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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): January 11, 2016**

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

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-36014**  
(Commission  
File Number)

**26-0662915**  
(IRS Employer  
Identification No.)

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

**02139**  
(Zip Code)

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

(Former Name or Former Address, if Changed Since Last Report)

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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))
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**Item 7.01 Regulation FD Disclosure.**

On January 11, 2016, Agios Pharmaceuticals, Inc. (the “Company”) intends to make a slide presentation at the 34th Annual J.P. Morgan Healthcare Conference. A form of the slide presentation is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information responsive to Item 7.01 of this Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 8.01 Other Events.**

On January 11, 2016, the Company issued a press release outlining its 2016 strategy and expected milestones for its development programs and research pipeline, each of which will be discussed at the Company’s presentation at the 34th Annual J.P. Morgan Healthcare Conference on January 11, 2016. The full text of the press release issued in connection with this announcement is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) The following exhibits are included in this report:

<u>Exhibit</u> <u>No.</u>	<u>Description</u>
99.1	Form of Presentation as of January 11, 2016.
99.2	Press release issued by Agios Pharmaceuticals, Inc. on January 11, 2016.

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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: January 11, 2016

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

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
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## **AgiOS in 2016**

JPMorgan Healthcare Conference

January 11, 2016

David Schenkein, M.D.  
Chief Executive Officer



## Cautionary Note Regarding Forward-Looking Statements

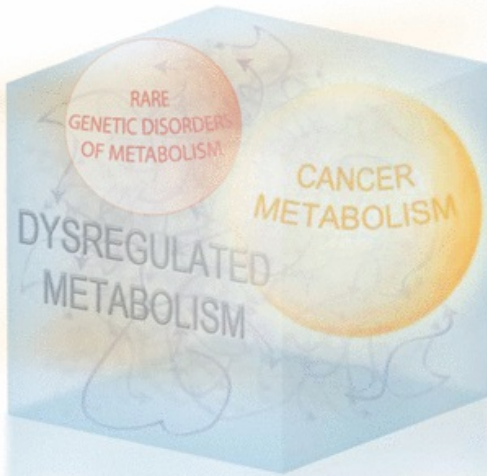
This presentation and various remarks we make during this presentation contain forward-looking statements of Agios Pharmaceuticals, Inc. within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of Agios' product candidates targeting IDH1/IDH2 or pyruvate kinase-R mutations or other genetic mutations, including AG-221, AG-120, AG-881, AG-348 and AG-519; its plans and timelines for the clinical development of AG-221, AG-120, AG-881, AG-348 and AG-519; its plans regarding future data presentations; its plans regarding its preclinical development activities; and the benefit of its strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "potential," "hope," "could," "would" 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, 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 presentation or the various remarks made during this presentation 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 agreement 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' Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, and other filings that Agios may make with the Securities and Exchange Commission in the future.

Any forward-looking statements contained in this presentation or in remarks made during this presentation 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, except as required by law.



## We Are Driven By a Clear Vision and Values

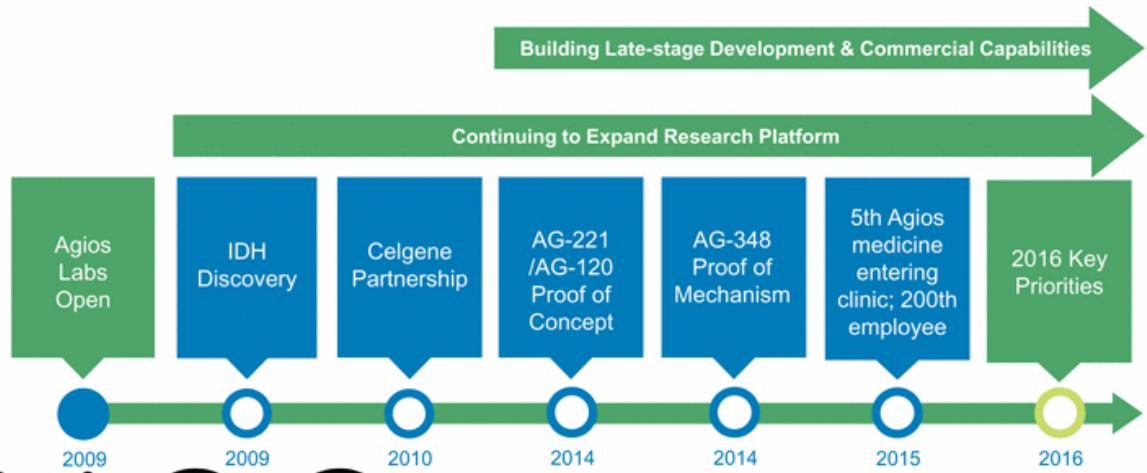


### VISION

*Agios is passionately committed to the fundamental transformation of patients' lives through scientific leadership in the field of cancer metabolism and rare genetic disorders of metabolism*



# Building a Great Sustainable Biopharmaceutical Company



agios





## Our 2016 Key Priorities: Maturing into a Late-stage Company



Rapid and broad late stage clinical development for IDHm inhibitors










Demonstrate clinical activity of PKR activators in patients



Advance research and initiate preclinical development of next wave research program



# Novel First-in-Class Clinical Portfolio

Candidate	Indication	Early Stage Clinical Development	Late Stage Clinical Development	Primary Commercial Rights
<b>AG-221</b> (IDH2m inhibitor)	R/R AML	Phase 3		 Agios U.S. Co-promotion and Royalty
	R/R AML	Phase 1 Dose Escalation	Expansion > 5 <sup>th</sup> Cohort	
	Frontline AML (Fit)	Phase 1b Combinations		
	Frontline AML (Unfit)	Phase 1/2 Combinations (Q1'16)		
	MDS/Heme Malig	Phase 1 Expansion	2 <sup>nd</sup> Expansion (2016)	
	Solid Tumors	Phase 1 Dose Escalation		
<b>AG-120</b> (IDH1m inhibitor)	Frontline AML	Phase 3 (2H'16)		  U.S. Rights      EX-U.S. Rights
	R/R AML	Dose Escalation	Expansion	
	MDS/Heme Malig	Phase 1 Expansion		
	Frontline AML (Fit)	Phase 1b Combinations		
	Frontline AML (Unfit)	Phase 1/2 Combinations (Q1'16)		
	Solid Tumors	Phase 1 Dose Escalation	Expansion	
	IHCC	Phase 2 (2H'16)		
<b>AG-881</b> (pan-IDHm inhibitor)	R/R AML	Phase 1 Dose Escalation		  Joint Worldwide Collaboration
	Solid Tumors	Phase 1 Dose Escalation		
<b>AG-348</b> (PK (R) Activator)	PK Deficiency	Phase 2 DRIVE PK		
<b>AG-519</b> (PK (R) Activator)	PK Deficiency	Phase 1		

