CENT GENE

Collaboration Between CENTOGENE and U-Diagnostics Increases COVID-19 Testing Capacities in the Netherlands

October 14, 2020

CAMBRIDGE, Mass. and ROSTOCK, Germany and BERLIN and BAARN, the Netherlands, Oct. 14, 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, and U-Diagnostics B.V., a Dutch medical laboratory, specialized in analysis in the field of clinical chemistry and hematology, medical microbiology, medical immunology, and pathological diagnostics, today announced that they have joined forces to provide increased COVID-19 testing to communities throughout the Netherlands. This partnership comes as the Netherlands is currently facing a shortage of testing capacities among the rapidly increasing number of infections. Both companies see this as part of their commitment to provide easily accessible testing solutions – underlining the importance of cross-border collaboration and innovation to keep communities and economies healthy.

As part of the agreement, U-Diagnostics, who has been offering coronavirus testing at a laboratory in the Netherlands since March 2020, has teamed up with CENTOGENE, a major provider of COVID-19 testing in Germany, to provide increased testing services throughout the Netherlands. CENTOGENE will assist in providing CentoSwabTM, its CE-labelled, two-component dry plastic swab for oropharyngeal swabbing, followed by reverse transcription polymerase chain reaction (RT-PCR) analyses of the samples in any of CENTOGENE's laboratories. By working together to leverage already existing technologies and workflows, the companies hope to greatly support the Netherlands in its testing efforts.

Prof. Arndt Rolfs, CEO of CENTOGENE, said, "We are truly committed to helping fight the novel coronavirus in the Netherlands. By working together with U-Diagnostics, we are confident of containing COVID-19 and preventing a further of the pandemic. It is only with such collaboration and willingness to think outside the box that we can really have a chance of fighting this pandemic."

In a joint statement, Maarten Cuppen, CEO of U-Diagnostics, and Dr. Albert Zwart, founder and CMO of U-Diagnostics, said, "With the significant expansion of available tests that we will be able to provide in the Netherlands and the sharing of our expertise, we will be able to make a substantial contribution to preventing further outbreaks and keeping our economy and communities running."

A Collaborative Testing Solution

CENTOGENE is dedicated to working together to provide quality testing to the global community. The test detects an infection of SARS-CoV-2 by detecting specific RNA molecules that originate from the genome of the disease-causing coronavirus. The diagnostic procedure includes: RNA extraction, transcription of the RNA into complementary DNA (cDNA) by means of reverse transcription, and amplification (multiplication) of virus-specific cDNA by means of polymerase chain reaction (PCR). The presence of cDNA in the amplification product shows that virus particles were in the sample, and thus indicates an active infection with SARS-CoV-2.

The method used is based on the published method by Prof. Drosten (Charité, Berlin). This test is referred to in the WHO documents as the "WHO Charité" test. The analytical steps and in particular the target sequences used to detect the viral RNA by RT-PCR correspond exactly with that of Corman et al. (2020; <u>PMID</u>: <u>31992387</u>), and were validated in interlaboratory tests, as well as in cooperation with the laboratory by Prof. Drosten. The test has also been validated in CENTOGENE's CAP / CLIA / ISO 15189 certified analytical laboratory and has received Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA) for use by authorized laboratories.

The samples, which are collected via U-Diagnostics or their partners, are collected using CentoSwab[™], CENTOGENE's CE-labelled two-component dry plastic swab for oropharyngeal swab sampling. A recent study by Beetz and Skrahina et al. (2020; <u>PMID: 32650631</u>) underlined that oropharyngeal swabs, including those collected by individuals themselves, to detect SARS-CoV-2 is an appropriate alternative to one performed by a healthcare professional or nasopharyngeal swabs. With oropharyngeal swabs, a sample can be collected and received results within hours – combining validated medical tools with peace of mind as we work to keep communities and economies open. The samples are then brought to a CENTOGENE laboratory for analyses, and results are returned to U-Diagnostics, who deliver the COVID-19 test reports to patients directly.

About U-Diagnostics

Founded in 1999 by Dr. Albert Zwart on request of the University Medical Center Utrecht as part of the Laboratory Center of the UMC Utrecht, U-Diagnostics is an innovative medical laboratory, specialized in analysis in the fields of clinical trials, clinical chemistry and hematology, medical microbiology, medical immunology, and pathological diagnostics.

U-Diagnostics performs laboratory analyzes for general practitioners, occupational health and safety services, health centers, government agencies, laboratories, and companies.

Thanks to an intricate network and the deployment of our company-run courier service, our U-Diagnostics offerings are available nationwide. U-Diagnostics is committed at all times to ensure that physicians maintain complete control over their practice and patient care.

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 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, 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 <u>www.sec.gov</u>.

Media Contact: CENTOGENE Ben Legg Corporate Communications press@centogene.com U-Diagnostics Maarten J.M. Cuppen Chief Executive Officer m.cuppen@u-diagnostics.com FTI Consulting Bridie Lawlor +1.917.929.5684 bridie.lawlor@fticonsulting.com