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 10, 2017

Agios Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36014**	**26-0662915**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

88 Sidney Street, Cambridge, MA	**02139**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 649-8600

(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 240.13e-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).

☐ 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 10, 2017, Agios Pharmaceuticals, Inc. (the "Company") issued a press release announcing updated clinical data from the Company's ongoing phase 2 DRIVE PK study evaluating AG-348 in patients with pyruvate kinase deficiency. On December 11, 2017, the Company issued a press release announcing new clinical data from the Company's phase 1 dose-escalation and expansion trial of ivosidenib in patients with relapsed or refractory acute myeloid leukemia ("AML") and an isocitrate dehydrogenase-1 ("IDH1") mutation. Also on December 11, 2017, the Company issued a press release announcing clinical data from (i) the ongoing phase 1 trial of enasidenib or ivosidenib in combination with induction and consolidation chemotherapy in patients with newly diagnosed AML with an isocitrate dehydrogenase-2 ("IDH2") or IDH1 mutation, and (ii) the ongoing phase 1/2 trial of enasidenib or ivosidenib in combination with azacitadine in patients with newly diagnosed AML with an IDH2 or IDH1 mutation ineligible for intensive chemotherapy. The Company presented these data at the 2017 American Society of Hematology Annual Meeting and Exposition held on December 9 – 12, 2017. The full text of the press releases issued in connection with this announcement are attached as Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Agios Pharmaceuticals, Inc. on December 10, 2017.
99.2	Press release issued by Agios Pharmaceuticals, Inc. on December 11, 2017.
99.3	Press release issued by Agios Pharmaceuticals, Inc. on December 11, 2017.

SIGNATURES

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.

AGIOS PHARMACEUTICALS, INC.

Date: December 11, 2017

By: /s/ David P. Schenkein
David P. Schenkein, M.D.
President and Chief Executive Officer

Exhibit 99.1

Agios Presents Updated Data from DRIVE PK Study Demonstrating AG-348 is Well-Tolerated and Results in Clinically Relevant, Rapid and Sustained Hemoglobin Increases in Patients with Pyruvate Kinase Deficiency

– Safety and Efficacy Profile Consistent with Previously Reported Data –

– Hemoglobin Increases >1.0 g/dL in 26 of 52 Patients Overall; Responses Remain Durable with Completion of Six Month Core Treatment Period –

– Two Global Pivotal Trials in PK Deficiency on Track to Initiate in First Half of 2018 –

ATLANTA, December 10, 2017 — Agios Pharmaceuticals, Inc. (Nasdaq:AGIO) presented updated data today from its wholly owned pyruvate kinase-R (PKR) activator, AG-348, demonstrating its potential as the first disease-modifying treatment for patients with pyruvate kinase (PK) deficiency at the 2017 American Society of Hematology (ASH) Annual Meeting and Exposition. PK deficiency is a rare, potentially debilitating, congenital anemia.

DRIVE PK is an ongoing global open-label, Phase 2, safety and efficacy trial evaluating AG-348 in 52 adult, transfusion-independent patients with PK deficiency. As of the July 14, 2017 data cut-off 43 patients had completed the six-month core dosing period and 9 patients discontinued treatment during the core dosing period. Of the 52 patients enrolled, 26 (50%) experienced a maximum hemoglobin (Hb) increase from baseline of >1.0 gram per deciliter (g/dL) during the six-month core period. For the 42 patients enrolled with at least 1 missense mutation, 25 (60%) experienced a maximum Hb increase from baseline of >1.0 g/dL. AG-348 remains well-tolerated with the majority of adverse events (AEs) being Grade 1 or 2. The median treatment duration was 37.5 weeks, with a maximum of 92.4 weeks.

“With some patients approaching two years of treatment, we are encouraged that AG-348 continues to be well-tolerated and demonstrates clinically relevant, sustained increases in hemoglobin in adults with PK deficiency,” said Rachael Grace, M.D., of the Dana-Farber Boston Children’s Cancer and Blood Disorder Center and a principal investigator for the study. “AG-348 has the potential to be the first therapy for patients with PK deficiency that targets the underlying cause of this chronic anemia and its associated complications.”

