# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

# **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 1, 2018

# **MEI Pharma, Inc.**

(Exact name of registrant as specified in its charter)

000-50484

(Commission

File Number)

Delaware (State of other jurisdiction of incorporation or organization)

> 3611 Valley Centre Drive Suite 500 San Diego, California (Address of principal executive offices)

51-0407811 (I.R.S. Employer Identification No.)

92130 (Zip Code)

Registrant's telephone number, including area code: (858) 369-7100

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2, below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14D-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13c-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

## Item 8.01. Other Events.

On December 1, 2018, MEI Pharma, Inc. (the "Company") issued a press release relating to the presentation of preclinical data for voruciclib in human derived acute myeloid leukemia (AML) cells lines and patient samples at the 2018 America Society of Hematology Annual Meeting (the "ASH Meeting"). A copy of the press release relating to voruciclib issued on December 1, 2018 is attached hereto as Exhibit 99.1 and incorporated herein by reference.

On December 2, 2018, the Company issued a press release relating to the presentation of Phase 1b clinical data for ME-401 in patients with indolent B-Cell Malignancies at the ASH Meeting. A copy of the press release relating to ME-401 issued on December 2, 2018 is attached hereto as Exhibit 99.2 and incorporated herein by reference.

On December 3, 2018, the Company and Helsinn Group, a Swiss pharmaceutical group, issued a joint press release relating to the presentation of interim data from a Phase 2 study evaluating pracinostat, a histone deacetylase inhibitor, in combination with azacitadine for the treatment of patients with IPSS-R high/very high-risk of Myelodysplastic Syndrome (MDS), at the ASH Meeting. A copy of the joint press release relating to pracinostat issued on December 3, 2018 is attached hereto as Exhibit 99.3 and incorporated herein by reference.

# Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of MEI Pharma, Inc., dated December 1, 2018 relating to voruciclib
99.2	Press release of MEI Pharma, Inc., dated December 2, 2018 relating to ME-401
99.3	Press release of MEI Pharma, Inc. and Helsinn Group, dated December 3, 2018 relating to pracinostat

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MEI Pharma, Inc.

By: /s/ Brian G. Drazba

Name: Brian G. Drazba

Title Chief Financial Officer and Secretary

Date: December 3, 2018



# MEI Pharma Presents Preclinical Data Demonstrating Voruciclib Synergistically Induces Apoptosis in Combination with Venetoclax in Acute Myeloid Leukemia Cells at the 2018 American Society of Hematology Annual Meeting

SAN DIEGO, December 1, 2018 – MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, today announced preclinical data presented at the 2018 American Society of Hematology (ASH) annual meeting demonstrating that voruciclib, MEI's orally available CDK9 inhibitor, synergistically induced apoptosis at clinically relevant concentrations when combined with venetoclax (marketed as Venclexta®) in human derived acute myeloid leukemia (AML) cells lines and patient samples. Voruciclib is currently being evaluated in a Phase 1b dose ranging study in patients with B-cell malignancies.

The data presented today demonstrate the synergistic induction of apoptosis of voruciclib when combined with venetoclax via the transient downregulation of MCL1 in multiple AML cell lines and patient samples. Inhibition of CDK9 blocks the production of MCL1, which is an established resistance mechanism to the BCL-2 inhibitor venetoclax.

"This study evaluating the synergistic activity of voruciclib in AML cells builds on existing preclinical data demonstrating similar activity in other B-cell malignancies, including diffuse large B-cell lymphoma and chronic lymphocytic leukemia, and reinforces the significant clinical utility voruciclib may hold when combined with inhibitors of BCL-2 in B-cell disease," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "As we progress in our ongoing Phase 1 study, we look forward to selecting the voruciclib clinical dose to evaluate in combination with venetoclax to clinically assess synergies and the opportunity for combination treatments across multiple indications."

The voruciclib ASH 2018 poster can be accessed on the MEI Pharma website.

## **About Voruciclib**

The CDK family of proteins are important cell cycle regulators. CDK9 is a transcriptional regulator of the myeloid leukemia cell differentiation protein ("MCL1"), a member of the family of anti-apoptotic proteins which, when elevated, may prevent the cell from undergoing cell death. Inhibition of CDK9 blocks the production of MCL1, which is an established resistance mechanism to the B-cell lymphoma ("BCL-2") inhibitor venetoclax.