## Today's Key 2016 Milestone Announcements

### IDHm Inhibitors

- Complete enrollment in AG-221 and AG-120 expansion arms in 2H
- Initiate Phase 3 study of AG-120 in frontline AML in 2H
- Initiate MDS expansion arm for AG-221
- Initiate randomized Phase 2 study of AG-120 in cholangiocarcinoma in 2H

### PKR Activators

- Present first data from DRIVE PK trial of AG-348 in 1H
- Present first data from AG-519 Phase 1 healthy volunteer study in 1H
- Present new findings from Natural History Study of PK deficiency in 2H
- Outline clinical development plans for PKR activators in beta-thalassemia in 2H

### Research

- Initiate preclinical development activities and publish on a new cancer metabolism program

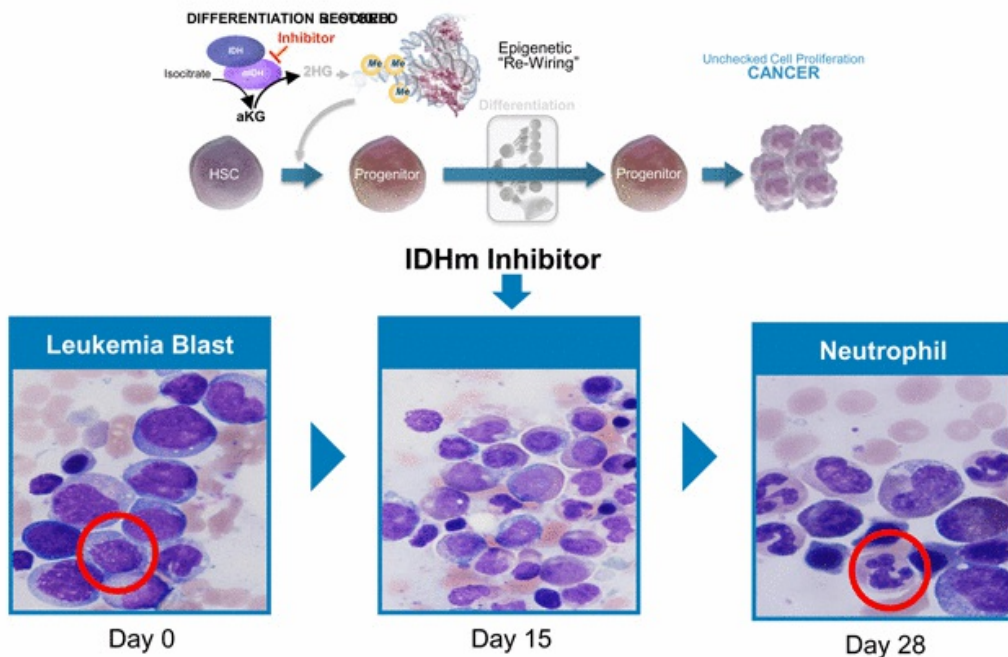


# Cancer Metabolism: IDH

*Using a pill once a day to repair a cancer cell*

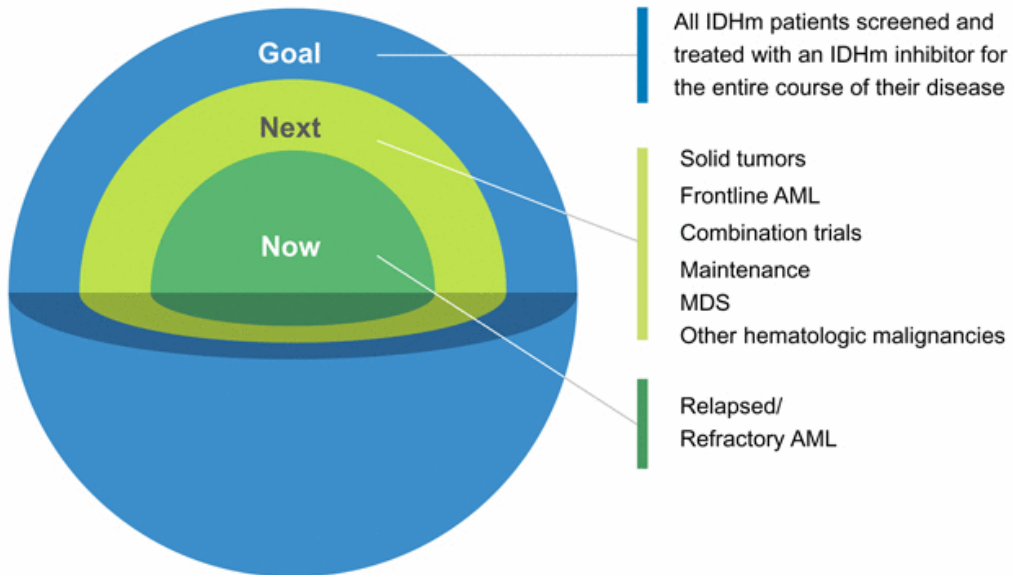


# Repairing an IDH Mutant Cancer Cell



# What's Possible for IDHm Patients

## A Roadmap for Speed and Breadth

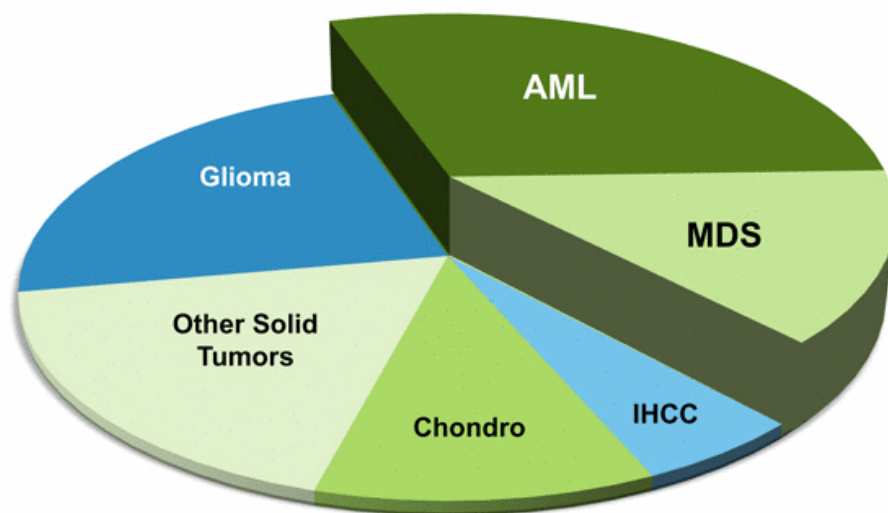


## Three IDHm Inhibitors Provide Maximum Opportunity

AG-221	AG-120	AG-881
<ul style="list-style-type: none"><li>▪ Potent, selective, reversible inhibitor of mutant isocitrate dehydrogenase-2 (IDH2)</li><li>▪ In Phase 3 clinical development</li><li>▪ Oral, once daily dosing, 100mg</li></ul>	