



MEI Pharma and Kyowa Kirin Announce Updated Clinical Data from the Phase 1b Study Evaluating ME-401 on an Intermittent Schedule in Patients with Follicular Lymphoma and Other B-cell Malignancies; Data to be Featured in the American Society of Clinical Oncology 2020 Virtual Scientific Program

- *83% overall response rate in patients with relapsed or refractory follicular lymphoma –*
- *Median duration of response in follicular lymphoma patients not reached across all patient subsets analyzed –*
- *Remains generally well-tolerated with 7% discontinuation rate due to adverse events in this study –*

SAN DIEGO and TOKYO, May 13 and 14, 2020 – MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing potential new therapies for cancer, and Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151), a global specialty pharmaceutical company creating innovative medical solutions utilizing the latest biotechnology, today announced updated data from a Phase 1b study of ME-401, an oral, once-daily, investigational drug-candidate selective for phosphatidylinositol 3-kinase delta (PI3K δ) in clinical development for the treatment of B-cell malignancies. These new data evaluating patients on an intermittent dosing schedule of ME-401 show that treatment was generally well tolerated with an 83% overall response rate in patients with relapsed or refractory (r/r) follicular lymphoma (FL) (n=36). These results will be featured in a poster discussion at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program May 29-31.

Additionally, these data show:

- Overall response rates in FL patients ranging from 76% to 89% across patient subsets analyzed (prior lines of therapy (1 vs \geq 2) or treatment group (i.e. monotherapy or in combination with rituximab)).
- Durable responses with no median yet reached (median follow-up of 13.2 months: range: 3.0-27.6) in all FL patients, across all patient subsets analyzed (prior lines of therapy (1 vs \geq 2), treatment group (i.e. monotherapy or in combination with rituximab) or tumor bulk (< 5 cm vs \geq 5 cm)).
- Seven Adverse Events of Special Interest (AESI) among all patients treated on the IS schedule (n=57), with no Grade \geq 3 AESI reported after Cycle 3; Four (7%) patients discontinued due to any adverse event. AESI's include diarrhea (2), colitis (2), ALT/AST (1), rash (1) and noninfectious pneumonitis (1).

The poster, titled "Tolerability and Durable Responses of the PI3K δ Inhibitor ME-401 Administered on an Intermittent Schedule in Relapsed/Refractory (R/R) Follicular Lymphoma (FL) and Other B-cell Malignancies," will be included in a poster discussion session at the ASCO Virtual Scientific Program and will be available for on-demand viewing online beginning on May 29, 2020 at 8:00 a.m. ET at <https://meetings.asco.org/am/virtual-program>. The poster will also be available for download via the [MEI Pharma website](#).

Andrew D. Zelenetz, M.D., Ph.D., Principal Investigator of the Phase 1b study and Professor of Medicine at Weill Cornell Medical College, Medical Director of Quality Informatics at Memorial Sloan Kettering Cancer Center, and Chair of the National Comprehensive Cancer Network's Non-Hodgkin Lymphoma Guideline Panel, commented: "In this study, ME-401 and its intermittent dosing strategy (one week on, 3 weeks off) continues to show high response rates which are durable to date, with patients having a median of 13.2 months on therapy. Additionally, ME-401 appears well-tolerated with a low incidence of Grade 3 adverse events of interest and a correspondingly low discontinuation rate due to adverse events. ME-401 is currently being evaluated in the phase 2 TIDAL study, and if the profile we are observing is maintained, this is a therapy that could meaningfully expand the role of PI3K δ in the treatment of B-cell malignancies."

Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma, added: "The ME-401 Phase 1b data continues to generate consistent efficacy and safety data across groups, including as a monotherapy and in combination with rituximab, which we believe underscores the compelling opportunity to provide an important new potential option to patients with B-cell malignancies. We are particularly encouraged that the follicular lymphoma patients in the Phase 1b study -- the focus of our ongoing Phase 2 TIDAL study -- now have a median time on therapy in excess of 1 year with responses that are durable to date while remaining generally well-tolerated."

Yoshifumi Torii, Ph.D., Vice President, Head of R&D Division of Kyowa Kirin, said "We believe this data is encouraging and shows the potential for a meaningful response rate and duration of response in patients with B-cell malignancies. We are working closely with MEI Pharma to expand the global development program for ME-401 and understand its potential for treating patients with B-cell malignancies worldwide."

