Nanox Receives MDR CE Mark for HealthOST, an Advanced AI-Powered Software for Spine Assessment

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- HealthOST identifies vertebral height loss and bone mineral density, which are key indicators of musculoskeletal disease
- Osteoporosis is a common progressive bone disease among adults over 50 years of age that causes bones to weaken, leading to fractures
- The software provides automated quantification of vertebral parameters from routine CT scans, delivering consistent and objective data to support physician evaluation, before life-altering fractures occur

PETACH TIKVA, Israel, June 05, 2025 (GLOBE NEWSWIRE) -- NANO-X IMAGING LTD ("Nanox" or the "Company", Nasdaq: NNOX), an innovative medical imaging technology company, today announced that its deep-learning medical imaging analytics subsidiary, Nanox AI Ltd, has received EU MDR CE (Conformité Européenne) mark certification for HealthOST, an SaMD (Software as a medical device) for bone health analysis, enabling its commercialization across Europe and ensuring compliance with the highest regulatory standards for medical software.

HealthOST is Nanox.AI's advanced Bone Solution, which analyzes routine CT scans to assess vertebral height loss and bone mineral density. Building on its FDA 510(k) clearance received in April 2022, HealthOST leverages AI to provide qualitative and quantitative analysis of the spine from CT scans to support clinicians in the evaluation and assessment of musculoskeletal disease of the spine, such as osteoporosis, which can remain undiagnosed until life-altering fractures occur.

Since the CT scans analyzed by HealthOST were performed for other clinical indications, no additional imaging, radiation or patient time is required, making it a cost-effective screening tool. HealthOST is seamlessly integrated with existing picture archiving and communication systems (PACS), and can enable timely and appropriate preventive care.

Osteoporosis is a common progressive bone disease among adults over 50 years of age that causes bones to weaken, leading to fractures. According to the World Congress of Osteoporosis, an estimated 66% of vertebral compression fractures, a strong indicator of osteoporosis, go undetected or unreported in routine CT diagnostic reporting. Early detection is crucial, as modern treatments can improve bone strength and reduce fracture risk, helping patients maintain independence and reducing healthcare needs. This need is particularly acute in Europe, where over 25.5 million women have osteoporosis and at least 23.8 million residents are at high risk of osteoporotic fractures.[i] The annual cost of osteoporosis-related fractures in Europe exceeds €56 billion, with cases expected to increase 25% by 2034 due to an aging population.[ii]

"This CE mark for HealthOST represents a significant expansion of our AI capabilities in Europe," said Erez Meltzer, Chief Executive Officer and Acting Chairman of Nanox. "Our AI technology demonstrates the Nanox end-to-end solution that can deliver immediate practical value to opportunities for proactive care. By integrating seamlessly into routine CT scans, HealthOST helps healthcare providers maximize their existing resources, while identifying patients who might otherwise fall through the cracks of traditional screening methods."

HealthOST is the upgraded version of HealthVCF, which was evaluated in the **A**I-enabled **D**etection of **O**steo**P**orosis for **T**reatment (ADOPT) study at four UK National Health Services (NHS) trusts – Cambridge, Bradford, Cardiff and Southampton – and coordinated by the long-standing clinical users at Oxford.

In the ADOPT study, HealthVCF analyzed 37,220 routine medical CT scans and identified over 3,450 new patients with vertebral compression fractures, up to six times more than the national average at NHS hospitals in the UK. These patients were asymptomatic, and the data underscores the importance of addressing the critical gap in detection of patients with vertebral fractures.

"Nanox.AI bone solution has proven to be a game-changer in bone health management," said Professor Kassim Javaid of the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford. "After successful integration with our clinical pathways, we saw its significant impact and chose to continue with it for another three years at Oxford. By enabling earlier identification of patients with vertebral fractures, Nanox.AI bone solution improved our system identification of patients at high fracture risk to improve patient outcomes and reduce the burden on healthcare systems through preventive care."

Healthcare facilities interested in implementing HealthOST can visit https://www.nanox.vision/ai-bone-solution/ for more information.

