MEI Pharma and Kyowa Kirin receive Orphan Drug Designation for Zandelisib for the Treatment of Follicular Lymphoma

SAN DIEGO, CA and BEDMINSTER, NJ, November 10, 2021 – MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, and Kyowa Kirin, Inc., an affiliate of Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151), a global specialty pharmaceutical company that utilizes the latest biotechnology to discover and deliver novel medicines, today announced that the U.S. Food and Drug Administration (FDA) granted orphan-drug designation (ODD) to zandelisib for the treatment of follicular lymphoma.

Orphan-drug designation is granted by the FDA to a drug or biologic intended to treat a rare disease or condition, which generally includes a disease or condition that affects fewer than 200,000 individuals in the U.S. ODD granted therapies entitle companies to development incentives including tax credits for qualified clinical trials, exemptions from certain FDA application fees, and the potential of seven years of marketing exclusivity in the event of regulatory approval. ODD does not shorten the duration of the regulatory review or approval process. For more information on ODD, please visit the FDA website at https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products.

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 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 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. and will pay MEI escalating tiered royalties on ex-U.S. sales.

Ongoing zandelisib studies include the TIDAL study (NCT03768505), a global Phase 2 trial evaluating zandelisib as a single agent across two cohorts: the first cohort for the treatment of adults with r/r FL and the second cohort for r/r marginal zone lymphoma (MZL), in both cases after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. Enrollment in the FL cohort is complete; enrollment in the MZL cohort is ongoing.

Subject to the results and discussions with FDA, data from each study cohort are intended to be submitted to FDA to support separate accelerated approval marketing applications under 21 CFR Part 314.500, Subpart H.

Also ongoing is the Phase 3 COASTAL study (NCT04745832) comparing zandelisib plus rituximab to standard of care chemotherapy plus rituximab, in patients with r/r follicular or marginal zone lymphomas who received ≥ 1 prior line of therapy, which must have included an anti-CD20 antibody in combination with chemotherapy or lenalidomide. COASTAL is intended to support marketing applications in the U.S. and globally. COASTAL is also intended to act as the required confirmatory study for potential U.S. accelerated approvals of zandelisib based on the TIDAL study.

Other ongoing studies include a Phase 2 pivotal study in Japan (NCT04533581) 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.

About Follicular Lymphoma

Follicular lymphoma (FL) is the most common indolent lymphoma, comprising about 20-30% of all non-Hodgkin lymphomas (NHL). The disease also forms on B cells, is chronic in most cases and tends to progress slowly. Most people diagnosed with FL are over 65 years of age. Sometimes follicular lymphomas can change into diffuse large B-cell lymphoma, a fast-growing (aggressive) type of NHL.

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 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 70-year heritage, we apply 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 our four regions – Japan, Asia Pacific, North America and EMEA/International – we focus on our 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.

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