CDK9 is also a transcriptional regulator of MYC, a transcription factor regulating cell proliferation and growth which contributes to many human cancers and is frequently associated with poor prognosis and unfavorable patient survival. Targeting MYC directly has historically been difficult, but CDK9 is a transcriptional regulator of MYC and is a promising approach to target this oncogene.

In August 2018 MEI dosed the first patient in a dose ranging Phase 1b clinical trial of voruciclib as a single agent in patients with relapsed and/or refractory B-cell malignancies after failure of prior standard therapies to determine the safety, preliminary efficacy and maximum tolerated dose. We also plan to evaluate voruciclib in combination with venetoclax to assess synergies and the opportunity for combination treatments across multiple indications.

# About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based pharmaceutical company focused on leveraging its extensive development and oncology expertise to identify and advance new therapies for cancer. The Company's portfolio of drug candidates includes pracinostat, an oral HDAC inhibitor that is partnered with Helsinn Healthcare, SA. Pracinostat has been 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 acute myeloid leukemia (AML) who are unfit for intensive chemotherapy. Pracinostat is also being developed in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are unfit for intensive chemotherapy. Pracinostat is also being developed in combination with azacitidine for the treatment of patients with high and very high-risk myelodysplastic syndrome (MDS). MEI Pharma's clinical development pipeline also includes ME-401, a highly differentiated oral PI3K delta inhibitor currently in a Phase 1b study in patients with relapsed refractory follicular lymphoma or CLL, and voruciclib, an oral, selective CDK inhibitor shown to suppress MCL1, a known mechanism of resistance to BCL-2 inhibitors. The Company is also developing ME-344, a novel mitochondrial inhibitor currently in an investigator-initiated study in combination with bevacizumab evaluating patients with HER2-negative breast cancer. Pracinostat, ME-401, ME-344 and voruciclib are investigational agents and are not approved for use in the U.S. For more information, please visit <u>www.meipharma.com</u>.

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 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.

# **Contacts:**

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# MEI Pharma Presents Clinical Data from Ongoing Phase 1b Study of ME-401 in Patients with Indolent B-Cell Malignancies at the 2018 American Society of Hematology Annual Meeting

- Data Support Complementary Potential of Intermittent and Continuous Dosing Schedules as Means to Optimize Clinical Risk-Benefit Ratio in Relapsed/Refractory Follicular Lymphoma Patients -

## -MEI Advancing ME-401 into Phase 2 Study Around Year-end 2018 to Pursue Accelerated Approval Strategy-

SAN DIEGO, December 2, 2018 – MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, today announced that results from an ongoing Phase 1b study support the complementary potential of intermittent and continuous dosing schedules of ME-401, a selective phosphatidylinositol 3-kinase ("PI3K") delta inhibitor, to optimize the clinical risk-benefit ratio in patients with relapsed/refractory follicular lymphoma. The data demonstrate that ME-401, as both a single agent and in combination with rituximab, continues to be associated with overall high objective response rates. In addition, low rates of Grade 3 immune-related adverse events (irAEs) were observed in patients on the intermittent dosing schedule while maintaining a high level of clinical response. These data are being presented today at the 2018 American Society of Hematology (ASH) Annual Meeting.

The data announced today continue to support the rationale for MEI's planned Phase 2 study that evaluates both a continuous (CS) and intermittent (IS) dosing schedule of ME-401 as a means to enhance the drug candidate's clinical profile and thus potentially deliver improved benefits to patients. The Phase 2 study is expected to start around year-end and is intended to support MEI's accelerated approval registration strategy if successful.

Patients in the Phase 1b study received ME-401 as a single agent (dosed on the CS or IS) and in combination with rituximab (dosed on the IS only) to explore treatment options for patients with B-cell malignancies. The IS dosing regimen consists of 60 mg given continuously, once-daily, for the first 2 cycles followed by 60 mg given on days 1-7 of a 28-day cycle and results showed:

- As a single agent, 76% objective response rate in patients with relapsed or refractory follicular lymphoma (FL), and 100% in all patients with chronic lymphocytic lymphoma (CLL) and small lymphocytic lymphoma (SLL).
  - In combination with rituximab, 78% objective response rate in patients with FL.
- Median duration of response has not been reached. The lead patient has a duration of response of approximately 20 months and the median follow-up is 9.3 months.
- Low rate of irAEs; 4 irAEs were reported in 36 patients administered the IS, with all cases occurring in the first 2 cycles following the switch to IS.
- 89% of patients switched to IS remain on therapy.
  - Disease control was maintained in 72% of these patients.
  - 70% of patients who resumed on the continuous daily dosing schedule (CS) recaptured a response after progressing on IS.

