MEI Pharma Reports Second Quarter Fiscal Year 2017 Results

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SAN DIEGO, Feb. 8, 2017 /PRNewswire/ -- MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, today reported results for its second quarter ended December 31, 2016. The Company also highlighted recent clinical progress and outlined key milestones for the year ahead.

"We begin the new calendar year with all of the pieces we need to be successful," said Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "We now have a partner with the operational and financial capabilities to support our Phase 3 AML program while we retain substantial long-term upside. We have a unique opportunity to return to MDS and apply what we learned in our prior studies with the prospect of significantly increasing the market potential for Pracinostat. We have two emerging drug candidates, ME-401 and ME-344, each expected to hit meaningful clinical inflection points in this year. And we have a healthy cash position to complement a strong clinical and regulatory team, all working to ensure that we execute on our development strategies. We're poised for an exciting year ahead and I'm eager to share our progress as it unfolds."

Clinical Highlights

- **Prolonged survival evaluated in Phase 2 study of Pracinostat and azacitidine in AML.** In December 2016, response and long-term survival data from a multi-center Phase 2 clinical study of the investigational drug candidate Pracinostat and azacitidine in elderly patients with acute myeloid leukemia (AML) who were not eligible for induction chemotherapy were presented at the American Society of Hematology Annual Meeting. Dr. Guillermo Garcia-Manero, MD Anderson Cancer Center, principal investigator of the study, reported a median overall survival of 19.1 (95%CI: 10.7-26.5) months, one-year survival of 62% and a complete response rate of 42%. 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. Pracinostat is an investigational agent and is not approved for use in the U.S.
- **Publication provides preliminary data for optimized dose of Pracinostat and azacitidine in MDS.** In January 2017, results from a Phase 2, randomized, double-blind study of Pracinostat and azacitidine in patients with untreated, higher risk myelodysplastic syndromes (MDS) were published online ahead of print in the journal *Cancer*. The preliminary study data suggest that poor tolerability, which led to more frequent and earlier drug discontinuations in the Pracinostat group, likely limited the overall efficacy of the combination. However, in an analysis of patients who received at least 4 cycles of therapy, a tendency toward improved response duration and overall survival was observed in the Pracinostat group. The authors conclude that alternative dosing should be evaluated to determine the potential of the combination.
- **First patients dosed in Phase 1b study of PI3K delta inhibitor ME-401.** In November 2016, a Phase 1b clinical study of ME-401 in patients with relapsed/refractory chronic lymphocytic leukemia (CLL) or follicular lymphoma began dosing patients. ME-401 is a potent and highly selective oral PI3K delta inhibitor with the potential for a wide therapeutic window that may lead to safer treatment options for patients with lymphomas. This study will enable the Company to study the safety and efficacy of ME-401 over time as it seeks to identify an optimal dose for Phase 2 studies.
- **Exposure data from Phase 1 study of ME-401 support improved therapeutic window.** In November 2016, data from a first-in-human clinical study of ME-401 in healthy volunteers were presented at the American Association of Pharmaceutical Scientists Annual Meeting. The presentation highlighted the formulation selection and development of ME-401, including levels of drug exposure that support the potential for an improved therapeutic window compared to first-generation PI3K delta inhibitors.
- **First patients dosed in clinical study of mitochondrial inhibitor ME-344.** In October 2016, an investigator-sponsored study of ME-344 in combination with the VEGF inhibitor bevacizumab (marketed as Avastin®) in patients with recently diagnosed HER2-negative breast cancer began dosing patients. The randomized, placebo-controlled study is expected to enroll a total of 40 patients and is being conducted in

collaboration with the Spanish National Cancer Research Centre in Madrid. Pre-clinical data from the collaboration showed substantially enhanced anti-tumor activity of ME-344 in cancer cells when combined with VEGF inhibitors due to a disruption of both mitochondrial and glycolytic metabolism.

Upcoming Milestones

- **Phase 3 study of Pracinostat in AML.** In August 2016, the Company entered into an exclusive license, development and commercialization agreement with Helsinn Healthcare, SA (Helsinn License Agreement) for Pracinostat in AML and other potential indications. Under the terms of the Helsinn License Agreement, the Company will receive a $5 million milestone payment upon the earlier of (i) dosing of the first patient in a Phase 3 study of Pracinostat and azacitidine in newly diagnosed AML patients who are unfit to receive induction therapy or (ii) March 1, 2017.
- **Phase 2 study of Pracinostat in MDS.** As part of the Helsinn License Agreement, the Company and Helsinn will work to explore an optimal dosing regimen of Pracinostat and azacitidine for the treatment of high and very high risk MDS. Enrollment in this study is anticipated to commence in the second quarter of calendar year 2017.
- **Phase 1b study of ME-401.** This study of ME-401 in patients with relapsed/refractory CLL or follicular lymphoma is now actively dosing patients and interim data is expected in the second quarter of calendar year 2017.
- **Investigator-sponsored study of ME-344.** This study of ME-344 and Avastin® in patients with HER2-negative breast cancer is now actively dosing patients and interim data is expected in the second half of calendar year 2017.

