MEI Pharma and Kyowa Kirin Announce Discontinuation of Zandelisib Development Outside of Japan Following Recent FDA Meeting

SAN DIEGO and TOKYO, December 5 and 6, 2022 — MEI Pharma, Inc. (Nasdaq: MEIP), a pharmaceutical company focused on advancing new therapies for cancer, and Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151), a Japan-based global specialty pharmaceutical company creating innovative medical solutions utilizing the latest biotechnology, today announced that after receiving the most recent guidance from a late November meeting with the U.S. Food and Drug Administration (FDA), the companies are discontinuing global development of zandelisib outside of Japan for B-cell malignancies. Kyowa Kirin is continuing the ongoing clinical trials including Phase 2 MIRAGE study evaluating Japanese patients with relapsed or refractory indolent B-cell non-Hodgkin lymphomas and will explore the potential for a submission to Japanese health authorities based on data from the MIRAGE and TIDAL clinical trials.

“Based on the most recent guidance received from the FDA at a late November meeting, we have jointly decided with Kyowa Kirin to discontinue development of zandelisib outside of Japan. We are very disappointed to share this decision in light of our belief in the potential of zandelisib to benefit patients and meet the ongoing need for new options to treat relapsed or refractory indolent non-Hodgkin lymphomas,” said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. “However, in light of FDA’s guidance, we no longer believe clinical development can be completed within a time period that would support further investment, or with sufficient certainty of the regulatory requirements to justify continued global development efforts.”

“We share MEI’s disappointment in making this decision,” said Yoshifumi Torii, Ph.D., executive officer, vice president, head of R&D division of Kyowa Kirin. “However, given the Phase 2 data we previously announced on zandelisib, we still see potential to continue the program in Japan to address unmet patient needs. We are continuing the Japanese clinical trials including Phase 2 MIRAGE trial and will consult the PMDA to understand the potential it offers for a regulatory submission.”

In March 2022, MEI Pharma and Kyowa Kirin reported the outcome of an end of Phase 2 meeting with the FDA wherein the agency discouraged a filing based on the single-arm Phase 2 TIDAL trial evaluating zandelisib in patients with relapsed or refractory follicular lymphoma. At this meeting, the FDA stated that a randomized trial should be used to support an initial zandelisib registration in patients with indolent non-Hodgkin lymphoma and, accordingly, data generated from single arm studies such as the Phase 2 TIDAL trial are insufficient to adequately assess the risk/benefit of PI3K inhibitors evaluating indolent non-Hodgkin lymphoma. At that time the FDA emphasized that the companies continue efforts with the ongoing randomized Phase 3 COASTAL trial evaluating patients with relapsed or refractory follicular or marginal zone lymphomas. Subsequently, at an April 2022 meeting of the FDA Oncology Drugs Advisory Committee, the committee voted that future approvals of PI3K inhibitors for hematologic malignancies should be supported by randomized data.

In late November 2022, MEI Pharma and Kyowa Kirin met with the FDA in a follow-up meeting to the March 2022 end of Phase 2 meeting. At this meeting, FDA provided further guidance regarding the design and statistical analysis for the COASTAL trial. Following the November meeting, the companies concluded that a clinical trial consistent with the recent FDA guidance, including modification of the COASTAL trial, would likely not be feasible to complete within a time period that would support further investment. As a result, global development of zandelisib for indolent forms of non-Hodgkin lymphoma, except for Japan, is being discontinued.

The discontinuation of zandelisib development outside of Japan is a business decision based on the most recent regulatory guidance from the FDA and is not related to the zandelisib clinical data generated to date. Kyowa Kirin is continuing the ongoing clinical trials including Phase 2 MIRAGE trial evaluating Japanese patients with relapsed or refractory indolent B-cell non-Hodgkin lymphomas and will explore submitting the MIRAGE and TIDAL trials for marketing authorization in Japan. MIRAGE is a Phase 2 trial, similar in design to the global Phase 2, single-arm, TIDAL trial. In November 2022 Kyowa Kirin and MEI announced positive topline data from the Phase 2 MIRAGE trial. MEI and Kyowa Kirin plan to immediately start winding-down ongoing clinical studies outside of Japan, including the Phase 3 COASTAL trial and the Phase 2 CORAL trial evaluating patients with relapsed or refractory chronic lymphocytic leukemia. Depending on the achievement of certain regulatory and commercial milestones in Japan, MEI may be eligible for additional payments from Kyowa Kirin under the current agreement. MEI may also be entitled to royalties on any sales of zandelisib in Japan.

About zandelisib
Zandelisib, a selective PI3Kδ inhibitor, is an investigational cancer treatment being developed as an oral, once-daily, treatment for patients with B-cell malignancies.
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 were to 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 pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes clinical stage candidates with differentiated mechanisms of action intended to address unmet medical needs and 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 and on LinkedIn.

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, without limitation, statements regarding: MEI's plans to discontinue development of zandelisib, wind down the currently ongoing clinical studies of zandelisib being conducted by MEI, , the potential, safety, efficacy, and regulatory and clinical progress of our product candidates, including the anticipated timing for initiation of clinical trials and release of clinical trial data and our expectations surrounding potential regulatory submissions, approvals and timing thereof, our business strategy and plans; and the sufficiency of our cash, cash equivalents and short-term investments to fund our operations. 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 ability to successfully wind down the currently ongoing clinical studies of zandelisib; our ability to negotiate a termination of the existing zandelisib global development and commercialization agreement between MEI and Kyowa Kirin and negotiate a license agreement for Japan; our failure to successfully commercialize 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, or the failure to obtain such approval, of our product candidates; uncertainties or differences in interpretation in clinical trial results; adverse effects on the Company's business as a result of the restatement of our previously issued financial statements; 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.