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 11, 2020

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.001 per share	**AGIO**	**Nasdaq Global Select Market**

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 1.01. Entry into a Material Definitive Agreement.

On June 11, 2020, Agios Pharmaceutics, Inc. (the "Company") entered into a royalty purchase agreement (the "Purchase Agreement") with RPI 2019 Intermediate Finance Trust, a Delaware statutory trust ("RPI"). Pursuant to the Purchase Agreement, the Company sold to RPI its tiered, sales-based royalty rights on worldwide net sales of Bristol Myers Squibb's IDHIFA® (enasidenib) product and any other product that contains the compound enasidenib as an active ingredient (the "Product"), as well as its rights to receive up to $55 million in outstanding regulatory milestone payments upon achievement of certain specified milestones with respect to the Product, and any replacements of those Product royalties and milestones (collectively, the "Royalty"), pursuant to the Discovery and Development Collaboration and License Agreement by and between Celgene Corporation ("Celgene") and the Company, dated as of April 14, 2010, as amended (the "License Agreement"). Celgene is a wholly-owned subsidiary of Bristol Myers Squibb. In consideration for the sale of the Royalty, RPI paid the Company $255.0 million in cash consideration at the closing of the sale.

Under the Purchase Agreement, and in connection with its sale of the Royalty, the Company has agreed to specified negative covenants with respect to the exercise of its rights under the License Agreement, including the Company's right to amend, assign and terminate the License Agreement. In addition, the Company has agreed not to commence or join any action for infringement of the Company's intellectual property rights to the extent such infringement is competitive with the Product without RPI's prior written consent. The Company has also agreed to enforce the License Agreement at RPI's direction with respect to any Celgene breach related to the Product, payments of the Royalty and the Company's intellectual property rights related to the Product. The Purchase Agreement also contains representations and warranties, other covenants, indemnification obligations and other provisions customary for transactions of this nature.

The Purchase Agreement will terminate 60 days following the date on which Celgene is no longer obligated to make any payments of the Royalty pursuant to the License Agreement. Upon termination of the License Agreement by Celgene for convenience or by the Company for Celgene's material breach or bankruptcy, the Company has the right to negotiate with RPI for the right to commercialize the Product and has otherwise agreed to license the intellectual property rights that it controls under the License Agreement related to the Product to a third party selected by RPI at RPI's direction and expense.

The foregoing description of the Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Purchase Agreement, which will be filed as an exhibit to the Company's quarterly report on Form 10-Q for the fiscal quarter ending June 30, 2020.

Item 8.01. Other Events.

The full text of the press release announcing the consummation of the transactions contemplated by the Purchase Agreement on June 12, 2020 is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

On June 12, 2020, the Company issued a press release announcing interim data from its ongoing phase 2 trial evaluating single agent mitapivat in non-transfusion-dependent α- and ß-thalassemia. Data from the study were featured in an oral presentation at the 25th European Hematology Association Annual Congress, which is being held virtually. Also on June 12, 2020, the Company issued a press release announcing that clinical proof-of-concept has been established based on a preliminary analysis in the phase 1 trial of mitapivat in patients with sickle cell disease. The full text of these press releases are attached as Exhibits 99.2 and 99.3, respectively, hereto and are incorporated herein by reference.

Cautionary Note Regarding Forward-Looking Statements

Statements in this Current Report on Form 8-K, Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 hereto contain forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding: Agios' use of proceeds from the transaction with RPI, developments regarding Agios' collaboration agreement with Celgene, the potential benefits of mitapivat, Agios' plans for the further clinical development of mitapivat 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 or its collaborators is developing will successfully commence or complete necessary preclinical and clinical development phases, 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, without limitation: risks and uncertainties related to the impact of the COVID-19 pandemic to Agios' business, operations, strategy, goals and anticipated milestones, including its ongoing and planned research activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products; 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 United States Food and Drug Administration, the European Medicines Agency or 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; and general economic and market conditions. These and other risks are described in greater detail in Agios' public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this Current Report, Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 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, except as required by law.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release issued June 12, 2020 (Purchase Agreement)
99.2	Press release issued June 12, 2020 (mitapivat for thalassemia)
99.3	Press release issued June 12, 2020 (mitapivat for sickle cell disease)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 12, 2020

