



**Kyowa Kirin and MEI Pharma Announce First Patient Dosed in Japanese Pivotal Phase 2 Study of Zandelisib in Patients with Indolent B-cell non-Hodgkin's Lymphoma**

TOKYO and SAN DIEGO, CA, October 2, 2020 –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 potential new therapies for cancer, today announced the first patient has been dosed in the pivotal Phase 2 study of zandelisib (formerly called ME-401), an oral, once-daily, investigational drug-candidate selective for phosphatidylinositol 3-kinase delta (PI3Kδ) in patients with indolent B-cell non-Hodgkin's lymphoma (iNHL) without Small lymphocytic lymphoma, lymphoplasmacytic lymphoma (LPL), and Waldenström's macroglobulinemia (WM) in Japan.

This Phase 2, multicenter, open-label, single-arm clinical study is conducted by Kyowa Kirin to evaluate zandelisib as monotherapy for treatment of Japanese patients with relapsed or refractory iNHL with at least two prior systemic therapies.

Yoshifumi Torii, Ph.D., Vice President, Head of R&D Division of Kyowa Kirin, said “I am pleased that we have initiated the clinical study to seek regulatory approval in Japan. We are committed to delivering zandelisib as a new potential treatment option for Japanese patients and their physicians. And we continue to work closely with MEI Pharma to expand the global development program for zandelisib.”

“The initiation of the Japanese Phase 2 pivotal study is an important addition to the zandelisib global development program,” stated Richard Ghalie, M.D., senior vice president, clinical development of MEI Pharma. “We are excited to continue working diligently in close partnership with Kyowa Kirin to build on the potential for zandelisib inside and outside the U.S., and to expand development into indications beyond 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 the Clinical Study>

Indication	iNHL* *SLL, WM and LPL are excluded
Phase	Phase 2
Design	Multicenter, open-label and single-arm study
Administration group	Zandelisib monotherapy
Primary Endpoint	Objective response rate (ORR)
Sample size	60
Estimated study completion	September 2024
Countries/Regions	Japan

### **About Zandelisib**

Zandelisib (formerly called ME-401) is an investigational cancer treatment being developed as an oral, once-daily, selective PI3K $\delta$  inhibitor for the treatment of B-cell malignancies. In March 2020 the U.S. FDA granted zandelisib Fast Track designation.

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Ongoing studies evaluating zandelisib include TIDAL (Trials of PI3K **DeltA** in Non-Hodgkin's Lymphoma) a Phase 2 clinical trial evaluating zandelisib as a monotherapy for the treatment of adults with follicular lymphoma after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. Subject to the results, upon completion TIDAL is intended to be submitted to FDA to support an accelerated approval marketing application under 21 CFR Part 314.500, Subpart H. Ongoing zandelisib studies also include a Japanese Phase 2 pivotal study in patients with iNHL without Small lymphocytic lymphoma, LPL and WM being conducted by Kyowa Kirin.

### **About Kyowa Kirin**

Kyowa Kirin commits to innovative drug discovery driven by state-of-the-art technologies. The company focuses on creating new value in four therapeutic areas: nephrology, oncology, immunology/allergy, and neurology. Under the Kyowa Kirin brand, employees from 40 group companies across North America, EMEA and Asia/Oceania unite to champion the interests of patients and their caregivers by discovering solutions to address unmet medical needs. You can learn more about the business of Kyowa Kirin at [www.kyowakirin.com](http://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 four clinical-stage assets, including zandelisib, currently in an ongoing Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. 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).

### **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.*