Agios Announces FDA Fast Track Designation Granted to AG-120 for Treatment of Patients with Acute Myelogenous Leukemia with an IDH1 Mutation

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CAMBRIDGE, Mass., May 18, 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to AG-120 for the treatment of patients with acute myelogenous leukemia (AML) who harbor an isocitrate dehydrogenase-1 (IDH1) mutation. AG-120 is a first-in-class, oral, selective, potent inhibitor of the mutated IDH1 protein being evaluated in two Phase 1 clinical trials, one in hematologic malignancies that recently initiated three expansion cohorts, and one in advanced solid tumors, including glioma.

"We are pleased that now both AG-120 and AG-221 have been granted Fast Track designation, demonstrating the FDA's commitment to facilitate the development and expedite the review of our lead IDH programs as important new therapies for people with AML who carry these mutations," said Chris Bowden, M.D., chief medical officer of Agios. "We look forward to presenting new data from the ongoing Phase 1 study at the EHA Annual Congress next month and remain on track to initiate a global, registration-enabling Phase 3 study in collaboration with Celgene in AML patients who harbor an IDH1 mutation in the first half of 2016."

The FDA's Fast Track Drug Development Program is designed to expedite clinical development and submission of New Drug Applications (NDA) for medicines with the potential to treat serious or life-threatening conditions and address unmet medical needs. Specifically, Fast Track designation facilitates frequent interactions with the FDA review team, including meetings to discuss all aspects of development to support approval, and also provides the opportunity to submit sections of an NDA on a rolling basis as data become available.

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' product candidates targeting IDH1/IDH2, including AG-221 and AG-120; its plans and timelines for the clinical development of AG-120; its plans regarding future data presentations for AG-120; and the benefit of its strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "potential," "possible," "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 March 31, 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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