By: /s/ Jacqualyn A. Fouse
Jacqualyn A. Fouse, Ph.D.
Chief Executive Officer

Agios and Royalty Pharma Announce $255 Million Purchase Agreement for IDHIFA® Royalty

– Royalty Pharma Acquires Rights to Agios' Royalty on IDHIFA® Worldwide Net Sales and Outstanding Regulatory Milestone Payments –

CAMBRIDGE, Mass. and NEW YORK, N.Y., June 12, 2020 — Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the field of cellular metabolism to treat cancer and rare genetic diseases, and Royalty Pharma today announced that Agios has sold its tiered, sales-based royalty rights on worldwide net sales of Bristol Myers Squibb's IDHIFA® (enasidenib), as well as its rights to receive up to $55 million in outstanding regulatory milestone payments from Bristol Myers Squibb, to Royalty Pharma for $255 million. Agios will continue to co-promote IDHIFA® and receive reimbursement from Bristol Myers Squibb for this co-promotion under its 2010 collaboration agreement with Celgene, a wholly owned subsidiary of Bristol Myers Squibb. Agios also retains the right to receive a $25 million payment upon achievement of a specified ex-U.S. commercial milestone event. IDHIFA® is an oral, targeted therapy approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation.

"It is an exciting time at Agios with multiple ongoing mid- and late-stage trials in each of our core therapeutic focus areas that we believe have the potential to make a meaningful difference in patients' lives. This non-dilutive funding provides us with additional financial flexibility as we continue to invest in advancing our robust clinical pipeline, including mitapivat across three rare disease indications and our IDH inhibitors in solid tumors and novel combination approaches for AML," said Jackie Fouse, Ph.D., chief executive officer of Agios. "Royalty Pharma, a pioneer in this space, is an industry leader in identifying promising late-stage and commercial therapies, and we are pleased with their recognition of IDH inhibition as an important therapeutic approach for hematologic malignancies."

"IDHIFA® is an innovative, targeted treatment that has benefited numerous AML patients who may otherwise have had few other treatment options," said Pablo Legorreta, founder and chief executive officer of Royalty Pharma. "We are delighted to partner with Agios, a biotechnology company that stands out for its strong scientific foundation and a track record of successful development of multiple innovative targeted therapies. The proceeds that Agios will receive today will help further their mission and fund their exciting pipeline that will drive the next phase of the company's growth."

Cowen served as financing advisor to Agios and Wilmer Hale served as legal advisor to Agios. Goodwin Procter LLP, Dechert LLP and Maiwald Patentanwalts- und Rechtsanwaltsgesellschaft mbH acted as legal advisors to Royalty Pharma on the transaction.

About the Agios/Celgene IDH Program

In 2010, Agios and Celgene Corporation, now a wholly owned subsidiary of Bristol Myers Squibb, entered into a collaboration agreement focused on cancer metabolism. Under the terms

of the agreement, Celgene has worldwide development and commercialization rights for IDHIFA® (enasidenib). Celgene and Agios are currently co-commercializing IDHIFA® in the U.S., and Agios continues to conduct certain clinical development activities within the IDHIFA® development program. Agios is eligible to receive a $25 million payment upon achievement of a specified ex-U.S. commercial milestone event, as well as reimbursement for costs incurred for its co-commercialization efforts and development activities.

About Agios

Agios is focused on discovering and developing novel investigational medicines to treat malignant hematology, solid tumors and rare genetic diseases through scientific leadership in the field of cellular metabolism. In addition to an active research and discovery pipeline across these three therapeutic areas, Agios has two approved oncology precision medicines and multiple first-in-class investigational therapies in clinical and/or preclinical development. For more information, please visit the company's website at www.agios.com.

