MEI Pharma and Kyowa Kirin Announce Global License, Development and Commercialization Agreement for ME-401

- *MEI Pharma and Kyowa Kirin will co-develop and co-promote ME-401 in the U.S.; MEI to book U.S. sales on 50-50 profit and cost sharing*
- *Kyowa Kirin obtains exclusive commercialization rights ex-U.S.; MEI to receive escalating tiered royalty payments on ex-U.S. sales*
- *MEI to receive $100 million in an upfront cash payment and is eligible to receive up to an additional $582.5 million based on the achievement of specified development, regulatory and commercial milestones*
- *MEI to host conference call on April 14 at 8:00 a.m. ET*

SAN DIEGO, and TOKYO, April 14, 2020 – MEI Pharma, Inc. (NASDAQ: MEIP) and Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151) today jointly announced that the companies have entered into a global license, development and commercialization agreement to further develop and commercialize MEI's ME-401, an oral, once-daily, investigational drug-candidate, selective for phosphatidylinositol 3-kinase delta (PI3Kδ), in clinical development for the treatment of B-cell malignancies. MEI and Kyowa Kirin will co-develop and co-promote ME-401 in the U.S., with MEI booking all revenue from U.S. sales. Kyowa Kirin has exclusive commercialization rights outside of the U.S.

ME-401 is being studied in the ongoing Phase 2 TIDAL clinical trial evaluating patients with relapsed or refractory follicular lymphoma which, subject to results, may support an accelerated approval of a marketing application with the U.S. Food and Drug Administration (FDA). An ongoing Phase 1b study is evaluating ME-401 as a monotherapy and in combination with rituximab (Rituxan®) or zanubrutinib (Brukinsa™) in patients with B-cell malignancies. Also, a Phase 1 study was initiated in 2019 evaluating ME-401 as a monotherapy in patients with indolent B-cell malignancy in Japan.

"This global partnership with Kyowa Kirin is a key step to achieving our goal of broadly developing and commercializing ME-401, optimizing the opportunity to benefit patients across multiple B-cell malignancies inside and outside the U.S., and also building value for our shareholders," said David M. Urso, J.D., chief operating officer & general counsel of MEI Pharma. "The decision to expand our alliance with Kyowa Kirin is based on the successful relationship we've built working together to date under our 2018 Japan license agreement, and the respect we have for Kyowa Kirin and their ability to jointly execute our shared vision of ME-401 in the U.S. and around the world."

"I am delighted to expand our agreement with MEI Pharma for the development and commercialization of ME-401 all over the world," said Tomohiro Sudo, Executive Officer, Director of Strategic Product Planning Department for Kyowa Kirin. "We believe that ME-401 may be an important new treatment option for patients and further enhances our global oncology pipeline."

About the Global License, Development and Commercialization Agreement
Under the terms of the agreement, which substantially retains and consolidates the terms of the 2018 license agreement between MEI and Kyowa Kirin to develop and commercialize ME-401 in Japan, MEI will receive a $100 million upfront payment from Kyowa Kirin. MEI is also eligible to receive up to $582.5 million in additional payments from Kyowa Kirin depending on the achievement of certain U.S. and ex-U.S. development, regulatory and commercial milestones.

If approved by FDA in the U.S., MEI and Kyowa Kirin will co-promote ME-401, with MEI booking all revenue from sales. MEI and Kyowa Kirin will share U.S. profits and costs (including development costs) on a 50-50 basis.

Outside the U.S., Kyowa Kirin will have exclusive commercialization rights, lead commercialization and book all revenues from sales of ME-401. Kyowa Kirin will pay MEI escalating tiered royalties on ex-U.S. sales starting in the teens. Kyowa Kirin will be responsible for all incremental ex-U.S. clinical development costs and all ex-U.S. regulatory, CMC and commercial costs.

The companies have agreed to a development plan designed to broadly evaluate ME-401 in patients with various B-cell malignancies, including in combination with other agents.

Conference Call & Webcast Information (Conducted by MEI)
When: April 14, 2020, 8:00 a.m. ET
Dial-in: 1-877-879-1183 (International Toll: 1-412-902-6703)
Conference ID: 0809665

Please join the conference call at least 10 minutes early to register. You can access the live webcast under the investor relations section of MEI's website at: www.meipharma.com. A replay of the conference call will be archived under events and webcasts for at least 30 days after the call.

About ME-401
ME-401 is an investigational treatment and not approved by the U.S. Food and Drug Administration (FDA) or other Health Authorities. Clinical development of ME-401 as an oral, once-daily, selective PI3Kδ inhibitor for the treatment of B-cell malignancies is ongoing. The U.S. FDA recently granted ME-401 Fast Track designation.

MEI is currently conducting two ongoing studies evaluating ME-401. The first is a Phase 2 clinical trial evaluating ME-401 as a monotherapy for the treatment of adults with relapsed or refractory follicular lymphoma after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. Subject to the results, upon completion of the Phase 2 clinical trial, ME-401 is planned to be submitted with the FDA to support an accelerated approval of a marketing application under 21 CFR Part 314.500, Subpart H. The second study is a multi-arm, open-label, Phase 1b dose escalation and expansion trial evaluating ME-401 as a monotherapy and in combination with other therapies or investigational agents in patients with relapsed or refractory B-cell malignancies. Additionally, a Phase 1 study was initiated by Kyowa Kirin in 2019 evaluating ME-401 as a monotherapy in patients with indolent B-cell malignancy in Japan.

About MEI Pharma
MEI Pharma, Inc. (Nasdaq: MEIP) is a late-stage pharmaceutical company focused on developing potential new therapies for cancer. Our portfolio of drug candidates contains four clinical-stage assets,

including one candidate in an ongoing global registration trial and another candidate in a Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. Each of our 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.

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 the four therapeutic areas: nephrology, oncology, immunology/allergy and neurology. Under the Kyowa Kirin brand, employees from 36 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.

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.