



# MEI Pharma Board of Directors Aligns on Strategy to Advance Voruciclib and ME-344

April 11, 2024

*– MEI Pharma Board Unanimously Determines, Based on Clinical Data Results, Not to Proceed with Second Capital Return Under 2023 Anson and Cable Car Cooperation Agreement: Conserving Capital, Prioritizing Measured Investment, Extending Operational Runway –*

SAN DIEGO--(BUSINESS WIRE)--Apr. 11, 2024-- MEI Pharma, Inc. (Nasdaq: MEIP), a clinical-stage pharmaceutical company evaluating novel drug candidates to address known resistance mechanisms to standard-of-care cancer therapies, today reported that the Company's Board of Directors unanimously agreed on a strategic plan to leverage recent positive voruciclib and ME-344 clinical data to prioritize clinical development of voruciclib while enabling development of a new ME-344 formulation for Phase 1 study. Additionally, the Company's Board of Directors unanimously determined not to proceed with a second return of capital under the October 31, 2023 Anson Funds and Cable Car Capital cooperation agreement in order to conserve resources and align strategic investment, and thereby extend the Company's operational runway.

"We are very fortunate as a development-stage therapeutics company to have two very promising oncology candidates, voruciclib and ME-344, that continue to generate data supporting their potential as novel therapeutics to benefit patients with cancer. With the MEI Board aligned around our strategy, we have a productive framework to advance both clinical programs in a manner intended to address significant medical needs while prioritizing a measured and objective-based allocation of our resources," said David Urso, president and chief executive officer of MEI Pharma. "Voruciclib, our investigational oral CDK9 inhibitor, in combination with venetoclax is being developed to treat patients with relapsed/refractory AML without an actionable mutation, representing a potential opportunity to address more patients in a mutation agnostic approach than mutation specific therapies such as FLT3, IDH or menin inhibitors. In addition, investigational ME-344 has the potential to treat patients across many types of solid tumors through a novel therapeutic strategy in combination with VEGF inhibitors, such as Avastin®, to create synthetic lethality in tumor cells."

"The entire MEI Board is pleased to unanimously align around a strategy that we believe is in the best interests of the Company's shareholders, with the intent to optimize the opportunity to judiciously advance both of the voruciclib and ME-344 development programs," stated Taheer Dato, director of MEI Pharma and principal and portfolio manager of Anson Funds. "Under the strategy, use of capital is measured and balanced to achieve key clinical objectives designed to optimize the development potential these product candidates hold to advance the standard of care for patients with cancer while also optimizing the interests of our shareholders."

Mr. Dato continued: "As we move forward, we have every confidence that execution of the strategy is in good hands with the MEI leadership team. They have significant experience in the clinical development of oncology therapeutics and are well suited to achieve success for patients and for the Company's shareholders."

## Return of Capital Determination

As previously disclosed, the Company's October 31, 2023 Cooperation Agreement with stockholders, including Anson Funds and Cable Car Capital, provided that a potential second return of capital could be authorized by the Board under certain circumstances as outlined in that agreement, subject to the exercise of the Board's fiduciary duties. Since data reported from Cohort 1 of the Phase 1b study exceeded a criterion for the potential second return of capital stated in the Agreement, the trigger for a return of capital was not met. The Board further unanimously determined, after deciding not to proceed with Cohort 2, that in the exercise of its fiduciary duties under applicable law, and in light

of its views on what path is in the best interests of the Company's stockholders, the Company would not proceed with any additional potential return of capital as permitted under the Cooperation Agreement.

## **Strategic Overview**

The strategy unanimously approved by the MEI Board of Directors provides for advancing clinical development of voruciclib, an investigational selective oral cyclin-dependent kinase 9 ("CDK9") inhibitor, to new value inflection points by the end of calendar year 2025 and for enabling a new formulation of ME-344, an investigational inhibitor of mitochondrial oxidative phosphorylation ("OXPHOS"). The plan builds on encouraging recently reported voruciclib clinical data and ME-344 data separately reported today.

Specifically with respect to voruciclib, the development objective is to optimize voruciclib for a Phase 3 study in combination with venetoclax (Venclexta®) in patients with relapsed and refractory ("R/R") acute myeloid leukemia ("AML"). Under the plan, the ongoing voruciclib development strategy will be guided by future clinical trial results and applicable regulatory authority advice. Subject to positive Phase 1 data later this year, MEI plans to amend the ongoing Phase 1 study to add a Phase 2 study arm, with enrollment in the Phase 2 arm anticipated to begin in 2025. This is anticipated to generate Phase 2 data by the end of 2025. Contingent on the success of the Phase 1/2 study, MEI plans to have the program ready to initiate a Phase 3 registration trial during 2026.