<ul style="list-style-type: none"><li>▪ Potent, selective, reversible inhibitor of mutant isocitrate dehydrogenase-1 (IDH1)</li><li>▪ In Phase 2 clinical development</li><li>▪ Oral, once daily dosing, 500mg</li></ul>	<ul style="list-style-type: none"><li>▪ Brain-penetrant, pan-IDH mutant inhibitor (IDH1 &amp; IDH2)</li><li>▪ In Phase 1 clinical development</li><li>▪ Oral, once daily dosing</li></ul>



## IDH Mutations Occur in Multiple Cancers



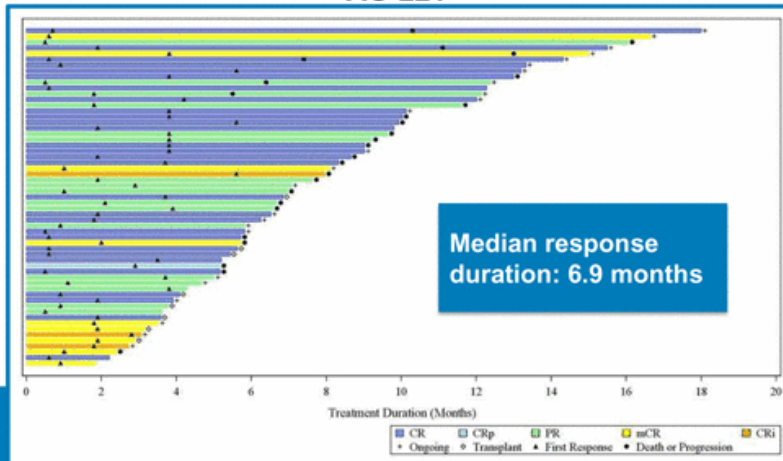
12 ~40K New Patients/Year; Mutation Occurs Early and Easily Detected with Genomic Testing



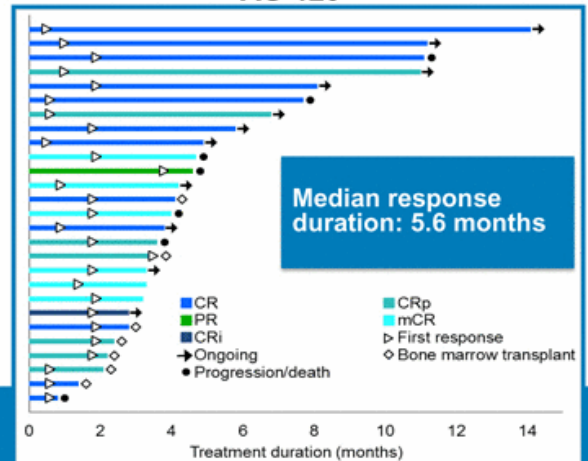


# AG-221 and AG-120 Represent a New Treatment Paradigm in AML

**AG-221**



**AG-120**



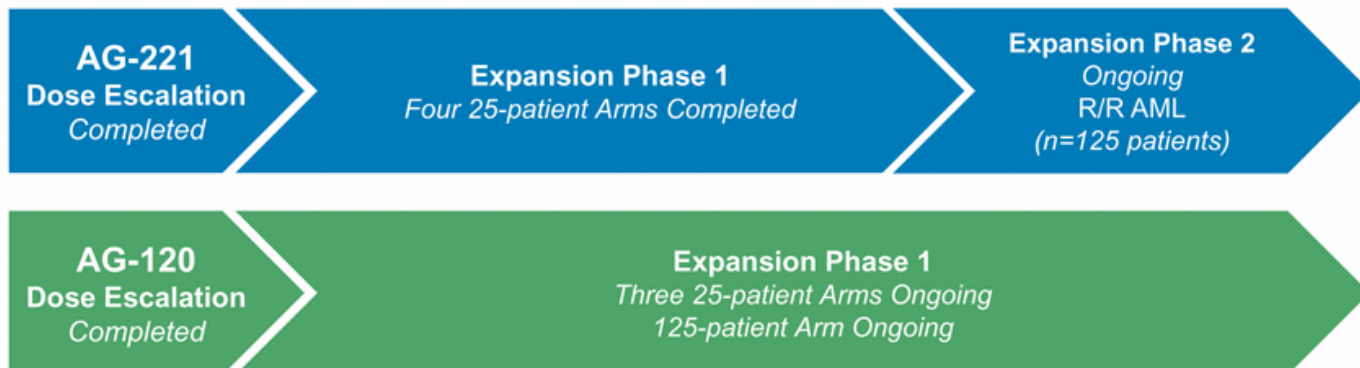
## First-in-Class, Oral, Potent, Selective, Reversible Inhibitors

- With ~300 patients treated, AG-221 and AG-120 demonstrate favorable safety profiles
- Impressive single agent complete and partial responses in relapsed/refractory IDHm AML
- Neutrophil and platelet improvements observed in non-CR responders and some patients with stable disease



## Phase 1 Programs Rapidly Defined Single-Agent Profile for IDHm Inhibitors in R/R AML

Phase 1 expansion cohorts designed to demonstrate compelling clinical benefit with registration quality data