About Royalty Pharma

Founded in 1996, Royalty Pharma is the industry leader in acquiring pharmaceutical royalties. Royalty Pharma funds innovation in life sciences both directly and indirectly: directly when it partners with life sciences companies to co-develop and co-fund products in late-stage clinical trials, and indirectly when it acquires existing royalty interests from the original innovators (academic institutions, research hospitals, foundations and inventors). The company's portfolio includes royalty interests in over 45 products including AbbVie and J&J's Imbruvica, Astellas and Pfizer's Xtandi, Biogen's Tysabri, Gilead's HIV franchise, Merck's Januvia, Novartis' Promacta, and Vertex's Kalydeco, Symdeko and Trikafta. Royalty Pharma is also a leading investor in pre-approval royalties, having since 2012 invested over $6.1 billion in royalties on development-stage product candidates. For more information, visit www.royaltypharma.com.

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uncertainties relating to a number of other important factors, including, without limitation: risks and uncertainties related to the impact of the COVID-19 pandemic to Agios' business, operations, strategy, goals and anticipated milestones, including its ongoing and planned research activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products; 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 FDA, the EMA or 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; 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, except as required by law.

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Exhibit 99.2

Agios First-in Class PKR Activator Mitapivat Demonstrates Sustained Hemoglobin Responses in Non-transfusion-dependent α- and ß-Thalassemia in Phase 2 Study

– Treatment with Mitapivat Induced Hemoglobin (Hb) Increase of ³1.0 g/dL in 12 of 13 (92%) Evaluable Patients, Including 4 of 4 (100%) α-Thalassemia Patients, During Weeks 4-12 –

– 7 of 8 (88%) Evaluable Patients Achieved Sustained Hb Response During Weeks 12-24 –

– Thalassemia Pivotal Development Plan Expected to be Finalized by Year-End 2020 and Initiated in 2021 –

– Company to Host Investor Webcast Today at 7:30 a.m. ET –

CAMBRIDGE, Mass., June 12, 2020 — Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the field of cellular metabolism to treat cancer and rare genetic diseases, today reported interim data from its ongoing Phase 2 study evaluating single agent mitapivat in non-transfusion-dependent α- and ß-thalassemia. Data from the study were featured in an oral presentation at the 25th European Hematology Association Annual Congress, which is being held virtually. Mitapivat is an investigational, first-in-class, oral, small molecule allosteric activator of wild-type and a variety of mutated pyruvate kinase-R (PKR) enzymes.

“These data are exciting and further validate the potential of PKR activation as an entirely new mechanism for treating thalassemia, including α-thalassemia, for which there have been few medical advancements,” said Kevin Kuo, M.D., hematologist at University Health Network, University of Toronto, and an investigator in the study. “Findings from the study indicate that activation of wild-type PKR by mitapivat, an oral treatment option, improved hemoglobin and associated markers of hemolysis and erythropoiesis in patients with α- and ß-thalassemia. In addition, the safety profile was consistent with previously published data for mitapivat.”

“We are pleased to share the impressive interim results from our clinical study of mitapivat in α-and ß-thalassemia, as the data validate pre-clinical work conducted in our laboratories and with academic collaborators and demonstrate the potential for PKR activators in hemoglobinopathies such as thalasemmia and sickle cell disease,” said Chris Bowden, chief medical officer at Agios. “Our focus now is to advance the development of mitapivat for these patients as quickly and efficiently as possible. By the end of the year, we expect to finalize a robust pivotal development plan that spans both α-and ß-thalassemia, as well as transfusion dependent and non-tranfusion dependent patients, with a goal of initiating a pivotal program in 2021.”

Mitapivat Phase 2 Proof-of-concept Study

The ongoing, open-label Phase 2 study is evaluating the efficacy, safety, pharmacokinetics and pharmacodynamics of mitapivat treatment in adults with non-transfusion-dependent α- and ß-thalassemia who have a baseline hemoglobin (Hb) concentration of £10 g/dL. The trial is fully enrolled with 20 patients, and includes a 24-week core period followed by a 2-year extension

period for eligible participants. All patients were treated with an initial dose of mitapivat 50 mg twice daily followed by a dose-level increase to 100 mg twice daily at the week-6 visit based on safety evaluations and Hb concentrations.