With regards to ME-344, the plan is to develop a new formulation for further clinical development to better leverage the opportunity to advance a novel approach to inducing synthetic lethality in tumors in combination with VEGF inhibitors such as bevacizumab (Avastin®). The Company has already initiated research and development activity of the new formulation with encouraging results, with the goal of increasing biological activity, improving convenience of administration and increasing commercial opportunity. Interrupting ME-344 clinical activity and developing a new formulation will immediately reduce ME-344 expenditures.

### Voruciclib

The Company recently reported initiation of enrollment in an expansion cohort of the ongoing Phase 1 study evaluating voruciclib plus venetoclax (Venclexta®), a B-cell lymphoma 2 ("BCL2") inhibitor, in R/R AML. The decision to open the expansion cohort was based on encouraging initial data demonstrating anti-leukemic activity, including complete responses in heavily pretreated patients. Additionally, at doses of 100 mg or more, initial results from correlative biomarker assay analyses of available samples from patients treated with the combination demonstrated anticipated decreases of myeloid leukemia cell differentiation protein ("Mcl-1"), including a greater decrease in Mcl-1 at higher doses. Reductions in Mcl-1 are consistent with the known mechanism of action of CDK9. Further, there was no evidence of overlapping toxicity with venetoclax and no dose limiting toxicities were observed.

Increasingly, venetoclax is being used as a standard treatment in patients with AML, but salvage therapy after venetoclax failure is common and yields limited benefit; only about 10% of patients respond to salvage therapy after venetoclax failure, representing a significant need for patients with AML. While mutation specific therapies, such as FLT3, IDH, and menin inhibitors, may be used in patients with such mutations, the majority of patients with AML do not have therapeutically actionable mutations. Thus, inhibition of CDK9 is a mutation agnostic therapeutic opportunity across the majority of patients with R/R AML, representing an addressable patient population larger than that of any mutation specific therapy.

### ME-344

As separately reported today, based on initial study results, 25% of evaluable patients with relapsed metastatic colorectal cancer ("mCRC") enrolled in Cohort 1 of the ongoing Phase 1b study evaluating ME-344 in combination with bevacizumab (Avastin®) reached a predetermined 16-week progression free survival ("PFS") threshold, exceeding the 20% threshold set in the Clinical Study Protocol. Patients were heavily pretreated and had failed standard therapies for their disease. The combination was also observed to have a generally well-tolerated safety profile.

The recently reported data represent new clinical support of the potential of ME-344 in combination with VEGF inhibitors such as bevacizumab to induce synthetic lethality in tumors; this is a novel therapeutic strategy to potentially provide benefit to patients in a well-tolerated manner. Further, there is a significant medical need to provide patients with colorectal cancer new treatment options in light of the fact that deaths from this disease are a leading cause of

cancer-related deaths in the U.S. and given that the incidence of colorectal cancer is increasing among those under 55.

While the threshold was met to proceed to Cohort 2, the Company believes the best approach to meet the need of patients with mCRC, and potentially patients with other cancers where VEGF inhibitors are standard-of-care, is to continue to advance ME-344 via development of a new formulation, building upon the ME-344 results to date. The Company believes that development of a new formulation represents the optimal approach to leveraging the potential of the program and the novel therapeutic strategy to induce synthetic lethality in tumors via the combination. The goal of the formulation effort is to increase biological activity, improve patient convenience of administration and increase commercial opportunity. This plan will reduce short-term expenditures on the ME-344 program and ultimately, if successful, create an enhanced formulation for continued clinical development

## About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical-stage pharmaceutical company committed to developing novel and differentiated cancer therapies. We build our pipeline by acquiring promising cancer agents and creating value in programs through development, strategic partnerships, out-licensing and commercialization, as appropriate. Our approach to oncology drug development is to evaluate our drug candidates in combinations with standard-of-care therapies to overcome known resistance mechanisms and address clear medical needs to provide improved patient benefit. The drug candidate pipeline includes voruciclib, an oral cyclin-dependent kinase 9 ("CDK9") inhibitor, and ME-344, a novel small molecule inhibitor of mitochondrial oxidative phosphorylation (OXPHOS). For more information, please visit [www.meipharma.com](http://www.meipharma.com). Follow us on X (formerly Twitter) @MEI\_Pharma and on LinkedIn.

## Forward-Looking Statements

*Certain information contained 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: 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; the sufficiency of our cash, cash equivalents and short-term investments to fund our operations; and our ability to fund future capital returns. 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; the availability or appropriateness of utilizing the FDA's accelerated approval pathway for 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; uncertainty regarding the impact of rising inflation and the increase in interest rates as a result; potential economic downturn; geopolitical conflicts; activist investors; 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. 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.*

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David A. Walsey  
MEI Pharma  
Tel: 858-369-7104

[investor@meipharma.com](mailto:investor@meipharma.com)

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