Expect to Complete Enrollment in Both 125-patient Expansion Arms in 2H'16

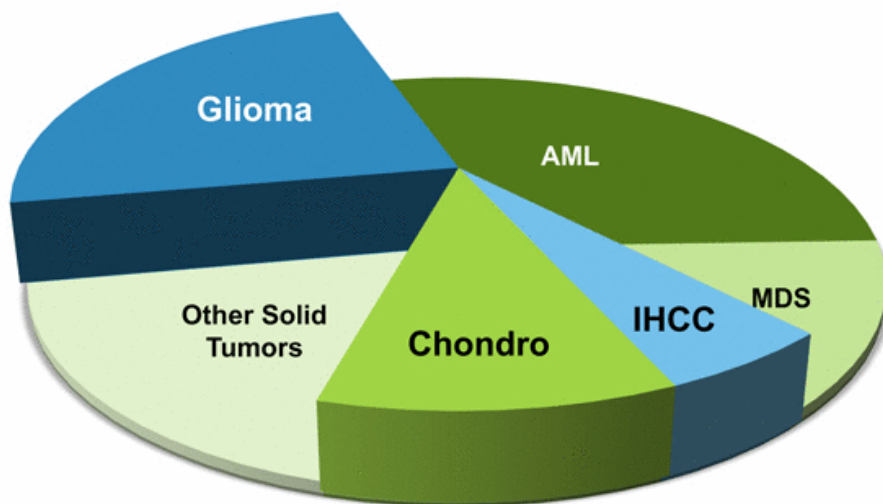


# Targeting Multiple Lines of Treatment in IDHm AML and Other Hematologic Malignancies

Relapsed AML	Newly Diagnosed (Untreated) AML		MDS / Other Heme Malig.
2nd+ Relapse	Intensive	Non-Intensive	Frontline to R/R
Phase 1 AG-221 Expansion	Phase 1 Induction (7+3) + AG-221 or AG-120	Phase 1 → 2 VIDAZA® + AG-221 or AG-120 (1Q'16)	Phase 1 AG-221 MDS Expansion Cohort (2016)
Phase 1 AG-120 Expansion	Phase 3 AG-120 in Frontline AML (2H'16)		
Phase 3 IDHENTIFY AG-221 vs SOC			Ongoing
			Planned



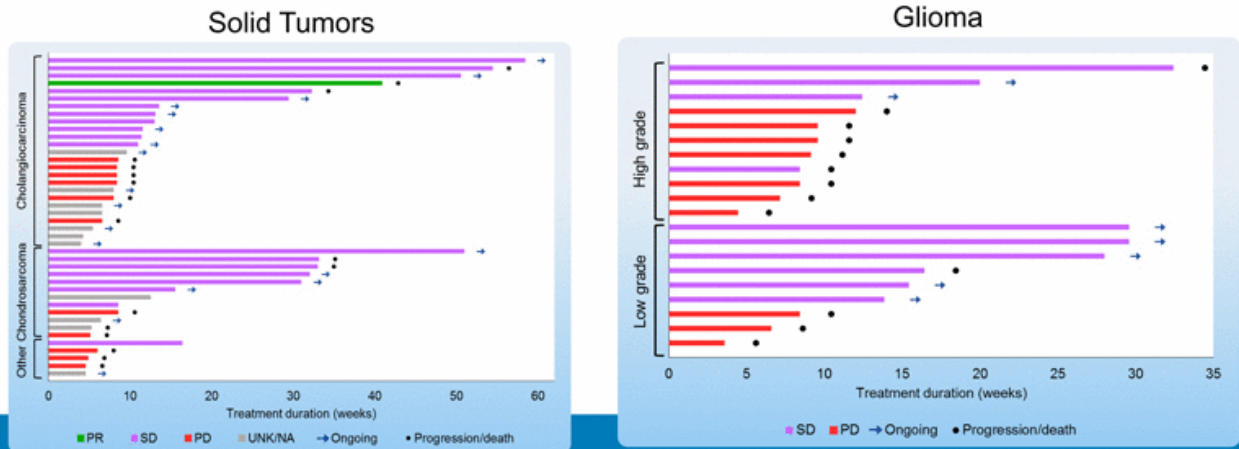
## IDH Mutations Occur in Multiple Cancers



16 ~40K New Patients/Year; Mutation Occurs Early and Easily Detected with Genomic Testing

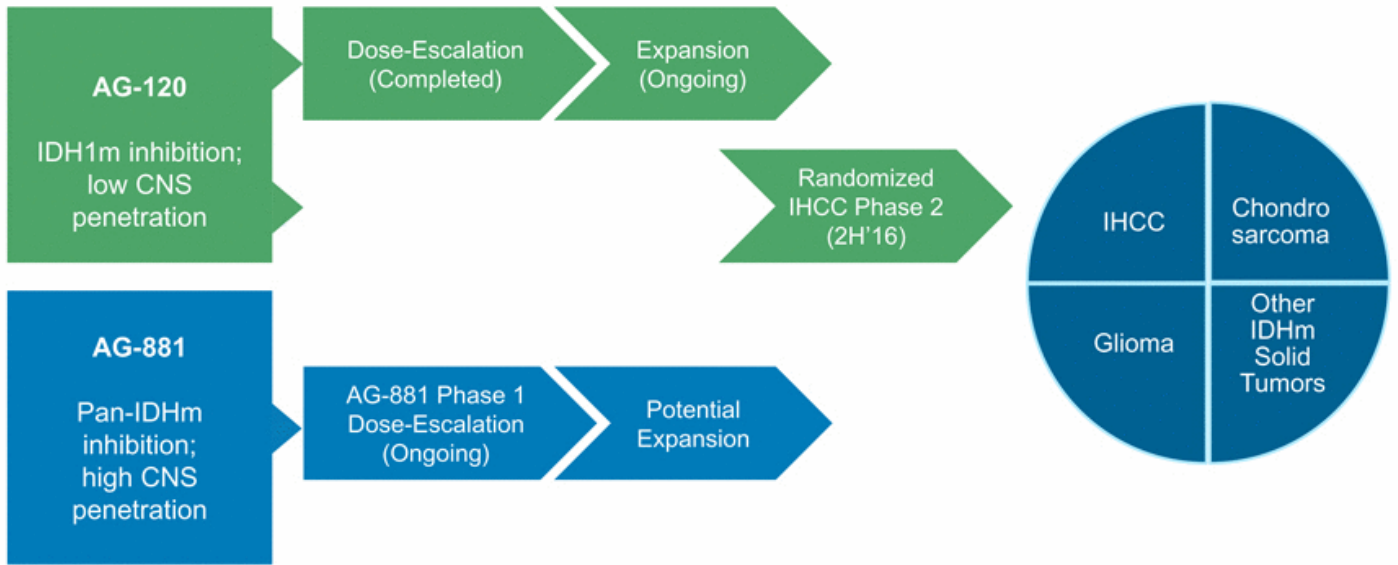


# Encouraging AG-120 Phase 1 Data in Solid Tumors



- AG-120 well tolerated (no MTD) and showed signs of clinical activity
- Reductions in tumor volume observed in some glioma patients
- Favorable PK properties, inhibition of 2HG in tumor and reduction in proliferation markers

