MEI Pharma Reports Second Quarter Fiscal Year 2021 Results and Operational Highlights

February 4, 2021

SAN DIEGO, Feb. 4, 2021 /PRNewswire/ -- MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, today reported results for the quarter ended December 31, 2020.

"We remain well positioned and focused on advancing zandelisib toward commercialization to deliver an improved therapeutic option to people living with B-cell malignancies," said
Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "We anticipate multiple important milestones from the zandelisib program this year, including topline data from our Phase 2 TIDAL study in the fourth quarter as we closely monitor for potential negative impacts related to the ongoing COVID 19 pandemic on the study, as well as more broadly across our business and development pipeline. In addition we look forward to reporting clinical data updates from the ongoing Phase 1b study and the continued expansion of the zandelisib clinical program evaluating additional indications and combinations, in particular the start of the Phase 3 study evaluating zandelisib in combination with rituximab in patients with second line follicular lymphoma around mid-year."

Dr. Gold continued: "Beyond the zandelisib development program, this year we look forward to the potential for more advances across our pipeline, including clinical data updates from the Phase 1 voruciclib program and our plans to advance ME-344 into a Phase 2 pilot study evaluating patients with solid tumors."

Anticipated Calendar Year 2021 Drug Candidate Pipeline Developments

Zandelisib – PI3K delta inhibitor for the treatment of various B-cell malignancies

- Completion of enrollment in the Phase 2 TIDAL study evaluating zandelisib as a monotherapy for patients with relapsed or refractor follicular lymphoma followed by the reporting of top line clinical data from the Phase 2 TIDAL study.
- Initiation of a second arm in the Phase 2 TIDAL study enrolling patients with relapsed or refractory marginal zone lymphoma.
- Initiation of the Phase 3 study of zandelisib in combination with rituximab evaluating follicular and marginal zone lymphoma patients who received one or more prior lines of treatment; this study is intended to act as the required confirmatory study for the potential accelerated approval of zandelisib in patients with relapsed or refractory follicular lymphoma.
- Clinical updates for the Phase 1b study of zandelisib, including the combination with zanubrutinib.

Voruciclib – CDK9 inhibitor for the treatment of B-cell malignancies and acute myeloid leukemia

- Program updates, including data from the Phase 1 program evaluating voruciclib.

ME-344 – tumor selective mitochondrial inhibitor

- Update plans for a potential Phase 2 pilot study of ME-344 in solid tumors.

Recent and Second Quarter Fiscal Year 2021 Corporate Highlights

- In January 2021, the Phase 1b trial arm exploring zandelisib in combination with zanubrutinib (marketed as BRUKINSA®), developed by BeiGene, Ltd., enrolled the first patient in a disease specific expansion cohort. The phase 1b study arm evaluating the combination is conducted under a clinical collaboration with BeiGene to evaluate safety and efficacy for the treatment of patients with various relapsed or refractory B-cell malignancies.

- In January 2021, MEI announced that the Phase 1b trial arm exploring zandelisib in combination with zanubrutinib in collaboration with BeiGene completed the safety evaluation stage in patients with B-cell malignancies and is expanding into disease specific B-cell malignancy cohorts. The *Safety Review Committee* recommended moving forward with a dosing regimen found to be generally well tolerated and active following a planned safety analysis.

- In October 2020, Kyowa Kirin Co. Ltd. and MEI announced that the first patient was dosed in the pivotal Phase 2 study of zandelisib in patients with indolent B-cell non-Hodgkin's lymphoma (iNHL) without small lymphocytic lymphoma (SLL), lymphoplasmacytic lymphoma (LPL), and Waldenström's macroglobulinemia (WM) in Japan. This Phase 2, multicenter is intended to support regulatory approval in Japan.

Second Quarter Fiscal Year 2021 Financial Results

- As of December 31, 2020, MEI had $180.1 million in cash, cash equivalents, and short-term investments with no outstanding debt.

- For the quarter ended December 31, 2020, cash provided by operations was $4.1 million compared to $10.5 million used in operations for the quarter ended December 31, 2019. Cash provided by operations in the 2020 period reflects $20.9 million cash received from the Japanese taxing authorities as a refund of withholding tax associated with the Kyowa Kirin commercialization agreement signed in April 2020.

- Research and development expenses were $22.2 million for the quarter ended December 31, 2020, compared to $8.3 million for the quarter ended December 31, 2019. The increase was primarily related to increased development costs associated with zandelisib, including increased activity in the TIDAL study and start-up costs related to the Phase 3 study, as well as increased personnel costs to support clinical trial activities.

