Agios to Receive $1.1 Billion in Milestone Payments Following FDA Approval of Vorasidenib

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– Agios Expects to Receive $905 Million Payment from Royalty Pharma and $200 Million Payment from Servier in Q3 2024; Payments Increase Agios' Pro-Forma Cash Position as of June 30, 2024, to $1.7 Billion –

– Strong Cash Position to Enable Agios to Prepare for Potential PYRUKYND® (Mitapivat) Launches in Thalassemia in 2025 and Sickle Cell Disease in 2026 and Drive Pipeline Progress –

CAMBRIDGE, Mass., Aug. 06, 2024 (GLOBE NEWSWIRE) -- Agios Pharmaceuticals, Inc. (Nasdaq: AGIO), a leader in cellular metabolism and pyruvate kinase (PK) activation pioneering therapies for rare diseases, today announced that the Company will receive a total of $1.1 billion in milestone payments following the U.S. Food and Drug Administration (FDA) approval of vorasidenib for adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery, including biopsy, sub-total resection or gross total resection. These payments include a $905 million payment from Royalty Pharma in connection with the vorasidenib royalty purchase agreement Agios announced in May 2024 and a $200 million payment from Servier in connection with Agios' divestiture of its oncology business in 2021.

"Today's FDA approval of vorasidenib is the first approval for a Grade 2 glioma in over 20 years and highlights both the executional excellence of the Servier team and Agios' expertise in discovering novel therapies for disease areas of high unmet need," said Cecilia Jones, chief financial officer at Agios. "The $1.1 billion in milestone payments triggered by today's approval further strengthens our cash position, which we expect will provide us with the financial independence to prepare for potential PYRUKYND® (mitapivat) launches in thalassemia in 2025 and sickle cell disease in 2026, as well as drive pipeline progress as we aim to build a multi-billion-dollar franchise."

Agios completed the sale of its oncology business to Servier on March 31, 2021. Under the terms of the agreement, Agios received $1.8 billion in upfront cash, an additional $200 million milestone payment upon FDA approval of vorasidenib, and 15% royalties on potential U.S. net sales of vorasidenib from the first commercial sale through loss of exclusivity. Agios had also retained rights to 5% royalties on U.S. net sales of Servier's TIBSOVO® (ivosidenib tablets), which it sold for a one-time payment of $131.8 million in 2022.

On May 28, 2024, Agios announced that the company agreed to sell its rights to its 15% royalty on potential U.S. net sales of vorasidenib to Royalty Pharma. Under the terms of the agreement, Agios receives an upfront payment of $905 million upon FDA approval of vorasidenib, and Royalty Pharma will receive the entirety of the 15% royalty on annual U.S. net sales of vorasidenib up to $1 billion and a 12% royalty on annual U.S. net sales greater than $1 billion. Agios will retain a 3% royalty on annual U.S. net sales greater than $1 billion.

About Agios

Agios is the pioneering leader in PK activation and is dedicated to developing and delivering transformative therapies for patients living with rare diseases. In the U.S., Agios markets a first-in-class pyruvate kinase (PK) activator for adults with PK deficiency, the first disease-modifying therapy for this rare, lifelong, debilitating hemolytic anemia. Building on the company's deep scientific expertise in classical hematology and leadership in the field of cellular metabolism and rare hematologic diseases, Agios is advancing a robust clinical pipeline of investigational medicines with programs in alpha- and beta-thalassemia, sickle cell disease, pediatric PK deficiency, MDS-associated anemia and phenylketonuria (PKU). In addition to its clinical pipeline, Agios is advancing a preclinical TMPRSS6 siRNA as a potential treatment for polycythemia vera. For more information, please visit the company's website at www.agios.com.

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