The ME-401 ASH 2018 poster can be accessed on the MEI Pharma website.

"The data presented today are very supportive of our rationale to investigate both a continuous and intermittent dosing regimen as part of our Phase 2 study evaluating ME-401 in follicular lymphoma and may also help advance its complementary potential to deliver improved benefits to patients in combination with other modalities," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "While advances have been made in the treatment of B-cell malignancies, there remains a significant need for innovative therapies across a range of indications and patient populations not addressed by current therapeutic options; we believe the emerging clinical profile of ME-401, as both a single agent or in combination, holds the potential to deliver improved clinical benefit to patients with B-cell diseases."

#### ME-401 Phase 1b ASH 2018 Data

ME-401 is being evaluated in an ongoing Phase 1b dose escalation study in patients with relapsed or refractory B-cell malignancies. Through October 2018, 60 patients were enrolled across three groups:

- Group 1 included 31 patients with relapsed FL (n = 22) or CLL/SLL (n = 9) who received ME-401 CS at doses <sup>3</sup>60 mg per day in the dose escalation phase of the study. Beginning in December 2017 a total of 17 patients from Group 1 (FL=9, CLL/SLL=8) advanced to the IS after in cycle 4 or later cycles.
- Group 2 included 16 patients with relapsed FL (n = 9), diffuse large B-cell lymphoma (n = 5), marginal zone lymphoma (MZL, n = 1), and CLL (n = 1) who received rituximab 375 mg/m<sup>2</sup> x 8 doses over 6 months and ME-401 dosed under the IS regimen after receiving ME-401 60 mg daily for the first two cycles.
- Group 3 may enroll up to 30 patients with relapsed FL/CLL/SLL in an expansion cohort of ME-401 using the IS regimen after receiving ME-401 60 mg daily for the first two cycles. In this group, 13 patients were enrolled to date with one FL patient reaching the Cycle 6 disease assessment as data cut off.

The median number of prior therapies of patients in the study is two and 50% of patients enrolled were <sup>3</sup> 3<sup>rd</sup> line of therapy. Responses are assessed after 2 cycles (58 days) and 6 cycles, and then every 6 cycles. Ninety-two percent of all patients were previously treated with an anti-CD20 antibody.

### **Objective Response Rates**

- The objective response rate of patients across all groups with FL is 76% (29/38) and for CLL/SLL is 100% (11/11).
  - As a single agent, 76% (22/29) objective response rate in patients with FL and 100% (10/10) in patients with CLL and SLL.
  - In combination with rituximab, 78% (7/9) objective response rate in patients with FL.

# Duration of Response

- In FL and CLL/SLL patients, the median follow-up is 9.3 months (range, approximately 2.1 to 19.5 months) with no median yet reached.
- Across all groups, failure-free survival (i.e. no disease progression on the continuous dosing schedule) in FL and CLL/SLL has not reached a median yet; median follow-up is 6.9 months (range 0.4 to 21.1 months).
- 72% of patients across all groups on the IS regimen have not experienced disease progression with a median follow-up of 7.9 months (range, 0.8 to 10.5 months).
  - Of the 10 patients that progressed on the IS regimen, 70% of patients retreated with daily dosing recaptured disease response.

# Rates of irAEs

• Of the 36 patients who switched to IS, only 11% (4/36) experienced an irAE after the switch. All 4 reported cases of irAEs occurred in the first 2 cycles after the switch to the IS regimen.

#### About ME-401

ME-401 is an investigational oral phosphatidylinositol 3-kinase ("PI3K") delta inhibitor; PI3K delta is often overexpressed in cancer cells and plays a key role in the proliferation and survival of hematologic cancer cells. ME-401 displays high selectivity for the PI3K delta isoform and has distinct pharmaceutical properties from other PI3K delta inhibitors. It is being clinically evaluated in patients with various B-cell malignancies. MEI is initiating a Phase 2 study to evaluate the efficacy, safety, and tolerability of ME-401 as a single agent in patients with follicular lymphoma after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. The Phase 2 study is intended to support an accelerated approval marketing application with the U.S. Food and Drug Administration.

