Zynex Announces Completion of Its Laser Pulse Oximetry Trial

ENGLEWOOD, Colo., Dec. 5, 2024 /PRNewswire/ -- Zynex, Inc. (NASDAQ: ZYXI) ("Zynex", "ZMS", "we" or the "Company"), an innovative medical technology company specializing in the manufacture and sale of noninvasive medical devices for pain management, rehabilitation, and patient monitoring, today announced that it has completed its clinical verification trial for their NiCO™ pulse oximeter overseen by anesthesiologist Dr. David MacLeod at Duke University.

Trial completion is a key milestone required by the FDA prior to submission of a 510(k) for clearance to market and sell the NiCO device for clinical use. With the completion of this study, Zynex now turns to final testing to ensure the operational safety of the device prior to 510(k) submission.

Zynex's NiCO pulse oximeter utilizes highly precise laser technology to measure blood oxygenation levels directly, as opposed to current pulse oximeter products, which only estimate oxygenation levels using LEDs. LED pulse oximeters have been shown to mismeasure oxygen levels in several populations, most prominently in individuals with darker skin pigmentation.

Zynex Monitoring Solutions' NiCO product line is a strategic investment for Zynex to enter the multi-billion dollar pulse oximetry market with entirely new pulse oximetry technology. The Company is confident that the clinical value of NiCO's unparalleled precision, accuracy, and safety will provide the right entry into this market space.

"The completion of our verification study is a pivotal event for Zynex Monitoring and the result of an enormous team effort. The bulk of the hard work is behind us at this point as we turn to submit NiCO for FDA clearance officially," said Donald Gregg, President of Zynex Monitoring Solutions.

"NiCO will be the first Zynex monitoring product to enter a mature and growing market whose entry will be enabled by its game-changing capabilities. We are excited to finally have all the required clinical studies behind us as we prepare our application for FDA clearance," added Thomas Sandgaard, Founder and CEO of Zynex.

About Zynex, Inc.

Zynex, founded in 1996, develops, manufactures, markets, and sells medical devices used for pain management and rehabilitation as well as non-invasive fluid, sepsis, and laser-based pulse oximetry monitoring systems for use in hospitals. For additional information, please visit: www.zynex.com.

Safe Harbor Statement
This release contains forward-looking statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. The Company makes no express or implied representation or warranty as to the completeness of forward-looking statements or, in the case of projections, as to their attainability or the accuracy and completeness of the assumptions from which they are derived. Factors that could cause actual results to materially differ from forward-looking statements include, but are not limited to, the need to obtain CE marking of new products, the acceptance of new products as well as existing products by doctors and hospitals, larger competitors with greater financial resources, the need to keep pace with technological changes, our dependence on the reimbursement for our products from health insurance companies, our dependence on third party manufacturers to produce our products on time and to our specifications, implementation of our sales strategy including a strong direct sales force, the impact of

COVID-19 on the global economy and other risks described in our filings with the Securities and Exchange Commission including but not limited to, our Annual Report on Form 10-K for the year ended December 31, 2023 as well as our quarterly reports on Form 10-Q and current reports on Form 8-K.

Any forward-looking statement made by us in this release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Investor Relations Contact:
Brian Prenoveau, CFA
MZ Group – MZ North America
ZYXI@mzgroup.us
+561 489 5315

SOURCE Zynex, Inc.