Patients in DRIVE PK were randomized to a starting dose of 50 mg or 300 mg twice daily, treated for six months in a core treatment period and then offered treatment in an extension period. Enrollment was completed in November 2016 with 52 patients. Nine subjects discontinued during the core treatment period. Thirty-six of 43 patients who completed the six month core treatment period entered the extension period. As of the data cut-off, 29 patients remain on treatment in the extension period.

"DRIVE PK has established a clear signal of activity for AG-348 in PK deficiency and was instrumental in informing the design of the pivotal program we are on track to initiate in the first half of 2018," said Chris Bowden, M.D., chief medical officer at Agios. "In addition to this clinical work, our planned global PKD patient registry will complement our patient finding efforts and further advance our understanding of the disease burden for this rare anemia."

Safety Data

A safety analysis conducted for all 52 treated patients as of the data cut-off shows that AG-348 continues to be well tolerated.

- The majority of treatment-related AEs were Grade 1-2; the most frequent were headache, insomnia and nausea.
- As previously reported, four patients experienced treatment-related AEs leading to discontinuation: pleural effusion (n=1), hypertriglyceridemia (n=1), pharyngitis/nausea (n=1) and anemia (n=1).
- As previously reported, four patients experienced treatment-related serious adverse events: withdrawal hemolysis followed by anemia (n=1), anemia (n=1), osteoporosis (n=1) and hypertriglyceridemia (n=1).
- A previously reported case of drug-related pharyngitis (n=1) was subsequently deemed unrelated to study drug.
- Measurements of hormone levels in men at doses ≤50 mg BID suggest mild aromatase inhibition by AG-348; ongoing follow-up will continue to assess potential clinical significance.

Efficacy Data

In the efficacy analysis 26 of 52 patients (50%) overall and 25 of 42 patients (60%) with at least one missense mutation achieved rapid and sustained Hb increases from baseline of >1.0 g/dL as of the data cut-off.

- In patients who had Hb increases of >1.0 g/dL, the mean maximum Hb increase was 3.4 g/dL (range 1.1-5.8 g/dL).
- The median time to first Hb increase of >1.0 g/dL was 10 days (range 7–187 days).
- As previously reported, the median baseline Hb in patients who experienced a maximum Hb increase of >1.0 g/dL was 9.7 g/dL (range 7.3–12.3 g/dL) vs. 8.0 g/dL (range 6.5–10.1 g/dL) in patients who did not experience the increase.

Pivotal Development Plan

Agios plans to initiate two global, pivotal trials in adults with PK deficiency in the first half of 2018 based on transfusion status:

- A randomized, placebo-controlled trial with a 1:1 randomization known as ACTIVATE is expected to enroll approximately 80 patients who do not receive regular transfusions. The primary endpoint of the trial is the proportion of patients who achieve a sustained hemoglobin increase □1.5 g/dL.

- A single arm trial of approximately 20 regularly transfused patients known as ACTIVATE-T will have a primary endpoint of reduction in transfusion burden over six months.

About Pyruvate Kinase Deficiency and Genetic Background

PK deficiency is a rare inherited disease that presents as hemolytic anemia, which is the accelerated destruction of red blood cells. The inherited mutations in PKR enzymes cause a deficit in cellular energy within the red blood cell, as evidenced by lower pyruvate kinase enzyme activity and a decline in ATP (adenosine triphosphate) levels and a build-up of upstream metabolites, including 2,3-DPG (2,3-diphosphoglycerate).

The current standard of care for PK deficiency is supportive, including blood transfusions, splenectomy, chelation therapy to address iron overload and/or interventions for other treatment- and disease-related morbidities. There is no approved therapy to treat the underlying cause of PK deficiency.

PK deficiency is an autosomal recessive disease whereby all patients inherit two mutations, one from each parent. More than 250 different mutations have been identified to date. The mutations observed in PK deficiency patients are classified in two main categories. A missense mutation causes a single amino acid change in the protein, generally resulting in some functional protein. A non-missense mutation is any mutation other than a missense mutation, generally resulting in little functional protein. It is estimated that 58 percent of patients with PK deficiency have two missense mutations, 27 percent have one missense and one non-missense mutation, and 15 percent have two non-missense mutations[1].