# About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based pharmaceutical company focused on leveraging its extensive development and oncology expertise to identify and advance new therapies for cancer. The Company's portfolio of drug candidates includes pracinostat, an oral HDAC inhibitor that is partnered with Helsinn Healthcare, SA. Pracinostat has been 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 acute myeloid leukemia (AML) who are unfit for intensive chemotherapy. Pracinostat is also being developed in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are unfit for intensive chemotherapy. Pracinostat is also being developed in combination with azacitidine for the treatment of patients with high and very high-risk myelodysplastic syndrome (MDS). MEI Pharma's clinical development pipeline also includes ME-401, a highly differentiated oral PI3K delta inhibitor currently in a Phase 1b study in patients with relapsed refractory follicular lymphoma or CLL, and voruciclib, an oral, selective CDK inhibitor shown to suppress MCL1, a known mechanism of resistance to BCL2 inhibitors. The Company is also developing ME-344, a novel mitochondrial inhibitor currently in an investigator-initiated study in combination with bevacizumab evaluating patients with HER2-negative breast cancer. Pracinostat, ME-401, ME-344 and voruciclib are investigational agents and are not approved for use in the U.S. For more information, please visit <u>www.meipharma.com</u>.

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.

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# Phase 2 Interim Data Evaluating the Combination of Pracinostat and Azacitidine in Patients with Myelodysplastic Syndrome Presented at the 2018 American Society of Hematology Annual Meeting

LUGANO, Switzerland and San Diego, USA, December 3, 2018: Helsinn Group, a Swiss pharmaceutical group focused on building quality cancer care products, and MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, today announced interim data from a Phase 2 study evaluating pracinostat, a histone deacetylase inhibitor, in combination with azacitadine for the treatment of patients with IPSS-R high/very high-risk of Myelodysplastic Syndrome (MDS). The data demonstrate a 9% discontinuation rate due to adverse events, a substantially lower rate than observed in an earlier study, as well as an encouraging 36% complete response rate among patients receiving at least 6 cycles of treatment. These data are being presented today at the 2018 American Society of Hematology (ASH) Annual Meeting.

The ongoing Phase 2 open-label study is evaluating a 45 mg dose of pracinostat in combination with azacitadine in order to improve safety/tolerability and retain patients in study longer than in an earlier Phase 2 study evaluating a 60 mg dose. Prolonged treatment is envisaged to result in a systemic exposure to pracinostat sufficient to achieve the desired treatment effect. The data reported today reinforce results from a planned May 2018 interim analysis meeting a predefined discontinuation threshold and suggest a reduced dose of pracinostat may allow MDS patients to remain on treatment longer and thereby increase the likelihood of a treatment response. If the current Phase 2 open-label study is successful, Helsinn intends to initiate a global registration study.

Ehab Atallah, M.D., Study Chair, Associate Professor of Medicine, Medical College of Wisconsin, said: "Treatment options for patients with a higher risk of MDS are still limited and following diagnosis the survival rate is less than 18 months with the current standard of care. At the time of the Phase 2 data announced this year in May, I was excited to see that this treatment demonstrated that it can be offered to patients as a combination therapy and potentially improve outcomes. We're pleased that the threshold for expansion of this study has been met, and I look forward to continuing to observe the progress of this combination treatment."

Ruben Giorgino, M.D. Ph.D. Helsinn Group Head of Clinical Development at Helsinn, commented: "Helsinn bolsters its commitment in developing pracinostat in combination with hypomethylating agents in patients with AML and with high risk MDS. Moving forward to the second stage of this really important Phase 2 clinical trial in MDS patients represents an important next step in our efforts to understand the potential benefit of pracinostat in these patients with poor prognosis and modest response to hypomethylating monotherapy".

Richard Ghalie, M.D., Senior Vice President, Clinical Development at MEI Pharma, commented: "The interim data demonstrating a 9% discontinuation rate due to adverse events, a substantially lower rate than observed in the earlier study, as well as an encouraging complete response rate to date of 36% of patients reaching the first disease assessment at 6 months, represents an opportunity to advance a promising new treatment for patients with high/very high-risk disease that currently have limited options."

