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): June 1, 2018

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).

Emerging growth company ☐

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 June 1, 2018, Agios Pharmaceuticals, Inc. (the "Company") issued a press release announcing clinical data from the Company's Phase 1 study evaluating single agent AG-881 in patients with isocitrate dehydrogenase ("IDH") mutant-positive advanced glioma and other solid tumors. On June 2, 2018, the Company issued a press release announcing updated 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 IDH1 mutation. On June 4, 2018, the Company issued a press release announcing new data from 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 American Society of Clinical Oncology (ASCO) Annual Meeting held June 1-5, 2018 in Chicago, Illinois. The full text of the press releases issued in connection with these announcements 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 June 1, 2018.
99.2	Press release issued by Agios Pharmaceuticals, Inc. on June 2, 2018.
99.3	Press release issued by Agios Pharmaceuticals, Inc. on June 4, 2018.

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: June 4, 2018

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

Exhibit 99.1

Agios Presents Data from Phase 1 Dose-Escalation Study of AG-881 in Patients with IDH Mutant Positive Advanced Glioma and Other Solid Tumors

- Favorable Safety Profile at Dose Levels Below 100 mg; 10 mg and 50 mg Doses Under Evaluation in Recently Initiated Glioma Perioperative Study -

- Evidence of Prolonged Disease Control Observed in Non-Enhancing Glioma Population with a Median Treatment Duration of 12 Months -

CHICAGO, June 1, 2018 — Agios Pharmaceuticals, Inc. (NASDAQ:AGIO), a leader in the field of cellular metabolism to treat cancer and rare genetic diseases, today presented the first data from the ongoing Phase 1 study evaluating single agent AG-881 in advanced glioma and other solid tumors. The data were featured in an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting. AG-881 is an investigational, oral, selective, potent inhibitor of mutant isocitrate dehydrogenase-1 (IDH1) and IDH2 enzymes, which was designed for enhanced brain penetrance for development in IDH-mutant glioma.

"IDH mutant glioma is a distinct disease where patients are typically diagnosed in their thirties and forties and endure a deteriorating quality of life from the side effects associated with multiple rounds of surgery, radiation and chemotherapy and ultimately die of their disease," said Ingo Mellinghoff, M.D., Memorial Sloan Kettering Cancer Center, an investigator for the study. "The AG-881 Phase 1 dose-escalation data are encouraging, as they demonstrate a favorable safety profile at lower dose levels and show signals of clinical activity that support further evaluation of the role of inhibiting mutant IDH in low-grade glioma."

"With no curative or approved targeted therapies for low-grade glioma and a poor long-term prognosis, we are committed to exploring the novel mechanism of action of our IDH inhibitors in this indication," said Chris Bowden, M.D., chief medical officer at Agios. "Data from our ivosidenib and AG-881 Phase 1 trials and the ongoing perioperative study, combined with feedback from regulators and the neurology community, will inform our pivotal development plan."

The ongoing Phase 1 dose-escalation trial is assessing the safety and tolerability of AG-881 in IDH1/2 mutant advanced solid tumors, including glioma. As of the March 29, 2018 data cut-off, 93 patients (52 with glioma and 41 with other solid tumors) have been treated with single agent AG-881. Enrollment is complete and 17 glioma patients and 1 non-glioma solid tumor patient remain on treatment. Study design, status and baseline characteristics for the 52 glioma patients are reported below.

- Forty-eight percent of patients (n=25) had World Health Organization (WHO) classified Grade 2 tumors, 42% (n=22) had Grade 3 tumors, 8% (n=4) had Grade 4 tumors and 2% (n=1) was unknown.

- Ninety-two percent of patients (n=48) had an IDH1 mutation and 6% (n=3) had an IDH2 mutation. One patient did not have a biopsy but was confirmed as IDH mutant positive due to 2-HG elevation by magnetic resonance spectroscopy (MRS).
- The median age of these patients is 42.5 years (ranging from 16-73 years).
- Patients received a median of two prior systemic therapies (ranging from one to six).
    - Seventy-three percent of patients (n=38) had previously received temozolomide and 58% percent (n=30) had previously received radiotherapy.
- Patients received daily doses of AG-881 ranging from 10 mg to 300 mg.
- The median treatment duration was seven months (ranging from 0-27 months) for all glioma patients, 12 months (ranging from 1-27 months) for non-enhancing glioma and 3 months (ranging from 0- 27 months) for patients with enhancing disease.

Safety Data

The safety analysis conducted for all 93 treated patients as of the data cut-off demonstrated that AG-881 has a favorable safety profile at dose levels below 100 mg.