- General and administrative expenses were $5.7 million for the quarter ended December 31, 2020, compared to $4.2 million for the quarter ended December 31, 2019. The increase primarily relates to general corporate expenses and personnel costs incurred during the quarter ended December 31, 2020.

- MEI recognized revenue of $9.2 million for the quarter ended December 31, 2020, compared to $1.0 million for the quarter ended December 31, 2019. The increase in revenue primarily related to the license agreement with Kyowa Kirin and included the recognition of fees allocated to research and development obligations, and reflect Kyowa Kirin's share of zandelisib costs which were $9.9 million for the quarter ended December 31, 2020.

- Net loss was $11.5 million, or $0.10 per share, for the quarter ended December 31, 2020, compared to net loss of $20.2 million, or $0.26 per share for the quarter ended December 31, 2019. The Company had 112,527,860 shares of common stock outstanding as of December 31, 2020, compared with 105,998,677 shares as of December 31, 2019.

- The adjusted net loss for the quarter ended December 31, 2020, excluding non-cash expenses related to changes in the fair value of the warrants issued in connection with the May 2018 financing (a non-GAAP measure), was $18.5 million, compared to an adjusted net loss of $11.8 million for the quarter ended December 31, 2019.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a late-stage pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates contains four clinical-stage assets, including zandelisib, currently in an ongoing Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. Each of MEI Pharma's 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.

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.

MEI PHARMA, INC.
CONDENSED BALANCE SHEETS
(In thousands, except per share amounts)

	December 31, 2020 (unaudited)	**June 30, 2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,877	$ 12,331
Short-term investments	170,267	170,299
Total cash, cash equivalents and short-term investments	180,144	182,630
Receivable for foreign tax withholding	-	20,420
Prepaid expenses and other current assets	13,888	5,594
Total current assets	194,032	208,644
Operating lease right-of-use asset	8,207	-
Property and equipment, net	1,641	1,084
Total assets	$ 203,880	$ 209,728
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,555	$ 2,437
Accrued liabilities	11,102	6,090
Deferred revenue	19,482	14,777
Operating lease liability	873	-
Total current liabilities	37,012	23,304
Deferred revenue, long-term	65,352	67,723
Operating lease liability, long-term	7,842	-
Warrant liability	20,176	40,483
Total liabilities	130,382	131,510

Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized; none outstanding	-	-
Common stock, $0.00000002 par value; 226,000 shares authorized; 112,528 and 111,514 shares issued and outstanding at December 31, 2020 and June 30, 2020, respectively	-	-
Additional paid-in-capital	364,278	355,452
Accumulated deficit	(290,780)	(277,234)
Total stockholders' equity	73,498	78,218
Total liabilities and stockholders' equity	$ 203,880	$ 209,728

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2020	**2019**	**2020**	**2019**
Revenue	$ 9,167	$ 1,008	$ 13,001	$ 2,165
Operating expenses:				
Cost of revenue	494	641	1,003	1,329
Research and development	22,224	8,281	35,220	17,243
General and administrative	5,650	4,195	11,565	8,325
Total operating expenses	28,368	13,117	47,788	26,897
Loss from operations	(19,201)	(12,109)	(34,787)	(24,732)
Other income (expense):				
Change in fair value of warrant liability	7,083	(8,439)	20,307	830
Interest and dividend income	164	318	439	692
Other income (expense)	500	13	495	(1)
Net loss	$ (11,454)	$ (20,217)	$ (13,546)	$ (23,211)
Net loss:				
Basic	$ (11,454)	$ (20,217)	$ (13,546)	$ (23,211)
Diluted	$ (18,537)	$ (20,217)	$ (33,853)	$ (23,211)
Net loss per share:				
Basic	$ (0.10)	$ (0.26)	$ (0.12)	$ (0.30)
Diluted	$ (0.16)	$ (0.26)	$ (0.30)	$ (0.30)
Shares used in computing net loss per share:				
Basic	112,524	78,577	112,480	76,103
Diluted	114,461	78,577	114,709	76,103

MEI PHARMA, INC.
Reconciliation of GAAP Net Loss to Adjusted Net Loss
(In thousands)
(Unaudited)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2020	**2019**	**2020**	**2019**
Net loss	$ (11,454)	$ (20,217)	$ (13,546)	$ (23,211)
Add: Change in fair value of warrant liability	(7,083)	8,439	(20,307)	(830)
Adjusted net loss	$ (18,537)	$ (11,778)	$ (33,853)	$ (24,041)

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