# Clinical Development Path in IDH1m Solid Tumors Will Be Data Driven

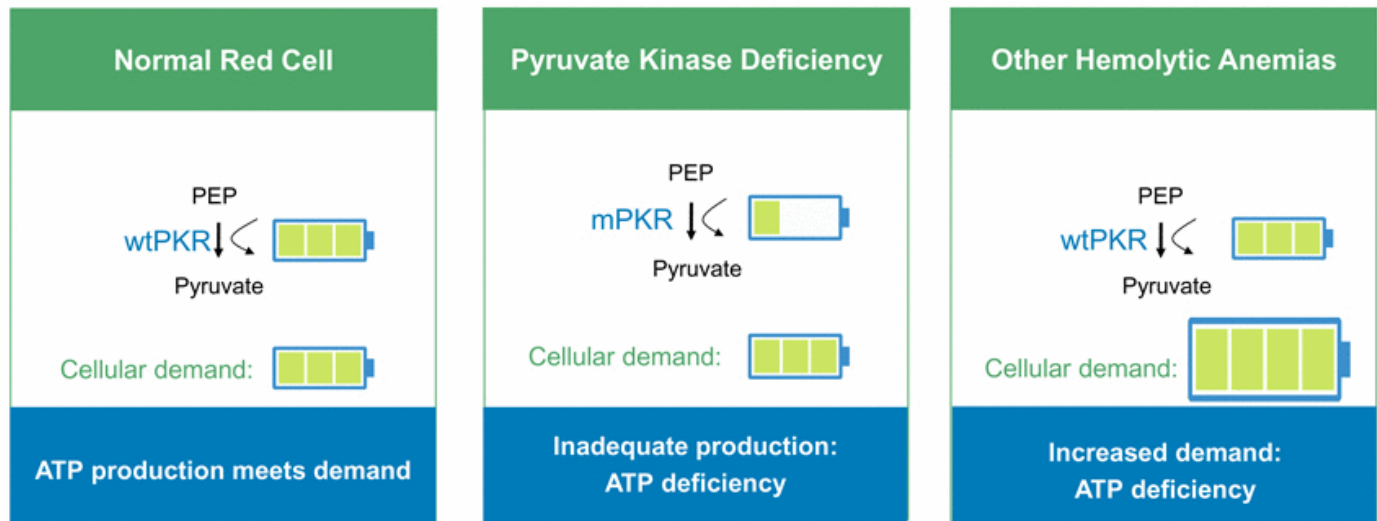


# Rare Genetic Metabolic Disorders: PKR

*Transforming a metabolic disorder with a small molecule*



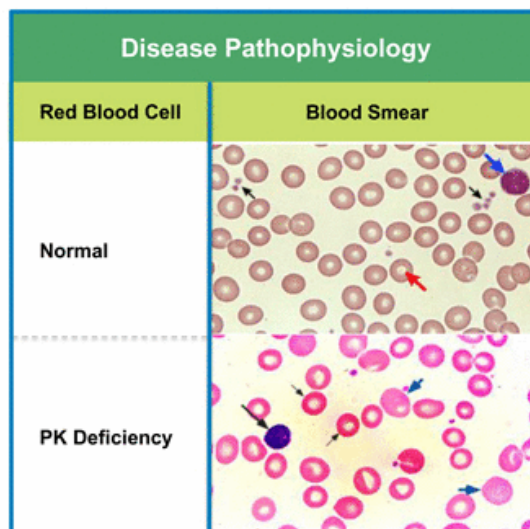
# Pyruvate Kinase-R (PKR) Activation Has Broad Potential in Red Cell Disorders





# PK Deficiency: What We Know Today

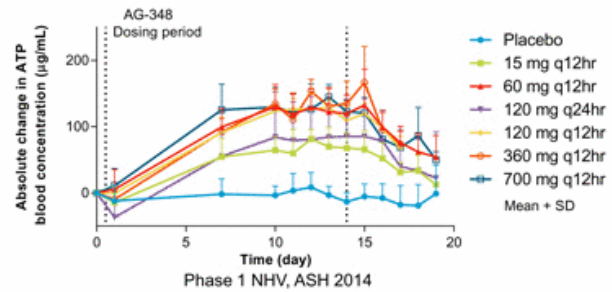
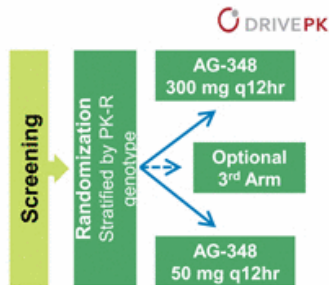
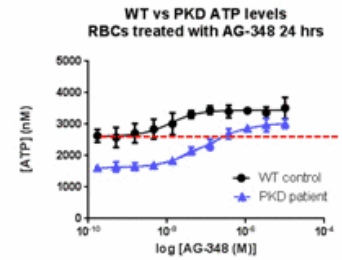
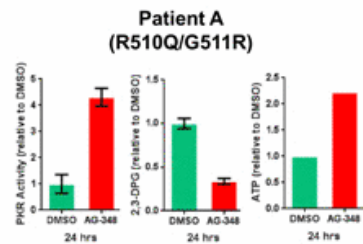
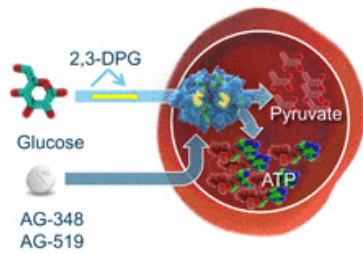
Disease Overview	
<b>Description</b>	<ul style="list-style-type: none"> <li>Rare genetic disease often presenting at birth as neonatal jaundice</li> <li>~2400 diagnosed in U.S. and EU5*</li> </ul>
<b>Etiology</b>	<ul style="list-style-type: none"> <li>Caused by mutations in PK-LR gene coding for Erythrocyte Pyruvate Kinase</li> </ul>
<b>Clinical Presentation</b>	<ul style="list-style-type: none"> <li>Lifelong hemolytic anemia and associated morbidities</li> </ul>
<b>Diagnosis</b>	<ul style="list-style-type: none"> <li>PKR enzyme activity and genetic testing</li> </ul>



