MEI Pharma Reports Fiscal Year 2016 Results

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SAN DIEGO, Sept. 6, 2016 /PRNewswire/ -- MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, today reported results for its fiscal year ended June 30, 2016.

"All of our efforts over the past year combined to set the stage for what has already been an exciting start to the new fiscal year, highlighted by Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and a global strategic partnership for Pracinostat," said
Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "We are proud to have a strong commercial partner in Helsinn now on board. With this partnership in place, we are well positioned to move forward with a fully funded Phase III study in acute myeloid leukemia (AML), evaluate an optimized dosing regimen in myelodysplastic syndrome (MDS) and maintain lucrative economics on the future commercial success of Pracinostat. In the process, we have significantly strengthened the financial position of our Company, enabling us to exploit our core strength in oncology drug development. We aim to leverage these resources in the coming year to continue to advance new treatment options for patients while creating value for our shareholders."

Recent Company Highlights

- **Strategic partnership for Pracinostatworth up to $464 million.** In August 2016, MEI Pharma entered into an exclusive licensing, development and commercialization agreement with Helsinn Healthcare, SA, a Swiss pharmaceutical corporation, for Pracinostat in AML and other potential indications. Under the terms of the agreement, Helsinn is granted exclusive worldwide rights to Pracinostat and will be responsible for funding its global development and commercialization. As compensation for such grant of rights, MEI Pharma will receive near-term payments of $20 million, including a $15 million upfront payment and a $5 million payment upon the earlier to occur of (i) dosing of the first patient in the upcoming Phase III study of Pracinostat in newly diagnosed AML patients unfit to receive induction therapy, or (ii) March 1, 2017. In addition, the Company will be eligible to receive up to $444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of Pracinostat. In a related transaction, Helsinn made a $5 million equity investment in MEI Pharma.
- **Significantly increased market opportunity for Pracinostat**. As part of the license, development and commercialization agreement, the Company will also collaborate with Helsinn to explore an optimal dosing regimen of Pracinostat in combination with azacitidine for the treatment of high-risk MDS. Based on its clinical experience with the combination, the Company believes that an optimized dose and schedule may show considerable promise in MDS, an indication with a significantly higher addressable patient population than that of AML. This Phase II clinical study is anticipated to commence in the first half of 2017.
- **Breakthrough Therapy Designation from FDA.** In August 2016, MEI Pharma announced that the FDA granted Breakthrough Therapy Designation for Pracinostat in combination with azacitidine for the treatment of patients with newly diagnosed AML who are ≥75 years of age or unfit for intensive chemotherapy. According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. In addition, the Company announced that agreement has been reached with the FDA on the proposed Phase III AML study design.
- **Long-term survival benefit in Phase II AML study**. The Breakthrough Therapy Designation is supported by data from a Phase II study of Pracinostat plus azacitidine in elderly patients with newly diagnosed AML, not candidates for induction chemotherapy. The study showed a median overall survival of 19.1 months and a complete response (CR) rate of 42% (21 of 50 patients). These data compare favorably to a Phase III study of azacitidine (AZA-AML-001), which showed a median overall survival of 10.4 months with azacitidine alone and a CR rate of 19.5% in a similar patient population. The combination of Pracinostat and azacitidine was generally well tolerated, with no unexpected toxicities. The most common grade 3/4 treatment-emergent adverse events included febrile neutropenia, thrombocytopenia, anemia and fatigue.
- **IND approved for next-generation PI3K delta inhibitor ME-401.** In March 2016, the FDA approved MEI Pharma's Investigational New Drug (IND) application for ME-401 in B-cell malignancies. PI3K delta is a

class of drugs that has shown promise in the treatment of B-cell malignancies, but with certain toxicities. The Company believes this provides an opportunity for a next-generation oral drug that can produce therapeutic responses at a safe, effective dose. The Company expects to dose the first patient in a Phase Ib dose-escalation study of ME-401 in patients with recurrent chronic lymphocytic leukemia or follicular non-Hodgkin's lymphoma in the third quarter of 2016.