- The majority of adverse events (AEs) reported by investigators were mild to moderate, with the most common (>33%) being fatigue, nausea, increases in alanine aminotransferase (ALT) and increases in aspartate aminotransferase (AST).
- Grade 3 or higher AEs were observed in 33% of all patients (n=31).
- Dose limiting toxicities (DLTs) of Grade 2 or higher elevated transaminases occurred in five glioma patients at the higher dose levels (□100 mg) and resolved to Grade ≤1 with dose modification or discontinuation. There were no treatment-related on-treatment deaths.
- A maximum tolerated dose (MTD) was not reached by Bayesian model; the doses chosen for further clinical development were based on safety, pharmacokinetics and pharmacodynamics data.

Efficacy Data

Efficacy data from the 52 glioma patients (23 with non-enhancing and 29 with enhancing disease) as of the data cut-off showed:

- One patient with non-enhancing disease and a 1p19q co-deletion had a sustained minor response according to the investigator by Response Assessment in Neuro-Oncology for low grade glioma (RANO-LGG) and remains on treatment.
- Seventy-five percent of patients (n=39) had a best response of stable disease, including 20 patients with non-enhancing disease.
- Thirty-five percent of patients (n=18, including 13 patients with non-enhancing disease) remained on treatment for □1 year.

Efficacy data from the 41 patients with non-glioma solid tumors as of the data cut-off showed:

- One patient with cholangiocarcinoma had a partial response, 37% of patients (n=15) had stable disease and 44% (n=18) had progressive disease.
- The median treatment duration was 2 months (ranging from 0-18 months).

Ongoing Perioperative Study in Glioma

A perioperative 'window' trial with ivosidenib and AG-881 (10 mg and 50 mg) in up to 45 IDH1m non-enhancing low-grade glioma patients is ongoing. The goal of the trial is to confirm CNS penetrance and tumor 2-HG suppression of ivosidenib and AG-881 as part of the strategy to finalize pivotal development plans by year-end 2018.

About Glioma

Glioma presents in varying degrees of tumor aggressiveness, ranging from slower growing (low grade glioma) to rapidly progressing (high grade glioma-Glioblastoma Multiforme). Common symptoms include seizures, memory disturbance, sensory impairment and neurologic deficits. The long-term prognosis is poor with a five-year survival rate of 33 percent. Approximately 11,000 low-grade glioma patients are diagnosed annually in the U.S. and EU and approximately 80 percent have an IDH1 mutation.

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

AG-881 is part of Agios' global strategic collaboration with Celgene Corporation focused on cancer metabolism. For AG-881, the companies have a joint worldwide development and 50/50 profit share collaboration, and Agios is eligible to receive regulatory milestone payments of up to $70 million.

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 TIBSOVO® (ivosidenib) and AG-881; Agios' plans for the further clinical development of TIBSOVO® and AG-881; 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 99.2

Updated Data from Ivosidenib Phase 1 Dose-Escalation and Expansion Trial in IDH1m Relapsed or Refractory AML Continue to Show Durable Responses as a Single Agent

- In 179 Relapsed or Refractory IDH1m AML Patients, Primary Endpoint of CR+CRh Rate of 31.8% with a Median Duration CR+CRh of 8.2 Months -

- Updated Data Suggest that R/R AML Patients with IDH1-Mutation Clearance Who Have Achieved CR/CRh Have Prolonged Duration of Remission and Overall Survival -

- Ivosidenib Phase 1 Data in Patients with IDH1m Advanced Hematological Malignancies Published Today in the New England Journal of Medicine -

CHICAGO, June 2, 2018 — 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 single agent oral ivosidenib (TIBSOVO®; AG-120) in patients with relapsed or refractory acute myeloid leukemia (R/R AML) and an isocitrate dehydrogenase-1 (IDH1) mutation. The data were presented in an oral session at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting. Ivosidenib is an investigational, first-in-class, oral, targeted inhibitor of the mutant IDH1 enzyme under FDA priority review for IDH1m R/R AML patients with a PDUFA action date of August 21, 2018.

Agios also announced the publication in the *New England Journal of Medicine* (NEJM) of data from the ongoing ivosidenib Phase 1 study in patients with advanced hematological malignancies and an IDH1 mutation. The NEJM manuscript, which was published online today and will appear in the June 21, 2018 print issue, provides analyses from the dataset presented at the 2017 American Society of Hematology (ASH) Annual Meeting, with a data cutoff date of May 12, 2017.

