

ALERCELL ANNOUNCES THE LAUNCH OF LENA Q51®

New innovative Leukemia Diagnostic Test

BOZEMAN, MONTANA, USA, January 24, 2023 /EINPresswire.com/ --ALERCELL, INC. announced today that it has introduced a new Research Use Only (RUO) <u>LENA Q51® Leukemia</u> <u>diagnostic</u> test for commercial sale. Lena Q51® was developed to detect up to 51 genes mutations associated with Leukemia.

LENA Q51[®] is available for early detection of any type of Leukemia and is a gigantic leap forward in Leukemia detection. The RUO LENA Q51[®] will be available while the company completes clinical trials and regulatory submissions to support U.S. Food and Drug Administration (EDA) approval for l



Drug Administration (FDA) approval for broader clinical use.

The innovative approach of LENA Q51[®] Leukemia Fusion Gene Kit is to target the gene mutations, the clonogenic gene rearrangements and abnormal gene expression. Fusion genes are one of the most common biomarkers in Leukemia and are caused by chromosome breakage and recombination. Test results are available in under three hours using a standard qPCR machine compared with traditional microbiology methods, which can take two to three days and longer to provide results.

The test has an easy-to-use protocol and can be run on standard qPCR equipment and is designed to handle the workflow in a clinical microbiology lab environment. The RUO LENA Q51 [®]employs industry standard PCR and DNA purification technology.

Frederic Scheer, chairman & CEO of Alercell, stated, "The new RUO LENA Q51[®] was designed to improve patient outcomes and help in selecting the appropriate therapeutics for Leukemia patients. Early detection enhances drastically the survival rates of patients and Alercell is focusing on making sure that we give every patient the best chances of survival".

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Initial clinical verifications will start soon, we are pleased to introduce the test for commercial sale for Research Use Only to hospitals and various cancer centers for control purposes and for pharmaceutical surveillance studies."

ABOUT ALERCELL

Alercell, Inc., a Montana company is a molecular diagnostics company pioneering novel therapeutics to discover, develop, and commercialize solutions for clinical unmet needs, with a primary focus in Oncology in-vitro Diagnostic Testing and Neuroscience. The company was

founded with the aim of providing more accurate and timely diagnostic tools for cancer patients worldwide. Alercell's mission is to make a difference in the fight against cancer by providing innovative and accurate diagnostic solutions that improve patient outcomes. The Alercell[®] mission is built on the foundation of "stopping it before it starts". Our genetics-based testing is the first line of assault against cancer & leukemia and infectious diseases. For more information, please visit: <u>www.alercell.com</u> and <u>www.Lenadx.com</u>

Forward-Looking Statements

This press release includes statements relating to Alercell RUO LENA Q51 [®] and its launch for Research Use Only. These statements and other statements regarding ALERCELL future plans and goals constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control, and which may cause results to differ materially from expectations. Factors that could cause our results to differ materially from those described include, but are not limited to, our ability to successfully, timely and cost-effectively develop, seek and obtain regulatory clearance for and commercialize our product and services offerings, the rate of adoption of our products and services by hospitals, other healthcare providers and pharmaceutical companies, the success of our commercialization efforts for the Research Use Only product offering, the effect on our business of existing and new regulatory requirements, and other economic and competitive factors. You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this press release and speak only as of the date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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