Agios Announces that Celgene Has Agreed to Exercise its Option to License AG-120 under Global Strategic Collaboration

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AG-120 would be the second investigational medicine licensed by Celgene and demonstrates strength and progress of cancer metabolism collaboration

CAMBRIDGE, Mass., Jan. 12, 2015 (GLOBE NEWSWIRE) -- Agios Pharmaceuticals, Inc. (Nasdaq:AGIO), a leader in the fields of cancer metabolism and rare genetic disorders of metabolism, today announced that its collaboration partner Celgene Corporation has agreed that it will exercise its option to obtain an exclusive license outside the United States for AG-120, a first-in-class, oral, potent inhibitor of the mutant IDH1 protein under the terms of the 2010 collaboration agreement. This would be the second IDH mutant inhibitor to be licensed by Celgene in less than a year. AG-120 is currently being evaluated in two Phase 1 dose escalation trials, one in advanced hematologic malignancies and the other in advanced solid tumors. Both trials are evaluating AG-120 in patients whose cancer harbors an IDH1 mutation. The first data from the AG-120 program were presented at the EORTC-NCI-AACR Symposium on November 19, 2014 in advanced hematologic malignancies. Agios expects to report the first data from the Phase 1 advanced solid tumor trial at a medical conference in 2015. Celgene's exercise of the option is subject to receipt of any required regulatory approvals including any applicable clearance under the Hart-Scott-Rodino Act. Agios is webcasting its corporate presentation from the 33rd Annual J.P. Morgan Healthcare Conference today at 2:30 p.m. PST (5:30 p.m. EST). The presentation will be followed by a webcast of its question and answer session at 3:00 p.m. PST (6:00 p.m. EST).

"Celgene's continued support of our investigational cancer medicines is of great importance to us, and we are pleased that they have agreed to license ex-U.S. rights to AG-120 while we retain full U.S. development and commercialization rights," said David Schenkein, M.D., chief executive officer of Agios. "We believe their decision demonstrates the potential opportunity of AG-120 and continues to validate our cancer metabolism platform and precision medicine approach to drug development. The combined development and commercial expertise of Agios and Celgene would allow us to expedite development of AG-120, and make this medicine available as soon as possible to patients globally."

"Licensing AG-120 would strengthen our collaboration with Agios and our commitment to innovative therapeutics in cancer metabolism," said Thomas Daniel, M.D., president of research & early development at Celgene. "The progress with AG-120 reinforces the value of Celgene's collaboration strategy with early stage companies pursuing potentially disruptive therapeutic research in emerging high potential areas."

Agios and Celgene entered into a global strategic collaboration in April 2010 to develop new therapeutics targeting cancer metabolism. By exercising its exclusive option under the terms of the agreement, Celgene would lead development and commercialization outside the United States for AG-120, and Agios and Celgene would equally fund the global development costs of AG-120 that are not specific to any particular region or country. Celgene would be responsible for development and commercialization costs specific to countries outside the United States, and Agios would be responsible for development and commercialization costs specific to the United States.Celgene would be eligible to receive royalties on any net sales in the U.S. Agios would be eligible to receive royalties on any net sales outside the U.S. and up to $120 million in payments on achievement of certain milestones.

About Agios Pharmaceuticals, Inc.

Agios Pharmaceuticals is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic disorders of metabolism 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 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 Agios' drug candidates targeting IDH1 and IDH2 mutations, including AG-120; the expected timing of data from the Phase 1 solid tumor trial of AG-120; Celgene's exercise of its license option, which is subject to receipt of any applicable required regulatory approvals; the potential benefits of the collaboration between Agios and Celgene, the related potential development opportunity for AG-120, and expected royalty and milestone payments under the collaboration; and the benefit of Agios' strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "potential," "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; 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, 2014, 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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