Fujirebio Europe and CENTOGENE Enter Partnership to Provide Rapid and High-Quality Preventive SARS-CoV-2 Antigen Testing

November 9, 2020

GENT, Belgium and CAMBRIDGE, Mass. and ROSTOCK, Germany and BERLIN, Nov. 09, 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 Fujirebio Europe announced today to have entered a partnership to leverage LUMIPULSE® G technology for large-scale COVID-19 antigen testing with further deployment in German airports.

As part of the agreement, Fujirebio will provide a steady supply of Lumipulse G SARS-CoV-2 Ag assays running on fully automated CLEIA-based LUMIPULSE G1200 instruments. Sample collection is to be performed by CENTOGENE via the usual oropharyngeal swabs, with the analysis of the samples performed at CENTOGENE test laboratories, and the LUMIPULSE G1200 then supporting by delivering high quality results in up to only 40 minutes from sample receipt in the laboratory. These instruments will be an integrated part of the existing sophisticated automated CENTOGENE workflow that ensures fast and direct delivery of results to customers on their smartphones or digital devices.

“We are very pleased that CENTOGENE has chosen Fujirebio and the Lumipulse G platform to step up their current RT-PCR based COVID-19 testing,” says Christiaan De Wilde, CEO of Fujirebio Europe. “We are certain that the speed, high sensitivity and high quality of the Lumipulse G SARS-CoV-2 Ag testing solution combined with the flexibility of our platform to fit in the existing CENTOGENE workflow will ensure a trustworthy and efficient testing offer.”

Dr. Volkmar Weckesser, Chief Information Officer at CENTOGENE, stated, “Over the past months, we have seen an increasing need for easily accessible, reliable, and rapid coronavirus tests. We have been able to establish a blueprint for this - having set up test centers at four of Germany’s largest airports in the last six months. We are very excited to now expand on these services with the support of Fujirebio’s advanced technology. With this highly validated, customer-friendly solution, we hope to play an integral role in preventing further outbreaks.”

Lumipulse G SARS-CoV-2 Ag was the first high-sensitive antigen assay launched on a fully automated chemiluminescent platform. It has been used by Japanese authorities since August this year for quarantine screening of arriving travelers in major international Japanese airports.

CENTOGENE has an exclusive cooperation with Lufthansa. The first test runs for these comprehensive, fast and high-quality COVID-19 antigen tests for use on flights from Hamburg will start on November 12th. Lufthansa passengers can have themselves tested free of charge on selected connections before departure.

“With our test strategy, we are pursuing the goal of using the data obtained to collect important knowledge in dealing with antigen tests. We are convinced that it is the only right way to further expand the established test infrastructure at the airports. The cooperation between Lufthansa and CENTOGENE, which are continuously expanding their capacities, serves as a benchmark for a successful test model,” said Christoph Leffers, Head of Task Force Testing Lufthansa Group.

About the Lumipulse G SARS-CoV-2 Ag assay

The Lumipulse G SARS-CoV-2 Ag assay is used on a LUMIPULSE G system for quantitative measurement of SARS-CoV-2 antigen in human nasopharyngeal swab fluid or saliva. It is used as an aid in the diagnosis of a SARS-CoV-2 infection and utilizes proven CLEIA (chemiluminescent enzyme immunoassay) technology.

The assay generates fast results (available in up to 40 minutes from sample receipt in the laboratory) using different sample types, including less invasive saliva samples.

About SARS-CoV-2

The 2019 novel coronavirus infection disease (COVID-19) is caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1,2] On January 7th, 2020, the World Health Organization (WHO) announced that the National Health Commission of China identified a new type of coronavirus, SARS-CoV-2.[3] The WHO declared a COVID-19 pandemic on March 11th, 2020, due to the worldwide spread of novel coronavirus infection.[4]

To detect the virus, lower respiratory tract specimen, nasopharyngeal swab fluid and saliva of the patient are shown to be reliable samples for the detection of the SARS-CoV-2 virus.[5,6] In general, the diagnosis of SARS-CoV-2 infection is made by molecular detection of the SARS-CoV-2 genes. Although nucleic acid-based tests can detect SARS-CoV-2 gene with high sensitivity, it is restricted by the needs of special equipment and turnaround time. Lumipulse G SARS-CoV-2 Ag is useful as an aid in the diagnosis of COVID-19 by detecting and quantifying the SARS-CoV-2 antigen in nasopharyngeal swab samples as well as saliva samples.

About Fujirebio

Fujirebio is a global leader in the field of high-quality IVD testing. It has more than 50 years’ accumulated experience in the conception, development, production and worldwide commercialization of robust IVD products.

Founded in 1950 in Tokyo, Japan, Fujirebio has over the years concluded a number of successful acquisitions of best-in-class IVD companies.

Examples include Centocor Diagnostics in 1998, CanAg Diagnostics in 2006 and Innogenetics in 2010. Today, Fujirebio's global presence includes offices in the United States, Latin America, Europe and Asia as well as a vast international distribution network.

Fujirebio has a strong and long-lasting tradition of collaborating with experts in the worldwide clinical community in the development of high-quality routine and truly novel biomarkers that cover a variety of disease states. Its IVD product lines span the range from specialized manual and automated testing to fully automated routine clinical laboratory testing solutions.

Fujirebio is a wholly-owned subsidiary of H.U. Group Holdings Inc. (formerly known as Miraca Holdings Inc. and listed on the Tokyo Stock Exchange – TYO: 4544) and employs more than 1.200 people in Asia, Europe and America.

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.

References:

1. Wu F, *et al.* A new coronavirus associated with human respiratory disease in China Nature, 579: 265-269, 2020.
2. Gorbalenya, A.E., Baker, S.C., Baric, R.S. *et al.* The species *Severe acute respiratory syndrome-related coronavirus:* classifying 2019-nCoV and naming it SARS-CoV-2. *Nat Microbiol* 5, 536–544 (2020)
3. WHO website: "Rolling updates on coronavirus disease(COVID-19)" (https://www.who.int/emergencies/diseases/novel-coronavirus-2019) Medical Research and Development.
4. WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020 (https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020)
5. Di Gennaro F, *et al.* Coronavirus Diseases (COVID-19) Current Status and Future Perspectives: A Narrative Review. Int J Environ Res Public Health, 17(8): 2690, 2020.
6. Iwasaki S, *et al.* Comparison of SARS-CoV-2 detection in nasopharyngeal swab and saliva [published online ahead of print, 2020 Jun 4]. J Infect. 2020; 81(2):e145-e147. doi: 10.1016/j.jinf. 2020.05.071.

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 www.sec.gov.

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