\* Based on genetic data and diagnosis rate



# PKR Activation Represents Therapeutic Approach to Treating PK Deficiency

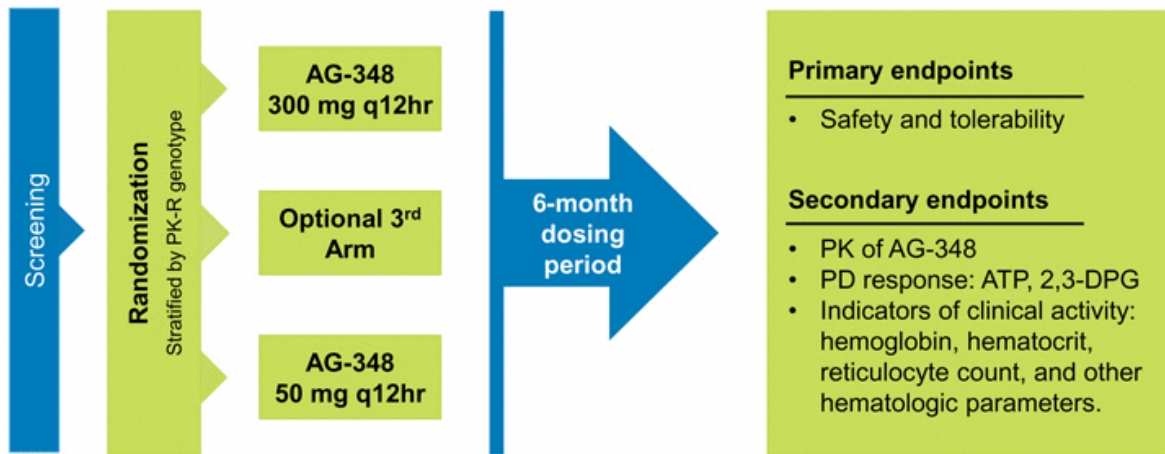


# AG-348 Global Phase 2 DRIVE PK Study

## Open and Enrolling



Transfusion-independent PK-deficient adults n=25 in each arm



First Data Expected 1H'16



# AG-519 Healthy Volunteer Study Open and Enrolling

## AG-519

- Potent, highly selective and orally bioavailable PKR activator
- Differentiated chemical structure versus AG-348
- No activity against the aromatase enzyme
- AG-519 has similar activity in vitro, in vivo and ex vivo (patient samples) relative to AG-348

## One protocol, two steps, healthy volunteers

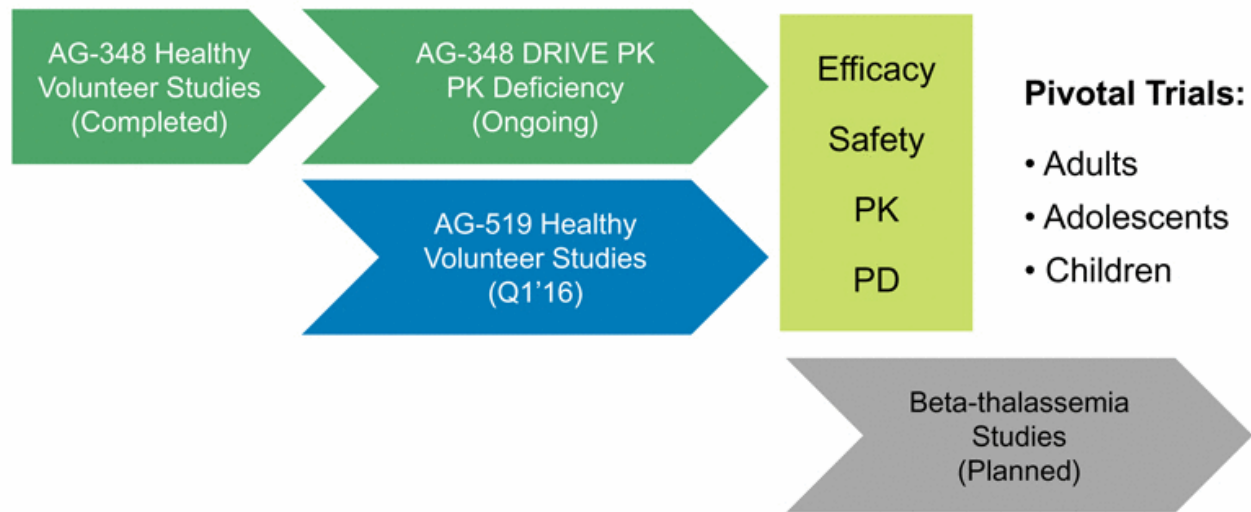
### Step 1: Integrated SAD/MAD

- 4 dose-ascending cohorts: 8 subjects per cohort (n=32)
- Placebo controlled (6A, 2P)

### Step 2: Bioavailability and Food Effect Study



# AG-519 Provides Optionality for Clinical Development



Clinical Data From Both Trials Available in 1H'16  
Will Determine Late-stage Development Path