As of the March 3, 2020 data cutoff, 18 patients were dosed and 13 were evaluable for the primary endpoint of a increase of ³1.0 g/dL from baseline in at least one assessment during weeks 4-12.

- Of the 18 patients dosed, 5 patients have α-thalassemia, 4 of which were evaluable for efficacy at the 12 week timepoint, and 13 patients have ß-thalassemia, 9 of which were efficacy evaluable.
- Median Hb at baseline was 8.43 (range 5.6-9.8) g/dL.
- Median treatment duration was 20.6 (range 1.1-50.0) weeks.
- Median age was 43.5 (range 29-67) years.

Efficacy Data

Efficacy data from the 13 efficacy evaluable patients as of the data cutoff demonstrated:

- The primary endpoint defined as a ³1.0 g/dL increase in Hb concentration from baseline at 1 or more assessments between week 4 and week 12 was met by 12 of 13 (92.3%) patients who had completed 12 weeks of treatment, including all 4 (100%) α-thalassemia patients and 8 of 9 (88.9%) patients with ß-thalassemia.
- For the 9 ß-thalassemia patients who completed 24 weeks of treatment, 8 of 9 achieved a Hb response defined as ³1.0 g/dL increase in Hb concentration from baseline at 1 or more assessments between week 12 and week 24. Of those responders, 7 of 8 met the criteria for sustained response defined as primary response and Hb response in ³2 assessments during weeks 12-24.
- The mean Hb change from baseline for all 13 efficacy evaluable patients was 1.34 g/dL over weeks 4-12. The mean change for α-thalassemia patients was 1.17 g/dL over weeks 4-12, and 1.43 g/dL for ß-thalassemia patients over weeks 4-24.
- Median (range) time to Hb increase of >1 g/dL among the Hb responders was 3.1 (1.4-7.1) weeks.
- Preliminary results for markers of hemolysis and erythropoiesis demonstrated improvements that were consistent with the Hb increase. Indirect bilirubin and lactate dehydrogenase showed declines in α- and ß-thalassemia patients, and erythropoietin achieved near normal levels in both groups by week 6.
- Preliminary analysis of adenosine triphosphate (ATP) levels showed mean increases of up to 92%, consistent with mitapivat's enhancement of glycolysis.

Safety Data

The safety analysis conducted on the 18 patients dosed as of the data cutoff demonstrated that the majority of adverse events (AEs) were consistent with previously published Phase 2 data for mitapivat in patients with pyruvate kinase (PK) deficiency.

- Grade 3 AEs were reported in two patients and neither was judged to be related to treatment.
- There were no serious adverse events (SAEs) and no AEs leading to treatment discontinuation. Post-data cutoff, one Grade 3 AE of renal dysfunction was reported, which was judged to be related to treatment by the investigator and resolved upon treatment discontinuation.
- Dose escalation to 100 mg twice daily was well tolerated and not associated with an increase in AEs.

Mitapivat Clinical Development

Agios has two ongoing global, pivotal trials in adults with PK deficiency that are fully enrolled.

- ACTIVATE: A placebo-controlled trial with a 1:1 randomization evaluating patients who do not receive regular transfusions. The primary endpoint of the trial is the proportion of patients who achieve a sustained hemoglobin increase of ³1.5 g/dL.
- ACTIVATE-T: A single arm trial of regularly transfused patients with a primary endpoint of reduction in transfusion burden over six months compared to individual historical transfusion burden over prior 12 months.

In addition, mitapivat is also being studied in sickle cell disease under a Cooperative Research and Development Agreement with the U.S. National Institutes of Health. Preliminary data establishing proof-of-concept for mitapivat in sickle cell disease were also disclosed today.

Mitapivat is not approved for use by any regulatory authority.

