MEI Pharma Reports Fiscal Year 2015 Results

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SAN DIEGO, Sept. 2, 2015 /PRNewswire/ -- MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, today announced results for its fiscal year ended June 30, 2015.

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"Despite a challenging end to the fiscal year, I am quite pleased with how the Company is positioned entering fiscal year 2016," said
Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "While we were obviously disappointed with the top-line data from our randomized study of Pracinostat in front-line myelodysplastic syndrome (MDS), our subsequent findings from the study, combined with the continued maturation of data from our ongoing study in acute myeloid leukemia (AML) and discussions with our clinical advisors, suggest that Pracinostat, in combination with hypomethylating agents (HMA) or other drug candidates, may still play a meaningful role in the treatment of patients with advanced hematologic diseases.

"Meanwhile," continued
Dr. Gold, "recent data surrounding the two other drug candidates currently in our pipeline, ME-344 and PWT143, only increase our enthusiasm regarding the potential of these assets and help to inform the next clinical studies anticipated to commence during the first half of calendar year 2016. In the meantime, abstracts relating to all three of our drug candidates have been submitted for presentation at the upcoming American Society of Hematology (ASH) Annual Meeting in December 2015. We are poised for an exciting year ahead and I look forward to providing updates on our progress."

Fiscal Year 2015 Company Highlights

- **Top-line data from randomized Phase II study of Pracinostat in front-line MDS.** In March 2015, the Company reported that the addition of Pracinostat to azacitidine (marketed as Vidaza®) did not increase the overall CR rate, the study's primary endpoint, compared to azacitidine alone in this population of intermediate-2 or high-risk patients with previously untreated MDS. Fatigue, gastrointestinal toxicities and myelosuppression occurred more frequently in the combination group and resulted in a higher rate of drug discontinuations compared to azacitidine alone. Data from event-driven endpoints, including overall survival, are still immature. Exploratory follow-up data suggest that patients receiving Pracinostat plus azacitidine for more than four cycles may derive benefit. These data have been submitted for presentation at the ASH Annual Meeting in December 2015.
- **Positive data from open-label Phase II study of Pracinostat in AML.** The combination of Pracinostat and azacitidine continues to produce a high rate of durable responses in this population of elderly patients with newly diagnosed AML. To date, the primary endpoint of complete response (CR) plus complete response with incomplete blood count recovery (CRi) plus morphologic leukemia-free state (MLFS) has been observed in 27 out of 50 patients (54%), of which 21 (42%) have achieved a CR. Most responses occured within the first two cycles and many continued to improve with ongoing therapy. Median overall survival has not yet been reached in the study; 31 patients (62%) continue to be followed (range: 9-19 months). The combination of Pracinostat and azacitidine was generally well tolerated in this study. The most common treatment-emergent adverse events include febrile neutropenia, thrombocytopenia, nausea and fatigue. Updated response and overall survival data have been submitted for presentation at the American Society of Hematology (ASH) Annual Meeting in December 2015.
- **Clinical milestone in Phase II study of Pracinostat in refractory MDS.** The objective of this study was to determine if the addition of Pracinostat to a HMA can improve clinical responses in MDS patients who progressed while on their HMA alone. Of the first 28 patients who received Pracinostat in combination with azacitidine or decitabine (marketed as Dacogen®), one achieved a partial response and two achieved marrow complete responses, exceeding the pre-specified clinical improvement rate for the study. The Company completed enrollment with 39 patients in this group and will continue to follow these patients for response and survival. A second group, patients with stable disease following initial HMA therapy, was closed due to insufficient enrollment. Pracinostat plus azacitidine or decitabine was generally well tolerated in the study.

The most common treatment-emergent adverse events included anemia, fatigue and gastrointestinal disorders.