Boston Children's Hospital, in collaboration with Agios, is conducting a Natural History Study to better understand the symptoms and complications of PK deficiency, identify patients and treatment centers, and capture other clinical data, including quality of life measures and genetic information.

About Agios

Agios is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic diseases through scientific leadership in the field of cellular metabolism. In addition to an active research and discovery pipeline across both therapeutic areas, Agios has multiple first-in-class investigational medicines in clinical and/or preclinical development. All Agios programs focus on genetically identified patient populations, leveraging our knowledge of metabolism, biology and genomics. For more information, please visit the company's website at www.agios.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding: the potential benefits of AG-348; Agios' plans for the further clinical development of AG-348; and Agios' strategic plans and prospects. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from Agios' current expectations and beliefs. For example, there can be no guarantee that any product candidate Agios is developing will successfully commence or complete necessary preclinical and clinical development phases; that positive safety and efficacy findings observed in early stage clinical trials will be replicated in later stage trials; or that development of any of Agios' product candidates will successfully continue. There can be no guarantee that any positive developments in Agios' business will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: Agios' results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; Agios' ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; Agios' ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing; Agios' ability to maintain key collaborations, such as its agreements with Celgene; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in Agios' public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Agios expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

# # #

1 Bianchi P et al. poster, 2017 ASH Annual Meeting

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Exhibit 99.2

New Data from Ivosidenib Phase 1 Dose-Escalation and Expansion Trial Demonstrate Durable Responses in Patients with IDH1m Relapsed or Refractory AML

- First Expansion Data and Updated Dose-Escalation Data Support NDA Submission for IDH1m R/R AML by Year End 2017 and Demonstrate Overall Efficacy and Safety Profile Consistent with Previously Reported Data -

- In 125 R/R AML Patients From the Primary Analysis Set, Combined CR+CRh Rate of 30.4% with a Median Duration of 8.2 Months -

- Company to Host Investor Event and Webcast Today at 8:00 p.m. ET -

ATLANTA, December 11, 2017 — Agios Pharmaceuticals, Inc. (NASDAQ:AGIO), a leader in the field of cellular metabolism to treat cancer and rare genetic diseases, today presented new efficacy and safety data from the ongoing Phase 1 dose-escalation and expansion study evaluating oral ivosidenib (AG-120) in patients with relapsed or refractory acute myeloid leukemia (R/R AML) and an isocitrate dehydrogenase-1 (IDH1) mutation. Ivosidenib is an investigational, first-in-class, oral, targeted inhibitor of the mutant IDH1 enzyme. Data in an oral session at the 2017 American Society of Hematology (ASH) Annual Meeting and Exposition demonstrated a complete response (CR) and CR with partial hematologic recovery (CRh) rate of 30.4% and an overall response rate (ORR) of 41.6% in the primary analysis set of 125 patients with R/R AML who received ivosidenib at 500 mg once daily and received their first dose at least 6 months prior to the May 12, 2017 analysis cutoff date. The CR+CRh rate is the primary endpoint of the study.

“New ivosidenib data from the expansion phase of the Phase 1 study is compelling and demonstrates impressive single-agent efficacy with durable responses in these high-risk relapsed or refractory AML patients,” said Courtney DiNardo, M.D., lead investigator and assistant professor, department of leukemia at the University of Texas MD Anderson Cancer Center. “Important measures of clinical benefit for patients treated with ivosidenib were also observed and include increases in transfusion independence and a decrease in the frequency of comorbidities such as febrile neutropenia and infections in responding patients.”