Financial Highlights

- As of December 31, 2016, the Company had $55.2 million in cash, cash equivalents and short-term investments, compared to $58.9 million as of September 30, 2016, with no outstanding debt. The Company believes its cash position will be sufficient to fund operations through at least fiscal year 2018.
- Research and development expenses were $1.6 million for the three months ended December 31, 2016, and $3.3 million during the six months ended December 31, 2016. This compares with research and development expenses of $3.2 million for the three months ended December 31, 2015, and $6.0 million for the six months ended December 31, 2015. The decrease was primarily due to a reduction in clinical trial expenses for Pracinostat and ME-344.
- General and administrative expenses were $2.0 million for the three months ended December 31, 2016, and $4.7 million for the six months ended December 31, 2016, compared to $1.9 million and $3.8 million, respectively, for the same periods in 2015. The year over year increase was primarily due to professional service costs associated with the Helsinn License Agreement.
- Revenues were $17.2 million during the three months ended December 31, 2016, and $18.3 million during the six months ended December 31, 2016, related to the Helsinn License Agreement. During the three and six months ended December 31, 2016, the cost of research and development revenue was $1.8 million and $2.9 million respectively. Cost of research and development revenue is comprised primarily of reimbursable third-party pass-through costs.
- Net income was $11.9 million, or $0.32 per basic and diluted share, for the three months ended December 31, 2016, and $7.6 million, or $0.21 per basic and diluted share, for the six months ended December 31, 2016. This compares to a net loss of $5.1 million, or $0.15 per basic and diluted share, for the quarter ended December 31, 2015, and a net loss of $9.7 million, or $0.28 per basic and diluted share for the six months ended December 31, 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 portfolio of drug candidates includes Pracinostat, an oral HDAC inhibitor that is partnered with Helsinn Healthcare, SA. Pracinostat was granted Breakthrough Therapy Designation from the U.S. Food and Drug Administration for use in combination with azacitidine for the treatment of patients with newly diagnosed AML who are unfit for intensive chemotherapy. The Company's clinical development pipeline also includes ME-401, a potent and highly selective 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.

MEI PHARMA, INC.
BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2016	June 30, 2016
	(unaudited)	
ASSETS		
Current assets:		
	$	$
Cash and cash equivalents	15,050	10,837
Short term investments	40,104	35,081
Total cash, cash equivalents and short-term investments	55,154	45,918
Prepaid expenses and other current assets	2,668	831
Total current assets	57,822	46,749
Intangible assets, net	348	366
Property and equipment, net	40	49
	$	$
Total assets	58,210	47,164
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
	$	
Accounts payable	382	$ 1,079
Accrued liabilities	2,938	4,433
Total current liabilities	3,320	5,512
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 100,000 shares authorized; none outstanding	-	-
Common stock, $0.00000002 par value; 113,000,000 shares authorized; 36,772,428 and 34,155,997 shares issued and outstanding at December 31, 2016 and June 30, 2016, respectively	-	-
Additional paid-in-capital	224,276	218,653
Accumulated deficit	(169,386)	(177,001)
Total stockholders' equity	54,890	41,652
	$	$
Total liabilities and stockholders' equity	58,210	47,164

MEI PHARMA, INC.
STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2016	2015	2016	2015
Revenues:				
License revenue	$ 17,101	$ -	$ 17,101	$ -
Research and development revenue	98	-	1,194	-
Total revenues	17,199	-	18,295	-

Operating expenses:				
Cost of research and development revenue	(1,771)	-	(2,865)	-
Research and development	(1,642)	(3,182)	(3,288)	(5,998)
General and administrative	(1,970)	(1,945)	(4,650)	(3,775)
Total operating expenses	(5,383)	(5,127)	(10,803)	(9,773)
Income (loss) from operations	11,816	(5,127)	7,492	(9,773)
Other income (expense):				
Interest and dividend income	69	26	124	53
Income tax expense	-	-	(1)	(1)
Net income (loss)	$ 11,885	$ (5,101)	$ 7,615	$ (9,721)
Earnings (loss) per share, basic	$ 0.32	$ (0.15)	$ 0.21	$ (0.28)
Earnings (loss) per share, diluted	$ 0.32	$ (0.15)	$ 0.21	$ (0.28)
Shares used in computing earnings (loss) per share:				
Basic	37,172,428	34,422,663	36,459,898	34,378,460
Diluted	37,216,532	34,422,663	36,501,134	34,378,460

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