About Nanox.AI

Nanox.AI is the deep-learning medical imaging analytics subsidiary of Nanox. Nanox.AI solutions are developed to target highly prevalent chronic and acute diseases affecting large populations around the world. Leveraging AI, Nanox.AI helps clinicians extract valuable and actionable clinical insights from medical imaging that otherwise may go unnoticed, potentially initiating further medical assessment to establish individual preventative care pathways for patients. For more information, please visit www.nanox.vision/ai.

About Nanox

Nanox (NASDAQ: NNOX) is focused on driving the world's transition to preventive health care by bringing a full solution of affordable medical imaging technologies based on advanced AI and proprietary digital X-ray source.

Nanox's vision encompasses expanding the reach of Nanox technology both within and beyond hospital settings, providing a seamless end-to-end solution from scan to diagnosis, leveraging AI to enhance the efficiency of routine medical imaging technology and processes, in order to improve

early detection and treatment and maintaining a clinically driven approach. The Nanox ecosystem includes Nanox.ARC – a multi-source digital tomosynthesis system that is cost-effective and user-friendly; Nanox.AI LTD – an AI-based suite of algorithms that augment the readings of routine CT imaging to highlight early signs often related to chronic diseases; Nanox.CLOUD – a cloud-based software platform that manages and stores data collected by Nanox devices, and provides users with tools for in-depth imaging analysis; Nanox.MARKETPLACE – a proprietary decentralized marketplace through Nanox's subsidiary, USARAD Holdings Inc., that provides remote access to radiology and cardiology experts, and a comprehensive teleradiology services platform. By improving early detection and treatment, Nanox aims to enhance better health outcomes worldwide. For more information, please visit www.nanox.vision

Forward-Looking Statements

This press release may contain forward-looking statements that are subject to risks and uncertainties. All statements that are not historical facts contained in this press release are forward-looking statements. Such statements include, but are not limited to, any statements relating to the initiation, timing, progress and results of the Company's research and development, manufacturing, and commercialization activities with respect to its X-ray source technology and the Nanox.ARC, the ability to realize the expected benefits of its recent acquisitions and the projected business prospects of the Company and the acquired companies. In some cases, you can identify forward-looking statements by terminology such as "can," "might," "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "should," "could," "expect," "predict," "potential," or the negative of these terms or other similar expressions. Forward-looking statements are based on information the Company has when those statements are made or management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Factors that could cause actual results to differ materially from those currently anticipated include: risks related to (i) Nanox's ability to complete development of the Nanox System; (ii) Nanox's ability to successfully demonstrate the feasibility of its technology for commercial applications; (iii) Nanox's expectations regarding the necessity of, timing of filing for, and receipt and maintenance of, regulatory clearances or approvals regarding its technology, the Nanox.ARC and Nanox.CLOUD from regulatory agencies worldwide and its ongoing compliance with applicable quality standards and regulatory requirements; (iv) Nanox's ability to realize the anticipated benefits of the acquisitions, which may be affected by, among other things, competition, brand recognition, the ability of the acquired companies to grow and manage growth profitably and retain their key employees; (v) Nanox's ability to enter into and maintain commercially reasonable arrangements with third-party manufacturers and suppliers to manufacture the Nanox.ARC; (vi) the market acceptance of the Nanox System and the proposed pay-per-scan business model; (vii) Nanox's expectations regarding collaborations with third-parties and their potential benefits; (viii) Nanox's ability to conduct business globally; (ix) changes in global, political, economic, business, competitive, market and regulatory forces; (x) risks related to the current war between Israel and Hamas and any worsening of the situation in Israel; (xi) risks related to business interruptions resulting from the COVID-19 pandemic or similar public health crises, among other things; and (xii) potential litigation associated with our transactions.

For a discussion of other risks and uncertainties, and other important factors, any of which could cause Nanox's actual results to differ from those contained in the Forward-Looking Statements, see the section titled "Risk Factors" in Nanox's Annual Report on Form 20-F for the year ended December 31, 2024, and subsequent filings with the U.S. Securities and Exchange Commission. The reader should not place undue reliance on any forward-looking statements included in this press release. Except as required by law, Nanox undertakes no obligation to update publicly any forward-looking statements after the date of this press release to conform these statements to actual results or to changes in the Company's expectations.

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