A total of 258 patients with advanced hematologic malignances and an IDH1 mutation were treated on the Phase 1 study, which included 78 patients in the dose-escalation portion and 180 patients from four dose-expansion Arms. Enrollment to the study is closed. This is the first presentation of data from the dose-expansion portion of the study. Safety data reported include all treated patients, and includes those who received ivosidenib at total daily doses ranging from 200 mg to 1200 mg in dose-escalation and 500 mg daily in dose expansion. A maximum tolerated dose was not reached in the dose-escalation portion of the trial. The primary analysis set is comprised of 125 R/R AML patients (92 patients from Arm 1 of the expansion and 33 patients from the dose-escalation who met the eligibility criteria for Arm 1 and received

ivosidenib at 500 mg once daily) who were enrolled at least 6 months prior to the primary analysis cutoff date of May 12, 2017. The median age of these patients is 67 (ranging from 18-87), and the median number of prior regimens is two (ranging from one to six).

“These data form the core of the efficacy analysis for our ivosidenib NDA submission, which is on track for the end of the year,” said Chris Bowden, M.D., chief medical officer of Agios. “We believe that these data validate the potential for ivosidenib to be a first-in-class therapy for patients with R/R AML and an IDH1 mutation.”

Safety Data

A safety analysis conducted for all 258 treated patients as of the data cut-off showed that ivosidenib continues to demonstrate a favorable safety profile. The most common adverse events (AEs) regardless of causality were diarrhea (33.3%), leukocytosis (30.2%), nausea (29.5%), fatigue (28.7%) and febrile neutropenia (25.2%).

Among the 125 R/R AML patients from the primary analysis set, adverse events of interest were the following:

- 8% reported Grade □3 leukocytosis, which was managed with hydroxyurea. No cases were fatal.
- 8% reported Grade 3 QT prolongation. Ivosidenib was reduced in one patient and held in five patients (for any grade of QT prolongation), and no cases were Grade 4 or fatal.
- 9.6% reported IDH-differentiation syndrome (IDH-DS), which was managed with corticosteroids and diuretics. None were Grade 4 or fatal.

Efficacy Data

Data from 125 R/R AML patients from the primary analysis set demonstrated a combined CR+CRh rate of 30.4% [95% CI 22.5, 39.3], which is the primary endpoint of the study. The CR rate was 21.6% (27 of 125 patients) [95% CI 14.7, 29.8] and the CRh rate was 8.8% (11 of 125 patients). CRh (complete remission with partial hematological recovery) is defined as <5% of blasts in the bone marrow, no evidence of disease and partial recovery of peripheral blood counts (platelets >50,000/microliter and ANC >500/microliter).

- Overall response rate (ORR) was 41.6% (52 of 125 patients).
- Median duration of response was 9.3 months [95% CI 5.6, 18.3] for patients who achieved a CR, 8.2 months [95% CI 5.5, 12.0] for patients who achieved a CR/CRh and 6.5 months [95% CI 4.6, 9.3] for all patients who responded.
- Median time to first response was 1.9 months (0.8-4.7) for all patients who responded, median time to CR was 2.8 months (0.9-8.3) for patients who achieved a CR, and median time to CR/CRh was 2.7 months (0.9-5.6) for patients who achieved a CR/CRh.
- At the time of the data cut-off, median overall survival (OS) as observed in the study has not yet been reached for patients who achieved a CR/CRh. OS was 9.3 months [95% CI 3.7, 10.8] for non-CR/CRh responders, 3.9 months [95% CI 2.8, 5.8] for non-responders, and 8.8 months [95% CI 6.7, 10.2] overall.

- Of the patients who were transfusion dependent at baseline and achieved a CR, 100% became independent of platelet transfusions and 84.6% became independent of red blood cell (RBC) transfusions during any 56-day post baseline period.
- Of the patients who were transfusion dependent at baseline and achieved a CRh, 71.4% became independent of platelet transfusions and 75.0% became independent of RBC transfusions during any 56-day post baseline period. Transfusion independence was also seen among non-CR/CRh responders and non-responders. Non-CR/CRh responders include patients with CR with incomplete hematologic recovery (CRi), CR with incomplete platelet recovery (CRp) and morphologic leukemia-free state (MLFS) who are not CRh.