The Phase 2 TIDAL (Trials of PI3K **DeltA** in Non-Hodgkin's Lymphoma) study is evaluating patients with r/r FL, and may support an accelerated approval of a marketing application with the U.S. Food and Drug Administration.

ME-401 is not yet licensed or approved anywhere globally and has not yet been demonstrated to be safe or effective for the treatment of follicular lymphoma and other B-cell malignancies.

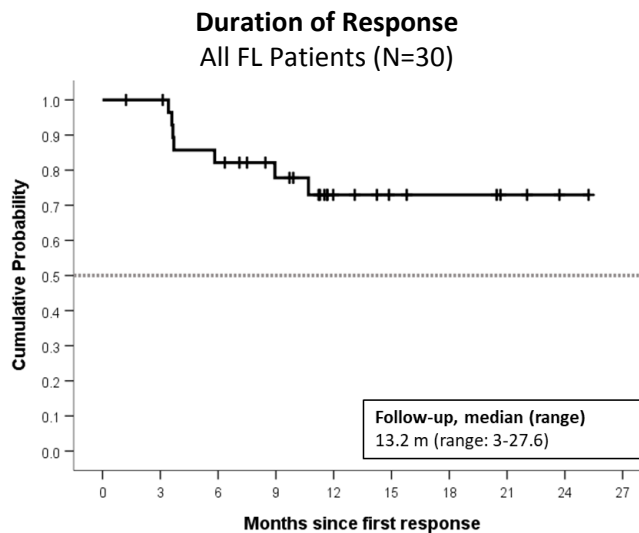
ME-401 Phase 1b Clinical Study

The ongoing Phase 1b clinical 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 in patients with relapsed or refractory B-cell malignancies. The data reported today is for patients receiving ME-401 administered on the intermittent schedule: once daily at 60 mg for two 28-day cycles and then on an intermittent schedule of once daily dosing for the first 7 days of each subsequent 28-day cycle (i.e. the intermittent schedule or IS). A total of 57 patients have been treated with ME-401 on the intermittent schedule, including 36 patients with r/r FL, 10 patients with r/r chronic lymphocytic leukemia (CLL), and 11 patients with other B-cell malignancies.

The overall response rate in 36 patients with r/r FL was 83%, with 22% achieving a complete response. The overall response rate was 76% in 17 patients administered ME-401 as a monotherapy and 89% in 19 patients administered ME-401 in combination with rituximab. The overall response rate in 9 evaluable patients with CLL was 89%.

Diagnosis	Evaluable Subjects N	ORR N (%)
FL	36	30 (83%)
By treatment group		
ME-401 monotherapy	17	13 (76%)
ME-401 + rituximab	19	17 (89%)
By prior lines of therapy		
1 prior	16	13 (81%)
≥ 2 prior	20	17 (85%)
CLL/SLL		
By treatment group	9	8 (89%)
ME-401 monotherapy	3	3 (100%)
ME-401 + rituximab	6	5 (83%)

Median duration of response in patients with FL has not yet been reached and median follow-up is 13.2 months (range: 3.0-27.6). Responses appear durable across patient subsets analyzed (prior lines of therapy (1 vs ≥ 2), treatment group (i.e. monotherapy or in combination with rituximab) or tumor bulk (< 5 cm vs ≥ 5 cm)).



ME-401 was generally well-tolerated. The rate of drug related grade 3 AEs is: diarrhea 3.5% (2/57); colitis 3.5% (2/57); rash 1.8% (1/57); ALT/AST elevation 1.8% (1/57); non-infectious pneumonitis 1.8% (1/57). No grade ≥ 3 AEs has been reported after Cycle 3, when patients are treated with the IS, and the discontinuation rate due to adverse events is 7% (4/57). There were no isolated grade 3 elevations in ALT and AST: such elevations were transient and in each case were associated with grade 3 diarrhea or rash.

About ME-401

ME-401 is an investigational cancer treatment being developed as an oral, once-daily, selective PI3K δ inhibitor for the treatment of B-cell malignancies is ongoing. In March 2020 the U.S. FDA granted ME-401 Fast Track designation.

In April 2020 MEI and Kyowa Kirin entered a global license, development and commercialization agreement to further develop and commercialize ME-401. 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.

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 r/r FL 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 to FDA to support an accelerated approval 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 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.

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.