said Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin. "Together with MEI Pharma, we hope to deliver zandelisib as a new treatment option to patients as soon as possible, and we commit to working with medical professionals and the patient community as an R&D-driven pharmaceutical company pursuing advances in life sciences and technologies."

About Zandelisib

Zandelisib (formerly called ME-401), a selective PI3K δ inhibitor, is an investigational cancer treatment being developed as an oral, once-daily, treatment for patients with B-cell malignancies. Differentiated by its molecular structure and pharmacologic properties, zandelisib is administered on an optimized dosing schedule consisting of daily therapy for induction/remission followed by intermittent dosing therapy intended to mitigate immune-related adverse events while providing continued therapeutic benefit.

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

Ongoing clinical studies of zandelisib include TIDAL (Trials of PI3K **DeltA** in Non-Hodgkin's Lymphoma), a global Phase 2 study evaluating zandelisib as a monotherapy across two study arms: the first study arm for the treatment of adults with relapsed and refractory follicular lymphoma and the second study arm for marginal zone lymphomas, in both cases after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. The primary endpoint of the study is the objective response rate. Subject to the results and discussions with FDA, data from each study arm are intended to be submitted to FDA to support separate accelerated approval marketing applications under 21 CFR Part 314.500, Subpart H.

COASTAL is the Phase 3 study evaluating zandelisib in combination with rituximab in patients with r/r indolent non-Hodgkin's lymphoma (iNHL). COASTAL is intended to support FDA approval for additional indications and regulatory marketing applications globally. COASTAL is also intended to act as the required confirmatory study for a potential U.S. accelerated approval of zandelisib in patients with r/r FL or MZL being evaluated in the Phase 2 TIDAL study who have received two or more prior lines of treatment.

Another Phase 2 pivotal study in Japan is evaluating zandelisib 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. This study is intended to support a Japanese filing with PMDA.

About PI3K Delta

Phosphatidylinositol 3-kinase delta ("PI3K δ ") is often overexpressed in cancer cells and plays a key role in the proliferation and survival of hematologic cancers. Zandelisib displays high selectivity for the PI3K δ isoform and has distinct pharmaceutical properties from other PI3K δ inhibitors.

About Follicular and Marginal Zone Lymphomas*

Follicular lymphoma (FL) is the most common indolent lymphoma, comprising about 20% of all non-Hodgkin's lymphomas (NHL), which is one of the most common cancers in the U.S., accounting for about 4% of all cancers. FL derives from a type of white blood cell called a B-lymphocyte, and tends to progress slowly in most cases. The average age of people with FL is about 60 years of age. Sometimes follicular lymphomas can change into diffuse large B-cell lymphoma, a fast-growing (aggressive) type of NHL.

Marginal zone lymphoma (MZL) is another group of indolent, or slow growing, lymphomas. The disease also forms on B-cells. MZL accounts for approximately 5% to 10% of all non-Hodgkin's lymphoma cases in the U.S. The average age of people with the most common form of marginal zone lymphoma is 60 years of age.

*American Cancer Society: <https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/key-statistics.html>, and <https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/b-cell-lymphoma.html>. Accessed June 16, 2021.

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 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 its four regions – Japan, Asia Pacific, North America and EMEA/International – we focus on its 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>.

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, 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. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.