Response in Untreated AML and MDS

An efficacy analysis was also presented for 34 untreated AML patients not eligible for standard of care therapies in expansion Arm 2 and from dose escalation whose starting dose was 500 mg daily and 12 myelodysplastic syndrome (MDS) patients in expansion Arm 3 and from dose escalation whose starting dose was 500 mg daily.

- Data from 34 untreated AML patients demonstrated a 55.9% ORR and a CR rate of 20.6%. The median duration of response was 9.2 months [95% CI 1.9, NE], and median duration of CR has not yet been reached.
- Data from 12 MDS patients demonstrated a 91.7% ORR and a CR rate of 41.7%.

Clinical Development in AML

Ivosidenib continues to be studied in the following ongoing clinical trials in AML:

- Phase 3 AGILE study evaluating the safety and efficacy of ivosidenib + azacitidine vs. placebo + azacitidine in adults with previously untreated IDH1m AML who are considered appropriate candidates for non-intensive therapy
- Phase 1b study of either ivosidenib or enasidenib in combination with standard induction and consolidation chemotherapy in newly diagnosed AML
- Phase 1/2 study of either ivosidenib or enasidenib in combination with azacitidine in newly diagnosed AML

Agios is on track to file a New Drug Application (NDA) for ivosidenib with the U.S. Food and Drug Administration by the end of 2017.

About the Phase 1 Trial for Ivosidenib in Advanced Hematologic Malignancies

Ivosidenib (AG-120) is being evaluated in an ongoing Phase 1 trial that includes a dose-escalation phase and four expansion arms, including:

- Arm 1: IDH1 mutant positive AML patients who relapsed after bone marrow transplantation, are in second or later relapse, refractory to initial induction or reinduction treatment, or who relapse within one year of initial treatment, excluding patients with favorable-risk status
- Arm 2: untreated IDH1 mutant positive AML patients who are not candidates for standard-of-care chemotherapy

- Arm 3: patients with other non-AML IDH1 mutant, relapsed or refractory advanced hematologic malignancies
- Arm 4: patients with relapsed IDH1 mutant positive AML not eligible for arm 1 who have failed or are unable to receive standard of care

About Acute Myelogenous Leukemia (AML)

AML, a cancer of blood and bone marrow characterized by rapid disease progression, is the most common acute leukemia affecting adults. Undifferentiated blast cells proliferate in the bone marrow rather than mature into normal blood cells. AML incidence significantly increases with age, and according to the American Cancer Society, the median age of onset is 66. The vast majority of patients do not respond to chemotherapy and progress to relapsed/refractory AML. The five-year survival rate for AML is approximately 20 to 25 percent. IDH1 mutations are present in about 6 to 10 percent of AML cases.

Investor Event and Webcast Information

Agios will host an investor event on Monday, December 11, 2017 beginning at 8:00 p.m. ET in Atlanta to review data presented at ASH. The event will be webcast live and can be accessed under "Events & Presentations" in the Investors section of the company's website at www.agios.com.

About Agios

Agios is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic diseases through scientific leadership in the field of cellular metabolism. In addition to an active research and discovery pipeline across both therapeutic areas, Agios has an approved oncology precision medicine and multiple first-in-class investigational therapies in clinical and/or preclinical development. All Agios programs focus on genetically identified patient populations, leveraging our knowledge of metabolism, biology and genomics. For more information, please visit the company's website at www.agios.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding: the potential benefits of ivosidenib; Agios' plans for the further clinical development of ivosidenib; and Agios' strategic plans and prospects. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from Agios' current expectations and beliefs. For example, there can be no guarantee that any product candidate Agios is developing will successfully commence or complete necessary preclinical and clinical development phases; that positive safety and efficacy findings observed in early stage clinical trials will be replicated in later stage trials; or that development of any of Agios' product candidates will successfully continue. There can be no guarantee that any positive developments in Agios' business will result

in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: Agios' results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; Agios' ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; Agios' ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing; Agios' ability to maintain key collaborations, such as its agreements with Celgene; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in Agios' public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Agios expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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Exhibit 99.3

