



CENTOGENE and Agios Expand Partnership for Clinical Development of PYRUKYND® (mitapivat) to Treat Children With Rare Blood Disease

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Working together on the world's first treatment that targets the underlying causes of pyruvate kinase ("PK") deficiency in children under the age of 18

- Expanded collaboration to include Phase 3 ACTIVATE-kids and ACTIVATE-kidsT studies
- CENTOGENE's genetic testing and Biodatabank identify causative mutations, including the UGT1A1 and PKLR genes, and supports precise diagnosis

CAMBRIDGE, Mass. and ROSTOCK, Germany and BERLIN, June 13, 2022 (GLOBE NEWSWIRE) -- Centogene N.V. (Nasdaq: CNTG), the commercial-stage essential biodata life science partner for rare and neurodegenerative diseases, today announced that it has expanded its long-standing PYRUKYND® (mitapivat) partnership with Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the field of cellular metabolism pioneering therapies for genetically defined diseases.

Agios' PYRUKYND® is a first-in-class, selective, small molecule activator of the pyruvate kinase (PK) enzyme. In February 2022, Agios received approval from the U.S. Food and Drug Administration (FDA) for PYRUKYND® for the treatment of hemolytic anemia in adults with PK deficiency, which represents the first and only approved disease-modifying treatment for this rare blood disorder. Since 2015, CENTOGENE has provided genetic testing services to Agios for the clinical development of PYRUKYND®.

The expanded agreement will now see CENTOGENE provide centralized lab support for Agios' two global, pivotal Phase 3 trials, ACTIVATE-kids and ACTIVATE-kidsT, which are being conducted to evaluate the efficacy and safety of mitapivat in children with PK deficiency between the ages of 1 to 17. CENTOGENE will continue to provide genetic testing to help identify causative mutations, including the UGT1A1 and PKLR genes, in study participants. The aim of the Phase 3 ACTIVATE-kids and ACTIVATE-kidsT studies is to test the efficacy of PYRUKYND® in pediatric patients with PK deficiency who do not receive regular transfusions and those who do receive regular transfusions, respectively. Agios will be coordinating and bearing the costs for the programs; other financial details were not disclosed.

"Our successful collaboration with Agios has already helped drive incredible clinical progress for this first-in-class PK activator as a potential therapy for children with pyruvate kinase deficiency, an under-served patient community urgently in need of treatment options. The expansion of our partnership confirms our ability to help advance novel treatment options that are able to influence health outcomes for patients globally," said Kim Stratton, CEO of CENTOGENE. "With our unparalleled diagnostic services and insights powered by the CENTOGENE Biodatabank, the world's largest real-world data repository for rare and neurodegenerative diseases, we offer the essential biodata that is often so critical in clinical development for our biotech and pharma partners."

Sarah Gheuens, M.D., Ph.D., Chief Medical Officer at Agios, said, "As we forge ahead with our global, pivotal trials in pediatric pyruvate kinase deficiency, we are pleased to expand our partnership with CENTOGENE to bring the first potential treatment for these patients one step closer to making an impact in the lives of these children and their families. At Agios, we know that great science requires world-class collaboration. Accelerating and streamlining our clinical trials is critical for bringing new innovations to patients as efficiently as possible, and CENTOGENE's solutions make them a great partner for this project."

Within the partnership, CENTOGENE's proprietary CentoCard® dried blood spot technology provides easy logistics for central diagnostic testing. Key assets to the partnership include the CENTOGENE Biodatabank, diagnostic expertise built on over 15 years of experience, and the Company's multiomic-based platform, which is pioneering access to commercial multiomic products on the market today.

In 2015, CENTOGENE originally entered into an agreement with Agios to provide support for Agios' PK deficiency clinical program. Last year, the contract was expanded to focus on additional trial support in thalassemia and sickle cell disease.

