CENTOGENE Expands Partnership With Agios to Generate Novel Insights Into Rare Blood Diseases

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Providing Global Clinical Trial Support for Thalassemia and Sickle Cell Disease Will Deepen Understanding of Disease Characterization in the Search for a Treatment

CAMBRIDGE, Mass., ROSTOCK, Germany and BERLIN, Nov. 04, 2021 (GLOBE NEWSWIRE) -- Centogene N.V. (Nasdaq: CNTG), a commercial-stage company focused on generating data-driven insights to diagnose, understand, and treat rare diseases, announced today that it has expanded its partnership with Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the field of cellular metabolism developing and delivering innovative treatments for genetically defined diseases. Under the terms of the new agreement, CENTOGENE will provide genetic testing and clinical trial support for Agios' three global, pivotal trials in thalassemia and sickle cell disease. Under a previous agreement, CENTOGENE provided support for Agios' pyruvate kinase ("PK") deficiency clinical program.

The Companies signed a commercial three-year fee-for-service agreement. Agios will be coordinating and bearing the costs for the programs; further financial details were not disclosed. This collaboration will offer patients access to genetic testing to help identify causative mutations, including *HBA1*, *HBA2*, and *HBB* genes. Agios' global clinical trials will enroll patients in North America, Europe, MENA, APAC, and LATAM. Samples will be collected using CENTOGENE's proprietary CentoCard® for dried blood spot analysis.

A key asset to the partnership is CENTOGENE's unique rare disease-centric Bio/Databank, which is positioned to accelerate precise diagnosis and continue to build novel insights into the genetic factors causing rare diseases.

"With our globally leading Bio/Databank of rare diseases, we are the partner of choice in discovery and development of rare disease treatments. Our data-driven insights enable both acceleration and de-risking of clinical trials," said Andrin Oswald, M.D., Chief Executive Officer at CENTOGENE. "Combining both CENTOGENE's expertise in genetics and unique global insights will lead to a better understanding of the disease biology of those rare diseases. This partnership will support the advancement of Agios' first-in-class PK activator as a potential therapy for thalassemia and sickle cell disease, two under-served patient communities in need of new treatment options."

"As we look ahead to initiating three global, pivotal trials in thalassemia and sickle cell disease by the end of the year, we are pleased to expand our partnership with CENTOGENE to better understand the underlying genetics of patients in our studies and the potential impact of our investigational medicine," said Sarah Gheuens, M.D., Ph.D., Chief Medical Officer at Agios. "At Agios, we know that great science requires world-class teamwork. By working with outstanding partners like CENTOGENE, we can together accelerate innovations that make a positive difference in patients' lives."

This agreement represents another significant milestone for CENTOGENE's mission to enable the cure of 100 rare diseases within the next 10 years. To learn more, visit: https://www.centogene.com/virtual-investor-event

About Thalassemia

Thalassemia is an inherited blood disorder, affecting approximately 18,000-23,000 people in the U.S. and France, Germany, Italy, Spain, and the United Kingdom ("EU5"), with many more in other parts of the world. The inherited mutations in hemoglobin genes cause the body to produce less hemoglobin than normal, which is essential in enabling red blood cells to carry oxygen, resulting in severe anemia and related complications.

There are two types of thalassemia, beta and alpha. Both present in an autosomal recessive manner, and approximately 5% of the global population has a mutation in the beta or alpha globin genes. Some patients require chronic transfusions which can be associated with long-term complications such as iron overload and associated organ damage. In patients who do not require chronic transfusions, serious complications can also occur, including pulmonary hypertension and thrombosis.

There have been recent therapeutic advances for beta-thalassemia; however, unmet needs remain, and further disease understandings and additional treatment options are needed. There are no approved treatments for alpha-thalassemia.

About Sickle Cell Disease

Sickle cell disease is an inherited red blood cell disorder, with approximately 120,000-135,000 people in the U.S. and EU5 affected, with many more in other parts of the world. Sickle cell disease is caused by the presence of a mutated form of hemoglobin, which blocks off blood vessels. As a result, blood is unable to properly flow, which can lead to severe pain and organ damage.

Sickle cell disease is associated with serious complications, including infection, acute chest syndrome and stroke, and can result in shortened life expectancy. Thanks to recent advances in research and clinical progress, there are treatment options available today; however, patients continue to suffer from acute and chronic pain as well as serious complications, and further therapeutic advances are needed.

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.

There are currently no approved disease-modifying therapies for PK Deficiency.
To learn more about ongoing clinical trials, please visit: https://www.agios.com/patients-caregivers/clinical-trials/

About Agios

Agios is focused on discovering and developing novel investigational medicines to treat genetically defined diseases through scientific leadership in the field of cellular metabolism. The company's most advanced drug candidate is a first-in-class pyruvate kinase R (PKR) activator, mitapivat, that is currently being evaluated for the treatment of three distinct hemolytic anemias. In addition to its active late-stage clinical pipeline, Agios has multiple novel, investigational therapies in clinical and preclinical development. 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 with over 3.9 billion weighted data points from approximately 600,000 patients 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, 2020, the Company collaborated with over 30 pharmaceutical partners.

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Forward-Looking Statement

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 worldwide economic conditions and ongoing instability and volatility in the worldwide financial markets, the effects of the COVID-19 pandemic on our business and results of operations, 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, 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 April 15, 2021, 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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