Data from Phase 1 Studies of Ivosidenib or Enasidenib in Combination with Full Doses of Standard of Care Chemotherapy Demonstrate Tolerability and Preliminary Clinical Activity in Newly Diagnosed AML Patients With an IDH Mutation

- Ivosidenib and Enasidenib Evaluated in Combination with Standard Induction (7+3) Chemotherapy or Azacitadine in Newly Diagnosed Patients From Two Phase 1 Studies -

- Phase 3 Trial of Ivosidenib or Enasidenib Combined with Standard Induction Therapy Planned for 2018 and Phase 3 AGILE Study of Ivosidenib in Combination with Azacitidine Ongoing, Both in Newly Diagnosed AML Patients with an IDH Mutation -

- Company to Host Investor Event and Webcast Today at 8:00 p.m. ET -

ATLANTA, Dec. 11, 2017 – Agios Pharmaceuticals, Inc. (NASDAQ:AGIO), a leader in the field of cellular metabolism to treat cancer and rare genetic diseases, today presented data from two studies evaluating ivosidenib (AG-120) and an investigational use of IDHIFA® (enasidenib) in patients with newly diagnosed acute myeloid leukemia (AML) and an isocitrate dehydrogenase (IDH)1 or IDH2 mutation. The data were presented as part of the scientific program at the 59th American Society of Hematology Annual Meeting in Atlanta.

"The totality of the data presented at ASH demonstrate the potential benefit of IDHm inhibitors in the frontline setting for patients with AML," said Eytan Stein, M.D., study investigator and attending physician in the leukemia service at Memorial Sloan Kettering Cancer Center. "The Phase 1 frontline combination trials showed that ivosidenib and enasidenib are well tolerated when combined with standard induction chemotherapy or azacitadine and both trials demonstrated early encouraging signs of efficacy. I look forward to evaluating both ivosidenib and enasidenib in late-stage, placebo-controlled clinical trials to understand the full impact of these medicines on newly diagnosed AML patients."

Combination with Standard Induction Chemotherapy

The first presentation, given by Dr. Stein, evaluated ivosidenib or enasidenib in combination with standard induction chemotherapy in patients with newly diagnosed AML and an IDH1 or IDH2 mutation. During induction, patients received either 500 mg of ivosidenib and 7 + 3 standard chemotherapy (daunorubicin 60 mg/m2/day or idarubicin 12 mg/m2/day x 3 days with cytarabine 200 mg/m2/day x 7 days) (n=32) or 100 mg of enasidenib and 7 + 3 standard chemotherapy (n=56). Of these patients, 69% in the ivosidenib arm and 57% in the enasidenib arm had de novo AML, while the remaining patients had secondary AML (sAML). For patients with sAML, 40% in the ivosidenib arm and 63% in the enasidenib arm had received prior hypomethylating agent therapy. After induction, patients could receive up to four cycles of consolidation chemotherapy while continuing ivosidenib or enasidenib. Patients who achieved a complete response (CR) or a complete response with incomplete neutrophil or platelet recovery (CRi/CRp) after consolidation could continue to take single agent ivosidenib or enasidenib daily for up to two years from day one of induction.

Ivosidenib Results

In the ivosidenib arm, the most common Grade 3 or higher non-hematologic adverse events during the induction period were febrile neutropenia (60%), blood bilirubin increased (9%), hypertension (9%), colitis (9%), increased alanine aminotransferase (9%) and increased aspartate aminotransferase (9%). The 30 and 60-day mortality rates were both 6%, and there were no dose-limiting toxicities. The median time to absolute neutrophil count (ANC) recovery (>500/µL) was 28.5 days (95% CI 27,34). Median time to platelet recovery (>50,000/µL) was 28 days (95% CI 26,34).

The CR+CRi/CRp rate for de novo patients was 91% (19/21) and 44% (4/9) for sAML patients. The overall best response of CR+ CRi/CRp rate for all patients was 77% (23/30).