- **Potential for improved therapeutic window for ME-401.** Results from a first-in-human, single ascending dose clinical study of ME-401 in healthy volunteers were presented at the American Association for Cancer Research Annual Meeting in April 2016. The data showed on-target activity of ME-401 at very low plasma concentrations. In addition, the results suggest that ME-401 has the potential for a superior pharmacokinetic and pharmacodynamic profile and an improved therapeutic window compared to idelalisib (marketed as Zydelig®), with a half-life that supports once-daily dosing. The goal of the upcoming Phase Ib study will be to demonstrate this therapeutic window in cancer patients. Interim data from the study is expected in the second quarter of 2017.
- **New clinical study of mitochondrial inhibitor ME-344 open for enrollment.** In August 2016, an investigator-sponsored study of the Company's mitochondrial inhibitor drug candidate ME-344 in combination with the vascular endothelial growth factor (VEGF) inhibitor bevacizumab (marketed as Avastin®) in patients with human epidermal growth factor receptor 2 (HER2)-negative breast cancer was opened for enrollment. The study is being conducted in collaboration with the Spanish National Cancer Research Centre in Madrid. Pre-clinical data from the collaboration showed mitochondria-specific effects of ME-344 in cancer cells, including substantially enhanced anti-tumor activity when combined with agents that inhibit the activity of VEGF. The data demonstrate that these anti-cancer effects are due to an inhibition of both mitochondrial and glycolytic metabolism. Data from the combination study with bevacizumab are expected in the fourth quarter of 2017.

Fiscal Year 2016 Financial Highlights

- As of June 30, 2016, MEI Pharma had $45.9 million in cash, cash equivalents and short-term investments, with no outstanding debt. Subsequent to the Company's year-end, it received a $15 million upfront payment in connection with its license, development and commercialization agreement with Helsinn and an additional $5 million in a related equity transaction.
- Net cash used in operations was $17.9 million for the year ended June 30, 2016, compared to $28.1 million for 2015. Net cash used in operations was $3.5 million for the fourth quarter ended June 30, 2016.
- Research and development expenses were $13.4 million for the year ended June 30, 2016, compared to $23.8 million for 2015. The decrease was primarily due to a reduction in clinical trial, production and development costs of Pracinostat.
- General and administrative expenses were $7.6 million for the year ended June 30, 2016, compared to $8.9 million for 2015. The decrease primarily relates to lower levels of share-based compensation expense.
- Net loss was $20.9 million, or $0.61 per share, for the fiscal year ended June 30, 2016, compared to $32.7 million, or $1.16 per share for 2015.

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 pipeline of drug candidates includes Pracinostat, an oral HDAC inhibitor that that has been granted Breakthrough Therapy Designation from the U.S. Food and Drug Administration in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia who are ≥75 years of age or unfit for intensive chemotherapy. The Company is also developing ME-401, a highly selective oral PI3K delta inhibitor, and ME-344, a novel mitochondrial inhibitor. 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,	
	2016	2015
	(In thousands, except share and per share data)	
Statement of Operations Data:		
Operating expenses		
Research and development	$ (13,403)	$ (23,823)
General and administrative	(7,601)	(8,948)
Total operating expenses	(21,004)	(32,771)
Loss from operations	(21,004)	(32,771)
Other income, net	142	77
Net loss	$ (20,862)	$ (32,694)
Net loss per share, basic and diluted	$ (0.61)	$ (1.16)
Shares used to calculate net loss per share, basic and diluted	34,400,441	28,204,356
	As of June 30,	
	2016	2015
	(In thousands)	
Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 45,918	$ 63,779
Total assets	47,164	64,750
Total liabilities	5,512	4,959
Accumulated deficit	(177,001)	(156,139)
Total stockholders' equity	41,652	59,791

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