- **Initiation of Phase II study of Pracinostat in myelofibrosis.** The goal of this study is to learn if Pracinostat, when given in combination with ruxolitinib (marketed as Jakafi® and Jakavi®), can help to control myelofibrosis, a rare disease of the bone marrow. The study, sponsored by the M.D. Anderson Cancer Center, began enrollment earlier this year and is expected to enroll 25 patients.
- **Cohort expansion in Phase Ib study of mitochondrial inhibitor ME-344.** The Company's study of ME-344 plus topotecan (marketed as Hycamtin®) advanced to the cohort-expansion stage after confirming the maximum tolerated dose of the combination in 14 patients. The expansion stage enrolled patients into two cohorts, ovarian cancer and small cell lung cancer, at nine sites in the U.S. and U.K. The combination of ME-344 and topotecan has been generally well tolerated in the study. The most frequent side effects are fatigue and gastrointestinal disturbances. The Phase Ib study enrolled a total of 13 small cell lung cancer patients and 28 ovarian cancer patients. The Company will continue to follow these patients for response and survival.
- **New findings show enhanced activity of ME-344 when combined with TKI.** The Company recently announced results from several pre-clinical studies demonstrating mitochondria-specific effects of ME-344 in cancer cells, including substantially enhanced anti-tumor activity when combined with a vascular endothelial growth factor receptor (VEGFr) tyrosine-kinase inhibitor (TKI) to inhibit both mitochondrial and glycolytic metabolism. These findings will help to inform the next clinical study of ME-344 in combination with a VEGFr TKI.
- **Encouraging preliminary data from first-in-human study of PWT143.** The Company initiated a first-in-human clinical study of PWT143, a highly selective oral inhibitor of phosphatidylinositide 3-kinase (PI3K) delta, in healthy subjects in June 2015. Preliminary data show measurable plasma levels of PWT143 as well as significant on target activity observed at the 10 mg starting dose level. In addition, the pharmacokinetic results suggest the potential for once-daily dosing. These data have been submitted for presentation at the ASH Annual Meeting in December 2015. The Company expects to initiate a Phase I study of PWT143 in patients with hematologic cancers during the first half of calendar year 2016.
- **Pharmaceutical industry veteran Kevan Clemens elected to Board of Directors.** Dr. Clemens has a long and distinguished career in the pharmaceutical industry, highlighted by his role as head of Global Oncology at Hoffmann-La Roche.
- **Strengthened balance sheet with $46 million public offering.** The net proceeds from the offering will enable the Company to continue to execute on its clinical development programs.

Fiscal Year 2015 Financial Highlights

- As of June 30, 2015, MEI Pharma had $63.8 million in cash, cash equivalents and short-term investments, with no outstanding debt. The Company believes its cash, cash equivalents and short-term investments will be sufficient to fund operations through at least calendar year 2016.
- Net cash used in operations was $28.1 million for the year ended June 30, 2015, compared to $19.5 million for 2014. Net cash used in operations was $6.7 million for the quarter ended June 30, 2015.
- Research and development (R&D) expenses were $23.8 million for the year ended June 30, 2015, compared to $19.3 million for 2014. The increase was primarily due to costs associated with Phase II clinical trials for Pracinostat, as well as costs associated with a Phase I clinical trial for ME-344 and pre-clinical costs related to PWT143. R&D expenses for the year ended June 30, 2015 included share-based compensation of $1.0 million.
- General and administrative expenses were $8.9 million for the year ended June 30, 2015, compared to $7.9 million for 2014. The increase primarily relates to higher levels of salaries and benefits.
- Net loss was $32.7 million, or $1.16 per share, for the fiscal year ended June 30, 2015, compared to $27.1 million, or $1.35 per share for 2014.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based oncology company focused on the clinical development of novel therapies for cancer. The Company's portfolio of drug candidates includes Pracinostat, a potential best-in-class, oral HDAC inhibitor currently in development for the treatment of advanced hematologic diseases, such as AML and MDS. The Company is also developing ME-344, a novel mitochondrial inhibitor that showed evidence of activity in a Phase I dose-escalation study in refractory solid tumors. In addition, the Company initiated a first-in-human study of PWT143, a highly selective PI3K delta inhibitor, in June 2015. For more information, please visit www.meipharma.com.

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; 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.

	Years Ended June 30,	
	2015	2014
	(In thousands, except share and per share data)	
Statement of Operations Data:		
Operating expenses		
Research and development	$ (23,823)	$ (19,331)
General and administrative	(8,948)	(7,897)
Total operating expenses	(32,771)	(27,228)
Loss from operations	(32,771)	(27,228)
Other income (expense), net	77	80
Net loss	$ (32,694)	$ (27,148)
Net loss per share, basic and diluted	$ (1.16)	$ (1.35)
Shares used to calculate net loss per share, basic and diluted	28,204,356	20,061,387
	As of June 30,	
	2015	2014
	(In thousands)	
Balance Sheet Data		
Cash, cash equivalents and short-term investments	$ 63,779	$ 48,793
Total assets	64,750	49,808
Total liabilities	4,959	4,616
Accumulated deficit	(156,139)	(123,445)
Total stockholders' equity	59,791	45,192

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