Enasidenib Results

In the enasidenib arm, the most common Grade 3 or higher non-hematologic adverse events during the induction period were febrile neutropenia (63%), blood bilirubin increased (9%), hypertension (9%) and bacteremia (9%). The 30 and 60-day mortality rates were 5% and 7%, respectively. There was one dose-limiting toxicity in the enasidenib combination arm consisting of persistent Grade 4 thrombocytopenia lasting beyond 42 days from the start of induction. The median time to ANC recovery (>500/µL) was 34 days (95% CI 29,35). Median time to platelet recovery (>50,000/µL) was 33 days (95% CI 29,50).

The CR+CRi/CRp rate for de novo patients was 67% (18/27) and 57% (13/23) for sAML patients. The overall best response of CR+CRi/CRp rate for all patients was 62% (31/50).

“The early results from these studies of ivosidenib and enasidenib in combination with traditional frontline AML treatment are highly encouraging and support the strategy to advance IDHm inhibitors into the newly diagnosed setting,” said Chris Bowden, M.D., chief medical officer of Agios. “We are focused on evaluating the IDHm inhibitors in late-stage studies that span the entire frontline setting with our ongoing Phase 3 AGILE study of ivosidenib in combination with azacitidine versus azacitidine and a planned Phase 3 study of ivosidenib and enasidenib in combination with 7+3 intensive chemotherapy.”

Combination with Azacitidine

The second presentation, given by Courtney DiNardo, M.D., evaluated an investigational use of enasidenib or ivosidenib in combination with azacitidine in patients with newly diagnosed AML unable to receive intensive chemotherapy. In the study, patients received 100mg (n=3) or 200mg (n=3) of enasidenib daily plus azacitidine or 500 mg of ivosidenib (n=11) plus azacitidine. At the data cutoff, 11 patients remained on the study (3 enasidenib, 8 ivosidenib).

Enasidenib Results

For patients receiving the enasidenib combination, the most common Grade 3-4 hematologic adverse event was neutropenia (33%, 2/6). The most common Grade 3-4 non-hematologic adverse events were pneumonia (33%, 2/6) and hyperbilirubinemia (33%, 2/6). IDH differentiation syndrome was reported in one patient.

Four of six patients had a response, including two CRs, one partial response (PR) and one morphologic leukemia-free state (MLFS).

Ivosidenib Results

For patients receiving the ivosidenib combination, the most common Grade 3-4 hematologic adverse events were anemia (18%, 2/11) and febrile neutropenia (18%, 2/11) with neutropenia and thrombocytopenia each with one event (9% each). The most common Grade 3-4 non-hematologic adverse event was pneumonia (18%, 2/11). IDH differentiation syndrome was reported in one patient.

Eight of 11 patients had a response, including four CRs, one CRi, one PR and two MLFS.

Neither IDHIFA nor ivosidenib are approved for the treatment of patients with newly diagnosed AML or approved in combination with azacitidine.

About IDHIFA

IDHIFA (enasidenib) is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase-2 mutation as detected by an FDA-approved test.

Important Safety Information

WARNING: DIFFERENTIATION SYNDROME

Patients treated with IDHIFA have experienced symptoms of differentiation syndrome, which can be fatal if not treated. Symptoms may include fever, dyspnea, acute respiratory distress, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, lymphadenopathy, bone pain, and hepatic, renal, or multi-organ dysfunction. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

WARNINGS AND PRECAUTIONS

Differentiation Syndrome: See Boxed WARNING. In the clinical trial, 14% of patients treated with IDHIFA experienced differentiation syndrome, which may be life-threatening or fatal if not treated. Differentiation syndrome has been observed with and without concomitant hyperleukocytosis, as early as 10 days and at up to 5 months after IDHIFA initiation. Symptoms in patients treated with IDHIFA included acute respiratory distress represented by dyspnea and/or hypoxia and need for supplemental oxygen; pulmonary infiltrates and pleural effusion; renal impairment; fever; lymphadenopathy; bone pain; peripheral edema with rapid weight gain; and pericardial effusion. Hepatic, renal, and multi-organ dysfunction have also been observed. If differentiation syndrome is suspected, initiate systemic corticosteroids and hemodynamic

monitoring until improvement. Taper corticosteroids only after resolution of symptoms. Differentiation syndrome symptoms may recur with premature discontinuation of corticosteroids. If severe pulmonary symptoms requiring intubation or ventilator support and/or renal dysfunction persist for more than 48 hours after initiation of corticosteroids, interrupt IDHIFA until signs and symptoms are no longer severe. Hospitalization for close observation and monitoring of patients with pulmonary and/or renal manifestation is recommended.