Investor Webcast Information

Agios will host an investor webcast today at 7:30 a.m. ET to review the mitapivat proof-of-concept data in sickle cell disease and Phase 2 thalassemia data presented at EHA. The event will be webcast live and can be accessed under “Events & Presentations” in the Investors section of Agios’ website at www.agios.com. The archived webcast will be available on Agios’ website beginning approximately two hours after the event.

About Agios

Agios is focused on discovering and developing novel investigational medicines to treat malignant hematology, solid tumors and rare genetic diseases through scientific leadership in the field of cellular metabolism. In addition to an active research and discovery pipeline across these three therapeutic areas, Agios has two approved oncology precision medicines and multiple first-in-class investigational therapies in clinical and/or preclinical development. 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 mitapivat; Agios’ plans for the further clinical

development of mitapivat 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, without limitation: risks and uncertainties related to the impact of the COVID-19 pandemic to Agios' business, operations, strategy, goals and anticipated milestones, including its ongoing and planned research activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products; 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; 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, except as required by law.

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Exhibit 99.3

Agios Announces Clinical Proof-of-Concept Has Been Established in Phase 1 Study of Mitapivat, First-in Class PKR Activator, in Sickle Cell Disease

– 5 of 8 (63%) Efficacy Evaluable Patients Achieved a Hemoglobin Increase of ³1.0 g/dL From Baseline –

– Safety Profile Consistent with Previously Published Phase 2 Data for Mitapivat in Patients with Pyruvate Kinase Deficiency or Expected in the Context of Sickle Cell Disease –

– Pharmacodynamics and Biomarker Data Support Mitapivat's Proposed Mechanism of Action –

– Data Support Advancement of Mitapivat to Pivotal Development in Sickle Cell Disease –

– Company to Host Investor Webcast Today at 7:30 a.m. ET –

CAMBRIDGE, Mass., June 12, 2020 — Agios Pharmaceuticals, Inc. (NASDAQ:AGIO), a leader in the field of cellular metabolism to treat cancer and rare genetic diseases, today announced that clinical proof-of-concept has been established based on a preliminary analysis in the Phase 1 trial of mitapivat (AG-348) in patients with sickle cell disease. The study is being conducted in collaboration with the National Institutes of Health (NIH) as part of a cooperative research and development agreement. Mitapivat is an investigational, first-in-class, oral, small molecule allosteric activator of wild-type and a variety of mutated pyruvate kinase-R (PKR) enzymes. Mitapivat has been shown to decrease 2,3-diphosphoglycerate (2,3-DPG) and increase adenosine triphosphate (ATP), and through this mechanism, it may reduce hemoglobin (Hb) S polymerization and red blood cell sickling.

The ongoing Phase 1 study has enrolled nine patients to date. Eight patients have completed all planned dose levels, and one patient discontinued within the first week due to a pre-existing condition and was subsequently lost to follow-up. Six patients were treated with three ascending dose levels of mitapivat (5 mg BID, 20 mg BID, 50 mg BID) for two weeks duration, respectively, followed by 9 or 12-day drug taper, and two patients received an additional ascending dose of 100 mg BID for two weeks before initiating the drug taper. Adverse events (AEs) reported during the study were generally consistent with those previously reported in pyruvate kinase (PK) deficiency or are to be expected in the context of sickle cell disease. One severe AE, a vaso-occlusive crisis, occurred during drug taper and was attributed as possibly related to the drug.

Seven of eight (88%) patients who completed all planned dose levels of mitapivat experienced a Hb increase, with five of eight patients (63%) achieving a hemoglobin increase of ³1.0 g/dL from baseline (range 1.0-2.7 g/dL). All five patients who achieved a hemoglobin increase of ³1.0 g/dL did so at doses of 50 mg BID or lower. Treatment with mitapivat was associated with decreases in hemolytic markers such as bilirubin, lactic acid dehydrogenase and reticulocytes. As expected, decreases in 2,3-DPG and increases in ATP levels were observed, consistent with the

proposed mechanism of action and comparable to that observed in healthy volunteer studies with mitapivat. Evaluation of sickling curves (t50) and oxygen dissociation curves (p50) were consistent with decreases in both sickling and HbS polymerization, further supporting the proposed mechanism of action.