About PYRUKYND® (mitapivat)

PYRUKYND® is a pyruvate kinase activator indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency. In February 2022, Agios received approval from the U.S. Food and Drug Administration (FDA) for PYRUKYND® for the treatment of hemolytic anemia in adults with PK deficiency, which represents the first and only approved disease-modifying treatment for adults with this rare blood disorder. It has also received a waiver from the European Medicines Agency (EMA) in accordance with a Pediatric Investigation Plan (PIP) for the treatment of PK deficiency in the pediatric population from birth to less than 1 year of age.

About PK Deficiency

Pyruvate kinase (PK) deficiency is a rare, inherited disease that presents as chronic hemolytic anemia, which is the accelerated destruction of red blood cells. The inherited mutations in the PKLR gene cause a deficit in cellular energy within the red blood cell, as evidenced by lower PKR enzyme activity, a decline in adenosine triphosphate (ATP) levels, and a build-up of upstream metabolites, including 2,3-DPG (2,3-diphosphoglycerate).

PK deficiency affects approximately 3,000-8,000 people in the U.S. and EU5. PK deficiency may result in serious complications, such as pulmonary hypertension, extramedullary hematopoiesis, and osteoporosis.

To learn more about the ACTIVATE-kids and ACTIVATE-kidsT clinical trials, please visit: <https://www.agios.com/patients-partners/patients-caregivers/clinical-trials/>

About Agios

Agios is a biopharmaceutical company that is fueled by connections. The Agios team cultivates strong bonds with patient communities, healthcare professionals, partners and colleagues to discover, develop and deliver therapies for genetically defined 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 leadership in the field of cellular metabolism, Agios is advancing a robust clinical pipeline of investigational medicines with active and planned programs in alpha- and beta-thalassemia, sickle cell disease, pediatric PK deficiency and MDS-associated anemia. In addition to its clinical pipeline, Agios has multiple investigational therapies in preclinical development and an industry-leading research team with unmatched expertise in cellular metabolism and genetics. For more information, please visit the company's website at www.agios.com.

About CENTOGENE

CENTOGENE engages in diagnosis and research around rare diseases transforming real-world clinical, genetic, and multiomic data to diagnose, understand, and treat rare diseases. Our goal is to bring rationality to treatment decisions and to accelerate the development of new orphan drugs by using our extensive rare disease knowledge and data. CENTOGENE has developed a global proprietary rare disease platform based on our real-world data repository of over 650,000 individuals representing over 120 different countries.

The Company's platform includes epidemiologic, phenotypic, and genetic data that reflects a global population, as well as a biobank of patients' blood samples and cell cultures. CENTOGENE believes this represents the only platform focused on comprehensive analysis of multi-level data to improve the understanding of rare hereditary diseases. It allows for better identification and stratification of patients and their underlying diseases to enable and accelerate discovery, development, and access to orphan drugs. As of December 31, 2021, the Company collaborated with over 30 pharmaceutical partners.

For more information, visit www.centogene.com and follow us on [LinkedIn](#).

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the U.S. federal securities laws. Statements contained herein that are not clearly historical in nature are forward-looking, and the words "anticipate," "believe," "continues," "expect," "estimate," "intend," "project," and similar expressions and future or conditional verbs such as "will," "would," "should," "could," "might," "can," and "may," are generally intended to identify forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause CENTOGENE's actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, negative economic and geopolitical conditions and instability and volatility in the worldwide financial markets, possible changes in current and proposed legislation, regulations and governmental policies, pressures from increasing competition and consolidation in our industry, the expense and uncertainty of regulatory approval, including from the U.S. Food and Drug Administration, our reliance on third parties and collaboration partners, including our ability to manage growth and enter into new client relationships, our dependency on the rare disease industry, our ability to manage international expansion, our reliance on key personnel, our reliance on intellectual property protection, fluctuations of our operating results due to the effect of exchange rates, our ability to streamline cash usage, our requirement for additional financing, or other factors. For further information on the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to CENTOGENE's business in general, see CENTOGENE's risk factors set forth in CENTOGENE's Form 20-F filed on March 30, 2022, with the Securities and Exchange Commission (the "SEC") and subsequent filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and CENTOGENE's specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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