



## **CENTOGENE's CentoCloud® Is Now CE-Marked as One of the Only Decentralized SaaS Platforms Compliant With European IVD Regulatory Framework**

May 25, 2022

### **CE-marked clinical decision support platform enables laboratories to provide best-in-class diagnostics of genetic diseases**

- CentoCloud, CENTOGENE's cloud-based Software as a Service (SaaS) platform, is CE-marked under the In Vitro Diagnostics Directive (98/79/EC)
- CE-marking is required for all in vitro diagnostic (IVD) devices to be placed in the European Economic Area (EEA) countries, as well as Iceland, Norway, and Liechtenstein, and indicates that the device may be legally commercialized in this area
- CentoCloud is one of the world's only CE-marked IVD software for genomic diagnostics; Considering the change in the European regulatory landscape with new In Vitro Diagnostic Regulation (IVDR 2017/746) taking full effect on May 26, 2022, this underlines CENTOGENE's commitment to meeting the highest industry standards

CAMBRIDGE, Mass. and ROSTOCK, Germany and BERLIN, May 25, 2022 (GLOBE NEWSWIRE) -- Centogene N.V. (Nasdaq: CNTG), the commercial-stage essential biodata life science partner for rare and neurodegenerative diseases, today announced that its cloud-based Software as a Service (SaaS) platform for the identification, prioritization, and classification of human genetic variants is now CE-marked under the In Vitro Diagnostics Directive (98/79/EC).

Centocloud enables laboratories around the world to establish and run state-of-the-art genomic testing and deliver the best diagnostic insights to local patients. As a cloud-based SaaS platform, Centocloud is specifically designed to support laboratories with the execution of superior Next Generation Sequencing (NGS)-based diagnostics. The Company's fully automated bioinformatics pipeline analyzes NGS data based on CENTOGENE's validated testing products, annotated with data from the CENTOGENE Biodatabank.

CE-marking is required for all in vitro diagnostic (IVD) devices sold in the European Economic Area (EEA) countries, as well as Iceland, Norway, and Liechtenstein, and indicates that the device may be legally commercialized in this area. Europe's new In Vitro Diagnostic Regulation (IVDR 2017/746) will take full effect on May 26, 2022.

As a CE-marked IVD, Centocloud can be applied to the clinical diagnosis of patients with genetic diseases. The clinical decision support platform is one of the world's only CE-marked IVD software for genomic diagnostics that is available via the cloud.

"At CENTOGENE, we are committed to enabling access to genetic testing for patients around world," said Kim Stratton, CEO of CENTOGENE. "With the new IVD regulation going into place later this week, Centocloud will be one of Europe's only commercialized software on the market – underlining our commitment to being at the forefront of offering safe and accessible patient solutions."

To learn more about how Centocloud facilitates the same high quality and diagnostic accuracy as CENTOGENE offers in its own certified state-of-the-art labs, visit: <https://www.centogene.com/diagnostics/centocloud>

### **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 of over 650,000 individuals 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, 2021, the Company collaborated with over 30 pharmaceutical partners.

For more information, visit [www.centogene.com](http://www.centogene.com) and follow us on [LinkedIn](#).

### **Forward-Looking Statements**

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 economic and geopolitical conditions and instability and volatility in the worldwide financial markets, 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, our ability to streamline cash usage, our requirement for additional financing, 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 March 30, 2022, 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.

**Media Contact:**

**CENTOGENE**

Ben Legg  
Corporate Communications  
[Press@centogene.com](mailto:Press@centogene.com)

Lennart Streibel  
Investor Relations  
[Investor.Relations@centogene.com](mailto:Investor.Relations@centogene.com)