CENTOGENE Receives FDA Emergency Use Authorization for COVID-19 Molecular Diagnostic Test

July 2, 2020

CAMBRIDGE, Mass. and ROSTOCK, Germany and BERLIN, July 02, 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 the company's SARS-CoV-2 RT-PCR test.

Prof. Arndt Rolfs, CEO of CENTOGENE, said, “Over the past several months, we have been working tirelessly to ensure that we provide the best possible molecular diagnostic testing to prevent the further outbreak of COVID-19 and support the return to a new normal. This authorization by the FDA is another milestone for our COVID-19 testing efforts that validates the quality, precision and reliability of our tests.”

“CENTOGENE is proud to have received this accelerated authorization from the FDA, which recognizes our continued commitment to the highest quality standards amid this global pandemic,” said Ellen Karges, SVP Regulatory Compliance & Quality Management. “Molecular testing is vital in diagnosing patients as early as possible, and we are confident that our test will support a successful fight against this novel outbreak especially in collaboration with our pharmaceutical partners, educational organizations and airports.”

About CENTOGENE’s SARS-CoV-2 RT-PCR Test

CENTOGENE’S SARS-CoV-2 RT-PCR test 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. It is intended to be used with samples of the upper respiratory tract (oropharyngeal swabs) collected from individuals suspected by their healthcare provider to have COVID-19, belonging to a risk cohort, or having been in contact with a confirmed COVID-19 patient.

The test is intended for use by qualified laboratory personnel to be performed in CENTOGENE’s CLIA certified high-complexity laboratories in Germany.

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 approximately 2.5 billion weighted data points from approximately 500,000 patients representing over 120 different countries as of December 31, 2019.

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 December 31, 2019, the Company collaborated with over 39 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 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. 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 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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