### The Phase 2 Study

The ongoing Phase 2 study is open-label and is investigating a 45 mg dose of pracinostat in combination with the standard dose of azacitidine in up to 60 patients with high and very high-risk MDS previously untreated with hypomethylating agents. The primary endpoints of the study are 1) safety and tolerability and 2) overall response rate, defined as complete remission (CR), partial remission (PR) and marrow CR. Secondary endpoints include CR rate, overall hematologic improvement (HI) progression-free survival and overall survival, among others.

As of the end of October 2018, 55 patients have completed at least one cycle of therapy. The data demonstrate a 9% discontinuation rate due to adverse events, 4% of which were early discontinuations (within the first 3 treatment cycles). Of note, 15% of patients discontinued because they advanced to Stem Cell Transplantation. The discontinuation rate reported today continues to meet the pre-defined threshold from the planned interim analysis conducted in May 2018 and is consistent with the discontinuation rate for azacitadine administered as a single agent.

In the group patients receiving at least 6 cycles of treatment, the complete response rate is 36%. The median duration on therapy is 4.7 months (range 0.5-13 months).

The 45 mg dose of pracinostat being evaluated in the Phase 2 is better tolerated than the 60 mg dose evaluated in a prior Phase 2 study. Treatment in the current Phase 2 study was generally well-tolerated: adverse events <sup>3</sup> Grade 3 reported in 20% or more of patients are febrile neutropenia, anemia, neutropenia and thrombocytopenia. It is notable that patients in the current study were diagnosed with higher-risk MDS than in the prior study.

The study was initially designed with two stages: the completed first stage that met the predefined discontinuation rate threshold, and a randomized and placebo-controlled second stage triggered upon meeting the pre-defined discontinuation threshold in the first stage. Based on the discontinuation rate meeting the pre-defined threshold in a planned interim analysis in May 2018, the study design was amended by substituting stage 2 with an expanded open-label portion to enroll up to 60 patients to obtain data to support the design of a registration study upon successful completion of the Phase 2 study.

# About Higher Risk MDS

Higher risk MDS (high and very high risk in the IPSS-R classification) is a serious medical condition, with median survival of less than 18 months. The high and very high-risk groups represent the highest unmet need in MDS, with median survival estimates of only 1.6 years and 0.8 years, respectively.

The only curative therapy is allogeneic stem cell transplantation (SCT), however most patients with MDS are not candidates for SCT given their typically advanced age, comorbidities and lack of a suitable donor. Standard therapy with HMAs in higher risk MDS provides modest responses, though azacitidine has been shown to improve survival when compared to conventional care regimens. Patients who do not respond to HMAs or progress after therapy with HMAs have a very poor outcome, with a median survival of less than one year.

### **About Pracinostat**

Pracinostat is an oral histone deacetylase ("HDAC") inhibitor that is in a pivotal Phase 3 study in combination with azacitidine for the treatment of adults with newly diagnosed acute myeloid leukemia ("AML") who are unfit for intensive chemotherapy. It is also being evaluated in a Phase 2 study in patients with high or very high-risk myelodysplastic syndrome ("MDS"). The U.S. Food and Drug Administration has granted Breakthrough Therapy Designation for pracinostat in combination with azacitidine for the treatment of patients with newly diagnosed AML who are <sup>375</sup> years of age or unfit for intensive chemotherapy.

In August 2016, Helsinn and MEI Pharma entered into an exclusive license, development and commercialization agreement for pracinostat in AML and other potential indications.

The agreement provides that Helsinn is primarily responsible for development and commercialization costs for pracinostat in AML and other indications, including MDS. Pracinostat is an investigational agent and is not approved for commercial use in the U.S. and any country worldwide.

# About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a robust drug development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland, the U.S., Monaco and China, as well as a product presence in approximately 190 countries globally.

## To learn more about Helsinn Group please visit www.helsinn.com

### About MEI Pharma

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#### MEI Pharma and Helsinn Group Forward-Looking Statements

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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.

For more information:

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MEI Pharma David A. Walsey VP of IR and Corporate Communications Tel: 858-369-7104 <u>investor@meipharma.com</u>

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