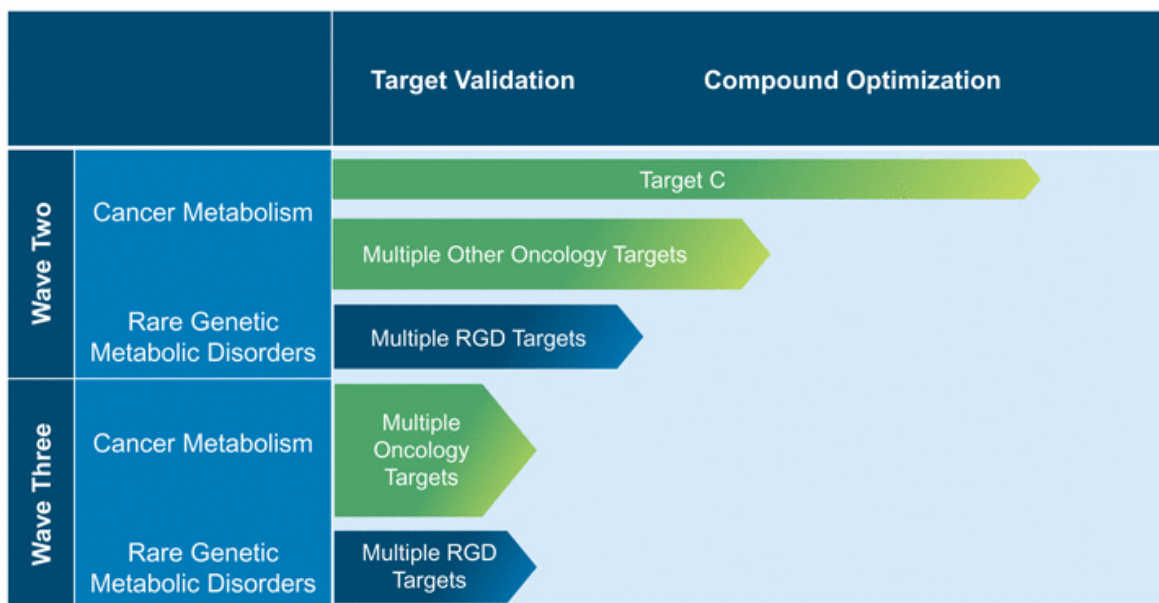


# Research

*Initiating the development of a new research program*

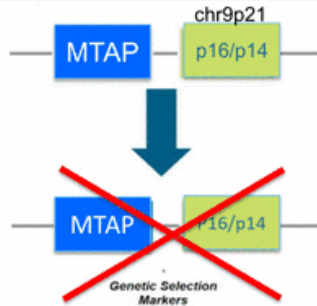


# Novel First-in-Class Research Portfolio



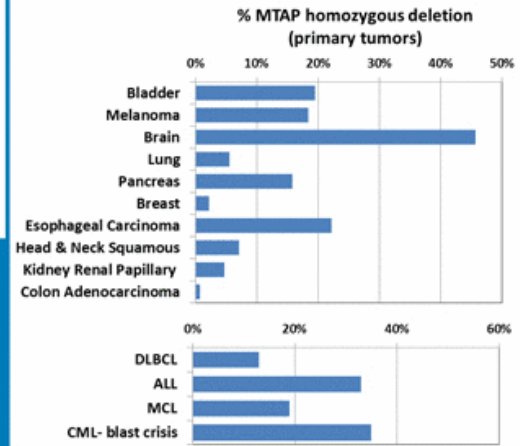
# Prevalent Deletions of MTAP Create Sensitivity to a Novel Pathway With Multiple Therapeutic Targets

## Deletion of metabolic gene adjacent to tumor suppressor p16/p14



- p16/p14 tumor suppressor locus deleted in 15% of all cancers
- Metabolic gene, MTAP, is adjacent to p16/p14 & typically co-deleted

## ~75,000 new patients/year in U.S. with MTAP deletion across many indications



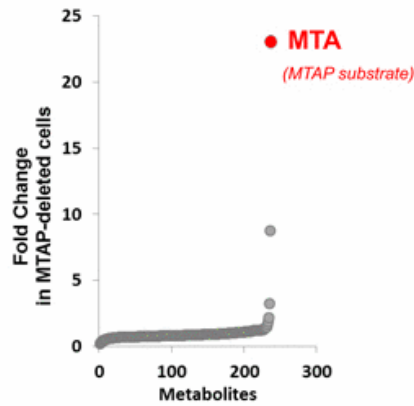
MTAP-deleted Tumors Constitute a Large, Genetically Defined Patient Population



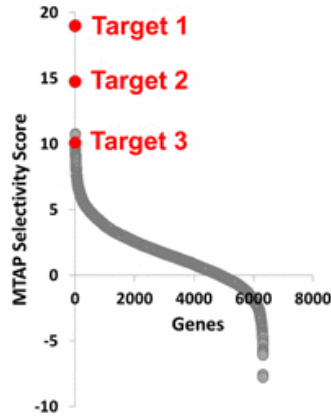


# Prevalent Deletions of MTAP Create Sensitivity to a Novel Pathway With Multiple Therapeutic Targets

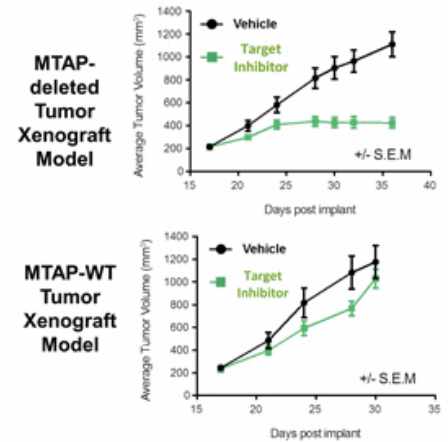
Upstream metabolite  
MTA accumulates  
when MTAP is deleted



Vulnerable pathway  
with multiple  
Therapeutic targets



Druggable by Agios inhibitors  
with precision medicine  
approach



## Key Takeaways

- Focus on Strategic Priorities and Execution:
  - Continue rapid, broad late-stage clinical development for our IDHm inhibitors
  - Demonstrate clinical activity of our wholly owned, PKR activators in patients
  - Advance research and initiate preclinical development of a new research program
- Building a great sustainable biopharmaceutical company
- Passionate in our vision to change patients' lives





### **AgiOS Outlines Key 2016 Goals and Priorities**

- Complete Enrollment of 125-Patient Expansion Cohorts for AG-221 and AG-120 in Relapsed/Refractory Acute Myeloid Leukemia in Second Half of 2016 -
- Present First Data from Phase 2 DRIVE PK Study for AG-348 in PK Deficiency and Phase 1 Healthy Volunteer Study for AG-519 in First Half of 2016 -
  - Initiate Preclinical Development of a Program from the Next Wave of Research -
  - Company to Present at the 34<sup>th</sup> Annual J.P. Morgan Healthcare Conference Today at 3:30 p.m. PST -

**SAN FRANCISCO, January 11, 2016** — Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the fields of cancer metabolism and rare genetic metabolic disorders, today outlined the company’s 2016 strategy and expected clinical development and research milestones in conjunction with the 34<sup>th</sup> Annual J.P. Morgan Healthcare Conference in San Francisco. The presentation will outline three strategic priorities for 2016: continue rapid and broad late-stage clinical development for its lead isocitrate dehydrogenase (IDH) mutant inhibitors in hematologic malignancies and solid tumors; demonstrate clinical activity of its wholly owned, global pyruvate kinase-R (PKR) activators in patients; and advance research and initiate preclinical development of a program from the next wave of research. The company will webcast its presentation on Monday, January 11, 2016 at 3:30 p.m. PST (6:30 p.m. EST) at [www.agios.com](http://www.agios.com).

