Celgene and Agios Announce Collaborations with Abbott for Diagnostic Identification of IDH Mutations in AML

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Companion diagnostic technology to be utilized with enasidenib (AG-221/CC-90007) and AG-120 development programs for relapsed/refractory acute myeloid leukemia (AML)

Approximately 20% of AML patients have an IDH mutation

SUMMIT, N.J. & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 12, 2016-- Celgene Corporation (NASDAQ:CELG) and Agios Pharmaceuticals, Inc. (NASDAQ:AGIO) today announced each company has entered into collaboration agreements with Abbott (NYSE: ABT), a leader in diagnostic technologies, to develop and commercialize companion diagnostic tests on Abbott's m2000 RealTi *m*e System to identify isocitrate dehydrogenase (IDH) mutations in acute myeloid leukemia (AML) patients. Celgene is currently developing enasidenib (AG-221/CC-90007), an IDH2 mutant inhibitor, for the treatment of patients with relapsed or refractory AML who have an IDH2 mutation. Agios is developing AG-120, an IDH1 mutant inhibitor, for the treatment of patients with relapsed or refractory AML who have an IDH1 mutation.

IDH1 and IDH2 mutations occur in approximately 20% of AML patients. An article published online this week in the journal *Leukemia* (Medeiros, Leukemia 2016) concluded that advances in the understanding of the genetics underlying myeloid malignancies are driving an era of development for targeted treatments such as IDH mutant inhibitors. The authors recommend that IDH mutational analysis should become part of the routine AML diagnostic workup and repeated at relapse to identify patients who may be eligible for targeted investigational treatments currently under clinical study.

"AML is a complex and heterogeneous disease, making it difficult to treat," said Han Myint, M.D., Vice President, Global Medical Affairs, Myeloid for Celgene. "IDH mutations lead to aberrant DNA methylation, causing a block in myeloid differentiation that leads to disease progression. Molecular profiling is important to identify genomic mutations which may have prognostic and potential treatment implications for patients with AML."

Abbott's m2000rt RealTi *m*e System, is a polymerase chain reaction (PCR) instrument designed to enable clinical laboratories to automate PCR and results analysis, simplifying the complex and manual steps often associated with molecular diagnostics. Both Celgene and Agios have incorporated this screening into clinical trial designs, including the recently initiated Phase 3 IDHENTIFY trial comparing enasidenib with conventional therapy in older patients with an IDH2 mutation and relapsed or refractory AML (NCT02577406).

"The field of personalized medicine is advancing at a rapid pace for a broad range of medical conditions, especially within hematology-oncology," said Chris Bowden, M.D., chief medical officer at Agios. "Our collaboration with Abbott will provide a test to help identify AML patients with IDH mutations who are in need of treatment options."

The m2000 system has not been FDA cleared or approved for use with enasidenib or AG-120.

Enasidenib and AG-120 have not been approved for any use in any country.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com. Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn, FaceBook and YouTube.

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.

Forward-Looking Statements

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. Neither Celgene nor Agios undertake any obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond each company's control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in the Annual Report on Form 10-K and other reports of each company filed with the Securities and Exchange Commission.

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