ContextVision announces first CE marked digital pathology product

STOCKHOLM – June 29, 2020 – ContextVision, a medical technology software company specializing in image analysis and artificial intelligence, today announced that its first digital pathology product in a planned portfolio has been granted CE mark status. This means that INIFY® Prostate Screening is now available for routine clinical use within the European Union.

"I am proud of the great performance by our outstanding multidisciplinary team in reaching this company milestone. Healthcare systems around the world are already under great stress due to heavy workloads and lack of resources – and both patient numbers and cancer rates are only increasing. Intelligent technology will be a vital key to addressing these challenges, with powerful tools supporting the medical professionals in terms of efficiency and precision," says Fredrik Palm, CEO at ContextVision.

"We are a first mover in what I am certain will become a billion-dollar market."

ContextVision is an independent world-wide leader within digital image enhancement for multiple imaging modalities. With its 35-year history of developing advanced software for digital image analysis and enhancement, it was a natural step forward to invest in and aim for a leading position within clinical pathology – a discipline where today's ongoing digitalization offers huge opportunities.

INIFY® Prostate Screening is a powerful AI-based software that predicts, outlines and quantifies suspected cancerous areas in a series of prostate biopsies. It pre-sorts slides in a worst-first order, allowing pathologists to get right to work on the most relevant areas. While the product can be used as a stand-alone unit, even more importantly it is designed to be seamlessly integrated into pathology laboratories' existing LIS (Laboratory Information Systems) or PACS (Picture Archiving and Communication Systems).

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The predicting engine in INIFY® Prostate Screening is built on deep learning algorithms, trained and adapted by ContextVision's skilled research scientists, resulting in proprietary high-performance algorithms with pixel-level accuracy. Our unique, patented MasterAnnotation™ method has been used to create the training data on which the engine is built. Here, multiplex immunofluorescent staining is used to objectively identify and highlight cancer areas and other structures with extreme precision, which in turn are quality assured by certified pathologists.

"We have been involved in the development of INIFY® Prostate Screening and can assure it fits laboratory needs. A prototype version of the product has been used daily for two years in our fully digital pathology workflow here in Catania, and I can testify that it is really easy to use, saves time and helps highlight suspicious areas for cancer," says Dr. Filippo Fraggetta, chief pathologist at the Pathology Unit of Cannizzaro Hospital.

ContextVision clearly sees the need for a product that can support the pathologist in identifying prostate cancer faster and more easily, with the highest possible precision. INIFY® Prostate Screening will facilitate the transformation of clinical pathology into a digital discipline, ultimately offering much higher quality and standardization.

"INIFY® Prostate Screening will allow pathologists to focus their time on assessing and examining prostate specimens containing suspicious cancer areas, while minimizing time spent on benign tissue. Knowing that collaboration with the medical profession is essential, we have worked closely with multiple pathology labs around the world, all at the forefront of digitalization. Now, with our first product available for clinical use within EU, we can expect several full installations in the clinical workflow this fall. We are a first mover in what I am certain will become a billion-dollar market," says Palm. *"Prostate cancer is the second most common cancer in the world among men, with 2.3 million biopsy procedures carried out annually in Europe and the US alone. With INIFY® Prostate Screening, we have laid a solid groundwork – which in turn can be further adapted to address other cancer types, such as colon and lung cancer."*

For further information, please contact ContextVision's CEO, Fredrik Palm, at +46 76 870 25 43 or visit www.contextvision.com.

About ContextVision

ContextVision is a medical technology software company specialized in image analysis and artificial intelligence. As the global market leader within image enhancement, we are a trusted partner to leading manufacturers of ultrasound, X-ray and MRI equipment around the world.

Our expertise is to develop powerful software products, based on proprietary technology and artificial intelligence for image-based applications. Our cutting-edge technology helps clinicians accurately interpret medical images, a crucial foundation for better diagnosis and treatment.

ContextVision is now entering the fast-growing digital pathology market. We are re-investing significantly in our product portfolio of decision support tools and we are dedicated to becoming a leading resource for pathologists to radically develop cancer diagnosis and improve patient care.

The company, established in 1983, is based in Sweden with local representation in the U.S., Japan, China and Korea. ContextVision is listed on the Oslo Stock Exchange under the ticker COV.

This information is subject to the disclosure requirements pursuant to section 5 -12 of the Norwegian Securities Trading Act.

This information is information that ContextVision is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, on June 29, 2020.