“The findings presented at ASCO demonstrate that single agent ivosidenib induced durable responses, in some cases with IDH1-mutation clearance, and led to favorable responses compared with historical patient outcomes in a high-risk, molecularly-defined R/R AML population,” said Daniel Pollyea, M.D., M.S., study investigator and clinical director of leukemia services at the University of Colorado School of Medicine. “Additional clinical benefits included transfusion independence and, in responding patients, reductions in advanced-grade infections and febrile neutropenia, indicating immune system recovery with functional neutrophils.”

“These data provide additional clinical and translational observations beyond the 2017 ASH presentation, including preliminary data suggesting that R/R AML patients with IDH1-mutation clearance in bone marrow who have achieved CR/CRh have prolonged remission durations and overall survival versus those without IDH1-mutation clearance,” said Chris Bowden, M.D., chief medical officer of Agios. “We believe the compelling single-agent efficacy coupled with a tolerable safety profile validate the potential for ivosidenib to be a first-in-class therapy for patients with R/R AML and an IDH1 mutation.”

Data Presented at ASCO

A total of 258 patients with advanced hematologic malignances and an IDH1 mutation were treated in the Phase 1 study. Enrollment to the study is closed. Complete safety and efficacy data are reported in 179 patients with R/R AML whose ivosidenib starting dose was 500 mg once daily. The median age is 67 (ranging from 18-87), and the median number of prior therapies is two (ranging from one to six). Of these patients, 33% had secondary AML and 24% had prior transplants. The data cutoff for the ASCO presentation was November 10, 2017.

Safety Data

As of the data cut-off, a safety analysis conducted for 179 treated R/R AML patients showed that ivosidenib demonstrates a favorable safety profile that is consistent with previously reported data for all 258 patients. The most common adverse events (AEs) of any grade > 25% regardless of causality were diarrhea (33.5%), leukocytosis (31.3%), nausea (31.3%), febrile neutropenia (29.1%), fatigue (28.5%) and electrocardiogram (ECG) QT prolonged (25.7%). Adverse events of interest were the following:

- 8% reported Grade □3 leukocytosis, which was managed with hydroxyurea.
- 10% reported Grade □3 ECG QT prolongation. Ivosidenib dose was reduced in two patients and held in 13 patients (for any grade of ECG QT prolongation).
- 10.6% reported IDH-differentiation syndrome (IDH-DS) of any grade, which was managed with corticosteroids and diuretics. Six patients had their dose temporarily held, no patients required dose reductions.
- No AEs of interest lead to any permanent treatment discontinuations or deaths.

Efficacy Data

Data from 179 R/R AML patients demonstrated an overall response rate (ORR) of 41.9% (75 of 179 patients) and a combined complete remission (CR) and CR with partial hematologic recovery (CRh) rate of 31.8% [95% CI 25.1, 39.2] which is the primary endpoint of the study.

- The CR rate was 24% (43 of 179 patients) [95% CI 18.0, 31.0] and the CRh rate was 7.8% (14 of 179 patients). CRh is defined as <5% of blasts in the bone marrow, no evidence of disease and partial recovery of peripheral blood counts (ANC >500/microliter and platelets >50,000/microliter).
- Median duration of response was 10.1 months [95% CI 6.5, 22.2] for patients who achieved a CR, 8.2 months [95% CI 5.6, 12.0] for patients who achieved a CR/CRh and 6.5 months [95% CI 5.5, 10.1] for all patients who responded.
- Median time to first response was 1.9 months (0.8-4.7) for all patients who responded and median time to CR/CRh was 2.0 months [95% CI 0.9, 5.6].
- Transfusion independence, defined as an absence of transfusions for at least 56 consecutive days on treatment, was observed across all response categories.
    - Of the patients who were transfusion dependent at baseline and achieved a CR, all became independent of platelet transfusions and 88.2% became independent of RBC transfusions during any 56-day post baseline period.

- Of the patients who were transfusion dependent at baseline and achieved a CRh, 75% became independent of platelet transfusions and 77.8% became independent of RBC transfusions during any 56-day post baseline period.
- Achievement of transfusion independence was also seen among non-CR/CRh responders and non-responders.

- Patients who achieved CR and CRh had lower rates of exposure-adjusted febrile neutropenia and Grade □3 infections during ivosidenib treatment than patients in other response categories.

Translational Findings

IDH1 mutation clearance, defined as absence of the IDH1 mutation with a sensitivity of 0.02–0.04% (2-4 x10-4), was observed in 23% (11/47) of patients with R/R AML who achieved CR or CRh and had molecular data available, including 28% (10/36) of patients with CR and 1/11 patients with CRh. Preliminary data suggest that R/R AML patients with IDH1-mutation clearance in bone marrow mononuclear cells who have achieved CR/CRh have prolonged remission durations and overall survival versus those without IDH1-mutation clearance.

