CENTOGENE Receives FDA Emergency Use Authorization for SARS-CoV-2 RT-PCR Assay for Individuals Without Symptoms or Other Reasons to Suspect COVID-19

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CAMBRIDGE, Mass. and ROSTOCK, Germany and BERLIN, Oct. 19, 2020 (GLOBE NEWSWIRE) -- Centogene N.V. (Nasdaq: CNTG), a commercial-stage company focused on rare diseases that transforms real-world clinical and genetic data into actionable information for patients, physicians, and pharmaceutical companies, today announced that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for 'CentoSure', the company's latest SARS-CoV-2 RT-PCR test. The EUA permits the usage of this test for individuals without any symptoms or suspicion of COVID-19 – supporting widespread testing for the global population.

Prof. Arndt Rolfs, CEO of CENTOGENE, said, "This emergency use authorization by the FDA is an extremely important further step to prevent a further spread of COVID-19, specifically in countries that have been heavily impacted, like the U.S. Our experiences to date show that infected people do not always develop symptoms or are unknowingly spreading the virus days before they start to feel sick. Broad preventative testing is the best way to detect SARS-CoV-2 infections and successfully preventing the next wave of infections to effectively fight the COVID-19 pandemic. We are proud to be able to support the global community by providing the best possible molecular diagnostic test available."

"We are excited to have been granted this emergency use authorization by the FDA – further validating our commitment to quality, precision, and reliability amid this global fight against the novel coronavirus," added Dr. Florian Vogel, Senior Vice President Clinical Lab Operations of CENTOGENE.

About CENTOGENE's CentoSure SARS-CoV-2 RT-PCR Assay
CENTOGENE'S CentoSure SARS-CoV-2 RT-PCR assay is a real-time test based on the reverse transcription polymerase chain reaction (RT-PCR) for the qualitative detection of SARS-CoV-2, the underlying virus causing COVID-19. This is a mutliplex test for two viral targets and a human gene, as extraction control for every sample.

The test has also been validated in CENTOGENE's CAP / CLIA / ISO certified analytical laboratory and has received Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA) for use by authorized laboratories. It is intended to be used with samples of the upper respiratory tract (oropharyngeal swabs) collected from individuals without symptoms or other reasons to suspect COVID-19. Once a sample has been collected, it is brought to a CENTOGENE laboratory for testing. Test results are delivered via CENTOGENE's Corona Test Portal – a secure digital platform following stringent data privacy measures and Health Insurance Portability and Accountability Act (HIPAA).

About CENTOGENE
CENTOGENE engages in diagnosis and research around rare diseases transforming real-world clinical and genetic data into actionable information for patients, physicians, and pharmaceutical companies. 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, including epidemiological and clinical data, as well as innovative biomarkers. CENTOGENE has developed a global proprietary rare disease platform based on our real-world data repository with over 3.6 billion weighted data points from approximately 570,000 patients representing over 120 different countries as of August 31, 2020.

The Company's platform includes epidemiologic, phenotypic, and genetic data that reflects a global population, and also a biobank of these patients' blood samples. CENTOGENE believes this represents the only platform that comprehensively analyzes multi-level data to improve the understanding of rare hereditary diseases, which can aid in the identification of patients and improve our pharmaceutical partners' ability to bring orphan drugs to the market. As of August 31, 2020, the Company collaborated with over 40 pharmaceutical partners covering over 45 different rare diseases.

Important Notice and Disclaimer
This press release contains statements that constitute "forward looking statements" as that term is defined in the United States Private Securities Litigation Reform Act of 1995, including statements that express the Company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results, in contrast with statements that reflect historical facts. Examples include discussion of our strategies, financing plans, growth opportunities and market growth. In some cases, you can identify such forward-looking statements by terminology such as "anticipate," "intend," "believe," "estimate," "plan," "seek," "project" or "expect," "may," "will," "would," "could" or "should," the negative of these terms or similar expressions. Forward looking statements are based on management's current beliefs and assumptions and on information currently available to the Company. However, these forward-looking statements are not a guarantee of our performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks, uncertainties and other variable circumstances, such as 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 govern-mental 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. Such risks and uncertainties may cause the statements to be inaccurate and readers are cautioned not to place undue reliance on such statements. Many of these risks are outside of the Company's control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this press release are made only as of the date hereof. The Company does not undertake, and specifically declines, any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments, except as required by law.

For further information, please refer to the Risk Factors section in our Annual Report for the year ended December 31, 2019 on Form 20-F filed with the SEC on April 23, 2020, Form 6-K containing our financial results for the three months ended March 31, 2020, filed with the SEC on June 15, 2020 and other current reports and documents filed with the U.S. Securities and Exchange Commission (SEC). You may get these documents by visiting EDGAR on the SEC website at www.sec.gov.

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