“The interim results from the Phase 1 study of mitapivat demonstrate for the first time that PKR activation has the potential to address chronic hemolytic anemia and impact markers of sickling in sickle cell disease patients as hypothesized based on the mechanism of action,” said Swee Lay Thein, M.B., B.S., F.R.C.P., F.R.C.Path., D.Sc., chief of the Sickle Cell Branch of the National Heart, Lung, and Blood Institute, NIH, and the principal investigator of the study. “The safety profile of mitapivat continues to be consistent with prior studies in both mutated and wildtype PKR, and hemoglobin responses were seen in 63% of patients. We are excited about these preliminary results, and I look forward to continuing to collaborate with Agios to advance this treatment for sickle cell disease patients.”

“First, I would like to thank the NIH and Dr. Thein for the incredible collaboration on this study. These data build on our six years of clinical experience with this mechanism and establish proof-of-concept for mitapivat as a potential novel approach for the treatment of sickle cell disease, a chronic lifelong condition with few treatment options,” said Chris Bowden, M.D., chief medical officer at Agios. “Looking ahead, we are focused on advancing mitapivat to pivotal development, with the goal of initiating a pivotal study next year.”

Mitapivat Phase 1 Trial in Sickle Cell Disease

The ongoing Phase 1 study, which can enroll up to 25 patients, is evaluating the efficacy, safety, pharmacokinetics and pharmacodynamics of treatment with mitapivat in adults with sickle cell disease. Six patients received three ascending dose levels of mitapivat (5 mg BID, 20 mg BID, 50 mg BID) for 2 weeks duration, respectively, followed by 9 or 12-day drug taper. The two patients most recently enrolled and all subsequent patients receive an additional ascending dose of 100 mg BID for two weeks before initiating the drug taper in order to further explore dose-response relationship. The primary endpoint of the study is safety and tolerability as assessed by frequency and severity of adverse events and laboratory parameters. Secondary endpoints included changes in hemoglobin, markers of hemolysis, 2,3-DPG and ATP levels and HbS polymerization.

Mitapivat Clinical Development

Agios has two ongoing global, pivotal trials in adults with PK deficiency that are fully enrolled.

- ACTIVATE: A placebo-controlled trial with a 1:1 randomization evaluating patients who do not receive regular transfusions. The primary endpoint of the trial is the proportion of patients who achieve a sustained hemoglobin increase of ^{3}1.5 g/dL.
- ACTIVATE-T: A single arm trial of regularly transfused patients with a primary endpoint of reduction in transfusion burden over six months compared to individual historical transfusion burden over prior 12 months.

In addition, mitapivat is being studied in an ongoing Phase 2 study in adults with non-transfusion-dependent ß- and α-thalassemia. Interim results from the study were reported today in an oral presentation at the 25th European Hematology Association Annual Congress (EHA).

Mitapivat is not approved for use by any regulatory authority.

Investor Webcast Information

Agios will host an investor webcast today at 7:30 a.m. ET to review the mitapivat proof-of-concept data in sickle cell disease and Phase 2 thalassemia data presented at EHA. The event will be webcast live and can be accessed under “Events & Presentations” in the Investors section of Agios’ website at www.agios.com. The archived webcast will be available on Agios’ website beginning approximately two hours after the event.

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 two approved oncology precision medicines 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 mitapivat; Agios’ plans for the further clinical development of mitapivat; 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 or its collaborators is developing will successfully commence or complete necessary preclinical and clinical development phases, 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, without limitation: risks and uncertainties related to the impact of the COVID-19 pandemic to Agios’ business, operations, strategy, goals and anticipated milestones, including its ongoing and planned research activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling

current or future approved products; 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, the EMA or 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; 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, except as required by law.

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