“We expect each of our programs to achieve important catalysts in 2016 that will bring us closer to our vision of helping people with cancer and rare genetic disorders,” said David Schenkein, M.D., chief executive officer at Agios. “We believe these milestones, coupled with our growing late-stage development and commercial capabilities, set Agios firmly on the path to become a sustainable, multi-product biopharmaceutical company with a strong research core and broad pipeline of first-in-class medicines.”

#### **IDH Mutant Inhibitors**

Dr. Schenkein continued, “We remain focused on executing on our ‘speed and breadth’ clinical development strategy for AG-221 and AG-120 in hematological malignancies, with the intent to complete enrollment of both 125-patient expansion cohorts this year. Further understanding the potential of our IDH mutant inhibitors in solid tumors remains a priority with several new and ongoing trials in 2016.”

AG-221, AG-120 and AG-881 are part of Agios’ global strategic collaboration with Celgene Corporation.



*Expected 2016 milestones for IDH mutant inhibitors in hematologic malignancies:*

- Complete enrollment of both 125-patient expansion cohorts for the Phase 1/2 study of AG-221 and Phase 1 study of AG-120 in patients with relapsed/refractory (R/R) acute myeloid leukemia (AML) in the second half of 2016
- Initiate a global, registration-enabling Phase 3 study of AG-120 in frontline AML patients with an IDH1 mutation in the second half of 2016
- Initiate an expansion arm in high-risk myelodysplastic syndrome patients for AG-221 in 2016
- Initiate a Phase 1/2 frontline combination study of AG-221 or AG-120 with VIDAZA® (azacitidine) in newly diagnosed AML patients not eligible for intensive chemotherapy in the first quarter of 2016
- Continue to enroll patients in the following ongoing clinical trials:
  - Phase 3 IDHENTIFY study of AG-221 vs. standard of care chemotherapy in R/R AML
  - Phase 1b frontline combination study of AG-221 or AG-120 with standard-of-care intensive chemotherapy in AML
  - Phase 1 dose-escalation and expansion study of AG-881 in IDH mutant positive hematologic malignancies

*Expected 2016 milestones for IDH mutant inhibitors in solid tumors:*

- Initiate a randomized Phase 2 study of AG-120 in IDH1 mutant positive cholangiocarcinoma in the second half of 2016
- Continue to enroll patients in the following ongoing clinical trials:
  - Expansion phase of the ongoing Phase 1 study of AG-120 in advanced IDH1 mutant positive solid tumors
  - Phase 1 dose-escalation and expansion study of AG-881 in IDH mutant positive solid tumors

**PKR Activators**

“Having initiated dosing in the Phase 1 healthy volunteer study of AG-519, we’ve completed the first of several key clinical milestones expected from our PKR activators in the first half of this year,” said Dr. Schenkein. “Notably, we expect to present the first data from this study and the Phase 2 DRIVE PK study for AG-348 in PK deficiency patients. There are currently no approved or disease-modifying treatments for PK deficiency, which drives our focus on advancing potential new treatment options for these patients.”

*Milestone announced today:*

- Dosing was initiated in an integrated single ascending dose (SAD) and multiple ascending dose (MAD) placebo-controlled Phase 1 study of AG-519 in healthy volunteers



*Expected 2016 milestones for PKR activators:*

- Present the first data from DRIVE PK, a global Phase 2, open-label safety and efficacy trial of AG-348 in adult, transfusion-independent patients with PK deficiency in the first half of 2016
- Present data from Phase 1 study of AG-519 in healthy volunteers as well as preclinical findings about the molecule in the first half of 2016
- Outline the clinical development plans for Agios' PKR activators in beta-thalassemia in the second half of 2016
- Present new findings from the Natural History Study of PK deficiency being conducted with Boston Children's Hospital in the second half of 2016

**Research Programs**

"We continue to focus on discovering and validating first-in-class targets that meet our high bar for development and align with our precision medicine strategy," said Scott Biller, Ph.D., chief scientific officer at Agios. "We are excited to move the first program in our next wave of investigational medicines into preclinical development this year."

- Agios scientists have discovered a novel pathway comprised of multiple targets with a shared vulnerability in MTAP-deleted tumors and have demonstrated that this pathway can be modulated by small molecule inhibitors, resulting in robust anti-tumor activity in animal models
- MTAP (methylthioadenosine phosphorylase) is a metabolic enzyme that is deleted in approximately 15 percent of all cancers. This deletion is readily detected by a simple genomic test, thus allowing the selection of patients predicted to be sensitive to the therapy.

*Expected 2016 milestones for research:*

- Publish preclinical findings on a new cancer metabolism program
- Initiate preclinical development activities for the first molecule in the next wave of novel investigational medicines

**Presentation at 34<sup>th</sup> Annual J.P. Morgan Healthcare Conference**

Agios will webcast its corporate presentation from the 34<sup>th</sup> Annual J.P. Morgan Healthcare Conference in San Francisco on Monday, January 11, 2016 at 3:30 p.m. PST (6:30 p.m. EST). A live webcast of the presentation can be accessed under "Events & Presentations" in the Investors and Media section of the company's website at [agios.com](http://agios.com). A replay of the webcast will be archived on the Agios website for at least two weeks following the presentation.

**About Agios**

Agios is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic metabolic disorders 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](http://www.agios.com).

#### **About Agios/Celgene Collaboration**

AG-221, AG-120 and AG-881 are part of Agios' global strategic collaboration with Celgene Corporation. Under the terms of the collaboration, Celgene has worldwide development and commercialization rights for AG-221 (CC-90007). Agios continues to conduct clinical development activities within the AG-221 development program and is eligible to receive up to \$120 million in payments on achievement of certain milestones and royalties on net sales. For AG-120, Agios retains U.S. development and commercialization rights and Celgene retains development and commercialization rights outside the U.S. Celgene is eligible to receive royalties on net sales in the U.S. Agios is eligible to receive royalties on net sales outside the U.S. and up to \$120 million in payments on achievement of certain milestones. 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.

VIDAZA® is a registered trademark of Celgene Corporation.

#### **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 Agios' product candidates targeting IDH1/IDH2 or pyruvate kinase-R mutations or other genetic mutations, including AG-221, AG-120, AG-881, AG-348 and AG-519; its plans and timelines for the clinical development of AG-221, AG-120, AG-881, AG-348 and AG-519; its plans regarding future data presentations; and the benefit of its strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "potential," "hope," "could," "would" 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, 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 agreement 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' Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, and other filings that Agios may make with the Securities and Exchange Commission in the future. 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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