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 the median age of diagnosis is 68. 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 27 percent. IDH1 mutations are present in about 6 to 10 percent of AML cases.

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.

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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

New Data from Phase 1 Study of Ivosidenib or Enasidenib in Combination with Azacitidine Demonstrate Robust Responses and a Well Tolerated Safety Profile in Newly Diagnosed IDHm AML Patients

- Safety Profile of Combination Therapies Consistent with Single Agent IDHm Inhibitors and Azacitidine -

- ORR of 78%, CR Rate of 44% and CR/CRi/CRp Rate of 65% in the Ivosidenib Arm; Molecular Clearance Observed in 7 Out of 21 Patients -

- Randomized Trials in Newly Diagnosed IDHm AML Patients Ineligible for Intensive Chemotherapy Ongoing, Including Phase 3 AGILE Study of Ivosidenib in Combination with Azacitidine -

CHICAGO, June 4, 2018 – Agios Pharmaceuticals, Inc. (NASDAQ:AGIO), a leader in the field of cellular metabolism to treat cancer and rare genetic diseases, today presented encouraging new data from a Phase 1 study evaluating ivosidenib (AG-120) or enasidenib (IDHIFA®; AG-221) in combination with azacitidine in newly diagnosed isocitrate dehydrogenase (IDH) mutant acute myeloid leukemia (AML) patients. The data were featured at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting.

"Patients with newly diagnosed AML who are ineligible for intensive "7+3" chemotherapy typically have poor outcomes and few available treatment options," said Courtney DiNardo, M.D., lead investigator and assistant professor, department of leukemia at the University of Texas MD Anderson Cancer Center. "With additional patients now treated in the ivosidenib arm of this Phase 1 study, the updated combination data demonstrate a favorable safety profile and impressive response rates vs. those expected with azacitidine alone. I look forward to further demonstrating the clinical benefit of utilizing an IDH inhibitor in combination with traditional frontline AML treatment as part of the ongoing Phase 1 and randomized trials."

About the Ongoing Phase 1/2 Study

The ongoing Phase 1/2 study is evaluating an investigational use of enasidenib or ivosidenib in combination with azacitidine in patients with newly diagnosed IDH mutant AML unable to receive intensive chemotherapy. In the Phase 1b portion of the study, 23 patients received 500 mg of ivosidenib daily plus azacitidine and 6 patients received enasidenib (n=3 at 100 mg and n=3 at 200mg) daily plus azacitidine.

- As of the March 15, 2018 data cutoff, 19 patients remained on study (17 ivosidenib, 2 enasidenib).
- Enrollment is complete for the ivosidenib Phase 1b portion. Enasidenib and azacitidine continue to be assessed in the randomized Phase 2 portion of the study.

Ivosidenib Results

Safety

- The most common adverse events (AEs) regardless of causality were nausea (61%, n=14), anemia (52%, n=12) and thrombocytopenia (48%, n=11).
- The most common Grade 3-4 AEs were anemia and thrombocytopenia (44%, n=10 each), and febrile neutropenia (39%, n=9).
- IDH differentiation syndrome was reported in three patients.

Efficacy

- Overall, 78% of patients (18/23) had a response
- The combined CR/CRi/CRp rate was 65% (15/23).
    - 44% (10 of 23 patients) had a complete response (CR)
    - 22% (5 of 23 patients) had a complete response with incomplete hematologic or platelet recovery (CRi/CRp)
    - All patients with a CR, CRi or CRp response remain on treatment as of the data cutoff with patients on study up to 19 months. The median duration of response has not been reached.
- The median time to first response was 1.8 months (range 0.7-3.8 months) and the median time to best response was 3.6 months (range 0.8-6.7 months).
- IDH1 mutation clearance was observed in 7 of 21 patients with available longitudinal VAF profiling

Enasidenib Results

Updated data from the six patients in the enasidenib and azacitidine combination presented in December 2017 were also shown.

Safety

- The most common AEs regardless of causality were hyperbilirubinemia (n=5) and abdominal pain, nausea, vomiting and pyrexia (n=4 each).
- The most common Grade 3-4 AEs were anemia and thrombocytopenia (n=3 each) followed by hyperbilirubinemia, neutropenia, lung infection and pneumonia (n=2 each).

Efficacy

- Overall, four out of six patients achieved a response, including 3 CRs and one MLFS.
- IDH2 mutation clearance was observed in 3 of 6 patients with available longitudinal VAF profiling

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

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 the median age of diagnosis is 68. 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 27 percent. IDH1 mutations are present in about 6 to 10 percent of AML cases.

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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.

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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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