Embryo-Fetal Toxicity: Based on animal embryo-fetal toxicity studies, IDHIFA can cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with IDHIFA and for at least 1 month after the last dose. Pregnant women, patients becoming pregnant while receiving IDHIFA, or male patients with pregnant female partners should be apprised of the potential risk to the fetus.

ADVERSE REACTIONS

- The most common adverse reactions (≥20%) included total bilirubin increased (81%), calcium decreased (74%), nausea (50%), diarrhea (43%), potassium decreased (41%), vomiting (34%), decreased appetite (34%), and phosphorus decreased (27%)
- The most frequently reported ≥Grade 3 adverse reactions (≥5%) included total bilirubin increased (15%), potassium decreased (15%), phosphorus decreased (8%), calcium decreased (8%), diarrhea (8%), differentiation syndrome (7%), non-infectious leukocytosis (6%), tumor lysis syndrome (6%), and nausea (5%)
- Serious adverse reactions were reported in 77.1% of patients. The most frequent serious adverse reactions (≥2%) were leukocytosis (10%), diarrhea (6%), nausea (5%), vomiting (3%), decreased appetite (3%), tumor lysis syndrome (5%), and differentiation syndrome (8%). Differentiation syndrome events characterized as serious included pyrexia, renal failure acute, hypoxia, respiratory failure, and multi-organ failure

LACTATION

Many drugs are excreted in human milk and because of the potential for adverse reactions in breastfed infants, advise women not to breastfeed during treatment with IDHIFA and for at least 1 month after the last dose.

Please see full Prescribing Information, including Boxed WARNING.

Investor Event and Webcast Information

Agios will host an investor event on Monday, December 11, 2017 beginning at 8:00 p.m. ET in Atlanta to review data presented at ASH. The event will be webcast live and can be accessed under “Events & Presentations” in the Investors section of the company’s website at www.agios.com.

About Agios

Agios is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic diseases through scientific leadership in the field of cellular metabolism. In

addition to an active research and discovery pipeline across both therapeutic areas, Agios has an approved oncology precision medicine and multiple first-in-class investigational therapies in clinical and/or preclinical development. All Agios programs focus on genetically identified patient populations, leveraging our knowledge of metabolism, biology and genomics. For more information, please visit the company's website at www.agios.com.

About Agios/Celgene Collaboration

IDHIFA® (enasidenib) is part of Agios' global strategic collaboration with Celgene Corporation focused on cancer metabolism. Under the terms of the 2010 collaboration agreement, Celgene has worldwide development and commercialization rights for IDHIFA® (enasidenib). Agios continues to conduct certain clinical development activities within the IDHIFA® (enasidenib) development program and is eligible to receive reimbursement for those development activities and up to $95 million in remaining payments assuming achievement of certain milestones, and royalties on any net sales. Celgene and Agios are currently co-commercializing IDHIFA® (enasidenib) in the U.S. Celgene will reimburse Agios for costs incurred for its co-commercialization efforts.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding: the potential benefits of ivosidenib and IDHIFA® (enasidenib); Agios' plans for the further clinical development of ivosidenib and IDHIFA®; and Agios' strategic plans and prospects. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from Agios' current expectations and beliefs. For example, there can be no guarantee that any product candidate Agios is developing will successfully commence or complete necessary preclinical and clinical development phases; that positive safety and efficacy findings observed in early stage clinical trials will be replicated in later stage trials; or that development of any of Agios' product candidates will successfully continue. There can be no guarantee that any positive developments in Agios' business will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: Agios' results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; Agios' ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; Agios' ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing; Agios' ability to maintain key collaborations, such as its agreements with Celgene; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk

Factors" included in Agios' public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Agios expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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