Zynex Submits FDA Application for its Next Generation Fluid and Blood Volume Monitor

ENGLEWOOD, Colo., Jan. 3, 2022 /PRNewswire/ -- Zynex, Inc. (NASDAQ: ZYXI), an innovative medical technology company specializing in the manufacture and sale of non-invasive medical devices for pain management, rehabilitation, and patient monitoring, today announced that it has submitted a 510(k) application to the U.S. Food and Drug Administration ("FDA") for the CM-1600, its next generation fluid monitoring system.

"I am thrilled to announce that we have submitted a 510(k) premarket notification to the FDA for our CM-1600. We have worked diligently at adding key enhancements to our FDA-cleared CM-1500 Fluid Monitoring System, including wireless connectivity to the non-invasive wrist wearable," said Thomas Sandgaard, CEO. "This 510(k) submission is an important step in the evolution of our fluid monitoring system, which we believe will become a vital tool to ensure optimal fluid management and quality care for patients at risk for hemorrhagic events."

"We are pleased to bring a meaningful treatment improvement to market through the submission of the CM-1600 to the FDA for 510(k) clearance," said Donald Gregg, Vice President, Zynex Monitoring Solutions. "The improved fluid and blood volume monitor will provide more accurate patient observance before, during, and after surgical procedures. We look forward to working closely with the FDA throughout the submission and clearance process to bring this next generation, first of its kind technology to the market."

The Zynex Fluid Monitoring System (CM-1500) is a 100% non-invasive solution for monitoring fluid changes throughout patient care environments. Patient fluid status is determined using an algorithm that combines the trends of several physiological parameters to generate a single Relative Index^{TM} (RI) value, allowing for fast interpretation of changes in fluid volume.

About Zynex, Inc.
Zynex, founded in 1996, markets and sells its own design of electrotherapy medical devices used for pain management and rehabilitation as well as developing noninvasive patient fluid, pulse oximetry and sepsis monitoring systems. 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, 2020 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.

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SOURCE Zynex
