



AgiOS Announces FDA Clearance of Investigational New Drug Application for AG-946, a Next-Generation PKR Activator

March 23, 2020

– Phase 1 Healthy Volunteers Study Expected to Begin in Mid-Year 2020 –

CAMBRIDGE, Mass., March 23, 2020 (GLOBE NEWSWIRE) -- Agios Pharmaceuticals, Inc. (NASDAQ: AGIO) today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's investigational new drug (IND) application for AG-946, a next-generation pyruvate kinase-R (PKR) activator. FDA has completed its 30-day safety review and granted approval to proceed with the proposed Phase 1 healthy volunteers study.

"As our eighth IND in just 10 years, AG-946 demonstrates the consistent productivity of our research engine and our leadership in the understanding of PKR activation," said Bruce Car, Ph.D., chief scientific officer at Agios. "By advancing AG-946 into the clinic, we have the opportunity to expand our PKR activation program and build on the expertise we established with our lead PKR activator, mitapivat, across a range of hemolytic anemias."

AgiOS expects to initiate the AG-946 Phase 1 study in mid-year 2020. The company continues to monitor the potential impact of the COVID-19 pandemic on clinical trial initiations and will provide additional updates as needed.

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 Agios' plans, strategies and expectations for the clinical development of its AG-946 program. The words "expect," "opportunity" 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, 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, market and global health 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.

Contacts

Investors:

Holly Manning, 617-844-6630
Director, Investor Relations
Holly.Manning@agios.com

Media:

Jessica Rennekamp, 857-209-3286
Associate Director, Corporate Communications
Jessica.Rennekamp@agios.com



Source: Agios Pharmaceuticals, Inc.